Confined Field Trial Guidelines for Uganda

For Field Experiments with Genetically Engineered Plants

Uganda National Council for Science and Technology, 2006

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An Elaboration of Critical Elements in the Regulation and Execution of Confined Field Trials

Prepared by Uganda National Council for Science and Technology

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Acknowledgements

Production of this Guideline together with its companion manuals: the Trial Managers' Handbook containing the standard Operating Procedures for Confined Field Trials, the Resource book for Regulators and the Inspection manual, is a major step forward in making research with genetically modified plants possible in Uganda. These documents collectively form what is known as an Integrated Confinement System (ICS) and were produced with contribution from a range of authorities and biosafety stakeholders in the country.

Members of the National Biosafety Committee, agricultural research scientists, and officials from the Crop Protection Department of the Ministry of Agriculture participated at various stages of preparing these manuals and their contributions and support are highly appreciated.

Special thanks go to the members of the drafting and editing team that included Dr. Mark Halsey formerly of Donald Danforth Plant Sciences Center, USA, Mr. Arthur Makara, UNCST, Ms. Grace Akao and Dr.Emmanuel Iyamulemye both of Crop Protection Department of MAAIF. Their concerted effort in putting these documents together and their continuous review is greatly appreciated. In a special way, we would like to acknowledge the technical backstopping from Program for Biosafety Systems (PBS) that facilitated UNCST in its efforts to put in place these documents in the effort to establish a functional Biosafety system in Uganda. Ms. Barbara Zawedde and Dr. Theresa Sengooba of PBS based at IFPRI, your input during the preparation of these documents as well as the administrative role you have continued to play in this and other Biosafety related endeavors is highly appreciated. These documents, we are sure, will go a long way in ensuring safe conduct of confined field research trials with genetically modified plants in Uganda.

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Preface

Understanding the nature of biological processes has advanced beyond observations, description of natural phenomena, growing of parts of tissues or even cell culture techniques, all of which have depended on chance and gross manipulation. Genetic manipulation techniques of biological processes at molecular level have been enhanced by Recombinant Deoxyribonucleic Acid (rDNA) technology. This has led to deliberate creation of new lines of Genetically Modified (GM) or Engineered (GE) organisms also frequently referred to as Living Modified Organisms (LMOs).

Application of rDNA in crop, animal and human growth and development systems is poised to enhance food production and security, health safety and environmental conservation and biodiversity maintenance. The rDNA technology enhances biological processes which otherwise would have taken place by chance or would be undirected, leading to timely, unacceptable and undesirable outcomes. However, directed and controlled outcomes of these processes should ensure food security, health safety and technological wellbeing of humanity. In tropical Africa where environmental risk factors have more significant influence agriculture production, this (rDNA) technology should be carefully and systematically adopted for laboratory and green houses (contained) testing, as well as open field (but confined) trials of crops.

A systematic approach to integrated contained/confined systems requires laboratory and glass houses infrastructure as well as small scale areas of restricted access in the open field for Confined Field Trials (CFT), respectively. A CFT area avoids human and animal interference, enhances reproductive isolation, easy surveillance, removal of volunteers and management of new genetic traits of crops introduced to the geographical area. CFT therefore calls for regulation of the adoption and implementation processes in crop biotechnology, requiring governments' approval, over-seeing the implementation and evaluation processes (development of best, or elimination of poor traits among crops) as well as establishment of effective control at the local environment through Regulatory Authorities and their inspectors. Regulatory activity requires permanent well trained staff that is well guided using available publicly accessible documents. This has necessitated the production of four companion manuals, by Uganda National Council for Science and Technology (UNCST). These four manuals are:

1: Confined Field Trial Guidelines, for field experiments with GE plants.
2: Trial Managers Handbook: Procedures and forms for field experiments with GE plants
3: Inspectors Handbook: Procedures for Biosafety Inspection of experiments with GE crops.
4: Resources for regulators to include models for regulation of experiments with GE plants.

