excellence through STEWARDSHIP

GUIDE FOR

STEWARDSHIP CONSIDERATIONS FOR THE COMMERCIALIZATION OF POST-PATENT GM PRODUCTS BY SECONDARY ENTITIES

Stewardship Considerations for the Commercialization Of Post-Patent GM Products by Secondary Entities[1]

The Global Stewardship Group (GSG) is a global non-profit organization that offers programs to companies and organizations with a variety of needs when it comes to plant biotechnology stewardship. GSG offers programs for management of transgene technology, other plant breeding innovations such as genome editing, as well as stewardship education. The GSG operates the Excellence Through Stewardship (ETS) program focused on stewardship in the development and commercialization of products in the transgenic plant biotechnology industry.

This document is designed to provide stewardship guidance for situations when a biotechnology-derived trait reaches the end of its patent protection and becomes available for use by entities other than the original developer (or "secondary entities"), subject to any applicable laws and regulations. The ETS program is designed to provide stewardship guidance across the plant product life cycle and is used as the basis for the guidance outlined below. Additional information on stewardship of biotechnology-derived plant products can be found at www.GSG.ag.

Introduction

As technology developers continue to innovate and develop new biotechnology-derived traits, earlier developed traits are reaching or have reached the end of their intellectual property protection and becoming "post patent." This gives an array of secondary entities the potential opportunity to enter the market with products incorporating these events. Original developers spend considerable time and resources developing and implementing appropriate stewardship programs and quality management systems for the research, development, production, and commercialization of new biotechnology-derived traits. These organizations, as participants in GSGs various programs, commit to a robust set of processes and procedures to maintain plant product integrity and responsibly manage the technology from development through commercialization to ultimate discontinuation of their products containing biotechnology-derived traits, regardless of intellectual property protection.

Secondary entities that seek to enter the market should consider key stewardship activities and quality management practices relevant to their operations before any activities with these post patent events. By implementing stewardship programs and quality management systems these entities can more effectively enter the market and maintain biotechnology acceptance and grower and market access. This document outlines key stewardship and quality management considerations for secondary parties as traits enter the post patent phase. This includes references to existing ETS documents that provide greater detail on some of these key considerations.

[1] Any organization that uses or further develops post-patent events.

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Scope and Objective

The scope of this document is products that include biotechnology-derived traits that are no longer covered by valid patent claims in the country of product commercialization or relevant importing countries.

The objective is to provide a guide to would-be secondary entities intending to engage in the commercialization of these post patent events on key stewardship considerations, including but not limited to:

- maintaining plants product integrity,
- product launch and discontinuation activities,
- stakeholder communication and engagement,
- resistance management activities, as applicable.

Stewardship Considerations

This section outlines key stewardship considerations for the introduction or distribution of biotechnology-derived plant or seed products into commercial distribution channels and markets.

Regulatory Responsibility: Prior to the commercial introduction or distribution of any biotechnology-derived plant or seed, the secondary entity should understand its independent responsibility for maintaining and if necessary, obtaining regulatory authorizations as part of its market launch activities. These may include environmental, food, and feed safety authorizations, as well as any other requirements under national seed and/or phytosanitary regulations. This may also include any issues related to stacked or combination events.

Any interested secondary entity should consider opportunities to collaborate with other relevant stakeholders with respect to applicable regulatory authorizations. This may include and is not limited to regulatory agencies and technology developers that hold regulatory approvals for the post patent events in countries where the secondary entity plans to produce, sell or where the importation of the event may occur. Ultimately, any entity handling, using, or commercialization products containing post patent events must take all steps within its control to follow appropriate stewardship practices and activities.

For example, as part of the *AgAccord* certain technology providers developed the *Generic Event Marketability and Access Agreement (GEMAA)*, which is intended "a predictable and transparent mechanism to address patent expiration for agricultural biotechnology events" in the U.S. More information on the *AgAccord* can be found at www.agaccord.org.

