PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 1: Introduction to the Integrated Confinement System

Unit 2: Confined Field Trial Guideline

Unit 3: Trial Manager's Handbook

Unit 4: Inspector's Handbook

Unit 5: Resources for Regulators

Mark E. Halsey, Ph.D.

February 2006

Prepared on behalf of the Program for Biosafety Systems (PBS), an IFPRI-managed program funded by the U.S. Agency for International Development (USAID)

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PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 1: Introduction to the Integrated Confinement System

A User's Guide

Procedures and Models to Ensure Biosafety in Experiments With Genetically Engineered (GE) Plants

Mark E. Halsey, Ph.D.

February 2006

Contents

Acknowledgements

These materials were originally developed in collaboration with the Uganda National Council for Science and Technology (UNCST), in support of their system for confined field trials. The documents developed for Uganda have been modified here to make them easily adaptable for other partners and to other situations.

This work would not have been possible without the encouragement, support and advice of many colleagues, especially those below. Specific contributions are shown at the beginning of each Unit.

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February 2006

Preface

In modern times, our understanding of the nature of biology has advanced beyond observation and description of natural phenomena, and beyond even cell-culture techniques that allow us to regenerate cells and tissues. Such previous methods depended on chance and gross manipulation to achieve their goals of producing superior organisms. Now, using the extremely precise techniques of genetic manipulation available thorough Recombinant Deoxyribonucleic Acid (rDNA) technology, we can alter biological processes at the molecular level. This has led to deliberate creation of new lines of Genetically Modified (GM) or Genetically Engineered (GE) organisms, also called Living Modified Organisms (LMOs).

The application of these technologies to crop, animal, and human systems is poised to enhance food production and security, human and animal health, environmental conservation, and the preservation of biodiversity. The rDNA technology now available enhances biological processes which otherwise would have taken place by chance, leading to undesired or unproductive outcomes. Now, we have the capability to control these processes with great precision, so that they may help ensure the well-being of humanity.

In tropical Africa, where environmental, population, and social factors have a very significant impact on food production and human health, new technologies must be carefully and systematically evaluated to determine their value and potential usefulness. A systematic and integrated approach to the evaluation of these new technologies requires evaluation in laboratories and glass houses, as well as in field trials conducted in the natural environment. The latter are called Confined Field Trials, or CFTs.

In a Confined Field Trial, researchers are able to safely evaluate crops with new genetic traits in their natural environment by following basic principles of confinement and biosafety. The regulation, conduct, and oversight of CFTs requires a comprehensive and integrated approach spanning all aspects of the trial, from the inception of planning to successful completion and reporting of the trial and results. As a result, the Program for Biosafety Systems (PBS) has produced these five companion booklets which comprise the *Integrated Confinement System for Genetically Engineered Plants*:

Unit 1: Introduction to the Integrated Confinement System
Unit 2: Confined Field Trial Guideline
Unit 3: Trial Manager's Handbook
Unit 4: Inspector's Handbook
Unit 5: Resources for Regulators

The Program for Biosafety Systems (PBS), working in collaboration with partner countries, including Uganda's National Council for Science and Technology (UNCST) and its Regulatory Authority, the National Biosafety Committee (NBC), has as its objective to "dedicate themselves to biosafety in biotechnology" in resource-poor countries especially in the tropics, by:

- Training human resources and building capacity in biosafety for experimental evaluation, including CFTs;
- Developing regulatory strategies and stimulation of policy;
- Engaging policy makers together with rDNA technology developers, research scientists, and Regulatory Authorities such as Uganda's NBC and Biosafety Inspectors.
- Enhancing the function and application of Biosafety systems, and facilitating the development of appropriate Biotechnologies.

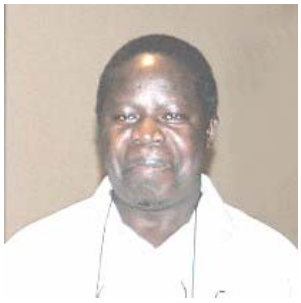
These booklets will be of value to all regulators, applicants, trial managers and biosafety inspectors, including those whose backgrounds may be in neither biological nor legal sciences. Their primary purpose is to provide a comprehensive framework of methods, procedures, processes and suitable forms in a single, unified resource which is available both to experts and to first-time users. They also serve as a guide to find other more locally relevant documents/texts to consult which may cover in greater detail the biology, the laboratory and ecological methods of the crops in question.

These documents are intended to provide a guideline or framework for effective biosafety systems for CFTs, and users are encouraged to modify and adapt them to their own existing systems,

according to their own requirements and operating structures. Interested parties are also encouraged to consult other sources of Biosafety and Biotechnology regulatory documents, to achieve the best possible synthesis for their particular purposes.

The development of this *Integrated Confinement System* would not have been possible without the insight of the National Research Council of the U.S. National Academy of Science, which recommended a 'systems approach' to the management of confinement of genetically engineered organisms. Resources for the project were provided by PBS and the International Food Policy Research Institute in Washington, D.C. Dr. Mark E. Halsey, of PBS and the Donald Danforth Plant Center in St. Louis, Missouri, provided leadership and served as the principal author, with a team of reviewers identified in the respective booklets. PBS's East African Director, Dr. Theresa Sengooba of the National Agricultural Research Organization (NARO) in Uganda, was the lead contact and organizational point for several workshops, seminars and consultations, facilitating local input and training for this program. The Uganda National Council of Science and Technology (UNCST) was the main collaborator and gave a sense of ownership in the development of these documents. As the Chairman of the National Biosafety Committee of the UNCST, the Regulatory Authority of Biosafety in Uganda, I am privileged to write this preface.

You are invited to make the best use of these booklets and are encouraged to share with PBS or UNCST-Uganda any suggestions or improvements you may identify.



Professor John Opuda-Asibo
BVM (Mak), MPH, Ph.D. (Minnesota)
Chairman NBC - Uganda

Foreword

Any country that decides to explore the benefits of modern biotechnology or GMO technology for national development must be prepared to do so in a safe and sustainable manner. Modern biotechnology is both controversial and regulated, and certain procedures must be observed so that safety standards are met and public concerns are adequately addressed. Initial testing must be carried out under carefully controlled and confined conditions, in order to obtain results that regulatory bodies can use to make informed decisions about approval for further testing or unrestricted release. Approval of GMO material for unrestricted release and use depends on the safety of the material and the benefit to society. The safety concerns surrounding GMOs normally relate to food/feed safety and to environmental impact. The food safety concerns are addressed at an international level by the FAO/WHO Food Standards programme implemented by Codex Alimentarius, a collection of internationally adopted food standards presented in a uniform manner, providing codes of practice and guidelines for food quality control as well as harmonization to facilitate international trade.

In the case of environment safety, however, uniform standards cannot be prescribed due to diversities in environment and the inherent biological nature of plants to be evaluated. The possibility of genotype by environment interaction necessitates testing under local conditions in the open environment. Evaluation of new genotypes in small scale field trials is a common and indispensable practice used by plant breeders. In the case of GMOs, this step is done without allowing genes or plant material to escape from the field trial site, and so these trials are called 'Confined Field Trials' (CFTs).

The *Integrated Confinement System for Genetically Engineered Plants* is intended to provide easily followed procedures which ensure biosafety in the testing of GMO plants under field conditions. These procedures and models are intended to help scientists and regulators in their efforts to develop a comprehensive national system for the purpose of regulating CFTs. The five booklets contained in the system are modeled on similar documents produced for Uganda by the National Council for Science and Technology in collaboration with the crop inspectorate unit of the Ministry of Agriculture, Animal Industry and Fisheries. Technical support for this activity was offered by the Donald Danforth Plant Science Center under the Program for Biosafety Systems, funded by the United States Agency for International Development. The Confinement System for Uganda was drafted by a technical team of scientists and regulators and was subjected to rigorous review by a cross section of stakeholders involved at various stages in regulating, implementing and monitoring CFTs.

The use of GMO crops is becoming increasingly widespread on a global basis, and several countries in Africa are already planting CFTs to evaluate these compelling new technologies. However, there are many scientists in the region who would like to test GMO materials for research purposes but are unable to do so until effective and nationally accepted systems are in place. The unrestricted use of GMO crops is, of course, subject to appropriate regulatory scrutiny and judicious decision making. In order to facilitate this process, it is critical that developing countries have the capacity to enable research of modern biotechnologies, especially through CFTs in the open field which provide relevant data about local environments.

I am confident that the *Integrated Confinement System* will provide a useful model that others may adopt and modify according to their specific requirements, for purposes of implementing CFTs and making informed decisions about GMO crops for their societies' needs.

Theresa Sengooba
East Africa PBS Regional Coordinator
February 23, 2006

1. Introduction

Experimental testing, especially in open 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 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.

Because GE plants are regulated by 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 eliminate lines that do not have desired characteristics, 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 or livestock (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 the Regulatory 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 Regulatory Authority 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.

2. Objectives

The Program for Biosafety Systems (PBS) 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 for our partner countries. Services are provided upon client request, and are often tailored to meet specific and pressing needs in the above areas.

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 of our partners and their societies.

Becoming aware of the need for a comprehensive approach to biosafety for confined field trials, PBS, in cooperation with partner countries and public research institutions, has developed this 'Integrated Confinement System' which is applicable to confined field trials, as well as contained glasshouse experiments.

The objectives of PBS 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 open field situations, such as confined field trials;
2. To enable partners in developing countries and public research institutions to easily and quickly create a customized, comprehensive, 'turn-key' system for regulating, executing and overseeing CFTs and other experimental trials;
3. To enable our partners, such as partner country regulators, Principal Investigators, Trial Managers and others, to focus their energies on critical issues of biosafety and confinement. With access to functional and practical tools for implementing the 'process' of experimental testing, we hope that our partners will be more free to focus on the critical issues related to their essential 'product'—regulation, management and oversight of GE crops;
4. To help endow our clients with the self-sustaining capacity, and the resulting confidence, to initiate evaluation of specific GE crops that may be of benefit to their countries for food security and poverty alleviation;
5. To encourage a modern, comprehensive and systems-based approach to the regulation of GE crops in our partner countries, in order to foster the overarching goal of biosafety in the testing and development of these crops.

We hope that the *Integrated Confinement System* presented here will meet these objectives, and will help to advance the goal of biosafety in the testing and development of GE crops.

3. What is an Integrated Confinement System?

In 2004, the National Research Council of the U.S. National Academies of Science completed and published a comprehensive analysis of the confinement of genetically engineered organisms (GEOs).[1] This analysis addressed broad issues of confinement related to many types of organisms, including plants, animals such as fish, shellfish and insects, and microbes. One recommendation that the committee proposed was the application of a new approach to the management of confinement, which they called the Integrated Confinement System, or ICS. The authors defined an ICS as "… a systematic approach to the design, development, execution and monitoring of the confinement of a specific GEO." 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 committee pointed out the similarity of this new approach to the 'system safety management' procedures used for many modern technologies, which represent a "…forward-looking, comprehensive, long-term approach… [ensuring] …that systems and techniques have safety designed in from the outset." 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.

By definition, an ICS requires that different, but interlocking, elements be 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.

Some or many of these elements are often missing in the regulatory and compliance systems of developing countries. The goal of PBS in providing these elements here is to help ensure a comprehensive and systematic approach for developers and regulators in those countries, so that the overarching goal of biosafety in the testing and development of GE crops for the benefit of those countries may be fully realized. We hope that the ICS proposed here is able to help meet that goal.

[1] Anonymous. 2004. Biological confinement of genetically modified organisms. Natl. Acad. Sci. Natl. Acad. Press, Washington, D.C. p. 8, 186-187.

4. Elements 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. These five units present model regulations, guidelines, forms and other resources for managers and regulators of confined field trials. All materials provided are public-access, and are available to all users without restriction.

Unit 1: Introduction to the Integrated Confinement System—A user's guide

Unit 2: Confined Field Trial Guideline—A model guideline for field experiments with Genetically Engineered Plants

Unit 3: Trial Manager's Handbook—Procedures and forms for conducting experiments with GE plants

Unit 4: Inspector's Handbook—Procedures for biosafety inspection

Unit 5: Resources for Regulators— Models for regulation of experiments with GE plants

Readers interested in more information about the role of confined field trials and best practices to ensure confinement are referred to the following complementary resource, available at the website shown:

Compliance Management of Confined Field Trials with Genetically Engineered Plants. July 2005. CropLife International: http://www.croplife.org/

Readers may also find the following resource useful for designing facilities and planning experiments to be conducted in glasshouses, screenhouses, or similar containment facilities:

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.

5. How to Use the Integrated Confinement System

The Units address the most important aspects of an ICS in a practical and functional fashion. Users are encouraged to match and coordinate specific elements into their existing systems, according to their particular needs. We urge all users to adopt the most useful, effective and efficient approach for their situation, whether that may be found here or elsewhere.

The documents are, of course, generalized to meet the fundamental needs of partners in developing countries and public research institutions. No general document can foresee all possible requirements, and it is intended that users will wish to adapt the documents to their specific situations. We hope that this process of adaptation will be facilitated by the style of the materials, including the recurring use of common phrases, such as 'this country', for which a specific country or institution could be substituted, 'Regulatory Authority', eliciting the name of a specific entity, and so forth. The materials are not necessarily intended to be exhaustive, but to provide sufficient variety of types of documents that an example may be found to meet specific user needs, after modest adaptation.

In the same way, the compliance forms and reports are intended to be customized for specific trials, sites and authorization codes by inserting those details prior to use. Where desired, the forms may be modified and adapted so as to be most useful in a specific circumstance. It has been our long-standing experience that the simpler, more direct and more specific a compliance form or checklist is, and the more the content focuses on the requirements at hand, the more useful, practical and functional it will be. Practical and specific forms advance the goal of biosafety by allowing trial personnel and others to focus on critical aspects of biosafety, compliance and management, and not on 'how to fill out the form.'

For suggestions on these materials, for help with specific problems, or to request on-going support, please contact the manager of the Regulatory Approval Strategies component of the Program for Biosafety Systems: Lawrence Kent, lkent@danforthcenter.org.

PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 2: Confined Field Trial Guideline

A Model Guideline for Field Experiments with Genetically Engineered Plants

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

Mark E. Halsey, Ph.D.

February 2006

Contents

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Katie Moon	Danforth Plant Science Center St. Louis, MO USA	Formatting and Editing

Material adapted from: *Requirements for the Conduct of Confined Field Trials of Genetically Engineered Plants in Uganda*, a guideline developed by PBS in collaboration with the Uganda National Council for Science and Technology (UNCST).

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February 2006

1. Glossary

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.

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 not approved for general release, in which 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).

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.

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.

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'.

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

2. Introduction

The purpose of this document is to provide a clear and concise summary of the regulatory requirements governing confined field trials of genetically engineered (GE) plants, in accordance with the relevant national guidelines administered by the Regulatory Authority. In the event of any conflict or inconsistency between this document and the terms or conditions of a more specific additional document provided by the Regulatory Authority 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'. In a confined field trial, genetic isolation and material confinement measures are used to restrict GE plant material to a specific area of the environment, the Trial Site. Confined field trials are small-scale research and pre-commercial activities, providing technology developers with the opportunity to evaluate the performance of genetically engineered 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 document establishes requirements specific to confined field trials and their implementation, and may be appended to existing national guidelines on biosafety and/or biotechnology.

No person may establish a confined field trial of any genetically engineered plant in this country without authorization from the Regulatory Authority under this guideline.

3. Legal Authority

This guideline derives its authority from [statutory authority], which designates [national body serving as competent Regulatory Authority] as the competent authority on all matters concerning Biotechnology and Biosafety. For the purposes of this guideline, the mandate of the Regulatory Authority includes approval and supervision of the testing and introduction of genetically engineered organisms, as specified in [national biosafety guidelines or other relevant authority].

4. Application for a Confined Field Trial

4.1 Submitting an Application

4.1.1 Application Form

The Regulatory Authority will publish an Application Form to be completed by Applicants for confined field trials. The Application Form will contain 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 will include information 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 GE material on the trial site, contingency plans and declaration section. The Regulatory Authority 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 the Regulatory Authority.

4.1.2 Where to Apply

The Application Form shall be completed and submitted by regular mail, by courier, or electronically to the Designated Representative [Secretary, Desk Officer, etc] of the Regulatory Authority:

[Contact details of Designated Representative of the Regulatory Authority]

4.1.3 When to Apply

Applications for a confined field trial must be received at least [90, or other specified interval] working days in advance of the proposed trial start date. The Designated Representative of the Regulatory Authority 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.

4.2 Review and Authorization

4.2.1 Process of Review and Authorization

Applications will be reviewed and approved or rejected by the Regulatory Authority. The Regulatory Authority may request technical advice and recommendations from the Scientific Advisory Panels, such as an Agricultural Sector Advisory Panel (ASAP) [or other relevant advisory body]. Scientific Advisory Panels are constituted as the technical advisory bodies of the Regulatory Authority, whose composition and function shall be detailed in approved Internal Operating Procedures (IOPs). The Regulatory Authority will issue a final determination of authorization within [90, or other specified interval] working days of receipt of the application.

Where authorization is granted, the Regulatory Authority 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 Regulatory Authority 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 given an opportunity for appeal. Guidance for Applicants seeking to appeal a decision shall be published by the Regulatory Authority.

4.2.2 Criteria for Approval or Rejection of Applications

The ASAP, if requested, shall evaluate the technical merits of each Application, and submit their recommendation to the Regulatory Authority.

The Regulatory Authority shall evaluate each Application and issue a final determination, taking into consideration technical recommendations and any aspects of the proposed work related to national policy.

A final determination of the Regulatory Authority to approve an Application shall be made by a 2/3 majority vote. Decisions of the Regulatory Authority on Applications under this Guideline shall be published on the official website or the Regulatory Authority.

4.2.3 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.

4.3 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". 'No CBI' or 'CBI deleted' versions of the Application Form shall be provided on the official Regulatory Authority website.

4.4 Fees

The processing of a confined field trial application requires the Applicant to pay a non-refundable fee to the Regulatory Authority 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 may 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 the Regulatory Authority and may be revised from time to time. The fee schedule shall also be made available on the official Regulatory Authority website.

5. Requirements for Confined Field Trials

5.1 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 engineered plant material.

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

5.2 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, the Regulatory Authority 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 the Regulatory Authority. Applicants should consult with the Designated Representative for information on any restrictions that may be in force, prior to submitting an Application.

5.3 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 engineered 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.

5.4 Procedures for Confined Field Trials

5.4.1 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 GE plant material from being consumed by humans and/or animals; and 3) preventing GE plants from escaping from confinement and 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 GE plant material, for reproductive isolation and material confinement of the GE plants on the field trial site, for disposal of plant material and volunteers at the trial site, and for contingency planning. General requirements for these activities are given in the sections following. SOPs addressing the requirements in detail, and for specific crop plants and circumstances, will be published by the Regulatory Authority for use by Authorized Parties and shall be posted on its official website for ease of accessibility.

5.4.2 Shipping and Storage

GE plants or plant parts must be shipped and stored in a fashion that clearly identifies them as GE material, prevents their release into the environment, and prevents them from being inadvertently mixed with non-GE material.