The Uganda's National Council for Science and Technology (UNCST) working in collaboration with the Crop Protection Department, Ministry of Agriculture, Animal Industry and Fisheries, the former whose committee, the National Biosafety Committee (NBC), is the Regulatory Authority, developed the objective to "Dedicate themselves to Biosafety in Biotechnology" by:-

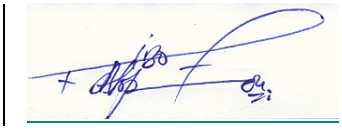
- Training human resources and capacity in CFT
- Developing regulatory strategies and stimulation of policy
- Engaging policy makers together with rDNA technology developers, research scientists, Regulatory Authorities such as Uganda's NBC and field Inspectors.
- Enhancing the functionalization, operationalization of the processes of Biotechnology and Biosafety and their application to development.

The CFT Guidelines for Uganda and companion manuals are valuable to all regulators including those whose backgrounds are neither biological nor legal sciences. The primary purpose of these manuals is to give a unified framework of methods, procedures, processes and suitable forms together in a comprehensive manner. They are now available, accessible, to expert scientists as checklist documents and to first-time users as well. They also give you a guide to consult other more relevant documents/texts which may cover in greater detail the biology, the laboratory and ecological methods of the crops in question.

The development of these Guidelines would not have been possible without the insight of the National Research Council of the U.S. National Academy of Science on GE's, which recommended the management of confinement through the integrated confinement system. PBS of IFPRI in Washington, D.C. which through the Donald Danforth Plant Centre in St. Louis, MO. USA, provided the resources. Dr. Mark E. Hasley of BPS – Donald Danforth Plant Centre gave the leadership of being the principal author with a team of reviewers identified in the respective manuals. PBS's East African Coordinator Dr. Theresa Sengooba provided the lead contact and organizational point for several workshops, seminars and consultations during the development of the local input and training for this program. As the Chairman of the NBC of UNCST, the Regulatory Authority of Biosafety in Uganda, I am privileged to write this preface on behalf of NBC.

While these documents may not cover all areas of CFT in this edition, there will be need to update them in future and for the users to feel free to consult other sources of Biotechnology Biosafety regulatory documents and websites.

You are invited to make the best use of these manuals and feel free to notify UNCST on any improvements you may identify.



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Chairman NBC - Uganda

Foreword

The process of modernizing agriculture in Uganda inevitably involves the application of new farming and agro-processing technologies such as genetic engineering of crop plants to increase yield and nutritional qualities, withstand biotic and abiotic stress conditions, 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 Confined Field Trial Guidelines for 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 crop plants. The guidelines and all the associated manuals have been developed following the Integrated Confinement System approach, which guarantees 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 in Uganda. We also recognize in a special way and express our gratitude to those who are contributing to agricultural modernization through application of genetic engineering.

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

Definitions

Anthesis: The time when a flower, plant or crop releases pollen.

Applicant: A party submitting an application for a confined field trial. Typically, the Applicant is the same as the Authorized Party (see), or is acting in collaboration with the Authorized Party.

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

Border Rows: A planting of the same or a different plant species around GM plants in the trial site, to serve as a means of reproductive isolation, or as a visual or physical barrier. Also called 'border rows', or 'pollen trap rows', when used for reproductive isolation.

Compliance: Fulfilling the requirements of the Terms and Conditions of Authorization, especially with regard to confinement measures.

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

Confined Field Trial (CFT): A field trial of GM plants that have not been approved for general release. In 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 (n): A segment of DNA to be transferred into a cell or tissue in the process of 'genetic modification' (see).

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

Facility Manager: The individual responsible for the supervision of a storage or testing facility.

Following Crop: A crop planted on a trial site after harvest or termination of a confined field trial.

Free-living: A plant living outside cultivation, or surviving without human intervention.

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)'** 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 GM plant material.

Material Confinement: Measures taken to ensure that GM plant material is not consumed by humans, livestock and animals.

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

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

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

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

Regulated: As used here, a GMOs 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.

Study Plan: Also known as the 'Protocol', the Study Plan establishes the technical objectives and required methodology of the trial, beyond those requirements related to confinement. A model of an appropriate Study Plan is given in Appendix 1.

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 Authorized Party or Principal Investigator as responsible for management and compliance of an authorized confined field trial. Trial Managers are authorized 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. Also call the 'Study Area'.

Trial Site Identification: A descriptive or numeric identifier for a single Trial Site, which may include multiple events, constructs, and/or Authorization Numbers.

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

PREAMBLE

Experimental testing, especially in field trials, 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. Exposing new lines or plants with new traits to the natural environment in the field is essential to research, development, characterization, and eventual recommendation of new varieties for the use and benefit of farmers and society.

