EXCELLENCE THROUGH STEWARDSHIP®

Advancing Best Practices in Agricultural Biotechnology

GUIDE FOR

Product Launch

OF

Biotechnology-Derived Plant Products

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The *Guide for Product Launch 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 process for launching 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 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 product launch stewardship process specific to its organization, and (2) in meeting any applicable legal requirements.

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Excellence Through Stewardship
1201 Maryland Ave SW – Suite 900
Washington, DC 20024

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ETS Guide for Product Launch Stewardship

INTRODUCTION

Organizations that develop and market biotechnology-derived plant products should consider policies for product launch stewardship as well as appropriate processes and plans that manage the commercialization activities. When carefully thought out, those steps will help an organization initiate actions that promote the responsible introduction of new products, minimize trade disruptions and facilitate the availability of crops and products with the appropriate function and composition for intended uses. The results of the planning will facilitate continued global adoption of plant biotechnology-derived products, and bring additional benefits and value to the marketplace.

The *Guide for Product Launch Stewardship* provides guidance to an organization in its development and implementation of the policy and related activities recommended above for biotechnology-derived plant products, including commodity and specialty crops and, where applicable, consideration of their derivative products and by-products. For example, an organization may choose to implement product launch stewardship activities that are designed to direct biotechnology-derived plant products and crops either to or away from specific markets.

Depending on the complexity of the organization, the product launch stewardship policy and related activities may be "stand-alone" elements or may be incorporated into the company's broader product-stewardship program.

Product Launch Stewardship Policy

An organization should develop a product launch stewardship policy that is suited to its business model, the nature of its products, and its product market(s). Such a policy will help guide the commercialization of biotechnology-derived products by directing, prior to product launch, due attention to regulatory approval requirements, market assessments, and other provisions. The Food and Agriculture Section of the Biotechnology Industry Organization (BIO) and CropLife International (CLI) have adopted product launch stewardship policies (see Appendices A and B). An organization may choose to use those policies and/or adopt similar policies as guidance in developing its own internal product launch policy. Whatever path is taken in the development of a product launch stewardship policy, it is important that representatives from the appropriate functions within the organization (e.g., stewardship, marketing, legal, licensing, production, regulatory, research, supply chain, and communications) be consulted.

Essential internal communication and organization-wide understanding of the product launch stewardship policy can be achieved by periodic training of appropriate employees, postings on company websites, and e-mail communication with employees. Furthermore, an organization will benefit from communicating its product launch stewardship policy to external stakeholders.

Product Launch Stewardship Activities

There are several activities that an organization should consider in honoring its commitment to product launch stewardship. Not all of the activities outlined below may be applicable or necessary for all organizations. Appropriate functions within an organization (e.g., stewardship, marketing, legal, licensing, production, regulatory, research, supply chain, and communications) should be consulted in the process of designing product launch stewardship activities to meet the specific needs of its products and markets.

1. Identify person(s) in the organization responsible for product launch stewardship.

The individual(s) responsible for product launch stewardship should have sufficient knowledge and experience to coordinate effectively with various functions in the organization (e.g., stewardship, marketing, legal, licensing, production, regulatory, research, supply chain, and communications). Their primary role is to develop appropriate product launch stewardship activities and to be a point of contact for groups internal and external to the organization.

2. Identify whether product is for commodity use or special use.

The intended use of a product or by-product, such as for commodity distribution or special uses, will help an organization assess its intended product launch stewardship activities. With the identification of the product's intended use, the organization can determine the appropriate scope of the market and trade assessment.

3. Conduct a market and trade assessment to identify key markets and key import activities prior to commercial launch of any new biotechnology-derived plant product (crop by event) in any country.

Prior to the commercial launch of a biotechnology-derived plant product, it is advisable to conduct a market and trade assessment of the product to assist in the development of regulatory, management and commercialization strategies. The assessment should map out the product's—and any by-product's—value chain[1], stakeholders (e.g., grower groups, government regulators, trade associations), market segments, and trade (e.g., import vs. cultivation, plant part vs. processed fraction, by-products). In addition, for products with special uses, the assessment can be the basis to develop special approaches to the product launch. These special approaches can help anticipate, manage and mitigate potential significant or unintended processing, product functional or compositional negative effects that may be manifested in crop use or processing streams. The assessment guides the organization in determining appropriate product launch activities and how best to work with the value chain and other stakeholders to maximize the value of the product and avoid potential trade disruptions. Such a market and trade assessment will also help to identify alternative production methods and conditions that are conducive to maintaining product integrity. The assessment should be reviewed at key points during product development and commercialization planning.

