Compliance management of confined field trials for biotech-derived plants









## Table of Contents

1.	EXECU	TIVE SUMMARY	. 3		
2.	INTRODUCTION TO CONFINED FIELD TRIALS				
	2.1.	Introduction	. 5		
	2.2.	Terminology	. 6		
		2.2.1. Contained Use	. 6		
		2.2.2. Confined Field Trial	. 6		
		2.2.3. Unconfined Environmental Release	. 7		
	2.3.	Purpose of Confined Field Trials	. 7		
	2.4.	Risk Management Approach to Confined Field Trials	. 8		
		2.4.1. Risk Mitigation for Confined Field Trials	. 8		
	2.5.	Conclusions	10		
3.	GLOBA	AL ADOPTION OF CONFINED FIELD TRIAL PROGRAMS	11		
	3.1.	Introduction	11		
	3.2.	Argentina	11		
	3.3.	Brazil	12		
	3.4.	Canada	13		
	3.5.	India	14		
	3.6.	Philippines	15		
	3.7.	South Africa	16		
	3.8.	Vietnam	17		
	3.9.	Conclusions	18		
4.	TRANS	PORTATION AND STORAGE OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL	19		
	4.1.	Introduction	19		
	4.2.	Training Personnel	19		
	4.3.	Transportation of Experimental Biotech-derived Plant Material	19		
		4.3.1. Disposition of Experimental Biotech-derived Plant Material	20		
		4.3.2. Records and Reports	20		
	4.4.	Storage of Experimental Biotech-derived Plant Materials	21		
		4.4.1. Disposition of Biotech-derived Plants	21		
		4.4.2. Records and Reports	21		
	4.5.	Corrective Action in the Event of an Unintended Release	22		
5.	MANA	GEMENT OF THE CONFINED TRIAL SITE	23		
	5.1.	Introduction	23		
	5.2.	Training Personnel	23		
	5.3.	Planting Confined Field Trials	23		
		5.3.1. Selecting the Irial Site	23		
		5.3.2. Marking the Irial Site	23		
		5.3.3. Mapping the Irial Site	24		
		5.3.4. Cleaning Field Equipment	25		
	5.4.	Reproductive Isolation of Confined Field Irlais	25		
	EE	5.4.1. Reproductive Biology of the Experimental Species	25		
	5.5.	5 5 1 Spatial lastation	20		
		5.5.1. Spallal Isolation	20		
		5.5.2. Temporal isolation	20 26		
		5.5.7. Removal of Howers	20 26		
		5.5.5. Tenting	20 26		
		5.5.6 Border Rows	20 27		
		5.5.7 Farly Crop Destruct	∠, 27		
	5.6	Corrective Action in the Event of an Unintended Release	27		
	5.7.	Records and Reports	<i>.</i> 27		

6.	HARVE	ST AND DISPOSITION OF MATERIALS FROM CONFINED FIELD TRIALS
	6.1.	Introduction
	6.2.	Retaining Plant Material Harvested from Confined Field Trials
	6.3.	Cleaning of Equipment
	6.4.	Early Termination of Trial Sites Prior to Seed Set
	6.5.	Disposition of Plant Material from a Trial Site
	6.6.	Transport of Harvested Materials from the Trial Site
	6.7.	Monitoring Trial Site Harvest
	6.8.	Corrective Action in the Event of an Unintended Release
	6.9.	Records and Reports
7.	MANA	GEMENT OF THE TRIAL SITE AFTER HARVEST
	7.1.	Introduction
	7.2.	Post-Harvest Restrictions
	7.3.	Monitoring the Post-Harvest Trial Site
	7.4.	Corrective Action in the Event of an Unintended Release
	7.5.	Records and Reports

#### APPENDICES

Appendix 1: Glossary of Terms	33
Appendix 2: Sample Transport SOP	37
Appendix 3: Sample Storage SOP	45
Appendix 4: Sample Confined Field Trial SOP	53
Appendix 5: Sample Harvest SOP	69
Appendix 6: Sample Post-Harvest SOP	77

#### FIGURES

Figure 1.	The regulatory framework for obtaining confined field trial approvals in Argentina $\ldots \ldots \ldots 11$
Figure 2.	The regulatory framework for obtaining confined field trial approvals in Brazil
Figure 3.	The regulatory framework for obtaining confined field trial approvals in Canada
Figure 4.	The regulatory framework for obtaining confined field trial approvals in India14
Figure 5.	The regulatory framework for obtaining confined field trial approvals in the Philippines $\ldots \ldots 15$
Figure 6.	The regulatory framework for obtaining confined field trial approvals in South Africa $\ldots \ldots 16$
Figure 7.	The proposed regulatory framework for obtaining confined field trial approvals in Vietnam $\ldots$ .17
Figure 8.	A sample shipment label
Figure 9.	An example of an identification label for the point of entry to a storage area $\ldots \ldots 21$
Figure 10.	An example of a trial site map

Compliance management of confined field trials for biotech-derived plants



### 1. Executive Summary

Since the earliest days of plant biotechnology, researchers and technology providers have focused on stewardship practices to help assure the safety and promote the responsible use of this technology. CropLife International and its members are committed to the responsible management of every product through each stage of the entire life cycle: from its inception in research, through product development, to commercialisation, to product discontinuation. The plant science industry is committed to ensuring compliance with science-based regulations worldwide and promoting responsible use of the technology.

CropLife International promotes a life cycle approach to the management of plant biotechnology products. The overall aim of this stewardship approach is to maximise the benefits and minimise any risk from using plant biotechnology products. The plant science industry is committed to promoting full and effective stewardship at the field level, and believes that the appropriate management and use of its products is an important element underpinning sustainable agriculture and optimising benefits and protecting the environment and public health.

The plant science industry also recognises that stewardship is a global issue. That is, development and production may occur in a different country or region than a product's eventual use, so appropriate tools need to be in place to ensure management of the whole cycle. While stewardship efforts must be globally harmonised, they must be locally applied and relevant to individual regions and their regulatory frameworks.

CropLife International and its network of regional

associations have established a guiding philosophy of proactive self-regulation, through which technology providers can work responsibly to protect people, animals, and the environment in order to help ensure a sustainable, healthy, abundant, and accessible food supply. The plant science industry is committed to doing its part to promote safety and trust in the world's food supply, and to support smooth trade transactions in the agricultural community.

In order to meet this commitment, the plant biotechnology industry has developed and implemented initiatives supporting product stewardship, quality management systems, and compliance with government regulations for biotechderived plants<sup>1</sup>. CropLife International and its regional member associations host training workshops around the world on a variety of stewardship topics, such as Compliance Management for Confined Field Trials, Insect Resistance Management, Integrated Weed Management, and Product Launch Stewardship of product launch and product discontinuation. In addition, CropLife International fully supports the Excellence Through Stewardship®2 industrycoordinated initiative that has been implemented to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotech-derived plant products.

Since 2005, CropLife International has coordinated Compliance Management for Confined Field Trials workshops around the world. The objective of these workshops is to help the development of a uniform approach to confined field trials and compliance with the terms and conditions of authorised confined field trials in different parts of the world.



<sup>1</sup> Biotechnology-derived plant products or plant products derived from modern biotechnology means the application of (1) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or (2) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection. This definition of modern biotechnology has been adopted by the Cartagena Biosafety Protocol under the Convention on Biological Diversity and the Codex Alimentarius Commission.

<sup>2</sup> http://www.excellencethroughstewardship.org/

#### 1. Executive Summary

Field-testing biotech-derived crops provides scientists with an opportunity to collect information on environmental interactions and agronomic performance that is critical to a full environmental safety assessment as required by regulatory authorities. In order to ensure environmental protection, this field-testing occurs under confined conditions that may include requirements for reproductive isolation, site monitoring, and postharvest land use restrictions.

Confined field trials of this type have been conducted for over 20 years. Yet even with this long history of safety, stewardship evolves and ongoing improvement to the management of these trials is key to maintaining the integrity of the regulatory system under which they are being conducted, and to maintain public confidence in the technology.

Overall, the objective of this field trial compliance document, together with training workshops, is to provide information that may be used to inform the development of a quality assurance program designed to:

 Help ensure uniform compliance with the terms and conditions of authorisation for confined field trials.

- Demonstrate responsible use and management of confined field trials.
- Demonstrate due diligence on the part of technology providers with respect to educating field trial managers and providing a paper-trail for audit and/or inspection purposes.
- Address a gap in many countries where there are no clear educational tools for regulators in this area.
- Serve to help countries with no national biosafety framework in place by (a) providing a model around which biosafety guidelines can be developed, and (b) demonstrating confidence that industry is committed to ensuring that trials are undertaken under appropriately controlled conditions (as summarised in these guidelines).

The principal activities involved in the safe management of confined field trials, as described in CropLife International's field trial compliance document, are summarised below and detailed throughout Chapters 4-7.





## 2. Introduction to confined field trials

#### 2.1. INTRODUCTION

The commercial success of plant biotechnology in Argentina, Canada, the United States, and other countries would not have been possible without having systems in place to permit the routine and safe conduct of confined experimental field trials. In order for plant biotechnology to be adopted in any country, a mechanism must exist whereby both locally developed and imported biotechnology applications can be evaluated in experimental trials for their potential usefulness and their biosafety impacts, before authorisation and introduction into local agriculture.

Even in countries that are not currently commercialising plant biotechnology products, there is a need to conduct open-field research with biotechderived plants. Moreover, contrary to popular belief, confined field trials are not always conducted solely for the purposes of product evaluation and eventual commercialisation; sometimes they are conducted only within a research context to collect agronomic and environmental data.

Within the product development pathway, confined field trials represent the first controlled introduction into the environment of biotech-derived plants. As such, they represent a distinct activity from work performed in contained facilities, such as laboratories, greenhouses, and screenhouses. At the point of confined field trials, the potential environmental risks of a particular biotech-derived plant may not be fully understood and this poses special challenges to regulatory oversight and environmental risk management.

Since the first trials were carried out in the United States in 1987, tens of thousands of confined field trials have been conducted in various countries around the world. Without exception, these trials have been conducted without a single documented case of harm to the environment, to animals or to humans. This is an impressive safety record and one that requires a commitment to good governance and responsible management that is shared between regulatory authorities and the technology developers.

The safe conduct of confined field trials can only be accomplished through the combination of a robust regulatory framework, science-based risk mitigation measures, a trained and vigilant inspection staff, and trained field personnel dedicated to abiding by the terms and conditions of trial authorisation. As evidenced by some experiences in both developing and industrialised countries, weaknesses in any of these areas become quickly apparent, usually to the detriment of public trust. Public opinion research has demonstrated that public acceptance of new technologies, including biotechnology, is largely dependent on confidence in regulatory structures and processes. Even more generally, trust in the integrity and institutional governance of regulatory bodies is essential to securing market access both at home and abroad. Likewise, the poor performance of some groups conducting confined field trials calls into question not only their own reputation, but also tarnishes the image of the entire development community and the technology.

This chapter introduces confined field trials and the role that such trials play in both the product development pipeline and the regulatory review process. The critical distinctions between field trial activities and those activities undertaken within either contained facilities or following unconfined, or commercial, environmental release are emphasised. In particular, the importance of adopting effective risk mitigation measures is stressed. In addition, this chapter discusses concepts and principles of reproductive isolation and other measures designed to mitigate adverse impacts on the environment.

#### 2.2. TERMINOLOGY

This compliance education document has adopted some specific terminology and definitions, which are described below. Additional terminology and definitions are included in a glossary in Appendix 1.

#### 2.2.1. Contained Use

Contained use refers to work with biotech-derived organisms within contained facilities, such as a laboratory, a greenhouse or a screenhouse. For contained use activities, there is a physical isolation from the environment and there is generally no introduction into the environment of viable biotechderived organisms or microorganisms. Activities carried on within contained facilities are generally performed subject to specific biosafety guidelines and under specified levels of containment. Contained use guidelines are usually formulated and enforced by an institutional biosafety committee (IBC) or, in some cases, by a national research council.

Depending on the country, guidelines for contained use of biotech-derived organisms may be promulgated as national regulations under some enabling legislation, or they may be voluntary codes of practice. Even when the guidelines are voluntary, such as those published by the National Institutes of Health (NIH) in the United States<sup>3</sup>, adherence to the guidelines is mandatory for any research conducted with government funds. As a rule, industrial scientists working within private organisations also adhere to the same or similar guidelines.

The NIH Guidelines, which have served as a working model for many countries, provide for four levels of containment, CL1 (containment level 1) through CL4, that specify increasingly stringent requirements, which are dependent on the risk category of the organism. The European Union regulates confined use of biotech-derived microorganisms under Directive 98/81/EC4 which is essentially similar to the NIH guidelines and provides for four Classes of safety. For example, work with recombinant Escherichia coli (strain K12), plant transformation vectors and biotechderived plants generally falls within CL2, the second biosafety level for contained research. Internationally, there is a high degree of standardisation between containment guidelines published in different countries and the stipulations of the different levels of containment are not significantly different.

#### 2.2.2. Confined Field Trial

The working definition that we have adopted within this compliance management document is that: "A confined field trial is a small-scale experimental field trial of a biotech-derived plant species performed under terms and conditions that mitigate impacts on the surrounding environment."

Embodied in this definition are three important considerations. Firstly, it is a small-scale activity, usually about one hectare (ha) or less. Some countries strictly regulate the size and number of confined field trials that can be conducted with a particular plant species-trait combination, while other countries do not. In addition, some countries have defined different categories of trials that are differentiated by the trial size. For the purposes of this document, they are all considered as confined field trials.

Secondly, a confined trial is an experimental activity conducted to collect data, either on agronomic performance or on potential biosafety impacts. It is usually the case that collection of such field trial data is a prerequisite to completing the environmental risk assessment. Additionally, field trials are carried out to produce sufficient plant material so that the developer can undertake research to address the information and data requirements for livestock feed and human food safety assessments.

Finally, the trial is conducted under conditions known to prevent the pollen- or seed-mediated dissemination of new genes into and within the environment, to prevent the persistence in the environment of the biotech-derived plant or its progeny, and to prevent the introduction of the biotech-derived plant or plant products into the human food or livestock feed pathways.

As it is generally used within this document, "confinement" of a field trial refers to reproductive isolation, but depending on circumstances, may also include some degree of physical isolation. On a caseby-case basis, specific methods of physical confinement may be advisable to prevent herbivory or the destruction of plant material by foraging animals, or the unauthorised harvest or removal of plant material by humans.

As a rule, most countries have a system of mandatory notification and/or environmental risk assessment before the approval of confined field trials, and have developed standards for reproductive isolation and monitoring in order to minimise any impact to the

<sup>&</sup>lt;sup>3</sup> http://oba.od.nih.gov/rdna/nih\_guidelines\_oba.html

<sup>&</sup>lt;sup>4</sup> http://www.biosafety.be/PDF/98\_81.pdf

## Compliance management of confined field trials for biotech-derived plants



environment or unintended release of plant material. Again, depending on the country, the requirements for applying for and conducting confined field trials may be embedded in regulations or they may exist as guidelines. In either case, there are provisions for an administrative process, a science advice function, and an inspectorate to verify compliance with the terms and conditions of authorisation or permitting.

#### 2.2.3. Unconfined Environmental Release

As it is used in this document, unconfined release refers to the environmental introduction of a biotechderived plant usually without the requirements for reproductive (or physical) isolation or post-harvest land use restrictions or monitoring for nearby related sexually compatible plant species. The authorisation for unconfined release is generally a government regulatory decision that is based on the outcome of a comprehensive biosafety environmental risk assessment and which may, or may not, include an assessment of non-safety issues (e.g., socio-economic factors). Depending on the regulatory framework in place, these decisions may take the form of a "deregulation", as occurs in the United States, or they may be in the form of authorisations or licenses for specific use. Approvals for unconfined release may be indeterminate or they may be time-limited, with or without requirements for post-commercialisation surveillance. Depending on the characteristics of the biotech-derived plant, there may also be requirements for insect resistance management plans or other specific post-approval risk mitigation measures, e.g. insect resistance management plans or weed resistance management plans.

In some countries, the authorisation for unconfined release is all that is required to permit commercial cultivation of the biotech-derived plant and use by farmers. However, in those countries that have systems of plant or variety registration for conventionally-bred plants, these systems will be an additional level of regulatory approval. For these countries, commercial use of the biotech-derived variety requires both biosafety approval and registration of the new variety within a national seed catalogue, or equivalent official journal.

#### 2.3. PURPOSE OF CONFINED FIELD TRIALS

Confined field trials are essential to the scientific, political and social success of any biosafety system, and are a necessary prerequisite to the unconfined (general) environmental release of biotech-derived plants. Confined field trials serve multiple purposes. For the plant breeder, they provide the first opportunity to evaluate the agronomic potential of novel plant-trait combinations in the open environment. In this regard, confined field trials serve the same purpose as conventional breeders' trials. As part of the core characterisation of a biotech-derived plant, it is necessary to measure the levels of protein expression from any newly introduced genes, both in a range of plant tissues and over the course of plant development. These measurements are generally performed on fieldgrown plants and are used to predict levels of exposure to novel dietary proteins for humans or livestock animals consuming the edible portions of the biotechderived plant or derived plant products. In addition, confined field trials permit the production of sufficient quantities of plant material for use in livestock feeding trials and to conduct compositional analyses, which are necessary for human food safety assessment.

Confined field trials are also necessary to collect the agronomic and ecological data required to complete the environmental safety assessment of the biotechderived plant. These types of studies may include: field surveys designed to assess the potential impacts on non-target, beneficial and endangered insects; evaluation of the environmental fate of novel plantexpressed proteins, particularly pest control proteins; and assessment of morphological characteristics that could signal any changes to agronomic impact.

For regulatory authorities, there is the opportunity to build public confidence in the biosafety regulatory system by demonstrating the safe conduct of confined field trials, including the monitoring and enforcement of regulatory standards. And for farmers, confined field trials provide them with an opportunity to appreciate first-hand the potential risks and benefits that may be afforded by the cultivation of these new crops.

#### 2.4. RISK MANAGEMENT APPROACH TO CONFINED FIELD TRIALS

As it is commonly expressed, risk is the product of two probability distributions – the likelihood of exposure to a hazard and the likelihood the hazard will cause serious harm. Risk assessment is often defined as a science-driven "process of obtaining quantitative or qualitative measures of risk levels, including estimates of possible health effects and other consequences as well as the degree of uncertainties in those estimates", free of the emotive factors that influence risk perception. The objective of risk assessment is to produce neutral and transparent risk information, including the identification of possible risk mitigation measures, to inform decision-making.

#### Risk = Hazard x Exposure

From a policy standpoint, it is important to distinctly separate the risk assessment and management of confined field trials from unconfined releases. At the level of an unconfined (general) release, the focus must be on rigorous risk assessment as the intent is widespread introduction of the modified plant into agriculture, usually with few or no provisions for risk mitigation. For unconfined releases, there is little or no possibility of controlling the exposure component of risk; therefore, to minimise risk both to the environment and to people and animals, regulators must be satisfied that potential hazards are not significant. Conversely, for a confined field trial, where the potential hazards may be largely unknown or at least not likely to be fully appreciated without data collected during the trial, the focus must be on minimising exposure through risk management - the terms and conditions that are necessary to permit safe trial conduct. This crucial distinction between unconfined environmental releases and confined field trials is not always sufficiently appreciated, either by regulators, national biosafety committees, or capacity builders and trainers.

The terms and conditions governing the conduct of confined field trials include specific provisions for reproductive isolation, physical security as necessary during transportation, planting, monitoring, harvesting, storage, disposition, and reporting (including archiving and access to trial records).

Together with a system of government inspection, these terms and conditions provide a system of controls that permit experimental plants to be safely evaluated on a small scale.

Generally, the activities of national biosafety committees and donor organisations have focused on risk assessment and in building the scientific knowledge capacity to carry out risk assessment. While very important, these activities have not prioritised the conditions for conducting confined field trials. In these situations, the overemphasis of exhaustive prior risk assessment can result in lengthy delays to the approval of field trials.

#### 2.4.1. Risk Mitigation Measures for Confined Field Trials

The risk mitigation measures governing the safe conduct of confined field trials comprise a threepronged approach that seeks to: (1) prevent the pollen- or seed-mediated dissemination of new genes into and within the environment; (2) prevent the persistence in the environment of the biotech-derived plant or its progeny; and (3) prevent the introduction of the biotech-derived plant or plant products into the human food or livestock feed pathways. When properly implemented, these measures help to ensure that the confined field trials do not negatively impact the environment at large, or a country's biodiversity, or animals or humans. Risk mitigation measures help ensure that the planting of confined field trials will not impact on commercial food production.

#### Preventing the Dissemination of New Genes

This is accomplished by imposing conditions of reproductive isolation on all plants within the confined trial site. Practically, reproductive isolation refers to the means used to control the movement of pollen from the confined trial site – thus minimising the introgression of new genes into neighbouring plants of the same or a sexually compatible species. In order for pollen-mediated gene flow and introgression to occur, a number of conditions must be satisfied. Under natural conditions, the two plants must be sexually compatible, fecundity must coincide, a pollen vector must be available, and the progeny plants must be fertile and able to persist in the environment.

The goal of reproductive isolation is to help ensure that biotech-derived plants under field trial do not



#### 2. Introduction to confined field trials

pollinate sexually compatible plants that are nearby, including other cultivated plantings or free-living plants of the same crop species, and any compatible wild plants of a species related to the crop. Functionally, this requires the implementation of cropspecific protocols to ensure reproductive isolation that may include one or more of the following measures, sometimes in combination: (1) removal of flowers; (2) bagging of flowers/tassels to prevent open pollination; (3) termination of the trial prior to flowering; (4) spatial and/or physical isolation from other sexually compatible plants; (5) use of border rows of conventional plants of the same variety to act as pollen traps for insect-pollinated species; or (6) temporal isolation of pollination (*i.e.*, planting earlier or later than any nearby sexually compatible plants).

The appropriate conditions for reproductive isolation are determined by the reproductive biology of the unmodified plant species. Important considerations include:

- Whether the plant is self-pollinating or cross-pollinating;
- Mechanisms for pollen dispersal (wind vs. insectvectored);
- Pollen viability;
- Presence of nearby sexually compatible relatives; and
- Cultivation practices of the crop (vegetative propagation vs. propagation through true seed).

Spatial isolation is the basic method of reproductive isolation for all plant species, and it is also the default method that will need to be invoked should other methods of reproductive isolation fail. Guidance on the appropriate distances for spatial isolation is typically based on the requirements for maintaining varietal purity taken from national seed certification regulations or from international seed certification schemes. For spatial isolation to be effective, the isolation distance must be regularly monitored for the presence of prohibited plants (*i.e.*, any plants that are sexually compatible with the biotech-derived plants within the confined field trial) and these should be removed before flowering.

In conducting the risk assessment for a confined field trial, one of the most important considerations is

whether the method of biotech improvement, or the trait introduced into the biotech-derived plant, is likely to have altered the basic reproductive biology of the unmodified plant species. If it has not, then the standard conditions known to be effective at reproductively isolating the conventional plant variety will also apply for the biotech-derived variety.

It is important that all affected parties have a good understanding of the confined field trials and what they will entail. As such, field trial managers are encouraged to communicate with neighbouring farmers about any planned trials especially if the reproductive isolation may have an impact on farm management of fields adjacent to the trials.

#### **Preventing Persistence in the Environment**

Confined field trials must be conducted in such a manner that the biotech-derived plant, or its offspring, will not persist in the environment. At the termination of the field trial, any viable plant material likely to give rise to volunteer plants in subsequent growing seasons should be managed to prevent persistence in the environment. To manage any volunteers (or progeny plants) that may arise, there should be a period of post-harvest land use restriction (*i.e.*, no planting of the same or a sexually compatible plant species), during which there is active monitoring for, and destruction of any volunteer or prohibited plants before flowering.

The period of post-harvest restriction depends on the plant species and particularly its seed dormancy characteristics. It may range from one year, as is typically the case for maize or cotton, to as long as five years for Polish canola (*Brassica rapa*). Again, from the risk assessment perspective it is important to consider whether the biotech improvement is likely to have altered any properties of seed dormancy. If it has not, then knowledge of the persistence of viable seed from the conventional variety in the soil can be used to determine the appropriate period of post-harvest restriction and monitoring.

**Preventing Introduction into the Food and Feed Pathways** Ensuring the experimental biotech-derived plant material does not enter any food or feed pathways from field trial sites is a major critical control point in the proper management of confined field trials. Environments where experimental plant material is routinely harvested for local consumption at the end of conventional trials represents the most likely scenario in which an unintended release of regulated material may happen during a confined field trial. Effective risk management to prevent animal or human consumption of regulated plant material requires:

- Controlling the movement of plant material to and from the trial site (transport and cleaning of any machinery used);
- Controlling the storage of seed and other plant material;
- Controlling the disposal of residual or excess plant material on the trial site – this could be excess planting materials, material remaining after harvest, material from roguing, detasseling or deflowering activities;
- Controlling the disposition of any material retained after harvest, such as seed that is saved for subsequent analyses; and
- Controlling unlawful harvest from the trial site.

