excellence through STEWARDSHIP

Guide for Stewardship of Biotechnology-Derived Plant Products

DISCLAIMER

The *Guide for Stewardship 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 stewardship program for 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 stewardship program specific to its organization, and (2) in meeting any applicable legal requirements.

This Guide is not, and should not be used as, a substitute for (1) a user's own individual understanding of its legal requirements, (2) consultation by a user with its legal counsel and other advisors, or (3) direct contact with appropriate regulatory agencies.

The Guide does not define or create legal rights or obligations, and Excellence Through Stewardship (ETS) specifically disclaims any such rights or obligations. ETS and its members do not make any warranties or representations, either express or implied, with respect to the accuracy or completeness of the information contained in this Guide, or the sufficiency of the general procedures and processes contained herein to eliminate risk inherent in the referenced operations or processes; nor do they assume any liability of any kind whatsoever resulting from the use of or reliance upon any information, procedures, conclusions, or opinions contained in this Guide. ETS assumes no responsibility to update this Guide.

December 2008; *Revised June 2011*; *August 2017; August 2022; in progress September 2025*

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Introduction

Stewardship is the responsible management of biotechnology-derived plant[1] products from their discovery and development to their use and eventual discontinuation so that users can maximize the benefits of innovation. Any organization engaged in discovering, developing, providing, licensing, selling, or distributing biotechnology-derived plant products should have a stewardship program in place. The plant science industry has a long history of demonstrating product stewardship through the design and implementation of training programs for product users, the development and implementation of best management practices and policies, and engagement with stakeholders. Excellence Through Stewardship® (ETS) supports the plant science industry and its stakeholders by promoting sound stewardship programs and quality management systems for the responsible management of biotechnology-derived plant products.

Purpose

The *Guide for Stewardship of Biotechnology-Derived Plant Products*[2] is designed to provide product developers, service providers, licensees, and others engaged in the plant biotechnology industry with general stewardship program guidance and specific stewardship considerations for each stage of the plant product life cycle. In addition, the Guide is intended to provide useful information to stakeholders including those selling, buying, and using biotechnology-derived plant products.

Scope

This Guide is designed to address stewardship across the entire biotechnology plant product life cycle from discovery and development, continuing through commercial use, and until eventually discontinuation.

Figure 1. Biotechnology Plant Product Life Cycle

[1] This document defines plant as any plant (including plant part) for or capable of propagation. Various references are made to seed and/or seed production methods and crop management. It is recognized that systems exist where plant production may be accomplished through non-seed based methods such as vegetative propagation and therefore the use of the term "seed" is not meant to limit the scope of this document.

[2] Although this Guide refers to seed products and grain, the guidance is applicable to other plant biotechnology products. However, this Guide is not intended to address conventional varieties.

The guidance in this document is intended to be flexible. Its application will differ according to the size, nature, and complexity of the organization involved in addition to the activity involved and the type of biotechnology-derived plant product. The general treatment of stewardship concepts in this Guide can be further supplemented using references listed in the Resources and Reference section in this Guide.

While many concepts included in this Guide are applicable across different technology types, the scope of this Guide is limited to stewardship of genetically modified, or transgenic plants and seeds. For the purposes of this Guide, the scope is defined as an organism created using biotechnology methods that have had genes and/or DNA sequences from another organism added to its genome through recombinant DNA techniques.

Format of this Guide

This Guide begins with the general goals and components of a Biotechnology-Derived Plant Products stewardship program. Following that, the Guide briefly explores the plant product life cycle. A stewardship scope "self-assessment" is then presented to assist the reader to understand where they may have stewardship responsibilities considering their operations. The Guide ends with a section for resources that can help one further develop their understanding of stewardship.

A Stewardship Program

A stewardship program is a tailor-made approach to the responsible management of a product throughout the complete life cycle. It should be designed and incorporated, as appropriate, to address the type and scope of the organization's operations and activities relative to the product life cycle.

