



Seeds
Canada

Semences
Canada

Best management practices for launching products of plant breeding innovations in Canada

2023 v1.2



Introduction

The commercial introduction of new plant products will play a critical role in making the food system more sustainable, resilient (mitigating climate change) and with benefits to producing a more nutritious food supply.

Not only do these plant products benefit overall food security, but they help to make significant social and economic contributions, keeping the Canadian agriculture sector competitive globally. Some traits also target objectives relevant to international trade such as reducing the presence of mycotoxins which can be a significant health issue.

Differences in pre-market regulatory policies and processes globally, including the operation of non-functional regulatory systems, can result in asynchronous approvals or regulatory status. These non-tariff trade barriers have the potential to lead to disruption in global trade that can affect an entire crop value chain. This document highlights the role of seed/plant product developers and the importance of open dialogue among all value chain stakeholders (from seed and plant product companies to exporters) to support innovation and the successful introduction of these products to the Canadian market, and as appropriate, to the global market.



This document highlights the role of seed/plant product developers and the importance of open dialogue among all value chain stakeholders.

Objectives

The goal of this guidance is to provide a framework for industry processes and communication about individual company product commercialization plans that supports innovation and trade. In support of this goal, this document builds upon existing information sharing best practices (such as the Canadian Grains Council Information sharing document¹), with the following focus:

- Provides **transparency** for the Canadian value chain on the processes developers take when introducing new innovative plant products to the Canadian market.
- Clarifies practices to support appropriate, timely, and consistent **consultations** with value-chain stakeholders to support international trade.
- Is **not specific to any particular breeding technology** and is applicable to new plant products containing traits that are subject to pre-market regulatory processes² in one or more key country of import for the relevant crop commodity.
- Provides **guidance** to the Canadian seed/plant product sector at large.

¹ <https://canadagrainscouncil.ca/wp-content/uploads/2017/08/CGC-Info-Sharing-Documents-Final.pdf>

² Includes government mandatory and voluntary processes such as approvals, notifications, consultations, or regulatory status verification required to support unconfined environmental release, food/feed use or import.

³ Defined as the transfer of title and control of seed to the purchaser for the planting and production of a crop or crop product.

⁴ The term trait is used generically and some products within scope of these processes may not have a discernible new trait but the product may nonetheless be subject to pre-market regulatory processes.

Scope

Plant products that are commercialized³ in Canada and contain a new trait(s)⁴ which is subject to government pre-market regulatory process² in one or more key country(ies) of import for the relevant crop commodities.



Background

Despite best efforts to harmonize and synchronize regulatory approaches, differences in regulatory status of plant products among key trading countries can occur due to multiple factors including different standards and predictability for regulatory timelines, which can be politicized and non-science based in some countries. This can lead to significant delays to commercialize products in the country of cultivation and lead to potential trade disruptions that can have significant and long-term impacts on Canadian competitiveness. Seed/plant product companies should engage within the value chain to find cooperative opportunities to advocate for harmonized science-based regulatory approaches to achieve synchrony in regulatory status for new innovative plant products.

To address potential challenges, provide transparency, increase access to innovation and reduce the risk of potential trade disruptions, there are existing international industry-developed best practices specifically for commercializing biotechnology-derived plant products, including product launch policies at **CropLife International (CLI)** and **Excellence Through Stewardship (ETS)**. These policies have provided a strong basis to inform the developer and value chain of product launch considerations and reduce the risk of the occurrence of commercialization activities that could lead to trade disruptions.



Differences in regulatory status of plant products among key trading countries can lead to significant delays to commercialize products.

Public disclosure and confidentiality

Development of new plant varieties and their commercialization plans may be conducted in a confidential manner. Certain information may be viewed as confidential business information that could provide competitive advantage. Nothing in this guidance requires a product developer to compromise the confidentiality of any information related to any product within the scope of this document. Discussions with certain value chain members may require structured confidentiality agreements.

Identification of key stakeholders and timing for consultation

The seed and plant breeding sector is diverse, both from an innovator and crop perspective, covering a large variety of different crops. It is recognized that different stakeholders throughout the value chain are interested in understanding relevant launch-related information at different points of time. The information of interest and timing of consultations will vary to meet the specific needs of products and markets, depending on the following:

- crop-type and specific crop innovation
- commercialization type (identity preserved, closed loop, commodity)
- commercial reach of the product – global, regional or Canada-only
- supply chains and markets
- end-users

Due to these differences, each crop and each product should be subject to a case by case assessment by the innovator to determine appropriate product commercialization considerations, including relevant processes, potentially impacted stakeholders and communication strategy. This guidance document outlines high-level recommended processes, which can be generally applied to the development of product specific plans.