This area of "plant material management" requires the implementation of effective and documented control processes, and a system of traceability, all of which are backed up by inspection and verification procedures.

One of the most important areas to be considered in an application for a confined field trial is the applicant's ability to satisfactorily implement an appropriate compliance management program. In this regard, the applicant's prior training and experience, coupled with the applicant's own history of successful compliance management, are significant factors that will influence the granting of a permit and approval of a field trial application.

#### 2.5. CONCLUSIONS

For confined field trials, the focus must be on the implementation of effective risk mitigation strategies rather than on exhaustive prior risk assessment. Other important messages from this chapter are that:

- Confined and unconfined activities are distinct and there should be a separate review and approval process for each;
- The questions that need to be considered for confined field trials are different than the questions for unconfined release; and
- Whether confined field trials can be performed safely and routinely.

In countries with no, or limited, experience in the design and implementation of audit, inspection, and enforcement systems in other areas, such as food safety or plant and animal health, there is limited risk management capacity. A main goal of this educational document is to provide information and tools to address the critical risk management weaknesses that, at an operational level, are limiting confined field trial approvals, and consequently the ability of developers to evaluate and farmers to access new products from agricultural biotechnology. This document will be of value to regulatory officials and inspection staff, and to developers and others engaged in the conduct of confined field trials.





## 3. Global adoption of confined field trial programs

#### 3.1. INTRODUCTION

While many countries are still in the process of implementing their field trial programs, there are countries that have successfully transitioned from field testing to commercial approvals. Brief case studies of seven countries are presented below, illustrating the variety of processes in use for the review and approval of field trial applications and different stages of development and experience with the regulation of confined field trials. All of the countries that initiated their biosafety regulatory programs more than 15 years ago have evolved during this time to successfully address confined field testing and product commercialisation. Countries initiating field trial regulation more recently are still adapting their processes to improve efficiency and to meet national needs with respect to a high level of regulatory compliance with confined field trials. The case studies identify which regulatory bodies are involved in the approval of field trials and how applications for field tests are processed.

#### 3.2. ARGENTINA

Regulatory responsibility for biotech-derived plants in Argentina rests with the Secretariat of Agriculture, Livestock, Fisheries and Food (SAGPyA). Argentina's biosafety framework was established in 1991 and is supported by regulatory resolutions, one law and some decrees (Figure 1). These were developed over 10 years and address specific aspects of regulating biotech-derived plants<sup>5</sup>. Applications for confined field trials are submitted to the National Institute of Seeds (INASE), the agency in charge of registering and controlling commercially marketed seed. They secure any applications containing confidential information and are responsible for field trial site inspections.

INASE forwards applications to the National Advisory Commission on Agricultural Biotechnology (CONABIA).<sup>6</sup> CONABIA is the multidisciplinary, interinstitutional advisory group responsible for evaluating scientific and technical issues associated with the





<sup>&</sup>lt;sup>5</sup> Resolutions: No. 289 (1997); No. 131 (1998); No. 226 (1997); No. 656 (1992); No. 837 (1993) and more; http://www.sagpya.mecon.gov.ar/new/O-0/programas/conabia/bioseguridad\_agropecuaria2.php

<sup>6</sup> http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/index.php

<sup>&</sup>lt;sup>7</sup> Adapted from Burachick, M. and P.L. Traynor. (2002). Analysis of a National Biosafety System: Regulatory Policies and Procedures in Argentina. ISNAR Country Report 63. International Service for National Agricultural Research, The Hague

potential environmental impacts of biotech-derived organisms. CONABIA has produced guidelines for carrying out confined field trials of biotech-derived crops<sup>8</sup>, reviews requests for confined trials and prepares recommendations for the Secretary of Agriculture to issue permits. CONABIA meetings are scheduled as needed and are held frequently before and during the planting season. Once a request has been reviewed, the coordination office communicates with applicants regarding the need for more information and, if any, specific trial conditions recommended by CONABIA. Once the applicant has provided any missing information and agreed to the conditions of the trial, the final decision is taken. When approved, a permit is issued by INASE on behalf of SAGPyA with any conditions regarding the conduct of the field trial appended.

#### 3.3. BRAZIL

In Brazil the biosafety regulatory framework was established by Law 11,105 of 2005 and later amended by Decree No. 5,591 of 2006 and Law 11,460 of 2007. These legal instruments establish two governing bodies for agricultural biotechnology: the National Biosafety Council (CNBS) and the National Technical Commission of Biosafety (CTNBio). The CNBS is a policy forming body and does not provide input on applications for confined field trials. The competent authority for national biosafety is the CTNBio,<sup>9</sup> which functions under the Ministry of Science and Technology. The CTNBio is responsible for all biosafety review and issues approvals for confined field trials under Normative Resolution No. 06 of November 2008,<sup>10</sup> which details the requirements for 'planned release' (CFT) of biotech-derived plants. This regulatory body is comprised of 18 to 27 members that include officials from federal ministries, technical experts and specialists representing consumer interests and small scale farming.

Any institution wishing to experiment with biotechderived plants must obtain a Certificate of Quality in Biosafety (CQB) from CTNBio and must have a functioning institutional biosafety committee (CIBio).<sup>11</sup> The CIBio approves applications for confined field trials before they are submitted by the applicant, who is the legal entity responsible for the trials. The information requirements for CFT applications are detailed in the Normative Resolution No. 06. Four paper copies and one electronic copy of the application must be submitted to CTNBio and measures are in place to protect confidential information. Requests to import biotech-derived plant material are submitted with CFT applications.

The CTNBio publishes a summary of each application in the Federal Official Gazette within 30 days of receipt of the application. A risk assessment of the planned trial is carried out on a case-by-case basis by at least two CTNBio Permanent Sub-commissions who submit their





<sup>8</sup> http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/reglamentaciones.php

<sup>9</sup> http://www.ctnbio.gov.br

<sup>10</sup> http://www.ctnbio.gov.br/index.php/content/view/12856.html

<sup>&</sup>lt;sup>11</sup> http://www.ctnbio.gov.br/index.php/content/view/143.html



#### 3. Global adoption of confined field trial programs

safety opinions to the CTNBio within 90 days. Requests to the applicant for additional information must be addressed within 90 days or the application is cancelled.

CTNBio can hold public hearings when it feels these are necessary. Applications are either approved with a decision document that is published in the Federal Official Gazette within 10 days of the decision, or dismissed with an order that explains why the request failed. A dismissal can be appealed.

#### 3.4. CANADA

The Canadian Food Inspection Agency (CFIA) regulates confined field trials through its Plant Biosafety Office (PBO)<sup>12</sup> and under Directive 2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada.<sup>13</sup> Applications are submitted to the PBO where they are reviewed internally and a decision is issued in the form of a permit with terms and conditions (T&C) under which the trial must be implemented. These T&C are case specific and provide the risk management confinement measures to be implemented to minimise any impact on the environment.

Applicants must be Canadian citizens or must designate a Canadian agent to submit the application. The information requirements for applications are detailed in Appendix 1 of the Directive.<sup>14</sup> Applicants need to indicate which food crops will be cultivated around the trial sites and any endangered species that live in the release environment. Both size and number of confined field trials are restricted and biotechderived plants developed for plant molecular farming (*i.e.*, the production of industrial and pharmaceutical compounds) have additional confinement and management conditions. Applicants may request to renew trials over several successive growing seasons where plants are perennial or trials will be repeated on the same site.

Applications for food and feed crops require 30 days for review and authorisation, while industrial and pharmaceutical crops require 60 days and may undergo additional reviews by the Pest Management Regulatory Authority (PRMA) and Health Canada, depending on the nature of the constructs used in the test plants. These reviews are co-ordinated by the PBO and do not require additional submissions. Fees are payable based on the number of field trial sites and the number of constructs being tested. There are mechanisms to deal with confidential business information and the PBO notifies provincial authorities of trials to be planted in their territory and provides for feedback from these offices prior to the final decision. A summary of field trial approvals is posted on the CFIA website and is sent to the BioTrack database of the Organisation of Economic Cooperation and Development.



#### Figure 3. The regulatory framework for obtaining confined field trial approvals for biotech-derived crops in Canada.

12 http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml

<sup>13</sup> http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml

<sup>&</sup>lt;sup>14</sup> http://www.inspection.gc.ca/english/plaveg/bio/dir/amforme.pdf

#### 3.5. INDIA

In India, research and release of biotech-derived crops is regulated under the "Rules for the manufacture, use, import, export and storage of hazardous microorganisms genetically engineered organisms or cells", 1989, notified under the Environment (Protection) Act of 1986.<sup>15</sup> These rules are implemented by the Ministry of Environment and Forests and the Department of Biotechnology, Government of India. The Act establishes seven competent authorities with direct relevance to biotechderived crop approvals:

- The Recombinant DNA Advisory Committee (RDAC) is constituted under the Department of Biotechnology (DBT) in the Ministry of Science and Technology and advises government on biotechnology in general. The RDAC drafted the Indian Recombinant DNA Safety Guidelines<sup>16</sup> in 1990.
- Institutional Biosafety Committees (IBSC) are constituted by organizations undertaking research and development activities with biotech-derived crops. Each IBSC includes a nominee of DBT as a member.
- The Review Committee on Genetic Manipulation (RCGM)<sup>17</sup> functions within the DBT. It reviews and approves research projects, recommends small scale field trials (final approval by Genetic Engineering Approval Committee), inspects facilities and issues clearance for import of

research material. The RCGM monitors research on biotech-derived crops in the laboratory, in contained environments and fields. In the case of biotechderived crops, experiments are conducted in contained greenhouses before decisions are taken to conduct field trials.

- The Genetic Engineering Approval Committee (GEAC)<sup>18</sup> functions within the Ministry of Environment and Forests and approves small and large scale field trials and commercial releases of biotech-derived crops.
- State Biotechnology Coordination Committees (SBCC) are constituted in each Indian state and headed by the Chief Secretary of State. These committees coordinate activities with the Ministry of Environment and Forests and have powers to inspect, investigate and take punitive action in the case of non-compliance with requirements pertaining to biotech-derived crops.
- District Level Committees (DLC) are constituted by the state governments to act as nodal agencies at the district level. They assess any damage due to release of biotech-derived crops and implement on-site control measures.
- The Monitoring cum Evaluation Committees (MEC) are established by the RCGM and GEAC for inspecting confined field trials.

The interaction of these authorities is shown in Figure 4.



Figure 4. The regulatory framework for obtaining confined field trial approvals for biotech crops in India (provided by BCIL).<sup>19</sup>

<sup>15</sup> http://www.envfor.nic.in/legis/env/env1.html

- <sup>16</sup> http://www.envfor.nic.in/divisions/csurv/geac/annex-5.pdf
- 17 http://dbtbiosafety.nic.in/committee/rcgm.htm
- <sup>18</sup> http://www.envfor.nic.in/divisions/csurv/geac/geac\_home.html

19 http://www.bcil.nic.in/



#### 3. Global adoption of confined field trial programs

In 2008 GEAC adopted an event-based approval system to simplify the distribution of local hybrids or varieties derived from conventional breeding with approved biotech events. They also produced guidelines on the implementation of confined field trials.<sup>20</sup> Two years ago the DBT under the Ministry of Science and Technology was given responsibility for setting up a national biotechnology regulatory authority to provide a single entry and approval point for all activities with biotech-derived organisms. Following extensive consultations, the DBT drafted the Biotechnology Regulatory Authority of India bill<sup>21</sup>, which may be presented to Parliament in 2009.

#### 3.6. PHILIPPINES

Biotech-derived crop trials and commercial approvals are regulated under Administrative Order 8 (2002)<sup>22</sup> issued by the Secretary of Agriculture. The Philippines biosafety review process (Figure 5) for biotech-derived crops is coordinated by the Bureau of Plant Industry<sup>23</sup>.

For confined field trials, the applicant must first undertake a risk assessment review with the Institutional Biosafety Committee (IBC) that functions for their organisation. The IBC includes a community representative in its membership and is responsible for any public outreach deemed necessary by the regulations. The application is submitted by the IBC to the Bureau of Plant Industry. This agency checks that the application fulfils the requirements of the regulations and guidelines<sup>24</sup> and then forwards it to the National Committee on Biosafety of the Philippines (NCBP) and the Scientific and Technical Review Panel (STRP) for a risk assessment review. The STRP considers environmental impact and food and feed safety issues. The NCBP considers the application, the risk assessment completed by the IBC, the STRP's biosafety recommendations, and public input before making its recommendation to the BPI. The BPIs decision to approve or not approve a field trial is forwarded to the applicant. Where approval is given, the BPI issues a permit and schedules inspections. Inspections are undertaken by the Bureau inspectorate and by members of the NCBP.

The regulatory approval process for confined field trials is fairly complex and involves four separate risk assessment reviews (the developer, the IBC, the STRP, and the NCBP), however, it appears to be working effectively. The amount of public information needed depends on the type of activity. First time applications for trials with a new biotech-derived organism in a new area can expect fairly extensive communication requirements which can include notification of community leaders, notices in public buildings, and public consultation meetings in the communities around field trial sites.





<sup>20</sup> http://www.envfor.nic.in/divisions/csurv/geac/biosafety.htm

- <sup>21</sup> http://dbtindia.nic.in/Draft%20NBR%20Act\_%2028may2008.pdf
- <sup>22</sup> http://biotech.da.gov.ph/Administrative\_Order.php
- 23 http://www.bpi.da.gov.ph/
- 24 http://www.ncbp.dost.gov.ph/ncbp/index.php

#### 3.7. SOUTH AFRICA

The approval process in South Africa has been operational since 1990. Initially an interim process was run through the Ministry of Agriculture's Directorate of Plant and Quality Control. This led to the development of the Genetically Modified Organism (GMO) Act (15, 1997)<sup>25</sup>, which was implemented in 1999 and amended in 2008<sup>26</sup>. Applications for all GM-related activities (registration of research facilities, contained use, greenhouse and clinical trials, field trials, general use, import and exports) are submitted to the Registrar of the GMO Act in the Ministry of Agriculture's Directorate of Biosafety. Copies of the Act, the regulations<sup>27</sup>, the guidelines<sup>28</sup> and details of permits issued are listed on the department's website<sup>29</sup>.

Applications are reviewed by an independent scientific advisory body (Figure 6). These reviewers sign confidentiality agreements before receiving the application as they have access to all confidential business information. This review sub-committee may request additional information from the applicant. The scientific advisory committee sends biosafety recommendations to the country's decision-making body, the GMO Executive Council. The Executive Council sits six times a year to review the applications and take decisions on approvals and refusals. Approvals result in the issuance of permits which detail the confinement and reporting conditions required for the activity. Refusals are issued as letters of rejection.

Applications must reach the Registrar's office by a predetermined date for each Executive Council meeting. They must be accompanied by the correct number of copies and the correct application fee.<sup>30</sup> A copy of the application with confidential business information deleted must be submitted for public access. In addition, where the regulations require public notification of an activity, *i.e.*, for field trials, the original notices from newspapers must be included. The Registrar's office commits itself to 90 days for field trial approvals and mostly keeps this timeframe. However, the clock stops when additional information is requested and this can cause decisions to take longer.

The Directorate of Biosafety uses plant quarantine inspectors to check compliance with permit





<sup>25</sup> http://www.nda.agric.za/docs/geneticresources/act15.htm

- <sup>26</sup> http://www.nda.agric.za/docs/geneticresources/amendment\_bill.pdf
- <sup>27</sup> http://www.nda.agric.za/docs/geneticresources/GMO\_R576.pdf
- <sup>28</sup> http://www.nda.agric.za/docs/geneticresources/forms\_pdf.htm; near bottom of page
- <sup>29</sup> http://www.nda.agric.za/docs/geneticresources/forms\_pdf.htm
- <sup>30</sup> Fee for 2009: R2550.00 (approx. US\$ 337.00) per application for field trial



#### 3. Global adoption of confined field trial programs

conditions. The inspectors may require prior notification of specific activities, such as harvest, to schedule inspections. These requirements are detailed in the permit.

The system functions fairly efficiently, but applicants need to be conscious of timeframes to ensure decisions are obtained in time for the planting season. First-time applications should be submitted with enough time for two sittings of the Executive Council in case a second submission is needed, or additional information is required which delays the scientific review.

#### 3.8. VIETNAM

The approval of field trial applications in Vietnam will be based on a biosafety management decree that has been drafted by the Ministry of Natural Resources and Environment (MoNRE) and was being reviewed by the Ministry of Justice in 2009. From here it will go to the government for approval. This decree will fall under the Biodiversity Law (Number 20/2008/QH12, effective on 1 July 2009).<sup>31</sup> Guidelines<sup>32</sup> for running confined field trials have been developed by the Ministry of Agriculture and Rural Development (MARD), have been subject to extensive stakeholder consultation and revision, and will be implemented once the decree is approved.

The draft regulations require that applicants submit dossiers for confined field trials and import of biotechderived plant material to MARD. The Advisory Council of GMO Biosafety Management within MARD will be responsible for appraising, reviewing, assessing and approving these applications. Public universities and institutions wishing to carry out confined field trials will need to apply to the Ministry of Science and Technology to be evaluated and verified as having sufficient capacity to undertake these activities. Approvals for confined field trials will be issued by MARD in the form of a permit and MARD will notify the MoNRE of the decisions on each application. A time frame of 60 days has been allocated for issuing import and field trial permits.

Information on the results of the field trials will be provided for public comment at the end of the trial season and the public will have 30 days to submit comments to the MoNRE.



#### Figure 7. The proposed regulatory framework for obtaining confined field trial approvals for biotech-derived crops in Vietnam.

<sup>31</sup> http://www.grain.org/brl/?docid=82017&lawid=3198

<sup>&</sup>lt;sup>32</sup> http://www.fas.usda.gov/gainfiles/200801/146293488.pdf

#### 3.9. CONCLUSIONS

The seven case studies illustrate how varied approaches are taken by governments to establish a functional regulatory system that permits the safe conduct of confined field trials. Argentina, Brazil, Canada, India, the Philippines, and South Africa have all developed their legislation, regulations and guidelines over time and benefited from experience gained in running field trials approved under interim regulations and guidelines before promulgating new laws and/or regulations. Vietnam is about to implement its regulatory process and has studied the CropLife International compliance program to help with the drafting of its confined field trial management process and guidance documents.

All of the countries have inter-ministerial, multidisciplinary decision-making bodies coordinated under one or more Ministries that draw on expertise from diverse scientific disciplines and from different agencies, academia or research organisations. All of the regulatory systems can constitute review committees with the correct expertise to evaluate specific applications. While the Philippines and South Africa may take socio-economic considerations into account when deciding to approve or reject a confined field trial application, the management practices required under permits for confined field trials are safety-based in all seven case study countries.

Since the publication in 2005 of the CropLife International handbook on Compliance Management of Confined Field Trials, at least four countries have used this format to develop their own field trial regulatory documents (Kenya, Tanzania, Uganda, and Bangladesh) and several public sector projects have used the handbook to establish best practices within their institutions. In Canada, CropLife Canada has adapted the program to reflect the Canadian regulations and the crop-specific requirements for major crops in the country. The Canadian regulatory agency officers review updates to this management program each year and highlight areas where compliance has been problematic in previous years. CropLife Canada runs annual training courses for field trial managers from the private and public sectors to improve their awareness of regulatory requirements and to highlight compliance infringement in previous seasons.

Since 2005, CropLife International has used this document for confined field trial training courses in China, Kenya, India, Mexico, the Philippines, Slovakia, South Africa, Southern Africa, and Vietnam. The document has also been used by other biosafety trainers for regional workshops in Southeast Asia, East Africa, and West Africa. The courses have been directed at both regulators and technology providers. These applications have improved consistency in field trial management and have established international standards designed to ensure a high level of regulatory compliance.



# 4. Transportation and storage of experimental biotech-derived plant material

#### 4.1. INTRODUCTION

When considering confined field trials there may be a tendency to focus on the conduct of the trial itself and to pay only peripheral attention to the manner in which experimental biotech-derived plant material is both transported and stored. This chapter provides guidance on appropriate practices that may be of value to organisations as they develop their own standard operating procedures (SOPs) for the secure transport and storage of experimental biotech-derived plants and plant material.

#### 4.2. TRAINING PERSONNEL

The authorised party should ensure that all personnel who may be involved in the shipment and/or receipt of experimental biotech-derived plant material, and those who may have access to material storage areas, are properly trained at regular intervals. This means that personnel should understand their responsibilities to ensure that: (1) this material is properly handled, packaged, labelled and stored; (2) appropriate records are kept; and (3) what actions should be taken and by whom in the event of an unintended release. Copies of relevant SOPs should be accessible to all personnel, however such access should be considered a supplement to, and in no way a replacement of, hands-on training of personnel.

#### 4.3. TRANSPORTATION OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL

It is important that appropriate permits are obtained before importing experimental biotech-derived plant material into a country. These may include phytosanitary permits and/or permits specifically for biotech-derived plants. If the country of import is a Party to the Cartagena Protocol on Biosafety, then the importing and exporting organisation should be aware of and comply with their obligations under the Protocol.

Some, but not all, countries may also have a requirement to notify federal and/or other regulatory authorities (*e.g.*, state or provincial governments) of the intra-country movement of experimental biotech-derived plant material. This may be through a simple notification procedure whereby a letter of intent is submitted to the regulatory authority, or it may be a more elaborate procedure requiring the submission of a detailed dossier for review by the regulators. Irrespective of how a government addresses the movement of experimental biotech-derived plant material within a country, it is important that both the

shipper and the recipient of such material are knowledgeable of and comply with all statutory or other requirements governing its transport. These may include provisions detailing the procedure for obtaining consent to move experimental biotechderived plants and other requirements such as the types of shipping containers that may be used, any labelling requirements for shipments, and a reporting regime. Some of this information may be provided by the regulatory authority in regulations or guidelines, while other details may only be made available to the authorised party as conditional terms and conditions affixed to a specific permit approval or authorisation.

Regardless of the plant species or type of plant material being shipped, experimental biotech-derived plants should be packaged in secure containers for transportation and should be kept separate from any other seed and/or plant material during transport. Shippers must comply with any regulatory requirements that specify the types of containers that must be used. In cases where the required packaging is not practical for the shipment of a specific experimental biotech-derived plant (e.g., whole plants in pots), the shipper may wish to contact the regulatory authority and request a variance from the packaging requirement. In this case, the shipper should provide an alternative to the mandated packaging format that would still provide an equivalent level of security. Any container or packaging format used for the transport and storage of experimental biotech-derived plant material must be capable of maintaining plant product integrity and so preventing seed or material loss.

Shipments of experimental biotech-derived plant material should be clearly labelled as such on the outside packaging. Again, in those circumstances where regulations or guidelines explicitly define what should be on a label, the shipper must ensure that this requirement is met. In those cases where there is no such guidance, it is recommended that the shipment label includes:

- 1. Permit Number for in-country movement (where applicable)
- 2. Permit Number for Import and/or Phytosanitary Certification (where applicable)
- 3. Plant species
- 4. Form of material (*e.g.* seed, budwood/shoots, transplants, tubers, whole plants)

- 5. Any seed treatment or other treatment of the material that may raise worker exposure concerns
- 6. Amount of material shipped (*e.g.* grams of seed, number of tubers)
- 7. Contact details in the event of damage and losses from the package

It may be useful to differentiate between small and large or bulk shipments of experimental biotechderived material (most commonly seed) as, from a practical standpoint, the packaging of each is likely to be different.

Small amounts of seed, or other types of plant material such as tubers, budwood or whole plants, may be shipped in a primary container such as a thick, plasticised bag (*e.g.*, 5 mil thickness) or a sealed envelope or package constructed of tear and moisture resistant material (*e.g.* bubble-padded 50 lb kraft paper, thick fibre lined 60 lb kraft paper, Tyvek<sup>™</sup> or equivalent). The primary container should then be placed in a sealed, leak-proof secondary container that may be constructed of materials such as shrink-wrap plastic, corrugated fibreboard, corrugated cardboard, wood, or other material of equivalent strength.

For larger seed shipments, the primary container could be a thick poly seed bag sealed within a sealed, leakproof secondary container such as a 55-gallon metal drum. Bulk shipments of experimental biotech-derived seed should not be transported in containers that are not secured against seed leakage, such as sloping or open wagons or wooden boxes. Holds of ships, rail cars, and transport truck containers should not be considered as primary or secondary containers.

#### 4.3.1. Disposition of Experimental Biotech-derived Plant Material

All containers used to transport experimental biotechderived seed should be cleaned prior to filling and after experimental biotech-derived plant material has been removed from them. Alternatively, containers may be destroyed after use by autoclaving, burning or deposition in a landfill depending on local allowances. Any residual plant material recovered during the process of cleaning should be rendered non-viable. Regulatory authorities may prescribe acceptable means for rendering experimental plant material nonviable and for its subsequent disposition. The shipper and recipient of experimental biotech-derived plant material should both be aware of how to effectively and securely dispose of any unwanted material. In cases where the regulator has not stipulated acceptable methods for material destruction and disposition, facility managers may wish to examine methods such as dry heat, steam heat, crushing, burning, or treatment with appropriately labelled herbicides and/or chemicals.

