



EXCELLENCE THROUGH STEWARDSHIP[®]

Advancing Best Practices in Agricultural Biotechnology

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.

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INTRODUCTION

Stewardship is the responsible way to manage biotechnology-derived plant products from their discovery and development, to their use and eventual discontinuation. Plant biotechnology stewardship for the product life cycle focuses on:

- A commitment to thorough testing for food, feed and environmental safety;
- Establishing and maintaining quality management systems and stewardship programs for management of biotechnology-derived plant products;
- Full compliance with applicable regulatory requirements;
- Maximizing technology benefits;
- 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; and
- Driving continuous improvement of quality managements systems and stewardship programs.

The plant science industry has a long history of demonstrating product stewardship through design and implementation of training programs for product users, development and implementation of best management practices and policies, and engagement with stakeholders.

The *Guide for Stewardship of Biotechnology-Derived Plant Products*¹ is designed to provide plant biotechnology product developers, service providers, licensees and stakeholders with an overview of stewardship considerations at different stages of the life cycle of biotechnology-derived plant products.

Excellence Through Stewardship® (ETS) supports the plant science industry and its stakeholders through a commitment to sound stewardship programs focused on quality management systems that promote agricultural sustainability.

¹ 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.

SCOPE AND OBJECTIVES

This Guide applies to stewardship across the entire biotechnology plant product life cycle (see Figure 1). The objective of this Guide is 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 associated stakeholders including those selling, buying and using biotechnology-derived plant products. Other Excellence Through Stewardship [Guides](#) are listed in the Resources and References Sections of this document. They offer additional information relating to stewardship activities across the product life cycle.

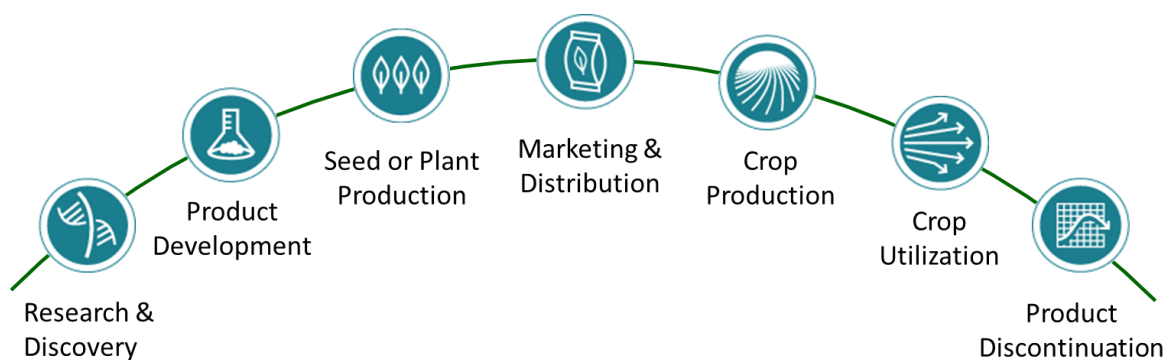


Figure 1. Biotechnology Plant Product Life Cycle

STEWARDSHIP CONSIDERATIONS ACROSS ALL STAGES OF THE PLANT PRODUCT LIFE CYCLE

An organization engaged in discovering, developing, providing, or licensing biotechnology-derived plant products should have a stewardship program and quality management system in place. These components should be tailored and incorporated, as appropriate, to address the type and scope of the organization's operations and activities relative to the product life cycle. A stewardship program is defined by an organization's structure and management systems, including roles, policies, processes, training, and documentation requirements for responsible product management.

Stewardship Program

The following eight elements must be established in all stewardship programs covering each stage of the product life cycle.

- **Structure**: Defined organizational structure, including defined 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.
- **Policies, Processes and Procedures**: Stewardship policies, processes and procedures which are integrated within quality management systems.
- **Awareness and Training**: Stewardship awareness and training programs for employees, contractors, cooperators, licensees and growers.
- **Communication**: Communication networks established for dissemination of information internally and externally to stakeholders.
- **Assessment and Verification**: Defined assessment and verification processes, including internal audits, to ensure stewardship programs and quality management systems are in place for applicable operations and in compliance with relevant regulations. These processes are critical in the determination and implementation of corrective and preventive actions as well as form the foundation for continuous improvements.
- **Management Review**: Stewardship program and quality management system reviews at key milestones throughout the plant product life cycle.
- **Plant Product Integrity**: Systems and processes for maintaining plant product integrity including product identity and traceability. For detailed guidance on this process, see [ETS Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products](#).

