UNCST

THE REPUBLIC OF UGANDA

National Guidelines for Field Trials of Genetically Engineered Plants

Uganda National Council for Science and Technology

December 2011

National Guidelines for Field Trials of Genetically Engineered Plants

Uganda National Council for Science and Technology

December 2011

ISBN: 978-9970-26-000-3

Uganda National Council for Science and Technology
Plot 6 Kimera Road, Ntinda, Kampala
P.O. Box 6884 Kampala, Uganda
Telephone: +256-414-705500/+256-312- 314800
Email: info@uncst.go.ug
www.uncst.go.ug

Recommended Citation: Uganda National Council for Science and Technology (2011). National Guidelines for Field Trials of Genetically Engineered Plants. UNCST. Kampala.

Contents

Foreword

Uganda's vision for the agricultural sector is to gradually transform the small scale peasantry agriculture to modern commercial farming. To realise this vision, a number of segments along the production chain have to be exploited among which, are the application of new farming and agro-processing technologies using tools such as genetic engineering of plants to increase yield, nutritional, and other value addition qualities.

Currently, climate change and associated impacts are posing a great challenge to food production. However with the advent of biotechnology, scientists are able to generate plants that can withstand biotic and abiotic stresses, resist diseases and pests, or to be used as bio-factories for pharmaceutical products. The generation, development and application of these genetic engineering techniques have biosafety implications, which must be carefully managed to ensure that the process and final products are safe for human consumption and the environment.

These Guidelines for Field Trials of Genetically Engineered Plants in Uganda are part of the several biosafety mechanisms that government has put in place to facilitate the testing and development of potentially useful genetically modified/engineered plants. The Guidelines and all other associated manuals have been developed to ensure that safety considerations are addressed right from the conception and inception of the trial to its completion.

Besides their use in field experiments of genetically modified plants, the Guidelines also provide a useful platform, both now and in the future, for expanding and sustaining collective scientific efforts of promoting the safe application of genetic engineering techniques in agricultural production systems in Uganda.

UNCST is grateful to all its partners, especially the Program for Biosafety Systems, for the support and cooperation in building an effective and efficient National Biosafety System for Uganda.

Dr. Peter Ndemere
Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

Acknowledgements

The Uganda National Council for Science and Technology (UNCST) acknowledges with gratitude the contribution of the Team that participated in developing these Guidelines. In particular, UNCST expresses thanks to the working group comprised of Dr. Yona Baguma, Mr. Julius Ecuru, Ms. Ruth Mbabazi-Tugume, Dr. Friday Agaba, Ms. Grace Akao and Mr. Danton Kabuye; and a support group from the Program for Biosafety Systems (PBS) comprised of Dr. Mark E. Halsey, Dr. Karen Hokanson, Dr. Theresa Sengooba, Mr. Arthur M. Makara and Mr. Herbert Oloka. Further, the UNCST acknowledges the logistical support provided by PBS during the preparation of the Guidelines. Finally, UNCST is thankful to all stakeholders who contributed in one way or another to the development of these Guidelines.

Acronyms

CBI	Confidential Business Information
CFT	Confined Field Trial
DNA	Deoxyribonucleic acid
ICS	Integrated Confinement System
GE	Genetically Engineered (Genetic Engineering)
GM	Genetically Modified (Genetic Modification)
IBC	Institutional Biosafety Committee
LMO	Living Modified Organism
MAAIF	Ministry of Agriculture, Animal Industry and Fisheries
MoU	Memorandum of Understanding
NBC	National Biosafety Committee
PBS	Program for Biosafety Systems
rDNA	recombinant DNA
RNA	Ribonucleic acid
SOP	Standard Operating Procedure
UNCST	Uganda National Council for Science and Technology

Preface

Understanding the nature of biological processes has advanced beyond observations of natural phenomena, growing of parts of tissues or even cell culture techniques, to genetic manipulation of biological processes using recombinant Deoxyribonucleic Acid (rDNA) technology. This has led to the development of new lines of Genetically Modified (GM) or Engineered (GE) organisms also referred to as Living Modified Organisms (LMOs). Application of rDNA technology in crop, animal and human growth and development systems is poised to enhance food production and ensure nutritional security/sufficiency. In tropical Africa where environmental risk factors have more significant influence on agricultural production, rDNA technology should be carefully and systematically adopted for laboratory and greenhouse testing, as well as field trials of crops.

A systematic approach to successful and safe research, development and eventual deployment of modern agro-biotechnology requires laboratory and screen-house infrastructure, facilities for primary small-scale field trials, as well as large-scale or multi-locational, advanced field trial sites, in the process of generating adequate scientific data that would eventually guarantee performance and safety of the technologies under assessment. A well regulated and monitored research system for genetically modified plants limits human and animal interference, and enhances reproductive isolation, protects the environment and ecosystems, and promotes surveillance, and management of new genetic traits of plants introduced to the geographical area. Establishment of field trials therefore, calls for regulation of plant biotechnology, requiring governments' approval and oversight of the implementation and evaluation processes. This underscores the importance of these guidelines developed by UNCST which is the Competent Authority for biosafety in Uganda.

These Guidelines support the thrusts of the National Biotechnology and Biosafety Policy (2008) which aim at developing regulatory strategies for modern biotechnology, training human resources and building infrastructure capacity for biotechnology research and development, and enhancing the application of biotechnology and biosafety in development. The Guidelines provide a unified framework of methods, procedures, processes for conducting field trials of genetically engineered plants in Uganda. They also form a basis for consulting other more relevant documents which may cover in greater detail the biology of the plants, laboratory and ecological methods, and regulatory considerations in question.

Definitions

Advanced Field Trials: These are trials, usually in the later stages of product development, which are conducted under controlled conditions but may be larger in size, off-station and multi-locational. It is a stage of product development meant for generation of real-field conditions data and information prior to general release approval (*also see* Multi-locational trials)

Applicant: A party submitting an application for authorisation of a field trial. Typically, the Applicant is the same as the Authorised Party (see Authorised Party), and/or any Party acting on behalf of the Authorised Party.