#### 4.3.2. Records and Reports

It is important to maintain adequate records of the transport of experimental biotech-derived plant materials as they move between research facilities, storage facilities and field trial sites. Such records may be examined by regulatory personnel to ensure that there is an adequate system in place for tracking the movement of experimental biotech-derived plants. When developing such a system where there is a chain of custody for all records, it is recommended that any related SOPs include steps to ensure that tracking the movement of experimental biotech-derived plant material is properly defined. The shipper should notify the recipient of the date, kind and amount of material that will be sent before it is shipped. Upon receiving

REGULATED PLANT MATERIAL TRANSPORT LABEL					
Shipment No. Item N	No. Unique Identifier or Event Name				
Permit No.	Plant species				
Form of Material Seed Budwood/Shoots Transplants Tubers Whole Plants					
Identify any Seed Treatment or Other Treatment of the Material					
Emergency Contact Person	Telephone				

#### Figure 8. A sample shipment label.



#### 4. Transportation and storage of experimental biotech-derived plant material

the material, the recipient should confirm that the shipment has arrived intact and that no material has been lost. The recipient should then inform the shipper that the shipment was received in satisfactory condition. An example of an SOP for transport of experimental biotech-derived plant material is provided in Appendix 2.

#### 4.4. STORAGE OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIALS

Most regulatory authorities require that experimental biotech-derived plant material be maintained in storage in such a way that there is no release into the environment. The regulatory authority may have prescriptive requirements for the storage facility manager to follow, and/or the manager should have an internal SOP to follow. The three key considerations for appropriate storage of experimental biotech-derived plant material are: segregation, security, and labelling.

Generally, a suitable storage area is one where the plant material can be stored separately from other experimental or conventional plant materials. Where appropriate, this should be a fully enclosed space (*e.g.*, filing cabinet, office, closet, cold room) with access doors that can be locked. If windows are present they should be closed and locked as well. Where a single storage area is used to store multiple samples of one or more biotech-derived events, each line, variety or event should be stored separately in a sealed, labelled container. This could be the primary container used for shipment. Labelling of storage areas should conform to any regulatory requirements. Where these do not exist, it is recommended that storage areas be clearly labelled as containing experimental biotech-derived plant materials. Labels should be posted at the point of access and it is recommended that access should be limited to authorised personnel only. An example of a storage area label is provided in Figure 9.

#### 4.4.1. Disposition of Biotech-derived Plants

Storage areas should be cleaned prior to, and immediately following, the period of storage. Any residual plant material recovered during cleaning should be rendered non-viable and disposed of by appropriate means (see 5.3.4). This also applies to any experimental biotech-derived plant material that is removed from storage for the purpose of disposition.

#### 4.4.2. Records and Reports

It is useful to maintain an inventory of all experimental biotech-derived plant material in storage, and of sub-samples that may be removed from the storage area when required for experimental or other purposes. This helps to ensure that the authorised party can track experimental materials in storage and can proactively identify if any material has been moved without permission. Similarly, it is important to ensure that storage areas are properly maintained so that unintended releases of experimental biotechderived plant materials do not occur. The storage area should be inspected at regular intervals and a record of such inspections should be maintained.

#### Figure 9. An example of an identification label for the point of entry to a storage area.

#### THIS STORAGE AREA CONTAINS EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL

Facility Name or Code: Building Name or ID: Room Number or Description:

ACCESS TO THIS STORAGE AREA IS LIMITED TO PERSONNEL DESIGNATED BY THE FACILITY MANAGER

Name of Facility Manager: Room Number: Telephone Number:

#### IN CASE OF EMERGENCY OR DAMAGE TO THE STORAGE AREA, CONTACT THE FACILITY MANAGER IMMEDIATELY

An example of an SOP for storage of experimental biotech-derived plant material that takes into account these suggestions is presented in Appendix 3.

#### 4.5. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

In the event of an unintended release into the environment of experimental biotech-derived plant material during transport or storage, the incident should be stabilised and as much of the experimental material recovered as possible. If a third-party is involved in transport or storage, the authorised party should be notified immediately of the situation. The location of an unintended release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an unintended release during transport or storage should be documented. An example of a Record of Corrective Action is provided in Appendix 2. It is usually a regulatory requirement for the authorised party to notify the regulatory authority whenever there is a reasonable basis to conclude that an unintended release has occurred. Most regulatory authorities stipulate the time frame in which such notifications must be made.

After a corrective action is taken to address a compliance infraction, the authorised party should undertake a timely review of the situation to identify its cause(s) and then institute any changes in management practices or additional training of personnel to ensure that the situation is not repeated.



## 5. Management of the confined trial site

#### 5.1. INTRODUCTION

Confined field trials of experimental biotech-derived crop plants provide public and private sector researchers with an opportunity to evaluate both the agronomic performance and the environmental suitability of these modified plants. In order to prevent the unintended release of such plants in the environment, field trials are managed according to a set of practices designed to confine the trial during the growing season and post-harvest period. These typically include methods that provide for reproductive isolation of the experimental plants, site monitoring, and restrictions on how the trial site may be used following harvest. Fundamental to the safe conduct of any confined field trial is ensuring that no plant material from the trial can be allowed to enter the human food or animal feed chains without prior consultation and approval by the appropriate regulatory authorities.

This chapter provides information about practices that can be undertaken to contribute to the safe management of field trials of experimental biotechderived plants during the growing season.

#### 5.2. TRAINING PERSONNEL

The authorised party should ensure that all personnel who may have access to or may work on the trial site during the current season, harvest and the post harvest period (see Chapter 7) are properly trained. This means that personnel should understand their responsibilities for ensuring that the trial remains confined, appropriate records are kept, and what actions should be taken and by whom in the event of damage to the trial site or an unintended release. The training should be consistent with the activities that each staff member may undertake. For example, compliance-related training of a graduate student responsible for in-field monitoring may be different from that provided to a person responsible for weeding the trial. Copies of relevant SOPs should be accessible to all personnel, however such access should be considered a supplement to, and in no way a replacement for hands-on training of field staff.

#### 5.3. PLANTING CONFINED FIELD TRIALS

#### 5.3.1. Selecting the Trial Site

Numerous considerations need be taken into account when selecting a trial site location for the purposes of conducting field trials of biotech-derived crop plants. First, trial managers should be aware of the ecosystems in proximity to the trial site in order to make a knowledgeable assessment of environmental safety issues. Second, the ability to maintain reproductive isolation should be examined when selecting a trial site. For example, the location and size dimensions of the trial site should be manageable so as to permit continual site monitoring. Third, longterm considerations should be addressed such as the implications of post-harvest restrictions on land-use. Fourth, the potential impacts on neighbouring thirdparties in the event of an unintended release should also be considered.

#### 5.3.2. Marking the Trial Site

23

Once selected, it is advisable to mark the four corners of each trial site with semi-permanent markers (*e.g.*, metal, PVC or fibreglass posts) suitable to permit identification of the trial site during the growing season and the period of post-harvest land use restriction. Alternatively, distances from the four corners of the trial site to permanent markers may be recorded. Permanent markers include landmarks such as telephone or power poles, fences, alleys, or roads. If possible, global positioning system (GPS) coordinates provide an excellent means of accurately recording the four corners of each trial site.

#### 5.3.3. Mapping the Trial Site

Maps of trial sites are very useful to those tasked with monitoring trial sites during the current season and post-harvest periods. Additionally, regulatory authorities may also require accurate maps to facilitate site inspections. Ideally, it is best to prepare maps of trial sites as soon as the trial site has been selected. In fact, some regulatory authorities require maps of trial sites as part of the application procedure as the site itself is subject to approval in addition to the material to be planted. Maps prepared in advance of planting should be reviewed at planting to ensure that the information on the preliminary map remains accurate.

Maps should be drawn to scale and provide details on the layout of the site and distances between the field trial and surrounding features. Where regulatory authorities have not stipulated the details to be included on a trial map, the following items may be considered as a guide for map preparation:

- 1. Trial manager's name and contact details.
- 2. The reference code for a trial site or trial(s) within a trial site, if applicable.
- 3. Trial permit number.
- 4. Legal or descriptive land location.
- 5. Exact trial site dimensions.
- 6. Total area planted with the experimental biotechderived plant material, including guard rows (square metres or hectares).
- Accurate distances to permanent markers or surrounding landmarks such as telephone poles, fences, alleys, or roads, and/or GPS coordinates if available.
- 8. Label all fields within the isolation distance by the common name of the crop.
- Indicate closest fields of the same species as the experimental biotech-derived plants up to one km from the trial site, where reasonable.
- Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, forests, and woodlots, conservation areas, preserves or other protected habitats).
- 11. Planting date.
- 12. Compass directions, with North at the top of the page.

#### Figure 10. An example of a trial site map.







 Permanent markers (need latitude and longitude data for each permanent marker)

Trial Site: 80m x 56m

Trial Manager: Mr Tom Jones Telephone: (014) 727-6396

Total area planted to confined trials: 2095m<sup>2</sup> Crop Species: Zea mays (maize) Planting Date: May 24, 2002 Permit No: 2004/104/6 Legal land description: "Sterkstroom" Marble Hill Limpopo



#### 5. Management of the confined trial site

#### 5.3.4. Cleaning Field Equipment

Equipment used to seed or plant confined field trials should be cleaned free of plant material based on visual inspection before entering the trial site, including seed and vegetative material that may be present from prior operations. Similarly, all equipment used to seed or plant the trial or that is used in trial maintenance should be cleaned on the trial site to eliminate the unintended transport and release of experimental material. Methods of cleaning may be stipulated in regulatory guidelines or in permit conditions and may include hand-cleaning, compressed air and high-pressure water.

It is also important that personnel working within the trial site ensure that the clothes and footwear they are wearing are also cleaned free of seed, pollen or other plant material before exiting the site.

Residual plant material recovered during the process of cleaning field equipment at the trial site should be rendered non-viable. Regulatory authorities may prescribe acceptable means for rendering plant material from the trial site non-viable and for its subsequent disposition. The trial manager and any staff working at the trial site should be made aware of how to effectively and securely dispose of any unwanted material. In cases where the regulator has not stipulated acceptable methods for material destruction and disposition, trial managers may wish to examine methods such as dry heat, steam heat, crushing, burning, or treatment with appropriately labelled herbicides and/or chemicals. Although it may be permissible to move material off the trial site so that it can be destroyed elsewhere (*e.g.*, an autoclave in a laboratory facility) it is recommended that material is disposed of on the trial site to limit the possibility of an unintended release by transporting it elsewhere.

## 5.4. REPRODUCTIVE ISOLATION OF CONFINED FIELD TRIALS

#### 5.4.1. Reproductive Biology of the Experimental Species

In order to establish the most effective means for achieving the reproductive isolation of a confined field trial, it is necessary to be familiar with the biology of the plant species and more specifically, with its reproductive biology. Useful information can be obtained from plant breeders, from experienced breeder seed producers, and from crop specialists. Most commonly, however, the regulatory authority will stipulate what it considers to be acceptable methods for maintaining reproductive isolation of the trial site. These may be provided in regulations or guidelines, or may be stipulated in the permit conditions.

In situations where the applicant requires information about the biology of the host species, they may wish to examine biology documents or species monographs. Detailed consensus documents describing the biology of 24 crop and tree species have been prepared by the OECD<sup>33</sup>. These include documents for: Oryza sativa (rice), Triticum aestivum (wheat), Solanum tuberosum (potato), Brassica napus (Argentine rape), Zea mays (maize), Beta vulgaris (sugar beet) and Glycine max (soybean). These biology documents can be used both as credible sources of information about the species reviewed, and as templates for the preparation of new monographs. It is important, however, to note that much of the value of biology documents lies in the country-specific information provided about the plant species. Consensus documents like those published by the OECD must be supplemented to reflect regional or national conditions. National regulatory authorities should be consulted as they may have biology documents available for reference.

<sup>&</sup>lt;sup>33</sup> http://www.oecd.org/document/51/0,2340,en\_2649\_34387\_1889395\_1\_1\_1\_1,00.html

#### 5.5. METHODS OF REPRODUCTIVE ISOLATION OF CONFINED FIELD TRIALS

Each confined trial site should be confined by one contiguous method of reproductive isolation. Some of the more commonly used methods are described below. The utility of any of these methods is cropspecific and careful consideration should be given to the method used.

#### 5.5.1. Spatial Isolation

Field trials of experimental biotech-derived plants may be reproductively isolated from other plants of the same species or from sexually compatible relatives by a minimum isolation distance. In many countries, the isolation distance used for confined field trials is the same as that for breeder seed production. It is essential that the authorised party and trial manager know what isolation distance is acceptable to the regulatory authority for any one crop species before planting the field trial so that adequate land can be set aside. The isolation distance must be kept free from any other plants of the same or related species. The regulatory authority may stipulate the prohibited species or it may be up to the authorised party to be aware of what, if any, sexually compatible relatives are known to be present in the area surrounding the field trial. Any plants of the same or related species found in the isolation distance should be removed before anthesis or seed set (depending on the requirements of the regulatory authority) and rendered non-viable (see 5.3.4). If the experimental biotech-derived plant is allowed to set seed in the isolation distance, a breach of reproductive isolation will have occurred and the isolation distance will typically be subject to postharvest restrictions. For this reason it is advisable that trial managers ensure they will be able to maintain control over the isolation distance during the postharvest period.

#### 5.5.2. Temporal Isolation

Under some environmental conditions, reproductive isolation of trial sites may be achieved by temporal isolation. This requires staggering the planting of the field trial so that pollen shed is completed in its entirety before or after pollen shed by any plants of the same species that may be cultivated within the reproductive isolation distance. Temporal isolation must be used cautiously and in many environments is not recommended because of the inherent variability in growing conditions that makes accurate prediction of the time to anthesis impossible. In order for temporal isolation to be effective, a regular system of monitoring must be undertaken to ensure that anthesis of experimental event(s) is not concurrent with anthesis of adjacent non-trial plants of the same species. If anthesis of the trial and non-trial plants is concurrent, a breach of reproductive isolation will have occurred.

Where temporal isolation has been breached and pollen shed by the experimental biotech-derived plant has occurred, the authorised party should be notified immediately to evaluate if confinement can be re-established by spatial isolation.

#### 5.5.3. Removal of Flowers

Field trials may be reproductively isolated from plants of the same or sexually compatible species grown within the isolation distance by removing the flowers from the experimental plants prior to pollen shed. As with temporal isolation, timely removal of flowers requires a rigorous monitoring program to be in place to ensure that all inflorescences are removed before anthesis. If the flowers of the experimental plant are allowed to shed pollen before they are removed, a breach of reproductive isolation will have occurred.

Where experimental plants are not deflowered prior to anthesis, the authorised party should be notified immediately to evaluate if confinement can be re-established by spatial isolation.

#### 5.5.4. Bagging

Field trials of crop species such as maize or cereal crops may be reproductively isolated from related species grown within the isolation site by placing bags sufficient to prevent any pollen release over the inflorescences of all the trial plants prior to anthesis. The inflorescences must remain bagged until anther desiccation is complete. If the inflorescences of the trial plants are allowed to shed pollen before they are bagged, a breach of reproductive isolation will have occurred.

Where the inflorescences of experimental plants are not bagged prior to anthesis, the authorised party should be notified immediately to evaluate if confinement can be re-established by spatial isolation.

#### 5.5.5. Tenting

Field trials may be reproductively isolated from related species grown within the isolation site by placing the test plants in pollen tents where the screening material is of a mesh size sufficient to prevent pollen release. The tents should be placed over the trial



#### 5. Management of the confined trial site

plants prior to anthesis. The plants must remain bagged until anther desiccation is complete. If the inflorescences of the trial plants are allowed to shed pollen before they are tented, a breach of reproductive isolation will have occurred.

Where experimental plants are not secured in tents prior to anthesis, the authorised party should be notified immediately to evaluate if confinement can be re-established by spatial isolation.

#### 5.5.6. Border Rows

Field trials of some crop species such as cotton or oilseed rape may be reproductively isolated from the same or related species growing within the isolation distance by planting an uninterrupted, perimeter border row of the conventional plant species. The width of the border row is species-specific and the authorised party and trial manager should consult with regulatory authorities to determine if border rows are acceptable for a specific species and, if so, how wide they should be planted. Typically the conventional variety used to plant the border row should be: (1) a variety that will mature concurrently with the biotechderived event(s); (2) planted at a density comparable to the trial plants; and (3) managed using standard agronomic practices. Field trial managers should monitor emergence of border rows closely and replant promptly if the stand is inadequate. In order for border rows to be effective, a regular system of frequent monitoring must be undertaken to confirm that anthesis of both the experimental and border row plants is concurrent.

Border rows raise specific management challenges such as the movement of field equipment through the rows, and remediation if flowering of the border variety is asynchronous with the trial plants. Additionally, if the experimental plant is expressing a herbicide tolerance trait that is not shared by the border row variety, great care must be taken to ensure that the herbicide-susceptible border row is not affected when the herbicide is applied to the trial plants.

If the border row is not maintained as above and reproductive isolation is breached, the authorised party should be notified immediately to evaluate if confinement can be re-established.

#### 5.5.7. Early Crop Destruct

Field trials can be reproductively isolated from the same or related species growing within the isolation distance by terminating the trial before anthesis. If the inflorescences of the trial plants are allowed to shed pollen before the trial is terminated, a breach of reproductive isolation will have occurred.

Where crop destruction is not completed prior to anthesis, the authorised party should be notified immediately to evaluate if confinement can be re-established by spatial isolation.

#### 5.6. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

In the event of an unintended release into the environment of experimental biotech-derived plant material during a confined field trial, the incident should be stabilised and as much of the experimental material recovered as possible. If a third-party is involved in the management of the field trial, the authorised party should be notified immediately of the situation. The location of an unintended release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an unintended release during the field trial should be documented. An example of a Record of Corrective Action is provided in Appendix 4. It is usually a regulatory requirement for the authorised party to notify the regulatory authority whenever there is a reasonable basis to conclude that an unintended release has occurred. Most regulatory authorities stipulate the time frame in which such notifications must be made.

After a corrective action is taken to address a compliance infraction, the authorised party should undertake a timely review of the situation to identify its cause(s) and then institute any changes in management practices or additional training of personnel to ensure that the situation is not repeated.

#### 5.7. RECORDS AND REPORTS

Trial managers must be committed to keeping core documents for trial site planting and management complete, up-to-date, and well organised to ensure that records can be easily retrieved. The complete

#### 5. Management of the confined trial site

audit trail of documentation may be requested at any time by internal or third party auditors, or regulatory authorities and so should be available for review. The content and quality of these materials may be used to judge whether the trial has met all the regulatory requirements, or may help to demonstrate due diligence should a question or problem arise during the performance of the trial, or during an audit of the compliance management program.

A regular monitoring program should be initiated at the time of planting and continue until harvest to ensure that the trial remains confined during the growing season. This will provide for early detection of any problems pertaining to reproductive isolation, and will allow prompt corrective action to be taken to address potential situations of non-compliance. Additionally, when reproductive isolation is achieved by temporal isolation, inflorescence removal or border rows, more frequent inspection of the trial and any plants of the same species in adjacent fields should be undertaken from the time the inflorescence emerges until the termination of flowering of the trial plants. Monitoring the trial site also provides an opportunity for observation and data collection as regards the experimental biotech-derived plants. This is of particular importance for researchers who may wish to move a product forward for commercialisation as monitoring for effects such as impact on non-target organisms, pest and disease susceptibility or altered behaviour (*e.g.*, enhanced dormancy, excessive morbidity) is needed to support an environmental risk assessment.

Any compliance-related problems encountered during the field season, whether technical or administrative in nature, should be reviewed annually. By doing so, trial managers can continually improve their in-house compliance management program to incorporate new activities based on experiences gained each year.

An example of an SOP for managing confined field trials is provided in Appendix 4.



### 6. Harvest and disposition of materials from confined field trials

#### 6.1. INTRODUCTION

The harvest of confined field trials of experimental biotech-derived crop plants needs to be carefully managed. Trials should be harvested in such a way as to prevent the unintended release of the biotechderived events and their persistence at the trial site. As with the trial itself, no plant material from the trial can be allowed to enter the human food or animal feed chains without prior consultation and approval by the appropriate regulatory authorities. This chapter provides information about practices that can be undertaken to contribute to the proper harvest of confined field trials.

#### 6.2. RETAINING PLANT MATERIAL HARVESTED FROM CONFINED FIELD TRIALS

It is quite common for the authorised party to want to keep plant material from the trial site. It may be that seed is needed for future trials or that plant tissues are required for subsequent laboratory analyses. Irrespective of the reason, the authorised party and any agents acting on their behalf must be aware of regulatory requirements that may address retention of plant material from the confined trial. Typically, the authorised party must have permission from the regulatory authority to keep harvested seed and/or plant tissues and in some cases will seek this permission in their application for field trial approval. In some jurisdictions an inspector representing the regulatory authority may have to be present at the harvest of the trial and confirm the amount and destination of any plant materials that are to be maintained.

#### 6.3. CLEANING OF EQUIPMENT

Equipment used to harvest confined field trials should be cleaned free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations. Similarly, all equipment used to harvest the trial should be cleaned on the trial site to eliminate the unintended transport and release of experimental biotech-derived plant material. Methods of cleaning may be stipulated in regulatory guidelines or in permit conditions and may include hand-cleaning, compressed air and highpressure water.

Residual plant material recovered during the process of cleaning field equipment at the trial site should be rendered non-viable. Regulatory authorities may prescribe acceptable means for rendering plant material from the trial site non-viable and for its subsequent disposition. The trial manager and any staff working at the trial site should be made aware of how to effectively and securely dispose of any unwanted material. In cases where the regulator has not stipulated acceptable methods for material destruction and disposition, trial managers may wish to examine methods such as dry heat, steam heat, crushing, burning, deep burial or treatment with appropriately labelled herbicides and/or chemicals.

## 6.4. EARLY TERMINATION OF TRIAL SITES PRIOR TO SEED SET

In some circumstances, for example because of unfavourable environmental conditions (*e.g.*, hail, drought, and hurricane) or because of compliancerelated considerations, a trial may have to be terminated before the planned harvest date. Trials that are to be terminated early should be destroyed before seed set and subsequently ploughed under or treated with appropriately labelled herbicides to render the plant material non-viable. Post-harvest restrictions (see Chapter 7) may apply immediately upon trial termination. For some species, seed of the experimental event may remain from planting and germinate to produce volunteers in subsequent years.

#### 6.5. DISPOSITION OF PLANT MATERIAL FROM A TRIAL SITE

Plant material from a trial site that is not retained for research purposes, such as unwanted grain, roots, stalks and leaves should be rendered non-viable by a means acceptable to the regulatory authority. In cases where the regulator has not stipulated acceptable methods for material destruction and disposition, trial managers may wish to examine methods such as burning, deep burial or treatment with appropriately labelled herbicides and/or chemicals. This applies to the trial plants and any border rows used for reproductive isolation. Where material may be removed from the trial site to a facility for subsequent analysis, storage or immediate disposition (e.g., incineration, autoclaving), care should be taken to ensure that the material is contained and transported appropriately.

#### 6.6. TRANSPORT OF HARVESTED MATERIALS FROM THE TRIAL SITE

All plant material harvested and transported from a trial site should be secured during transport from the trial site to the receiving facility to prevent any unintended release. For more information about the appropriate transport of experimental biotech-derived plant material, see Chapter 4.

#### 6.7. MONITORING TRIAL SITE HARVEST

The trial manager or his/her designate should monitor harvest to ensure that:

- 1. Material that is to be retained is not inadvertently mixed with other plant material during harvest;
- 2. Material to be removed from the trial site is properly labelled before transport;
- 3. All other plant material is rendered non-viable and disposed of on the trial site; and
- 4. Harvest equipment is cleaned free of all experimental biotech-derived plant material before leaving the trial site.

#### 6.8. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

In the event of an unintended release into the environment of experimental biotech-derived plant material during harvest of confined field trials, the incident should be stabilised and as much of the experimental material recovered as possible. If a thirdparty is involved in harvest, the authorised party should be notified immediately of the situation. The location of an unintended release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an unintended release during harvest should be documented. An example of a Record of Corrective Action is provided in Appendix 5. It is usually a regulatory requirement for the authorised party to notify the regulatory authority whenever there is a reasonable basis to conclude that an unintended release has occurred. Most regulatory authorities stipulate the time frame in which such notifications must be made.

After a corrective action is taken to address a compliance infraction, the authorised party should undertake a timely review of the situation to identify its cause(s) and then institute any changes in management practices or additional training of personnel to ensure that the situation is not repeated.