The extent of the market and trade assessment will depend on the processing and use of the product and on the scope and complexity of the product's value chain. For example, an evaluation may be quite brief if the product is not processed and the market is targeted and local. Or, it could be quite complex if the product is highly processed into multiple derived products and is globally traded. (See Appendix C for an example of a market and trade assessment for commodity soybean. While the example in Appendix C is for a food/feed crop, it should be understood that product launch stewardship practices are equally applicable to non-food/feed products e.g., plant-made pharmaceuticals, biofuels and like products).

In conducting the market and trade assessment, an organization should consult at an early stage with the value chain for the specific crop. There is an additional layer of complexity with exports of biotechnology-derived crops because some portions of the value chain may export goods to different countries and authorizations applied asynchronously across different countries for the same commercial product can lead to trade disruptions. In addition, for products with special uses, the products may need specific management plans depending on the results of the assessment. Consequently, coordination with the value chain downstream of the organization at an early stage is important. Remember that other trade groups may or may not implement differing stewardship activities.

Factors to consider in conducting a market and trade assessment include:

- The countries importing the product(s);
- The types of products (direct product, by-product, processed product) and approximate volume of export to these markets;
- The regulatory system and how it functions in each country;
- The status of regulatory approval in each country[2];
- Submissions to appropriate jurisdictions; and
- Adherence to international standards, (e.g., the International Plant Protection Convention (IPPC[3]) and the Cartagena Protocol on Biosafety[4]).

For products with intended special uses, additional factors to consider in conducting a market and trade assessment may include:

- The types and nature of the special use;
- Whether the special use product has multiple uses and whether unique handling, distribution or other operational conditions exist;
- Characterization of the product process or ingredient flows;
- Whether significant, unintended processing, product functional or compositional negative effects are likely to be caused; and
- Whether the product might be exported as grain, processed fractions or food/feed end products.

Global market and trade information on many crops can be obtained from government agencies (e.g., USDA ERS[5] or FAS[6]) or from grower groups (e.g., the National Corn Growers Association[7] or American Soybean Association[8]).

4. **Develop regulatory and commercialization plans to meet applicable regulatory requirements in key production and importing countries (as determined by the market and trade assessment) prior to commercialization of a new biotechnology-derived product.**

To synchronize launch efforts, regulatory timelines and assumptions should be communicated to the various organizational functions (e.g., stewardship, marketing, communications, licensing, production, and supply chain). There should be close communication between the research and commercial group(s) and the individual(s) who plan regulatory timelines. Contingency plans for product commercialization should be developed in case the regulatory approval process for a particular country takes longer than expected.

An organization should consult with the value chain during the regulatory process. That source may be able to provide input in the early stages when the organization is still debating on the list of countries to which submissions might prove fruitful and in later stages when the product moves closer towards gaining approval(s).

5. **For products with special use traits, develop management, mitigation and incident response plans (as determined by the market and trade assessment) prior to commercialization of a new biotechnology-derived products.**

Management plans, informed by the market and trade assessment for the special use trait and in dialogue with relevant stakeholders, would address significant and negative unintended processing, product functional or compositional effects, as appropriate to the likelihood or presence of the special use trait. The management plan, developed in dialogue with relevant, potentially affected stakeholders, could include identification and management of critical control points and plans to address potential escape or unintended presence of the trait.

6. **Make a detection method available to stakeholders when and where appropriate.**

A detection method will enable stakeholders to verify the crop identity. Depending on the type of detection method to be developed, this process may begin before regulatory studies are initiated. An organization should consult with stakeholders to obtain their inputs on desired specifications for the detection method.

7. **Communicate broadly and transparently with stakeholders and employees regarding plans for company-specific product launch stewardship and their implementation.**

The development and implementation of a communication plan for product launch stewardship is recommended for guiding company personnel and informing stakeholders. Different

stakeholders (e.g., licensees, government regulators, grower associations, grain traders, and food and feed value chains) may need different types/levels of information at different stages. Communication to stakeholder groups often begins during the pre-commercial scale-up of the product and can continue throughout the marketing phase.

Summary

The development of an organization-specific product launch stewardship policy and related activities should be tailored to the organization, the biotechnology-derived plant product involved, and the relevant product markets. The effort should include market and trade assessments, management plans, careful planning to meet appropriate regulatory timelines before product launch, and consistent communication with stakeholders and employees.

