



Seeds
Canada

Semences
Canada

Stewardship Considerations and Best Practices

for Responsibly Introducing Seeds
Containing Generic Novel Traits
to the Canadian Marketplace



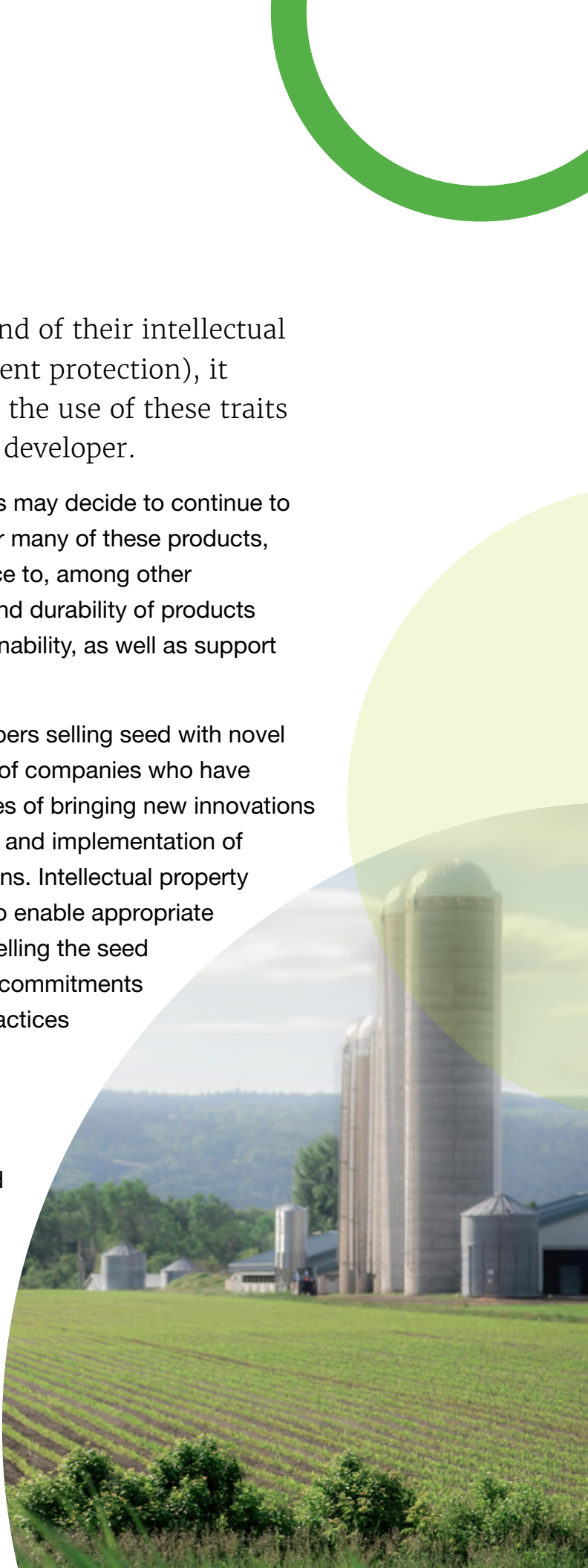
Background

As biotech novel traits reach the end of their intellectual property protection (including patent protection), it creates potential opportunities for the use of these traits by entities other than the original developer.

In these situations, the original developers may decide to continue to market the product or exit the market. For many of these products, stewardship practices are typically in place to, among other consideration, help protect the integrity and durability of products to support grower productivity and sustainability, as well as support international trade.

Historically the number of original developers selling seed with novel traits has been limited to a small number of companies who have experience in dealing with the complexities of bringing new innovations to the market. This includes development and implementation of market assessments and stewardship plans. Intellectual property protection, such as patents, has helped to enable appropriate license agreements with both licensees selling the seed and with growers, which typically require commitments to implement elements of stewardship practices and plans.

As new entities seek to market these products, some may not have similar experience or expertise in developing and implementing measures to best steward a product and support international trade.



Scope

This document is related to the commercialization of seed products containing traits that:

- 1 Are subject to pre-market regulatory authorizations in Canada or in one or more key export markets,
- 2 Patents having claims in Canada on the trait(s) contained in such seed products have expired, and
- 3 An entity other than the original developer is marketing or planning to market the trait.

For the purpose of this document, such products will be referred to as seeds with generic novel traits (SGNT).