Under the ETS Program, Stewardship programs focus on the following throughout the plant product life cycle:

- A commitment to thorough testing for food, feed, and environmental safety
- Full compliance with applicable regulatory requirements
- Maximizing technology benefits and access to innovation
- Maintaining plant product integrity
- Facilitating the flow of trade in agricultural products
- Active engagement with the value chain to evaluate and promote appropriate stewardship approaches
- Driving continuous improvement of quality management systems and stewardship programs

A Closer Look at Stewardship

The following elements must be established in a stewardship program as applicable, considering the nature and stage of the product life cycle of business operations.

a. Quality Management System

Quality Management Systems (QMS) serve as the foundation for a properly functioning stewardship program. Quality Management consists of the systems, processes, and documented information needed to establish stewardship and maintain quality in each phase of the product life cycle. The QMS should be tailored to the type and scope of operations for an organization, and development of a QMS should begin in the early stages of project planning, and continue throughout development, breeding, production, and commercial activities.

QMS Principles	Customer Focus	Continuous Improvement
	Leadership	Evidence-based Decision Making
	Staff Involvement	Stakeholders Relation Management
	Process Approach	

Some key QMS components are summarized below:

I. **Policies, Processes and Procedures**

Establish and communicate the quality policy and quality objectives (including integrity of the biotechnology-derived plant products) of the organization, possibly based on a risk and opportunities assessment and on regular alignment within management teams. Determine and provide the processes, responsibilities, and resources necessary to reach the quality objectives.

II. **Customer Expectations**

Determine the needs and expectations of customers and other stakeholders in the overall context of the organization. Stakeholders may include regulatory authorities, licensees, business partners, growers, and other members of the value chain whose business interests may be affected by the development and commercialization of biotechnology-derived plant products.

III. **Management Structure**

Define organizational structure, including roles and responsibilities for establishing, maintaining, and improving stewardship policies and practices across the product life cycle to ensure accountability for stewardship across all global regions where activities occur involving biotech-derived products.

IV. **Awareness and Training**

Design stewardship awareness and training programs for employees, contractors, cooperators, licensees, and growers. Develop a training process and provide the training necessary to ensure that relevant personnel have the required competencies and skills to perform activities for which they are responsible. Develop and implement measures to assess the effectiveness of training.

V. **Communication**

Establish communication networks for informing internal and external stakeholders of key developments and decisions, e.g., upcoming product launches of new/novel plant biotechnology derived plant products.

VI. **Critical Control Points (CCPs)**

Establish the CCPs and necessary procedures, actions, and relevant records for each one identified.

VII. **Documentation**

Determine, develop, and update the relevant documented information needed to ensure the effective implementation of each process. Implement a specific process to ensure the management and control of such documented information. Documented information should be relevant and readable;

controlled to maintain content integrity; clearly and consistently identified; deployed to relevant users; reviewed in a timely manner; and retrievable.

VIII. **Management of Nonconformities**

Determine and implement means for preventing nonconformities and non-compliances and thereby eliminating their causes.

IX. **Assessment, Verification, and Continuous Improvement**

Define assessment and verification processes, such as key performance indicators, internal audits, and inspections, to ensure the stewardship program and quality management systems are in place and are improved periodically through audits, process reviews, etc. Develop, establish, and implement a process for continuous improvement of the quality management system including processes reviews (with a re-assessment of risk and opportunities).

X. **Customer Feedback & Complaint Handling**

Establish processes to capture and manage customer feedback related to product attributes or use.

XI. **Management Review**

Organize periodic review by management of an organization's stewardship program and associated quality management system at key milestones throughout the plant product life cycle.

b. Maintaining Plant Product Integrity (MPPI)

Design and implement systems and processes for maintaining plant product integrity including product traceability, identity, and purity for activities in Research in the Laboratory, Research in Containment Facilities, Confined Field Trials, Plant & Seed Multiplication, and Commercial Plant & Seed Distribution. *See the ETS Guide for Maintaining Plant Product Integrity for additional information*.

c. Co-existence

Co-existence may also be considered part of a general stewardship program. This is the practice of growing crops with different quality characteristics or intended for different markets in close proximity without becoming commingled and thereby possibly compromising the economic value of both. Co-existence is based on the premise that farmers should be free to cultivate the crops of their choice using the production system they prefer, whether they are GM, conventional or organic. More information on co-existence can be found on the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) website[3].