When plants have traits introduced by modern genetic techniques such as recombinant DNA (rDNA) technology, they are called 'genetically modified' (GM), 'genetically engineered' (GE), or 'living modified organisms' (LMOs). The testing of these types of plants is regulated by government agencies, which oversee their evaluation and must give their approval on a case-by-case basis before a new GE variety may be placed on the market in a general or unrestricted release.

Regulation of GE plants requires that the government, research on experimental lines or varieties prior to their approval for release is conducted under controlled conditions, either in a laboratory or glasshouse ('contained' testing), or in a restricted area outdoors, which is called a 'confined field trial' (CFT).

CFTs are used to determine whether a new genetic trait is effective in the local environment, to select those lines with the best characteristics for further testing, to backcross the desired trait into varieties of local interest, to gather data or plant material required for environmental impact and food safety assessment to be used in applying for general release, and to scale-up plant material for introduction prior to approval for general release.

A Confined Field Trial has several key characteristics:

- It is an experimental activity, conducted prior to approval for general release.
- It is done in the open field, thus exposing the plants to the natural environment.
- It is done on a small scale, typically 1 ha or less.
- Access to the field site is restricted to authorized personnel. The site may be on a restricted-access government facility, such as an experiment station. Where necessary, a fence with a lockable gate may be installed to restrict access to the site.
- The GE plant material and genes being tested are confined to the field trial site using measures to ensure that the genes in pollen or seed do not escape from the trial site (reproductive isolation), that the GE material is not eaten by humans, livestock or other

animals (material confinement), and that the GE plants and any volunteers arising from the trial are destroyed after the test and do not persist in the environment.

- The measures for confinement are set forth in detail by UNCST, the biosafety competent authority, in the Terms and Conditions of Authorization of the confined trial, and must be strictly followed by the Authorized Party and trial personnel.
- The UNCST maintains surveillance over the trial by means of inspections and by reports required from the Authorized Party on the conduct of the trial.

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 food security. When plants with GE traits are being tested, the field trials must be carefully managed in order to assure that experimental material remains confined, so that no effect on the environment and human or animal health is allowed.

OBJECTIVES

The UNCST, under its mandate, is dedicated to ensuring biosafety in the testing and development of genetically engineered crops, by providing support in training, capacity building, regulatory strategies and policy development.

Experience has shown that there are many aspects to the regulation and implementation of confined trials—policy makers, technology developers, scientists, regulators and field inspectors all have their own unique perspectives and needs. Just as many parts are required for an automobile to run, a comprehensive approach is needed to functionalize the process of evaluation of GE plants. Such a comprehensive system helps to facilitate project planning and to ensure the consistent application of biosafety principles in the experimental phases of the development of GE plants for the potential benefit to society.

Becoming aware of the need for a comprehensive and encompassing approach to biosafety for confined field trials, UNCST has developed this ‘Integrated Confinement System’ which is applicable to confined field trials, as well as contained glasshouse experiments.

The objectives of UNCST in developing and publishing this system for unrestricted public use are several-fold:

1. To ensure biosafety in the testing and evaluation of modern, genetically–engineered agricultural products, especially where that testing is done in field situations;
2. To enable Uganda establish a customized, comprehensive, ‘turn-key’ system for regulating, executing and overseeing CFTs and other experimental trials;

3. To enable regulators, Authorized Parties, Trial Managers and others, to focus their energies on critical issues of biosafety and confinement.
4. To establish a comprehensive and systems-based approach to the regulation of GE crops in Uganda.

WHAT IS AN INTEGRATED CONFINEMENT SYSTEM?

Integrated Confinement System (ICS) is a systematic approach to the design, development, execution and monitoring of the confinement of a specific GEO. The ICS approach puts biosafety as a primary goal in the testing and development of GEOs, so that adequate safety provisions can be built–in from the start, during the earliest phases of project conception and planning. This is conceived as the most "effective and efficient way to prevent safety failures," and also the preferable approach for public research institutions with limited resources.

The key elements of an ICS envisioned by the committee are:

- Commitment by top management;
- Establishment of written plans to be implemented, including those for documentation, monitoring, and remediation;
- Training of employees;
- Dedication of permanent staff to maintain continuity;
- Use of standard operating procedures and good management practices;
- Periodic audits by an independent entity;
- Periodic internal review and adaptive management;
- Reporting to an appropriate regulatory body.