Authorised Party: The addressee of the Letter of Authorisation is called the Authorised Party. The Authorised Party shall be a permanent resident of Uganda, or shall designate an agent who is a permanent resident. 'Authorised Party' is construed herein to include any designated agents thereof. The Authorised Party accepts full responsibility for compliance with the Terms and Conditions of authorisation, including all associated legal and financial obligations.

Biosafety: The safe development, transfer and application of biotechnology and its products.

Compliance: Fulfilling the requirements of the Terms and Conditions of Authorisation.

Compliance Infraction: Violation of the Terms and Conditions of Authorisation.

Confined Field Trial (CFT): A field trial of a Genetically Engineered plant that has not been approved for general release. In a CFT, measures for reproductive isolation and material confinement are enforced in order to confine the experimental plant material and genes to the trial site.

Confinement: Restriction of an organism and its genetic traits to a specific and defined area of the environment, herein called the 'confined field trial site' or the 'trial site'.

Construct: A segment of DNA to be transferred into a cell or tissue in the process of 'genetic modification'.

Early Safety Data: For purposes of these guidelines, 'early safety data' refers to environment and food and feed safety assessment data collected prior to advanced field testing of GE plants in Uganda.

Event: A single instance of modification of a specific plant species and type using a specific genetic construct.

Field Trial: For purposes of these guidelines, a field trial is an experiment of a GE plant conducted in the field.

Genetic Confinement: See **'Reproductive Isolation'.**

Genetic Engineering/Genetically Engineered (GE): The genetic modification of organisms by recombinant-DNA techniques. For the purposes of this document, the terms 'genetically engineered (GE)', 'transgenic', 'genetically modified (GM)', genetically modified organism (GMO)', 'living modified organism (LMO)', 'bioengineered organism' and 'regulated' are equivalent.

Genetic Modification/Genetically Modified (GM): See 'Genetic Engineering'.

Incident: Any occurrence that causes, or threatens to cause, a breach of confinement of GE plant material.

Integrated Confinement System: This is a systematic approach to the design, development, execution and monitoring of the confinement of a specific GE organism

Material Confinement: Measures taken to ensure that all GE plant parts or tissue are materially maintained within the confines of the approved field trial site or storage facility and does not enter the food or feed supply/chain.

Multi-locational Trials: These are field experiments that are conducted in more than one location under controlled conditions, sometimes for purposes of variety verification and assessing the genotype and environment effects on the lines under study.

Novel genes: Introduced or modified genes in the GE plant.

Pollen-mediated Gene Flow: The transfer of genes from one plant to another in pollen by successful fertilisation.

Primary Field Trials: These are trials, usually in the earlier stages of product development, which are conducted under controlled conditions and are typically small-scale and on a research or experiment station where controls may be more strictly enforced.

Prohibited Plants: Plants that are sexually compatible under natural conditions with the GE plants being grown under confinement, and are thus prohibited from the established spatial isolation distance of a confined field trial.

Progeny: As used in this document, clonal or sexual offspring of GE plants.

Propagative Plant Material: Plant material such as seeds or cuttings capable of establishing and surviving in the natural environment with or without human intervention.

Regulatory Authority: The government body having the statutory authority to regulate an activity.

Regulated: As used here, a GMO that has not been approved for unrestricted release.

Reproductive Isolation: Measures taken to prevent, principally, pollen-mediated gene flow from plants in the trial site to nearby sexually compatible species. Also known as 'genetic confinement'.

Sexually Compatible: Capable of cross-pollinating and forming viable hybrids without human intervention.

Spatial Isolation: A method of achieving reproductive isolation by separating plants in the trial site by a defined distance from prohibited plants.

Temporal Isolation: A method of achieving reproductive isolation by preventing the flowering times of two crops from overlapping, usually by separating the planting dates in time.

Trial Manager: The individual(s) at a particular trial site, designated by the Authorised Party or Principal Investigator as responsible for management and compliance of an authorised field trial. Trial Managers are authorised to complete and sign documentation, forms and notes applicable to the trial.

Trial Site: The area of a field trial that is confined by one or more continuous methods of reproductive and/or material isolation.

Volunteers: Progeny arising from the GE crop in a confined field trial site.

CHAPTER 1 GENERAL PROVISIONS

1.1 Background

Uganda is Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD). The Protocol provides an international regulatory framework to reconcile the respective needs of trade and environmental protection with respect to the rapidly growing global biotechnology industry. Article 19 binds each Party to the Protocol to designate one national focal point to be responsible on its behalf for liaison with the Secretariat of the CBD on biosafety matters. The Protocol also provides for establishment of one or more Competent national authorities to be responsible for administrative functions required by the Protocol. The Focal point for Uganda is the Ministry responsible for Environment while the Uganda National Council for Science and Technology is the Competent Authority.

1.2 Policy and legal context

These Guidelines derive authority from the UNCST Act (Cap 209) of the Laws of Uganda Sections 3 and 4, which mandates UNCST to regulate research and experimental development activities in Uganda. The Guidelines have been developed in accordance with the UNCST Act (Cap 209) and the National Biotechnology and Biosafety Policy 2008 and taking into account other relevant sector laws and international obligations. No person shall establish a field trial of any genetically modified plant within Uganda without authorisation under these Guidelines or any other applicable laws of Uganda.

1.3 Objectives

The UNCST, under its mandate, is dedicated to ensuring biosafety in biotechnology research, and development of genetically engineered plants, by providing support in training, capacity building, regulatory strategies and policy development. These Guidelines support the development of a coherent system for evaluation of human and environmental safety of GE plants.

These Guidelines are based on the 'Integrated Confinement System (ICS)' approach which combines contained glasshouse experiments, primary field trials, as well as advanced field trials. The ICS approach puts biosafety as a primary goal in the testing and development of GE organisms, so that adequate safety provisions can be in-built during the earliest phases of project conception and planning. This prevents safety failures and is particularly appropriate for public research institutions with limited resources. An ICS thus, provides clear procedures to be applied in the GE plant research and development process. These include: regulatory application process; regulatory review, decision and communication; trial execution, compliance, inspection and oversight; monitoring and reporting.

