



EXCELLENCE THROUGH STEWARDSHIP[®]

Advancing Best Practices in Agricultural Biotechnology

GUIDE FOR
**Incident-Response
Management**
OF
**Biotechnology-Derived
Plant Products**

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The *Guide for Incident-Response Management of Biotechnology-Derived Plant Products* (“Guide”) is solely an educational tool and is guidance to assist users in developing and implementing their own organization-specific process for managing incidents with plant biotechnology products.

The Guide is flexible and its application will differ according to the size, nature and complexity of the organization and products involved. The Guide is representative and not exhaustive. It is the responsibility of any user of this Guide to consider that user’s specific circumstances (1) when developing a incident-response management process specific to its organization, and (2) in meeting any applicable legal requirements.

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CONTENTS

Introduction	1
Incident-Response System	2
A Stepwise Guide to Incident-Response Management	3
Step 1. Notification of Potential Incident	4
Step 2. Verification of Incident	5
Step 3. Scope the Incident	5
Step 4. Convene Incident-Response Team	6
Step 5. Develop and Implement Response Plan	6
Step 6. Process Improvement	7
Summary	7
APPENDICES	
Appendix A. Table 1: Possible Occurrence of Potential Incidents Throughout the Life Cycle	8
Appendix B. Incident-Response Planning	9



Introduction

This Guide is designed to provide guidance for the prompt management and resolution of incidents involving plant biotechnology products. Potentially, incidents can occur at any stage of the product life cycle. Therefore, an organization should have systems, processes, procedures, and resources in place to respond to potential incidents involving biotechnology-derived plant products across the life cycle.



Biotechnology Plant Product Life Cycle



Incident-Response System

An organization should have an incident-response system in place that is tailored to its type and scope of operations and activities. This could include having:

- Defined **roles and accountabilities** for incident response, including response team leadership and subject-matter experts in regulatory, legal, compliance, commercial, research, supply chain, and communications
- Defined **process flow diagram** for incident response
- Defined **escalation process** including response triggers that define appropriate reactions to specified types of incidents
- Established **communication networks** for dissemination of information internally and externally
- Defined **stakeholder maps** to facilitate timely inclusion of key parties
- Defined **documentation requirements**, as appropriate and as determined by legal counsel
- Established ongoing **training program** to embed the defined incident-response system, processes and procedures into the organization

Advance planning and preparation is important to the successful resolution of an incident. In the design, development, and implementation of incident-response processes and procedures, an organization should take into account the variety of activities and types of potential incidents that may occur.

Examples of potential incidents that may occur throughout the product life cycle could include:

- Unintended/unauthorized release of propagative plants into the environment
- Unexpected/unauthorized third-party intervention
- Product non-conformance
- Detected levels of biological traits at unapproved levels
- Unexpected research study findings
- Non-compliance with laws and/or permits
- Significant seed-quality failure



See Appendix A for possible occurrences of potential incidents throughout the life cycle.

By anticipating the types of potential incidents that may occur, an organization can prepare and establish response teams, processes, and tools specific to such types of incidents. For example, if an organization is involved in conducting confined field research trials it would be useful for the organization to have a defined process in place for reporting an unauthorized release to the relevant government authorities, when appropriate, and having reporting tools and contact lists readily available.

A Stepwise Guide to Incident-Response Management

The following table lists the steps of a typical incident-response process. Each organization should define and implement an incident-response process to meet its needs in achieving timely and effective management and solution of an incident.

Step 1	Notification of Potential Incident
Step 2	Verification of Incident
Step 3	Scope the Incident
Step 4	Convene Incident Response Team
Step 5	Develop and Implement Response Plan
Step 6	Process Improvement



Step 1: Notification of Potential Incident

Internal. The person who initially identifies or suspects a potential incident quickly outlines the circumstances so that it can be swiftly and accurately promulgated to appropriate experts and managers within the organization; and then managed according to the subsequent steps in the process. A basic potential-incident-response form should be available to collect information as appropriate and in accordance with the following organization-accepted procedures.

- Description of incident
- Time, date, and place of incident
- Involved personnel
- Promulgation process for information (at the local and/or global level)
- Events leading up to incident
- Any associated factors or circumstances
- Potential indirect effects (e.g., health, safety, environment)
- Proposed next steps
- Name of personnel receiving report

This preliminary report is important to the successful management of the incident. It may initially be a verbal report to a supervisor or other manager, but it rapidly should become a record-and-communication document according to organization guidelines.

External. Potential incidents may also be identified by external sources (e.g., auditors, consultants, cooperators). As feasible, there should be response procedures established with these external sources for prompt notification of an incident to the organization. Organization personnel should be designated and trained to react appropriately in the process of taking information from these external sources as described above.



Step 2: Verification of Incident

Initial notification of a potential incident should be communicated to the appropriate internal contact(s) (e.g., stewardship, regulatory, quality, compliance, and/or legal), who should confirm whether there has been an incident and its nature (e.g., unauthorized release, product nonconformance, vandalism, natural disruption due to inclement weather, etc.).

At this point, it is important to confirm that there has been no mistaken identification and that an incident involving the organization's product has truly been verified as indicated. For example, if a seed-quality problem is identified after planting, qualified organization personnel will need to confirm that this is a product issue and not a result of misidentification by a distributor or grower.

Step 3: Scope the Incident

A small team of subject-matter experts should rapidly scope out the potential impact and magnitude of the incident. In addition to physical consequences, the potential regulatory implications, regulatory obligations, and liability/litigation risks should be evaluated by reviewing the appropriate documents, such as government regulations, permit conditions, contracts, and legal agreements.