[3] https://www.isaaa.org/resources/publications/pocketk/foldable/Pocket%20K51%20(English).pdf

d. Product Design & Event Selection

Determine technical and regulatory considerations once transformed plant lines are available for advancement. Conduct safety assessments to evaluate genetic elements for factors which may impact human and environmental safety such as:

- Potential for allergenicity or toxicity of expressed proteins.
- Technical and regulatory implications of selectable markers, if used.

e. Opening, Transitioning, & Closing Sites

Establish a process for development and implementation of an opening, transition or closure/exit plan for a site or facility which will be, is currently, or has been involved in the development or management of biotechnology-derived plant products.

f. Product Launch

Develop a holistic policy and process for the responsible launch and commercialization of biotechnology-derived plant products. This should include the development of a Product Launch Stewardship Policy and a Product Launch Stewardship Plan. This plan may include, but is not limited to, activities such as organizing a product launch team, conducting a market and trade assessment, developing regulatory approval and commercialization plans, making a detection method available (if technically feasible), and communicating with stakeholders. *See the ETS Guide for Product Launch for additional information.*

g. Insect Resistance Management & Product Use

Establish a process to develop and manage strategies for effective and proper product use to sustain its value. This includes but is not limited to resistance management. Conduct early risk assessment components such as choice of targets, mode of action, stacking, refuge requirements, monitoring of efficacy, grower guidance for product use and conditions of use. *See the ETS Guide for Insect Resistance Management for additional information.*

h. Licensing, Contracting & Partnerships

Develop and implement a process for contracts, licenses and partnership agreements that ensures appropriate stewardship and quality management processes and practices consistent with the organization's stewardship program are required of and conveyed to third-party licensees, contractors, and partners. This includes activities such as in-licensing/out-licensing; confined field trials; research

and regulatory studies (e.g., efficacy and animal feeding studies); multiplication fields; processing, conditioning, storage, and distribution; product genetic integrity; waste management; and material disposition.

An organization should consult with industry, legal and functional expertise for appropriate terms and requirements, based on material, activity, and geography.

In addition, implement stewardship awareness, training, assessment, and verification programs for contractors and licensees.

i. Product Discontinuation

Develop a holistic process for responsible discontinuation of biotechnology-derived plant products. This process should include, but is not limited to, activities such as defining the discontinuation scope and timeline, identifying a discontinuation team, planning for ongoing regulatory requirements, developing a communications plan, and considering a strategy to address unintended presence (i.e., AP, LLP). See *the ETS Guide for Product Discontinuation for more information*.

j. Incident Response

Ensure a process is designed and in place to effectively manage potential incidents involving biotechnology-derived plant products. Potential incidents can occur at any stage of the product life cycle. Therefore, an organization should have processes, procedures, and resources in place to respond to potential incidents involving such products during each stage of the product life cycle. *See the ETS Guide for Incident Response for additional information*.

The Plant Product Life Cycle

The Biotechnology Plant Product Life Cycle is an overview of the voyage a plant product takes. The steps are summarized below:

The *Research and Discovery* stage includes activities that identify and evaluate the specific genes, proteins, and other elements that may be used to produce or construct a new plant product through biotechnology. Stewardship for this stage of the product life cycle includes ensuring that the processes for design and construction result in the intended material and that integrity is maintained.

The *Product Development* stage includes activities that occur before a biotechnology-derived plant product is commercialized. These activities include, but are not limited to, the continuation of plant transformation and regeneration, event selection in contained facilities or confined field trials, and event evaluation to determine suitability for intended use and to generate data for regulatory submissions. At this stage, ensure availability of relevant diagnostic tests to confirm product identity and to address determined needs. Stewardship for this stage of the life cycle includes ensuring that systems are in place to maintain plant product integrity, achieve regulatory compliance, manage product launch, and plan for effective and proper product use to sustain its value.

The *Seed or Plant Production* stages include activities designed to ensure that plant products are grown according to defined standards to meet regulatory requirements and product specifications for integrity (i.e.,

identity, purity, and performance). Products at this stage could be unauthorized[4], stewarded[5], or fully authorized[6].