#### 6.9. RECORDS AND REPORTS

All activities related to harvest or early termination of a trial site should be recorded immediately following completion and retained by the trial manager. An example of an SOP for the harvest of confined field trials is provided in Appendix 5.



## 7. Management of the trial site after harvest

#### 7.1. INTRODUCTION

Regulatory authorities generally place restrictions on how land planted with confined field trials can be used in the year(s) following trial harvest. These restrictive, post-harvest measures are designed to ensure that any volunteers emerging after trial harvest are eliminated from the trial site, to prevent the establishment of the experimental biotech-derived event and to ensure that no experimental biotechderived plant material is allowed to enter the human food or animal feed chains without prior consultation with the appropriate regulatory authorities. This chapter provides information about practices that can be undertaken to contribute to the safe management of confined field trial sites after harvest.

#### 7.2. POST-HARVEST RESTRICTIONS

Confined field trial sites are usually subject to a period of post-harvest land use restriction for a period of one or more years depending on the crop species. The post-harvest period begins immediately after harvest or termination of the trial.

During the post-harvest period, all prohibited plants, which include volunteers of the experimental biotechderived events and any sexually compatible relatives, should be removed from the trial site before anthesis. These plants should be rendered non-viable and disposed of by a means acceptable to the regulatory authority. A common method is to rogue out prohibited plants and then burn or bury them on the trial site. Monitoring for and disposition of prohibited plants also applies to the isolation distance around the trial site if reproductive isolation was breached during the trial.

If volunteer plants from the trial (or other related species) are permitted to complete anthesis during the post-harvest period the regulatory authority may require an additional term of post-harvest land use restriction. Pollen shed by the volunteer may lead to persistence of the experimental biotech-derived event through production of hybrid progeny when plants of the same or related species are present in the area surrounding the trial site.

The trial site should not be used for subsequent cultivation of the same or related species to the experimental biotech-derived event as to do so will make monitoring and removal of volunteers difficult. This also applies to the isolation distance when it is included in post-harvest restrictions (*i.e.*, where a

breach of reproductive isolation occurred during the current season). However, some regulatory authorities may permit exceptions to this standard practice:

- The trial site may be planted with the same experimental biotech-derived event or another experimental biotech-derived event of the same plant species. The trial site will be subject to the same regulations and/or permit conditions as the previous confined field trial (unless additional conditions are added by the regulatory authority). Post-harvest restrictions are then applied after harvest of the subsequent confined field trial(s).
- The trial site may be planted with a conventional variety of the same plant species as the experimental biotech-derived event. The trial site will be subject to the same regulations and/or permit conditions as the previous confined field trial (unless additional conditions are added by the regulatory authority). All of the conventional plant material harvested from the trial site during the period of post-harvest restrictions will have to be handled in the same way as the experimental biotech-derived plant material because of the potential of adventitious presence of the experimental material (effective volunteer monitoring would not be possible). Post-harvest restrictions are then applied after harvest of the subsequent confined field trial(s).

#### 7.3. MONITORING THE POST-HARVEST TRIAL SITE

Monitoring of the trial site (and isolation distance when required) during the post-harvest period should be initiated as soon as the trial is harvested or terminated and must continue for the mandated period during that period of time when conditions are favourable for volunteer germination and growth. The trial manager or his/her designate should frequently monitor the post-harvest trial site to ensure that no prohibited plants are present on the trial site.

#### 7.4. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

In the event of an unintended release into the environment of experimental biotech-derived plant material during management of the trial site after harvest, the incident should be stabilised and as much of the experimental material recovered as possible. If a third-party is involved in the management of the field site after harvest, the authorised party should be notified immediately of the situation. The location of an unintended release should be marked and managed to ensure that no additional release of material occurs. Any corrective actions taken to address an unintended release during the management of the trial site after harvest should be documented. An example of a Record of Corrective Action is provided in Appendix 6. It is usually a regulatory requirement for the authorised party to notify the regulatory authority whenever there is a reasonable basis to conclude that an unintended release has occurred. Most regulatory authorities stipulate the time frame in which such notifications must be made. After a corrective action is taken to address a compliance infraction, the authorised party should undertake a timely review of the situation to identify its cause(s) and then institute any changes in management practices or additional training of personnel to ensure that the situation is not repeated.

#### 7.5. RECORDS AND REPORTS

All activities related to post-harvest monitoring of a trial site should be recorded and retained by the trial manager. An example of an SOP for the harvest of confined field trials is provided in Appendix 6.



## Appendix 1: Glossary of Terms

**Agricultural biotechnology:** A range of tools, including traditional breeding techniques, which improve domesticated plants, animals, or microbes to enhance their traits with regard to ease of efficiency of production or their end use qualities and characteristics. Modern biotechnology today includes recombinant DNA techniques.

Anthesis: The time of flowering or pollination. Anthesis is complete when flowering or pollination is complete.

**Applicant:** A permanent resident of [country] or designated agent to whom all correspondence with respect to the application for a confined field trial including the notification of authorisation shall be addressed.

**Authorisation:** An approval, clearance, or other grant of authority that comes from a responsible governmental entity and covers a particular article, product, or activity. This may include authorisation for transboundary transport of plant material, conduct confined field trials, and release biotech-derived plants for the purpose of cultivation.

**Authorised Party:** The addressee on the notification of authorisation who shall accept full responsibility for compliance with all terms and conditions of authorisation.

**Biotech-derived** (also known as genetically engineered): The genetic modification of organisms by recombinant-DNA techniques.

**Biotechnology:** The application of a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

**Confinement:** The control of viable seed or vegetative propagating material planted in the field in a manner that mitigates the spread of pollen or other propagative plant parts out of the confined field trial area.

**Construct:** An engineered chimeric DNA fragment designed to be transferred into a cell or tissue; may be synonymous with vector fragment or vector. Typically, the construct comprises the gene or genes of interest, a marker gene, and appropriate control sequence as a single package.

**Containment:** The control of viable seed or vegetative propagating material in a manner that mitigates their release outside of their controlled development in the laboratory, greenhouse, seed-conditioning or -storage facility.

**Containment facility:** Any facility designed to limit access by unauthorised personnel as well as egress of controlled plant material.

**Disposition:** The act or means of devitalization and disposal of plant material.

**Documentation:** Recorded information such as specifications, quality manuals, quality plans, records, and procedure documents.

Early termination: Termination of a trial before the anticipated completion date or before the onset of flowering.

**Event:** A genotype produced from the transformation of a plant species using a specific genetic construct. For example, two lines of the same plant species that are transformed with the same or different constructs constitute two events.

**Facility:** Sites that are contiguous, under common control by a company or individual, and have a grouping of equipment or individuals engaged in a common process.

**Facility manager:** For the purpose of the SOPs included in this manual, shall be the Authorised Party or the person designated by the Authorised Party as responsible for the storage (before or at planting, during planting, and after harvest) of the experimental biotech-derived plant material.

Field trial: The planting of one or more biotech-derived plants in a single experiment.

**Gene:** The fundamental physical and functional unit of heredity. A gene is typically a sequence of DNA that encodes a specific functional product (such as a protein or RNA molecule).

**Germplasm:** An individual, group of individuals, or a clone representing a genotype, variety, species, or culture, held in an *in situ* or *ex situ* collection.

Host material: The untransformed plant or the genotype that was used to create the biotech-derived event.

**Introgression:** The common phenomenon in which genes move from one population to another, usually via pollen carried by wind, or animal pollinators such as birds or insects.

Line: A group of individuals derived by descent from a single individual within a species.

**Permanent markers or landmark:** Physical signs or markers used to identify or designate boundaries of a confined field trial (*e.g.*, telephone poles, fences, alleys, roads, or steel poles).

**Plant material:** Propagatable material (*e.g.*, seed, transplants, tubers, rhizomes, shoots, budwood, whole plant), and non-propagatable material (*e.g.*, leaves, non-viable material).

**Plant product integrity:** Specific to this manual, plant product integrity (PPI) is the specific identity of a plant and purity of populations of the plant that are established and maintained using appropriate measures.

Primary container: The container into which biotech-derived plant material is placed.

**Product discontinuation:** Removal from the market, by the technology owner, of authorised commercial biotechderived products that have reached the end of their commercial life cycle.

Product launch: The introduction of an authorised biotech-derived plant product into commerce.

Product withdrawal: Recovery of product from the supply chain and/or commerce.

**Prohibited plants:** These include all volunteers of the same species as planted in the confined field trial, and sexually compatible related plant species.

Propagatable: Any plant or plant part that can be used in the field to regenerate a whole plant.

**Quality management:** A component of stewardship, which comprises the processes and systems to establish and maintain quality in each phase of the product life cycle.

**Recipient:** For the purpose of this SOP shall be the Authorised Party, Trial Manager or Facility Manager, who receives regulated biotech-derived plant material.

Recombinant DNA: The DNA formed by combining segments of DNA from different sources.

**Regulatory authority:** The authority charged with the responsibility of regulating importation and environmental introduction of any biotech-derived plant.

Roguing: The uprooting or destruction of unwanted plants from fields or meadows.

Sanitised: Determined to be free of all plant material based on visual inspection.

Secondary container: The container into which a primary container is placed.

**Shipper:** The Authorised Party or the person identified by the Authorised Party as being responsible for ensuring the appropriate transport of biotech-derived plant material.


#### Appendix 1: Glossary of Terms

Standard Operating Procedure (SOP): An established, written method or set of methods that describes how to routinely perform a given task.

**Stewardship:** Product stewardship is the responsible management of a product from its inception through to its ultimate end and discontinuation. In agricultural biotechnology, stewardship includes careful attention to the safety of products, and their market impact.

Trait: A genetically determined characteristic.

**Transformation:** The process of incorporating DNA into an organism's genome. There are several methods to do this in plants. The most commonly used methods for plant transformation are Agrobacterium-mediated transformation and biolistic transformation.

**Trial Manager:** The person designated by the Authorised Party as responsible for the activities of the confined field trial/trials.

**Trial site:** The area where one or more field trials of one or more experimental biotech-derived plant events may be grown.

**Trial site location:** The geographic location of a trial site as identified by an address, legal and location, or GPS coordinates.

**Unintended release:** Any unauthorised release of experimental biotech-derived plant material into the environment, including into the human food and/or livestock feed chains.

**Variety:** Subdivision of a species for taxonomic classification. Used interchangeably with the term cultivar to denote a uniform, stable group of individuals that is genetically and possibly morphologically distinct from other groups of individuals in the species.

**Vector:** A small self-replicating DNA molecule (plasmid, virus, bacteriophage, or artificial DNA molecule) that can be used to deliver DNA into a cell.

**Volunteers:** Plants of the same species as the experimental biotech-derived plant that may germinate and grow in the trial site and/or isolation distance.



### Appendix 2: Sample transport SOP

# STANDARD OPERATING PROCEDURE (SOP) FOR THE TRANSPORT OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL WITHIN [COUNTRY]

Note: This Standard Operating Procedure (SOP) is intended solely as an example that may be used as an educational resource by organisations that are developing or revising their own quality management programs for confined field trials of experimental biotech-derived plants. This example should not be used as a substitute for the user's own understanding and compliance with regulations governing the conduct of such trials.

#### A. DESCRIPTION OF THE ACTIVITY

A.1. To ensure compliance with requirements for transport of experimental biotech-derived plant materials in [country].

#### B. SCOPE

B.1. This SOP applies to experimental biotech-derived plant material imported into [country] and experimental biotech-derived plant material transported: to, from or between contained facilities; to, from or between confined field trial sites and contained facilities; and experimental biotech-derived plant material destined for export.

#### C. SOP AUTHORISATION

Name of Authorised Party: Title: Signature: Date: Implementation Date: In Effect Until:

#### D. TERMINOLOGY

Possible terms that could be relevant in this SOP. For specific definition, see Appendix 1.

- D.1. Applicant
- D.2. Authorised Party
- D.3. Biotech-derived
- D.4. Biotech-derived event
- D.5. Biotech-derived plant material
- D.5. Event
- D.7. Facility manager
- D.8. Plant material
- D.9. Primary container
- D.10. Propagatable
- D.11. Recipient
- D.12. Regulatory authority
- D.13. Sanitised
- D.14. Secondary container
- D.15. Shipper
- D.16. Trial Manager
- D.17. Unintended release

#### E. GENERAL REQUIREMENTS FOR THE TRANSPORT OF ALL BIOTECH-DERIVED PLANT MATERIAL

- E.1. The Authorised Party and all other agents acting on behalf of the Authorised Party shall comply with this SOP.
- E.2. All biotech-derived plant material shall be stored in secure containers for transportation.
- E.3. All biotech-derived plant material shall be kept separate (secured in a primary container) from other plant material during transport.

- E.4. All biotech-derived plant material shall be clearly labelled.
- E.5. The Authorised Party shall ensure that appropriate containers are supplied to all agents working on their behalf for the purpose of transporting the biotech-derived plant material.

#### F. SPECIFIC REQUIREMENTS FOR THE TRANSPORT OF BIOTECH-DERIVED PLANT MATERIAL

- F.1. The requirements in this section apply to biotech-derived plant material, imported into [country] and biotech-derived plant material transported: to, from or between contained facilities; to, from or between confined field trial sites and contained facilities; and biotech-derived plant material destined for export from [country].
- F.2. The requirements of this section also apply to non-biotech-derived plant or approved biotech-derived plant material that will accompany biotech-derived plant material when transported within the same secondary container.
- F.3. Biotech-derived plant material shall be secured within a primary container as described in F.5.
- F.4. Each sealed, primary container shall contain only biotech-derived plant material of a single type (*e.g.*, seed, tubers, leaf material, budwood/shoots) derived from one line of a single event.
- F.5. The primary container shall be a bag of no less than 5 mil thickness or a sealed envelope or package constructed of tear and moisture resistant material (*e.g.* seed envelopes, polythene bags, sealed box).
- F.6. The primary container shall be placed within a sealed, leak-proof secondary container. Multiple primary containers of biotech-derived plant material of multiple events may be placed within a single secondary container.
- F.7. The secondary container shall be resistant to breakage and water damage and shall be constructed of materials such as corrugated fibreboard, corrugated cardboard, wood, or other material of equivalent resilience.
- F.8. Primary and secondary containers used to transport biotech-derived plant material shall be sanitised prior to filling and after the plant material has been removed, if intended to be re-used. Alternatively, containers may be destroyed by autoclaving or burning.
- F.9. Any residual biotech-derived plant material recovered during the process of sanitisation shall be destroyed by dry heat, steam heat, incineration, crushing, or treatment with appropriately labelled herbicides and/or chemicals and disposed of at an approved land fill site.
- F.10. Primary and secondary containers shall be labelled in accordance with the requirements of Section G.
- F.11. The shipper shall notify the recipient of an impending shipment prior to shipment as outlined in I.2.3

#### G. LABELLING OF CONTAINERS FOR THE TRANSPORT OF BIOTECH-DERIVED PLANT MATERIAL

- G.1. Primary containers shall be labelled with a user identification number (*e.g.*, event name or number or other unique identifier), the type of biotech-derived plant material contained within, and the Shipment Number found on the Record of Transport.
- G.2. The original Record of Transport shall be placed within the secondary container.
- G.3. All secondary containers used to transport biotech-derived plant material shall be labelled with a Transport Label securely affixed to the outside. The Transport Label shall identify the shipper and receiver, emergency contact details, and that the container contains biotech-derived plant material.

#### H. TRANSPORT OF LIVING MODIFIED ORGANISMS (LMOS) TO PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

- H.1. It is the Authorised Party's responsibility to be cognisant of and ensure that all obligations under the Cartagena Protocol on Biosafety<sup>34</sup> that may be triggered by the import of LMOs<sup>35</sup> for use in confined field trials will be met before the material is shipped. This includes ensuring the appropriate application of the Advance Informed Agreement procedure (Articles 7-10, 12, 13).
- H.2. Shipments of LMOs that will be exported for planting in confined field trials in the Party of import must be accompanied by documentation that clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and

<sup>34</sup> http://www.biodiv.org/biosafety/protocol.asp

<sup>&</sup>lt;sup>35</sup> "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Article 3.g.). "Modern biotechnology" means the application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Article 3.i.)



#### Appendix 2: Sample transport SOP

address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter (Article 18.2.c).

#### I. ACCOMPANYING DOCUMENTATION FOR THE TRANSPORT OF BIOTECH-DERIVED PLANT MATERIAL

- I.1. Where primary containers of biotech-derived plant material of multiple events may be included within a single secondary container, a Transport Inventory List shall be affixed to the Record of Transport.
- I.2. The following documents shall be signed, dated and secured to/within the secondary container by the Shipper:
- I.2.1. The original Record of Transport, with attached Transport Inventory List where applicable, shall be placed in the secondary container.
- I.2.2. The Transport Label shall be affixed to the outside of the secondary container.
- 1.2.3. The original Record of Transport, with attached Transport Inventory List where applicable, shall be faxed to the Receiver before being placed within the secondary container.
- 1.3. Copies of all accompanying documents (including Plant Import Permit, Phytosanitary Certificate where applicable) shall be retained by the Shipper.

#### J. RECEIPT OF TRANSPORTED GOODS

- J.1. When a shipment of biotech-derived plant material is received, the following actions shall be immediately undertaken by the Recipient:
- J.1.1. Verification that the Record of Transport listed in paragraph I.2.1 accompanied the shipment and was duly signed by the Shipper.
- J.1.2. If the original Record of Transport, and Transport Inventory List where applicable, listed in paragraph I.2.1 are absent from the shipment, the Recipient shall contact the Shipper and request copies be transmitted immediately.
- J.1.3. Until such time as the original Record of Transport documents are received and the inventory confirmed, materials shall be placed into secure storage and no further action shall be taken with the materials.
- J.2. The Recipient shall complete the Receipt of Shipment section of the original Record of Transport, including the confirmation that the containers used for transport were not breached.
- J.3. If the secondary container was breached the Recipient shall ensure that the primary container was not breached and that none of the seed and/or plant material has been lost by confirming the weight of the shipment and/or number of plants or plant parts.
- J.4. If it cannot be confirmed that an unintended release of plant material has not occurred, follow the corrective action requirements in Section K.
- J.5. A copy of the completed Record of Transport shall be faxed to, and retained by, the Shipper.

#### K. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

- K.1. If it cannot be assured that an unintended release of plant material is suspected during transport, the Recipient shall treat this as a case of unintended release and immediately notify the Authorised Party who will initiate appropriate reporting and corrective actions.
- K.2. In the event of a confirmed unintended release of biotech-derived plant material all attempts shall be made to recover as much of the biotech-derived plant material as possible. This material shall be destroyed.
- K.3. The location of an unintended release shall be marked and monitored to ensure that all the biotechderived plant material arising from the unintended release (*e.g.*, volunteer plants) is destroyed. The period of monitoring will be determined in consultation with the Authorised Party.
- K.4. In the event of a confirmed unintended release during transport the Recipient shall immediately notify the Authorised Party by telephone. The Authorised Party shall notify the Regulatory Authority immediately by telephone and in writing within 24 hours of any unintended release.
- K.5. The unintended release of biotech-derived plant material during transport shall be immediately documented by the Recipient in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Recipient and copies shall be submitted by facsimile to the Authorised Party who shall ensure that the same records are faxed to the Regulatory Authority.

#### L. RECORD KEEPING

- L.1. Copies of the Record of Transport, including the Transport Inventory List if appropriate, as completed by the Recipient shall be forwarded to the Shipper and the Authorised Party. The original copy shall be retained by the Recipient.
- L.2. All records associated with the transport of biotech-derived plant material shall be available for inspection by the Regulatory Authority upon request.

#### M. RELATED SOPS

M.1. The following SOPs shall also be consulted: [List any related SOPs]

#### N. REVIEW AND DISTRIBUTION

- N.1. This SOP shall be reviewed by the Authorised Party no less than annually.
- N.2. Revised SOPs will be distributed to all agents acting on behalf of the Authorised Party, who shall then destroy their older copy.
- N.3. Archival copies of this SOP shall be maintained by the Authorised Party for no less than [X] years.

#### O. ASSURANCE

- 0.1. I have read this document and approve of its contents. I certify that this document will be made available to all personnel to which it applies.
- 0.2. Name of Authorised Party (please print):

Signature of Authorised Party:

Date:



#### Appendix 2: Sample transport SOP

SHIPMENT NU	SHIPMENT NUMBER:					RECORD OF TRANSPORT					
				INSTRU	ICTIONS						
This Record of Tr	ansport shou	uld be complete	d for every sh	nipment of reg	ulated material a	and can serve as	the waybill f	for materia	als in transit.		
For shipment of a For shipments of n	single experi nultiple items	mental biotech- , complete and	derived event affix one or m	, complete the nore copies of	e Biotech-derive	ed Event Identif t on page 2.	ication inforr	mation on	this page.		
Following completion of this record by the shipper, one copy should be forwarded to the Recipient Following completion of this record by the receiver, one copy should be returned to the shipper an Authorised Party.							r e-mail befo py should be	re the ship e forwarde	oment is sent. d to the		
In the event of an The incident and a	unintended re any corrective	elease during st e action taken sh	orage, the Au nould be reco	ithorised Party rded on the <b>R</b>	y should be notifi ecord of Correct	ied immediately l ctive Action forn	by telephone n.	and facsi	mile or e-mail. PAGE 1 of 2		
SHIPPER Last Name		First Name		MI	RECEIVER Last Name		First Name	Name MI			
Company/Organisation Department/Section					Company/Organisa	tion	Department/Se	ection			
Street Address			Street Address								
City Sta	ate/Province	Zip/Postal Cod	e Count	try	City	State/Province	Zip/Postal	Code	Country		
Telephone Fa	csimile	Electronic Mail	•		Telephone	Facsimile	Electronic Mai	I			
PRE-SHIPMENT CHECK-OFF         Primary Method of Transport         Rail       Road       Air       Ship       Other (give details):				BIOTECH-DERIVED EVENT IDENTIFICATION           User ID Number         Permit No.           Plant Species         Specify Amount of Material Shipped				TION laterial Shipped			
Name of Carrier			Telephone		Form of Motorial		Identifi	any Cood Tr			
Primary Shipping Container Plastic Bag Paper Packet Other (detail below) Other details of Primary Shipping Container				Budwood/Shoots       Seeds         Whole Plants       Transplants         Rhizomes       Tubers							
Type of Secondary Shipp	ping Container				Receipt of Shipment         All Inventory Checked and Complete         Yes         All Accompanying Documentation Received				eived Yes		
Condition of Shipping Co	ontainers	detail below)	Containers Conf Free of Plant Ma Prior to Loading	irmed Yes aterial No	Condition of Shipping Containers      Primary     Container     Intact     Breached     Secondary     Intact     Breached     Secondary     Intact     Breached				ntact Breached		
Accompanying Documentation         Import Permit       Phytosanitary Certificate         Copy of Permit Conditions       Advanced Informed Agreement         Other (detail below)       Other Accompanying Documentation				Other details on Co	ondition of Shipping Ce	ontainers of Docu	imentation				
SHIPMENT VE Signature of Shipper	ERIFICATIO	ON Ship	oment Date (YYYY	Y-MM-DD)	RECEIPT V Signature of receive	<b>/ERIFICATIO</b>	N	Date of Rece	eipt (YYYY-MM-DD)		

## **RECORD OF TRANSPORT**

PAGE 2 of 2
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BIOTECH-DERIVED EVENT INV	ENTORY LIST	
Item No. Unique Identifier or Event Name	Permit No.	Specify Exact Amount of Material Shipped
Form of Material Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material
Item No. Unique Identifier or Event Name	Permit No.	Specify Exact Amount of Material Shipped
Form of Material Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material
Item No. Unique Identifier or Event Name	Permit No.	Specify Exact Amount of Material Shipped
Form of Material Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material
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Form of Material Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material
Item No. Unique Identifier or Event Name	Permit No.	Specify Exact Amount of Material Shipped
Form of Material Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material
Item No. Unique Identifier or Event Name	Permit No.	Specify Exact Amount of Material Shipped
Form of Material  Form of Material  Seeds Budwood/Shoots Rhizomes Whole Plants Transplants Tubers	Plant Species	Identify any Seed Treatment or Other Treatment of the Material



#### Appendix 2: Sample transport SOP

#### INSTRUCTIONS

### **RECORD OF CORRECTIVE ACTION**

The **Record of Corrective Action** is used to document all corrective actions taken to mitigate or resolve a situation involving the **unintended** release of an experimental biotech-derived event during transport, storage, harvest or the post-harvest period or any breach of reproductive isolation during the field testing of an experimental biotech-derived event.

A copy of this Record of Corrective Action, together with any other relevant records (i.e. Record of Transport, Record of Storage Inspection & Inventory, Record of Spatial Isolation, Record of Harvest, etc), should be forwarded by facsimile or e-mail to the Authorised Party.