- Potential Incidents: A process to effectively manage potential incidents involving biotechnology-derived plant products. For detailed guidance on this process, see ETS [Guide for Incident-Response Management of Biotechnology-Derived Plant Products](#).

The following five considerations should be established in stewardship programs as applicable.

- Contractors and Licensees: Develop and implement a process for contracts and licenses that ensures appropriate stewardship and quality management processes and practices consistent with ETS program are required of third party licensees and contractors who manage biotechnology derived seed and plant products across the product life-cycle.
- Product Launch: A policy and process for the responsible launch and commercialization of biotechnology-derived plant products. For detailed guidance on this process, see ETS [Guide for Product Launch Stewardship of Biotechnology-Derived Plant Products](#).
- Insect Resistance Management: 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. For detailed guidance on this process, and specifically on Insect Resistance Management, see ETS [Guide for Resistance Management of Biotechnology-Derived Plant Products](#).
- Product Discontinuation: A process for responsible discontinuation of biotechnology-derived plant products. For detailed guidance on this process, see ETS [Guide for Product Discontinuation of Biotechnology-Derived Plant Products](#).
- Site Closure: A process for development and implementation of a closure/exit plan for a site which is currently or has been involved in the development of biotechnology-derived plant products.

STEWARDSHIP CONSIDERATIONS AT EACH STAGE OF THE PLANT PRODUCT LIFE CYCLE

The following are stewardship considerations relevant to each of the seven stages of the Biotechnology Plant Product Life Cycle, as illustrated in Figure 1. While these considerations are included as examples, they may not be comprehensive. It is essential that organizations consult scientific and regulatory expertise in designing and managing stewardship processes for each stage of the plant product life cycle.



Research and Discovery

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 product and that plant product integrity is maintained.

The following five considerations should be assessed and included, where appropriate, in stewardship programs related to research and discovery.

Quality Management, Product Identity and Traceability

Implement a quality management system for maintaining plant product integrity. Refer to the ETS [Guide for Maintaining Plant Product Integrity of Biotechnology Derived Plant Products](#), for guidance on establishing such a system to maintain identity and traceability of all biotechnology-derived plant products across the Research and Discovery activities.

Responsible Laboratory and Contained Facility Practices

Conduct routine inspections of the laboratory and contained facility to confirm that the appropriate level of containment is being maintained. Inspection activities should be recorded in accordance with an organization's record keeping and documentation procedures and any applicable regulations. [Laboratory and Containment facility inspection templates](#) can be found in the [Members Only](#) section of the ETS website.

Product Design

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.

Product Selection

Determine technical and regulatory considerations once transformed plant lines are available for advancement.

Licensing/Contracts

This includes agreements with third parties for activities such as in-licensing, research studies, and material disposition. An organization should consult with 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.



Product Development

The *Product Development* stage includes activities that occur before a biotechnology-derived plant product can be commercialized. These activities include 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.

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 following four considerations should be assessed and included, as appropriate, in stewardship programs related to product development.

Quality Management

Implement a quality management system for maintaining plant product integrity. Refer to the ETS [Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products](#), for guidance on establishing such a system, including verifying that procedures and systems are in place that address and manage biotechnology-derived plant products across Product Development activities.

Product Launch

Develop a product launch plan, including a process for market and trade assessment, used in the development of regulatory and commercialization strategies. Also, consider product life cycle and product discontinuation as part of the product launch planning process. The ETS [Guide for Product Launch Stewardship of Biotechnology-Derived Plant Products](#) and ETS [Guide for Product Discontinuation of Biotechnology-Derived Plant Products](#) provide relevant guidance.

Licensing/Contracts

This includes agreements with third parties for activities such as: in-licensing/out-licensing; confined field trials; research and regulatory studies (e.g., efficacy and animal feeding studies); processing, conditioning and storage; and, material disposition. An organization should consult with 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.