5.4.3 Reproductive Isolation

To prevent the escape of genes from the trial site, 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 is by use of a spatial isolation distance between plants in the trial site and any plants with which the GE plants are sexually compatible, which are designated as 'prohibited plants'. Minimum spatial isolation distances vary depending on the reproductive biology of the plant species. 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. Guidance for reproductive isolation of specific crops in specific circumstances will be published by the Regulatory Authority.

5.4.4 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 to prevent loss of GE material from the site.

5.4.5 Harvest and Disposal of GE Plant Material

No plant material from a confined field trial site may be used as human food and/or livestock feed. Plant material harvested from a confined trial that is not retained for future research work shall be disposed of in order to prevent it from entering human food or livestock feed.

5.4.6 Post-Harvest Requirements

Progeny arising from the GE 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 period of post-harvest restriction and monitoring will be defined by the Regulatory Authority.

5.4.7 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 GE material.

6. Reports

6.1 Submitting Reports

Reporting allows the Authorized Party to inform the Regulatory Authority of 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 the Designated Representative of the Regulatory Authority and copied to the appropriate IBC. Reports shall be reviewed by the Regulatory Authority, which may refer them to the ASAP or other Scientific Advisory Panel for technical advice. The Regulatory Authority shall provide any necessary response or guidance to the Authorized party.

6.2 In-Season Reports

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

Planting Report: The Authorized Party shall submit details of trial establishment within ten (10) working days after the completion of planting at the trial site. A final field site map shall also be submitted at this 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 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 ten (10) working days after the completion of harvest at the site or termination of the trial.

6.3 Other Reports

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

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

6.4 Summary Reports

Experimental Report: The Authorized Party shall submit an Experimental 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.

Post-Harvest Report: The Authorized Party shall submit a Post-Harvest Report within six (6) months after the completion of the post-harvest period. The Post-Harvest 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 Regulatory Authority concerning results of the trial.

7. Records

7.1 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. The Regulatory Authority will publish example forms which may be used by the Authorized Party for guidance in record keeping.

7.2 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 GE 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 GE traits or plant material, including **corrective actions** taken or planned. **Additional records** may be required depending on specific circumstances.

8. Inspection

Inspectors from the Regulatory Authority shall have the authority to 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 the Regulatory Authority.

9. 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 the Regulatory Authority, according to the requirements herein. Supplementary Terms and Conditions may also be imposed specific to the particular confined field trial at the discretion of the Regulatory Authority.

Appendix 1. Model Application Form for a Confined Field Trial

This application form consists of seven parts:

1. **Administrative Information**
2. **Plant Information**
3. **Trial Description**
4. **Genetic Confinement**
5. **Material Confinement**
6. **Records, Personnel, and Planning**
7. **Declaration**

1. Administrative Information

Purpose of Application:
[Application for a confined field trial for (name of crop species and introduced trait).]

Previous Applications or Approvals:
[Information on the status of this crop and trait, including pending, approved, or denied applications for field trials and commercial releases here or in other jurisdictions. Indicate also if this is a new application or a renewal.]

Applicant:
[Name of applying institution, which may also include the name of the Principal Investigator or other key personnel.]

Institutional Address:

Telephone (s):

Fax:

E-mail:

Contact Details of Principal Investigator:

Name of Lead Scientist:

Address:

Telephone (s):

Fax:

E-mail:

Proposed Location and Size of Trial:
[Name, address, email, phone, and facsimile of the Trial Manager as well as GPS information or description of the exact location and size of the trial site (attach sketch map).]

Proposed Duration of Trial:

Expected starting date:

Expected termination date:

2. Plant Information

2.1 Unmodified Plant Information

This section describes the characteristics of the unmodified plant as it relates to confinement. Important information pertains to the plant's reproductive mechanisms and its ability to escape, establish, and persist in the environment into which it is being introduced.

Plant Species Name (common and scientific):

Center of Origin:
[What is the center of origin of the unmodified plant?]

Reproductive Mechanism of the Plant:
[Describe the reproductive biology of the plant. This information may be obtained from Organization for Economic Co-Operation and Development (OECD) biology consensus documents or similar sources, and should include relevant information on: inter- and intra-specific breeding; pollen production, dispersal, and viability; seed production and dispersal; seed dormancy; capacity for vegetative reproduction.]

Tendency to Weediness:
[Is the unmodified plant regarded by agricultural experts as a weed in regions where it is cultivated? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plant? NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.]

Allerginicity:
[Is the plant species known to be a source of substances that are toxic or allergenic to humans or animals? If yes, identify the substances and levels that induce toxicity or allergenicity and the affected species.]

2.2 Modified Plant Information

This section is intended to provide information on known or intended effects of the genetic modification or introduced trait that may effect confinement measures employed in the confined trial.

Describe the Intended Phenotypic Changes to the Plant:

Intended Reproductive Effects:
[Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes effect strategies for confinement?]

What is the source of the genetic material? Is the source of the genetic material likely to affect the safe conduct of a confined field trial? If yes, how?
[Describe any known or intended introduction of infectious agents, plant, animal, or human pathogens or allergens or toxins.]

Changes in Toxicity or Plant Composition:
[Describe any changes to toxicity, allergenicity, or significant changes in composition intended by the genetic modification.]

Describe the Features of the Genetic Construct:
[Include coding sequences, promoters, enhancers, termination, and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex.]

3. Trial Description

This section describes the purpose of the field trial, the experimental design and data to be collected, including anticipated pesticide use. Include a description of the habitat at the site, and any organisms of conservation concern that may be in the general area.

Trial Description:

4. Genetic Confinement

This section describes the measures to be taken to ensure confinement of the genetically modified plants and genes. It is based on knowledge of the unmodified crop and the intended genetic modification.

Provide a map showing the location of the trial site, surrounding fields, and relevant geographic features such as streams or waterways.

Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting in viable seeds?

Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site:
[Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and/or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology.]

Describe measures in place to control trial plant volunteers after termination of the trial:
[Describe the crops to be allowed following the confined trial, duration of monitoring for volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site.]

5. Material Confinement

This section describes the mechanisms by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

Packaging:
[Describe how the genetically modified plant material will be packaged and labelled for transport to the trial site and measures for cleaning and/or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported.]

Harvesting, Transport, and Storage:
[Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported.]

Disposal and Clean-Up:
[Describe how surplus planting material will be disposed of at the trial site, how any equipment used during planting or other farm operations will be cleaned, and how harvested materials and crop residues will be disposed.]

Site Security:
[Describe measures in place to ensure security of the trial site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc…]

6. Records, Personnel, and Planning

Records and Documentation:
[Describe measures in place to ensure adequate documentation of all confinement measures and data requirements as described herein.]

Personnel:
[Describe measures in place to ensure that trial personnel will have appropriate education, experience, and training to adequately perform assigned duties for confinement and technical requirements of the trial.]

Contingency Plans:
[Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the Authorized Party, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects.]

7. Declaration

I hereby certify that the information in the application and all attachments is complete and accurate to the best of my knowledge and belief:

Signature of Principal Investigator for Applying Institution:

Date:

Signature of Lead Scientist of Collaborating Institution:

Date:

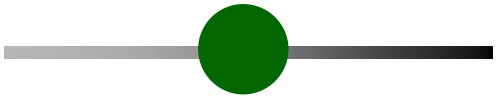
PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 3: Trial Manager's Handbook

Procedures and Forms for Conducting Experiments with Genetically Engineered Crops

A Guide to the Safe Conduct of Confined Field Trials
For Authorized Parties, Principal Investigators and Trial Managers



Mark E. Halsey, Ph.D.

February 2006

Contents

Acknowledgements

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Deborah Garvin, M.S., RQAP-GLP	Pacific Rim Consulting Hood River, OR USA	Technical Review
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February 2006

1. Glossary

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, or acts 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.

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 not approved for general release, in which 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)', and 'living modified organism (LMO)' are equivalent.

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

Guard 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.

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 or livestock.

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 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 from prohibited plants by a defined distance.

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 spacing out the planting dates.

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 within a confined field trial site.

2. Introduction

This unit provides instructions in the form of Standard Operating Procedures (SOPs) for all aspects of biosafety for confined field trials (CFTs). The SOPs give detailed instructions for shipping and storage; establishment, maintenance and conduct of CFTs; sampling of plant tissues; termination and post-harvest management of the trial site; and reporting of results to the Regulatory Authority. The forms provided are intended as model formats for collecting typical information required for documentation of compliance requirements. These forms are intended to be customized by the Authorized Party for ease of use in fulfilling specific requirements, as indicated in the Terms and Conditions of Authorization for a particular trial. Similarly, the formats suggested for reporting of results may also be modified, if needed to meet specific requirements set forth by the Regulatory Authority for a particular trial.

The procedures provided here are for the use of all Principal Investigators, Trial Managers, technical personnel, agents of the Authorized Party, and government officials engaged in planning, conducting or overseeing confined field trials of GM plants.

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 and 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.

It should be noted that it is the responsibility of the Authorized Party to ensure compliance with the Terms and Conditions of Authorization, and that this responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of conducting confined trials. Similarly, the responsibility of the Authorized Party and its employees is not limited to the fulfilment of these procedures in achieving the goals of confinement outlined above; they are required to take all reasonable steps to achieve these goals.

Experience for many years in many areas of the world has shown that confined field trials can be conducted safely, with no harm to the environment, humans or animals, by following a systematic approach to their conduct. This approach is based on careful planning, establishment of clear requirements and procedures, on-going education, effective communication, and careful oversight.

The procedures defined herein apply to all GM materials of any crop undergoing authorized confined field testing. It should be well-noted that the Terms and Conditions of Authorization issued by the Regulatory Authority are the governing document for a specific trial. The requirements listed in the Terms and Conditions shall take precedence over the requirements of these SOPs, in case of any conflict or inconsistency.

3. Data Quality and Integrity

3.1 Introduction

Adequate records are critical to establish the compliance of the Authorized Party with the Terms and Conditions of Authorization and other relevant requirements. Clear, authentic and readily accessible records shall be maintained to document critical activities. The Regulatory Authority therefore publishes the attached model forms which may be used by the Authorized Party for guidance in developing forms for use in their specific confined trials.

3.2 Instructions for Completing Forms and Documents

Record information directly, promptly and legibly with blue or black pen. Do not use pencil or whiteout.

Date format is Day, Month, Year. Use metric (SI) units such as kg, m, ha for all measurements.

If there is not enough space on a page to record all data or explanations needed, add a page and complete the entry there.

Areas left blank for any reason must be lined-out, initialed and dated.

It is acceptable to carry identical information down through a column by use of a line drawn between the first entry and the same entry repeated in the last space of the column.

Changes to entries should be made by drawing one line through the original entry so as not to obscure it, indicate the reason for the change, then initial and date the entry.

Common Correction Codes used to show the reason for a change should be circled, dated and initialed. Common Codes are listed in Table 1.

Table 1. Common Correction Codes

CE	**= Communication Error**	**NA**	**= Not Applicable**
CL	**= Clarification**	**NI**	**= Not Inspected**
EE	**= Entry Error**	**RC**	**= Recalculation**
EQ	**= Equipment Malfunction**	**RE**	**= Reevaluation**
LE	**= Late Entry**	**SP**	**= Spelling Error**
ME	**= Missing Entry**	**TE**	**= Transcription Error**
ML	**= Mislocation of Entry**	**WO**	**= Write Over**

The person(s) recording data should date and initial all entries on the day of entry. If multiple entries (by different persons or on different dates) are made on one page, a date and initial are required for each individual entry.

Each page shall include the Trial Site Identification. After each page has been completed, it must be signed and dated by the Trial Manager to verify that the information is accurate, legible and complete.

Any additional supplemental records not recorded on the forms provided must be labeled with the description of the trial, and include sufficient explanation for a third party to easily understand the additional documentation.

3.3 History of Changes

This form is used to highlight significant changes from previous versions when a new version is published.

Prior Version Number	Summary of Changes
1.0	
2.0	
3.0	
4.0	

4. SHIPPING AND STORAGE

4.1 Packaging and Labeling

4.1.1 Packaging Materials

All GM plant material for shipping or transport must be packaged in such a fashion to prevent any accidental release. Multiple layers of packaging are required, according to the material being transported. The inner container, usually in direct contact with the GM plant material, is called the 'primary container', and is enclosed within 'secondary' and perhaps 'tertiary' containers. Each layer of packaging must be of such construction and sturdiness to independently prevent the release of the material under normal conditions, and each layer must be independently closable or sealable. It is advisable, but not required, that at least one layer of packaging be waterproof. Examples of appropriate packaging are given below:

Seeds. Seeds for transport must be contained in three layers of packaging. The inner (primary) container must not allow seeds to become trapped or hidden within, and must be easily verified to be free of all seed. Examples of appropriate primary containers for seeds are: metal cans, plastic bottles, plastic bags. Fibre bags may be appropriate if the mesh size and construction are adequate for the type of seeds being contained. Appropriate secondary containers include: plastic or metal cans or boxes, cardboard or fibreboard boxes or wooden boxes of close-fitted construction. Appropriate tertiary containers include any of the examples of secondary containers listed, as well as wooden boxes or crates. Seed of different experimental units may be separated in sub-containers within the primary container, for example, lines of maize seed in planting envelopes may be placed within a metal can serving as the primary container.

Vegetative Material Capable of Propagation. Examples of this category include plantlets for transplanting, 'stakes' for the propagation of cassava, cut potato 'seed pieces', etc. Propagative materials must be contained in two layers of packaging. Examples of appropriate packaging materials are: plastic tubes or pots, metal, cardboard or fibreboard boxes and nylon bags.

Material Not Capable of Propagation. Examples of this category include devitalized plant materials and vegetative materials such as leaf samples that cannot propagate. These materials must be contained in two layers of packaging, such as plastic or paper bags or envelopes, wooden, fibreboard or cardboard boxes, etc.

Special Case Materials. If large amounts of material are to be transported as the result of a confined field trial, guidance should be sought from the Regulatory Authority on specific

packaging requirements appropriate to the material proposed to be transported. For small amounts of material, packaging shall be done as described above.

4.1.2 Labeling

Each layer of required packaging must be labeled with sufficient information to establish the identity of the contents, and the contact details of an official contact person. The label must also contain the following statement or equivalent verbiage: 'Genetically Modified Plant Material For Research Purposes Only. Do Not Use for Food or Feed'. An approved 'Do Not Eat' symbol, found in the Appendix, shall also be included. The Authorization Code Number issued by the Regulatory Authority shall be included on all packages.

4.1.3 Retention of Packaging

The primary container with its associated labeling is typically used for storage of the GM plant material. All primary containers shall be retained for the duration of the authorization period or until a designated agent of the Regulatory Authority authorizes their disposal or release.

4.1.4 Disposal or Recycling of Packaging Materials

When disposal or release has been authorized, the primary containers that are in contact with GM plant material shall be cleaned of propagative plant material. The process of cleaning will vary with the type of container and the material being contained. After the packaging has been verified and documented to be free of plant material, it may be disposed of by burying, incineration or similar means. Outer layers of packaging that are not in contact with GM plant material may be returned to general use without restriction, unless a breach of the primary container has occurred, in which case packaging that has come in contact with GM plant material is treated as primary packaging, according to the requirements described herein.

4.2 Shipment and Receipt

4.2.1 Shipping Documentation

All shipments of GM plant material must be accompanied by a Shipping Form that establishes its identity and the identity of the originating and receiving parties. The Shipping Form serves as an official record of transport and chain-of-custody documentation. A model of an appropriate Shipping Form is in the Appendix. Additional inventory lists may be attached to the Shipping Form, if necessary, in order to list all items in a particular shipment. The recipient of the shipment shall retain a copy of the completed Shipping Form, and all other documentation included in the shipment (e.g., Phytosanitary Certificates, Import Permits, etc). A copy of the completed Shipping Form shall be sent to the originator, to confirm receipt of the shipment. Copies of all documentation associated with shipment of GM plant material shall be copied to the Regulatory Authority and the appropriate Biosafety Inspection Department. The originals shall be retained by the Authorized Party or his agent.

4.2.2 Receipt

Careful verification of receipt is critical to maintaining valid documentation and preventing inadvertent release of GM material. The receiving party shall observe the following requirements upon receipt of shipment:

- Complete the recipient information on the Shipping Form.
- Verify that packaging is intact, and that no release of GM material has occurred. Note any damage to containers in the space provided on the Shipping Form. If any release of GM material is suspected or occurred, notify the Regulatory Authority immediately, following the procedures defined on the 'Incident Report' Form in SOP 'Incidents'.
- Verify that all items listed on the Shipping Form and any inventory lists have been received. Notify the shipper and/or carrier immediately to locate any missing packages or items. If a package or item cannot be located, notify the Regulatory Authority immediately, following the procedures defined on the 'Incident Report' Form.

- Register shipment items into inventory in secure storage as defined below.
- Prepare copies of completed documentation to be retained in the study file at the field trial site.

4.3 Storage

4.3.1 Secure Storage

All GM plant material must be stored and maintained in such a fashion as to preserve its identity, security and integrity, and to prevent it from being consumed by humans, livestock or other animals. To achieve these goals, all GM material shall be stored in a facility or storage area in which:

- Access is restricted to authorized personnel;
- The facility or storage area is sign-posted with the information 'GM Plant Material – Not for Use in Food or Feed', or equivalent verbiage;
- GM material is kept separate from non-GM materials being stored or maintained in the same facility or area;
- GM material is clearly marked or labeled, to prevent misidentification with non-GM materials.

4.3.2 Storage Inventory

A current inventory of all GM materials being stored or maintained in a facility or storage area shall be maintained and available for inspection by designated agents of the Regulatory Authority.

4.4 Appendices

4.4.1 Approved 'Do Not Eat' Symbol

4.4.2 Model Shipping Form

SHIPPER	RECEIVER
Name:	Name:
Title/Organization:	Title/Organization:
Address :	Address:
Phone/Fax:	Phone/Fax:
Email:	Email:

SHIPPING INFORMATION

	Shipped		Received			Shipped		Received	
Line	Amount	By	Amount	By	Line	Amount	By	Amount	By
Total									

Packaging:		Shipper Initial	
Conveyance:		Shipper Initial	
Depart [origin]:	Date:	Time:	
Arrive [destination]:	Date:	Time:	

RECEIVING INFORMATION

Note: Receiver records following information and 'received' columns above.

Received on (date/time):	Received and checked by (print):
Title and location of receiver:	
Total [amount] received:	Phytosanitary permit enclosed? Yes No
Notes on condition upon receipt (damaged containers, etc):	
Storage/transport after receipt:	
Receiver Signature:	Date:

4.5 History of Changes

This form is used to highlight significant changes from previous versions when a new version is published.

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5. TRIAL CONDUCT

5.1 Establishing the Trial

5.1.1 Site Security

All sites used for testing of GM plants are required to have adequate security in order to safeguard the GM material and prevent it from being consumed by humans, livestock and other animals. All sites shall have provisions for limiting access to authorized personnel, and for restricting the site from incursion by livestock or large animals. Proposed sites may be inspected by Biosafety Inspectors or other agents of the Regulatory Authority for compliance with this provision as a condition of trial authorization.