Each product should be subject to a product specific assessment and plan.

Innovator processes



Commercializing new plant products to the Canadian market should support both continued innovation and market choice for Canadian crops and products.

Seed/plant product developers commercializing new plant products should develop a product commercialization plan that includes the following:

Pre-commercialization

1

At an appropriate, pre-commercial stage, innovators to develop:

A

Product specific engagement plans, including identification of relevant stakeholders.

For bulk grain products, commodity groups and exporters of record should be among the relevant stakeholders identified.

B

Market and trade assessments to assist in the development of regulatory, management and commercialization strategies.

This includes identification of key countries of import for the relevant crop/crop commodities. As these countries can change, regular consultation with the value chain (e.g. through relevant commodity or crop marketing committees/groups) is important to ensure appropriate input is provided to the innovator and shared across stakeholders.

C

As appropriate, stewardship plans (e.g. material management for segregation) including considerations for:

Seed or plant material production;
Handling; and
Management of the harvested crop



2

When growing plants prior to commercial planting (e.g. seed bulk up trials), where regulatory requirements have been met in Canada but prior to authorization in one or more key country(s), **follow generally accepted seed/plant product quality practices**, and industry best practices designed to prevent unintended low level presence in commerce. This includes field isolation and processing/transportation sanitation practices. Such practices may differ by crop with specific guidance maintained and updated from a variety of other sources.

3

Prior to commercialization, the innovator will initiate **consultation** with the relevant stakeholders (from 1.A. above), and include the following:

- A** As necessary, request confidentiality of communications that occur prior to public disclosure in order to recognize realities of a competitive marketplace.
- B** Discuss a product commercialization plan that considers the market and trade assessment (from 1.B. above).
- C** Discuss key information, including at a minimum: the crop, trait development method, global regulatory status, and any stewardship/segregation requirements that may be needed.
- D** Provide advance notice, including timelines, of plans to commercialize seed or plant products. Ideally this should occur at least six months prior to discussions with agri-retailers regarding the first sale of seed/plant material.⁵
- E** Consider feedback received from stakeholders during the consultation.



⁵ Note that due to the unpredictable nature of regulatory approvals, plans to commercialize can change at the last minute that can result in stopping of sales or implementation of stewarded programs (planned in advance as a contingency as per step 4).

4

Develop plans to meet applicable regulatory requirements in key production

and importing countries (as determined by the market and trade assessment) prior to commercialization. In the event that an innovator intends to commercialize a product prior to meeting requirements in key countries, the innovator will conduct consultations (following the timelines set out in section 3.D. above) with the value chain to discuss **market considerations and stewardship plans** that may be needed. For bulk grain products launched without regulatory clarity in key markets, revised quality management and communications plans will be needed, and should include the following:

A

Support a shared understanding with relevant stakeholders (as identified in 1.A. above) on how quality control management systems that are already in place within the grain handling systems will be used to ensure the crop and crop commodities are segregated appropriately.

B

Provide training where appropriate, for seed/plant product distribution partners (seed growers, seed distribution channels).

C

Implement point of sale communication with growers regarding stewardship programs for specific products (including why it is needed, e.g. regulatory status).

D

Where grain is intended to enter the grain handling system, develop and share with relevant parties a grain handling plan which includes identification of value chain stakeholders involved in grain management, processing, export, etc. as appropriate.

E

Provide updated commercialization plans to stakeholders as per above (3), if they are substantially changed.

5

Following consultation with value chain stakeholders, participate in functional voluntary transparency mechanism(s) for products covered by this document. (i.e. [Health Canada Transparency Initiative for Non-Novel Products from Plant Sources](#) and [Seeds Canada's Canadian Variety Transparency Database](#))



Post-commercialization

- 1 Encourage establishment and participation in ongoing dialogue with stakeholders to share information on evolving markets and trade environments.
- 2 When situations arise where there is significant change in market and trade circumstances, such as:
 - change in key countries for the commodity
 - product regulatory status changes in key country
 - product commercialization plans change

The innovator should consult with the value chain stakeholder on any changes that may be implemented with regards to the marketing and stewardship of the product.