Regulatory Planning & Compliance

- Develop a science-based regulatory strategy to collect appropriate human safety, product efficacy and environmental safety data to meet regulatory requirements appropriate for intended product use plans.
- Ensure compliance with regulations for confinement and/or containment during global transport, import/export, and field testing. Reference sources for this component can be found in CropLife International's [Compliance Management of Confined Field Trials for Biotech-derived Plants](#).



Seed or Plant Production

The *Seed or Plant Production*² stages include activities designed to ensure that plant products are grown according to defined standards to meet regulatory requirements and product specifications for purity and performance. Product at this stage could be regulated, stewarded, or fully authorized and commercial.

Co-existence may also be considered at this stage. 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 CropLife International webpage, [Co-existence: biotech, conventional and organic](#).

The following four considerations should be assessed and included, as appropriate, in stewardship programs related to seed or plant production activities.

Quality Management

² 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.

Implement or adapt a quality management system for maintaining plant product integrity and quality consistent with internal standards for seed or plant production and processing. Refer to the ETS [Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products](#), for guidance on establishing such a system.

Licensing/Contracts

This includes agreements with third parties for 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 and storage; waste management; and, material disposition. An organization should consult with 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.

Regulatory Compliance

Assure compliance with appropriate regulations for relevant activities such as varietal registration, transport, production, seed treatment, and storage of plant materials.

Product Launch

Implement the product launch stewardship plan for seed or plant increases to support product launch. The ETS [Guide for Product Launch Stewardship of Biotechnology-Derived Plant Products](#) provides relevant guidance.



Marketing and Distribution

The *Marketing and Distribution* stage includes activities related to the distribution of product 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 following eight considerations should be assessed and included, as appropriate, in stewardship programs related to seed or plant marketing and commercial distribution.

Product Launch

Implement the product launch stewardship strategy for the product. The ETS [Guide for Product Launch Stewardship of Biotechnology-Derived Plant Products](#) provides relevant guidance. BIO's [Product Launch Stewardship](#) policy and CropLife International's [Product Launch Stewardship General Guidelines](#) provides relevant guidance.

Education and Training

Educate distribution, value chain, and grower stakeholders to support awareness and understanding of specific product deployment strategies, including specific guidance to enable stakeholders to define stewardship practices supporting appropriate product use. Examples include [Insect Resistance Management](#) (IRM), [Weed Resistance Management](#) (WRM), and seed treatment practices³. For detailed guidance on this process, and specifically on Insect Resistance Management, see ETS [Guide for Resistance Management of Biotechnology-Derived Plant Products](#).

Quality Management

Implement or adapt systems for maintaining and documenting plant product integrity, inventory control and product traceback⁴. Refer to the ETS [Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products](#) relevant modules for guidance on establishing such system.

Product Identity and Traceability

Maintain identity and traceability of all biotechnology-derived plant products.

Licensing/Contracts

This includes agreements with third parties for activities such as: in-licensing/out-licensing; processing, conditioning, storage and distribution. An organization should consult with 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.

Product Withdrawal or Recall

Implement a process for controlling materials in internal supply chains, as well as recalling and controlling material in commercial distribution chains. These processes must specify what documentation needs to be completed and retained.

Regulatory Compliance

Ensure compliance with applicable regulations (e.g., conditions of authorization, monitoring requirements, labeling and traceability requirements, import/export and phytosanitary requirements).

Product Discontinuation Plan

Develop a plan for product discontinuation that addresses regulatory registration strategies, potential impacts on market licensing agreements globally and integrates the needs of

³ An example that may include relevant guidance for seed treatment practices is the [Guide to Seed Treatment](#) Stewardship, produced by the American Seed Trade Association and CropLife America.

⁴ Traceback is the ability to follow the movement of a biotechnology-derived plant through specified stages of development for production and distribution of seeds or plants to growers.

stakeholders in the value chain. The ETS [Guide for Product Discontinuation of Biotechnology-Derived Plant Products](#) provides relevant guidance.



Crop Production

The *Crop Production* stage includes activities involved in the cultivation for harvest of an authorized, commercially available biotechnology-derived seed or plant. The following five considerations should be assessed and included, as appropriate, in stewardship programs related to commercial crop and plant production.