Maintaining Plant Product Integrity: 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. Refer to the *ETS Guide for Maintaining Plant Product Integrity* for additional detail.

Seed and Plant Multiplication: Develop and implement procedures for the processing, conditioning, treating, storing, and packaging of products resulting from seed and plant multiplication.

Transportation and Storage: Develop and implement procedures for the movement or transport of materials from production or processing locations to and from subsequent processing or storage locations prior to commercial distribution, and storage and control of products and inventory in various stages of processing and packaging prior to commercial distribution.

Market and Trade Assessment: Conduct a market and trade assessment to identify key markets and key import activities prior to commercial launch of any biotechnology-derived plant product (crop by event) in any country or engage, as able, with the original developer to understand regulatory status and ongoing regulatory activities by the original developer, if any. Refer to the *ETS Guide for Product Launch* for additional detail.

Stakeholder Engagement: Communicate broadly and transparently with stakeholders and employees regarding plans for company-specific product launch stewardship, product-specific stewardship activities, including, without limitation, related to resistance management and availability of detection methodology, and their implementation. Secondary entities can demonstrate their commitment to proactively engaging in dialogue about activities by interacting, as possible, with a variety of stakeholders. Including but not limited to:

- The value chain, including farmers, growers, the grain trade, fresh produce, food and feed sectors, and retailers.
- Government legislatures and agencies
- International organizations
- Researchers in government and academia
- Non-profit and advocacy organizations
- Stakeholders in both cultivation and import countries to ensure that they know about product sales, cultivated acres, etc. as needed to fulfill regulatory requirements.

Detection Methods: Ensure the availability of an appropriate detection method and reference material. This could involve making an appropriate method publicly available or ensuring the commercial availability of a test. Consider engaging with the original developer as applicable. CropLife International (CLI) maintains the CropLife Detection Methods Database with additional information related to existing detection methods. This database "comprises full descriptions of validated DNA methods based on PCR, and lists providers for protein-based detection methods for GM crops produced by CropLife members." More information can be found at www.detection-methods.com.

Product Discontinuation: Discontinued products are defined as 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. Generally, an organization will begin to develop a plan for discontinuation once a business decision has been made to discontinue a product. This typically occurs several years prior to the date of last sale. During this period, it is important to develop a strategy for all applicable countries/geographies including identifying the product to be discontinued and establishing the timing of the discontinuation in each geography.

Incident Response: Develop management, mitigation and incident response plans as appropriate. Refer to the *Guide for Incident Management* for additional detail.

Quality Management Systems (QMS) Considerations

A QMS serves 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.

Developing and implementing a documented QMS for biotechnology-derived plant products consists of multiple steps as described below.

- **Quality Policy and Objectives**: 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 the processes and responsibilities necessary to reach the quality objectives.

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

- **Resources**: Determine and provide the resources necessary to reach the quality objectives.

- **Training**: Determine a training process and provide the trainings necessary to relevant personnel to ensure they have the required competencies and skills to perform activities in the defined processes.

- **Critical Control Points** (CCPs) and relevant actions for verification of Plant Product Integrity (PPI): Establish the CCPs and necessary procedures, actions, and relevant records for each Critical Control Point (CCP).

- **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.

- **Metrics and periodic auditing/assessments**: Determine and implement measures, key performance indicators, and audit processes to assess the effectiveness, efficiency, and conformance of each process.

- **Management of nonconformities**: Determine and implement means for preventing nonconformities and eliminating their causes.

- **Continuous improvement**: Develop, establish, and implement a process for continuous improvement of the quality management system including annual management reviews, processes reviews (with a re-assessment of risk and opportunities).

Insect Resistance Management (IRM) Considerations

For products that contain biotechnology-derived traits targeting pests, there is a benefit to focus on Insect Resistance Management (IRM) or Integrated Pest Management (IPM). This requires a diverse set of tools and practices that are best identified and determined based on local farming operations and cultural practices. More information on IRM can be found in the *ETS Guide for Insect Resistance Management*.