The *Marketing and Distribution* stage includes activities related to the product launch, sales, and distribution of products through both the internal supply chain and the external distribution chains to customers. Prior to the commercial sale of any biotechnology-derived seed or plant product, the product developer or its licensee should have secured all necessary regulatory authorizations in the country of launch as well as in key import markets.

The *Crop Production* stage includes activities involved in the cultivation for harvest of an authorized, commercially available biotechnology-derived commodity.

The *Crop Utilization* stage includes the use of biotechnology-derived plant product commodities for food, feed, fiber, or other purposes (e.g., biofuels, industrial applications).

The *Product Discontinuation* stage includes activities involving authorized commercialized biotechnology-derived plant products that have reached the end of their commercial life cycle and all sales of materials under the organization's control have been terminated where applicable. Product discontinuation is recognized by the plant biotechnology industry as a routine part of the product life cycle and is different from product withdrawals and recalls. The discontinuation of a product is a business decision and considers many factors. These include prevailing regulatory requirements, market forces and product replacement.

[4] *Unauthorized*: Biotechnology-derived plant material or event that has not been authorized by the relevant competent authorities for release into the environment for purpose of cultivation or for use in the food and feed chains.
[5] *Stewarded:* In a country of cultivation, material that has received authorization for purpose of cultivation or for use in the food and feed chains, but is pending authorization from key import countries with functioning regulatory systems.
[6] *Fully authorized*: Material, commercial or not, that has received authorization for purpose of cultivation or for use in the food and feed chains in all local and key import markets.

Stewardship Scope Assessment

An organization's exact operations are unique to their business – e.g., one organization's *Seed or Plant Production* activities will differ from another's - and hence any stewardship program will be unique to that organization. Thus, an organization looking to implement a stewardship program must thoroughly understand the contents of each Guide and Module offered by the Excellence Through Stewardship Program before determining if that Guide or Module is applicable to their operations.

Below is a self-assessment tool to help facilitate an organization's understanding of what Guide or Modules might be applicable to their implementation of a stewardship program. After considering all the Guide and Modules offered in the ETS Program, please indicate whether the Guide or Module is applicable to the activities you conduct in a phase of the plant product life cycle. Note that for ETS members, GSG staff will help to assess the relevancy of components based on the scope of the company during the on-boarding process.

	Organization's Plant Products Life Cycle Activities						
Guide/Module	Research & Discovery	Product Development	Seed or Plant Production	Marketing & Distribution	Crop Production	Crop Utilization	Product Discontinuation
Stewardship							
Incident Response							
MPPI: Research in the Laboratory							
MPPI: Research in Containment Facilities							
MPPI: Confined Field Trials							
MPPI: Plant & Seed Multiplication							
MPPI: Commercial Plant & Seed Distribution							
Product Launch							
Product Discontinuation							
Insect Resistance Management							

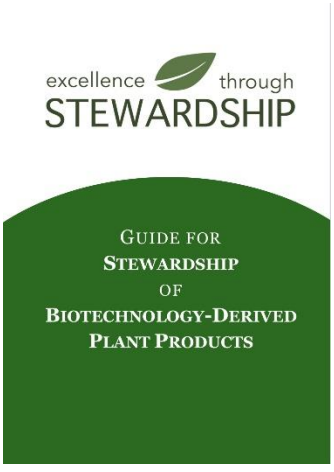
Resources

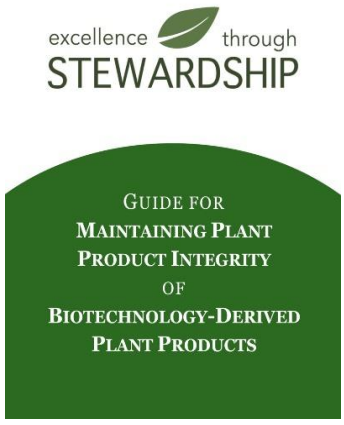
The ETS website provides public access to each of the ETS Guides which are available in English, Spanish, Portuguese, Chinese, and French. There is also a suite of *Members Only* tools designed to provide additional information and guidance for ETS members.