Education and Training

Provide appropriate communication and training regarding product management practices that enhance the long-term efficacy of the product; e.g., resistance management.

Product Use

Implement product management practices to enable appropriate use. These include grower guidance for product use and conditions of use. Examples include [Insect Resistance Management](#) (IRM), [Weeds Resistance Management](#) (WRM), and seed treatment practices. For detailed guidance on this process, and specifically on Insect Resistance Management, see ETS [Guide for Resistance Management of Biotechnology-Derived Plant Products](#).

Product Identity and Traceability

Maintain identity and traceability of all biotechnology-derived plant products.

Licensing/Contracts

This includes agreements with third parties for activities such as: in-licensing/out-licensing; processing, conditioning and storage; and, material disposition. An organization should consult with 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, licensees, and growers.

Customer Feedback/Complaint Handling

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



Crop Utilization

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 following four considerations should be assessed and included, as appropriate, in stewardship programs related to crop utilization.

Product Integrity

- Assess regulatory and stakeholder requirements for trait identity and purity in grain or other plant products.
- Promote stakeholder systems, where applicable, for maintaining and documenting plant product integrity, inventory control and traceability.
- Ensure availability of relevant diagnostic tests to confirm product identity and to address determined needs.

Regulatory Compliance

Ensure compliance with applicable regulations (e.g., import/export approvals and end-use requirements).

Stakeholder Feedback

Implement processes to capture and appropriately manage stakeholder feedback related to trade, product attributes, or use.

Commodity Identity and Traceability

Where identity preservation is required, maintain identity and traceability of identity-preserved biotechnology-derived plant products.



Product Discontinuation

The *Product Discontinuation* stage includes activities involving products that were authorized for commercial use but have since reached the end of their commercial life cycle. Product discontinuation is recognized by the plant biotechnology industry as a normal part of the product life cycle and is separate and distinct 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. The ETS [Guide for Product Discontinuation of Biotechnology-Derived Plant Products](#) should be referenced for additional information.

When implementing a stewardship program relating to product discontinuation, the following three considerations should be assessed and included as appropriate.

Product Discontinuation Plan

Develop and execute a plan that addresses regulatory requirements, market forces, product replacement and licensee capacity for compliance. Develop and implement appropriate stewardship and quality management requirements to consider during and following product discontinuation.

Product Discontinuation Process

Implement appropriate processes for product discontinuation planning, communication, execution and documentation.

Product Identity and Traceability

Maintain identity and traceability of products. Document use, destruction, or other consideration of materials that are not sold as planting seed.

RESOURCES

This Guide is intended to give the reader an overall view of the product life-cycle and considerations for stewardship at each stage of the life-cycle. ETS has developed additional resources that provide more detailed information on stewardship and quality management at specific life-cycle stage, to conduct self-assessments or prepare for audits, and when additional considerations may be needed for example during commercial launch of a product or when managing incidents.

www.ExcellenceThroughStewardship.org

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.

The screenshot shows the homepage of the Excellence Through Stewardship (ETS) website. At the top left is the ETS logo, "EXCELLENCE THROUGH STEWARDSHIP®", with navigation links for "About", "Membership", "Public Resources", and "Members Only". On the top right, there is a "REGISTER" button, a language selection dropdown menu, and a search bar with the placeholder text "Enter search criteria...".

The main banner features a photograph of a vast agricultural field with rows of green crops and a dirt path leading into the distance. Overlaid on the image is the text: "Advancing Best Practices in Stewardship with over 50 Members Worldwide".