Therefore, the objectives of these Guidelines are to:

i. Ensure biosafety in the testing and evaluation of GE plants, especially where testing is done in field situations;

ii. Establish a coherent system for regulating, executing and overseeing field trials of GE plants; and

iii. Equip regulators, Authorised Parties, and Trial Managers, with tools for risk assessment and management of field trials for GE plants.

1.4 Scope

These guidelines shall apply to all field trials of genetically modified plants in Uganda. For the purpose of this document, field trials include such trials as primary field trials, advanced field trials/multi-location field trials, and any other such field trial of transgenic plants as may be prescribed by the Competent Authority.

1.5 GE technology and the need for biosafety

A field trial is a critical step in the development of new plant varieties, whether these are produced by conventional breeding methods or through modern genetic engineering techniques. Testing new lines or plants with new traits in the natural environment is essential to research, development, characterisation, and eventual recommendation of new varieties for the use and benefit of farmers and society. The testing of GE plants is regulated by government agencies, which oversee their evaluation and must grant approval on a case-by-case basis before a new GE variety may be officially released and included in the national variety list.

Regulation of GE plants requires that research on experimental lines or genotypes prior to their approval for release as varieties be conducted under controlled conditions, either in a laboratory or glasshouse ('contained' testing), or in a confined area outdoors, which is called a 'confined field trial' (CFT). Field trials may be limited to a small-scale at research or experimental stations (primary field trials), or may be grown in multiple locations or on a larger scale (advanced field trials), which may be in specific agro-ecological zones and not necessarily at research stations. Primary field trials are typically conducted in the early stages of product development, when less may be known about the characteristics and safety of the plants. Advanced field trials usually become necessary in the later stages of product development, when typically more is known about the characteristics and the safety of the plants.

Field trials can also be used in later stage product development for various purposes, including to:

i. determine whether a new genetic trait is effective in the local environment;

ii. select those lines with the best characteristics for further testing, to backcross the desired trait into varieties of local interest;

iii. gather data or plant material required for environmental and food safety assessment to be used in applying for general release; and,

iv. bulk-up plant material or seed prior to approval for general release.

1.6 Purpose and types of field trials

Field trials play a critical role in the evaluation and development of new varieties and techniques that can improve agricultural productivity, alleviate poverty and increase nutritional and food security. When plants with GE traits are being tested, the field trials must be carefully managed in order to ensure that experimental material remains confined,

to prevent adverse effects on the environment and human or animal health. Specifically, the purpose of confinement is to;

i. Prevent the escape from the trial site of novel genes in pollen, seed or other plant parts;

ii. Prevent GE plant material from entering food or feed chains; and

iii. Prevent GE plants from escaping, establishing and persisting in the environment.

Field trials may be categorised into two; primary field trials and advanced field trials.

a) Primary field trials

These trials are typically:

i. Conducted at early stages of product development

ii. Conducted under appropriate biosafety compliance condition

iii. Small scale, usually less than one hectare, and carried out at, but not limited to, research stations, and

iv. Used to evaluate for performance, proof of concept, and efficacy of the GE trait under field conditions.

b) Advanced field trials

These trials are typically:

i. Conducted at later stages of product development,

ii. Conducted under appropriate biosafety compliance conditions,

iii. Usually larger in field size compared to primary field trials,

iv. Sometimes conducted off-station and in multi-environments reflecting relevant agro-ecological conditions,

v. Meant for generation of data under real growing conditions and information prior to general release approval, and

vi. Conducted to provide additional data for food and feed safety, environmental safety and agronomic characterisation.

1.7 Authorisation for conducting field trials

1.7.1. Primary field trials

Authorisations for primary field trials shall be granted by UNCST upon thorough review of application documents (*First Schedule*) submitted to the National Biosafety Committee (NBC) by intending researchers. The NBC shall, among other factors, consider the following before making decisions on GE field trials:

i. Project relevance and benefit of the GE trials to Uganda,

ii. Efficacy data under containment (in Uganda or elsewhere),

iii. Efficacy data under confinement, or commercial plantings in other countries, and

iv. Adequacy of the proposed confinement measures.

1.7.2 Advanced field trials

Authorisations for advanced field trials shall be granted by the UNCST on a case by case basis upon review by the NBC. The NBC shall, among other factors contained in the application forms (*First Schedule*), require and consider the following from applicants:

i. Justification for the multiple locations or large-scale of the trials based on knowledge of the technology and stage in the development process,

ii. Available and relevant early safety data of the GE plant to human, animal and plant health; and to the environment (Safety data from credible sources in other countries where the GE plant has been tested under containment, confinement, or grown commercially shall also be considered),

iii. Adequacy of proposed confinement measures,

iv. Justification that the methods for conducting the experiments and confinement, in combination with early safety data, shall minimise risk to humans, animals, plants and the environment.

1.8 Characteristics of a field trial

A Field Trial of GE plants has several key characteristics:

i. It is an experimental activity, conducted prior to approval for general release.

ii. It is done in the open field, thus exposing the plants to the natural environment.

iii. It is done on a small scale, typically 1 ha or less in case of a primary field trial, or more than 1 ha but usually less than 10 ha (cumulative) in case of an advanced field trial.

iv. Access to the field site is limited. In the case of primary field trials, the site may be on a restricted-access facility, such as a government experiment station.

v. The GE plant material and genes being tested are confined to the field trial site using measures of material and genetic confinement to minimise the likelihood of the genes in pollen or seed escaping from the trial site, the GE material entering the food or feed supply/chain, and the GE plants or any volunteers arising from the trial persisting in the environment after the trial.

vi. For all field trials, appropriate measures for confinement must be proposed by the authorised party and determined acceptable by the regulatory authority based on the scale of the trial and what is known about the safety of the GE plants, on a case-by-case basis. Measures of confinement may differ for primary and advanced field trials of the same genotype.

CHAPTER 2 APPROVAL OF FIELD TRIALS OF GE PLANTS

2.1 Submitting an application

2.1.1 Application process

UNCST avails application forms to be completed by Applicants for different types of research, including field trials of genetically modified plants. The forms can be obtained from the UNCST website (www.uncst.go.ug) and the National Biosafety Committee (NBC) Secretariat. The information required in consideration of a field trial authorisation includes details about:

i. the Applicant and his/her affiliation,

ii. the plant species to be tested,

iii. the genetic construct or novel genetic material and its associated phenotype to be tested,

iv. the location, size and number of the proposed trial site(s); an appropriate map(s),

v. measures to be taken to accomplish genetic and material confinement of the GE material on the trial site, contingency plans and declaration section.