The ICS requires that different, but interlocking, elements are in place at the outset of project planning, so that all requirements can be taken into account for planning and resourcing purposes. The required elements, when applied to experimental testing of agricultural biotechnology, include procedures to support a spectrum of activities, including: the regulatory application process; regulatory review, decision and communication; trial execution, compliance, inspection and oversight; monitoring and reporting.

UNITS OF THE INTEGRATED CONFINEMENT SYSTEM

There are several key aspects to the regulation and implementation of experimental trials of GE crops, and the ICS Units presented here are intended to meet the overall requirements of each aspect. Several of the items are unique to the PBS ICS, but in some cases materials addressing an aspect already exist, and are referenced here with an electronic link. All materials provided are public-access, and are available to all users without restriction.

1. **Confined Field Trial Guideline:** *A model guideline*
2. **Trial Managers Handbook:** *Procedures and forms for conducting experiments with GE plants*
3. **Inspector's Handbook:** *Procedures for biosafety inspection*
4. **Resources for Regulators:** *Models for regulation of experiments with GE plants*

Readers interested in more information about confined field trials, may find the following resources useful:

Compliance Management of confined field trials with genetically engineered plants. July 2005. Crop Life International. http://www.croplife.org/

UNCST website: http://www.uncst.go.ug

A Practical Guide to Containment – Greenhouse Research with Transgenic Plants and Microbes 2001. D. Adair, R. Irwin and P.L. Traynor. Information Systems for Biotechnology, Virginia Tech (USA): http://www.isb.vt.edu.

CFT Guidelines for Uganda

Appendix 5 of the National Biosafety Guidelines

1.0 INTRODUCTION

The purpose of this document is to provide a clear and concise summary of the regulatory requirements governing confined field trials of genetically modified (GM) plants in Uganda, in accordance with the 'Guidelines on Biosafety in Biotechnology for Uganda' ('National Guideline'), which are administered by the Uganda National Council for Science and Technology (UNCST). Supporting documents and guidance shall be published by UNCST and made available on its website [http://www.uncst.go.ug], which should be consulted by Applicants and Authorized Parties. In the event of any conflict or inconsistency between this document and the terms or conditions of a more specific additional document provided by UNCST or the National Biosafety Committee (NBC) for accomplishing the purposes of this Guideline, the Terms and Conditions of such additional document will govern.

Confined field trials are examples of 'controlled field experiments' or 'multiple field plots' defined under Sec. 2.2(d) and Sec. 3.8(b and c) of the National Guideline. In a confined field trial, genetic and material confinement measures are used to restrict GM plant material to a specific area of the environment, and these research trials may thus be considered as extensions of contained experimentation, as defined in Sec. 3.4.1 of the National Guideline. Confined field trials are small-scale research and pre-commercial activities, providing technology developers with the opportunity to evaluate the performance of genetically modified plants, to collect data required for safety assessment, variety testing, registration, and seed certification purposes, and to engage in scale-up production prior to regulatory approval. This Unit establishes requirements specific to confined field trials and their implementation.

No person may establish a confined field trial of any genetically modified plant within Uganda without authorization under these guidelines.

1.1 LEGAL AUTHORITY

This Guidelines derives its authority from UNCST Statute No. 1 of 1990; Sec. 3 & 4, which designates UNCST as the competent authority on all matters concerning Science and Technology, including Biotechnology and Biosafety.

2.0 APPLICATION FOR A CONFINED FIELD TRIAL

2.1 Submitting an Application

2.1.1 *Application Form*

UNCST avails an Application Form to be completed by Applicants for confined field trials, which is also available on the its website (www.uncst.go.ug). The Application Form contains sufficiently detailed instructions to allow the Applicant to complete the form correctly and expeditiously. The information required in consideration of a confined field trial authorization include details about: the Applicant and his/her affiliation, the plant species to be tested, the genetic construct and its associated phenotype to be tested, the proposed trial site including an appropriate map, measures to be taken to accomplish genetic and material confinement of the GM material on the trial site, contingency plans and declaration section. UNCST may revise the specific information required and the format of the Application Form if necessary.