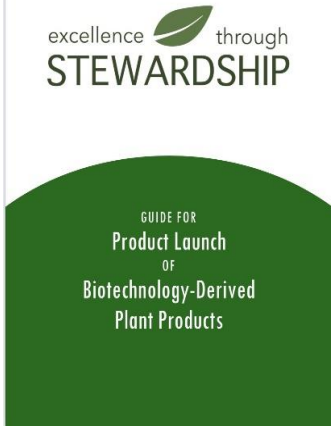
www.ExcellenceThroughStewardship.org

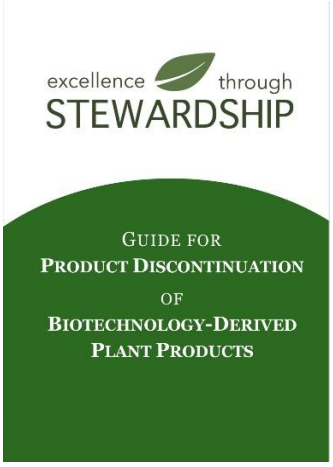
ETS Guides

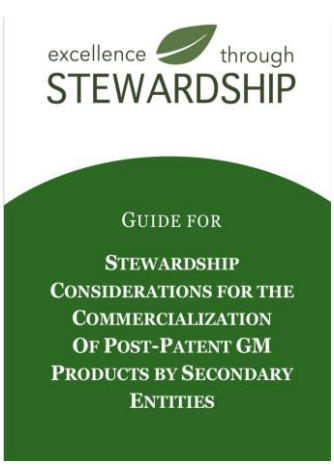
The ETS Guides are designed to promote stewardship and quality management across the entire plant biotechnology industry regardless of crop type and size, scope, location, regulatory scheme, or type of organization. They provide direction on how to develop and implement stewardship programs and quality management systems from discovery through commercialization and post-market activities. An organization can use the assessment tool above to identify which Guides, and modules within certain Guides, require additional focus to refine and customize a stewardship program for their operations, activities, and product life cycle components.











ETS Members Only Resources

The Self-Assessment Tool – This tool was developed to assist other members in implementing the program. This can be used to identify measures currently in place and potential gaps. The tool also includes an *Action Plan* tab where you can list any gaps or areas to improve on current procedures for review and to track progress on closing the gaps. Each tab includes the control points or areas of concern, what objective evidence one should consider, and some example assessment questions that one may choose to ask internally.

QMS Basics – These include training presentations on several of the key areas related to quality management systems and the ETS program. These may be used to enhance the general understanding of basic quality management issues and how they relate to the plant biotechnology industry and the ETS program.

Sample Forms – Examples of forms that can be customized for documentation of various processes involving plant biotechnology-derived plant products. ETS does not mandate the use of specific forms for use when implementing the program. However, as a service to our members we have developed several sample forms or templates that may be used.

Audit Resources – These include Audit Checklists, the ETS Audit Guide, and the GSG Auditor Training online course.

Implementation Path – This path outlines a 10-step process that begins with onboarding and progressing a member organization through to an ETS Program Audit and then continuous improvement. New members can choose to follow the outlined pathway or create their own if it meets the ETS requirements.

Webinars – Webinars cover a range of topics relevant to Excellence Through Stewardship including quality management systems, auditing, ETS program training, and more. These recorded webinars are given by expert representatives from our member companies and include detailed insight into the considerations surrounding the stewardship of plant products.

For questions, to request additional information, or inquire about membership in ETS please contact us via email: info@gsg.ag

Additional Public Resources

ISO 9001-2015[7]

The International Organization for Standardization (ISO)[8] family of standards collectively provides a framework that an organization may use to develop, implement, and maintain quality management systems.

ISO identifies seven management principles (listed above in "A Closer Look at Stewardship") that can be used to lead an organization towards improved performance. These principles are the basis of the standards for quality management systems within the ISO 9000 family.