UNCST may from time to time revise the specific information required and the format of the Application Form.

The Application is first submitted to the Institutional Biosafety Committee (IBC), which must review the application and assure itself of availability and suitability of the proposed facilities for the safe conduct of the trials. After obtaining the IBC's recommendation, the applicant then submits the application with the IBC recommendation to the UNCST with a copy to the IBC Chairperson. The process is summarised in Figure 1 below:

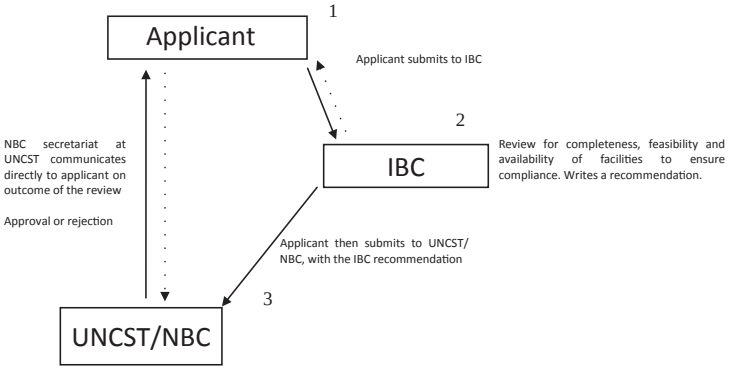

Figure 1: Field Trial Permit Application Process

2.1.2 Where to apply at UNCST

The application shall be submitted by hand, or regular mail, or courier, and must also be submitted electronically to:

National Biosafety Committee (NBC) Secretariat

Uganda National Council for Science and Technology

Plot 6 Kimera Road, Ntinda, Kampala

P. O. Box 6884, Kampala, Uganda

Telephone: +256-414-705500 / +256-312-314800

Fax: +256-414-234579

Email: info@uncst.go.ug

Website: http://www.uncst.go.ug

The UNCST will issue an acknowledgement of receipt to the applicant one working day after receiving the application. The acknowledgement of receipt shall include date of receipt of the application. Subsequent to receipt of application, The NBC Secretariat will check the application for completeness within 10 working days. If the application is found incomplete, the applicant shall be notified and the application shall not proceed for review. The applicant is responsible for providing all required information.

2.2 Review and authorisation

2.2.1 Review of applications

The NBC shall review the application within ninety (90) working days subject to the time taken by the applicant to provide any additional information required. Applications will be reviewed and approved by the National Biosafety Committee (NBC). Should need arise, the NBC may co-opt additional expertise or may obtain expert opinion from an independent reviewer or constitute a task force for purposes of reviewing certain applications. The NBC shall issue a decision and UNCST shall inform the applicant of the decision made.

The decision shall include:

i. Name of institution to undertake the trial,

ii. Composition and competence of the research team,

iii. Title or other appropriate information describing the field trial,

iv. Locations where field trial is to be conducted,

v. The authorised starting and end dates of the field trial,

vi. A reference code (e.g., Year – Crop – Serial Number) to be used on all subsequent correspondence relating to the authorised trial, and

vii. The terms and conditions under which the authorisation is granted.

2.2.2 Renewals

Renewal of authorisation for a field trial shall be considered for trials with the same crop, trial site(s), event(s), and phenotypic trait, and following previously approved protocols. The process for submission and authorisation of a renewal is the same as described in section 2.1 above for a new application. The request for renewal shall be sought from the NBC, and shall be accompanied by a justification and a progress report of the previous trial. The NBC decision shall be communicated to the applicant within a period of 90 working days from receipt of application for renewal of permit, with a copy to the IBC. The communication shall set out the basis for the decision.

2.2.3 Withdrawal of application

The applicant may withdraw an application any time. Once an application is withdrawn it can only be re-submitted as a new application.

2.2.4 Amendments to an existing authorisation

The Applicant may apply to the UNCST, through the IBC, for an Amendment to an existing Authorisation by submitting relevant details, including the section of the Authorisation being amended, the purpose of the requested change, and the exact wording of the relevant section(s) as amended.

Amendments shall be reviewed on a case-by-case basis, depending on the scope and impact of the changes being requested. The UNCST may require that the Applicant submit a new application encompassing requested amendments, depending on the scope thereof. Approved amendments shall be copied to the IBC.

2.2.5 Approval or rejection of applications

The NBC shall evaluate each Application and issue a final decision, taking into consideration technical issues and any aspects of the proposed field trial related to national policies in Uganda.

Where authorisation is denied, the Applicant shall be informed of the reason(s). The applicant may however reapply taking into consideration the issues raised in the decision rejecting the application. The decision to reject the application does not take away the applicant's right to seek redress.

2.2.6 Quorum

The quorum shall be fifty percent (50%) of NBC members. A final decision of the NBC to approve an application shall be made by consensus of the members and if consensus cannot be achieved, by a 2/3 majority vote of the members present. Decisions of the NBC on Applications under these Guidelines shall be publishable by the UNCST through appropriate media.

2.3 Terms and conditions of approval

Standard Terms and Conditions for the conduct, documentation and reporting of an authorised confined field trial shall be issued to the Authorised Party on approval of the trial by the UNCST in accordance with the requirements described in these Guidelines. Supplementary Terms and Conditions may also be imposed specific to the particular field trial at the discretion of the UNCST. Terms and Conditions shall be issued by the UNCST at the same time with the Letter of Clearance.

2.4 Confidential business information

In situations where completion of the application would entail the disclosure of confidential business information (CBI) or trade secrets, a 'CBI' and a 'CBI-deleted' application shall be submitted, and each shall be marked accordingly. The CBI-deleted copy shall be a true copy of the CBI application except where text has been deleted. The point of each deletion shall be clearly marked and the term "CBI-DELETED" shall be placed at the top right hand side of all pages affected. The Applicant shall provide a written justification for information claimed as CBI. If an application does not contain CBI, then only one copy of the application is required and each page shall be marked "NO CBI". Applications submitted without 'CBI' –'NO CBI' indication shall be deemed to be NO CBI applications. Both the No CBI and the CBI deleted versions of the Application form may be posted on the UNCST website (www.uncst.go.ug).