5.1.2 Planting

Planting of GM material must not be done prior to the authorization date given in the official Terms and Conditions of Authorization issued by the Regulatory Authority. Areas of non-GM plants used for borders, buffers or guard rows may be planted prior to the authorization date, if desired.

5.1.3 Personnel

The Authorized Party shall ensure that all personnel involved with handling the GM plant material from receipt of the shipment through the field trial to devitalisation are trained on the nature of the material being handled and the requirements of all relevant SOPs. Where seed or other propagative material is being harvested, an inspection and verification procedure will be implemented to ensure that no such material inadvertently trapped in workers' clothing or bodies is removed from the site.

5.1.4 Equipment

All equipment used to plant a confined field trial shall be cleaned of any propagative GM plant material before being moved from the trial site. Appropriate cleaning methods include manual removal, brushing, compressed air, vacuuming or water. All planting equipment shall be inspected after cleaning and verified to be free of propagative plant material by trial personnel. Disassembly may be required when necessary to verify that the equipment is free of propagative plant material.

5.1.5 Disposal of Excess Material

Any excess planting material, and any propagative material recovered during the cleaning of equipment shall be recorded and devitalized by heat, incineration, deep burial, chemical treatment, grinding or crushing. If excess planting material is retained, it shall be packaged, transported and stored in accordance with SOP requirements.

5.1.6 Identification of the Trial Site and Plots

The trial site shall be identified with a sign that gives the Authorization Code Number(s) and the information 'GM plants – For Research Purposes, Not for Food or Feed. Authorized Personnel Only', or equivalent verbiage. All four corners of the trial site shall be marked with posts suitable to permit identification of the site during the growing season and for the period of post-harvest restriction. GPS coordinates of the Trial Site and distance to a permanent landmark such as a tree, house, well or fence may also be helpful in establishing the location of the Trial Site for future reference. Each individual plot of GM plants within the trial site shall have a label establishing the specific identity of the GM plants. A map of the site is required showing the location of the trial site. Requirements for trial site maps and an example of an appropriate map are found in the Appendix.

5.1.7 Record of Planting

A Record of Planting and a final plot map shall be submitted to the Regulatory Authority within five (5) days after the completion of planting.

5.2 Reproductive Isolation

5.2.1 Introduction

To prevent the escape of genes in pollen (pollen-mediated gene flow) from the trial site, GM plants shall be isolated from sexually compatible plant species in proximity to the trial site. Sexually compatible plants are called 'prohibited plants', and are described in detail in the Terms and Conditions of Authorization of each trial. The techniques used vary with the particular crop species, as described below.

5.2.2 Spatial Isolation

Enforcing a spatial isolation distance is the primary means of assuring reproductive isolation. Isolation distances are derived from observations and experiments of plant breeders, and are described in Table 1. The spatial isolation distance shall be monitored by the Trial Manager as described below, and all prohibited plants shall be destroyed or removed prior to flowering, otherwise a breach of reproductive isolation shall have occurred.

Table 1: Spatial Isolation Requirements for Common Crops

Plant Species	Minimum Spatial Isolation Distance (m)	Prohibited Plant Species	Monitoring Interval, at least once each (period)
Maize (*Zea mays*)	200	Zea mays	1 month
Cassava (*Manihot esculenta*)	100	Manihot esculenta Ceara rubber tree (Manihot glaziovii)	1 month
Cotton (*Gossypium hirsutum*)	200	Gossypium hirsutum	1 month
Banana (*Musa spp.*)	Inbreds: 100 Fertile Hybrids: 200	Ensente, Musa sp.	Monthly during vegetative growth; bi-weekly after flowering

5.2.3 Early Crop Destruction

Where the objectives of a particular trial may be achieved before the GM plants flower, early crop destruction may be used as a means of reproductive isolation. When a trial is destroyed before flowering, this trial may be allowed within the spatial isolation distance of other trials that are intended to flower. The Trial Manager shall document and verify that the GM plants in the Trial Site were destroyed or rendered incapable of flowering prior to any release of pollen.

5.2.4 Removal of Flowers Prior to Pollen Shed

Where male flowers may be readily identified prior to pollen production, as in the case of maize (Z. mays,) cassava (M. esculenta) and banana (Musa sp.), these flowers may be removed prior to pollen production. Frequent inspection, as specified in Table 2, is required to ensure that all male flowers are removed, thus verifying that no pollen was allowed to be shed.

5.2.5 Prevention of Viable Pollen Production or Release

The production of viable pollen may be prevented through genetic means such as male sterility, or the release of pollen may be prevented by physical means such as the bagging of male flowers (tassels) in maize. Where these techniques are proposed as the primary means of reproductive isolation for a confined field trial, the Applicant is required to submit justification and detailed methodology to support the proposal.

Table 2: Requirements for Alternative Methods of Reproductive Isolation

Crop	Method	Requirements
Banana	Bagging and Removal of Male Bud	Bag flower and remove male bud as soon as the distal female bracts curl to expose last formed fingers. Guard rows of 3 m (1 row) are required.
Cassava	Guard Rows	3 m (3 rows) width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Cassava	Removal of Flowers	Inspect weekly during flowering period, remove at flower bud stage before flowers open.
Cotton	Guard Rows	12 m width required. Inspect weekly for integrity and flowering characteristics during the period of flowering of the GM plants.
Maize	Bagging of Tassels	Inspect daily during flowering period, bag tassels at emergence prior to pollen shed.
Maize	Removal of Male Flowers ('detasseling')	Inspect daily during flowering period, remove tassels before fully emerged, prior to pollen shed.

5.2.6 Guard Rows

Establishment of guard rows (pollen-trap rows) is appropriate in crops that are insect-pollinated, such as cotton (*G. hirsutum*) and cassava (*M. esculenta*). The guard rows attract pollinating insects, thus limiting the spread of GM pollen (USDA-APHIS, 2000; Berkey et al., 2002; Llewellyn and Fitt, 1996).

To be effective, plants in the guard rows must flower at the same time as the GM plants and be of approximately the same growth habit and stature. The simplest way to achieve this is to use plants of the same or very similar non-modified genotype as the GM plants, planted at the same time

and in the same fashion. Guard rows must completely surround the GM trial site on all sides, and must not have any continuous gap (alley way or pathway) transversing the guard rows. The Trial Manager shall document that the guard rows are intact and that the GM plants and guard rows have a similar flowering period and growth habit.

When guard rows are used for genetic isolation, the exterior of the plot, measured from the outside of the guard rows, shall be a minimum distance from any prohibited plants as a secondary mechanism of reproductive isolation. The entire area including the guard rows shall be considered to be the 'Trial Site' for purposes of post-harvest restriction and volunteer monitoring.

5.2.7 Temporal Isolation

Where the flowering interval of a crop is limited in duration and can be adequately predicted, temporal isolation may be used as an effective method of reproductive isolation. To achieve temporal isolation of two crops, the planting dates are separated in time, so that there is no possibility of any overlap in the flowering intervals, and pollen-mediated gene flow may in this fashion be prevented. Temporal isolation is often used in situations where the distance available for spatial isolation is limited, such as on experimental farms with several trials of the same crop.

When temporal isolation is to be employed, a clear plan for its effective use shall be established in advance by the Authorized Party, and approved by the Regulatory Authority. Such plans will include provision for adequate control of crop development factors such as irrigation, and provision for adequate margins of safety, so that this method may be ensured to be effective in practice.

5.2.8 Breach of Reproductive Isolation

Breach of reproductive isolation is an extremely serious incident, and shall be reported to the Regulatory Authority according to instructions found herein. The Authorized Party may be required by the Regulatory Authority to destroy the field trial or any prohibited plants within the spatial isolation distance immediately. The Authorized Party shall be responsible for any legal or financial consequences resulting from breach of reproductive isolation. Remedies for specific instances of breach of reproductive isolation are described below.

5.2.9 Breach of Spatial Isolation Distance

Where prohibited plants are allowed to flower within the spatial isolation distance, these plants must be destroyed. In this case, the post-harvest restriction and monitoring requirements may be made more stringent and the period of post-harvest monitoring may be extended, at the discretion of the Regulatory Authority.

5.2.10 Breach of Alternative Methods of Reproductive Isolation

Where any alternative method of reproductive isolation mentioned here has occurred, the minimum spatial isolation distance becomes the default method of reproductive isolation, and the Authorized Party shall be required to enforce such isolation distance and shall be responsible for any legal and financial obligations that may be incurred.

5.3 Monitoring the Trial

5.3.1 Introduction

All confined field trial sites shall be monitored by trial personnel and Biosafety Inspectors, in order to ensure reproductive isolation and material confinement, and to gather data on the characteristics of the GM plants being tested. Additional data beyond that described in this section may be required by the Regulatory Authority, and these requirements shall be incorporated in the Terms and Conditions of Authorization.

5.3.2 Reproductive Isolation

The minimum spatial isolation distance shall be inspected by the Trial Manager for prohibited plants at least monthly from planting until harvest of the confined trial. All prohibited plants must be

destroyed before they flower. The process of inspection, identification and destruction of prohibited plants will be recorded and verified by trial personnel.

Where alternative methods of reproductive isolation are authorized, monitoring requirements vary with the crop and method employed. Monitoring intervals are suggested in Table 1.

5.3.3 Plant Growth and Development

The growth and development of GM plants shall be monitored <u>at least weekly</u> from planting until harvest of the confined trial. Any unanticipated effects on growth and development of the GM plants, compared to non-modified control plants, shall be reported to the Regulatory Authority.

5.3.4 Target Effects/Efficacy of the GM Plants

Prior to beginning the trial, the Authorized Party shall design a monitoring program adequate to establish the efficacy of the genetic modification(s) in the trial. Any unanticipated target effects of the genetically engineered plants, compared to non-GM control plants, shall be reported to the Regulatory Authority.

5.3.5 Non-Target Effects of the GM Plants

Monitoring for specific non-target effects may be required, depending on the crop and genetic modification in the trial. The Authorized Party may suggest a monitoring program for non-target pests, diseases or for environmental impacts, including details in the Application for Confined Field Trial, or elements of non-target monitoring may be required as a condition of authorization by the Regulatory Authority. Any unanticipated effects of the genetically modified plants on non-target species, compared to non-modified control plants, shall be reported to the Regulatory Authority.

5.3.6 Post-Harvest Monitoring

Post-harvest monitoring and reporting is required for all confined field trial sites.

5.4 References

Berkey, D.A., Savoy, B.R., Miller S.R. and Johnson, P.G. (2002). Pollen dissemination from adjacent field of genetically enhanced cotton in the Mississippi delta. Proc. Beltwide Cotton Conf. Atlanta, GA.

Llewellyn, D. and Fitt, G. (1996). Pollen dispersal from two fields of transgenic cotton in the Namoi Valley, Australia. Mol. Breed. 2: 157 – 166.

USDA-APHIS. (2000). Minimum land, isolation, field and seed standards. 7 CFR 201.76, Table 5.

5.5 Appendices

5.5.1 Preparation of Trial Site Maps

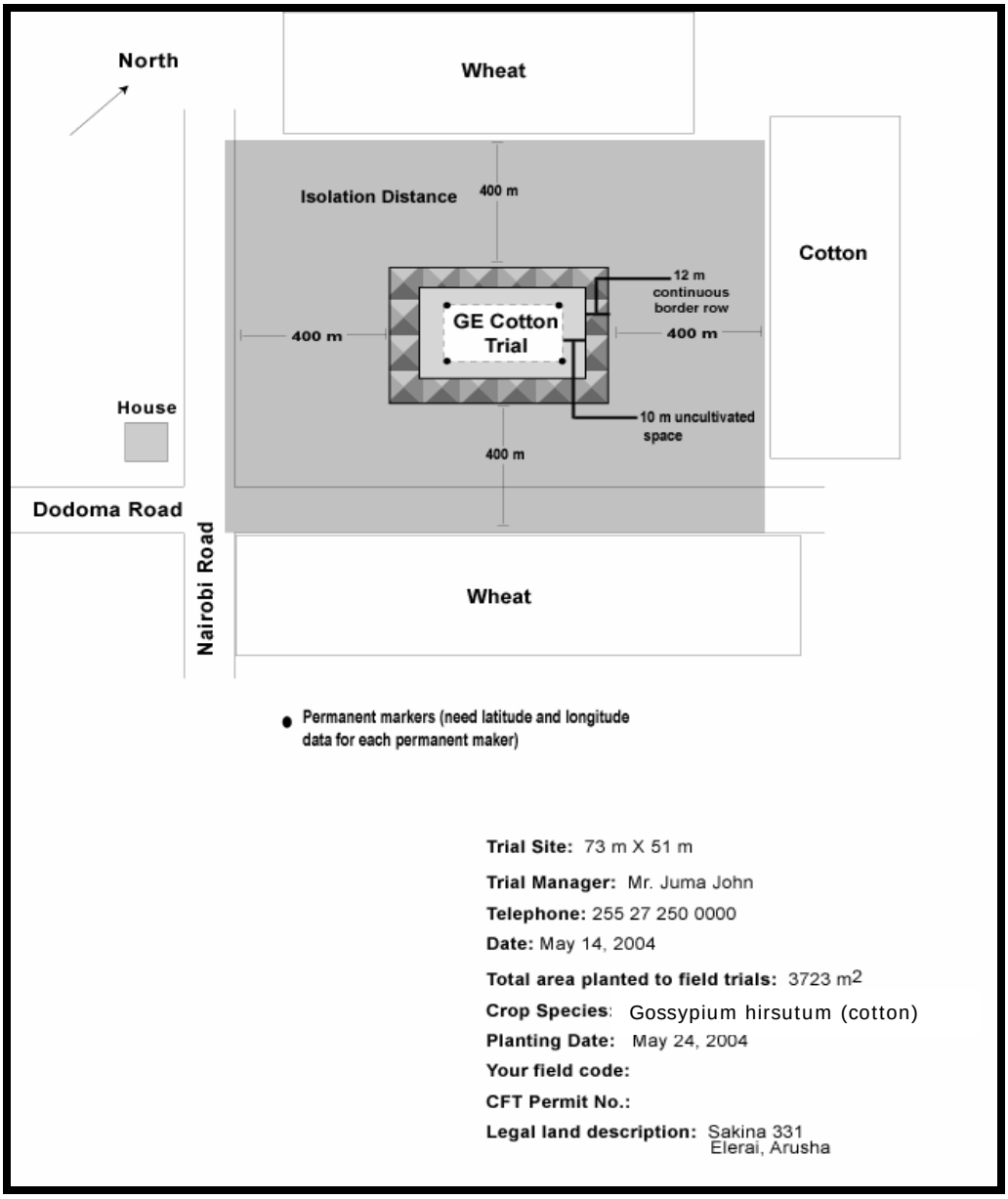
A preliminary map of the confined field trial site shall be submitted with the application, and a final field map is required with the Planting Report submitted within five (5) days after completion of planting at each site. All maps shall be legible and precise, drawn on plain paper with crisp line drawings and block letters. Maps on lined or graph paper, or photocopies of road or topographical maps will not be accepted. The following information must be included on each map:

- The general location of the field trial (city/town/region), and sufficient information to locate the trial site from the nearest town. The latter may be a map of the local area, indication of a specific milepost or landmark on a major road, or written directions to the trial site.
- Compass directions, with North at the top of the page.
- The legal land description.
- Location of the trial site in relationship to permanent landmarks such as roads, buildings or

fences. GPS coordinates of the site may be provided, if available. The location of the trial site must be recorded with enough precision that current year and post-harvest monitoring and inspection may be accomplished.

- Exact trial dimensions shall be noted on final field maps.
- Surrounding crops within the spatial isolation distance shall be indicated when these are known.
- If the area of a previous trial is still under post-harvest restriction at the same site, the restricted area should be indicated.
- The name and phone number of the trial manager or field contact shall be given.
- For final field maps, the Authorization Code Number(s) and planting date of the trial shall be included.

Table 3: Example of Properly Prepared Map with One Trial at a Single Trial Site



Map courtesy Dr. Roshan Abdallah, Tropical Pesticides Research Institute, Arusha, Tanzania.

5.5.2 Model Forms

PLANTING OF CONFINED TRIAL					
Trial Site Identification:					
Authorization Code Number(s):			**Planting Date:**		
Instructions: Record the information requested below. Use additional pages if needed to record any notes or details. Excess planting material should be disposed of by [approved method], or according to specific instructions.					
Line Number	**Amount Planted**	**Amount Retained**	**Line Number**	**Amount Planted**	**Amount Retained**
Comments on Planting:					
Intended Purpose of Retained Plant Material:					
Storage Location:			Storage Location Secure: Yes No		
Comments:					
Shipping Containers Sterilized/Inspected/Destroyed by (Circle All That Apply): Bleach Solution / Burned / Other (describe)					
Treated/Disposed of by (Initials)			Date		
Total Genetically Modified Planted	Seed		Plots		Ha
Total Area, Including Non-GM Plants and Plots	Length (m)		Width (m)		Ha
Reminder: Include a verified, signed and dated plot map in the study file. Plant [approved borders] according to the approved plot diagram. Complete and submit Planting Report with final plot map within five (5) days of completing planting.					
Checked for Accuracy and Completeness by Trial Manager **Signature:** **Date:**					

ISOLATION MONITORING

Trial Site Identification:

Authorization Code Number(s):

Instructions: Inspect [distance] surrounding the trial site each [interval], starting at planting. Identify and destroy any prohibited plants – [list] -- within the [distance] isolation area. Continue monitoring until the GM plant material in the trial site is destroyed.

Inspection Date (Day/Month/Year)	Prohibited Plants Present? What Growth Stage?	Prohibited Plants Destroyed? By What Method?	Comments	Verified By (Initials)
Example: *14 July 2005*	*Yes–2 seedlings*	*Yes-hoe*	*None*	*SM*

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

WEEKLY PLOT OBSERVATIONS									
Trial Site Identification:									
Authorization Code Number(s):									
Evaluated By:									**Date:**
Plot	**Rep**	**Line**	**Insects (Scale)**		**Diseases (Scale)**			**Hgt (cm)**	**Comments/ Other Observations**
1	1								
2	1								
3	1								
4	1								
5	1								
6	1								
7	2								
8	2								
9	2								
10	2								
11	2								
12	2								
13	3								
14	3								
15	3								
16	3								
17	3								
18	3								
19	4								
20	4								
Line Avg:									
Checked for Accuracy and Completeness by Trial Manager									
Signature:									**Date:**

PHONE AND COMMUNICATION LOG

Trial Site Identification:

Authorization Code Number(s):

Instructions: Keep a copy of this form at your desk. Record all phone conversations, and all relevant personal communications. When the log is full, file and obtain a new blank copy.

Spoke With	Date/Time	Mode*	Summary	Initials

***Ph = phone; Con = conversation ; F = fax communication ; E = email. Note 'To' or 'From'.**

FLOWER BUD REMOVAL WEEKLY REPORT

Trial Site Identification:

Authorization Code Number(s):

Instructions: Summarize results of flower bud removal each [time], starting [time] after planting in soil, or earlier if branching is observed. Dispose of all flower buds by [method]. Answer Y/N except as indicated.