The requirements for quality management systems as specified in ISO 9001:2015 are universal and can be applied by any organization that wishes to establish a quality management system for biotechnology-derived plant products.

HACCP[9]

The Hazard Analysis and Critical Control Point (HACCP)[10] system is an internationally accepted, science-based, and systematic tool to assess risks and hazards and to establish control systems that focus on prevention rather than on end-product testing. Components of HACCP contribute to responsible management of biotechnology derived plant products.

The HACCP system consists of the seven principles listed below, applied in a logical sequence:

Principle 1	Conduct a hazard analysis.
Principle 2	Determine the Critical Control Points.
Principle 3	Establish critical limit(s).

[7] This does not imply that this Guide is compliant with ISO standards. Furthermore, an organization is not required to be ISO-certified to successfully complete an ETS Audit but must have a functional QMS in place.
[8] http://www.iso.org/iso/home/about.htm
[9] As with ISO, it is not required to be HACCP-certified to successfully complete an ETS Audit.
[10] FAO. 2023. Introduction to Hazard Analysis and Critical Control Point (HACCP). FAO Good Hygiene Practices (GHP) and Hazard Analysis and Critical Control Point (HACCP) Toolbox for Food Safety. Rome. https://doi.org/10.4060/cc6246en

Principle 4	Establish a system to monitor control of the CCP.
Principle 5	Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
Principle 6	Establish procedures to verify that the HACCP system is working effectively.
Principle 7	Establish documentation concerning all procedures and records appropriate to these principles and their application.

GLP[11]

Good Laboratory Practices (GLP) establish a set of standards, practices, records required for lab, containment facilities, and field activities. GLP can be supportive of QMS and ISO and may be required for regulatory submissions.

Inventory Systems

Integral to quality management systems that address plant product integrity is the implementation of an inventory system. Inventory systems should effectively manage traceability of all material identification, labeling[12], tracking, and disposition[13] (e.g., of plasmids, constructs, plantlets, samples, plants, and seed). This is essential to retrieving information pertinent to the identity, location, and quantity of these materials at any given time throughout the product life cycle for biotechnology-derived materials.

For example, in the laboratory, organizations may employ a commercial or customized Laboratory Information Management System (LIMS) designed specifically for research and development labs. Typically, a LIMS connects analytical instruments in the lab to one or more workstations or personal computers where data is collated, sorted, and organized into various report formats based on the type of report required. Smaller organizations could select a manual or automated inventory management system that includes procedures for sample identification. This can include features such as the generation of sample labels; generation of replacement labels; tracking changes in status (for example, sample in storage, sample discontinued); linking sub-samples to source samples; and tracking container-to-container transfers (e.g., for plant tissue culture).

[11] As with HACCP, it is not required to be GLP-certified to successfully complete an ETS Audit.
[12] For the purposes of this guide, labeling means to affix with a label that is marked with a name and/or other identifying information (e.g., bar code) that can be used to confirm construct or transformant identity.
[13] Describes what was done with the plant material (e.g., planted, destroyed, devitalized, buried, stored, sold, cultured, processed for analysis or manufacture).

Confined Field Trials

Reference sources for this component can be found in CropLife International's *Compliance Management of Confined Field Trials for Biotech-derived Plants.*

Guide Summary

This Guide is intended to provide a high-level introduction and overall approach for stewardship of biotechnology-derived plant products throughout the product life cycle. Stewardship requirements are briefly outlined for each stage of the product life cycle. Additionally, a "self-assessment" tool is provided to help direct an organization to specific ETS Guides where more detailed information is provided involving stewardship industry best practices and quality management for specific life-cycle stages. Member resources also are provided to help customize individual Stewardship programs.

Abbreviations/Acronyms

AP	Adventitious Presence
CCP	Critical Control Points
ETS	Excellence Through Stewardship
GLP	Good Laboratory Practices
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
LLP	Low Level Presence
QMS	Quality Management System
MPPI	Maintaining Plant Product Integrity

Definitions

Please refer to the ETS Guide for Maintaining Plant Product Integrity

References

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3. Excellence Through Stewardship. *Guide for Incident-Response Management of Biotechnology-Derived Plant Products*.

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