2.5 Benefit sharing

Reasonable efforts shall be made to share the expected benefits or potential benefits from the proposed GE trials among participating researchers, their institution(s) and the Government of Uganda. The UNCST shall require that all memoranda of understanding (MOUs) and other agreements with partners in the proposed field experiments be furnished during the application process. With the exception of repeat applications, any Application submitted shall include a benefit analysis which should identify and evaluate potential benefits which may arise from activities proposed in the Application.

2.6 Fees

The processing of a field trial application requires the Applicant to pay a non-refundable fee to UNCST upon submission of each application. No additional fee is required when supplementary information is submitted to address deficiencies of an application submitted previously. The fee schedule shall be published by UNCST and may be revised from time to time. The fee schedule may also be obtained from the NBC Secretariat or the UNCST website.

2.7 Informed consent on utilisation of field sites

The Applicant shall obtain informed consent from the land owner/trustee for the site where GE field trials shall be conducted. Consent shall be by signed agreement between the Applicant and the land owner or trustee and should be valid for the period of the study including the post- harvest monitoring period. The Applicant shall ensure that the land owner, trustee, as well as immediate neighbouring community is adequately trained and informed about the nature of experiments to be conducted at the site. For purposes of this section, a trustee / land owner shall include a farmer, institution, authorised government agency, and any other entity recognised by the laws of Uganda. A sample consent form shall be submitted to the NBC Secretariat at the UNCST along with the application.

2.8 Withdrawal of authorisation

The UNCST with recommendation from the NBC may withdraw authorisations due to non-compliance or for unforeseen circumstances. Withdrawal of authorisation shall be at the discretion of the UNCST and shall be indicated in writing to the "Authorised Party".

CHAPTER 3 CONDUCTING FIELD TRIALS

3.1 Responsibility of the authorised party

The Authorised Party shall ensure compliance with the Terms and Conditions of authorisation to conduct a field trial. The Authorised party shall be responsible to the actions of employees, subcontractors and agents engaged for the purpose of establishing and maintaining the trial site or handling the genetically modified plant material.

Compliance infractions shall include, among others, unauthorised or accidental release, entry of GE plant material into human or animal food chain while still under trials or gross negligence of the stated Terms and Conditions. Fines as appropriate shall be imposed by UNCST or courts of law for instances of non-compliance.

3.2 Field trial resources and personnel

The Authorised Party is required to have the physical and personnel resources sufficient to comply with all Terms and Conditions of authorisation. Adequacy of proposed trial sites, facilities and personnel shall be verified as a condition of trial authorisation. Trial managers and technical personnel shall provide evidence of education, training or experience in the safe handling of genetically modified organisms. An Application for a trial will be rejected if there are reasonable grounds to believe that the Applicant does not have sufficient resources or personnel to comply with the Terms and Conditions of authorisation.

3.3 Procedures for establishment of field trials

Field trials of GE plants in Uganda shall be conducted according to Standard Operating Procedures (SOPs) as published by and/or acceptable to UNCST. UNCST shall review SOPs for GE Trials from time to time and may also publish crop Specific SOPs in light of the differences in biology and cultivation practices for some crops. Authorised parties are required to obtain copies of the latest editions of the SOPs.

3.3.1 Establishment procedures

The following steps are crucial in the establishment of field trials involving transgenic plants:

i. Site identification (includes informed consent from land owner, see section 2.7),

ii. Site suitability and development (to include fencing, ploughing, and isolation monitoring, among others in accordance with specific SOPs),

iii. Site verification and commissioning,

iv. Acquisition, storage and transfer of planting materials,

v. Planting (including pre-planting compliance training),

vi. General field / site maintenance,

vii. Harvesting, and

viii. Post – harvest management.

3.3.2 Shipping and storage

GE plants or plant parts must be shipped and stored in a fashion that clearly identifies them as GE material, that prevents their unintended release into the environment, and that prevents them from being inadvertently mixed with non-GE material. Detailed requirements are found in the SOP for Shipping and Storage outlined in the Trial Manager's Handbook.

3.3.3 Reproductive isolation

GE plants being tested shall be reproductively isolated from sexually compatible plant species in proximity to the trial site. The primary means of achieving reproductive isolation shall be established according to measures outlined in the Trial Manager's Handbook.

3.3.4 Field site maintenance and monitoring

The trial site shall be maintained and monitored during the course of the trial in order to restrict gene flow and loss of GE material from the site. Field Site maintenance and monitoring shall be conducted according to the SOP for Confinement outlined in the Trial Manager's Handbook.

3.3.5 Training

The Applicant shall ensure that personnel involved in the field trials are adequately trained for biosafety compliance for the different plant growth stages.

3.3.6 Harvest / termination and disposal of GE plant material

The Applicant shall ensure that staff involved/to be involved in harvesting and termination operations are adequately trained on trial termination / harvest SOPs. Plant material harvested from a confined field trial that is not retained for future research work shall be disposed of according to the requirements of the SOP for disposal as outlined in the Trial Manager's Handbook or handled according to the terms and conditions of the trial. The NBC has the discretion to establish disposal methods appropriate to field trials at different stages of product development depending on the trial objectives, trial size, and nature of the novel genetic material.

3.3.7 Post-harvest management

The authorised party shall prevent growth and establishment of the progeny ['volunteers'] arising from the GE plants after termination of the trial. Depending on the nature of the propagative material remaining in the trial site and the biology of the crop plant, a post-harvest period and management practices shall be as outlined in the Trial Manager's Handbook.

3.3.8 Incident contingency planning

The Authorised Party will establish a contingency plan for actions to be taken in case of emergency, or of unauthorised or accidental release of GE material. Details are found in the SOP for Incidents in the Trial Manager's Handbook.