Week of (Dates)	Number of Inspections This Interim	Flower Buds Present?	All Flower Buds Removed Prior to Pollen Production?	Flower Buds Disposed of in On-Site Disposal Pit?	Verified By (Initials)

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

5.6 History of Changes

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6. SAMPLING

6.1 Introduction

One objective of a confined field trial may be to obtain samples of different plant tissues, in order to identify genetic elements, determine levels of expression of proteins or other plant constituents, or to establish composition of the plant tissues. Types of samples and the tissues to be sampled vary widely, depending on the specific objectives of the trial. Specific sampling requirements and methodologies are typically established in the Study Plan.

In all cases, however, fundamental principles of sample cleanliness, sample identification and sample integrity generally apply. These fundamental principles are outlined in this Procedure.

6.2 Avoid Contamination

To obtain samples and resulting data that are scientifically valid and useful, it is critically important to avoid mixing even the smallest amount of tissues between different samples, an occurrence called 'cross-contamination'. This is achieved by strictly following these simple measures:

- Wear clean disposable gloves when sampling, and change them after each plot or entry is sampled;
- Wash thoroughly all sampling tools and rinse them with clean solvent (e.g., clean water) between sampling different plots or entries;
- Do not contaminate samples with chemicals, dirt or soil. Use a clean plastic drop cloth or other clean surface to place samples on, if necessary;
- Follow instructions in the Study Plan to determine the order in which samples are taken. Typically, the non-GM control will be sampled first, followed by the GM entries, but this may vary depending on the plant materials and objectives of the trial.
- Always use new sample bags as the primary container for the samples, i.e., the container directly in contact with the sample itself. Securely close each container after placing the sample inside.
- Place control samples in separate secondary and tertiary containers from the GM samples. If separate secondary containers are not available, samples may be double contained and physically separated.

6.3 GM Tissue Sample Collection

Collect the type and amount of tissue required by the Study Plan. An inexpensive scale such as a bathroom scale may be used to determine approximate amounts in the field. Do not wash, strip, brush or trim the samples unless these steps are specified in the Study Plan.

Unless otherwise specified by the Study Plan, all samples should be placed on dry ice or in a freezer within 30 minutes of collection, and should be maintained at or below freezing during processing and shipment.

6.4 Sample Identification

Follow instructions in the Study Plan for sample identification or coding. Completely fill out all required information on the sample bag prior to or at the time of sampling. Always use a permanent marker pen if sample information is recorded directly on the sample bag. All samples shall be labeled uniquely, and in a fashion that cannot be lost, obscured or obliterated. The date of collection of each sample shall also be recorded on the sample bag or primary container.

6.5 Sample Storage

Follow instructions in the Study Plan for sample storage. Typically, samples are required to be frozen soon after collection, and maintained in a frozen state.

6.5.1 Equipment Requirements

If specified by the Study Plan, samples may be maintained on dry ice for several days, if no freezers are available. The amount of dry ice should be monitored at least twice a day, and more dry ice added as needed. Monitoring and addition of ice shall be documented.

If freezers are available, these should be capable of maintaining an average temperature within the range acceptable for sample storage, and this capability shall be verified before use with an appropriate temperature monitoring device such as a minimum/maximum thermometer for a period of at least three (3) days. The temperature range recorded should be within +/- 3ºC for the monitoring period.

If multiple freezers for the storage of control and GM samples are not available, these samples should be stored in separate parts of the freezer, e.g., on separate shelves.

Freezers should be located in a clean and secure area away from direct sunlight. Electrical outlets used should be grounded and the Trial Manager shall verify that the circuits used are not overloaded. The outlet should not be connected to a wall switch that could accidentally be turned off, and the cord and plug should be secured or protected so that the plug cannot be inadvertently pulled from the outlet. There should be unobstructed airflow around the coils and adequate space within the freezer to maintain the integrity of the samples.

A sample storage log shall be maintained for all samples in storage. This log shall record the following information: Trial Site Identification, a brief description of the samples stored or sample identification, date and person storing the samples, date and person shipping the samples.

6.5.2 Equipment Monitoring

Equipment used for sample storage should be monitored by use of a recording device such as a minimum/maximum thermometer. A temperature log shall be maintained recording the minimum, maximum and current temperature, as well as the date and initials of the recorder, at least weekly while samples are being stored. A suggested contingency to verify that constant freezing temperature has been maintained is to invert a small container such as a test tube with frozen water in the bottom into a larger container such as a beaker. If the temperature rises above freezing for an appreciable amount of time, the ice will fall out of the small container. The samples should then be checked for defrosting, and this occurrence noted in the study file.

6.5.3 Equipment Failure

In case a freezer fails due to power outage or malfunction, limit the number of times that the freezer is opened, to retain cold in the freezer. If the failure lasts longer the 24 hours, or the temperature exceeds 0ºC for more than a few minutes, place dry ice in the freezer to maintain the samples in frozen condition.

6.6 Sample Packaging and Shipment

Sample packaging and shipment shall conform to requirements established by the Regulatory Authority appropriate to sample type, and to relevant SOP requirements. Typically, samples of non-propagative tissues, e.g., leaf samples taken for laboratory analysis, require no special packaging or labeling.

Special steps may be required to maintain sample integrity of delicate tissue samples during shipment, such as the inclusion of dry ice.

The following procedures are generally appropriate, depending on objectives or sample types:

- Samples should be shipped in new boxes or containers;
- If possible, control and GM samples should be shipped in separate containers;
- When shipments have multiple containers, the containers should be numbered sequentially, and the total number of containers indicated on the Shipping Form;
- A manifest listing all samples in the shipment should be included in 'Box #1' of the shipment. Write 'Packing Slip Enclosed' on the appropriate container;
- Dry ice may be required to maintain the samples in the frozen state, in which case a minimum of approximately 5 to 10 kg of dry ice per 1 kg of packaged sample (weight of sample plus associated packaging) is appropriate, distributed equally above and below the samples. Alternatively, shipping by specialized carrier such as a freezer truck may be required. Where samples are to be shipped frozen, close coordination with the receiver is advisable, to ensure sample integrity during shipment and receipt. Document all communication with the Authorized Party and/or sample recipient on an appropriate Communication Form. Consult the Study Plan for specific recommendations and requirements according to trial and sample type.

6.7 History of Changes

This form is used to highlight significant changes from previous versions when a new version is published.

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7. TRIAL TERMINATION

7.1 General Requirements

7.1.1 Early Crop Destruction

The requirements of this SOP apply equally to trials undergoing normal harvest, and those that are terminated prior to normal harvest. The term 'harvest' is construed herein to include early termination of a trial, as applicable. If a trial has been terminated prior to flowering as a measure of reproductive isolation, the post-harvest restriction may be waived upon written approval by the Regulatory Authority.

7.1.2 Consumption and Persistence

Two of the overarching goals in the conduct of any confined field trial are: 1) preventing consumption of GM plant material by humans or livestock, and 2) preventing GM plants from establishing and persisting in the environment. The Authorized Party, Trial Managers and all trial personnel are required to take all reasonable steps to ensure that these goals are accomplished, including, but not limited to, compliance with the procedures described herein.

7.1.3 Notification of Intent to Harvest

The Authorized Party shall notify the Regulatory Authority at least five (5) working days prior to the intended date of harvest, in order that an Inspector may be present during harvest. The presence of an Inspector is at the discretion of the Regulatory Authority, and is not a requirement of this SOP.

7.1.4 Personnel

All personnel involved in harvest activities will be instructed by the Trial Manager on the nature of the material being harvested and on the requirements of this SOP. Where seed or other propagative material is being harvested, an inspection and verification procedure will be implemented to ensure that no such material inadvertently trapped in workers' clothing is removed from the site.

7.1.5 Equipment

All equipment used to harvest a confined field trial shall be cleaned of plant material before being moved from the trial site. Appropriate cleaning methods include manual removal of seed or plant parts, brushing, compressed air, vacuuming or water. All harvest equipment shall be inspected after cleaning and verified to be free of plant material by trial personnel. Disassembly may be required to verify that the equipment is free of plant material.

7.1.6 Guard Rows

In cases where guard rows have been used as a measure of reproductive isolation, plant material in these rows is assumed to be GM, and is subject to all requirements for devitalization and disposal described in this SOP.

7.1.7 On-Site Disposal

GM plant material shall be disposed of at the confined field trial site, unless off-site movement has been authorized by the Regulatory Authority.

7.1.8 Retention of Material

If any plant material is to be retained from the trial for research purposes, the details of this activity shall be specifically authorized by the Regulatory Authority.

7.1.9 Packaging, Transport and Storage

Any GM plant material authorized for off-site movement is subject to the requirements of the relevant SOP.

7.1.10 Incident and Corrective Action

Any incidents of inadvertent release arising from harvest activities are subject to the reporting requirements as described in the relevant SOP.

7.2 Devitalization and Disposal

7.2.1 Devitalization

Plant material may be devitalized by heat, incineration, deep burial, chemical treatment, grinding or crushing, or by cultivation into the soil. Where deep burial is used, the depth must be sufficient to prevent accidental exposure of the material or the emergence of living plants. In most cases, a depth of 1 m of soil covering the top of the plant material is sufficient to achieve these goals. Herbicides for devitalization shall be applied according to labeled use instructions for this country, according to the national guidelines, unless specifically authorized by the Regulatory Authority.

7.2.2 Disposal

Plant material may be disposed of by incineration, deep burial or by cultivation into the soil.

7.2.3 Post-Harvest Monitoring

Confined field trial sites are subject to post-harvest restriction and monitoring, as described in relevant SOPs. Where plant material is devitalized or disposed of by burial or by cultivation into the soil, the disposal areas are also subject to post-harvest monitoring.

7.3 Records and Reports

Details of harvest and disposal shall be recorded by trial personnel on appropriate forms; see the Appendix for an example. A Harvest Report shall be submitted by the Authorized Party within ten (10) working days after the completion of harvest at the site.

7.4 Appendices

7.4.1 Model Harvest and Crop Destruction Form

HARVEST AND CROP DESTRUCTION FORM

Trial Site Identification:

Authorization Code Number(s):

Instructions: Record the information requested below. Use additional pages if needed to record any notes or details. Harvested material must be disposed of by [authorized method] after final harvest yields are obtained.

Describe Harvest Method and Equipment Used:

Harvest Date	Equipment Cleaned On-Site (Y/N)	All Viable Plant Material Retained On-Site (Y/N)	Verified By (Initials):

Describe Procedure for Destruction of Plant Materials, Including Dates:

Notes or Comments on Harvest and Destruction of Crop Material:

Reminder: Permit Terms and Conditions [do/do not] allow any plant material from the trial to be retained on-site. [All/excess] material must be disposed of by [authorized method].

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

7.5 History of Changes

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8. POST-HARVEST MANAGEMENT

8.1 Procedures

8.1.1 Post-Harvest Restriction

All confined field trial sites with GM plants are subject to post-harvest restriction and post-harvest monitoring. These requirements allow volunteers of the GM plants to be identified and destroyed, so that:

- The GM plant material is not consumed by humans or livestock.
- GM plants cannot outcross with plants outside the trial site.
- GM plants cannot persist in the environment.

8.1.2 What is Restricted

No plants may be grown on the trial site that would interfere with the identification and destruction of volunteers from the GM trial. This restriction typically includes the crop species itself, and any other plants that are similar in morphology and/or growth habit. If volunteers are to be controlled by herbicide application, it is preferable that the following crop not be sensitive to the proposed herbicide. Table 4 shows crops that are typically acceptable for use following different GM crops.

A GM trial of the same crop as grown in the previous confined field trial is usually acceptable, when grown under specific Terms and Conditions of Authorization issued by the Regulatory Authority.

The post-harvest restriction may be waived upon approval of the Regulatory Authority, if the GM plants in the trial site were not allowed to set seed and this has been verified by the Authorized Party.

8.1.3 Post-Harvest Period

The post-harvest restriction and monitoring begins at harvest or termination of the trial, and continues for the duration of the post-harvest period. The post-harvest period is designed to extend beyond the time when the seed bank of GM plants in the soil is depleted, and the trial site may be returned to unrestricted usage. Post-harvest periods for common crops are shown in Table 4. The post-harvest period may be terminated earlier than the full time shown in the Table, upon approval

of the Regulatory Authority, if no volunteers are noted for three (3) monitoring intervals favorable for crop germination and growth.

Table 4: Post-Harvest Requirements for Common Crops

Plant Species	Examples of Appropriate Following Crops	Post-Harvest Period (years)	Monitoring Interval, at least once each (months)
Maize (Zea mays)	Short Stature Dicots (e.g., squash, melon, vegetables)	1	1
Cassava (Manihot esculenta)	Maize or other grain	1	3
Cotton (Gossypium hirsutum)	Maize or other grain	1	1
Banana (Musa spp.)	Maize, cotton, short stature dicots	1	3

8.1.4 Post-Harvest Monitoring

Trial personnel shall monitor the trial site at the intervals shown in Table 4, recording the presence and growth stage of volunteers, and the method of their destruction. A model of an appropriate Volunteer Monitoring Form may be found in the Appendix.

8.1.5 Guard Rows

In cases where guard rows have been used as a measure of reproductive isolation, the area of the guard rows is considered to be part of the trial site, and is subject to all requirements described in this SOP.

8.1.6 Breach of Spatial Isolation during the Season

Where there has been an established breach of spatial reproductive isolation distance during the season—where prohibited plants have been allowed to flower within the spatial isolation distance—the spatial isolation distance shall also be subject to post-harvest restriction and monitoring requirements described in this SOP.

8.1.7 Destruction of Volunteers

Volunteers shall be destroyed before flowering, and shall be disposed of within the trial site in a fashion that prevents consumption by humans or livestock. Appropriate methods of destruction include chemical treatment or cultivation into the soil. Herbicides for devitalization shall be applied according to labeled use instructions according to the national guidelines, unless specifically authorized by the Regulatory Authority. If volunteers are allowed to flower within the trial site, this constitutes a serious breach of compliance.

8.1.8 Equipment

All equipment used to destroy volunteers on a confined field trial site shall be cleaned of plant material before being moved from the trial site. Appropriate cleaning methods include manual removal of plant material, brushing, compressed air, vacuuming or water. All such equipment shall be inspected after cleaning and verified to be free of plant material by trial personnel.

8.1.9 Non-Compliance

Where there has been an established breach of compliance with these requirements, the post-harvest restriction shall be extended for an additional post-harvest monitoring period. If prohibited

plants are present in the spatial isolation distance at the time of flowering of the volunteers, and there is a possibility that they may have cross-pollinated with the volunteers, then the post-harvest restriction shall extend to the spatial isolation distance required for the GM plants. The Authorized Party shall be responsible for any legal or financial obligations incurred due to any incident of non-compliance.

8.2 Records and Reports

Details of post-harvest management of the trial site, including monitoring and destruction of volunteers and establishment of any following crop shall be recorded by trial personnel. A model of an appropriate Post-Harvest Monitoring Form may be found in the Appendix. A Final Report shall be submitted by the Authorized Party within six (6) months after the completion of the post-harvest period.

8.3 Appendices

8.3.1 Model Volunteer Monitoring Form

VOLUNTEER MONITORING				
Trial Site Identification:				
Authorization Code Number(s):				
Instructions: Inspect the trial site for volunteers each [time period], starting one month after harvest. Identify and destroy any volunteer [crop] and note the method. Continue monitoring until the end of the post-harvest interval, xxx months after harvest.				
Inspection Date (Day/Month/Year)	**Volunteers Present?**	**If Present, What Growth Stage?**	**Volunteers Destroyed? Method of Destruction.**	**Verified By (Initials)**
Example: 14 July 2006	***Yes***	***Seedlings***	***Yes – Cultivation***	***SM***
Checked for Accuracy and Completeness by Trial Manager				
Signature:			**Date:**	

8.4 History of Changes

This form is used to highlight significant changes from previous versions when a new version is published.

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9. INCIDENTS

9.1 Principle Goals

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 or livestock; and 3) preventing GM plants from 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.

The Terms and Conditions of Authorization of each specific confined field trial, and the SOPs and relevant documents published by the Regulatory Authority, are intended to assist the Authorized Party in achieving the three goals. It is the responsibility of the Authorized Party to ensure compliance with the applicable guidance associated with the confined trial and the handling of GM plant material. 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 GM plant material. The Authorized Party is required to take all reasonable steps to ensure that these three goals are accomplished, including, but not limited to, compliance with all Terms and Conditions and relevant guidance given by the Regulatory Authority.

9.2 Infractions

Serious compliance infractions or incidents involve direct violation of the three principle goals. For example: planting without authorization; accidental or unauthorized release of GM plant material; consumption of GM plant material by humans or livestock; or failure to monitor and destroy volunteers. For such serious incidents, or for gross negligence of compliance requirements, substantial fines may be imposed by the Regulatory Authority for each instance.

9.3 Notification

Where an accidental or unauthorized release of GM plant material has occurred or is suspected, the Regulatory Authority shall be notified orally as soon as is practical and in writing within 24 hours of the incident. A model of an appropriate Incident Reporting Form may be found in the Appendix. All notifications or reports shall be submitted to the Secretary of the Regulatory Authority:

Title:
Address:

Telephone:
Facsimile:
Email:
Website:

9.4 Corrective Actions

9.4.1 Unauthorized or Accidental Release

Where unauthorized or accidental release of GM plant material has occurred or is suspected, the following steps should be taken:

1. **Stabilize the situation.** Prevent any further loss of material or deterioration of the situation.
2. **Prevent consumption.** Prevent material from being eaten by humans or livestock.
3. **Recover the material.** Recover all material possible.
4. **Notify the Regulatory Authority.** Notify the Regulatory Authority as described above, and follow any instructions given.
5. **Mark or record the exact location.** Mark or record the exact location, in case follow up monitoring is required.
6. **Dispose of material.** If necessary, dispose of any GM plant material in an appropriate fashion.
7. **Follow-up monitoring or detection.** Follow up monitoring may be required at the discretion of the Regulatory Authority.

9.4.2 Other Incidents

In the case of other incidents or serious compliance infractions, notify the Regulatory Authority as described above, and follow any instructions given.

9.5 Contingency Planning

Good contingency planning for serious incidents, however unlikely, is the key to successful amelioration of any exposure or environmental impact from these incidents. The Authorized Party shall establish a contingency plan in accordance with the requirements of this SOP, and shall provide training for all trial personnel on this SOP or other authorized contingency plan.