										PAGE 1 of 2		
RECORD IN Last Name	NITIATE	D BY Firs	t Name		МІ	TRIAL SITE Site Location Code		Trial Site Size (r X	m x m)   1	No. of Trials at this site		
Company/Organisat	tion	Dep	artment/Section			Legal or Descriptive Land Loca	tion of Trial Site	9				
Street Address						-						
						Distance to Nearest Field of Same Species (m) Distance to Nearest Commercial Crop of any kind (m) Distance under the Manager's control?						
City	State/Provir	nce	Zip/Postal Code	Country	у	Inflorescence Removal, Bagging or Tenting						
Telephone	Facsimile	Elec	tronic Mail			Spatial Isolation	arly Crop Destr	uct Border	Rows			
ACTIVITY REQUIRING CORRECTIVE ACTION Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections Transport Storage Planting Monitoring Harvesting Other If other, describe below						IDENTIFICATION OF COMPLIANCE ISSUE         Check all that apply         Unauthorised Shipment       Article Lost during Shipment         Primary Shipping Container Breached       Record of Transport Missing         Unintended Release during Transport       Received at Wrong Destination						
TRANSPORT AND STORAGE					Unintended Release duri	ng Storage	Bre	ach of Gua	rd Row Isolation			
Shipment No. Item No.			Item No.			Breach of Spatial Isolation Other				elow)		
Facility Code Storage Loca			Storage Locati	on Identifier		- Details of Compliance						
Building Name or IE	)		Room Number	or Description	sription							
Street Address (if di	ifferent from a	above)										
<b>IDENTIFIC</b>	ATION C	OF AFFE	CTED BIO	TECH-DE	RIVED EV	ENT						
Permit No.		Plant Species		Approx. Amou Affected Mater	int of rial (kg)	Form of Material	Shoots T	Transplants Tubers Whole Plants				
Permit No.		Plant Species		Approx. Amou Affected Mater	nt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole Plants		
Permit No.		Plant Species	i	Approx. Amou Affected Mater	nt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole Plants		
Permit No.		Plant Species		Approx. Amou Affected Mater	nt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole Plants		
Permit No.		Plant Species		Approx. Amou Affected Mater	int of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole Plants		
Permit No.		Plant Species		Approx. Amou Affected Mater	nt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole Plants		

# RECORD OF CORRECTIVE ACTION

			PAGE 2 of 2
DESCRIPTION OF CORREC Check all that apply	TIVE ACTION TAKEN		
Destruction of Exp. Biotech-derived Event	Recovery of Spilled Material	Impose Post Harvest Restrictions	Roguing of Prohibited Plants
Other (details below)	Imposition of Spatial Isolation Zo	ne Destruction of Neighbouring Crop	Destruction of Trial
Details of Corrective Action taken			
THIS SECTION IS TO BE CO COMMUNICATION WITH RE	MPLETED BY THE AU GULATORY AUTHORIT	THORISED PARTY	
Name of Official first contacted Departme	ent or Office Teleph	one Facsimile	E-mail Date first contacted
Summarise communication outcomes, including a Attach any written correspondence or transcripts	greed options for risk mitigation. Itemise of oral communications.	all communications, recording date and individuals	involved.
VERIFICATION	heen Signature of Essility I	Janagar Trial Managar or Authorized Detu	Data Signed (VVVV MM DD)
carried out in accordance with approved standard operating procedures and with applicable regulation	ons	vanager, mai wanager or Authonsed Party	Date Signed (1111-MiN-DD)
governing the transport, storage and field testing experimental biotech-derived plant material	U		
	By my signature about	e. I state that the information contained becain in	
	accurate and complet	te to the best of my knowledge and belief	



# STANDARD OPERATING PROCEDURE (SOP) FOR THE STORAGE OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL WITHIN [COUNTRY]

Note: This Standard Operating Procedure (SOP) is intended solely as an example that may be used as an educational resource by organisations that are developing or revising their own quality management programs for confined field trials of experimental biotech-derived plants. This example should not be used as a substitute for the user's own understanding and compliance with regulations governing the conduct of such trials.

#### A. DESCRIPTION OF THE ACTIVITY

A.1. The appropriate storage of experimental biotech-derived plant material in [country].

#### B. SCOPE

B.1. This SOP applies to experimental biotech-derived plant material stored at containment facilities and stored at the trial site.

#### C. SOP AUTHORISATION

Name of Authorised Party: Title: Signature: Date: Implementation Date: In Effect Until:

#### D. TERMINOLOGY

Possible terms that could be relevant in this SOP. For specific definition, see Appendix 1.

- D.1. Authorised Party
- D.2. Biotech-derived
- D.3. Biotech-derived event
- D.4. Biotech-derived plant material
- D.5. Facility Manager
- D.6. Plant material
- D.7. Propagatable
- D.8. Regulatory authority
- D.9. Sanitised
- D.10. Unintended release

#### E. GENERAL REQUIREMENTS

E.1. The Authorised Party and all other agents acting on behalf of the Authorised Party shall comply with this SOP.

#### F. REQUIREMENTS FOR STORAGE OF BIOTECH-DERIVED PLANT MATERIAL

- F.1. The requirements in this section shall be applied to the storage of all biotech-derived plant material.
- F.2. The Facility Manager shall ensure the suitability of all storage facilities prior to accepting shipments of biotech-derived plant material.
- F.3. A storage area shall be a fully enclosed space (*e.g.*, filing cabinet, office, closet). Access doors shall be lockable. Windows shall be closed and locked.
- F.4. A storage area for biotech-derived plant material shall be used exclusively for such articles.
- F.5. Where a storage area may be used to store multiple samples of one or more biotech-derived events, each sample shall be stored separately in a sealed container such as the primary container used for shipment.
- F.6. All storage areas shall be clearly labelled as containing biotech-derived plant material in accordance with the requirements of Section G.

- F.7. Access to storage areas shall be limited to personnel authorised by the Authorised Party or Facility Manager.
- F.8. Areas or units shall be designated for storage of biotech-derived plant.
- F.9. Storage areas for biotech-derived plant material shall be sanitised prior to, and immediately following, the period of storage.
- F.10. The addition of biotech-derived plant material to, or removal of biotech-derived plant material from, the storage area shall be recorded on the Record of Storage Inspection and Inventory.
- F.11. Any biotech-derived plant sample withdrawn from storage for the purpose of disposition shall be destroyed by dry heat, steam heat, crushing, burning, or treatment with appropriately labelled herbicides and/or chemicals.

#### G. LABELLING OF THE STORAGE AREA

- G.1. The storage area shall be labelled as containing biotech-derived plant material (see Annex 1 for a sample label).
- G.2. The Storage Area Label shall be affixed to the point of access to the storage area.

#### H. INSPECTION OF THE STORAGE AREA

- H.1. Inspection of the storage areas shall be completed monthly by the Facility Manager to ensure that storage conditions are maintained in accordance with this SOP. Each inspection shall be recorded on the Record of Storage Inspection and Inventory.
- H.2. The Record of Storage Inspection and Inventory shall be retained by the Facility Manager.

#### I. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

- I.1. If an unintended release of plant material is suspected during storage, the Facility Manager shall treat this as a case of unintended release and immediately notify the Authorised Party who will initiate appropriate reporting and corrective actions.
- I.2. In the event of a confirmed unintended release of biotech-derived plant material all attempts shall be made to recover as much of the biotech-derived plant material as possible. This material shall be destroyed.
- 1.3. The location of an unintended release shall be marked and monitored to ensure that all the biotechderived plant material arising from the unintended release (*e.g.*, volunteer plants) is destroyed. The period of monitoring will be determined in consultation with the Authorised Party.
- 1.4. In the event of a confirmed unintended release during storage the Facility Manager shall immediately notify the Authorised Party by telephone. The Authorised Party shall notify the Regulatory Authority immediately by telephone and in writing within 24 hours of any unintended release.
- 1.5. The unintended release of biotech-derived plant material during storage shall be immediately documented by the Facility Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Facility Manager and copies shall be submitted by facsimile to the Authorised Party.

#### J. RECORD KEEPING

- J.1. The Facility Manager shall retain the Record of Storage Inspection and Inventory.
- J.2. All records associated with the storage of biotech-derived plant material shall be available for inspection by the Regulatory Authority upon request.

#### K. RELATED SOPS

K.1. The following SOPs shall also be consulted: [List any related SOPs]

#### L. REVIEW AND DISTRIBUTION

- L.1. This SOP shall be reviewed by the Authorised Party no less than annually.
- L.2. Revised SOPs will be distributed to all agents acting on behalf of the Authorised Party, who shall then destroy their older copy.
- L.3. Archival copies of this SOP shall be maintained by the Authorised Party for no less than [X] years.



#### M. ASSURANCE

M.1. I have read this document and approve of its contents. I certify that this document will be made available to all personnel to which it applies.

Name of Authorised Party (please print):

Signature of Authorised Party:

Date:

#### ANNEX 1: EXAMPLE OF A STORAGE AREA LABEL

### THIS STORAGE AREA CONTAINS EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL

Facility Name or Code: Building Name or ID: Room Number or Description:

ACCESS TO THIS STORAGE AREA IS LIMITED TO PERSONNEL DESIGNATED BY THE FACILITY MANAGER

Name of Facility Manager: Room Number: Telephone Number:

### IN CASE OF EMERGENCY OR DAMAGE TO THE STORAGE AREA, CONTACT THE FACILITY MANAGER IMMEDIATELY

INSTR	UCTIONS	RECOR	D OF ST	ORA	GE IN	SPEC	TION & I	NVENTOR
This Record of	of Storage Inspect	ion and Inventory is	divided into two pa	arts: Stor	age Inspecti	i <b>on</b> and <b>Inv</b>	entory Change.	
The Storage I	nspection section sl	hould be completed <b>C</b> d releases of biotech-	ONCE EVERY FOU	R (4) WI	EEKS by the	Facility Ma	nager to ensure tha	t storage conditions
An entry into I	nventory Change	should be made each	time an amount of	f a biotec	ch-derived ev	ent is adde	d to, or removed fro	om, storage inventory.
Only authorise	ed persons should a	add or remove biotech	n-derived event san	nples fro	m storage an	d no materi	ial should be remov	ed from storage for
This Record of	of Storage Inspecti	ion and Inventory st	nould be retained by	y the Fa	cility Manage	r. When eith	ner the Storage Insp	pection or Inventory
Change sheet	is full, the Facility N	Manager should exch	ange it for a new pa	age and	retain the cor	mpleted pag	je. by telephone and fr	accimila or a mail
The incident a	and any corrective a	ction should be recor	ded on the Record	l of Corr	ective Action	n form.	by telephone and is	PAGE 1 of t
				STO				PAGE 1 012
Last Name		First Name	MI	Building	Name or ID	JEITES	Room Number or Desc	cription
Company/Organisa	ation C	Department/Section		Street A	ddress (if differen	t from left)		
Street Address				-				
				City	State	e/Province	Zip/Postal Code	Country
City	State/Province	Zip/Postal Code	Country					
Telephone	Facsimile E	Electronic Mail		-				
STOBAGE								
Inspection Date	Biotech-derived	Storage Area Secure	Storage Area Clean ar	nd Free	Storage Area c	learly Reco	ords of Storage	Facility Manager
(YYYY-MM-DD)	Material kept separate		of any Waste or Plant	Detritis			No.	Signature
Inspection Date	Biotech-derived	Storage Area Secure	Storage Area Clean ar	nd Free	Storage Area c	learly Reco	ords of Storage	Facility Manager
(YYYY-MM-DD)	Material kept separate		of any Waste or Plant	Detritis			Yes No	Signature
Inspection Date	Biotech-derived	Storage Area Secure	Storage Area Clean ar	nd Free	Storage Area c	learly Reco	ords of Storage	Facility Manager
(1111-100)	Yes No	Yes No		Deulus	Yes		Yes No	Signature
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean an of any Waste or Plant	nd Free Detritis	Storage Area c	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	] No	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	] N₀ 🗌	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	] N₀ 🛛	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	] No □	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	N₀	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
	Yes No	Yes No	Yes No		Yes	] No □	Yes No	
Inspection Date (YYYY-MM-DD)	Biotech-derived Material kept separate	Storage Area Secure	Storage Area Clean ar of any Waste or Plant	nd Free Detritis	Storage Area c Labelled	learly Reco	ords of Storage ntory Changes Available	Facility Manager Signature
Increation Data	Yes No	Yes No	Yes No	d Fra -	Yes		Yes No	Facility Managers
(YYYY-MM-DD)	Material kept separate	Storage Area Secure	of any Waste or Plant	Detritis	Labelled	Inve	ntory Changes Available	Signature
	Yes No	Yes No	Yes No		Yes	No	Yes No	



## **RECORD OF STORAGE INSPECTION & INVENTORY**

				PAGE 2 of 2
INVENTO ENTRY OR REM	RY CHANGE OVAL OF MATERIAL FROM INVENTORY			
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining
Addition Removal	Date (YYYY-MM-DD)	Name of Authorised Person	Signature of Authorised Person	
Item Number	Unique Identifier or Event Name	Permit Number	Amount Added or Removed	Amount Remaining

INSTR	UCTIONS	RECORD OF CORRECTIVE ACTIO								
The Record of release of an isolation duri	of Corrective Act experimental bing the field testin	ion is used to do otech-derived e g of an experime	ocument all co vent during t ntal biotech-c	orrective action ransport, stor derived event	ons taken to mitigate or re rage, harvest or the post- t.	esolve a siti harvest per	uation involvi iod or any <b>br</b> Record of Str	ng the <b>u</b> reach of	inintende f reprodu	ed Ictive
Inventory, Rec	cord of Spatial Isc	plation, Record of	Harvest, etc	), should be t	forwarded by facsimile or	e-mail to th	ne Authorised	l Party.	spection	u
									PAG	E 1 of 2
RECORD I Last Name	INITIATED BY	, First Name		MI	TRIAL SITE       Site Location Code       Trial Site Size (m x m)       No. of Trials at this si       X					s at this site
Company/Organis	Company/Organisation Department/Section				Legal or Descriptive Land Loc	ation of Trial Sit	e			
Street Address						1				
					Distance to Nearest Field of Same Species (m)	Distance to N Commercial of any kind (i	Vearest Crop m)	Is the Is Distance Manage	olation o under the r's control?	Yes No
City	State/Province	Zip/Postal Code	Countr	ry -	Inflorescence Removal, I	Bagging or Tent	ing			
Telephone	Facsimile	Electronic Mail			Spatial Isolation	Early Crop Dest	ruct Borde	r Rows		
ACTIVITY	REQUIRING	CORRECTIVI	<b>ACTION</b>		IDENTIFICATION	OF COM	PLIANCE	ISSU	E	
Indicate the Categ	Storage	anting Monitorin	g Harvesti	ing Other	Check all that apply		Ar	ticle Lost o	luring Shipm	ient
If other, describe b	If other, describe below									sina
					Unintended Release during Transport					ination
TRANSPO		PACE				ing Charage		each of C	word Daw law	
Shipment No.	INT AND STO	Item No.				ing Storage		each or G		Diation
					Details of Compliance					
Facility Code		Storage Loca	tion Identifier							
Building Name or I	ID	Room Numbe	er or Description		-					
Street Address (if o	different from above)				-					
IDENTIFIC	ATION OF AF	FECTED BIO	DTECH-DE	RIVED E	/ENT					
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material					
					Seeds Budwood/	Shoots T	ransplants	Tubers	Whole	Plants
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material					
					Seeds Budwood/	Shoots T	ransplants	Tubers	Whole	Plants
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material					
					Seeds Budwood/	Shoots T	ransplants	Tubers	Whole	Plants
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of prial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material					
				. 21	Seeds Budwood/	Shoots T	ransplants	Tubers	Whole	Plants
Permit No.	Plant S	pecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material		_			
					Seeds Budwood/	Shoots T	ransplants	Tubers	Whole	Plants



### **RECORD OF CORRECTIVE ACTION**

PAGE 2 of 2	
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DESCRIPTION OF CORRECT	TIVE ACTION TAP	KEN			
Destruction of Exp. Biotech-derived Event	Recovery of Spilled Mat	terial Imp	ose Post Harvest Restrictions	Roguing of Prohib	bited Plants
Other (details below)	Imposition of Spatial Iso	blation Zone	truction of Neighbouring Crop	Destruction of Tria	al
Details of Corrective Action taken					
THIS SECTION IS TO BE CO	OMPLETED BY TH	IE AUTHORISED	PARTY		
COMMUNICATION WITH RE           Name of Official first contacted         Departm	EGULATORY AUTH nent or Office	IORITIES Telephone	Facsimile	E-mail	Date first contacted
Summarise communication outcomes, including Attach any written correspondence or transcripts	agreed options for risk mitigation of oral communications.	n. Itemise all communications	s, recording date and individuals	involved.	
VERIFICATION	a been Cirrecture of	Eacility Monogor, Trial Marga	ger or Authorized Ports	Date O're	
carried out in accords detailed in this report have operating procedures and with applicable regular operating the teappart storage and field teappart	d of	raciity Manager, mai Mana	ger of Authonsed Faity	Date Sign	טטיאט (דידידיאוואי-טט)
experimental biotech-derived plant material					
	By my signa	ture above, I state that the in	formation contained herein is		
	accurate and	a complete to the best of my	knowledge and belief		



#### STANDARD OPERATING PROCEDURE (SOP) FOR MANAGING FIELD TRIALS OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL WITHIN [COUNTRY]

Note: This Standard Operating Procedure (SOP) is intended solely as an example that may be used as an educational resource by organisations that are developing or revising their own quality management programs for confined field trials of experimental biotech-derived plants. This example should not be used as a substitute for the user's own understanding and compliance with regulations governing the conduct of such trials.

#### A. DESCRIPTION OF THE ACTIVITY

A.1. To ensure compliance with requirements for the conduct of confined field trials of experimental biotech-derived plant materials in [country].

#### B. SCOPE

B.1. This SOP will cover all confined field trials of experimental biotech-derived plant material cultivated in [country].

#### C. SOP AUTHORISATION

Name of Authorised Party: Title: Signature: Date: Implementation Date: In Effect Until:

#### D. TERMINOLOGY

Possible terms that could be relevant in this SOP. For specific definition, see Appendix 1.

- D.1. Anthesis
- D.2. Authorised Party
- D.3. Biotech-derived
- D.4. Biotech-derived plant material
- D.5. Field trial
- D.6. Permanent markers or landmark
- D.7. Prohibited plants
- D.8. Regulatory authority
- D.9. Trial Manager
- D.10. Trial site
- D.11. Trial site location
- D.12. Unintended release
- D.13. Volunteers

#### E. GENERAL REQUIREMENTS

E.1. The Authorised Party and all other agents acting on behalf of the Authorised Party shall comply with this SOP.

#### F. REQUIREMENTS FOR PLANTING FIELD TRIALS

- F.1. All equipment used to seed, plant or maintain the field trial site shall be free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations.
- F.2. All equipment used to seed or plant confined field trials or equipment that is used in the maintenance of the trial site shall be cleaned on the trial site to eliminate unintended transport of experimental biotech-derived plant material from the trial site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water. Any plant material recovered shall be rendered non-viable a means acceptable to the regulatory authority and disposed of on site.

- F.3. A map of the trial site shall be prepared by the Trial Manager and appended to the Record of Planting. Instructions for the preparation of maps are provided in Annex 1.
- F.4. A Record of Planting shall be completed for each field trial site. A copy of the Record of Planting, with the appended map, shall be submitted to the Authorised Party within five (5) working days following the completion of planting. The original Record of Planting shall be retained by the Trial Manager.

#### G. PERFORMANCE REQUIREMENTS FOR FIELD TRIALS OF BIOTECH-DERIVED CROP PLANTS

- G.1. All four corners of each trial site, including border rows where applicable, shall be clearly marked with permanent markers (*e.g.*, fence post, PVC piping) suitable to permit identification of the trial site during both the growing season and the mandated period of post-harvest land use restriction.
- G.2. All field trial sites shall be reproductively isolated from any sexually compatible species, sub-species or varieties that are not part of the trial by the methods described in paragraphs G.4 to G.6.
- G.3. A single field trial site shall be reproductively isolated in its entirety by no less than one continuous method of reproductive isolation.
- G.4. Spatial isolation of field trial sites.
  - G.4.1. Trial sites of experimental biotech-derived plants shall be spatially isolated from other plants of the same or related species by the minimum isolation distance mandated by regulatory authorities. The spatial isolation distance shall be continuous and completely enclose the confined trial.
  - G.4.2. The Trial Manager shall ensure that the trial site and surrounding isolation distance shall be kept free of all prohibited plants, including volunteers, by implementing a program of regular monitoring and roguing (see paragraph H).
  - G.4.3. Any prohibited plants in the isolation distance shall be removed before anthesis.
  - G.4.4. If any prohibited plants within the isolation distance are permitted to complete anthesis, a breach of reproductive isolation will have occurred.
  - G.4.5. Any prohibited plants removed from the isolation distance shall be rendered non-viable by a means acceptable to the regulatory authority and disposed of on the trial site.
- G.5. Isolation of field trial sites by inflorescence removal.
  - G.5.1. Trial sites of experimental biotech-derived plants shall be reproductively isolated from other plants of the same or sexually compatible species by the removal of all inflorescences from the trial plants prior to anthesis.
  - G.5.2. The Trial Manager shall ensure that all inflorescences of the trial plants are removed prior to anthesis by implementing a program of regular monitoring (see paragraph H).
  - G.5.3. The removed inflorescences shall be rendered non-viable by a means acceptable to the regulatory authority and disposed of on the trial site.
  - G.5.4. Where the inflorescences of trial plants are not removed prior to anthesis, reproductive isolation may be re-established by spatial isolation if the conditions for spatial isolation can be met (see paragraph G.4).
  - G.5.5. Where the inflorescences of trial plants are not removed prior to anthesis, and reproductive isolation of the trial cannot be re-established by spatial isolation, the trial shall be terminated.
- G.6. Isolation of field trial sites with border rows.
  - G.6.1. Field trials of experimental, biotech-derived plants shall be reproductively isolated from sexually compatible species by planting an uninterrupted perimeter border row of non-biotech-derived plants of the same or similar variety and at a planting density comparable to the experimental plants. The border row shall be continuous and completely enclose the confined trial site.
  - G.6.2. The non-biotech-derived border row shall be planted with a variety that will mature concurrently with the experimental plants and will be managed using standard agronomic practices.
  - G.6.3. The Trial Manager shall ensure that anthesis of trial plants is concurrent with anthesis of the plants in the border row by implementing a program of regular monitoring (see section H).
  - G.6.4. If any trial plants begin flowering prior to the plants in the border row or continue flowering after the border row plants have finished flowering, a breach of reproductive isolation will have occurred. Reproductive isolation shall be re-established by spatial isolation, provided the conditions for spatial isolation can be met (see paragraph G.4).
  - G.6.5. If the physical integrity of the border row is compromised and cannot be re-established, a breach of reproductive isolation will have occurred and shall be re-established by spatial isolation, provided the conditions for spatial isolation can be met (see paragraph G.4).



- G.6.6. Where reproductive isolation of the biotech-derived plant cannot be re-established by spatial isolation, the trial shall be terminated.
- G.7. Isolation of field trial sites through early crop destruction.
  - G.7.1. When early crop destruction is used as a method of reproductive isolation, field trials of experimental biotech-derived plants shall be terminated or destroyed prior to inflorescence emergence.
  - G.7.2. The Trial Manager shall monitor the growth stages of the trial plants for inflorescence emergence by implementing a programme of regular inspection (see section H).
  - G.7.3. The trial plants or any residual plant material at the trial site shall be rendered non-viable by a means acceptable to the regulatory authority and disposed of on the trial site.

#### H. MONITORING OF THE FIELD TRIAL BY THE TRIAL MANAGER

- H.1. The Trial Manager, or a person so designated for this purpose by the Trial Manager, shall inspect the trial site no less than once EVERY FOUR WEEKS from the time of planting until the time of harvest.
- H.2. The Record of Spatial Isolation shall be used to document all inspection activities needed to ensure spatial reproductive isolation of the trial site.
- H.3. The Record of Inflorescence Removal shall be used to document all inspection activities needed to ensure that all inflorescences of plants in trial are removed prior to anthesis.
- H.4. When reproductive isolation is achieved by inflorescence removal, DAILY INSPECTION of the trial site shall be undertaken from the time the inflorescence emerges to ensure that inflorescences are removed prior to anthesis.
- H.5. When reproductive isolation is achieved by early crop destruction, inspection of the trial shall be undertaken ONCE EVERY WEEK prior to inflorescence emergence to ensure that trial termination is completed before inflorescences emerge.
- H.6. The Record of Early Crop Destruct shall be used to document all inspection activities needed to ensure termination prior to the inflorescence emergence.
- H.7. The growth stage of any prohibited plants shall be recorded at the time of inspection.

#### I. OCCURRENCE OF NON-COMPLIANCE

- 1.1. The Trial Manager shall notify the Authorised Party immediately and in writing within 24 hours of any situation where reproductive isolation of the trial site has been breached.
- I.2. The Authorised Party shall determine the subsequent course of action.