3.4 Inspection

Biosafety inspectors from the Ministry responsible for Agriculture and any other concerned Ministry or Government Agency as well as any other agencies authorised by UNCST shall inspect proposed and established field trial sites for transgenic plants and associated support facilities for adequacy and compliance with the Terms and Conditions of authorisation

throughout the trial and the post-harvest restriction period. All inspections shall be performed in accordance with the Terms and Conditions of approval and on a cost-recovery basis according to fee schedules established by the UNCST. Authorised Parties are required to provide due cooperation to inspectors during the field trial inspection process.

CHAPTER 4 REPORTING

4.1 Reports

4.1.1 Reporting procedure

Reporting is mandatory and an essential component of the compliance framework. All reports shall reference the authorisation code assigned to the trial, and shall be submitted to UNCST and copied to the IBC Chairperson. Reports submitted to UNCST shall be reviewed by the NBC. The IBC shall also review reports and include these into the IBC annual reports.

4.1.2 Types of reports

The following reports are required during the progress of the field trial:

i. Trial Establishment: The Authorised Party shall submit to UNCST details of trial establishment within five (5) working days after the completion of planting at the trial site. The report shall include the planting date, the amount of material planted, method of storage or disposal of any remaining GE plant material after planting, the size of the trial site and the fate of the stored surplus material if any. A final field site map shall also be submitted. Guidance on preparation of site maps is as indicated in the relevant SOP in the Trial Manager's Handbook.

ii. Isolation distance: The Authorised Party shall submit reports on the isolation distance monitoring depending on the plant under trial as part of the trial establishment report.

iii. Trial Progress: Trial progress [performance] reports shall be documented by the trial manager depending on the growth habit of the plant and the nature of data that is collected. The frequency and format of such report(s) shall be established according to the Terms and Conditions of authorisation to conduct the field trial.

iv. Mid-season: The Authorised Party shall submit a mid-season report detailing the progress of the trial from planting to the middle of the crop growing season. The mid-season report shall be submitted within a period of fifteen (15) working days after the middle of the crop growing season.

v. Harvest/Termination: The Authorised Party shall submit details of the site termination/ harvest within five (5) working days after the completion of harvest at the site. The report will include the date and method of harvest, disposal or storage of any harvested materials, plans for usage of retained materials (if any) and the method of destruction of any residual plant material on or off the site. An interim technical report at termination shall also be submitted to the UNCST.

In the event that GE material is harvested from the trial site for further analysis during the course of the trial or at the end of the trial, the Authorised Party shall submit a report on the type of analyses conducted and disposal mechanism for such materials. For the avoidance of doubt, disposal and handling of such material outside the trial site shall be conducted in accordance with SOPs for handling and storage of GE plant materials outlined in the trial Manager's Handbook.

vi. Post-harvest monitoring: The Authorised Party shall document and provide records of volunteer monitoring and destruction activities according to the terms and conditions of approval.

vii. Incident and corrective action report: The Authorised Party shall orally notify UNCST immediately, and in writing within 24 hours, of any incident involving an accidental or unauthorised release of genetically modified plant material. The report shall include any corrective actions taken or planned to confine GE material and ameliorate the incident.

viii. Unanticipated effects report: The Authorised Party shall notify UNCST in writing within five (5) working days if the GE plants exhibit any substantial unanticipated characteristics, or if any unusual event occurs that may jeopardise the confinement of the GE plants.

ix. End of field trial report: This is a crucial report. The Authorised Party shall submit an end of project report to UNCST within ninety (90) days after termination of the field trial. The end of project report must be comprehensive and shall include, but not limited to, technical data clearly explaining findings, trends and implications of the research trial; compliance with SOPs and any other terms and conditions; challenges experienced in the trials; and major conclusions. The Report shall also include a summary of observations on volunteers and their destruction, any data and analysis not previously submitted, and any responses required of the Authorised Party by the NBC concerning results of the trial.

4.2 Records

4.2.1 Record Keeping

The required documentation shall be guided by UNCST requirements and the SOP for a given trial. All trial records shall reference the authorisation code assigned to the trial, and shall bear the identity of the person responsible for the activity, the identity of the person making the record, and the date. Trial records shall be stored for a minimum period of five (5) years after completion of the trial by the Authorised Party.

All records on a given trial shall be kept up-to-date and shall be made available to the regulators upon request.

4.2.2 Records required

Records required shall include:

i. all trial reports,

ii. **transportation**, including a description of the material transported, method of transport and authorised custody;

iii. **storage**, including location and security;

iv. **material confinement** at the trial site, including site security and cleaning of equipment to ensure that no propagative material is removed from the trial site;

v. **disposal** of any GE material, including methods used;

vi. Monitoring and enforcement of **reproductive isolation**, including a description of the activities performed within the trial site and enforcement of the spatial isolation distance or other method used;

vii. **critical phases** of experimental progress, including planting, trial progress and harvest; Monitoring for **unanticipated effects** and other required observations, according to the specific trial;

viii. **post-harvest** monitoring, identification and destruction of volunteers;

ix. Records of any **unauthorised or accidental release** of GE traits or plant material, including **corrective actions** taken or planned;

x. periodic records on status of any GE plant materials stored.

Additional records may be required and these will be specified in writing by the UNCST.

A file or folder containing all the filled compliance forms, any other regulatory information recorded during the trial, and other relevant documentation related to the details of the trial, must be maintained by the Trial Manager, to be accessible to the Regulatory Authority upon request. Details on keeping such records can be found in the relevant SOP in the Trial Manager's Handbook.

4.3 Information dissemination

The Authorised Party shall make all reasonable efforts to engage with the community at all stages of the trial and this may include packaging and sharing appropriate information with the community and stakeholders such as the NBC/UNCST, local leaders, media and the general public. The Authorised Party shall ensure that all agents authorised to communicate any information concerning the field trials do so responsibly.