9.6 Appendices

9.6.1 Model Incident and Corrective Action Reporting Form

INCIDENT AND CORRECTIVE ACTION FORM

Trial Site Identification:

Authorization Code Number(s):

In case of any breach of confinement, follow these steps:

1. **Stabilize the situation.**
2. **If material is released, recover all material possible.**
3. **Take all actions necessary to prevent material entering food and feed. Mark the site of release.**
4. **In the case of accidental release, inform the Authorized Party and the Regulatory Authority immediately by phone.**
5. **Complete and fax incident report within 24 hours. Contact numbers are given below.**

AP Manager	Regulatory Authority
Phone (O):	**Phone (O):**
Phone (M):	**Phone (M):**
Fax:	**Fax:**

Describe the breach of confinement, including personnel involved and corrective actions taken:

COMMUNICATION LOG

Number or Person Contacted	Date/Time	Mode*	Summary of Communication and Agreed Actions	Initials

***Ph = phone; Con = conversation ; F = fax communication ; E = email. Note 'To' or 'From'.**

Summarize current situation and corrective actions taken or agreed upon:

Checked for Accuracy and Completeness by Trial Manager

Signature: **Date:**

9.7 History of Changes

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10. REPORTING

10.1 How to Report

All reports shall be submitted by regular mail, courier, facsimile, or electronically to the Secretary of the Regulatory Authority:

Title:
Address:

Telephone:
Facsimile:
Email:
Website:

Reports required are described in the sections below. All reports shall reference the Authorization Code Number assigned to the trial.

10.2 In-Season Reports

The following reports are required during the conduct of the trial.

10.2.1 Trial Establishment Report

The Authorized Party shall submit details of site establishment within five (5) working days after the completion of planting at the site. The report will include the planting date, the amount of material planted, disposal of any surplus GM plant material remaining after planting, and the size of the trial site. A final field site map shall also be submitted at this time.

10.2.2 Trial Progress Report

The Authorized Party shall submit a progress report after completion of the flowering period of the crop. The report will include flowering information and results of activities enforcing reproductive isolation.

10.2.3 Harvest Report

The Authorized Party shall submit details of site harvest within ten (10) working days after the completion of harvest or termination 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.

10.3 Other Reports

The following reports are required in the unusual circumstances described below.

10.3.1 Incident and Corrective Action Report

The Authorized Party shall orally notify the Regulatory Authority immediately, and in writing within 24 hours, of any incident involving an accidental or unauthorized release of genetically engineered plant material. The report will include any corrective actions taken or planned to contain GM material and ameliorate the incident.

10.3.2 Unanticipated Effects Report

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

10.4 Summary Reports

The following summary reports are required for each confined field trial.

10.4.1 Experimental Report

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

10.4.2 Post-Harvest Report

The Authorized Party shall submit a Final Report within six (6) months after the completion of the post-harvest period summarizing observations on volunteers and their destruction.

10.5 Model Report Formats

PLANTING REPORT FOR CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Code Number(s):	**Authorized Party:**		
Trial Manager:	**Phone/Fax:**		
Trial Approval Date:	**Planting Date(s):**		
PLANTING			
Total genetically modified material planted:		Ha (required)	
		Plants (optional)	
		Plots (optional)	
Total area planted, including borders:		Ha	
Comments:			
DISPOSITION OF PLANTING MATERIAL			
Unless otherwise noted, check Yes or No in the appropriate box.		YES	NO
Was excess GM planting material destroyed?			
If yes, how?			
Was any GM planting material retained?			
If yes, where is it being stored?			
If yes, what amount was retained?			
Were there any significant occurrences during planting that may have affected confinement of the GM material?			
If yes, describe:			
Comments:			
Trial Manager Signature:	**Date:**		
Date Submitted:			
Required Attachments ▪ **Final Field Map** ▪ **Completed 'Planting of Confined Trial' Form**			

TRIAL PROGRESS REPORT FOR CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Code Number(s):	**Authorized Party:**		
Trial Manager:	**Phone/Fax:**		
Planting Date(s):			
Date Flowering Began:	**Date Flowering Ended:**		
REPRODUCTIVE ISOLATION AND CONFINEMENT			
List measures taken to assure reproductive isolation and confinement:			
Comments:			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
Were all measures for reproductive isolation carried out according to requirements?			
If no, describe:			
Was any breach of reproductive isolation noted during flowering?			
If yes, describe:			
If yes, was an Incident Report filed?			
Comments:			
Trial Manager Signature:	**Date:**		
Date Submitted:			

HARVEST REPORT FOR CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Code Number(s):	**Authorized Party:**		
Trial Manager:	**Phone/Fax:**		
Planting Date(s):	**Harvest Date:**		
HARVEST RESULTS			
Unless otherwise noted, check Yes or No in the appropriate box.		**YES**	**NO**
Method of harvest:			
Was any harvested GM material disposed of?			
If yes, how?			
Was any harvested GM material retained?			
If yes, where?			
Amount:			
Method of destruction of residual plant material on the site:			
Were there any significant occurrences during harvesting that may have affected confinement of the GM material?			
If yes, describe:			
Comments:			
Trial Manager Signature:	**Date:**		
Date Submitted:			
Required Attachments ▪ **Completed 'Harvest and Destruction' Form**			

INCIDENT AND CORRECTIVE ACTION REPORT	
Trial Site Identification:	
Authorization Code Number(s):	**Authorized Party:**
Trial Manager:	**Phone/Fax:**
Attach a completed Incident and Corrective Action form to this cover sheet. Use the space provided below if needed to summarize details of the incident, corrective actions, follow-up actions in-progress or planned, or current status.	
Trial Manager Signature:	**Date:**
Date Submitted:	
Required Attachments ▪ **Completed 'Incident and Corrective Action' Form**	

UNANTICIPATED EFFECTS REPORT			
Trial Site Identification:			
Authorization Code Number(s):	**Authorized Party:**		
Trial Manager:	**Phone/Fax:**		
Planting Date(s):			
Describe any substantial unanticipated or unusual effects observed in the trial, either with the GM plants themselves, or on non-target organisms or the environment (attach additional pages if needed):			
Unless otherwise noted, check Yes or No in the appropriate box.		***YES***	***NO***
Are the unanticipated effects observed likely to affect the confinement of the GM material, or result in changes to confinement measures used?			
If yes, describe:			
Trial Manager Signature:	**Date:**		
Date Submitted:			

EXPERIMENTAL REPORT FOR CONFINED FIELD TRIAL	
Trial Site Identification:	
Authorization Code Number(s):	**Authorized Party:**
Reported By/Title :	**Phone/Fax:**
Planting Date(s):	**Harvest Date(s):**
Attach a complete report summarizing observations, methods of observation, data and analysis of experimental results, and any unanticipated effects observed. Provide an Executive Summary of the report in the space below (attach additional pages if needed).	
Signature:	**Date:**
Date Submitted:	
Required Attachments ▪ **Experimental Results and Conclusions**	

POST-HARVEST REPORT FOR CONFINED FIELD TRIAL			
Trial Site Identification:			
Authorization Code Number(s):	**Authorized Party:**		
Reported By/Title:	**Phone/Fax:**		
Planting Date(s):	**Harvest Date:**		
POST-HARVEST RESULTS			
Unless otherwise noted, check Yes or No in the appropriate box.		***YES***	***NO***
Has a Termination Report on experimental results been submitted to the Regulatory Authority?			
Was monitoring for volunteers carried out during the post-harvest period according to requirements?			
Summarize observations on volunteers:			
Were all volunteers identified and destroyed prior to flowering?			
Method of Destruction:			
No volunteers have been observed on the trial site since (date):			
Were there any significant occurrences during the post-harvest period that may have affected confinement of the GM material?			
If yes, describe:			
Comments:			
Signature:	**Date:**		
Date Submitted:			

10.6 History of Changes

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Appendix 1. Model Study Plan

1. Cover Sheet

Study Title: [Descriptive title and year, used as header on all pages]
Principal Investigator: **Individual**
Postal address and contact details – phone, fax, email

Cooperating Investigators: **Individuals, if any**
Postal address and contact details – phone, fax, email

Table 1. Field Site(s) and Field Investigator(s)

Location(s)	Field Investigator(s) Name, Address and Phone Number
[physical location of field sites, gps of Trial site if available]	

Read and understood:

_____ _____
Field Investigator **Date**

2. Purpose

[Brief description of the trial materials and objectives.]

3. Regulatory Compliance

This field study contains regulated genetically modified plants. Therefore, strict adherence to regulatory requirements described in the Terms and Conditions of Authorization (date), and [other relevant standards] is required. All procedures, including this Study Plan and any Standard Operating Procedures (SOPs) relating to confinement of the regulated plant material must be read, understood and followed.

4. Procedures

Specific procedures to be used in this study to comply with regulations include but are not limited to the following:

1. Ship and maintain regulated plant tissues so they are not released into the environment and are not mixed with non-regulated material. Shipments will be double contained and identified as containing genetically modified (GM) material.

2. Plant and label all plots in a manner to prevent inadvertent mixing of regulated plants with non-regulated plants.
3. [List specific and critical measures for genetic or material confinement, such as isolation distances, alternative methods of reproductive isolation, etc.]
4. All plants in the Trial Site [including border plants] must be destroyed at harvest time, by one or more of the following methods: [list approved methods].
5. Clearly identify the Trial Site, including border rows, using permanent landmarks or equivalent, to allow periodic monitoring of volunteer plants for a [one-year?] period following harvest.
6. Establish a monitoring program for volunteer plants in the Trial Site to ensure that all volunteer plants in subsequent growing season (specific post-harvest restriction interval) will be destroyed. Monthly monitoring is required.
7. Do not plant the Trial Site with [list restricted crops] for minimum [post-harvest restriction] after harvest to allow monitoring of volunteers in the field in the following growing season. [List crops that may be grown in the Trial Site following the study].

5. Study Dates

Proposed Start Date:

Proposed Termination Date:

6. Definitions

Alleyways are unplanted areas between blocks or replicate plots.

Border rows or border plants are the plants surround the plot area. In this study, the border rows are part of the Trial Site and will be treated as regulated for purposes of destruction and disposal.

Field Site is the entire facility including the building(s), roads, and entire acreage.

Isolation Zone is the area between the Trial Site and any cassava intended for food or feed usage.

Trial Site is the location that includes the experimental plants and border rows or plants.

[List additional definitions critical to the study.]

7. Study Design

7.1 Starting Plants

Starting plants will be provided by [who?], and will be shipped to the Field Investigator according to all relevant regulatory requirements. [Shipment details may be added, if important.]

7.2 Characterization of Starting Material

[What characterization of the plants/seeds/starting material will be done before shipping?]

Table 2. Summary of Test and Control Starting Materials

Material Code	Variety Identification	Lot Number	Phenotype
Test Varieties:			
Control Variety:			
Border variety:			

7.3 Starting Plants Shipment, Receipt and Storage

Movement of regulated genetically modified plants will follow strict adherence to requirements by using chain-of-custody forms to document receipt, storage, handling and disposition.

Record the total number of [plants, amount of seed, etc.] received and planted. Cross-check identification or lot numbers with plant/bag labels.

Save all shipping containers for possible inspection by regulatory officials during the study period, if requested. If the shipping containers are destroyed, record the date and method of destruction.

7.4 Identification of Field Site and Plots

The Field Site(s) is/are identified in Table 1.

The Trial Site within the Field Site includes experimental plants and border plants. All four corners of the Trial Site must be staked with durable markers such as metal or sturdy wooden stakes, so that the area can be identified during the study, and for the required post-harvest monitoring period.

Stake each row [or each plot] with line number and plot number (each row/plot must be staked with durable markers, such as a wooden or plastic stake or flag). All labeling and plot identification must be robust enough to last the entire study or be replaced as needed throughout the course of the study.

A site-specific field plot diagram identifies the unique randomization scheme of the plots in this study, and is given in Figure 1.

7.5 Description of Experimental Design

Field Design. The experimental plants will be planted in a [randomized complete block design/or other with xx blocks or replicates]. Each block (replicate) will consist of xxx plots (xxx experimental lines and xxx control lines). Each plot will comprise x rows of xx plants each, or xx plants total. Plant spacing will be xx within plots and xx between plots, as shown in Figure 1.

Figure 1. Plot Design and Randomization

[Plot diagram, showing north direction]

Planting. It is expected that all plants/seeds will be planted or destroyed. Record details of planting and destruction of excess starting material on the appropriate forms.

Border Plants. [Describe any provisions for border plants or rows.]

Isolation Zone. Establish an isolation zone between regulated Trial site (including the border plants)

and any [list prohibited plants]. This zone must be at least xxx meters on all sides of the Trial site. The isolation zone may be planted with [what crops], or any/all portions may be left fallow.

7.6 Agronomic Practices during the Growing Season

Maintenance Pesticides. It is important to maintain a normal agronomic crop with respect to disease, weed and insect infestations, by monitoring and treating (if necessary) in a timely manner. Maintenance pesticides applied for this study must be commercially registered products. Apply maintenance pesticides at the rate recommended on the manufacturer's product label. For each application, apply the maintenance pesticide to all plots and border rows uniformly at the same rate. Record all pesticide applications information (e.g., product, formulation, date applied, rate, and target pest) in the study notes.

Cultivation. Cultivate the Trial Site as needed, in order to obtain an agronomically acceptable crop. Record all cultivation practices in the study notes.

Fertilizer. Uniformly fertilize all plots as needed in order to obtain an agronomically acceptable crop. Record all fertilizer applications as composition (percent N-P-K) and total amount (kg/ha) applied in the study notes.

Irrigation. Uniformly irrigate all plots as needed according to local practice, to produce an agronomically acceptable crop. Record irrigation amounts and dates in the study notes.

7.7 Observations

Collect and record the following data for each plot according to the method and frequency indicated.

Growth and Development. During the trial, take the following observations on each plot, at least [weekly/monthly], including the following observations: [observations and metric or scale to be used]. Note any unusual morphological effects or other unusual observations.

Harvest Observations. At harvest, record the following data for each [plant or plot]:

[List required observations and metrics to be used]

Data will be pooled on a plot basis for analysis.

8. Sampling

Collect samples in the following order: (1) control plots, (2) test plots. To avoid cross contamination, thoroughly clean the sampling equipment between sampling of different plots.

To minimize protein degradation, place all tissue samples on dry ice within 30 minutes after sampling. Keep tissue samples frozen during transport from the Trial Site to the preparation and storage facility, and until needed for analysis.

8.1 Sample Types and Procedures

[List required sample types, timings and amounts]

8.2 Sample Labeling

Durable, unique and clear sample labels that will be affixed to each sample container. If a coding system is used to label the sample containers, a copy of the cross-reference code index must be included in the study file.

8.3 Sample Handling and Storage

All plant tissue samples must be placed on dry ice in the field immediately following collection, within **30 minutes**. Tissue samples will be stored frozen in uniquely-labeled sample containers and maintained at dry-ice temperatures after collection.

Samples will be analyzed [where, when, by whom]. [List provisions for sample shipment, if any is anticipated, or 'No sample shipments are anticipated']. Appropriate precautions should be taken to ensure that samples will remain frozen during shipment, no leakage occurs between samples, and all sample packages are appropriately labeled.

9. Sample Preparation and Analyses

Sample preparation and analyses are not covered in this field trial Study Plan. [A brief description of the analyses to be done may be provided for informational purposes.]

10. Records to be Maintained

10.1 Field Site Records

In addition to the specific information requested in this Study Plan, information on the study site must be provided, including:

1. A field site map showing access to the Trial site from local roads;
2. Trial Site diagram showing the exact location of all plots in relationship to permanent landmark(s);
3. A description of the Trial Site, including soil series and type, crops grown the previous season, and any other field data that may be relevant to this Study Plan.

10.2 Field Data Requirements

Record all study-related data on forms provided, or record the relevant information on notebook pages. All forms, notes and other raw data, such as Sample Handling Forms, must be filled out promptly, accurately, and in indelible blue or black ink (no pencil). All entries must be dated on the day of entry, and signed or initialed by the person making the entry. If more than one individual records data on a page, it must be clear which individual recorded specific data. Any exact copies of raw data substituted for the original must be certified by the person making the copy.

Photographs showing the Trial Site, sampling or other procedures are helpful in documenting the study. Photographs are strongly recommended for illustrating any abnormal growth or event that could affect the results. If possible, certify photographs by including photograph date, study, and signature/initials of the photographer.

10.3 Weather Data

The weather data required by this Study Plan or the duration of this study are maximum/minimum monthly air temperatures, monthly rainfall, and irrigation (if applied) including dates and amounts. Record any other weather data or events that may influence the conduct or integrity of the study. In addition to actual weather data, provide normal average monthly air temperatures (maximum/minimum) and rainfall data for a ten or more year basis from the nearest weather station (if possible).

10.4 Field Report

The Principal Investigator or his delegate will prepare and submit reports as required by regulations.

10.5 Record Retention

Always store the study file and notes in a secure location. Check the study file and all forms for completeness. All original raw data will be retained by the Principal Investigator after the completion of all required reports.

11. Field Study Conduct

11.1 Study Plan

This study will be conducted in accordance with this Study Plan and applicable Standard Operating Procedures (SOPs).

Document any planned change to this Study Plan prior to implementation, and document any unplanned change to the Study Plan or SOPs in the study file.

11.2 Reporting

All reporting required by the Regulatory Authority shall be completed in a timely manner. Retain copies of all Regulatory Authority and Authorized Party correspondence and reports in a file during the field study.

11.3 Destruction of Plant Material

Once the required samples are obtained, any crop residue, included in the entire Field Trial Site, including border plants, must be destroyed. [List approved methods of crop destruction].

11.4 Post Harvest Monitoring

A program for monitoring volunteer plants must be established to ensure that all volunteer plants in the subsequent growing season, a minimum of [post-harvest period] after harvest, will be appropriately eliminated. Record the post-harvest monitoring data according to SOP requirements on the forms provided.

12. Quality Control Recommendations

Quality Control (QC) oversight to ensure scientific credibility is highly recommended and may be performed by a qualified technical party for the following segments of this plan:

1. Facility and Record prior to trial establishment
2. Planting
3. Flower Bud Removal [or other critical phase, depending on the trial]
4. Sampling
5. Sample Shipment
6. Study File Data Review

A qualified technical party may perform the QC functions for technical compliance with Terms and Conditions of Authorization, Study Plan and SOP requirements. If requested, access to the Trial Site(s) must be allowed for Biosafety Inspectors and other agents of the Regulatory Authority.

13. References

[List any references cited]

PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 4: Inspector's Handbook

Procedures for Biosafety Inspection of Experiments with Genetically Engineered Crops

A Guide for Biosafety Inspectors and Trial Personnel

Mark E. Halsey, Ph.D.

February 2006

Contents

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February 2006

1. Glossary

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, or acts 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.

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 not approved for general release, in which 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)', and 'living modified organism (LMO)' are equivalent.

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

Guard 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.

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 or livestock.

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 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 from prohibited plants by a defined distance.

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.

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

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 within a confined field trial site.

2. Introduction

For the benefits of new technologies such as GM crops to be made available to the citizens of this country, these technologies must be evaluated realistically in confined field trials (CFTs). It is only through these trials that the true benefits, as well as potential drawbacks, of new agricultural technologies can be discovered, and a basis established for their general use. These trials must, however, be conducted in a way that ensures that no harm to the environment, people or animals comes about as a result.