#### J. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

- J.1. If unintended release of experimental biotech-derived plant material is suspected to have occurred from the trial site, the Trial Manager shall treat this as a case of unintended release and immediately notify the Authorised Party who will initiate appropriate reporting and corrective actions.
- J.2. In the event of a confirmed unintended release of experimental material, all attempts shall be made to recover as much of the material as possible. This material shall be destroyed.
- J.3. The location of an unintended release shall be marked and monitored to ensure that all the experimental material arising from the unintended release (*e.g.*, volunteer plants) is destroyed. The period of monitoring will be determined in consultation with the Authorised Party.
- J.4. In the event of a confirmed unintended release during the field trial the Trial Manager shall immediately notify the Authorised Party by telephone. The Authorised Party shall notify the Regulatory Authority immediately by telephone and in writing within 24 hours of any unintended release.
- J.5. The unintended release of experimental material during the field trial shall be immediately documented by the Trial Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Trial Manager and copies shall be submitted by facsimile to the Authorised Party.

#### K. RECORD KEEPING

- K.1. The Record of Planting and map for each trial site shall be retained by the Trial Manager in the Compliance Document Binder.
- K.2. The Record of Spatial Isolation for each trial site shall be retained by the Trial Manager.
- K.3. The Record of Inflorescence Removal for each trial site shall be retained by the Trial Manager.
- K.4. The Record of Early Crop Destruct for each trial site shall be retained by the Trial Manager.

#### L. RELATED SOPS

L.1. The following SOPs shall also be consulted: [List any related SOPs]

#### M. REVIEW AND DISTRIBUTION

- M.1. This SOP shall be reviewed by the Authorised Party no less than annually.
- M.2. Revised SOPs will be distributed to all agents acting on behalf of the Authorised Party, who shall then destroy their older copy.
- M.3. Archival copies of this SOP shall be maintained by the Authorised Party for no less than [X] years.

#### N. ASSURANCE

N.1. I have read this document and approve of its contents. I certify that this document will be made available to all personnel to which it applies.

Name of Authorised Party (please print):

Signature of Authorised Party:

Date:

#### ANNEX 1: INSTRUCTIONS FOR PREPARATION OF FIELD TRIAL MAPS

- 1. A map of the trial site shall be prepared by the Trial Manager and appended to the Record of Planting.
- 2. Maps must provide sufficient detail to allow government inspectors to locate each field trial during the current and post-harvest seasons.
- 3. Maps must be drawn to scale and provide details on the layout of the site and distances between the field trial and surrounding features.
- 4. The dimensions of trial site and distances to permanent markers must be accurately reported.
- 5. The following items shall be included on each map of a field trial site:
  - a. Trial Manager's name and contact details.
  - b. A reference code for a trial site or trial(s) within a trial site, if applicable.
  - c. Permit number from the regulatory authority.
  - d. Legal or descriptive land location.
  - e. GPS coordinates, if applicable. The use of GPS locator numbers for each corner of the trial site is required to provide the most accurate information to enable verification of the trial location. All GPS coordinates must be obtained using units with accuracy of at least plus or minus 5 meters. The model of the unit and datum used shall also be recorded.
  - f. Exact trial site dimensions.
  - g. Total area planted with the biotech-derived plant material, including guard rows (hectares or square meters).
  - h. Distances to permanent markers or surrounding landmarks such as telephone poles, fences, alleys, roads or steel poles that can be located by a metal detector.
  - i. Label all fields within the isolation distance by the common name of the crop.
  - j. Indicate closest fields of same species as the biotech-derived plant material that may fall within or border the isolation distance.
  - k. Include any natural ecosystems adjacent to the trial site (natural habitats, waterways, forests, and woodlots, hedgerows), where reasonable.
  - I. Planting date.
  - m. Compass directions, with North at the top of the page.

INSTRUCTIONS				RECO	RD O	F PL/	ANTING
This Record of Planting should	be completed to document	the planting c	of all regulated material a	t a field trial	site.		
Use the following two-letter code	es to designate the destruction	on method for	excess planting materia	l:			
DH – dry heat SH – steam h	neat BU – burning DB	– deep buria	al CT – chemical trea	tment CR	– crushing		
Following completion of this rec	ord by the <b>Trial Manager</b> , or	ne copy shoul	d be forwarded to the Au	thorised Par	ty.		
In the event of an unintended re	lease during planting, the Au	ithorised Part	v should be notified imm	ediatelv bv te	elephone and	d facsimile	or e-mail.
The incident and any corrective	action taken should be recor	rded on the R	ecord of Corrective Act	tion form.			
							PAGE 1 of 1
TRIAL MANAGER		1	TRIAL SITE	1			
Last Name	First Name	м	Site Location Code		Trial Site Size (	m x m) No	of Trials at this sit
Company/Organisation	Department/Section		Legal or Descriptive Land Loc	ation of Trial Site			
Street Address			-				
			Species of Biotech-derived Ev	ent			
City State/Province	Zip/Postal Code Count	ry					
Telephone Facsimile	Electronic Mail		-				
			Distance to Nearest Field of Same	Distance to N Commercial C	earest Crop	Is the Isolation Distance und	on Ve
Was all Machinery inspected and	Indicate how Machinery used for See	ding, Planting	Species (m)	of any kind (m	1)	Manager's c	ontrol? No
confirmed free of Plant Material prior to entering the Trial Site?	or Cultivation was cleaned at the Tria	Il Site	TRANSPORTATIC		GULATE	Shipment	
Yes		Other (details below)	Shipped to the Trial Site attack	ned?	Yes No	ompinion	
No No	High Pressure Water		Was any Plant Material Shippe	ed from	Yes No	lf YES, en	er Shipment No.
Border Rows Spatial Isolation	Early Crop Destruct	flowering	Other				
DATA SHEET FOR RECO	ORDING PLANTING IN	FORMATI	ION				
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
		r lance (lig)			moulou		
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction	Date Plant	ed (YYYY-MM-DD)
		r lance (lig)			moulou		
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
User's Reference Code/Event Name	Permit No.	Amount Planted (kg)	Excess Amount Destroyed (kg	/No. Plants)	Destruction Method	Date Plant	ed (YYYY-MM-DD)
TRIAL MANAGER VERI	ICATION						
This activity has been carried out in accord approved standard operating procedures a	dance with Signature of and with	Trial Manager			Date	Signed (YYY	Y-MM-DD)
applicable regulations/permit conditions for management of field trials of experimental, crop plants	r the biotech-derived						

By my signature above, I state that the information contained herein is accurate and complete to the best of my knowledge and belief

#### INSTRUCTIONS

### **RECORD OF SPATIAL ISOLATION**

The spatial isolation distance should be inspected no less than ONCE EVERY FOUR (4) WEEKS during the growing season for the presence of prohibited plants.

If any prohibited plants within the isolation distance are permitted to complete anthesis, a breach of reproductive isolation will have occurred.

This **Record of Spatial Isolation** should be used to record inspection, including roguing as may be necessary. Inspections should be carried out by the **Trial Manager** or a person designated by the **Trial Manager**.

This Record of Spatial Isolation should be retained by the Trial Manager.

In the event of a **breach of reproductive isolation**, the Authorised Party should be notified immediately by telephone and facsimile or e-mail. The incident and any corrective action taken should be recorded on the **Record of Corrective Action** form.

									PAGI	E 1 of 2	
TRIAL MAN Last Name	NAGER	First Name		МІ	TRIAL SITE Site Location Code		Trial Site	e Size (m x m) X	No. of Trials	at this site	
Company/Organisa	tion	Department/See	tion		Legal or Descriptive Land Location of Trial Site						
Street Address					Species of Biotech-de	erived Event					
City	State/Province	Zip/Postal (	Code Cou	untry							
Telephone	Facsimile	Electronic Mail			Distance to Nearest     Field of Same     Species (m)	Disi Cor of a	tance to Nearest mmercial Crop any kind (m)	Distan Manag	; the Isolation Yes Jistance under the Manager's control?		
BIOTECH-D	DERIVED EV		R TRIAL			I		I			
Reference Code/ Event Name	Permit No.		Date Planted (	(YYY-MM-DD)	Reference Code/ Event Name	Permit No.		Date Pla	Planted (YYYY-MM-DD)		
Reference Code/ Event Name	Permit No.	Permit No. Date Pla		(YYY-MM-DD)	Reference Code/ Event Name	Permit No.		Date Planted (YYYY-MM-DD)			
Reference Code/ Event Name	Permit No.	Permit No. Date Planted (YY		(YYY-MM-DD)	Reference Code/ Event Name	Permit No.		Date Pla	Date Planted (YYYY-MM-DD)		
Reference Code/ Event Name	Permit No.	Permit No. Date Planted (YYYY-			Reference Code/ Permit No. Date Event Name Date			Date Pla	Planted (YYYY-MM-DD)		
DATA SHE	ET FOR REC		NSPECTIO	NS FOR TH	E PRESENCE	OF PRO	HIBITED P	LANTS			
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments a	and Observation	ns		Inspector's Initia	als	
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments	and Observation	ns		Inspector's Initia	als	
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments a	and Observation	ns		Inspector's Initia	als	
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments	and Observation	ns		Inspector's Initia	als	
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments	and Observation	ns		Inspector's Initia	als	
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments	and Observation	ns		Inspector's Initials		
Date Inspected (YYYY-MM-DD)	Prohibited F Present Yes	Plants G P No	rowth Stage of any rohibited Plants	Action take	n. Additional Comments	and Observation	ns		Inspector's Initia	als	



## **RECORD OF SPATIAL ISOLATION**

				PAGE 2 of 2
DATA SHEET F	OR RECORDING	INSPECTIONS	FOR THE PRESENCE OF PROHIBITED PLAN	NTS (CONTINUED)
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of any Prohibited Plants	Action taken. Additional Comments and Observations	Inspector's Initials
ADDITIONAL C	OMMENTS AND	OBSERVATIONS	8	
TRIAL MANAG	ER VERIFICATIO	N		
This activity has been carried out in accordance with approved standard operating procedures and with applicable regulations/permit conditions for the management of field trials of experimental, biotech-derived error plants		Signature of Tria	Il Manager Dat	te Signed (YYYY-MM-DD)
		By my signature accurate and co	above, I state that the information contained herein is mplete to the best of my knowledge and belief	

INSTR	UCTION	IS			R	ECOF	RD (	OF IN	FLC	DRES	SCEN	CE F	REMO	VAL
Prior to inflores	scence en d until <b>Al</b>	nergeno L inflore	e, the trial si	te should b	be inspe moved f	cted no les	s than (	ONCE EVE	RY FO	UR (4) WE	EEKS. Follo	wing infl	orescence	
If ALL inflores	cences ha	ve not	been remove	d. prior to	the bea	inning of pa	llen she	ed. a bread	ch of re	productiv	ve isolation	will hav	ve occurred	<b>1</b> .
This Record of by the <b>Trial M</b> a	f Infloresco anager or	ence Re a perso	emoval shou on designate	d be used d by the <b>Tr</b>	to recor	d inspection	n and ir	florescenc	e remo	val activitie	es. Inspectio	ons shou	Ild be carrie	d out
This <b>Record o</b>	of Inflores	cence	Removal she	ould be retain	ained by	/ the Trial N	lanage	r.						
In the event of The incident a	a <b>breach</b> nd any co	of rep rrective	roductive is action taken	olation, the should be	e Autho recorde	rised Party ed on the <b>R</b>	should ecord o	be notified of Correcti	immed ve Acti	iately by te <b>on</b> form.	elephone an	nd facsim	nile or e-mai	I.
TRIAL MAN	NAGER		First Name			MI	TRIA Site Lo	AL SITE cation Code			Trial Site Siz	ze (m x m)	No. of Trials	at this site
Company/Organisa	tion		Department/Se	rtion			Legal o	r Descriptive I	and Loca	tion of Trial S	X ite			
City	State/Provi	nce	Zip/Postal	Code	Country									
Telephone	Facsimile		Electronic Mail				Distanc Field of Species	e to Nearest Same s (m)		Distance to Commercial of any kind	Nearest Crop (m)	Is the Distan Manag	Isolation ce under the ger's control?	Yes No
BIOTECH-D	DERIVE	DEVE		R TRIA	L		<u> </u>							
Reference Code/ Event Name	Permit N	No.		Date Plant	ed (YYYY	MM-DD)	Referer Event N	nce Code/ lame	Permit	No.		Date Pla	inted (YYYY-MN	1-DD)
Reference Code/ Event Name	Permit N	No.		Date Plant	ed (YYYY	-MM-DD)	Referer Event N	nce Code/ lame	Permit	No.		Date Pla	inted (YYYY-MN	1-DD)
Reference Code/ Event Name	Permit N	No.		Date Plant	ed (YYYY	·MM-DD)	Referer Event N	nce Code/ lame	Permit	No.		Date Pla	inted (YYYY-MN	1-DD)
Reference Code/ Event Name	Permit N	No.		Date Plant	ed (YYYY	-MM-DD)	Referer Event N	nce Code/ lame	Permit	No.		Date Pla	inted (YYYY-MM	1-DD)
DATA SHEI	ET FOR	REC	ORDING I	NSPECT	IONS	AND INF	LORI	ESCENC	E REI	MOVAL				
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F	Removed	Pollen Shed Observed		Additional C	omments	and Observa	tions		Inspector's Initia	als
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F	Removed Flowering	Pollen Sher Observed	d No	Additional C	omments	and Observa	tions		Inspector's Initia	als
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F	Flowering	Pollen Shea Observed	<sup>ј</sup> №	Additional C	omments	and Observa	tions		Inspector's Initia	als
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F Yes No	Complete Removed	Pollen Shed Observed	Indext     Additional Comments and Observations     Inspect       s     No     No			Inspector's Initia	als			
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F Yes No	Removed Flowering Complete	Pollen Shed Observed d Yes	d No	Additional C	omments	and Observa	tions		Inspector's Initia	als
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F Yes No	Removed Flowering Complete	Pollen Sher Observed Yes	d No	Additional C	omments	and Observa	tions		Inspector's Initia	als
Date Inspected/Tim (YYYY-MM-DD/00.00 a	ie Gro am/pm) Tria	wth Stage I Plants	of Ir	florescences F Yes No	Removed Flowering Complete	Pollen Shee Observed	d No	Additional C	omments	and Observa	tions		Inspector's Initia	als



## **RECORD OF INFLORESCENCE REMOVAL**

							PAGE 2 of 2
DATA SHEET F		inspi	ECTIONS	AND INFLORE	ESCENCE REMOVAL (CON	ITINUED)	L
Date Inspected/Time (YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants	Infloresce Yes	nces Removed	Pollen Shed Observed	Additional Comments and Observations	In	spector's Initials
			Flowering Completed	Yes No			
Date Inspected/Time (YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants	Infloresce Yes	nces Removed	Pollen Shed Observed	Additional Comments and Observations	In	spector's Initials
		□ No	Flowering Completed	Yes No			
Date Inspected/Time (YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants	Infloresce Yes	nces Removed	Pollen Shed Observed	Additional Comments and Observations	In	spector's Initials
		No No	Flowering Completed	Yes No			
(YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants	Infloresce Yes	nces Hemoved	Observed	Additional Comments and Observations	In	spector's Initials
Data Increased (Time	Crowth Stone of	No No	Flowering Completed	Yes No	Additional Comments and Observations		en estevia laitiala
(YYYY-MM-DD/00.00 am/pm)	Trial Plants	Yes	nces Removed	Observed	Additional Comments and Observations	111	spector s mitiais
Date Inspected/Time	Growth Stage of	No Infloresce	Flowering Completed	Yes No	Additional Comments and Observations	In	spector's Initials
(YYYY-MM-DD/00.00 am/pm)	Trial Plants	Yes					speciol s miliais
Date Inspected/Time	Growth Stage of	Infloresce	Completed	Pollen Shed	Additional Comments and Observations	In	spector's Initials
(YYYY-MM-DD/00.00 am/pm)	Trial Plants	Yes	Elowering				
Date Inspected/Time	Growth Stage of	Infloresce	Completed	Pollen Shed	Additional Comments and Observations	In	spector's Initials
(YYYY-MM-DD/00.00 am/pm)	Trial Plants	Yes		Observed			
Date Inspected/Time	Growth Stage of	Infloresce	Completed nces Removed	Pollen Shed	Additional Comments and Observations	In	spector's Initials
(YYYY-MM-DD/00.00 an/pm)	mai Plants		Flowering	Yes No			
Date Inspected/Time	Growth Stage of Trial Plants		nces Removed	Pollen Shed	Additional Comments and Observations	In	spector's Initials
(		Yes	Flowering Completed	Yes No			
Date Inspected/Time (YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants		nces Removed	Pollen Shed Observed	Additional Comments and Observations	In	spector's Initials
			Flowering Completed	Yes No			
Date Inspected/Time (YYYY-MM-DD/00.00 am/pm)	Growth Stage of Trial Plants	Infloresce Yes	nces Removed	Pollen Shed Observed	Additional Comments and Observations	In	spector's Initials
		□ No	Flowering Completed	Yes No			
FATE OF PLAN	IT MATERIAL						
Describe how removed plant material was destroy	ed Dry Heat	Steam H	leat Burnin	g Deep Burial	Chemical Treatment Crushing	Other (detail be	low)
		0005					
ADDITIONAL C	OMMENTS AND	OBSE	RVATIONS	•			
TRIAL MANAG	ER VERIFICATIO	N					
This activity has been carr approved standard operation	ied out in accordance with ing procedures and with		Signature of Trial	Manager		Date Signed ()	(YYY-MM-DD)
management of field trials crop plants	of experimental, biotech-deri	ved					
			By my oignoture	about I state that the is	formation contained barain is		

By my signature above, I state that the information contained herein accurate and complete to the best of my knowledge and belief

INSTR	UCTIONS			REC	ORD OF	BO	RDE	R RO	W IS	OLATIO	ON
Prior to inflores and until ALL I	scence emergence biotech-derived ev	e, trials shoul vents have co	d be inspect ompleted <b>ant</b>	ted no less than the	ONCE EVERY FOU	JR (4) AILY.	WEEKS. F	Following in	florescen	ce emergence	)
If any biotech-o stage <b>OR</b> if the	derived events be ere are physical g	gin anthesis   aps in the bo	prior to the b rder row, a <b>b</b>	order row plants preach of reprod	OR complete anth luctive isolation w	esis a /ill ha	ifter the bor ve occurre	der row pla <b>d</b> .	nts have	finished this	
This Record of person design	Border Row Isolated by the <b>Trial N</b>	ation should b <b>/anager</b> .	be used to re	ecord inspection	activities. Inspectio	ns sho	ould be carr	ied out by t	he <b>Trial I</b>	Manager or a	
This Record o	f Border Row Isc	plation shoul	d be retained	d by the <b>Trial Ma</b>	inager.						
In the event of The incident ar	a <b>breach of repr</b> nd any corrective	oductive iso action taken	<b>lation</b> , the A should be re	Authorised Party corded on the R	should be notified i ecord of Correctiv	mmeo <b>/e Act</b>	liately by te i <b>on</b> form.	lephone an	d facsimi	le or e-mail.	
										PAGE 1	of 2
TRIAL MAN	IAGER	First Name		мі	TRIAL SITE Site Location Code			Trial Site Siz	e (m x m)	No. of Trials at th	nis site
Company/Organisat	tion	Department/Sect	ion		Legal or Descriptive La	and Loca	ation of Trial Sit	e			
Street Address					Species of Biotech-der	ived Ev	ent				
City	State/Province	Zip/Postal C	ode Co	ountry							
Telephone	Facsimile	Electronic Mail	Letronic Mail Distance to Nearest Field of Same Species (m) Distance to Nearest Commercial Crop Distance under Manager's con						e under the er's control?	] Yes ] No	
BORDER R Variety(ies) used for	ROW INFORM	ATION			Date Planted (YYYY-M	IM-DD)	Was there C	omplete Germi	nation of the	Border Row?	Yes
Describe Corrective	Action taken to attain f	unctional Border	Rows				Is Border Ro	w Density ade	quate?	Yes	No
							Is Border Ro	w Growth adeo	quate?	Yes	No
							Is Border Ro	w intact?		Yes	No
BIOTECH-D	DERIVED EVE	NT UNDE	R TRIAL				1				
Reference Code/ Event Name	Permit No.		Date Planted	(YYYY-MM-DD)	Reference Code/ Event Name	Permi	t No.		Date Plan	ted (YYYY-MM-DD	))
Reference Code/ Event Name	Permit No.		Date Planted	(YYYY-MM-DD)	Reference Code/ Event Name	Permit No.			Date Planted (YYYY-MM-DD)		
DATA SHEE		ORDING IN	ISPECTIC	ONS							
Date Inspected	Growth Stage of	Trial Plants	in Flower?	Growth Stage of	Border Row Plants	Add	litional Commer	nts and Observ	ations	Inspecto	or's
(1111-00)	mai Plants	Yes	No	border Row Plants						muais	
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants	in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Add	litional Commer	nts and Observ	ations	Inspecto	or's
,		Yes	No		Yes No						
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants	in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Add	litional Commer	nts and Observ	ations	Inspecto Initials	or's
		Yes	No		Yes No						
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants	in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Add	litional Commer	nts and Observ	ations	Inspecto Initials	or's
Date Inspected	Growth Stage of	Trial Plants	In Flower?	Growth Stage of	Border Row Plants	Add	litional Commer	nts and Observ	ations	Inspecto	or's
(YYYY-MM-DD)	Trial Plants			Border Row Plants	in Flower?				-	Initials	
Date Inspected	Growth Stage of	Trial Plants	in Flower?	Growth Stage of	Border Row Plants	Add	litional Commer	nts and Observ	ations	Inspecto	or's
(YYYY-MM-DD)	Trial Plants	Ves.	No	Border Row Plants	in Flower?					Initials	



### **RECORD OF BORDER ROW ISOLATION**

						PAGE 2 of 2
DATA SHEE	FOR RECOR	DING INSPECTION	ONS (CONTINI	JED)		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Trial Plants in Flower?	Growth Stage of Border Row Plants	Border Row Plants in Flower?	Additional Comments and Observations	Inspector's Initials
		Yes No		Yes No		
ADDITIONAL	COMMENTS	AND OBSERVAT	IONS			
TRIAL MANA	AGER VERIFIC	ATION				
This activity has been approved standard op	carried out in accordance erating procedures and	e with Signatur	re of Trial Manager		Date Signed (YYY	Y-MM-DD)
management of field t crop plants	rials of experimental, bio	tech-derived				

By my signature above, I state that the information contained herein is accurate and complete to the best of my knowledge and belief

INSTR	UCTIONS		RECORD OF EARLY CROP DESTRUCT							
Prior to inflore before inflores	scence emergence	e, the trial sit	e should be ir	nspected no les	s than ONCE EVE	ERY WEEK to ensure	that trial term	ination is com	pleted	
If any experim	ental biotech-deri	ved events ad	hieve anthes	is before the tri	al is terminated, a	breach of reproduct	ive isolation	will have oc	curred.	
This <b>Record o</b> remaining on t	of Early Crop De the trial site.	struct should	be used to re	cord inspectior	n and trial terminat	ion activities and the f	ate of residua	l plant materi	al	
This Record of	of Early Crop De	struct should	be retained b	y the Trial Mar	nager.					
In the event of The incident a	f a <b>breach of rep</b> Ind any corrective	roductive iso action taken	lation, the Au should be rec	uthorised Party corded on the <b>R</b>	should be notified Record of Correct	immediately by telepl ive Action form.	hone and facs	imile or e-ma	il.	
								PAG	E 1 of 2	
TRIAL MAI	NAGER	First Name		МІ	TRIAL SITE Site Location Code	Tr	ial Site Size (m x r X	n) No. of Trials	at this site	
Company/Organisa	ation	Department/Sec	ion		Legal or Descriptive I	Land Location of Trial Site				
Street Address					Species of Biotech-de	erived Event				
City	State/Province	Zip/Postal C	ode Cou	untry						
Telephone	Facsimile	Electronic Mail			Distance to Nearest Field of Same Species (m)	Distance to Near Commercial Crop of any kind (m)	est Is ti Dis Mai	ne Isolation tance under the nager's control?	Yes	
MACHINE	RY USED FOR		STRUCT		ON-SITE DE	STRUCTION OF	PLANT M	ATERIAL		
Was all Machinerv	inspected and confirme	d free of			Indicate the Methods	of Destruction of Plant Mater	rial at the Trial Site	, 		
Plant Material prior	to entering the Trial Si	te?	Yes No		Dry Heat	Steam Heat	Burning	Chemical Tre	atment	
Indicate how Mach	inery was cleaned at th	e Trial Site followi	ng Crop Destruct	Other (detail below)	Discing	Plowing	Deep Burial	Other (detail	below)	
vacuuming	Compressed Air	High-Press		Utier (detail below)						
BIOTECH-I	DERIVED EVI	ENTS AT T	RIAL SITE							
Reference Code/	Permit No.		Date Planted (	(YYY-MM-DD)	Reference Code/ Permit No. Date Pl			Planted (YYYY-MI	nted (YYYY-MM-DD)	
Event Name					Lvent wane					
Reference Code/	Permit No.		Date Planted (	(YYY-MM-DD)	Reference Code/	Permit No.	Date	Planted (YYYY-MI	M-DD)	
Event Name					Event Name					
Reference Code/	Permit No.		Date Planted (	(YYY-MM-DD)	Reference Code/	Permit No.	Date	Planted (YYYY-MI	M-DD)	
Event Name					Event Name					
Reference Code/	Permit No.		Date Planted ()	(YYY-MM-DD)	Reference Code/	Permit No.	Date	Planted (YYYY-MI	M-DD)	
Event Name					Event Name					
DATA SHE	ET FOR REC	ORDING IN	ISPECTIO	NS AND CF	 ROP DESTRUC	Т.				
Data Inspected	Crowth Store of	Crop Destr	unt Deuterment	Dellen Ched	Additional Cam	ments and Oksen stigns		laa	nector's	
(YYYY-MM-DD)	Trial Plants	Yes	uct Penormed	Observed	Additional Con	iments and Observations		Init	ials	
		No No	Complete	Yes	No					
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Crop Destr	uct Performed	Pollen Shed Observed	Additional Corr	ments and Observations		Ins	pector's ials	
		No No	Complete	Yes	No					
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Crop Destr	uct Performed	Pollen Shed Observed	Additional Corr	nments and Observations		Ins	pector's ials	
			Complete	Yes	No					
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Crop Destr	uct Performed	Pollen Shed Observed	Additional Corr	nments and Observations		Ins	pector's ials	
			Complete	Yes	No					