Submission of the Application shall be through the Institutional Biosafety Committee (IBC), whose officers must ensure completeness of the application form and verify availability of the proposed facilities before endorsing and forwarding the application to UNCST.

2.1.2 Where to apply

The application form shall be completed and submitted by regular mail, by courier, or electronically to:

National Biosafety Committee (NBC) Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884
Kampala, Uganda
Telephone: 256-41-250499
Fax: 256-41-234579
Email: uncst@uncst.go.ug
Website: http://www.uncst.go.ug

2.1.3 When to apply

Applications for a confined field trial must be received at least 90 working days in advance of the proposed trial start date. The NBC Secretariat will review the application for completeness within 10 working days, and initiate the official review process if the application is found to be complete. Applications that are incomplete or deficient are returned to the Applicant with a listing of information required to address any deficiencies within the 10 working days mentioned earlier. Any additional information required is subject to the timelines for review described herein, from the date of its submission.

2.2 Review and Authorization

2.2.1 Process of Review and Authorization

Applications will be reviewed and approved or rejected by the National Biosafety Committee (NBC). The NBC may request technical advice and recommendations from the relevant Sector. The NBC will issue a final determination of authorization within 90 working days of receipt of the application by UNCST.

Where authorization is granted by NBC, the Executive Secretary of UNCST shall issue a Letter of Authorization, which shall include the following elements:

1. The authorized starting and termination dates of the confined field trial. The term of the authorization shall be determined by the NBC as appropriate for the crop and experimental objectives.
2. A reference code (e.g., Year – Crop – Serial Number) to be used on all subsequent correspondence relating to the authorized trial.
3. The final Terms and Conditions under which the authorization is granted.

Where authorization is denied, the Applicant shall be informed of the reason(s) and provided with an opportunity to reapply or appeal.

2.2.2 Criteria for Approval or Rejection of Applications

The NBC shall evaluate each Application and issue a final determination, taking into consideration technical recommendations and any aspects of the proposed work related to national policies in Uganda.

A final determination of the NBC to approve an application shall be made by a 2/3 majority vote. Decisions of the NBC on Applications under this Guideline shall be published on the UNCST website.

2.2.3 Renewals

Renewal of authorization for a confined field trial may be considered for trials with the same crop, trial site(s) and phenotypic trait as previously authorized. The process for submission and authorization of a renewal is the same as described above for a new application.

2.3 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 facsimile 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". Both the No CBI and the CBI deleted versions of the Application form shall be posted on the UNCST website (www.uncst.go.ug).

2.4 FEES

The processing of a confined 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 take account of the complexity of the application, e.g., number of genetic constructs, locations, or experimental units, and

whether the submission is a new application or a renewal. The fee schedule shall be published by UNCST and may be revised from time to time. The fee schedule shall also be made available on the UNCST website (www.uncst.go.ug).

3.0 CONDUCTING CONFINED FIELD TRIALS

3.1 Responsibility of the Authorized Party

It is the responsibility of the Authorized Party to ensure compliance with the Terms and Conditions of authorization. This responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of establishing and maintaining the trial site or handling the genetically modified plant material.

Compliance infractions include unauthorized or accidental release, entry of GM plant material into human or animal food while still under test or gross negligence of stated Terms and Conditions. Substantial fines may be imposed by UNCST for instances of non-compliance.

3.2 Size and Number of Confined Field Trials

In order to maintain the integrity of the review and approval system, and to ensure adherence to the requirements described herein, UNCST may restrict the number of confined field trial applications or approvals granted, and/or the size of authorized trials. These restrictions shall be determined by specific circumstances, and may be applied with respect to Applicants, genetic constructs, phenotypic traits, field sites or other criteria at the discretion of UNCST. Applicants should consult with the NBC Secretariat for information on any restrictions that may be in force, prior to submitting an Application.

3.3 Trial Resources and Personnel

The Authorized Party is required to have the physical and personnel resources sufficient to comply with all Terms and Conditions of authorization. Proposed trial sites shall be inspected and their adequacy verified as a condition of trial authorization. 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 confined field 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 authorization.

3.4 Procedures for Confined Field Trials

3.4.1 Establishment of procedures

Procedures for the conduct of confined field trials are intended to accomplish three important goals: **1) preventing the escape from the trial site of novel genes in pollen, seed or other plant parts, 2) preventing GM plant material from being consumed by humans and/or animals,** and **3) preventing GM plants from escaping from confinement, establishing and persisting in the environment.** With the achievement of these three goals, novel genes and their products may be confined to the field trial site, and their release into the general environment prevented.