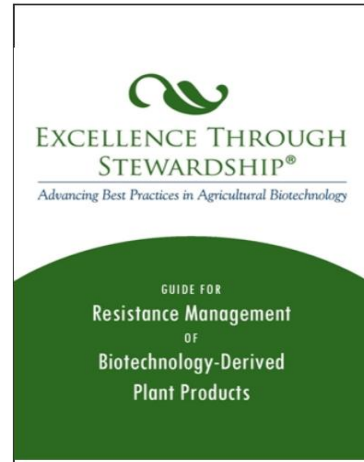
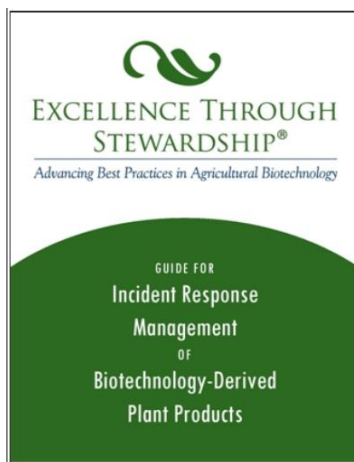
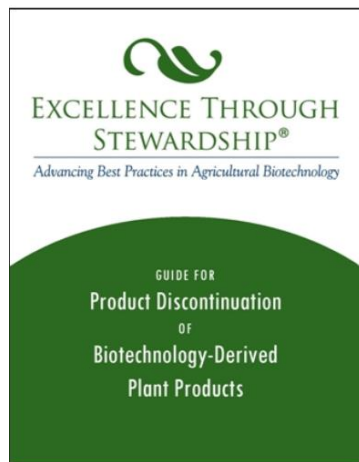
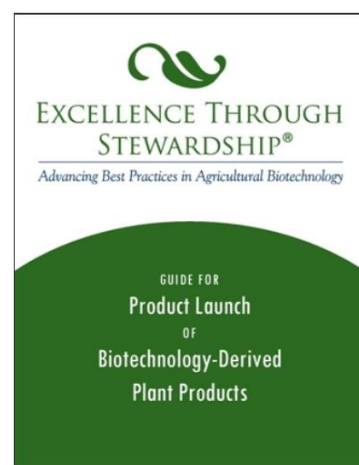
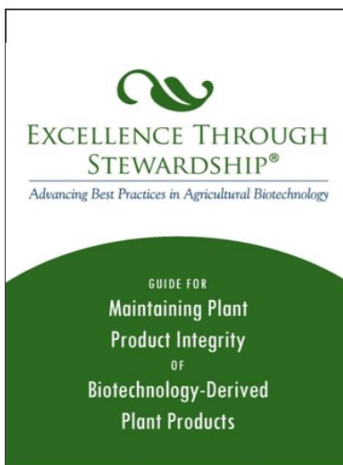
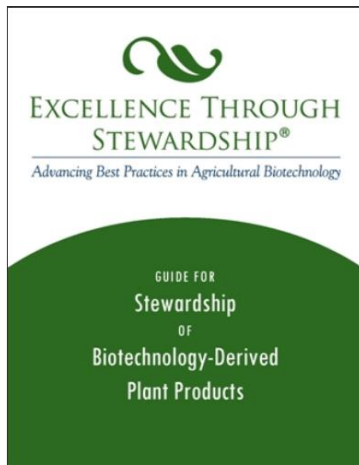
Below the banner, the page is divided into four columns:

- SUCCESSFUL AUDITS:** Includes a Bayer logo and a list of audit dates and recipients: 6/22/2018 (Welcome Hinkely S.A.), 3/29/2018 (Congratulations Satus Ager), 1/26/2018 (Beijing DaBeiNong Biotechnology Co., Ltd), and 12/7/2017 (Welcome Satus Ager S.A.).
- LATEST NEWS:** A link to "more" news.
- CONTACT US:** A message: "We encourage you to send us your questions & feedback by clicking here".
- SIGN IN:** A login form with fields for "Username" and "Password", a "Remember Me" checkbox, a "Sign In" button, and links for "Forgot your password?" and "Haven't registered yet?".

At the bottom of the page, there is a horizontal navigation bar with seven circular icons representing different stages of the plant product lifecycle. Below the icons is the text "The Plant Product Lifecycle" and a link "click to learn more".

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 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. They are flexible enough to be helpful whatever the regulatory systems under which the activity may be conducted.



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 you should consider and some example assessment questions that you 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 – 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, a presentation on preparing for an ETS Program Audit, and the ETS Audit Training slide deck.

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

Webinars –ETS 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. ETS is committed to continuing to produce relevant webinars and encourages our members to attend and participate in the question and answer sessions.

For questions, to request additional information, or inquire about membership in ETS please contact ETS Global Headquarters via telephone: +1 (202) 292-4684; or via email: info@ets.bio

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