Objectives

As entities seek to market SGNTs in Canada, it is important they consider stewardship activities and best practices for bringing such products to the market. This document provides information that should be duly considered for establishing a responsible marketplace for SGNTs in Canada and maintaining access to innovation by growers and the market. It also provides considerations and best practices that are intended to support efficient and fair entry of SGNTs to the Canadian marketplace.

The considerations and best practices outlined below seek to:

- Support innovators who wish to exit the market at their discretion, and
- Support SGNT marketers to educate themselves on stewardship considerations and practices related to, among other considerations:
 - maintenance of existing key import market authorizations¹,
 - communication with value chain stakeholders, and
 - product stewardship related to maintenance of product durability and efficacy.

¹As determined through a process consistent with that outlined in the Excellence Through Stewardship, Guide for Product Launch of Biotechnology-Derived Plant Products

Stakeholder Considerations and Best Practices

Considerations for the original developer

- ▶ Continue to secure existing export market time-limited authorizations while marketing the product and for an appropriate time after to allow for appropriate transfer (if negotiated/applicable) and/or discontinuation processes as discussed further below.
- ▶ Engage in dialogue when approached by SGNT marketers or value chain stakeholders interested in becoming involved in the maintenance of existing export market time-limited authorizations.
 - The specifics of these discussions are outside the scope of this document and will be determined on a case by case basis at each party's discretion.
- ▶ Make publicly available, relevant product-specific stewardship practices that help to protect the product and its integrity, efficacy and durability in the marketplace (e.g. product use guides).
- ▶ When removing a specific product from the market and making the decision to discontinue the maintenance of existing time-limited export market authorizations, consider the following:
 - **Follow existing guidance around product discontinuation such as:**
 - “Excellence Through Stewardship [Guide](#) for Product Discontinuation of Biotechnology-Derived Plant Products”.
 - CropLife/Canadian Seed Trade Association “Product Discontinuation/Product Phase-Out [Checklist](#)”.
 - Consult the value chain (including commodity association market access committees where applicable) on any product regulatory status changes in key countries as per the CropLife Canada “[Best management practices for launching plant breeding innovations](#)”.
 - Communicate to the value chain known expiry dates for time-limited export market authorizations with sufficient advance notice, recognizing that grain may stay in the handling system for a year or more, after it is harvested.
 - Specific timelines for when this communication should occur are not provided here as they will differ based on a variety of factors including the biology of the crop, nature of the product, export markets, and regulatory processes. Ideally this notice should provide sufficient time to implement relevant business planning processes as needed, including timely discontinuation processes, as appropriate for the situation.



Considerations for entities marketing SGNTs

(e.g. seed companies other than the original developer selling generic seed)

- ▶ Follow the CropLife Canada “[Best management practices for launching plant breeding innovations](#)”, as though marketing a new product. This should take place in advance of any seed sales and involves conducting (or obtaining a previously conducted) a market access assessment and consultation with the value chain regarding intentions to market the product.
- ▶ Proactively engage in dialogue with the original developer with respect to the developer's plans for maintaining existing time-limited approvals in export markets.
- ▶ Taking due consideration of consultations, develop a plan with respect to how existing export market time-limited authorizations will be maintained or other considerations for supporting trade as needed. This may include considerations for sharing or taking on responsibility of maintaining existing approvals.
- ▶ If an SGNT marketer pursues maintaining regulatory approvals for an SGNT, communicate relevant information to the value chain as described above for the innovator.
- ▶ Be aware of and promote any product specific stewardship practices that may be needed to protect the product and its integrity, efficacy and durability in the marketplace. This information should be publicly available by the original developer as per above (e.g. product use guides).
- ▶ When the original developer provides the value chain with notification of their intent to discontinue the maintenance of existing time-limited export market authorizations, and no other entity has already arranged to take on this responsibility, any plans by an SGNT marketer to continue sales of the product should be done in consultation with the value chain.
 - It should be recognized that it can take several years to transfer or obtain new approvals and therefore initiating such processes after a notification of discontinuation may not provide enough time to secure approvals prior to expiry.
- ▶ When a decision is made to remove a specific product from the market, follow existing guidance around product discontinuation as noted above for the original developer.

CropLife Canada and Seeds Canada will work outside of its membership to encourage a supportive environment for SGNT transitions.