In order to establish effective procedures to achieve these goals, Authorized Parties are required to follow Standard Operating Procedures (SOPs) for the safe transport and storage of GM plant material, for reproductive isolation and material confinement of the GM plants on the field trial site, for disposal of plant material and volunteers at the trial site, and for contingency planning. SOPs addressing the requirements in detail for specific crop plants are given detail in Unit 3 for use by Authorized Parties and shall also be posted on the UNCST website www.uncst.go.ug for ease of accessibility. These SOPs include those in the sections following.

3.4.2 Shipping and storage

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

3.4.3 Reproductive Isolation

To prevent the escape of genes from the trial site, GM 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 is by use of a spatial isolation distance between plants in the trial site and any plants with which the GM plants are sexually compatible, which are designated as ‘prohibited plants’. Minimum spatial isolation

distances vary depending on the reproductive biology of the plant species. Guidance for specific crops and circumstances will be availed by UNCST.

Alternative methods of reproductive isolation may be used in place of or in addition to spatial isolation distance, depending on the crop plant and the circumstances of the specific trial. Examples of alternative methods may be found in the SOP for Confinement.

3.4.4 Field Site Maintenance and Monitoring

The trial site will be maintained and monitored during the course of the trial in order to restrict gene flow and loss of GM material from the site. Details may be found in the SOP for Confinement.

3.4.5 Harvest and Disposal of GM Plant Material

No plant material from a confined field trial site may be used as human food and/or animal feed. Plant material harvested from a confined trial that is not retained for future research work shall be disposed of according to the requirements of the SOP for Disposal.

3.4.6 Post-Harvest Requirements

Progeny arising from the GM plants at the field trial site are known as ‘volunteers’, and must be prevented from establishing and flowering 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 will be defined. Details of post-harvest management may be found in the SOP for Post-harvest Management.

3.4.7 Contingency Planning

The Authorized Party will establish a contingency plan for actions to be taken in case of emergency, or of unauthorized or accidental release of GM material. Details may be found in the SOP for Incidents.

4.0 REPORTS

4.1 Submitting Reports

Reporting allows the Authorized Party to inform UNCST on progress and results of the confined field trial, including unusual or unanticipated effects or occurrences. All reports shall reference the authorization code assigned to the trial, and shall be submitted to UNCST and copied to the IBC Chairman. Reports shall be reviewed by the NBC. The UNCST will provide any necessary response or guidance to the Authorized party.

4.2 In-Season Reports

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

Trial Establishment Report: The Authorized 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 GM 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 time.

Trial Progress Report(s): One or more reports may be required depending on the growth habit of the crop plant and the nature of data that is to be collected. Such report(s) shall be submitted to UNCST according to the Terms and Conditions of authorization to conduct the field trial.

Harvest Report: The Authorized Party shall submit details of site harvest within five (5) working days after the completion of harvest at the site. The report will include the date and method of harvest, the storage or disposal of any harvested materials, and the method of destruction of any residual plant material on the site.

4.3 Other Reports

Incident and Corrective Action Report: The Authorized Party shall orally notify UNCST immediately, and in writing within 24 hours, of any incident involving an accidental or unauthorized release of genetically modified plant material. The report shall include any corrective actions taken or planned to confine GM material and ameliorate the incident.

Unanticipated Effects Report: The Authorized Party shall notify UNCST in writing within five (5) working days if the GM plants exhibit any substantial unanticipated characteristics, or if any unusual event occurs that may jeopardize the confinement of the GM plants.

4.4 Final Reporting

Interim Report: The Authorized Party shall submit an Interim Report within six (6) months after termination of the trial summarizing observations, methods of observation, data and analysis of experimental results concerning the trial, required observations, and any unanticipated effects.

Final Report: The Authorized Party shall submit a Final Report within six (6) months after the completion of the post – harvest monitoring period. The Final Report shall include a summary of observations on volunteers and their destruction, any data and analysis not previously submitted, and any responses required of the Authorized Party by the NBC concerning results of the trial.