This Manual is intended as a resource for use by Biosafety Inspectors and others designated by the Regulatory Authority to inspect or oversee confined field trials or facilities for compliance with the applicable national guidelines

Biosafety in the conduct of confined field trials is ensured by adherence to the requirements found in several types of documents:

- Standard Operating Procedures (SOPs), such as those found in Unit 3, the Trial Manager's Handbook, give specific instructions to field trial personnel for managing GM plants and plant products in the following areas:
  - Data Quality and Integrity
  - Shipment and Storage
  - Trial Conduct
  - Sampling
  - Termination
  - Post-Harvest Management
  - Reporting
  - Incidents and Contingency Planning
- This Inspector's Manual, which is a companion booklet to the Trial Managers Handbook, provides instructions for Biosafety Inspectors and other designated agents of the Regulatory Authority for inspection and oversight of confined trials.
- Terms and Conditions of Authorization for conduct of a specific trial, issued by the Regulatory Authority upon approval of a specific trial.
- The Study Plan, which contains technical instructions for the conduct of a specific trial, provided by the Authorized Party to trial personnel.
- Guidance Documents, which provide informal instructions from the Regulatory Authority on management of GM testing for Applicants and Authorized Parties.

Individuals inspecting CFTs must be familiar with all of these documents in order to fully comprehend and discharge their duties in an effective manner. It is especially critical that Inspectors have complete command of the requirements found in the Terms and Conditions of Authorization issued by the Regulatory Authority for a specific trial, and the SOPs providing guidance for trial conduct. The requirements found in these documents are the foundation for biosafety in the conduct of confined field trials, and form the basis of the inspection procedures outlined in this manual.

It is typical that an Inspector or other official will be questioned about the basis, exact meaning and interpretation of these requirements by trial personnel. Careful responses founded on outstanding knowledge are critical to building understanding and fostering self-compliance in Principle Investigators, Trial Managers and other trial personnel, and in ensuring biosafety in testing of GM plants. It should be well-noted by Inspectors and other responsible parties that the Terms and Conditions of Authorization for a particular trial are the governing document for that trial, should there be any conflict or inconsistency with other published requirements. Typically, individuals routinely inspecting GM trials will be provided with specific training in all aspects of biotechnology, biosafety and specific procedures as relevant to those trials or activities for which they have oversight responsibility.

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 and 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.

It is the responsibility of the Authorized Party to ensure compliance with the Terms and Conditions of Authorization, and this responsibility extends to the actions of employees, subcontractors and agents engaged by the Authorized Party for the purpose of conducting confined trials. Similarly, the responsibility of the Authorized Party and its employees is not limited to the fulfilment of these procedures in achieving the goals of confinement outlined above; they are required to take all reasonable steps to achieve these goals.

Biosafety is a primary goal of the Regulatory Authority, and is best served when all requirements and procedures are clearly known in advance by the responsible parties. Clear and established procedures, on-going education and oversight, and clear communication are the cornerstones of a productive working relationship between Regulators and trial personnel, serving the goals of safe and productive testing of GM crops for the benefit of this country and its citizens.

3. Objectives

The main objective of this manual is to provide instruction and guidance to Inspectors of confined field trials. Inspection and oversight for confined trials serve several purposes:

- A field trial inspection is the only certain means of assessing a trial and verifying compliance with the Terms and Conditions of Authorization and other requirements of a specific trial.
- Inspection is needed to determine if facilities used for storage of GM plant material comply with relevant requirements.
- Inspection of trial documents ensures that the requirements of data quality and integrity are met.
- The Inspector may use the opportunity to increase awareness of trial requirements with the Trial Manager and Authorized Party, thus helping to ensure continuing biosafety.
- The Inspector is available to the Trial Manager and Authorized Party to answer questions and provide clarification of any requirements.
- The process of inspection improves the knowledge and skill of the Trial Manager and Authorized Party in fulfilling the requirements of the trial. This helps foster self-compliance, and advances the goal of continued and safe testing of GM crops.

This Manual provides a basis for a logical and step-wise approach to preparing for the inspection, conducting the inspection of the field site and documentation, interviewing field personnel for pertinent information, obtaining necessary confirmation of key information, writing the inspection report, notifying the Regulatory Authority of inspection results and findings, and implementing any corrective actions that may be required resulting from the inspection.

Strict adherence to procedures and requirements for the confinement of GM plants and plant products is critical in safeguarding regulated GM material, preventing the release of the material into the general environment, and preventing any unauthorized material from being used as food or feed.

4. Preparing for Inspection

Timing of inspections is typically based on crop-growth stage, progress or status of the trial, or upon specific request from the Regulatory Authority. 'Critical Stages' at which an inspection may be targeted are: planting, prior to flowering, during flowering, at harvest, and during post-harvest monitoring. Inspection prior to flowering of the experimental GM crop is always recommended, so that isolation distances and other measures of reproductive isolation may be verified. An inspection of the Applicant's proposed facility and records may also be required as a condition of approval of a CFT application.

In addition to biosafety, the Inspector will also verify compliance with requirements found in the Study Plan provided by the Authorized Party to trial personnel. Phytosanitary inspections are also conducted when required. Authorization to conduct a CFT does not exempt the Authorized Party from phytosanitary requirements.

The Inspector must prepare him/herself in advance of any inspection—both mentally, and by obtaining the appropriate documents and equipment required to carry out the inspection. The Inspector shall assemble, and be familiar with, the following documents prior to a site inspection or visit:

- A copy of the Letter of Authorization, including the specific Terms and Conditions of the trial;
- Site location map;
- Contact details of the Trial Manager and/or Authorized Party;
- Copies of relevant SOPs being used at the site or facility;
- A copy of this manual and Inspection Checklists, a clipboard, notepaper and pens;
- A copy of the Study Plan for the trial to be inspected;
- Any additional technical information that may be needed, for example: crop growth stages, a list of pesticides approved for use in the crop, etc;
- Previous inspection reports for the site to be inspected, if available.

The Inspector typically arranges in advance a mutually agreed upon time for the visit with the Trial or Facility Manager, except where an unannounced inspection is to be done. When inspections are scheduled in advance, the Authorized Party should also be notified of the upcoming visit. The responsible IBC may be informed, if desired.

Unannounced inspections may be carried out at any time at the discretion of the Regulatory Authority, without prior notification of the Authorized Party or Trial Manager. Inspections may be carried out at any time during working hours. The Trial or Facility Manager must provide access to the trial site and storage area, and must make records available for the purpose of inspection by the Regulatory Authority's Inspectors and other designated agents.

In addition to the documents required for any site visit, certain equipment may also be helpful, depending on the circumstances:

- A GPS unit;
- A camera;
- A timepiece;
- A measuring tape or measured rope appropriate to verify isolation distances;
- Inspector's credentials (if not personally known to the Trial Manager);
- Transport to/from the site;
- Other equipment or resources at the discretion of the Inspector.

5. The Process of Inspection

A typical field site inspection is conducted in the following steps:

1. The Inspector prepares him/herself for the Inspection by becoming familiar with the biosafety requirements and technical aspects of the trial, and by arranging the visit with the Trial Manager. If the Inspector has any questions concerning the SOPs, the specific Terms and Conditions of the trial, or any technical aspects of the crop, trait or trial, these questions should be clarified before the site visit.
2. Upon arriving at the site, the Inspector conducts a brief interview with the Trial Manager, in order to be updated on trial progress and any areas of question or concern.
3. The Inspector conducts a visual examination of the site, facility or processes being inspected, and takes careful note of compliance with requirements, using the checklists or notes.
4. The Inspector reviews documents and files, noting adherence to trial requirements and standards for data quality and integrity.
5. The Inspector interviews the Trial Manager or other trial personnel, if needed, to address any questions or points of clarification. Note that steps 3, 4, and 5 may be completed in any order, and each may be repeated as needed.
6. The Inspector completes a draft of the checklists, noting any concerns or issues.
7. The Inspector conducts an exit interview with the Trial Manager, pointing out any findings or areas of concern, answering any questions, and advising the Trial Manager on follow-up steps and on any upcoming compliance requirements.
8. In the case of significant findings of non-compliance, the Inspector shall inform the Regulatory Authority immediately, preferably while still at the site. The Regulatory Authority shall determine an appropriate course of action and communicate requirements to the Trial Manager and/or any other responsible persons, as well as the Authorized Party.
9. The Inspector completes a report on the inspection and forwards it to the Regulatory Authority within three working days after returning to his/her workplace. Reports shall be submitted to the Regulatory Authority, following details found in Section 6.10.
10. All notes, checklists and submitted reports shall be maintained by the Inspector in secure storage.

Critical elements of inspection for each aspect of a typical confined field trial are detailed in the following sections, and are functionalized by the associated checklists found at the end of the Manual. Checklists are provided to support typical requirements for each aspect of compliance, and are intended to be customized to account for specific requirements of a particular trial or site.

6. Critical Aspects of Inspection

6.1 Inspection of Facility and Records at the Trial Site

Inspection of the facility and records may be required in advance of the trial as a condition of approval, or at any other time during the trial and post-harvest period. The critical aspects of the facility and records of a site where GM plant material is to be stored or tested are: adequacy and security of the facility and storage area; adequacy and training of personnel; and adequacy of the proposed trial site. Inspectors shall conduct an examination of the facility and records, taking note of specific requirements in the above areas.

6.2 Shipping of GM Plants and Plant Products

The critical aspects of compliance with procedures for shipping GM plant material are: maintaining security and control over the material; maintaining the identity of the material; and completing documentation requirements so that security, control and identity of the material may be demonstrated.

Inspectors shall conduct an examination of the facility and documents in accordance with the SOP, taking note of the following:

- Packaging and labeling;
- Shipping documentation;
- The storage area for GM material.

6.3 Conduct of Field Trials with GM Plants

The critical aspects of conduct for a field trial with GM plants are: maintaining security and control over the material in the field site; maintaining reproductive isolation of the trial site; preventing the release of propagative plant material from the trial site; and completing documentation requirements so that confinement of the material may be demonstrated.

Inspectors shall conduct an examination of the trial site and documents in accordance with the SOP, taking note of the following:

- Site security and trial establishment;
- Measures for reproductive isolation;
- Monitoring, documentation and reporting requirements.

6.4 Study Plan from the Authorized Party

The Study Plan or 'Protocol' for a confined field trial typically includes details that are not directly related to biosafety, but rather to the technical objectives and methodology of the trial. However, compliance with technical instructions is critical to obtaining valid, understandable and useful results, and is thus a legitimate concern of the Regulatory Authority and Biosafety Inspectors. Lack of compliance with the Study Plan may also be an indicator of deficiencies in other areas, due to lack of personnel, resources or knowledge.

Inspectors shall conduct an examination of the trial site and documents in accordance with the Study Plan, taking note of the following:

- Experimental design, plot layout and labeling requirements;
- Observation and sampling requirements and methodology;
- Trial maintenance and monitoring requirements;
- Any other technical requirements found in the Study Plan.

6.5 Termination of Confined Field Trial

The critical aspects of termination of a confined trial are: maintaining security and control over the material in the field site; preventing the release of propagative plant material from the trial site; appropriate measures for destruction of material in the trial site, or for storage and shipping of any material to be retained; and completing documentation requirements so that confinement of the material may be demonstrated.

Inspectors shall conduct an examination of the trial site and documents in accordance with SOPs or other requirements, taking note of the following:

- Procedures employed or to be employed in terminating the trial;

- Measures for devitalization and disposal of material from the trial;
- Documentation and reporting requirements.

6.6 Post-Harvest Management of the Trial Site

The critical aspects of post-harvest management of a confined trial are: maintaining security and control over the field site; preventing the release of plant material from the trial site into human or animal food or feed; and identifying and destroying volunteers at the trial site.

Inspectors shall conduct an examination of the trial site and documents in accordance with SOPs or other requirements, taking note of the following:

- Post-harvest restriction requirements;
- Post-harvest monitoring and documentation requirements.

6.7 Incidents Affecting the Trial

The critical aspects of effective response to any incidents involving GM plant material are: preventing the release of GM plant material into the general environment; preventing GM plant material from being consumed by humans or animals; and preventing GM material from establishing and persisting in the environment.

Inspectors typically review the documentation related to any incident, taking note of the response, follow up actions and documentation of the incident. An inspection of the site of the incident may be required by the Regulatory Authority, which will provide specific requirements for such inspection, according to the characteristics of the incident.

6.8 Data Quality and Integrity of Trial Records

Data quality and integrity standards are intended to ensure that all documentation associated with the trial is clear, authentic, and available to trial personnel. Data quality is essential to validation of both confinement measures and technical methodology used in the trial. Inspectors shall conduct an examination of the trial files and documentation, taking note of its adequacy and compliance with SOP or other requirements.

6.9 Exit Interview

An exit interview with the Trial Manager is critical to on-going education, understanding and communication. The Inspector shall review with the Trial Manager(s) any significant results or findings from the Inspection, and shall note any issues, concerns or questions raised by the trial personnel. Agreed follow up actions and responsibilities shall also be noted.

6.10 Inspection Report

The Inspector shall complete an Inspection Report, providing a brief narrative of the inspection, noting any significant findings or areas of concern on the part of the Inspector or Trial Manager, and also any agreed follow up actions, including any need for re-inspection. Attach copies of all applicable Inspection Records to the Inspection Report.

The Inspection Report shall be submitted to the Regulatory Authority within 3 working days after the Inspector has returned to his/her workplace. The report shall be submitted to the Regulatory Authority as follows:

Title:
Address:

Telephone:
Facsimile:
Email:
Website:

7. Model Forms for Typical Inspection Requirements

FACILITY AND RECORDS INSPECTION – INSPECTION RECORD			
Trial Site or Facility:			
Authorization Code Number(s), if any:	**Manager:**		
Inspector:	**Date of Inspection:**		
FACILITY			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Can the facility be secured from unauthorized access?			
Is there sufficient space and equipment for personnel to discharge duties relevant to the trial?			
Comments:			
STORAGE AREA			
Can the storage facility be secured from unauthorized access?			
Is there sufficient space in the storage facility for GM and non-GM materials to be kept separate?			
Is the storage facility adequate to protect GM material from theft, and from damage due to natural causes or animals such as rodents?			
Is there a current inventory list available for GM material in storage?			
Comments:			
PERSONNEL			
Are the number of personnel on-site/planned adequate?			
Do all Trial Managers [those authorized to sign documents for trial] have a current Training File?			
Have all Trial Managers been recently trained [within the past 1 year] on the relevant SOPs and other trial requirements?			
If no, is a date for this training planned? If planned, when: *Note: If training has not yet been carried out, a re-inspection of training documentation is required after the planned training date. This must be noted in the Inspection Report.*			
Comments:			
PROPOSED FIELD TRIAL SITE			
Is the location of the proposed field trial site established and marked?			
Is the field trial site adequately prepared at this time to commence the trial? *Note 'yes' if adequate at this time, or comment on specific deficiencies. If any deficiencies are noted, a re-inspection is required. This must be noted in the Inspection Report.*			
Fencing in place and secure?			
Provision for security guards?			
Reproductive isolation distance appears to be adequate and enforceable?			
Resources in-place or planned to carry out other measures of reproductive isolation?			
Necessary equipment available?			
Provision for disposal of material in place or planned?			
Other (describe):			
Comments:			
Inspector Signature:	**Date:**		
Manager Signature:	**Date:**		

SHIPPING & STORAGE OF PLANT MATERIAL – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
PACKAGING AND LABELLING			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Is the number of packaging layers sufficient for the material?			
Is each layer of packaging sufficient to prevent loss?			
Is each layer of packaging labeled as required?			
If the packaging has not been retained, has authorization for disposal been documented?			
How was the packaging material disposed of?			
Comments:			
SHIPMENT DOCUMENTATION			
Are all Shipping Forms adequately completed, signed and dated?			
Are copies of all shipping documents available in the trial file?			
Comments:			
STORAGE AREA			
Is the storage area restricted to authorized personnel only?			
Is the area sign-posted according to requirements?			
Are GM plant materials kept separate from non-GM materials?			
Are GM plant materials clearly identified?			
Is a current inventory list available for GM materials in the storage area?			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

CONDUCT OF CFT WITH GM PLANTS – INSPECTION RECORD

Trial Site Identification:	
Authorization Code Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

TRIAL ESTABLISHMENT

Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.	**YES**	**NO**
Are site fences and security measures sufficient to meet requirements?		
Was all GM material planted after the authorization date in the Terms and Conditions?		
Authorization Date: / Planting Date(s):		
Are provisions for training site personnel adequate?		
Are measures for cleaning equipment and personnel adequate to prevent off-site movement of GM material?		
Has excess planting material been disposed of properly or retained in secure storage?		
Do measures for identification/labelling of trial site and plots meet requirements?		
Has a Record of Planting, including a final map of the trial site prepared according to requirements, been completed and submitted to the Regulatory Authority within five (5) days after planting?		
Does the size of the trial area meet requirements (not larger than permitted)? Actual measurement:_____ m X _____ m = _____ square meters		

Comments:

REPRODUCTIVE ISOLATION

Is the Spatial Isolation Distance verified to be free of Prohibited Plants at the time of inspection?		
Has the Spatial Isolation Distance been monitored and documented according to requirements?		
Were any/all prohibited plants in the Spatial Isolation Distance identified and destroyed before flowering?		

List all other measures for reproductive isolation, procedure/equipment for enforcing the measure, and whether the provisions for enforcing the measure and in place and meet requirements:

Isolation Measure	Procedure/Equipment Required	In Place? (Y/N)

[Ensure that the Trial Manager understands specific requirements for carrying out and documenting all measures of reproductive isolation.]

Comments:

MONITORING

Has plant growth and development been monitored and documented according to requirements?		
Are target effects being monitored and documented according to requirements?		
Have any non-target effects been noted?		
If yes, have they been monitored and documented according to requirements?		