This includes working with partners to advocate that value chain stakeholders:

- ▶ Communicate general information to seed marketers on the importance of market access considerations associated with distributing products including SGNTs.
- ▶ As needed, provide specific input to seed marketers to support the development of market access plans.
- ▶ Be aware of, promote and/or adopt (as relevant) good stewardship practices promoted by seed developers.
- ▶ Consult with relevant seed developers of potential changes to export markets as they arise.
- ▶ Consider providing support for maintaining ongoing authorizations as needed (e.g. when original developer exits the market but the value chain sees value in continuing to market the product).

Appendix

Existing Stewardship and Best Practices Information and Resources

Domestic regulatory authorization

In Canada, plants with novel traits (and novel food/feed derived therefrom) require certain authorizations from the Canadian Food Inspection Agency and Health Canada prior to their commercial release. Generally, seed (and the food/feed derived from) that is derived from seed that has already been approved in Canada is exempt from further pre-market requirements. However, in some cases, a product is approved with conditions or use restrictions which may subject the SGNT to CFIA oversight. It is up to each marketer of the seed to ensure all domestic regulatory requirements are met in advance of and in support of commercial sale of its products.

Guidance for pre-commercial regulatory requirements can be found here:

- ▶ **Food** - <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods.html>
- ▶ **Feed** - <https://inspection.canada.ca/animal-health/livestock-feeds/novel-feeds/eng/1370227088259/1370227136675>
- ▶ **Environment** - <https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/eng/1300137887237/1300137939635>

International regulatory authorizations

Acquiring and maintaining regulatory authorizations in key markets are a component for supporting trade of many crops grown in Canada. As entities consider selling SGNTs, it is important they understand the processes involved in securing and maintaining export market authorizations, including regulatory approval timelines that can take several years. Furthermore, some countries have authorizations that are time-limited and require regular renewal (e.g. China, European Union). Considerations around what authorizations may be applicable, and if identified, how these authorizations are maintained should be considered by entities selling SGNTs as early as possible in the development of their business plans. Advance awareness and planning is a critical part of both corporate and industry risk management strategies.

CropLife Canada and Seeds Canada encourage companies who market SGNTs to refer to the CropLife Canada "[Best management practices for launching new plant breeding innovations](#)". These best practices are of particular importance for bulk handled grain commodities as they encourage proactive communication among value chain stakeholders to facilitate international trade. Entities can also refer to the "[Excellence Through Stewards Product Launch Guidelines](#)" for additional details on how to conduct an export market assessment.

Resistance Management Stewardship

Plants with novel traits such as herbicide tolerance and insect or disease resistance traits benefit from stewardship measures to help preserve the durability of the trait and delay the potential development of resistance. Various established networks, platforms and resources are publicly available and entities marketing SGNTs should utilize these resources to gain familiarity with relevant best practices and promote them with their customers. Such resources include:

- **Certified agronomists and crop advisors** who provide individualized advice to farmers based on the latest science and information from academics and seed companies.
- **Commodity associations** that conduct crop-specific research and publish guides on rotations, pest management, herbicide tolerance stewardship (for both novel and non-novel products) and other sustainable cropping practices.
- **Academia**, providing research and advice.
- **Seed company** educational resources that include product technology use guides, stewardship agreements, websites and training programs for staff, seed retailers and growers.
- **The Canadian Corn Pest Coalition (CCPC)**, a collaborative group of experts promoting the proper stewardship of corn pest management technologies (www.cornpest.ca).
- **CropLife Canada's Manage Resistance Now** platform (www.manageresistancenow.ca) which collects input from many of the groups listed above including industry, provincial agronomists, academia and the CCPC. This platform also supported an associated Certified Crop Advisor (CCA) specialist designation in resistance management.
- The global **Herbicide Resistance Action Committee (HRAC)** and **Insecticide Resistance Action Committee (IRAC)** administered by CropLife International and operated by members of the crop protection industry.
- **The Midge Tolerant Wheat Stewardship** industry coalition representing plant breeders, government, seed growers, seed distributors and producer groups. The team is committed to maintaining the viability of Midge Tolerant Wheat by educating Canadian wheat producers on the importance of proper stewardship of the technology (<https://midgetolerantwheat.ca/>).
- **Excellence Through Stewardship** (<https://www.excellencethroughstewardship.org/>), a global non-profit organization that promotes the adoption of product stewardship programs and quality management systems through provision of technical guidance and conducting of audits for compliance.

In addition to resistance management, there may be other product specific stewardship activities that are beneficial or appropriate for a given product. It is the responsibility of each marketer and all users of the product to be aware of, promote, and support the implementation of any applicable practices.



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