



PROGRAM FOR BIOSAFETY SYSTEMS

A partnership program for biosafety capacity development

PBS, a program managed by the International Food Policy Research Institute (www.ifpri.org), supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS effectively addresses biosafety through an integrated program of research, capacity development, and outreach. PBS is funded by the U.S. Agency for International Development (USAID).

INTEGRATED CONFINEMENT SYSTEM FOR GENETICALLY ENGINEERED PLANTS

A COMPREHENSIVE APPROACH TO BIOSAFETY FOR CONFINED FIELD TRIALS

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A country that is setting out to explore the benefits of modern agricultural biotechnology for national development must be prepared to do so in a safe, systematic and transparent manner. The *Integrated Confinement System for Genetically Engineered Plants* provides model procedures and documents for the regulation and conduct of Confined Field Trials (CFTs) with genetically engineered (GE) plants. These models may be used by regulators and scientists in their efforts to develop a comprehensive national system ensuring biosafety, accountability and transparency in field evaluations of GE plants.

Overview of the Integrated Confinement System (ICS) Handbook

In a Confined Field Trial, researchers are able to safely evaluate GE plants in the natural environment by following simple procedures of biological confinement and good management practices. Planning for biosafety procedures in the conduct of a CFT requires a comprehensive approach that foresees all the individual steps required to perform a field trial, from initial planning through trial conduct and oversight, post-harvest management, and final reporting.

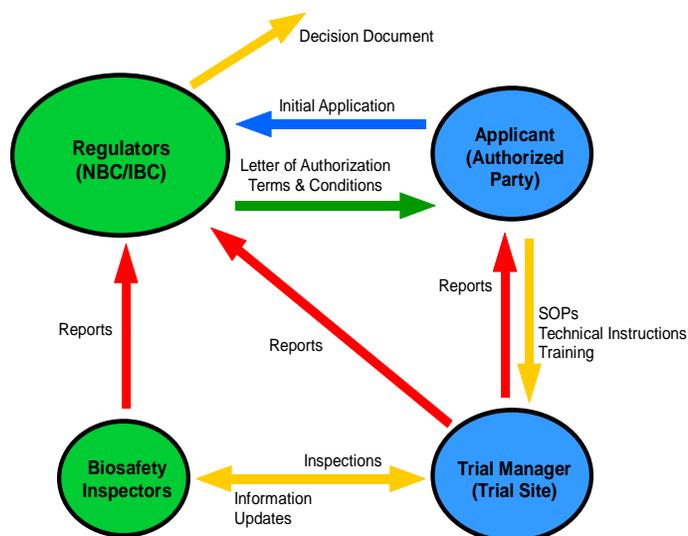
The primary purpose of the *Integrated Confinement System*, which is summarized in this policy brief, is to provide practical and user-friendly models of these procedures along with supporting documents in a single, unified resource that users may freely modify and adapt for their own specific needs. Intended users include regulators, product developers, trial managers, and biosafety inspectors. The models provided will help to ensure biosafety by allowing the reader to quickly and easily create a modern, customized “Quality Management System” for the regulation, conduct and oversight of CFTs. The practical and functional nature of the materials will help to endow users with the capacity and confidence to evaluate GE crops that may be of benefit to their countries for food security and poverty alleviation.

Unit 1: Introduction to the Integrated Confinement System

The ICS materials originated in PBS collaborations with Kenyan and Ugandan scientists working to develop biosafety systems for CFTs in those countries. Realizing the importance and need for the materials produced by these fruitful collaborations, PBS has provided the relevant documents in generic format in the ICS handbook. The approach of the ICS materials is grounded in “Good Laboratory Practices” (GLP) regulations, such as those applied by the Organisation for Economic Co-operation and Development (OECD) and the United States Environmental Protection Agency (USEPA) for laboratory and field studies. The ICS materials distil the vast experience of many experts in the execution of GLP-type field studies, in order to present a system employing the best of GLP principles in systematic, accountable and reproducible documentation for field trials.

The approval and implementation of a regulated field trial requires that regulatory bodies, research scientists and product developers communicate within their groups, with each other, and with stakeholders in an organized and sequential fashion (see **Figure 1**). The ICS materials provide practical and functional models for these interactions as applied to regulated field trials, so that the goal of biosafety in the testing and development of GE crops is achieved.

Figure 1: A Generalized Scheme of Communications during the Approval and Conduct of Regulated Trials with GE plants



Unit 2: Confined Field Trial Guideline

This Unit provides a Model Application Form for a Confined Field Trial, which is an essential first step in the regulatory pathway, as well as a critical tool for planning for biosafety measures throughout the trial. The form provides a clear and comprehensive format for capturing and presenting all critical aspects of the trial and proposed confinement measures for evaluation by the Regulatory Authority. A “Guideline” specific to CFTs is also given. This Guideline is a stand-alone document covering legal aspects and general requirements for CFTs, and may be appended to a broader Biosafety/Biotechnology Guideline.

Unit 3: Trial Manager’s Handbook

This Unit provides Standard Operating Procedures (SOPs) and model forms for the execution of a CFT. SOPs include: Data Quality and Integrity, Shipping and Storage, Trial Conduct, Sampling, Trial Termination, Post-harvest Monitoring, Incidents and Reporting. A Model Study Plan for technical aspects of the trial is included. There are many suggested formats for documentation forms and reports to capture field data; these forms are practical and user-friendly for field personnel.

Unit 4: Inspector’s Handbook

This Unit covers procedures for biosafety inspections that provide independent oversight of CFTs. Elements covered include: Preparing for an Inspection, the Process of Inspection, and Critical Aspects of Inspection at different phases of the trial (Facility and Records, Shipping, Study Conduct, Post-harvest Monitoring, etc). Suggested formats are given for the Exit Interview with the Trial Manager and the Inspection Report. Model forms for typical inspection requirements are presented in an easy-to-use ‘checklist’ format.

Unit 5: Resources for Regulators

This Unit provides models for the Regulatory Authority, including Internal Operating Procedures (IOPs) and suggested formats for regulatory documents. IOPs include those for the National and Institutional Biosafety Committees, as well as for a technical advisory panel, should one be desired. A procedure is also defined for the development and approval of documents such as SOPs and IOPs. Suggested formats for Decision Documents, Authorization Letters/Permits and Annual Reports are also given, as well as a checklist for compliance with the Advanced Informed Agreement requirements of the Cartagena Protocol on Biosafety.

Overall, the goal of PBS is to help ensure biosafety by fostering a modern, comprehensive and systems-based approach to the regulation, management and oversight of field trials with GE plants. We hope that the materials provided in the Integrated Confinement System will help to advance this goal.

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FOR MORE INFORMATION: Halsey, M. 2006. *Integrated Confinement System for Genetically Engineered Plants*. St. Louis, Missouri, USA: Donald Danforth Plant Science Center. <http://www.ifpri.org/pbs/pdf/ics.pdf>

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