Comments:

Inspector Signature:	**Date:**
Trial Manager Signature:	**Date:**

CFT INCIDENT – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
INCIDENTS AND INFRACTIONS			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Any incidents noted?			
Note: If no incidents occurred, skip the following questions and sign below.			
If any serious incidents or compliance infractions have occurred or have been noted, have they been reported to the Regulatory Authority according to requirements?			
Have corrective actions been taken according to requirements?			
Are any required follow-up measures being carried out?			
If yes, describe:			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

CFT STUDY PLAN – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL DESIGN AND ESTABLISHMENT			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Do the plots, plot layout and experimental design on the ground agree with the site map provided?			
Do the plots, plot layout and experimental design meet the requirements of the Study Plan?			
Are the plot labels and/or identification present, clear, and meet requirements?			
Do any buffers, borders and other site details meet requirements?			
Comments:			
OBSERVATION AND SAMPLING			
Have all required observations been made according to the defined methodology?			
Has any required sampling been done according to the defined methodology?			
Has any required storage, shipping or analysis of samples been carried out according to the defined methodology?			
Have all reports required by the Authorized Party been submitted according to requirements?			
Comments:			
COMPLIANCE WITH OTHER INSTRUCTIONS *[LIST SPECIFIC INSTRUCTIONS, ACCORDING TO TRIAL]*			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

CFT TERMINATION – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TERMINATION OF THE TRIAL			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Was the Regulatory Authority notified at least five (5) days prior to termination or harvest?			
Are measures for cleaning equipment and personnel adequate to prevent the off-site movement of propagative GM plant material?			
Is any plant material to be retained?			
If yes, have the details of this activity been authorized by the Regulatory Authority?			
Is any GM material to be moved off-site for disposal or retention?			
If yes, are the measures in place for packaging, labelling and transporting adequate to meet requirements?			
Comments:			
DEVITALIZATION AND DISPOSAL			
Are the measures in place for on-site disposal adequate?			
Describe measures for on-site disposal or devitalization:			
Comments:			
RECORDS AND REPORTS			
Has a Termination Report been completed and submitted to the Regulatory Authority within ten (10) days after termination of the trial?			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

CFT POST-HARVEST – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
POST-HARVEST RESTRICTION			
Unless otherwise noted, check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
What following crop is being grown or proposed?			
Does the following crop meet requirements?			
Does the Authorized Party retain control over the trial site for the post-harvest period?			
Comments:			
POST-HARVEST MONITORING			
Is post-harvest monitoring being carried out and documented according to requirements?			
Are volunteers being destroyed and disposed of according to requirements?			
List measures for destruction and disposal of volunteers:			
Are measures for cleaning equipment used to destroy volunteers adequate?			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

CONFINED FIELD TRIAL OR FACILITY – INSPECTION REPORT	
Trial Site Identification:	
Authorization Code Number(s):	**Trial Manager:**
Inspector:	**Date of Inspection:**

CROP GROWTH STAGE OR TRIAL STATUS AT TIME OF INSPECTION

PROVIDE A BRIEF NARRATIVE OF THE INSPECTION (ATTACH ADDITIONAL PAGES IF NEEDED)

ITEMS OF CONCERN, UNANSWERED, OR REQUIRING RE-INSPECTION

Item	Re-Inspection? (Y/N)

Comments:

SIGNIFICANT CONCERNS OF TRIAL MANAGER AND/OR INSPECTOR

FOLLOW-UP ACTIONS AGREED UPON, RESPONSIBILITY, AND TARGET DATE

Follow-Up Action	Responsibility	Target Date	Re-Inspection? (Y/N)

Comments:

Inspector Signature:	Date:
Date Submitted:	

REVIEW OF TRIAL RECORDS AND EXIT INTERVIEW WITH TRIAL MANAGER – INSPECTION RECORD			
Trial Site Identification:			
Authorization Code Number(s):	**Trial Manager:**		
Inspector:	**Date of Inspection:**		
TRIAL RECORDS AND FILES			
Check Yes or No in the appropriate box, or note 'NI' = Not Inspected.		**YES**	**NO**
Are copies of SOPs, Terms and Conditions of Authorization and other relevant documents readily available to trial personnel?			
Are trial records and files organized and stored in a secure area?			
Are trial records and files readily available to trial personnel?			
Are trial records and files complete and up-to-date?			
Are record keeping/documentation standards being followed adequately?			
Have all required reports been submitted promptly?			
Are copies of all reports included in the trial files?			
Comments:			
EXIT INTERVIEW (ATTACH ADDITIONAL PAGES IF NEEDED)			
Significant comments or concerns of Inspector:			
Significant comments or concerns of Trial Manager:			
Any follow-up actions agreed upon, and responsibilities:			
Comments:			
Inspector Signature:	**Date:**		
Trial Manager Signature:	**Date:**		

PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

Integrated Confinement System for Genetically Engineered Plants

Unit 5: Resources for Regulators

Procedures and Models for Regulation of Experiments with Genetically Engineered Plants

A Guide to Evaluation, Decision, and Communication
For National Biosafety Committees and Institutional Biosafety Committees

Mark E. Halsey, Ph.D.

February 2006

Contents

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February 2006

1. Glossary

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.

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 not approved for general release, in which measures for reproductive isolation and material confinement are enforced, in order to confine the experimental plant material and genes to the trial site for a defined period of time.

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

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 (rDNA) 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 or animals.

NBC: The National Biosafety Committee, the body responsible and competent for the regulation of GMOs in this country. Usually synonymous with 'Regulatory Authority' (see).

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 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. Typically, the NBC is the Regulatory Authority for matters concerning GMOs. Alternatively, the NBC exercises the regulatory role for a higher body, in which it resides.

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.

Trial Manager: The individual(s) at a particular trial site, designated by the Authorized Party as responsible for management and compliance of an authorized confined field trial. Trial Managers are authorized to complete and sign documentation, forms and notes for the Trial file.

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 plants in a confined field trial site.

2. Introduction

This manual gives procedures, examples and models for the use of Regulators in overseeing aspects of biosafety in regard to agriculture, and especially to the testing of genetically modified plants in contained testing in glasshouses and in confined field trials. Several types of example documents are found here:

- The Internal Operating Procedures (IOPs) give detailed instructions for the functioning of the National Biosafety Committee (NBC), the Agricultural Sector Advisory Panel (ASAP) to the NBC, the Institutional Biosafety Committees (IBCs), and for adoption and publication of official documents. The format provided for functioning of the ASAP may also be applied to other Sectoral Advisory Panels, for example, the Food Safety Advisory Panel, or the Environmental Impact Advisory Panel.
- Guidance Documents are provided as models for the Regulatory Authority on matters such as Fee Schedule, development and use of Biology Documents, Standard Terms and Conditions of Authorization, and Appeals Process for regulatory decisions. These documents represent informal guidance to Applicants and Authorized Parties to assist with planning for field trials and other regulated activities, and may be changed without notice from time to time. The exact requirements for any particular regulated activity are determined by the Terms and Conditions applied to that specific activity. Specific Terms and Conditions and other official requirements supercede the provisional requirements found in the Guidance Documents. The list of Guidance Documents found here is not intended to be exhaustive, but rather to provide useful formats that may be adapted and applied to additional needs as they arise.
- Aspects of Communication for Regulators is intended as a brief introduction to 'risk communication', in order to effectively communicate with the public and other stakeholders. A listing of references for further reading is also given.
- Appendices have example documents, including: a model format for a regulatory Decision Document; a Letter of Authorization/Permit; elements of the Annual Report on Biosafety by an IBC, and a checklist for Advanced Informed Advice (AIA) requirements.

All procedures and formats here are intended to be customized by the Regulatory Authority for adoption in their country, and to be built on as additional or specific needs may arise.

The procedures and models provided are for the use of all officials engaged in regulating, overseeing or explaining agricultural biotechnology and its applications in this country. The regulatory procedures may also be of interest to Applicants, Authorized Parties and other interested stakeholders seeking to understand and to make use of the Regulatory Authority.

Experience for many years in many areas of the world has shown that experimentation with agricultural GMOs, including confined field trials, can be conducted safely, with no harm to the environment, humans or animals, by following a systematic approach. This approach is based on careful planning, establishment of clear requirements and procedures, on-going education, effective communication, and careful oversight, and is embodied in the ICS published by PBS. This system may be used to help ensure biosafety in the testing of GMOs, in order to evaluate their risks and to secure their benefits for the citizens of this country.

3. Internal Operating Procedure for the National Biosafety Committee (NBC)

3.1 Mission of the NBC

The mission of the NBC, or other duly constituted national Regulatory Authority, shall be to provide regulatory oversight and enforcement on behalf of the citizens of this country for all matters concerning biosafety in the research, development and utilization of genetically–modified organisms. The NBC has the ultimate responsibility to protect individuals, the community and the environment by working to minimize the potential hazards that may be associated with applications of rDNA technology, while facilitating the beneficial utilization of the technology for the citizens of this country.

3.2 Composition of the NBC

Consistent with the mission of the NBC, members shall represent diverse stakeholders from society, covering a wide range of concerns that may potentially be affected by biotechnology. Members shall be competent technical representatives from sectors which shall include, but are not limited to: science and technology, agriculture, human health and safety, environmental affairs, industry, trade, foreign affairs, and social concerns. Members may be drawn from universities or other institutions of learning, government ministries or agencies, private industry, or from society as a whole without reference to particular affiliation.

The NBC shall comprise no fewer than [number of] members, of which 2/3 shall constitute a quorum for purposes of taking official decisions and actions. A Chairperson shall be appointed to facilitate meetings and decision-taking by the group.

A Secretariat shall be established to handle technical and business affairs of the NBC, to assist the Chairperson, and to facilitate all NBC functions and interactions. The Secretariat shall be headed by the Secretary of the NBC ('the Secretary'), which shall be a full-time position, in order to discharge all duties and responsibilities of the Secretariat. The Secretary shall be an ex-officio member of the NBC. The requirement of ex-officio status for the Secretary shall not exclude the possibility that he/she may be selected as an official member of the NBC.

3.3 Selection and Approval of Members

Members of the NBC shall be nominated by the minister of the designated lead ministry for biotechnology. If no lead ministry is designated, then the individual responsible ministries shall nominate NBC members. Following review of the candidate's qualifications and expertise, and taking account of the requirements for diverse representation, candidates shall be chosen by the head of state (President or Prime Minister). Candidates shall become voting members of the NBC upon accepting the position and so informing the Secretary in writing.

Members of the NBC shall serve a term of [number of] years from their confirmation, and are eligible for additional terms under the process of nomination and confirmation described above.

A member of the NBC may resign at any time, upon submitting an official letter of resignation to the Secretary. Open seats shall be filled following the process described above.

3.4 Terms of Reference of the NBC

1. To evaluate Applications for experimental use of biotechnology in contained and controlled field testing, to approve or deny such Applications, and to impose such Terms and Conditions of Authorization as may be appropriate for specific trials. Aspects of evaluation for experimental use shall be:

a. The Applicant, including their resources and facilities;

b. The nature of the specific project, including the nature of the genetic construct, phenotype and species to be tested;

c. Appropriateness of proposed measures for containment or confinement;

d. Aspects of the proposed work related to national biotechnology policy.

2. To evaluate Applications for general release of products of biotechnology, including importation of food and feed commodities, to approve or deny such requests, and to impose any Terms and Conditions of Authorization as may be appropriate. Aspects of evaluation for general release shall be:

   a. The nature of the genetic construct and phenotype to be released;

   b. Characteristics of the species to be released;

   c. Evaluation of any potential hazards related to food safety or environmental risk;

   d. Assessment of previous use or experience with the product in the country or in other parts of the world;

   e. Aspects of the proposed release related to the national interest of the country and its citizens, or to national biotechnology policy.

3. To review reports of on-going research projects involving GMOs not yet approved for release, including oversight of annual reports of IBCs supervising experimental trials.

4. To oversee any required monitoring and associated reports for GMOs approved for experimental or unrestricted release.

5. To oversee and ensure that resources are adequate to fulfill regulatory requirements for biotechnology research and development, including the training, staffing and equipping of IBCs and other subsidiary regulatory bodies.

6. To maintain a database on all biotechnology research projects and approved releases in this country.

7. To liaise with government ministries and agencies as required for the regulation and development of biotechnology.

8. To notify the government and citizens of relevant advances, opportunities or issues related to biotechnology or biosafety.

3.5 Code of Conduct and Confidentiality

Members of the NBC are to be bound by rules governing their conduct as representatives of the citizens of this country. Members shall protect all information given to them in confidence in the course of their work, including Confidential Business Information (CBI). Members shall be required to execute a confidentiality agreement applying to their responsibilities with the NBC. Information supplied in confidence to members of the NBC in the discharge of their duties shall not be used for personal gain.

3.6 Reimbursement for Official Activities

Members of the NBC shall be entitled to reimbursement for reasonable expenses incurred during discharge of their official duties. Such reimbursement shall cover meals, travel, lodging and any other approved expenses.

3.7 Issuing Recommendations, Advice and Counsel

Deliberations of the NBC may be conducted in formal meetings, small groups, or in electronic collaboration depending on the circumstances. Formal meetings shall be held at least four (4) times per year.

Routine business matters, including recommendations and counsel, shall be approved by simple majority vote, where this is needed to resolve conflicts. Approvals for testing or release of GMOs shall be approved by a 2/3 majority vote. Minority opinions may be issued jointly or severally, as desired by the dissenting members.

Approvals for testing or release of GMOs, or the results of other deliberations that may be of significance to general stakeholders, shall be publicized in the form of Decision Documents appropriate to the circumstance. Decision Documents shall summarize the question, the decision and the rationale for such decision. Decision Documents shall be made available on the official website of the NBC, for access by diverse stakeholders. [An example Decision Document may be found in the Appendix.]

3.8 Change History

This form is used to highlight significant changes from previous versions when a new version is published.

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4. Internal Operating Procedure for the Agricultural Sector Advisory Panel (ASAP)

4.1 Mission of the ASAP

The mission of the ASAP shall be to provide technically proficient and scientifically sound advice, recommendations and counsel to the NBC on all matters related to plant agriculture and plant biotechnology.

4.2 Composition of the ASAP

Consistent with the mission of the ASAP, members shall be technically competent scientists knowledgeable in aspects of agriculture, plant biology, plant biotechnology and plant biosafety. Where specific technical expertise may be required to augment the existing knowledge base of the ASAP, the ASAP shall identify and consult with external resources as needed to fulfill its responsibilities.

The ASAP shall comprise no fewer than [number of] members, of which 2/3 shall constitute a quorum for purposes of issuing recommendations. The Secretary of the NBC shall be an ex-officio member of the ASAP, serving as its liaison with the NBC. The requirement of ex-officio status for the Secretary shall not exclude the possibility that he/she may be selected as an official member of the ASAP.

4.3 Selection of Members

Members of the ASAP shall be nominated by the Ministry of Agriculture or by the NBC. Nominees shall become members of the ASAP upon accepting the nomination and so informing the Secretary in writing.

Members of the ASAP shall serve a term of [number of] years from their confirmation, and are eligible for additional terms under the process of nomination and acceptance described above.

A member of the ASAP may resign at any time, upon submitting an official letter of resignation to the Secretary. Open seats shall be filled following the process of nomination and acceptance described above.

4.4 Terms of Reference of the ASAP

1. To evaluate technical aspects of Applications for experimental use of plant biotechnology in contained and confined field testing, to issue recommendations for approval or denial of such Applications at the request of the NBC, and to recommend supplemental Terms and Conditions of Authorization that may be appropriate for specific trials, if necessary. Aspects of technical evaluation for experimental use shall be:
    a. The Applicant, including their resources and facilities;
    b. The nature of the specific project;
    c. The nature of the genetic construct and phenotype to be tested;
    d. Characteristics of the plant species and effects on the plant of the genetic modification to be tested;
    e. Appropriateness and efficacy of proposed measures for confinement of the organism to be tested.
2. To evaluate technical aspects of Applications for general release of products of plant biotechnology, including importation of food and feed commodities, and to issue recommendations for approval or denial at the request of the NBC. Aspects of technical evaluation for general release shall be:
    a. The nature of the genetic construct and phenotype to be released;
    b. Characteristics of the plant species to be released;
    c. Evaluation of any potential hazards to food safety or the environment;
    d. Assessment of previous use or experience with the product the country or in other parts of the world.
    e. Evaluation of proposed risk management procedures associated with the release.
3. To provide expert advice and counsel on Reports or other documents submitted to the NBC related to plant biotechnology.
4. To identify needs and provide recommendations to the NBC or other government bodies for training, resources or infrastructure required in support of agricultural plant biotechnology or biosafety.
5. To provide any other expert advice, counsel or recommendation at the request of the NBC.

4.5 Code of Conduct and Confidentiality

Members of the ASAP are to be bound by all rules governing the conduct of members of the NBC, as described in the applicable Internal Operating Procedure and Guideline.

4.6 Reimbursement for Official Activities

Members of the ASAP shall be entitled to reimbursement for reasonable expenses incurred during discharge of their official duties. Such reimbursement shall cover meals, travel, lodging and any other approved expenses.

4.7 Issuing Recommendations, Advice and Counsel

Deliberations of the ASAP may be conducted in formal meetings, small groups, or in electronic collaboration depending on the circumstances.

Recommendations, advice and counsel shall be approved by simple majority vote, where this is needed to resolve conflicts. Minority opinions may also be issued jointly or severally, as desired by the dissenting members.

[Optional: The ASAP shall submit a yearly summary report to the Regulatory Authority, outlining the status of agricultural biotechnology in the country and in the world.]

4.8 Change History

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5. Internal Operating Procedure for Institutional Biosafety Committees (IBCs)

5.1 Mission of the IBC

The mission of the IBC shall be to provide on-going oversight and guidance for institutional scientists on all matters relating to biosafety and biotechnology in which the Institution is involved. The IBC serves as the representative body of the scientific, government or research institution with regard to the regulation and enforcement of biosafety in biotechnology research.

5.2 Composition of the IBC

Consistent with the mission of the IBC, members shall be technically competent scientists knowledgeable in aspects of agriculture, biology, biotechnology and biosafety. Members shall be selected so that they collectively have the expertise and capability to assess the safety of rDNA research, and to identify any potential risk to public health or the environment. If the Institution is to engage in rDNA research with plants, at least one member must have expertise in plant biology; an animal expert is also required if animal research is to be undertaken. At least one member should represent laboratory technical staff, and at least one member shall not be affiliated with the Institution (apart from their membership on the IBC), but shall represent the interest of the community at large (e.g., officials of governmental bodies or persons active in medical, human health or environmental protection in the local area).

A Biological Safety Officer (BSO) shall be appointed by the Institution, and is also a member of the IBC. The BSO serves as the Chairperson and functions as Secretary of the IBC. In this role, the BSO liaises with scientists and administrators of the Institution, with the NBC, and with any other relevant stakeholders.

The IBC shall comprise no fewer than five (5) members, of which three (3), or 3/5 of a larger group, shall constitute a quorum for purposes of issuing recommendations.

5.3 Selection of Members

Members of the IBC may be nominated by the various departments of the Institution, and also by the administration of the Institution. Nominees are appointed by the Institutional administration, with the advice of the BSO, if desired. Nominees shall become members of the IBC upon acceptance of their appointment in writing to the BSO.

Members of the IBC shall serve a term of three (3) years from their appointment, and are eligible for additional terms under the process described above.

A member of the IBC may resign at any time, upon submitting an official letter of resignation to the BSO. Open seats shall be filled following the process of nomination and acceptance described above.

5.4 Terms of Reference of the IBC

1. To represent the Institution in all matters of biosafety, the supervision of biotechnology research and the enforcement of all applicable rules and regulations concerning biosafety and biotechnology research.
2. To report on institutional projects, progress and developments to the NBC, including regular reporting on compliance with biosafety requirements, and any incidents or deviations from approved requirements.
3. To ensure that the Institution maintains clear, authentic and accessible records of the procedures and personnel for all biotechnology projects.
4. To ensure that Institutional facilities, personnel and procedures are adequate to carry out approved projects according to the applicable requirements of those projects.
5. To evaluate Applications for biotechnology research in contained and confined field testing, and to deny or to endorse and transmit to the NBC such Applications. Aspects of IBC evaluation for experimental use shall be:
    a. The completeness of the Application for experimental use permit;
    b. The Applicant, including their experience and expertise;
    c. The nature of the specific project, including the genetic construct, phenotype and plant species to be tested;

d. Appropriateness of proposed measures for containment or confinement;

e. The adequacy of the facilities, personnel and resources available to carry out the biosafety requirements proposed for the research.

