ANIMAL PROTEIN CROP
STEWARDSHIP

Guide for Stewardship of Biotechnology-Derived Animal Protein Crops

APCS is a program for Stewardship of Plant Molecular Farming Products Expressing Animal Proteins in Crops used for Food and Feed

Purpose: This **Animal Protein Crop Stewardship (APCS)** program outlines a comprehensive set of activities to be implemented by developers where at least one of the recombinant animal proteins expressed in the plant is a known major food allergen, and a subset of practices to be implemented for products that are not a known major food allergen but may present properties that could impact grain grading or may have considerations for vegetarian, halal, kosher or other qualified diets.

The program outlined here is designed specifically for these types of products, comprising guidance for activities throughout the product life cycle. This life cycle begins with the concept in the lab and contained facilities, continues through field plantings, and extends to post-harvest storage, movement and processing activities, through product discontinuation. The purpose of this program is to enhance traceability and control for

these types of products by developers or others handling or using such products at every step of the product life cycle and supply chain. This is accomplished by implementing appropriate stewardship activities to enable responsible use and identify relevant critical control points (CCPs).

Leveraging industry best practices developed over decades for the stewardship of GM crops provides a solid foundation for this framework. Building on that solid foundation, this framework enables a developer to construct stewardship practices that are fit-for-purpose for this class of agricultural products by taking into account current industry guides and stewardship practices with appropriate practices, processes, controls, and technologies tailored to these products. The proper design and implementation of such practices will enable the developer to create and commercialize its products in a responsible manner, increase grower and consumer access to these products, and benefit stakeholders across the value chain.

Successfully implementing the APCS program will equip a developer with tools to maximize appropriate product placement and maintain product identity of its materials, and to enable products to be brought to market at scale. This framework establishes a uniform and consistently applied approach to assist in the responsible production of these agricultural products across the industry. Ultimately, this will benefit not just the biotechnology industry, but also the farmers, consumers, and the environment that these innovative products aim to serve.

Objective: The APCS program establishes industry guidance for the development, growing and processing of products expressing animal proteins in crops intended to be used for food and feed. This program incorporates a third-party auditing component that will cover the practices to be adopted by developers.

Scope: This document provides base stewardship considerations for the responsible production of products that express animal proteins intended for human consumption in crops used for food or feed including but not limited to grains, oilseeds and tubers. Additional guidance is available that is applicable to all stages of the product life cycle, from initial research concept through development, contained facilities, field plantings, post-harvest storage, movement and processing activities, through product discontinuation.

General Stewardship

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. This program is intended to support the plant science and molecular farming industry and its stakeholders by promoting sound stewardship programs and quality management systems for the responsible management of biotechnology-derived plant products across the product life cycle.

The *Guide for Stewardship of Biotechnology-Derived Animal Protein Crops* is designed to provide product developers, service providers, licensees, and others engaged in the development or handling of these products with general stewardship program guidance and specific stewardship considerations for each stage of the plant product life cycle.

The Plant Product Life Cycle

The APCS program is designed to address stewardship across the entire biotechnology plant product life cycle from discovery and development, continuing through commercial use, and until eventual discontinuation.

Figure 1. Biotechnology 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.

[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.

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[2], stewarded[3], or fully authorized[4].

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.

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[2] *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.
[3] *Stewarded:* In a country of cultivation, material that has received authorization for the purpose of cultivation or for use in the food and feed chains but is pending authorization from key import countries with functioning regulatory systems.
[4] *Fully authorized*: Material, commercial or not, that has received authorization for the purpose of cultivation or for use in the food and feed chains in all local and key import markets.

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.

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.

Established GSG 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

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 Systems (QMS): 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.

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. 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.
vi. Management of Nonconformities: Determine and implement means for preventing nonconformities and non-compliances, and thereby eliminating their causes.

vii. Assessment and Verification: 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.

viii. Customer Feedback & Complaint Handling: Establish processes to capture and manage customer feedback related to product attributes or use.

ix. 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.

c) Co-existence: Co-existence may also be considered as 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.

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.

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) 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.

i. An organization should consult with industry, legal and functional expertise for appropriate terms and requirements, based on material, activity, and geography.
ii. Implement stewardship awareness, training, assessment, and verification programs for contractors and licensees.

Additional Key Considerations

- Regulatory and Legal Requirements
    - Follow and adhere to all applicable legal and regulatory requirements: Developers should review and follow all applicable legal requirements.
- Comprehensive Risk-Based Assessment
    - Assessment: Every developer should perform a risk-based assessment and hazard analysis throughout the applicable stages of the product life cycle to understand the risks and identify critical control points ("CCPs") as a basis for planning and development of the closed loop system. Based on the risk assessment for each phase of a closed loop system, determine the relevant CCPs to develop preventive measures, as well as monitoring and verification procedures.
- Crop Selection
    - Consideration of crop biology: Developers should consider the appropriate crop species for development, including the biology of the crop species, its sexual compatibility, and how those factors impact the potential for unintended product distribution.
    - Outcrossing potential and mitigation: While outcrossing potential should be considered and mitigated for all crops, developers using plant species which are not primarily self-pollinating, should implement relevant practices or measures to limit the potential for outcrossing.
- Communication and Operational Visibility
    - Readily available contact information: Developer contact information should be readily accessible on the company's website or other platforms to facilitate access to information for applicable stakeholders.
    - Stakeholder engagement: A developer should proactively and regularly communicate and collaborate with stakeholders, including members of the value chain, and regulators in any region where they are producing.
- Focus on Continuous Improvement and Adapting with Scale

- Developers should continuously re-evaluate the controls, systems and processes that comprise its stewardship program and implement improvements to relevant processes.

GSG Resources [Build Out]

The Self-Assessment Tool – This tool was developed to assist other members in implementing the program. It 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 Fundamentals eLearning Course – These include training on several of the key areas related to quality management systems and GSG programs. This training may be used to enhance the general understanding of basic quality management issues and how they relate to the plant biotechnology industry and GSG programs.

Sample Forms – Examples of forms that can be customized for documentation of various processes involving plant biotechnology-derived plant products. GSG 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 Audit Guide, and the How to Prepare for a GSG Program Audit online course.

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

Webinars – Webinars cover a range of topics relevant to Excellence Through Stewardship including quality management systems, auditing, GSG 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 any GSG Program please contact us via email: info@gsg.ag

Additional Public Resources

ISO 9001-2015[5]

The International Organization for Standardization (ISO)[6] 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[7]

The Hazard Analysis and Critical Control Point (HACCP)[8] 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.

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[5] 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.
[6] http://www.iso.org/iso/home/about.htm
[7] As with ISO, it is not required to be HACCP-certified to successfully complete an ETS Audit.
[8] 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

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).
Principle 4	Establish a system to monitor control of the CCPs.
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[9]

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[10], tracking, and disposition[11] (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.

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[9] As with HACCP, it is not required to be GLP-certified to successfully complete an ETS Audit.
[10] 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.
[11] Describes what was done with the plant material (e.g., planted, destroyed, devitalized, buried, stored, sold, cultured, processed for analysis or manufacture).

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).

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 animal protein crops 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 resources where more detailed information is provided involving stewardship industry best practices and quality management for specific life cycle stages. Member resources are also provided to help customize individual Stewardship programs.

DISCLAIMER

The *Guide for Stewardship of Biotechnology-Derived Animal Protein Crops* ("Guide") is solely an educational tool and is guidance to assist users in developing and implementing their own organization-specific stewardship program for these 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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