This is the start of what may be a long and more comprehensive process to understand the investigation findings and full consequences of the incident. However, the initial scoping exercise needs to be fast and extensive so that the appropriate internal and external response mechanisms can be initiated with appropriate information communicated to key stakeholders.

This initial scoping exercise should comprise the following details:

- Clear definition of the incident
- Initial quantification
- Definition of potential impacts
- Identification of potential legal requirements (e.g., reporting obligations)
- Scenario analysis of actions and consequences
- Identification of stakeholder (regulators, customers, grain trade, food chain, etc.)
- Review of relevant agreements and potential insurance coverage under applicable policies



Step 4: Convene Incident-Response Team

The response-team structure and membership will depend upon the initial assessment of the scope, the potential impact of the incident, and the expertise needed to manage the situation. The response team leader should have the expertise, time, and resources to manage the issue in an expedient manner. It is important to have clarity on roles and responsibilities, as well as transparency and coordination across sub-teams. Sub-teams, with local or global focus, may also be needed for major incidents so that specific stakeholder needs are covered (e.g., government staff, industry trade partners, distributors, local or international media).

Step 5: Develop and Implement the Response Plan

Clear analysis with timely and effective response can lead to successful resolution of an incident. A dedicated response team should focus on resolving the incident. Response activities should consider the framework of stakeholder commitments, regulatory requirements, contractual obligations, and other legal requirements that may include confidentiality responsibilities. Efforts should be undertaken to maintain customer, trade, and public confidence.

Members of the incident-response team should develop a response plan and implement remedial actions. The response plan should identify the actions to be taken, the persons accountable for the actions, and when the actions should be completed (see example in Appendix B). The response plan will need continuous updating as new facts emerge and should be transparent as a working tool to all team members. Generally, it is most effective for one team member to own the plan, to emphasize and monitor consistency and accuracy. This person or another team member should monitor and document the ongoing resolution process.

Stakeholders should be identified and appropriately informed of an incident and any potential impacts on them. Communications should take place within the relevant regulatory and legal framework. Incoming questions should be adequately addressed by informed expert staff.



Step 6: Process Improvement

At an appropriate phase in managing the incident, it may be necessary to conduct an internal investigation and to recommend process improvements that could be made to help reduce the likelihood of similar future incidents. Corrective actions should be reviewed for effectiveness after an appropriate time.

A review of the organization's incident response process and procedures should also occur in a timely manner following an incident. Any necessary process improvements and training should be implemented to correct identified deficiencies.

Summary

Incidents should be dealt with quickly and effectively to minimize impact on the organization and its stakeholders. Preparedness followed by directed and effective response is important to successful incident response, together with the implementation of corrective and/or preventative actions that can help reduce the likelihood of a reoccurrence. Prompt and thoughtful response actions will help to maintain strong stakeholder relations.

APPENDIX A

TABLE 1
Possible Occurrence of Potential Incidents Throughout the Life Cycle

POTENTIAL INCIDENT	LIFE CYCLE						
	Gene Discovery	Plant Development	Seed Production	Seed Marketing & Distribution	Crop Production	Crop Utilization	Product Discontinuation
Unauthorized release		✓	✓	✓	✓	✓	
Unauthorized third party intervention	✓	✓	✓	✓	✓	✓	✓
Product non-conformance			✓	✓	✓	✓	
Traits at unapproved levels		✓	✓	✓	✓	✓	✓
Unexpected research study findings		✓	✓	✓	✓	✓	
Non-compliance with laws	✓	✓	✓	✓	✓	✓	✓
Seed quality failure			✓	✓	✓		

Note: A check mark indicates a potential incident that is more likely to occur at the phase identified at the top of the column than at other times in the life cycle. It does not mean that an incident may not occur at other phases of the life cycle.

APPENDIX B

Incident-Response Planning

The following is a sampling of actions that may need to be taken to manage an incident involving biotechnology-derived plant products. This is not intended to be a comprehensive list nor is it a prioritized list. A response team will need to evaluate each incident on a case-by-case basis and develop an appropriate response plan for the type and scope of incident at issue.

Overview and Administration

- Determine what actions have been and should be taken.
- Identify internal and external stakeholders.
- Develop a strategy and response plan for resolving the incident.
- Document and monitor the actions taken to address the incident.
- Document corrective actions and/or preventive measures taken.

Regulatory and Legal

- Determine what laws, regulations, and/or contractual obligations apply, if any.
- Collate and have available any relevant safety information.
- Determine the status of any relevant product approvals, e.g., what permits and/or registrations have been approved and which are pending approval and in what countries.
- Determine what regulatory authorities are involved and associated reporting obligations, if any, and time requirements.
- Notify and/or report incident to government agencies, as required.
- Establish liaison with authorities, regulatory, and trade, as appropriate.

Analytical and Product Quality

- Confirm product nonconformance through specific analytical test(s).
- Determine the requirement for any additional validated detection methods and/or tools and make them available, if appropriate.



Supply Chain and Operations

- Isolate and/or retrieve plant material/seed/grain lot.
- Collate inventories and product returns/recalls.
- Dispose of non-conforming materials, as appropriate.
- Conduct in-field or product monitoring, if necessary.

Communications

- Develop and implement communication strategy for key audiences.
 - Sequence of messages
 - Content of messages
 - Timing
 - By whom
 - Frequency
 - Channels for distribution
- Identify internal and external audiences, such as:

Internal

- Management
- Employees
- Retirees
- Contractors/consultants
- Shareholders/investors

External

- Distributors/suppliers
 - Growers/customers
 - Government agencies
 - Trade/industry organizations
 - Food and feed chain
 - Universities/Academia
 - Scientific community
- Prepare internal and external communication messages.
 - Designate spokespersons—internal and external.
 - Communicate with internal and external stakeholders.
 - Debrief on post-incident perception and document key learnings.