FIRST SCHEDULE

Uganda National Council for Science and Technology

(Cap 209 of the Laws of Uganda)

The National Biosafety Committee (NBC)

APPLICATION FORM

No…….(NBC Official Use Only)

APPLICATION FORM FOR FIELD TRIALS OF GENETICALLY ENGINEERED PLANTS IN UGANDA

For Official Use Only by NBC Secretariat

Application No.:	
Title of Research undertaking:	
Institution (s):	
Principal Investigator:	
Proposed Start Date:	
Proposed End Date:	

PREAMBLE

- To be completed by the Applicant (Principal Investigator) and first submitted to the Institutional Biosafety Committee (IBC). After obtaining IBC recommendation and institutional endorsement, the Applicant shall submit the application to the National Biosafety Committee (NBC) at the UNCST.

- The boxes are expandable and thus can be electronically filled. Questions requiring Yes/No answers can be answered by clicking on the appropriate Yes/No box. All relevant questions to your study should be answered and be sure to include complete information, attaching continuation sheets and any other relevant information as may be necessary to facilitate the evaluation of the application.

- Applicants are required to provide further information as may be requested by National Biosafety Committee (NBC).

- In calculating the time periods for communication to the Applicant, any time for which the Competent Authority through the NBC must wait for additional relevant information requested from the Applicant shall not be counted toward the number of days accrued.

- Applications judged to be illegible, incomplete or vague shall be returned to the Applicant.

- Applicants are informed that assessments of the application will bear financial costs, which will be met by the applicant.

- Original, duly signed (by both the Applicant and the IBC's Chairman or Institutional Biosafety Officer/IBC Secretary) hard copies of the application, the number of which shall be specified by the NBC should be returned to:

The National Biosafety Committee (NBC) Secretariat,
Uganda National Council for Science and Technology,
P.O. Box 6884 Kampala, Uganda
Tel. +256-414-705500/+256-312-312800 Fax: +256-414-234579
Email: info@uncst.go.ug

1. Table of contents (to be developed by applicant after completing the form)

2. General information

i) Name of the Applicant (Principal Investigator):

ii) Position:

iii) Institutional Address:

iv) Department /Division/ Programme:

v) Telephone (office): Mobile: Fax:

vi) E-mail:

vii). Title of the proposed field trial project:

viii). Proposed date of commencement of the field trial project

ix). Proposed date of completion of the field trial project:

x). Please indicate with justification whether your study is a primary or an advanced field trial *(refer to National Guidelines for Field Trials of GE Plants for clarity on differences between the two types of trials)*

xi). Name all the Institutions both national and International that are involved in this work, giving their full contact addresses, including physical, email, and telephone addresses of the contact persons in these institutions

National:

International:

xii). Do you have funding commitment for this project? ☐ Yes ☐ No

xiii). What is/are your External and Internal Funding Agency (ies) or Source(s)?

xiv). Attach a complete proposal for this project with a budget.

3. Specific information:

i). Were /are any of the following genes, viruses, factors, or conditions involved in the work?

Yes	No		
☐	☐	a)	Deliberate transfer of drug resistance into organisms that do not acquire them naturally? (except for approved host-vector systems that contain antibiotic resistance markers)
☐	☐	b)	Deliberate transfer of rDNA into humans?
☐	☐	c)	Deliberate formation of rDNA-containing genes that produce vertebrate toxins with LD50 less than 100ng/kg of Body weight?
☐	☐	d)	Using animal or human pathogens (Risk Groups 2-4 and restricted agents) as host vector systems?
☐	☐	e)	Using human or animal pathogen DNA cloned into non-pathogenic prokaryote or lower eukaryote host-vector systems?
☐	☐	f)	Using infectious animal or plant DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems? (work with animal pathogens requires a sanitary Certificate and an Import Permit from the relevant government agency(ies)
☐	☐	g)	Altering an animal genome by recombinant DNA or testing viable rDNA modified microorganisms in whole animals? (work with plant pathogens requires a Phytosanitary Certificate and an Import Permit from the Ministry of Agriculture, Animal Industry and Fisheries)
☐	☐	h)	Experiments involving restricted and controlled release of rDNA modified plants or animals (this requires review by IBC and NBC)

Give an explanation of your answers in A (a-h) above wherever it was a **Yes** indicating clearly which of the subsections a-h you are referring to:

ii). Project Description (Please provide a brief project description including objectives, methodology and time frame of the different project activities):

iii). Host Organism (List the Biosafety Level, name and taxonomic classification):

iv). Describe the vector(s) used and their sources

v). **Personnel**- Apart from the Principal Investigator (PI) List the Names and Titles of all the other individuals that will be engaged in the experiments beginning with the Trial Manager for the field trial. Attach abridged curriculum vitae (not more than one page) for the PI as well as those of the other personnel to be involved with the trial (not more than half a page each).

vi). What arrangements do you intend to put in place for effective health and environment monitoring

vii). Training- Indicate the steps taken or to be taken to ensure that personnel identified above are familiar or will be familiar with Biosafety Guidelines, laboratory policies and Confined Field trial Guidelines and Standard Operating Procedures and other specific instructions from the IBC and NBC pertaining to the project as the case may be. Evidence of the training shall be provided to the NBC Secretariat prior to planting the trial.

viii). Briefly describe the proposed locations of the trial (s) in broad terms such as district, county sub-county, village (*details to be given in section 4d(i)*).

ix). In case of an advanced field trial, state whether the necessary consent forms have been completed, land use permission has been secured and community consultations have been conducted (please attach evidence as applicable)

4. Information on the p lant:

a. Unmodified plant information

i). Name the unmodified plant (common and scientific names)

ii) . Describe the reproductive mechanisms of the plant: (Attach any additional information on the biology of the plant)

- Pollen production
- Pollen dispersal
- Pollen viability
- Seed production
- Seed dispersal
- Seed dormancy
- Vegetative reproduction

iii). Is Uganda a primary centre of diversity or origin of the plant species? ☐ Yes ☐ No

iv). Is Uganda a secondary centre of diversity for the plant species? ☐ Yes ☐ No

v). Is the plant considered to have a weedy tendency? ☐ Yes ☐ No
If Yes, please describe.

vi). Is the plant considered naturally invasive? ☐ Yes ☐ No
If Yes, please describe

b. Modified plant information:

i). Describe the genetic modification that was done to the plant.

ii). Has genetic modification altered the reproductive biology of the plant? Please explain

iii). Does the introduced genetic material give rise to any infectious agents?