Here are some key considerations when implementing best practices for IRM:

- **Develop and Implement Market Deployment Strategy:** IRM stewardship activities, including education, monitoring for technology adoption and compliance with refuge requirements, and promotion of BMPs should be integrated into the local commercial business model and activities.

- **Develop and Implement Educational Materials and Training Program:** Education/training programs should be developed and implemented for key stakeholders specific to their role in the IRM plan.

- **Communications:** Organizations should develop adequate educational materials and communication tools as necessary to communicate broadly and transparently regarding IRM plans requirements that are specific to the product.

- **Documentation and Record Keeping:** IRM plan documentation and record keeping linked to the IRM stewardship activities should be fully integrated into your Quality Management System and Stewardship Program.

- **Maintenance of IRM Plan and Compliance with Requirements:** The activities that are conducted at this phase support ongoing stewardship to ensure continuing compliance to the IRM plan and to monitor issues which may require action, including adjustments to the plan.

Additional information on IRM can be found at https://irac-online.org/.

Herbicide Resistance Management (HRM) Considerations

The Herbicide Resistance Action Committee (HRAC) is an international body founded by the agrochemical industry to help protect crop yields and crop quality by supporting efforts in the fight against herbicide-resistant weeds. HRAC has developed a *Guideline to the Management of Herbicide Resistance w*hich includes guidance for the prevention and management of herbicide resistance. These guidelines and more information on HRC can be found at www.hracglobal.com.

The Excellence Through Stewardship Program

The ETS Program promotes the global adoption of stewardship and quality management for the full product life cycle of biotechnology-derived plant products. The program supports the responsible management of agricultural biotechnology, the continued adoption of plant biotechnology globally, and the enhanced value of biotechnology-derived plant products in the marketplace.

Stewardship is the responsible management of a product from its inception through to its use and ultimate discontinuation. In plant biotechnology, stewardship includes careful attention to the responsible introduction and use of products.

The program is available to any corporation, academic, or governmental organization that utilizes plant biotechnology in research, development, or manufacture of plant biotechnology products or owns, handles, or controls plant biotechnology products. Participation in ETS is encouraged for entities involved with plant biotechnology to achieve a truly robust approach to stewardship. ETS aspires to enhance acceptance and sustainability of plant biotechnology.

More information on program participation and its benefits can be found at www.excellencethroughstewardship.org.

Summary

Implementing appropriate stewardship programs and quality management systems can greatly assist secondary parties as they seek opportunities to enter the biotechnology-derived plant product marketplace with products containing post patent events. This will

help entry into the market, while promoting responsible use and supporting technology acceptance and grower and consumer access.

Disclaimer

This guide is solely an educational tool and is guidance to assist users in developing and implementing their own organization-specific stewardship processes.

The guide is flexible, and its application will differ according to the size, nature and complexity of the organization and products involved. The guidance 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 process 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 the appropriate regulatory agencies.

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References

- *Guide for Stewardship of Biotechnology-Derived Plant Products* - provides an overview of stewardship considerations at different phases of the life cycle of biotechnology-derived plant products.
- *Guide for Maintaining Plant Product Integrity of Biotechnology-Derived Plant Products* - provides detailed guidance on how to develop and implement a stewardship program and quality-management system that will assist in maintaining plant product integrity from product development through commercialization and post-market activities.
- *Guide for Product Launch Stewardship* - assists an organization in its development and implementation of activities recommended for the commercial launch of biotechnology-derived plant products, including commodity and specialty crops and, where applicable, their derivative products and by-products.
- *Guide for Product Discontinuation Stewardship*
- *Guide for Insect Resistance Management* - provides guidance on the development and implementation of a resistance management program(s).
- The *AgAccord* comprises two separate agreements – www.agaccord.org:
    - The Generic Event Marketability and Access Agreement (GEMAA℠)
    - The Data Use and Compensation Agreement (DUCA).