### **RECORD OF EARLY CROP DESTRUCT**

									PAGE 2 of 2	
DATA SHEE	T FOR RECOR	rding insf	PECTION	IS AND CR	OP	DESTRUCT (CC	ONTINUED)	L		
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Crop Destruct P	erformed	Pollen Shed Observed		Additional Comments and	d Observations		Inspector's Initials	
		<u> </u>	Complete	Yes	No					
(YYYY-MM-DD)	Trial Plants	Yes	erformed	Observed		Additional Comments and Observations			Inspector's Initials	
Date Inspected	Growth Stage of	Crop Destruct P	Complete erformed	mplete Ves V		Additional Comments and	d Observations		Inspector's	
(YYYY-MM-DD)	Trial Plants	Yes		Observed	No				Initials	
Date Inspected (YYYY-MM-DD)	Growth Stage of Trial Plants	Crop Destruct P	erformed	Pollen Shed Observed		Additional Comments and	d Observations		Inspector's Initials	
(		Ves	Complete	nplete Yes No						
DATA SHEE	T FOR RECOR	RDING DISF	POSITIO	N		I				
Reference Code/Ever	nt Name		Permit No.		Des	truct Date	Trial Manager Signa	ture		
Boforonoo Codo/Evor	at Nama		Pormit No		Dee	truct Data	Trial Managar Signs	turo		
	it Name		r ennit No.		Des		manager olyna	luie		
Reference Code/Ever	nt Name		Permit No.		Des	truct Date	Trial Manager Signa	ture		
Reference Code/Event Name			Permit No.		Destruct Date		Trial Manager Signa	ture		
Reference Code/Event Name		Permit No.	Permit No.		truct Date	Trial Manager Signa	ture			
Reference Code/Event Name		Permit No.		Des	truct Date	Trial Manager Signa	ture			
Reference Code/Ever	nt Name		Permit No.	o. Destruct Date		Trial Manager Signa	ture			
Reference Code/Ever	nt Name		Permit No.		Des	truct Date	Trial Manager Signa	ture		
ADDITIONAI	L COMMENTS	S AND OBSI	ERVATIC	ONS (Indica	te n	nethod of destr	uction of pla	nts)		
TRIAL MAN	AGER VERIFIC	CATION								
This activity has been approved standard op applicable regulation	carried out in accordan	ice with with	Signature o	f Trial Manager				Date Signed (YYYY	-MM-DD)	
management of field t crop plants	rials of experimental, bio	otech-derived								
	By my signature above, I state that the information contained herein is accurate and complete to the best of my knowledge and belief									

INSTRU	UCTIONS	RECORD OF CORRECTIVE ACTION								ΓΙΟΝ
The Record of release of an isolation durin	f Corrective Acti experimental bio	i <b>on</b> is used to do otech-derived ev g of an experimen	cument all co vent during to ntal biotech-co	orrective action ransport, sto derived event	ons taken to mitigate or r rage, harvest or the post- t.	esolve a situ -harvest per	uation involvi iod or any <b>br</b>	ng the u each o	unintende f reprodue	d ctive
A copy of this F Inventory, Reco	Record of Correc ord of Spatial Iso	tive Action, toget lation, Record of	her with any Harvest, etc	other relevant), should be	nt records (i.e. Record of forwarded by facsimile or	Transport, F r e-mail to th	Record of Sto e Authorised	orage In Party.	ispection &	k
									PAG	E 1 of 2
RECORD IN Last Name	NITIATED BY	First Name		мі	TRIAL SITE Site Location Code		Trial Site Size ( X	(m x m)	No. of Trials	at this site
Company/Organisat	tion	Department/Section			Legal or Descriptive Land Loc	ation of Trial Sit	e			
Street Address					Distance to Nearest Distance to Nearest Is the Isolation			olation	Yes	
City	State/Province	Zip/Postal Code	Countr	v	Field of Same Species (m)	Commercial of any kind (I	Crop n)	Distanc Manage	e under the er's control?	No No
Telephone	Facsimile	Electronic Mail			Inflorescence Removal,	Bagging or Tent	ing			
						Early Crop Dest	ruct Borde	r Rows	_	
ACTIVITY F Indicate the Categor	REQUIRING C	Corrective Action and	complete the rel	evant sections	IDENTIFICATION Check all that apply	OF COM	PLIANCE	ISSU	E	
Transport	Storage Plan	nting Monitoring	Harvesti	ng Other	Unauthorised Shipment		Art	ticle Lost o	during Shipme	ənt
If other, describe be	elow				Primary Shipping Container Breached Record of Transport Missing					
					Unintended Release dur	ring Transport	Re	eceived at	Wrong Destir	nation
TRANSPOR	RT AND STO	RAGE			Unintended Release dur	ing Storage	Br	each of G	uard Row Iso	lation
Shipment No.		Item No.			Breach of Spatial Isolation	on	□ ot	her (detai	below)	
5 10 0 1					Details of Compliance					
Facility Code		Storage Locat	ion Identifier							
Building Name or ID	)	Room Numbe	r or Description		-					
Street Address (if di	ifferent from above)				-					
IDENTIFICA	ATION OF AF	FECTED BIO	TECH-DE	RIVED E	/ENT					
Permit No.	Plant Sp	pecies	Approx. Amou Affected Mate	ınt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole I	Plants
Permit No.	Plant Sp	pecies	Approx. Amou Affected Mate	int of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole I	Plants
Permit No.	Plant Sp	pecies	Approx. Amou	int of	Form of Material					
		Affected Mate		nai (kg)	Seeds Budwood/	Shoots T	ransplants	Tubers	Whole I	Plants
Permit No.	Plant Sp	pecies	Approx. Amou Affected Mate	ınt of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole I	Plants
Permit No.	Plant Sp	pecies	Approx. Amou Affected Mate	int of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole I	Plants
Permit No.	Plant Sp	pecies	Approx. Amou Affected Mate	int of rial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole I	Plants



### **RECORD OF CORRECTIVE ACTION**

PAGE	2	of	2
PAGE	2	στ	2

DESCRIPTION OF CORRECT	TIVE ACTION TAKEN	4			L
Check all that apply					
Destruction of Exp. Biotech-derived Event	Recovery of Spilled Material	Imp	ose Post Harvest Restrictions	Roguing	of Prohibited Plants
Other (details below)	Imposition of Spatial Isolation	Zone Des	truction of Neighbouring Crop	Destructi	on of Trial
Details of Corrective Action taken					
THIS SECTION IS TO BE CO	MPLETED BY THE A	UTHORISED	PARTY		
COMMUNICATION WITH RE			Facsimile	F-mail	Date first contacted
Name of Onicial Inst Contacted Departme		ephone	1 desimile	L-mai	Date inst contacted
Summarise communication outcomes, including a Attach any written correspondence or transcripts of	greed options for risk mitigation. Iten of oral communications.	nise all communications	, recording date and individuals	involved.	
VEDIEIOATION					
VERIFICATION The corrective actions detailed in this report have	been Signature of Facili	ity Manager, Trial Manag	per or Authorised Party	D	ate Signed (YYYY-MM-DD)
carried out in accordance with approved standard operating procedures and with applicable regulation	ons	,	,		
governing the transport, storage and field testing of experimental biotech-derived plant material	of				
	By my signature a accurate and com	bove, I state that the in plete to the best of my I	formation contained herein is knowledge and belief		



## Appendix 5: Sample harvest SOP

# STANDARD OPERATING PROCEDURE (SOP) FOR THE HARVEST/TERMINATION AND DISPOSITION OF FIELD TRIALS OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL WITHIN [COUNTRY]

Note: This Standard Operating Procedure (SOP) is intended solely as an example that may be used as an educational resource by organisations that are developing or revising their own quality management programs for confined field trials of experimental biotech-derived plants. This example should not be used as a substitute for the user's own understanding and compliance with regulations governing the conduct of such trials.

#### A. DESCRIPTION OF THE ACTIVITY

A.1. The appropriate termination/harvest and disposition of field trials of biotech-derived plants in [country].

#### B. SCOPE

B.1. This SOP will cover the harvest or termination of all confined field trials of experimental biotechderived plant material cultivated in [country].

#### C. SOP AUTHORISATION

Name of Authorised Party: Title: Signature: Date: Implementation Date: In Effect Until:

#### D. TERMINOLOGY

Possible terms that could be relevant in this SOP. For specific definition, see Appendix 1.

- D.1. Authorised Party
- D.2. Biotech-derived
- D.3. Biotech-derived plant material
- D.4. Early termination
- D.5. Field trial
- D.6. Regulatory authority
- D.7. Trial Manager
- D.8. Trial site
- D.9. Trial site location
- D.10. Unintended release

#### E. GENERAL REQUIREMENTS

E.1. The Authorised Party and all other agents acting on behalf of the Authorised Party shall comply with this SOP.

#### F. REQUIREMENTS FOR HARVEST OF TRIAL SITES

- F.1. The requirements in this section apply to the harvest of all confined trial sites, including trial sites that may be prematurely terminated prior to the anticipated harvest date.
- F.2. No plant material from the trial site, including material from border rows, shall enter the human food or animal feed chains.
- F.3. All equipment used to harvest the trial site shall be free of plant material before entering the trial site, including seed and vegetative material that may be present from prior operations.
- F.4. All equipment used to harvest a trial site shall be cleaned on the trial site to eliminate unintended transport of plant material from the site. Acceptable methods of cleaning include hand-cleaning, compressed air, vacuuming of remaining seed, and high-pressure water.
- F.5. Any residual plant material recovered during the process of cleaning field equipment shall be destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labelled herbicides and/or chemicals and disposed of on the trial site in a burial pit.
- F.6. All activities related to harvest of a trial site shall be recorded in the Record of Harvest/Termination.

#### G. EARLY TERMINATION OF TRIAL SITES

- G.1. Trial sites that are terminated before trial completion (before seed set or before formation of ear, tuber or any reproductive material) shall be destroyed appropriately as described in section H.
- G.2. Post-harvest restrictions shall apply to trial sites that are terminated early where propagative material may remain from planting and volunteer in subsequent years.
- G.3. All activities related to early termination of a trial site shall be recorded in the Record of Harvest/ Termination and Disposition.

#### H. DESTRUCTION OF BIOTECH-DERIVED PLANT MATERIAL

- H.1. Plant material from a trial site that is not retained for research purposes, including border rows, shall be destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labelled herbicides and/or chemicals and disposed of in a burial pit on the trial site.
- H.2. The Trial Manager shall monitor harvesting at trial sites to ensure that all experimental biotech-derived plant material that is not retained is disposed of as described in H.1.

#### I. TRANSPORT OF HARVESTED MATERIALS FROM THE TRIAL SITE

I.1. All plant material harvested from a trial site and retained shall be secured during transport from the trial site to the receiving facility to prevent any unintended release.

#### J. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

- J.1. If an unintended release of experimental biotech-derived plant material is suspected to have occurred from the trial site, the Trial Manager shall treat this as a case of unintended release and immediately notify the Authorised Party who will initiate appropriate reporting and corrective actions.
- J.2. In the event of a confirmed unintended release of experimental material, all attempts shall be made to recover as much of the material as possible. This material shall be destroyed.
- J.3. The location of an unintended release shall be marked and monitored to ensure that all the experimental material arising from the unintended release (*e.g.*, volunteer plants) is destroyed. The period of monitoring will be determined in consultation with the Authorised Party.
- J.4. In the event of a confirmed unintended release during harvest the Trial Manager shall immediately notify the Authorised Party by telephone. The Authorised Party shall notify the Regulatory Authority immediately by telephone and in writing within 24 hours of any unintended release.
- J.5. The unintended release of experimental material during harvest shall be immediately documented by the Trial Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Trial Manager and copies shall be submitted by facsimile to the Authorised Party.

#### K. RECORD KEEPING

K.1. The Record of Harvest/Termination and Disposition shall be completed by the Trial Manager immediately following harvest or early termination of a trial site. One copy shall be retained by the Trial Manager and one copy shall be submitted to, and retained by, the Authorised Party.

#### L. RELATED SOPS

L.1. The following SOPs shall also be consulted: [List any related SOPs]

#### M. REVIEW AND DISTRIBUTION

- M.1. This SOP shall be reviewed by the Authorised Party no less than annually.
- M.2. Revised SOPs will be distributed to all agents acting on behalf of the Authorised Party, who shall then destroy their older copy.
- M.3. Archival copies of this SOP shall be maintained by the Authorised Party for no less than [X] years.

#### N. ASSURANCE


## Appendix 5: Sample harvest SOP

N.1. I have read this document and approve of its contents. I certify that this document will be made available to all personnel to which it applies.

Name of Authorised Party (please print):

Signature of Authorised Party:

Date:

INSTRUCTIONS RECORD OF HARVEST/TERMINATION											
This <b>Record of Harvest/Termination</b> should be completed following harvest or early termination and disposition of plant material at a trial site, and should document the method of harvest, the harvest date(s), and the fate of all harvested materials and any residual plant material remaining on the trial site.											
The <b>Record of Harvest/Termination</b> should be retained by the <b>Trial Manager</b> and a copy should be forwarded to the Authorised Party within <b>FIVE (5) DAYS OF HARVEST/TERMINATION</b> of the trial.											
In the event of a <b>breach</b> The incident and any cor	of reproductive rective action tal	isolation, the Auth ten should be record	orised Party ded on the <b>F</b>	should be notified immed Record of Corrective Act	liately by telephone and : <b>ion</b> form.	facsimile or e-mail.					
Last Name	First Name		м	TRIAL SITE Site Location Code	Trial Site Size (	m x m) No. of Trials at this site					
Company/Organisation	Departmen	/Section		Legal or Descriptive Land Loca	ation of Trial Site						
Street Address				Species of Biotech-derived Eve	ent						
City State/Provir	ICE ZIP/Pos	tal Code Countr	У	Distance to Nearest	Distance to Nearest	Is the Isolation Yes					
Telephone Facsimile	Electronic N	fail		Field of Same Species (m)	Commercial Crop of any kind (m)	Distance under the Manager's control?					
	Reason for Termination Planned Termination Corrective Action										
HARVEST MACHIN	IERY			Was All Machinery Inspected a	nd Confirmed Free of						
Method used for Harvest Dessicate and Combine	Swath and Com	bine By Hand		Than Matcha pro to choring		Yes No					
				Indicate how Machinery was cl	eaned at the Trial Site following I	Harvest					
Machinery used for Harvest				Vacuuming Comp	ressed Air High-Pressure	Water Other (below)					
Large Combine Sn	nall Combine	Other (detail below)									
ON-SITE DESTRUC	CTION OF PL	ANT MATERIA	L								
Indicate the Methods of Destruct	on of Regulated Plant	Material at the Trial Site									
Dry Heat Steam Hea	at Burning	Chemical Treatment	Discing	Plowing Deep Burial	Other (below)						
DATA SHEET FOR	RECORDING	HARVEST AN	ID RETEN	ITION OF PLANT M	ATERIAL						
Reference Code/Event Name	Permit No.	Amount Harv	ested (kg) Qu	uantity Retained/Stored (kg)	Harvest Date	Type of Material Retained					
Biotech-derived Events Shipmen	t No.	Biotech-derived Events Beceived into Storage	Storage Facility	Manager Address and Telephone	Number	- Grain/Seed					
						Vegetative Material					
Reference Code/Event Name	Permit No.	Amount Harv	ested (kg) Qu	uantity Retained/Stored (kg)	Harvest Date	Type of Material Retained					
Biotech-derived Events Shipmen	t No.	Biotech-derived Events	Storage Facility	Manager Address and Telephone	Number	- Grain/Seed					
Shipped from Site		Received into Storage				Vegetative Material Whole Plants					
Reference Code/Event Name	Permit No.	Amount Harv	ested (kg) Qu	uantity Retained/Stored (kg)	Harvest Date	Type of Material Retained					
Biotech-derived Events Shipmen	t No.	Biotech-derived Events	Storage Facility	Manager Address and Telephone	Number	Grain/Seed					
		Yes No				Vegetative Material					
Reference Code/Event Name	Permit No.	Amount Harv	vested (kg) Qu	uantity Retained/Stored (kg)	Harvest Date	Type of Material Retained					
Biotech-derived Events Shipmen Shipped from Site	t No.	Biotech-derived Events Received into Storage	Storage Facility	Manager Address and Telephone	Number	Graín/Seed					
Yes No		Yes No				Whole Plants					



Appendix 5: Sample harvest SOP

RECORD	OF HARVES	T/TERMINATION

							PAGE 2 of 2
DATA SHEET FOR RECORDING		VEST AND	RET	ENTION OF PLANT MATE	ERIAL (CON	TINUED)	
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of Ma	aterial Retained
Biotech-derived Events Shipment No.	Biotech-d	erived Events Sto	orage Fa	cility Manager Address and Telephone Numb	er	Grain	1/Seed
Shipped from Site	Received	into Storage				Vege	tative Material
	Yes	s 🛄 No				Who	le Plants
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of Ma	aterial Retained
Biotech-derived Events Shipped from Site	Biotech-d Received	erived Events Sto into Storage	orage Fa	cility Manager Address and Telephone Numb	er		etative Material
Yes No	Yes	s 🗌 No				Who	le Plants
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of M	aterial Retained
Biotech-derived Events Shipment No.	Biotech-d	erived Events Sto	orage Fa	cility Manager Address and Telephone Numb	er	Grain	1/Seed
							tative Material
Beference Code/Event Name Permit No		Amount Harveste	ed (ka)	Quantity Retained/Stored (kg)	Harvest Date	Type of M	le Plants
						Grain	n/Seed
Biotech-derived Events Shipment No.	Biotech-d Received	into Storage	orage Fa	cility Manager Address and Telephone Numb	er		atative Material
Yes No	Yes	s 🗌 No				Who	le Plants
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of Ma	aterial Retained
Biotech-derived Events Shipment No.	Biotech-d Beceived	erived Events Sto	orage Fa	cility Manager Address and Telephone Numb	er	Grain	1/Seed
	Yes	s No					tative Material
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of Ma	aterial Retained
Biotech-derived Events Shipment No.	Biotech-d	erived Events Sto	orage Fa	cility Manager Address and Telephone Numb	er	Grain	n/Seed
Shipped from Site	Received	into Storage				Vege	tative Material
	Ye:	s 🛄 No				Who	le Plants
Reference Code/Event Name Permit No.		Amount Harveste	ed (kg)	Quantity Retained/Stored (kg)	Harvest Date	Type of Ma	aterial Retained
Biotech-derived Events Shipment No. Shipped from Site	Biotech-d Received	erived Events Sto into Storage	orage Fa	cility Manager Address and Telephone Numb	er		etative Material
Yes No	Yes	s 🗌 No				Who	le Plants
ADDITIONAL COMMENTS AND	OBSE	RVATIONS	5			I	
TRIAL MANAGER VERIFICATIO	N						
This activity has been carried out in accordance with approved standard operating procedures and with		Signature of Tria	ıl Manag	er		Date Signed (YYY	Y-MM-DD)
applicable regulations/permit conditions for the management of field trials of experimental, biotech-deriv	/ed						
crop plants							
		By my signature	above. I	state that the information contained herein is	6		
		accurate and cor	mplete to	the best of my knowledge and belief			