5.0 RECORDS

5.1 Record Keeping

Adequate records are critical to establish the compliance of the Authorized Party with this Guideline and other relevant requirements. Clear, authentic and readily accessible records shall be maintained, documenting critical activities defined in the following section. Each record shall include the authorization code of the trial, the identity of the person responsible for the activity, the identity of the person making the record, and the date. UNCST will make available and also post on its website (www.uscst.go.ug) forms which may be used by the Authorized Party for guidance in record keeping.

5.2 Records Required

Records required include: **Transportation**, including a description of the material transported, method of transport and authorized custody; **Storage**, including location and security; **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; **Disposal** of any GM material, including methods used; 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; **Critical phases** of experimental progress, including planting and harvest; Monitoring for **unanticipated effects** and other required observations, according to the specific trial; **Post-harvest** monitoring, identification and destruction of volunteers; Records of any **unauthorized or accidental release** of GM traits or plant material, including **corrective actions** taken or planned. **Additional records** may be required depending on specific circumstances.

6.0 INSPECTION

Inspectors from the Ministry responsible for Agriculture as well as any other agents authorized by UNCST may inspect proposed and established confined field trial sites and associated support facilities for adequacy and compliance with the Terms and Conditions of authorization throughout the trial and post-harvest restriction period. All inspections are performed on a cost-recovery basis according to fee schedules published by UNCST on its website (www.uncst.go.ug).

7.0 TERMS AND CONDITIONS FOR CONFINED FIELD TRIALS

Standard Terms and Conditions for the conduct, documentation and reporting of an authorized confined field trial shall be published by UNCST, according to the requirements in Sec 3 of these Guidelines. Supplementary Terms and Conditions may also be imposed specific to the particular confined field trial at the discretion of the UNCST. Terms and Conditions shall be included in the Letter of Authorization issued by the UNCST.

Appendix 1. Application Form for a Confined Field Trial

Uganda National Council For Science And Technology

(Established by the Act of Parliament of the Republic of Uganda)

The National Biosafety Committee (NBC)

APPLICATION FORM

No……(NBC Official Use Only)

FOR CONTAINED USE AND CONFINED FIELD TRIALS (CFT) OF GENETICALLY ENGINEERED ORGANISMS IN UGANDA

PREAMBLE

- To be completed by individual researchers and submitted to the Institutional Biosafety Committee (IBC) after whose comments it is forwarded to the National Biosafety Committee (NBC) for reviewing.
- 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
- The applicant is required to answer as many questions as possible to facilitate evaluation of the application.
- Applications judged to be illegible, incomplete or vague would be returned to the Applicant
- Applicants are informed that assessments of the application will bear some financial cost, which will be met by the applicant. Applicants are required to provide further information as may be requested by National Biosafety Committee (NBC).
- Original, duly signed hard copy (by both the Applicant and the IBC's Chairman or Institutional Biosafety Officer) should be returned to:

The NBC Secretariat,
Uganda National Council for Science and Technology,
P.O. Box 6884, Tel. 256-41-250499
Fax. 256-41-234579 Kampala, Uganda
Email: biosafetyoffice@uncst.go.ug; uncst@uncst.go.ug; uncst@starcom.co.ug
www.uncst.go.ug

I. General Information

Name of the Applicant (Principal Investigator):

Position:

Institutional Address:

Department /Division/ Programme:

Telephone Fax:

E-mail:

The NBC will send all the Correspondences to your Campus Address unless otherwise indicated below:

i. Title of the Proposed Research Project:

ii. Proposed date of Commencement of the project (must be at least 270 days from the day of submission of a completed application to the Competent Authority; If additional information is required and you are to re-submit the application, counting of the days starts at the time of re-submission).

iii. Proposed Date of Completion of the Project:

iv. Name all the Institutions both local and International that are involved in this work, giving their full addresses and Contact physical and email addresses as well as phone contacts of the contact persons in these institutions

Local:

International:

v. Have you requested for Funding Support to this Project? ☐ Yes ☐ No

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

vii. Attach a complete proposal for this project with a budget. Kindly indicate Confidential Business Information (CBI), if any and it will be treated with utmost confidentiality.

II. Specific Information:

A. 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 weigh?
☐	☐	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 eukayote 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 from Department of Veterinary Services and an Import Permit).