iv). Has the genetically modified plant been tested or commercially released in Uganda or elsewhere? Please explain

v) Early efficacy data: Describe results of tests of the expression and efficacy of the target phenotype from the laboratory, screen house and primary field trial stages, as applicable.

vi). Has another country rejected an application for the planned field trial testing of this crop or genetic event? If so, which country and on what basis?

vii). Provide an Annex of information for each genetic element (or feature) of the construct including coding sequences, promoters, enhancers, termination and polyadenylation signal sequences, and their source organism, involved in your work (Please clearly indicate Confidential Business Information, justifying why it is confidential, such that it is considered for keeping confidential by the IBC, NBC and the UNCST)

viii) Provide an annex or a thorough description of the method of transformation used; specify the selectable marker(s) used, clarifying on the safety of the marker(s)

c. Early food and environmental safety data: In the case of an advanced confined field trial, available information regarding food and environmental safety, collected from other field trials or available from other sources, may be provided to support the approval of the trial as follows:

i) Early food safety data (if a food crop) that may include: *identity of the new protein and its mode of function; whether the new protein (or nutrient) has been used safely in food before; a description of the intended effect of the new protein; an assessment of the amino acid similarity between the new protein and known allergens and toxins; the overall stability of the protein with respect to enzymatic degradation using appropriate in vitro assays; any preliminary data from animal feeding tests, if available.* (*Additional sheets or separate reports may be added as Annexes*).

ii) Early environmental safety data that may include: phenotypic data (such as vigour, days to flowering, plant height, etc.) compared to non-GE counterparts; plant-insect interactions; plant-disease interactions; plant-abiotic stress interactions; status and effect on below-ground and above-ground biodiversity; effects on non-targets, gene flow, etc. (Additional sheets or separate reports may be added as Annexes).

d. Material and genetic confinement:

Measures to minimise gene flow from the field trial, persistence of plant material in the environment, or entry of material into the food or feed pathways.

i). Provide information on the proposed trial site size and location, surrounding fields and geographic features as well as the proposed isolation of your field (*a map of the proposed site and associated permanent structures must also be attached*).

ii). Are there any sexually compatible wild relatives of the plant species in Uganda?
☐ Yes ☐ No
If yes, Describe them:

iii). If yes, are these within the vicinity of the trial site? ☐ Yes ☐ No

iv). Describe the mechanisms you intend to use to minimise gene flow justifying each of the mechanisms proposed. For instance:

- Isolation distances,
- Detasseling or removal of floral parts,
- Temporal isolation,
- Termination of trial before flowering
- Use of guard rows/pollen traps/ windbreaks
- Measures to prevent seed dispersal from the test area
- Any other mechanism as may be applicable
- Include and describe climatic and geo-physical data that may influence the reproductive isolation methods suggested.

v). What type of data do you intend to collect and what will be your method of record keeping? (*your record keeping must be consistent which the requirements of the field trial Standard Operating Procedures and/or according to the requirements of the NBC*).

vi). Describe how the genetically engineered plant material will be packaged for transport to the trial site.

vii). Describe how the packaging material will be cleaned and/ or disposed after use.

viii). Describe how the packaging material containing the genetically engineered material will be marked/ identified during the transportation to the trial site.

ix) Describe measures to inhibit unauthorised removal of material from the trial site: These may include but are not limited to fencing, guarding, locked gate or locating the trial in an adequately isolated area.

x). What additional measures, if any, shall be taken to minimise and possibly preclude local fauna and humans from removing material from the trial site?

xi). Describe how surplus planting material will be recorded and disposed at the trial site.

xii). Describe how equipment used in the planting and other farm operations will be cleaned.

xiii). Describe the training that you will provide to the security guard and other personnel regarding measures to ensure material confinement.

xiv). How will the materials be harvested?

xv). Will any of the harvested material be retained and if so, for what purpose and under what transport and storage conditions?

xvi). How will the harvested materials and plant residues be disposed?

xvii). Will material be removed away from the field trial site for further analysis?

☐ Yes ☐ No . If yes, explain how these will used and destroyed.

xviii). Describe the post-trial plans to control volunteers on the site. The description should give reference to the following:

- Cropping patterns on the site;
- Duration of monitoring;
- Frequency of monitoring;
- Disposal of any identified volunteers;
- Any other means; and,
- Record keeping.

f. Contingency plans

Describe your contingency plans in the event of accidental release of genetically engineered plant material. The description should make reference to notification of the authorities, Recovery of the material, confinement of the material, and to any other measures that you may employ (Refer to the Incidents Standard Operating Procedure)

5. Declaration form

a. Declaration by the applicant

I hereby declare that the information provided in this Application is complete and accurate. I am familiar with and agree to abide by the relevant portions of the current biosafety guidelines and other specific instructions from the IBC, the NBC and any other regulatory requirement as far as implementation of the proposed field trial is concerned. No elements in my research will be implemented without prior review and approval by the IBC and the NBC as the case may be.

Name: _____

Signed: _____ Date: _____

Professional Title: _____

b. IBC recommendation

a. Comment on the suitability of the premises, staff capacity, resources and authenticity of the information given in this application.

b. Briefly explain how and at what frequency will the IBC monitor the activities of this project, giving approximate time intervals at which the IBC will furnish the NBC with reports about this work (except for emergencies that must be reported within the shortest time possible).

c. Provide a list of Names and Addresses of all Members of the IBC indicating those that were involved in reviewing this application.

c. Declaration by the IBC Chairman or IBC Biosafety Officer/ Secretary to the IBC

I declare that the proposal set out in this application has been considered by a properly constituted IBC of which I am the authorised representative and whose views on the proposal are accurately set out in Section 5 (b) of this form.

Name: _____

Signed _____ Date: _____

Title with respect to the IBC _____

Authorised representative of Institutional Biosafety Committee

_____

GE banana trials at NARL-Kawanda

GE cotton trials at Mubuku-Kasese

Notes

Notes

National Biosafety Committee (NBC) Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884 Kampala, Uganda
Tel: 256-414-705500/256-312-314800.
Fax: 256-414-234579
Email: info@uncst.go.ug
Website: www.uncst.go.ug

ISBN 978-9970-26-000-3