6. To identify needs and provide recommendations to Institutional administration for training, resources or infrastructure required in support of biotechnology or biosafety.

7. To provide any other expert advice, counsel or recommendation at the request of the Institutional administration or the NBC.

5.5 Code of Conduct and Confidentiality

Members of the IBC are to be bound by all rules governing the conduct of members of the NBC, as described in applicable Internal Operating Procedures and Guidelines.

5.6 Reimbursement for Official Activities

Members of the IBC shall be entitled to reimbursement from the Institution for reasonable expenses incurred during discharge of their official duties. Such reimbursement shall cover meals, travel, lodging and any other expenses normally approved under the financial rules of the Institution.

5.7 Issuing Recommendations, Advice and Counsel

Deliberations of the IBC may be conducted in formal meetings, small groups, or in electronic collaboration depending on the circumstances.

Recommendations, advice and counsel shall be approved by simple majority vote, where this is needed to resolve conflicts. Minority opinions may also be issued jointly or severally, as desired by the dissenting members.

The IBC shall provide an official 'Annual Report on Institutional Biotechnology and Biosafety' to the NBC and Institutional administration each year during which the Institution or its members are engaged in regulated biotechnology research. This report describes in detail the progress of contained and confined testing at the Institution, and forms the basis for oversight of contained testing by the NBC. A format for the annual report is given in the Appendix. The report will be approved by the IBC and signed by the BSO. Additional reports may also be required for specific circumstances, and are described under applicable SOPs.

5.8 Change History

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6. Internal Operating Procedure for Documents

6.1 Development of SOPs and Other Documents

As indicated in the name, an SOP represents 'Standard' procedures, intended to provide useful guidance to Authorized Parties, field trial personnel and others on critical activities under a variety of conditions. It is recommended that existing documents, experienced researchers and relevant technical experts be consulted in the development of SOPs and similar documents. Resources may be identified nationally, regionally or internationally, as required.

The Secretary of the NBC, assisted by appropriate delegates of his/her choosing, typically takes a lead role in identifying needs and assembling background materials and personnel for the development and revision of documents.

6.2 Review and Approval

Published SOPs and other official documents such as the Application for Confined Field Trial represent formal guidance from the Regulatory Authority for Applicants and Authorized Parties wishing to work with GMOs in this country. As such, an appropriate review process is required in order that these documents reflect the best technical inputs and most advanced thinking on critical issues affecting the safety, appropriateness and validity of any regulated trials undertaken.

In order to achieve these goals, drafts of official guidance documents shall be reviewed and approved at three levels:

1. The Secretary conducts an informal and ongoing review of drafts under development, to ensure congruence with relevant guidelines, clarity of meaning, and fulfillment of stated objectives.
2. The relevant Sector Panel conducts a technical review. Members of the Sector Panel or the NBC may make revisions or modifications as desired, in order to achieve the best technical standards appropriate to the situation. A final draft is reviewed and approved by the NBC.
3. The Secretary publishes the approved version according to procedures described below.

The development, revision, review and approval process shall be overseen by the Secretary, who coordinates the various activities and may establish timelines for completion of the activities. Reviews and approvals may be accomplished in formal meetings, in small groups, or through electronic collaboration, as determined by the situation. Decisions shall be taken by simple majority vote, where this step may be needed to resolve any conflicts.

6.3 Revision of Existing Documents

The Secretary shall monitor suggestions and feedback on documents in use, and may initiate revision of these documents if necessary. Review, revision and approvals of existing official documents shall follow the procedures described herein.

6.4 Guidance Documents

The Regulatory Authority also publishes informal 'Guidance Documents' for the information and assistance of Applicants and Authorized Parties. As the guidance found in these documents is informal, the full development and review process outlined herein is not required. The Secretary shall review the Guidance Documents routinely, and may publish revisions or additional Guidance Documents if necessary, in consultation with the NBC.

6.5 Publication

Upon approval of a document to be published, the Secretary assigns an appropriate 'Version Number' and 'Effective Date' to the document, provides 'change protection' for the document (e.g., by converting it to pdf format), and places it on the official website of the Regulatory Authority. Previous versions shall be withdrawn from the website, unless needed for on-going activities, as described below.

Where a previous version of a document has been cited in the Terms and Conditions of Authorization of an on-going trial, that version shall remain in effect for the term of that trial as indicated in the Letter of Authorization. If a previous version of a document thus remains in use, that version shall also be maintained on the website for reference by the Authorized Party until expiration of the authorization(s) to which it applies.

The Secretary shall provide hard copies or changeable versions of documents to Applicants or Authorized Parties as needed.

6.6 Archiving

An officially approved hard copy of each version of each document shall be maintained by the Secretary in a secure location.

6.7 Change History

This form is used to highlight significant changes from previous versions when a new version is published.

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7. Guidance Documents

7.1 Introduction

Guidance Documents represent informal guidance on standards or procedures for reference by Applicants and other interested parties. The guidance in these documents is subject to change without notice, and the requirements described may be altered or superceded by official guidance issued by the Regulatory Authority, such as the Terms and Conditions of Authorization for a particular trial. Applicants and others should consult the Guidance Documents, as well as all relevant Guidelines, SOPs and other published guidance in preparation and planning for any activities involving regulated GMOs.

7.2 Fee Schedule

Application Fees for Confined Field Trials: To defray the cost of processing, review and approval of confined field trial Applications, the following fees will be assessed for each Application for a confined or contained trial. The fee indicated shall be submitted by the Applicant with each Application, and is non-refundable.

APPLICATION FEES [CURRENCY]			
	Single Site/Single Construct (Base fee)	**Each Additional Site and/or Construct**	**Maximum per Single Application**
New Applications			
Renewals			

Inspection Fees: Routine inspection by designated agents of the Regulatory Authority is a critical aspect of compliance monitoring. Fees are assessed on a cost-recovery basis for each official inspection required, and shall be submitted to the Secretary of the NBC upon his/her request from time to time during the course of the trial and post-harvest period.

INSPECTION FEES [CURRENCY]		
Daily Fee, per Inspector	**Mileage, per km from Inspector's base**	**Maximum per Single Inspection**

7.3 Biology Documents

An understanding of the reproductive biology of the unmodified host organism is critical to the design of effective methods of reproductive isolation for confined field trials. Crop Biology Documents are published from time to time by various bodies including Regulatory Authorities, and are also available from sources such as the OECD, KEPHIS and the USDA. Applicants are encouraged to use these published biology documents to complete the relevant portions of the Application, provided that local conditions are adequately addressed in the documents cited.

In cases where an adequate published document or relevant information does not exist, the Applicant may be required to prepare and submit a Crop Biology Document along with the Application. OECD format is preferred for Crop Biology Documents. An outline of this format is given below, or consult published OECD documents for further guidance.

1. Part A – Biology of the plant species
    a. General description, cultivation and use as a crop plant in this country
    b. Brief outlook at breeding, seed production and agronomic practices
    c. Reproductive biology
    d. The centers of origin and genetic diversity
    e. Tendency to weediness or invasiveness

2. Part B – Sexually compatible related species
    a. Interspecies / genus hybridization
    b. Potential for introgression of genes into related species
    c. Occurrence of related species in this country or region
    d. Summary of the ecology of related species
3. Part C – Potential interactions with other organisms
4. Part D – Recommended methods for achieving reproductive isolation

If any biology documents are required to be submitted by the Applicant, the document(s) shall be subjected to an external peer review by at least two independent reviewers, which shall include experts appointed by the Regulatory Authority.

7.4 Standard Terms and Conditions for a Confined Field Trial

Field trials are a critical step in the development of new plant varieties, including those produced with modern genetic techniques such as genetic modification (GM). Exposing plants with new traits to the natural environment in the field is essential to research, development, and characterization of new varieties for the use and benefit of farmers and society. GM plants and their genes being tested in field research situations are confined to a restricted area outdoors, which is called a 'confined field trial' (CFT).

Confined field trials are small scale research activities done in the open field. Access to the confined trial site is restricted to authorized personnel. GM plant material and genes in test are confined to the trial site by measures ensuring that the genes in pollen or seed do not escape from the trial site (reproductive isolation), that the GM material is not eaten by humans or livestock and does not persist in the environment following the trial (material confinement).

The NBC establishes specific Terms and Conditions of Authorization for each confined field trial, which include specific measures to be taken by the Authorized Party to ensure reproductive isolation and material confinement of the GM material in test. The following are Standard Terms and Conditions that are typically required for all confined field trials in this country:

1. It is the responsibility of the Authorized Party to ensure compliance with these 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 engineered plant material.
2. 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) maintaining control of the GM plant material, thus preventing it from being lost and/or consumed by humans or livestock; and 3) preventing GM plants from establishing and persisting in the environment. The Authorized Party is required to take all reasonable steps to ensure that these three goals are accomplished, including, but not limited to, compliance with all Terms and Conditions of Authorization given herein.
3. The Authorized Party shall comply with Standard Operating Procedures (SOPs) and other requirements established to ensure that the three important goals above are achieved. These procedures shall be provided to Trial Managers and personnel by the Authorized Party, and must be readily available for reference at the trial site. Trial personnel are required to read and understand the SOPs, and to be trained on their specific requirements prior to beginning the trial.
4. Trial Managers and other personnel involved in the management of the confined trial are required to provide documentation of education, training and experience appropriate to their responsibilities. This documentation shall be available for inspection and evaluation by Biosafety Inspectors or other agents of the Regulatory Authority.

5. Reproductive isolation of the trial site shall be accomplished in the following manner:
    a. Spatial Isolation Distance: _____
    b. Plants prohibited within the spatial isolation distance: _____
    c. [And/or: Other reproductive isolation methods, if required]: _____
6. To ensure that GM material is confined on the field trial site, the following additional requirements shall be imposed:
    a. The trial site shall be completely enclosed within a fence designed to exclude man and livestock that might consume the plants and thereby damage the trial.
    b. [If desired]: The trial site shall be subject to [timing and duration of] surveillance by watchmen provided by the Authorized Party, from the period of planting until destruction of the GM plant material within the trial site.
7. The authorized trial is also subject to all requirements given in the Guideline for Confined Field Trials that are not explicitly mentioned herein.
8. Supplemental Terms and Conditions may be imposed at the discretion of the NBC.

7.5 Appeals Process for Regulatory Decisions

Recognizing that all decisions have the potential for error to some degree, the Regulatory Authority hereby establishes the following procedure for the Appeal of Regulatory Decisions to the Regulatory Authority:

The Party wishing to appeal shall draft a letter outlining in detail the issue, the decision they wish to appeal, and facts supporting their appeal.

The Party submits said letter to the Secretary of the NBC, following the procedures for submitting an Application for Confined Trial, as outlined in the relevant Guideline.

The NBC shall convene for the purpose of hearing the appeal, at which time the Party making the appeal may submit further written or oral arguments.

The NBC shall issue a formal decision on the appeal, according to relevant procedures.

Appendix 1. Decision Document

A Decision Document is required for all approvals/rejections of Applications for GMO tests, and may also be used for other significant actions of the Regulatory Authority. The Decision Document describes the proposed trial, describes the process of assessment and decision, safety and other concerns raised, risk mitigation procedures addressing the concerns, Terms and Conditions and Dates of Authorization (for approvals), or reasons for rejection (for rejections). Any CBI or other confidential information should not be included in the Decision Document, which is for public communication, and is also used to comply with requirements of the Cartagena Protocol in reporting to the Biosafety Clearing House. A general format for Decision Documents follows.

NATIONAL BIOSAFETY COMMITTEE OF [COUNTRY]
COMMUNICATION OF DECISION
Internal Reference Number:
In regard to Application for: *[Applicant and brief summary of planned trial and objectives]*
The National Biosafety Committee (NBC) conducted the following assessment:
[Summary of information gathering process and deliberations. This includes the date of receipt of the Application, description of information gathering process, resource people, dates of meetings held in review of the Application, and date of final vote for approval or rejection.]
The following confinement and risk mitigation procedures are proposed in order to ensure the safe conduct of the activity:
[Summary of proposed confinement measures. These become the basis of the Terms and Conditions of Authorization.]
The following additional considerations were identified during the assessment and deliberations:
[Any other significant issues identified.]

DECISION	
The NBC, having conducted a thorough assessment, having considered the safety issues, risk mitigation options available, and other concerns identified, has [approved / rejected] the Application.	
TERMS AND CONDITIONS OF AUTHORIZATION	
The activities authorized shall be carried out in accordance with Terms and Conditions of Authorization described below.	
The following reasons are cited in rejection of the Application [if rejected]:	
[Indicate reasons for rejection, and point out any areas where changes or amendments to the Application would be grounds for reconsideration.]	
AUTHORIZATION	
The period of this Authorization shall begin on [date], and extend until [date].	
Authorization/Permit Number(s):	
Signature, Chairperson of the NBC	**Date**
Signature, Secretary of the NBC	**Date**
Original: File **Copies: Regulatory Authority website** **Biosafety Clearing House**	**For further information, contact:** *[Contact details of NBC]*

Appendix 2. Authorization Letter/Permit for Confined Field Trial

A Letter of Authorization (LOA) is issued by the Regulatory Authority for each project approved, which serves as the official permit for the project. As such, a copy of the LOA must be included in the trial documents, and be available for inspection by Biosafety Inspectors or other agents of the Regulatory Authority. The LOA lists the Terms and Conditions applicable to the trial, and is the governing document for conduct of the trial, if there is any conflict or inconsistency between the Terms and Conditions given in the LOA and any other documents, such as SOPs. LOAs must be on official letterhead of the Regulatory Authority. Essential elements of an LOA follow.

Name and contact details of the Authorized Party.

Is hereby authorized to conduct the following:

[A brief description of the project, including the crop species, phenotype of the modification, location of the trial or project, and the activities that are authorized]

Valid from *[date]* until *[date]* – Dates of Authorization.

Authorization number(s):

The *[trial or project]* shall be conducted under the following Terms and Conditions:

[List all Terms and Conditions, including any Supplemental Terms and Conditions]

Chairperson of NBC:

[Signature and Date]

For further information, contact:

Secretary of the NBC:

[Contact details]

Appendix 3. Annual Report of the IBC on Biotechnology and Biosafety

The IBC of each Institution is required to file an 'Annual Report on Biotechnology and Biosafety' on behalf of the Institution with the NBC and Institutional Management. The Annual IBC Report shall include the following elements:

1. A Roster of IBC members, indicating the role or expertise of each, and including a biographical sketch of each member;
2. An executive summary of progress in the areas of biotechnology and rDNA research at the Institution during the reporting period. The summary should point out any issues or areas of concern that may require the attention of the NBC;
3. A summary of each approved biotechnology research project in progress during the reporting period. The summary shall include the following information:
    a. Project title;
    b. Principal Investigator and other personnel associated with the project;
    c. A brief description of the project, including the objectives, scale, general methodology and physical containment level (i.e., BL1-P, etc), if applicable;
    d. The location(s) where the research is being carried out;
    e. A description of containment or confinement procedures being used to ensure biosafety for the project. Provisions for waste disposal and emergency procedures, including emergency contact information shall be included. Supplemental information, such as applicable SOPs, protocols or technical instructions, may be attached to the report as references or substantiating information. If there are any provisions for medical surveillance, these should be noted;
    f. A summary of oversight and inspection procedures employed by the IBC during the reporting period with respect to the project;
    g. A summary of any concerns or issues either occurring or foreseen with regard to the project and its continuation.
4. A summary of institutional, non-project specific, biosafety activities during the reporting period, including training, inspections and oversight;
5. A summary of any concerns or issues either occurring or foreseen with regard to the Institution and its biological research program;
6. Signatures of all members of the IBC, with dates.

Appendix 4. Checklist for Compliance with the Advanced Informed Agreement Requirements of the Cartagena Protocol

This Checklist provides references to information required under the Advanced Informed Agreement process as required by the Cartagena Protocol on Biosafety and Regulation (ED) No 1946/2003 of the European Parliament and of the Council on Transboundary Movements of Genetically Modified Organisms.

	AIA NOTIFICATION REQUIREMENT	REFERENCE TO NOTIFICATION OR ADDITIONAL INFORMATION
A	Name, address, and contact details of the exporter.	
B	Name, address, and contact details of the importer.	
C	Name and identity of the GMO, as well as the domestic classification, if any, or the biosafety level of the GMO in the State of export.	
D	Intended date(s) of the transboundary movement, if known.	
E	Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.	
F	Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.	
G	Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism(s) related to biosafety.	
H	Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the GMO.	
I	Intended use of the GMO or products thereof, namely, processed materials that are of GMO origin, containing detectable novel combinations of replicable genetic material obtained through techniques listed in Annex 1 A, Part 1 of Directive 2001/18/EC.	
J	Quantity or volume of the GMO to be transferred.	
K	A previous and existing risk assessment report consistent with Annex II of Directive 2001/18/EC.	
L	Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal, and contingency procedures, where appropriate.	
M	Regulatory status of the GMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the GMO is banned in the State of export, the reason(s) for the ban.	
N	Result and purpose of any notification by the exporter to other States regarding the GMO to be transferred.	
O	A declaration that the abovementioned information is factually correct.	

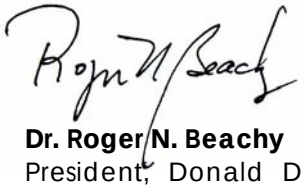
Afterword

Clear and practical regulation procedures are required for the conduct, reporting and inspection of confined field trials with genetically engineered crops, so that they may be executed with confidence and safety. Such field trials are essential for agricultural researchers and scientists to be able to assess the performance of modern technologies designed to increase nutrition or impart resistance to biotic or abiotic stresses. It is only through multiple rounds of field trials that we can determine whether or not a new technology works, is beneficial to society, and is safe for general release in actual field conditions. Field trials, therefore, are essential for adapting biotechnologies to local conditions and creating products that can benefit local farmers and consumers.

Field trials cannot, however, be conducted in countries that lack workable systems to regulate them. My institution, like virtually all institutions conducting biotechnology research worldwide, will not conduct a field trial in a country that does not have safety regulations; nor can we conduct a field trial in a country that has unworkable, overly burdensome regulations. For this reason, I am pleased to see this *Integrated Confinement System for Genetically Engineered Plants* developed by PBS. The System provides a sensible, science-based approach to regulating field trials in a way that ensures safety, while at the same time enabling research and development to move forward. Through properly prescribed measures for genetic and material confinement, field trials can be conducted in a way that minimizes risks while maximizing opportunities to realize benefits.

Those developing countries that establish workable systems to conduct safe confined field trials will attract the attention of international institutions (such as my own) that wish to build partnerships with local institutions for the testing, development, and deployment of improved planting materials. These countries will be the ones that will derive the first, and greatest, benefits from agricultural biotechnology.

The International Mission of the Donald Danforth Plant Science Center is "to use plant science to help improve agriculture, health, and nutrition in developing countries." We hope that this *Integrated Confinement System for Genetically Engineered Plants* will help developing countries to establish the safe regulatory conditions under which this mission can be achieved, in partnership with all who wish to use biotechnology to better the human condition.



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