☐ ☐ 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 from Department of Crop Protection and an Import Permit)

☐ ☐ h) Experiments involving more than 10 litres of culture? Laboratory experiments involving less than 10 litres of culture and in Risk Group 1 (must be reviewed by IBC which submits copies of application and decision documents to NBC).

☐ ☐ i) Experiments involving restricted and controlled release of rDNA modified plants or animals (this requires review by IBC and NBC)

☐ ☐ j) Deliberate release of rDNA-modified plants or animals into the environment- this requires review by the NEMA, IBC and the NBC

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

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

C. Host Organism (List the Biosafety Level, name and strain of the organism):

If it is *Escherichia coli,* is it enteropathogenic, enteroxigenic, enteroinvansive or a strain bearing K1 antigen?

☐ Yes ☐No

Note: If your answer is Yes, it is a risk group 2 agent requiring BL2.

D. Describe the used or to be used vectors and their sources

E. Proposed containment and /or Confinement Measures: Please specify physical, Biological or a Combination of levels you intend to use.

L. List the Disposal method of plants and other materials to be used in the experiment:

M. **Location(s)-**List the Names of the Buildings, room numbers (*where applicable*) of all the laboratories in which the experiments will be conducted. Attach a site map or maps.

N. **Personnel**- List the Names and Tittles of all the other individuals than you that will be engaged in the experiments beginning the Trial Site Manager for the field trial. Attach your curriculum vitae and profile as well as those of the other personnel to be involved with the trial.

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

.

P. **Training**- Indicate the steps taken or to be taken to ensure that laboratory 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.

III. Information on the Plant:

A. Unmodified Plant Information

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

b. Describe the reproductive mechanisms of the plant:

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

c. Is Uganda a centre of origin of the plant species? ☐ Yes ☐No

d. Is the plant considered to have a weedy tendency or is naturally invasive? ☐ Yes ☐ No

B. Modified Plant Information:

a. Describe the genetic modification that was done to the plant

b. Has genetic modification altered the reproductive Biology of the plant? Please explain

c. What is the source of the introduced genetic material? Please Explain

d. Does the introduced genetic material give rise to any infectious agents

e. Has the genetically modified plant been tested or commercially released elsewhere? Please explain

f. Has another country rejected an application for the planned Confined Field Trial testing of this organism or genetic event? If so, which country and on what basis?

g. Provide an Annex of information for each genetic element (or feature) of the construct including coding sequences, promoters, enhancers, termination and polyadenylation signal sequences involved in your work (Indicate confidential Business Information and it will be treated so by the IBC, NBC and the Competent Authority)

h. Provide an annex or a thorough description of the method of modification

C. Genetic Confinement:

This serves to inhibit gene flow from the field trial

a. Provide information on the proposed trial site size and location, surrounding fields and geographic features as well as the proposed isolation distance of your field from the nearest crop of the same or related species at the anticipated time of the trial (a trial site map must also be attached)

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

c. Describe the mechanisms you intend to use to contain 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

d. 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 CFT Standard Operating Procedures and/or according to the requirements of the NBC*)

e. 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
- Record keeping

D. Material Confinement

Serves to keep the material out of food and feed pathways

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

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

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

e. Describe measures to inhibit unauthorized removal of material from the trial site: These may include but are not limited to fencing, Guarding, Locked gate.

f. What additional measures, if any, shall be taken to preclude local fauna from removing material from the trial site?

g. Describe how surplus planting material will be recorded and disposed off at the trial site

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

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

j. How will the materials be harvested?

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

l. How will the harvested materials and crop residues be disposed off?

m. Describe your post harvest or post trial termination monitoring plans.

E. 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)

IV. DECLARATION FORM

A. Declaration by the Applicant

I hereby declare that the information provided in this Application Form 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 and the NBC as well as the Crop Protection Department of the Ministry of Agriculture, Animal Industry and Fisheries as far as implementation of the proposed project 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 Section:

a. Comment on the suitability of the premises, staff 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 IV (B) of this form.

Name: _____

Signed_____Date:_____

Title with respect to the IBC _____

Authorized representative of Institutional Biosafety Committee

For more information contact:

National Biosafety Committee (NBC) Secretariat
Uganda National Council for Science and Technology
P.O. Box 6884, Kampala, Uganda
Telephone: 256-41-250499
Fax: 256-41-234579
Email: uncst@uncst.go.ug
Website: http://www.uncst.go.ug