1. Value chain can be defined as "a string of companies or collaborating players who work together to satisfy market demands for specific products or services."
2. A database of the commercial status of certain agricultural biotechnology products can be found at http://www.biotradestatus.com.
3. https://www.ippc.int
4. http://www.cbd.int/biosafety/
5. https://www.ers.usda.gov/topics/international-markets-trade/
6. https://apps.fas.usda.gov/gats/default.aspx
7. http://www.ncga.com/
8. http://www.soygrowers.com/

APPENDIX A

BIO Food and Agriculture Section Policy on Product Launch Stewardship

The BIO Food and Agriculture Section Policy on Product Launch Stewardship is a global document that sets forth general policy statements and recommended processes for market and trade assessments as guidance for organizations engaged in the launch of biotechnology-derived plant products. This policy supports actions that facilitate the flow of goods in commerce, minimize trade disruptions, and facilitate the availability of crops and products with the appropriate function and composition for intended uses.

Additional information can be found on the BIO Website[1].

[1] https://www.bio.org/articles/product-launch-stewardship-food-and-agriculture-section

APPENDIX B

CropLife International Product Launch Stewardship Guideline

The CropLife International (CLI) Product Launch Guideline is a global document that supports actions facilitating the flow of goods in commerce and minimizing trade disruptions. Prior to commercialization, individual CLI member organizations are encouraged to meet applicable regulatory requirements in key countries identified in a market and trade assessment that have functioning regulatory systems and are likely to import the new biotechnology-derived plant products.

Additional information can be found on the CLI website[2].

[2] https://croplife.org/plant-biotechnology/stewardship-2/product-launch-stewardship/

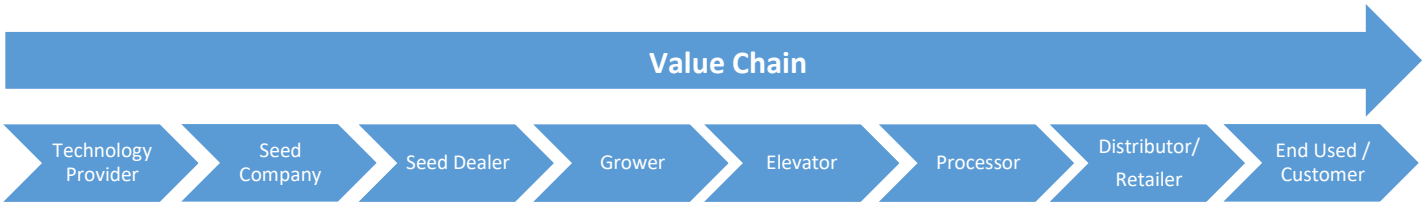
APPENDIX C

EXAMPLE OF A MARKET AND TRADE ASSESSMENT: COMMODITY SOYBEAN

Following is a sample market and trade assessment for commodity soybean. This example is intended as guidance and is representative only. Individual organizations are encouraged to develop their own market and trade assessment approach that will be best suited to their business model, the specific nature of their product, and their product market.

While the market and trade assessment example discussed here involves a food/feed crop, it should be understood that product launch stewardship practices are applicable to food/feed and non-food/feed (e.g., plant-made pharmaceuticals, biofuels) products alike.

The value chain for commodity soybean intended for food/feed use can be illustrated as below:



To expand, a typical value chain could consist of the following elements:

1) A technology provider discovers and develops the trait in soybeans, and licenses that trait to a seed company or produces and markets the seed.
2) A seed company may develop a trait and then produces and markets the seed.
3) The seed dealer sells and then distributes the seed to growers.
4) The grower plants the seed and harvests the soybean grain.
5) The grain is transported to an elevator for grading, drying and storage.
6) It is then sold to a processor, which may convert it into products such as soybean oil, soybean meal, soy protein, and others. Or it is sold to foreign buyers and exported to importing countries such as China.
7) It may then go to other companies for further processing, or as ingredients for other products.
8) The finished product is shipped to a distributor/wholesaler, which sells it to a grocery store or for animal feed.
9) Finally, the consumer purchases the end product.