The Record of Corrective Action is used to document all corrective actions taken to mitigate or resolve a situation involving the unintend release of an experimental biotech-derived event.         A copy of this Record of Corrective Action, together with any other relevant records (i.e. Record of Transport, Record of Storage Inspection Inventory, Record of Spatial Isolation, Record of Harvest, etc), should be towarded by facsimile or e-mail to the Authorised Party.         Pace Address       TRIAL_SITE         Distribution (Corrective Action, together with any other relevant records (i.e. Record of Transport, Record of Storage Inspection Inventory, Record of Spatial Isolation, Record of Harvest, etc), should be towarded by facsimile or e-mail to the Authorised Party.         Pace Address       Trial Site Size (in x.m)       No. of Trial Site Size (in x.m)       No. of Trial Site Size (in x.m)         Company/Organization       Department/Becton       Legal or Decriptive Land Location of Trial Site Size (in x.m)       No. of Trial Site Size (in x.m)         Company/Organization       Department/Becton       Counter of Nameer Site Size (in x.m)       No. of Trial Site Size (in x.m)         Company/Organization       Department/Secton       Counter of Nameer Site Size (in x.m)       No. of Trial Site Size (in x.m)         Company/Organization       Department/Secton       Counter of Nameer Site Size (in x.m)       No. of Trial Site Size (in x.m)         Company/Organization       Department/Secton       Counter of Nameer Site Size (in x.m)       No. of Trial Site Size (in x.m)	RECORD OF CORRECTIVE ACTION								NS	INSTRUCTIO
RECORD INITIATED BY Lata Name       First Name       M       TRIAL SITE She Location Code       Tail She Size (m x m) X       No of Trie X         Company/Organisation       Department/Section       Ligal or Descriptive Land Location of Trial She       Ligal or Descriptive Land Location of Trial She         Street Address       Distance to Neareed Pack of Bame       Is the footBatton Distance under the Distance to the Manager's authority Distance to the Manager's authority Pack of Bame         Ory       State/Province       ZapPastal Code       Country       Interscence Removal, Bagging or Terring         Betwoet the Category of Activity Requiring Correct-le Action and complete the relevant accion If Transport       Bacter of Activity Requiring Correct-le Action and complete the relevant accione If Transport And Storage       Description       Description Content the Activity Shipping Container Breached       Perceived al Wong Description         TRANSPORT AND STORAGE Solpment No.       Item No.       Item No.       Item No.       Perma No.       Perma No.       Perma No.       Description         Strenge Location Identifier       Building Name or ID       Record of Tansport of Approx. Annourt of Affected Material (ig)       Form or Manarai       Transplants       Toters (whee Permit No.         Part Specicies       Approx. Annourt of Affec	d ctive	g the <b>unintended</b> <b>ach of reproduct</b> age Inspection & Party.	uation involvin riod or any <b>br</b> Record of Sto ne Authorised	resolve a siti -harvest per Transport, I r e-mail to th	ons taken to mitigate or r rage, harvest or the post t. nt records (i.e. Record of forwarded by facsimile o	orrective acti ransport, sto derived even other releva ), should be	cument all co vent during t ntal biotech-co her with any Harvest, etc	is used to do <b>ch-derived e</b> f an experiment Action, toget on, Record of	ctive Action nental biote eld testing of of Corrective patial Isolation	The Record of Correc release of an experim isolation during the fie A copy of this Record c Inventory, Record of Sp
RECORD INITIATED BY Last Name         First Name         MI         TRIAL SITE Site Location Code         Trail Site Size (m x m) x         No. of Trial x           Company/Organisation         Department/Section         Legal or Descriptive Land Location of Trial Site         x           Street Address         Distance in Normert Back of Bane Sectors (m x m)         No. of Trial x         No. of Trial x           City         State/Province         ZapPostal Code         Country         Elegation of Trial Site         In the Instant Generative Company of any kind (m)         In the Instant Manager's control?           City         State/Province         Electronic Mail         Descriptive Land Location of Trial Site         In the Instant Manager's control?           Activity Requiring Corrective Action Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections If other, describe below         Internet on Normert Control of CoOMPLIANCE SISUE           TRANSPORT AND STORAGE Shipment No.         Item No.         Item No.         Primary Shipping Container Breached Unintended Release during Storage         Breach of Gaud Row Is Storage Location Identifier           Building Name or ID         Room Number or Description         Form of Material         Storage Location Identifier           Building Name or ID         Room Number or Description         Form of Material         Elegen descriptive of Shoreds         Transplants         Tubers	E 1 of 2	PAGE								
Company/Organisation         Department/Section           Street Address         Legal or Descriptive Land Location of Trial Site           City         State/Province         ZipPostal Code         Country         Distance to Nearest Species (m)         Distance to Nearest Species (m)         Distance to Nearest Species (m)         Is the isolation of any kind (m)         Is the isolation Manager is control?           City         State/Province         ZipPostal Code         Country         Inforescence Removel. Bagging or Tenting         Is the isolation Bardet the Category of Activity Requires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Action and complete the relevant section indicate the Category of Activity Reguires Corrective Active Action and complete the relevant section is the activity of Activity Reguires Corrective Active	s at this site	n x m) No. of Trials a	Trial Site Size (		TRIAL SITE Site Location Code	MI		rst Name	ED BY	RECORD INITIAT
Street Address       Distance to Nearest Field of Same       Distance to Nearest Field of Same       Distance to Nearest Field of Same       Is the Isolation Distance under the Manager's control?         City       State/Province       Zip/Postal Code       Country       Intersection to Nearest Field of Same       Distance to Nearest Field of Same       Distance to Nearest Field of Same       Distance to Nearest Field of Same       Is the Isolation Distance under the Manager's control?         Telephone       Facinitie       Electronic Mail       Intersection Comparison       Electronic Mail         ACTIVITY REQUIRING CORRECTIVE ACTION Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections If andre, describe below       IDENTIFICATION OF COMPLIANCE ISSUE Check all hat apply         Transport       Is the Isolation If other, describe below       Article Lost during Shipment       Article Lost during Shipment         TRANSPORT AND STORAGE Shipment No.       Item No.       Item No.       Breach of Spatial Isolation       Other (detail below)         Facility Code       Storage Location Identifier       Breach of Spatial Isolation       Other (detail below)         Item No.       Part Species       Approx. Amount of Affected Material (kg)       Form of Material         Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material         Permit No.       Plant Species			te	ation of Trial Sit	Legal or Descriptive Land Loc	1		epartment/Section	De	Company/Organisation
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City       State/Province       ZipPostal Code       Country         Telephone       Facsimile       Electronic Mail       Spatial Isolation       Early Crop Destruct       Border Rows         ACTIVITY REQUIRING CORRECTIVE ACTION       Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections       IDENTIFICATION OF COMPLIANCE ISSUE         Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections       IDENTIFICATION OF COMPLIANCE ISSUE         I' tother, describe below       Planting       Monitoring       Harvesting       Other         I' tother, describe below       Planting       Monitoring       Harvesting       Other         TRANSPORT AND STORAGE       Item No.       Item No.       Breach of Spatial Isolation       Other (detail below)         Facility Code       Storage Location Identifier       Breach of Spatial Isolation       Other (detail below)         Building Name or ID       Room Number or Description       Storage Isolation Identifier       East of Compliance         Building Name or ID       Room Number or Description       Form of Material       Seeds       Budwood/Shoots       Transplants       Tubers       Whole         Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material       Seeds       Budwood/Shoots	Yes No	Is the Isolation Distance under the Manager's control?	Nearest Crop m)	Distance to I Commercial of any kind (	Distance to Nearest Field of Same Species (m)					
Telephone       Facsimile       Electronic Mail <ul> <li>Bypatial isolation</li> <li>Early Crop Destruct</li> <li>Border Rows</li> </ul> ACTIVITY REQUIRING CORRECTIVE ACTION       IDENTIFICATION OF COMPLIANCE ISSUE         Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections       IDENTIFICATION OF COMPLIANCE ISSUE         I'rransport       Storage       Planting       Monitoring       Harvesting       Other         I'rdife, describe below       Primary Shipping Container Breached       Record of Transport Mis       Period Quard Row Is         TRANSPORT AND STORAGE       Item No.       Item No.       Item No.       Primary Shipping Container Breached       Breach of Quard Row Is         Shipment No.       Item No.       Item No.       Item No.       Breach of Spatial Isolation       Other (detail below)         Details of Compliance       Storage Location Identifier       Building Name or ID       Room Number or Description       Details of Compliance         Street Address (if different from above)       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material         Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material       Transplants       Tubers       Whole         Permit No.       Plant Species			ting	Bagging or Tent	Inflorescence Removal,	У	Countr	Zip/Postal Code	ovince	City State/Pro
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Indicate the Category of Activity Requiring Corrective Action and complete the relevant sections       Check all that apply         Transport       Storage       Planting       Monitoring       Harvesting       Other         If other, describe below       If other, describe below       Primary Shipping Container Breached       Record of Transport Mis         TRANSPORT AND STORAGE       Unintended Release during Storage       Breach of Guard Row Is         Shipment No.       Item No.       Breach of Spatial Isolation       Other (detail below)         Facility Code       Storage Location Identifier       Breach of Spatial Isolation       Other (detail below)         Building Name or ID       Room Number or Description       Details of Compliance       Details of Compliance         IDENTIFICATION OF AFFECTED BIOTECH-DERIVED EVENT       Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material         Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material       Transplants       Tubers       Whole         Permit No.       Plant Species       Approx. Amount of Affected Material (kg)       Form of Material       Seeds       Budwood/Shoots       Transplants       Tubers       Whole		SSUE	IPLIANCE	OF COM	IDENTIFICATION		ACTION	RRECTIVE	RING CO	ACTIVITY REQUI
If other, describe below       Itenness in the tenness in tenness in tenness in the tenness in tenne	ent	de Lost during Shipmen	Art		Check all that apply	evant sections	complete the rel	rrective Action and	ty Requiring Cor	Indicate the Category of Activity
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Permit No.         Plant Species         Approx. Amount of Affected Material (kg)         Form of Material	Plants	Tubers Whole Pla	Transplants	'Shoots 🔲 T	Form of Material	unt of rial (kg)	Approx. Amou Affected Mate	95	Plant Specie	Permit No.
Affected Material (kg)					Form of Material	unt of	Approx. Amou	es	Plant Specie	Permit No.
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Permit No.     Plant Species     Approx. Amount of Affected Material (kg)     Form of Material       Seeds     Budwood/Shoots     Transplants     Tubers     Whole	Plants	Tubers Whole Pla	Transplants	'Shoots T	Form of Material	unt of rial (kg)	Approx. Amou Affected Mate	95	Plant Specie	Permit No.
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Permit No.     Plant Species     Approx. Amount of Affected Material (kg)     Form of Material       Seeds     Budwood/Shoots     Transplants     Tubers     Whole	Plants	Tubers Whole Pla	Transplants	'Shoots T	Form of Material	unt of rial (kg)	Approx. Amou Affected Mate	95	Plant Specie	Permit No.



Appendix 5: Sample harvest SOP

# **RECORD OF CORRECTIVE ACTION**

PAGE 2 of 2
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DESCRIPTION OF CORRECT Check all that apply	CTIVE ACTION TA	KEN			
Destruction of Exp. Biotech-derived Event	Recovery of Spilled M	laterial	Impose Post Harvest Restrictions	Roguing of Prohibit	ed Plants
Other (details below)	Imposition of Spatial I	solation Zone	Destruction of Neighbouring Crop	Destruction of Trial	
Details of Corrective Action taken					
THIS SECTION IS TO BE C	OMPLETED BY T	HE AUTHORIS	ED PARTY		
COMMUNICATION WITH RE	EGULATORY AUT		Facsimile	F-mail	Date first contacted
Summarise communication outcomes, including	agreed options for risk mitigat	ion. Itemise all communic	l ations, recording date and individuals	involved.	
	or oral communications.				
VERIFICATION					
The corrective actions detailed in this report hav carried out in accordance with approved standar	e been Signature	of Facility Manager, Trial I	Manager or Authorised Party	Date Signed	d (YYYY-MM-DD)
operating procedures and with applicable regula governing the transport, storage and field testing experimental biotech-derived plant material	tions g of				
	By my sign accurate a	nature above, I state that and complete to the best of	the information contained herein is f my knowledge and belief		



# STANDARD OPERATING PROCEDURE (SOP) FOR POST-HARVEST MANAGEMENT OF FIELD TRIALS OF EXPERIMENTAL BIOTECH-DERIVED PLANT MATERIAL WITHIN [COUNTRY]

Note: This Standard Operating Procedure (SOP) is intended solely as an example that may be used as an educational resource by organisations that are developing or revising their own quality management programs for confined field trials of experimental biotech-derived plants. This example should not be used as a substitute for the user's own understanding and compliance with regulations governing the conduct of such trials.

## A. DESCRIPTION OF THE ACTIVITY

A.1. The appropriate post-harvest management of field trials for biotech-derived plants in [country].

#### B. SCOPE

B.1. This SOP will cover all confined field trials of experimental biotech-derived plant material cultivated in [country].

## C. SOP AUTHORISATION

Name of Authorised Party: Title: Signature: Date: Implementation Date: In Effect Until:

## D. TERMINOLOGY

Possible terms that could be relevant in this SOP. For specific definition, see Appendix 1.

- D.1. Anthesis
- D.2. Authorised Party
- D.3. Biotech-derived
- D.4. Biotech-derived plant material
- D.5. Field trial
- D.6. Prohibited plants
- D.7. Regulatory authority
- D.8. Trial Manager
- D.9. Trial site
- D.10. Trial site location
- D.11. Unintended release
- D.12. Volunteers

#### E. GENERAL REQUIREMENTS

E.1. The Authorised Party and all other agents acting on behalf of the Authorised Party shall comply with this SOP.

#### F. REQUIREMENTS FOR POST-HARVEST OF CONFINED TRIAL SITES

- F.1. Trial sites of experimental biotech-derived plants shall be subject to the period of post-harvest land use restriction specified by the Regulatory Authority.
- F.2. The post-harvest period begins immediately upon harvest of the trial site or termination of the trial site for any other reason.
- F.3. During the post-harvest period, no plant material from trial sites shall enter the human food or animal feed chains.
- F.4. The Authorised Party shall ensure that the Trial Manager maintains ownership and/or control of the trial site during the post-harvest period. This assurance shall be obtained in writing before the trial site is planted.

- F.5. The Trial Manager shall ensure that no plants of the same or sexually compatible species as the plants grown in the confined trial are cultivated on the trial site during the post-harvest period. This prohibition also applies to: the border row area if that means of reproductive isolation was used during the prior growing season and to the isolation distance if it is included for post-harvest monitoring (see F.9.1).
- F.6. The Trial Manager shall ensure that the trial site is inspected for the presence of volunteers or other prohibited plants no less than ONCE EVERY FOUR WEEKS during the period that post-harvest land use restrictions are in effect.
- F.7. During the post-harvest period, all volunteers and other prohibited plants shall be eliminated from the trial site before anthesis, destroyed by dry heat, steam heat, incineration, crushing, deep burial, or treatment with appropriately labelled herbicides and/or chemicals, and disposed of on the trial site in a burial pit.
- F.8. If any prohibited plants are permitted to complete anthesis the period of post-harvest restriction shall be extended by another twelve months.
- F.9. Only the trial site, including the border row area (where applicable), shall be subject to land use restrictions during the post-harvest period with the following exception:
- F.9.1. Where spatial isolation was used during the trial period and a breach of reproductive isolation was deemed to have occurred, the trial site area plus the isolation distance shall be subject to post-harvest restrictions.
- F.10. All post-harvest inspections and related activities shall be recorded in the Record of Post-Harvest Inspection.

## G. MONITORING OF THE POST-HARVEST TRIAL SITE

- G.1. The Trial Manager, or a person so designated as an inspector by the Trial Manager, shall inspect the field trial site no less than ONCE EVERY FOUR WEEKS during the growing season(s) for the period that post-harvest land use restrictions are in effect.
- G.2. At the time of inspection the growth stage of any prohibited plants shall be recorded on the Record of Post-Harvest Inspection.

## H. CORRECTIVE ACTION IN THE EVENT OF AN UNINTENDED RELEASE

- H.1. If an unintended release of experimental biotech-derived plant material is suspected to have occurred from the trial site during the post-harvest period, the Trial Manager shall treat this as a case of unintended release and immediately notify the Authorised Party who will initiate appropriate reporting and corrective actions.
- H.2. In the event of a confirmed unintended release of experimental material, all attempts shall be made to recover as much of the material as possible. This material shall be destroyed.
- H.3. The location of an unintended release shall be marked and monitored to ensure that all the experimental material arising from the unintended release (*e.g.*, volunteer plants) is destroyed. The period of monitoring will be determined in consultation with the Authorised Party.
- H.4. In the event of a confirmed unintended release during the post-harvest period the Trial Manager shall immediately notify the Authorised Party by telephone. The Authorised Party shall notify the Regulatory Authority immediately by telephone and in writing within 24 hours of any unintended release.
- H.5. The unintended release of experimental material during the post-harvest period shall be immediately documented by the Trial Manager in a Record of Corrective Action. The original Record of Corrective Action shall be retained by the Trial Manager and copies shall be submitted by facsimile to the Authorised Party.

## I. RECORD KEEPING

- I.1. The Record of Post-Harvest Inspection shall be completed by the Trial Manager during each growing season when post-harvest land use restrictions are in place.
- I.2. After the post-harvest period is completed, the Trial Manager shall provide a copy of the Record of Post-Harvest Inspection to the Authorised Party and retina the original.

## J. RELATED SOPS

J.1. The following SOPs shall also be consulted: [List any related SOPs]



## K. REVIEW AND DISTRIBUTION

- K.1. This SOP shall be reviewed by the Authorised Party no less than annually.
- K.2. Revised SOPs will be distributed to all agents acting on behalf of the Authorised Party, who shall then destroy their older copy.
- K.3. Archival copies of this SOP shall be maintained by the Authorised Party for no less than [X] years.

#### L. ASSURANCE

L.1. I have read this document and approve of its contents. I certify that this document will be made available to all personnel to which it applies.

Name of Authorised Party (please print):

Signature of Authorised Party:

Date:

INSTR	UCTIONS		F	RECOR	DO	F PO	ST-HAR	VEST	INSF	PECTION
Trial sites shout the period that normally the back	uld be inspected for post-harvest restination	or the presen rictions are ir	ce of prohibite n effect. The pe	d plants no les eriod of post-h	ss than <b>C</b> arvest re	NCE EVE	ERY FOUR (4) W egins on the date	EEKS durin of terminat	g the grow ion of the t	ring season for rial, which is
If any <b>breach</b>	of reproductive is	solation occ	urred during pe	erformance of	the trial,	the post-h	narvest restriction	s, including	the require	ements for
This Record o	of Post-Harvest Ir	ispection sh	ould be retaine	ed by the Trial	Manage	r. Upon c	ompletion, a cop	/ of the sign	ied Record	d of Post-
Harvest Inspe	ection should be for	orwarded to t	the Authorised	Party.	-					
In the event of The incident a	a breach of repr	oductive iso	blation, the Au	thorised Party	should b lecord o	e notified f Correcti	immediately by to ve Action form	elephone an	nd facsimile	e or e-mail.
										PAGE 1 of 2
	NAGER	First Name		L MI				Trial Site Si	70 (m v m)	No. of Tripla at this sit
Last Name		First Name			Sile Loca			X		NO. OF THAIS AT THIS SID
Company/Organisa	tion	Department/Sec	tion		Legal or	Descriptive L	and Location of Trial S	ite		
Street Address					Species	of Biotech-de	rived Event			
Olto	Oberta (Dereviewer	71:0 (De state) 0			_					
City	State/Province	Zip/Postal C	ode Cour	ntry	Distance	to Nearest	Distance to	Nearest	Is the Iso	
Telephone	Facsimile	Electronic Mail			Field of Species	Same (m)	Commercia of any kind	l Crop (m)	Distance Manager	under the 's control? No
					Area Un	der Post-Han	vest Restrictions	Isolation Dista	ance (m) F	Post-Harvest Year
					Tria	al Area Only	Isolation Zone			1 2
BIOTECH-D	DERIVED EVE	NTS PRE	VIOUSLY A	T THE TRI	AL SIT	E				
Reference Code/	Permit No.		Date Planted (Y	YYY-MM-DD)	Reference	e Code/	Permit No.		Date Plante	ed (YYYY-MM-DD)
Event Name					Event Na	ame				
Beference Code/	Permit No.		Date Planted (Y)	YYY-MM-DD)	Reference	e Code/	Permit No.		Date Plante	ed (YYYY-MM-DD)
Event Name					Event Na	ame				
Poforonoo Codo/	Pormit No		Data Blantad (V)		Poforon	o Codo/	Bormit No.		Data Blanta	
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DATA SHE	ET FOR RECO	DRDING IN	NSPECTION	NS FOR TH	E PRE	SENCE	OF PROHIBI	TED PLA	NTS	
Date Inspected	Prohibited Plants	Growth Sta	ige of any	Method of Destru	iction	Additional	Comments and Obser	vations (i.e. Spe	ecies of Prohib	bited Inspector's
(1111-1000)		o	Fidilits	or Frank Wateria		Fidnis ide	nuneu)			muais
Date Inspected	Prohibited Plants	Growth Sta	ige of any	Method of Destru	iction	Additional	Comments and Obser	vations (i.e. Spe	ecies of Prohib	bited Inspector's
(YYYY-MIM-DD)		Prohibited	Plants	of Plant Material		Plants Ide	ntified)			Initials
Date Inspected	Prohibited Plants	Growth Sta	ige of any	Method of Destru	iction	Additional	Comments and Obser	vations (i.e. Spe	ecies of Prohib	bited Inspector's
(YYYY-MM-DD)	Present	Prohibited	Plants	of Plant Material		Plants Ide	ntified)	·		Initials
Date Inspected	Prohibited Plants	o Growth Sta	ge of anv	Method of Destru	iction	Additional	Comments and Obser	vations (i.e. Sne	ecies of Prohir	bited Inspector's
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Data la second	Yes N	0		Mathe	ation	A	Comments on 1 Ol	valian- "	aning of D 11	ited large t
(YYYY-MM-DD)	Prohibited Plants Present	Browth Sta Prohibited	ige of any Plants	of Plant Material	iction	Additional Plants Ide	comments and Obser ntified)	vations (i.e. Spe	ecies of Prohib	Initials
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Date Inspected (YYYY-MM-DD)	Prohibited Plants Present	Growth Sta Prohibited	ige of any Plants	Method of Destru of Plant Material	iction	Additional Plants Ide	Comments and Obser ntified)	vations (i.e. Spe	ecies of Prohib	bited Inspector's Initials
	Yes N	0								



# **RECORD OF POST-HARVEST INSPECTION**

						F	PAGE 2 of 2
DATA SHEET	FOR RECOR	DING INSPI	ECTIONS FOR TH	E PRESENCE (	OF PROHIBITED PL	ANTS (CONT	INUED)
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of a Prohibited Plants	ny Method of Destru of Plant Material	ction Additional C Plants Ident	comments and Observations (i.e. S ified)	Species of Prohibited	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of a Prohibited Plants	ny Method of Destru of Plant Material	ction Additional C Plants Ident	comments and Observations (i.e. S ified)	Species of Prohibited	Inspector's Initials
Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of a Prohibited Plants	ny Method of Destru of Plant Material	ction Additional C Plants Ident	omments and Observations (i.e. 5 ified)	Species of Prohibited	Inspector's Initials
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Date Inspected (YYYY-MM-DD)	Prohibited Plants Present Yes No	Growth Stage of a Prohibited Plants	ny Method of Destru of Plant Material	ction Additional C Plants Ident	omments and Observations (i.e. S ified)	Species of Prohibited	Inspector's Initials
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Date Inspected (YYYY-MM-DD)	Prohibited Plants Present	Growth Stage of a Prohibited Plants	ny Method of Destru of Plant Material	ction Additional C Plants Ident	omments and Observations (i.e. S ified)	Species of Prohibited	Inspector's Initials
ADDITIONAL	COMMENTS	AND OBSE	RVATIONS				
TRIAL MANA This activity has been approved standard op applicable regulations, management of field to crop plants	AGER VERIFIC carried out in accordanc erating procedures and /permit conditions for the rials of experimental, bio	e with with tech-derived	Signature of Trial Manager			Date Signed (YYYY-N	M-DD)
			By my signature above, I state accurate and complete to the I	that the information conta best of my knowledge and	ined herein is belief		

INSTR	UCTIONS	RECORD OF CORRECTIVE ACTION										
The <b>Record o</b> release of an isolation durir	The <b>Record of Corrective Action</b> is used to document all corrective actions taken to mitigate or resolve a situation involving the <b>unintended</b> <b>release of an experimental biotech-derived event</b> during transport, storage, harvest or the post-harvest period or any <b>breach of reproductive</b> <b>isolation</b> during the field testing of an experimental biotech-derived event.											
A copy of this Inventory, Rec	Record of Correc ord of Spatial Iso	tive Action, toget lation, Record of	her with any Harvest, etc	other relevar ), should be t	nt records (i.e. Record of forwarded by facsimile or	Transport, I e-mail to th	Record of Sto le Authorised	orage In I Party.	spection a	&		
									PAG	E 1 of 2		
RECORD II	NITIATED BY	First Name		MI	TRIAL SITE Site Location Code		Trial Site Size X	(m x m)	No. of Trial	s at this site		
Company/Organisa	ation	Department/Section			Legal or Descriptive Land Loca	ation of Trial Sit	e					
Street Address												
					Distance to Nearest Field of Same Species (m)	Distance to N Commercial of any kind (	Vearest Crop m)	Is the Is Distance Manage	olation e under the er's control?	Yes		
City	State/Province	Zip/Postal Code	Countr	У	Inflorescence Removal, E	Bagging or Tent	ing					
Telephone	Facsimile	Electronic Mail	·		Spatial Isolation	arly Crop Dest	ruct 🗌 Borde	r Rows				
ACTIVITY I	REQUIRING C	ORRECTIVE	ACTION		IDENTIFICATION	OF COM	PLIANCE	ISSU	E			
Indicate the Catego	ory of Activity Requiring	Corrective Action and	complete the rel	evant sections	Check all that apply							
If other, describe be	elow		Harvesti	ng 🚺 Other				ticie Lost (	auring Snipm	ent		
					Primary Shipping Contain	ner Breached		ecord of Ti	ansport Miss	ing		
					Unintended Release duri	ng Transport	Re	eceived at	Wrong Desti	nation		
TRANSPO	RT AND STO				Unintended Release duri	ng Storage	Br	each of G	uard Row Isc	lation		
Shipment No.		Item No.			Breach of Spatial Isolation	n	Ot	her (detai	below)			
Facility Code		Storage Locat	ion Identifier		Details of Compliance							
					_							
Building Name or II	D	Room Numbe	r or Description									
Street Address (if d	lifferent from above)				-							
IDENTIFIC	ATION OF AF	FECTED BIO	TECH-DE	RIVED E	/ENT							
Permit No.	Plant Sp	ecies	Approx. Amou Affected Mate	unt of erial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants		
Permit No.	Plant Sp	ecies	Approx. Amou Affected Mate	unt of rrial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants		
Permit No.	Plant Sp	ecies	Approx. Amount of Affected Material (kg) Form of Material Seeds Budwood/Shoots Transplants Tubers Whole Plants						Plants			
Permit No.	Plant Sp	ecies	Approx. Amou Affected Mate	unt of rrial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants		
Permit No.	Plant Sp	ecies	Approx. Amou Affected Mate	unt of prial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants		
Permit No.	Plant Sp	ecies	Approx. Amou Affected Mate	unt of rrial (kg)	Form of Material	Shoots T	ransplants	Tubers	Whole	Plants		





# **RECORD OF CORRECTIVE ACTION**

DESCRIPTION OF CORREC	TIVE ACTION 1	AKEN					L
						( Deck likite d	Directo
Destruction of Exp. Biotech-derived Event		Material		ose Post Harvest Restrictions	- Hogui	ng of Prohibited	Plants
Other (details below)	Imposition of Spati	al Isolation Zone	Des	ruction of Neighbouring Crop	Destru	iction of Trial	
Details of Corrective Action taken							
THIS SECTION IS TO BE CO	OMPLETED BY	THE AUTHO	RISED	PARTY			
COMMUNICATION WITH RE	GULATORY AL			Facsimile	E-mail	I	Date first contacted
		reichnone			Linui		Date inst contacted
Summarise communication outcomes, including a	agreed options for risk mitig	gation. Itemise all com	munications	, recording date and individuals	involved.		
Attach any written correspondence or transcripts	of oral communications.						
VERIFICATION							
The corrective actions detailed in this report have carried out in accordance with approved standard	e been Signatu	re of Facility Manager	, Trial Manag	er or Authorised Party		Date Signed (	YYYY-MM-DD)
operating procedures and with applicable regulati governing the transport, storage and field testing experimental biotech-derived plant material	of						
	By my accurat	signature above, I stat e and complete to the	e that the inf best of my l	ormation contained herein is nowledge and belief			



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Date of publication: April 2010

Printed on 100% recycled paper with vegetable-based inks