In preparing a market and trade assessment, stakeholders should be identified, and stakeholder consultation plans put in place for each identified stakeholder. Stakeholders include those directly involved in the value chain (e.g., growers, grain traders, processors, distributors). These groups often have trade organizations to represent their industry, and consultation with these organizations can be very valuable during the planning of a product launch. (In the case of U.S. soybeans, examples include The American Soybean Association, National Grain and Feed

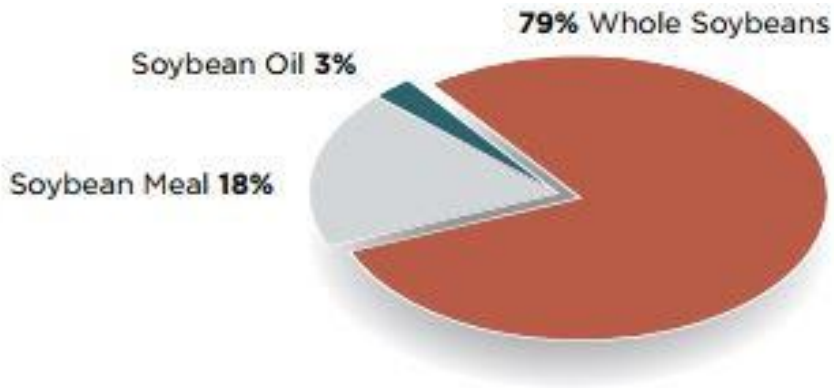
Association, Grocery Manufacturers' Association, and North American Export Grain Association. Other stakeholder groups to consider include domestic and international regulators and academics.

A complete market and trade assessment also considers the need for alternative production methods and conditions to maintain product integrity and/or identity. The launch of a soybean product intended for the commodity market generally will not need to consider alternative production methods or conditions for maintaining product integrity and/or identity. Where needed, "Identity Preservation" (IP) methods and conditions are well established for soybean, as there are a number of IP high-value soybean traits currently on the market (e.g., clear hilum, high protein).

Trade and market information on commodity soybean is available from the American Soybean Association; the data is available at Soy Stats[1]. An example of Soy Stats data showing U.S. soybean and soy product exports, and the 10 largest export countries for these products is given below.

U.S. Soybean & Soy Products Exports 2014

Source: USDA, FAS



[1] http://www.soystats.com/

Top Ten U.S. Export Customers $ Million 2014

Source: SoyStats 2015, USDA, WADB

WHOLE SOYBEAN EXPORTS	
CUSTOMER	VALUE (MILLIONS)
China	$14,798
Mexico	$1,815
Indonesia	$1,042
Japan	$995
Taiwan	$729
Germany	$550
Spain	$511
Netherlands	$429
South Korea	$361
Turkey	$345
All Others	$2,626

SOYBEAN MEAL EXPORTS	
CUSTOMER	VALUE (MILLIONS)
Mexico	$850
Philippines	$590
Canada	$522
Venezuela	$435
Thailand	$287
Dominican Republic	$192
Columbia	$192
Vietnam	$181
Ecuador	$171
Guatemala	$168
All Others	$1,905

SOYBEAN OIL EXPORTS	
CUSTOMER	VALUE (MILLIONS)
Mexico	$187
China	$132
Dominican Republic	$124
Peru	$57
Columbia	$39
Nicaragua	$38
Guatemala	$37
Morocco	$36
Canada	$34
South Korea	$27
All Others	$101

Source: SoyStats 2015, USDA, WAOB.

Several of the export countries listed above have established biotechnology regulatory frameworks. Other countries are in various phases of developing their regulatory framework for biotechnology-derived crops. Thus, an organization planning the commercialization of a biotechnology-derived commodity soybean for food and feed uses may expect to conduct market and trade assessments, develop commercialization plans, and submit dossiers for import, food and feed use (grain, meal or oil) in all those countries with a functioning regulatory system.

In this example regulatory submissions for a biotechnology-derived soybean product would begin with cultivation approval in the United States. Regulatory approvals by major import countries such as China should be a key consideration in the launch strategy of a soybean trait. Although the United States does not export soybean grain to Canada, soybean meal and oil are major exports to Canada. Thus, regulatory submissions to Canada would be expected. Some countries (e.g., Japan) may also require an additional cultivation approval, even though cultivation is not planned in the country.

The biotechnology-derived soybean product may also be commercialized with contemporary cultivation submissions in other countries, such as Argentina and Brazil. In that case, a market assessment, regulatory plan and commercialization plan matrix would be developed taking into account each country of cultivation and each of those countries' key export markets.

This example is based on a regulatory submission beginning with cultivation in the United States. Depending on the countries involved, there may be other commercialization and launch plans and approvals required.