

## PRODUCT DISCONTINUATION/PRODUCT PHASE-OUT CHECKLIST

### INTRODUCTION:

Agricultural biotechnologies, like all new technologies, evolve. As new biotechnology derived seeds are introduced into the market, older products may be taken out of production as a normal and predictable part of a product's lifecycle. Once seed sales are discontinued, the presence of these seeds will diminish.

Lifecycle stewardship of plant biotechnology products is a core activity for CropLife Canada and the Canadian Seed Trade Association member companies. The process described in this Discontinued Products/Product Phase-Out checklist is intended to facilitate Canadian companies taking a product off the market either globally, or in Canada. This process incorporates the Excellence through Stewardship (ETS) [Guide for Product Discontinuation of Biotechnology Derived Plant Products](#), but is specific to Canadian companies, rules and regulations. Canadian companies, who are members of ETS, have agreed to be audited against the EST guides.

### DEFINITIONS:

- **Discontinued products** are authorised commercial plant biotechnology seed products that have reached the end of their commercial life cycle and sales have terminated globally, but may still be present in food, feed and grain supply.
- **Product Phase-out (PPO)** refers to products which are discontinued regionally.
- **Product Discontinuation (PD)** is the process to terminate the sales of a commercial seed product.
- **Channel discontinuation** is the normal utilization of a discontinued product or its derivatives (food, feed or other products) in the commodity chain leading to diminishing low level presence.
- **Low Level Presence (LLP)** is the adventitious presence of biotechnology-derived plant material that has undergone a full safety assessment and been authorized for use in food, feed, grain and derived products in one or more countries but not in the country of import.

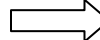
### CHECKLIST - PRODUCT DISCONTINUATION PROCESS:

Timeline: **Product Launch**  **Commercial Life**  **Decision to Discontinue Product**

- Ensure licensee agreements:
  - Take product discontinuation/phase-out timelines into account
  - Address transfer of stewardship accountability (e.g., IRM, reporting or monitoring)
- Consider timing of patent(s)
- Consider timing of next generation product(s)
- Consider timing of registration (eg: prior to growing season, vs mid or at harvest)
- Consider product lines affected by the discontinuation, and portfolio consequences
- Evaluate impact of discontinuation on third parties and downstream value chain

**Timeline: Decision to Discontinue Product**  **Development of PD Team**

- Designate leader of Product Discontinuation Team - Should have breadth of experience
- Define regional or local sub-teams, as needed
- Ensure key functional representation, consider: crop team, legal, regulatory, public affairs, industry affairs, stewardship, breeding, commercial, licensing, production/manufacturing, research, supply chain, quality control

**Timeline: Development of PD Team**  **Create and implement PP/PPO Plan**

**General Considerations:**

- |                                                        |                                                                     |
|--------------------------------------------------------|---------------------------------------------------------------------|
| <input type="checkbox"/> Accountability/responsibility | <input type="checkbox"/> Stakeholders/Customers/Commercial Partners |
| <input type="checkbox"/> Timing                        | <input type="checkbox"/> Key Actions/Milestones                     |
| <input type="checkbox"/> Triggers                      | <input type="checkbox"/> Audits/verification                        |

**Regulatory (import/export, food, feed, and cultivation):**

- Review regulatory status of all relevant products
- Consider any time-limited authorizations
- Consider timing of registration during calendar year
- Consider measures to address LLP (testing and tolerance for LLP after discontinuation)
- Keep reference samples for detection methods
- Formal notification of government regulators that product has been discontinued
- Address ongoing regulatory requirements:
  - Conditions for use of product after discontinuation/phase out
  - Ensure conditions of registration are fulfilled during the discontinuation/phase out process
- Consider varietal de-registration/de-listing, if applicable

**Communication (National and International):**

- Develop a communication plan from initial decision to discontinue to completion of discontinuation
- Consider timing of key events and communicate these milestones with stakeholders (last year of production / last year of sales)
- Consider / communicate the product replacement plan
- Consider audience(s), timing and key message development
  - External : regulators, government officials, growers, trade associations, dealers, academics
  - Internal: Crop Team, Legal, Regulatory, Public Affairs, Stewardship, Breeding, Commercial, Licensing, Production/Manufacturing, Research, Supply Chain, Quality Control

**Manage Inventory: (evaluate each seed source - determine whether to retain, utilize or destroy)**

- Define disposition approaches for material(s) in the value chain to minimize market exposure
- Consider internal seed inventory: research, greenhouses, breeding, testing labs, seed archives, seed storage/warehouses, regulatory labs, and contra-season nurseries
- Consider external seed inventory: academic (breeders, researchers), cooperators, germplasm depositories, licensees, distributors/dealers, growers, seed tollers, testing facilities, government
- If possible, allow an appropriate amount of time for third parties in the value chain to utilize materials via normal channels
- If a regional phase out, determine international seed needs or send out from existing stock
- Determine seed that needs to be retained (e.g., for reference materials), and consider:
  - Approved storage location(s)
  - Segregation from commercial products
  - Labeling of containers to assure seed identification and appropriate use

**Third Parties (including tollers, academics, cooperators, distributors/dealers) and Licensees**

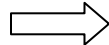
- Develop discontinuation plan for each third party or licensee:
  - Review contracts/licenses incl. sub-licenses for trait R&D and commercialization
    - Ensure /amend contracts to include timing of discontinuation/phase out
    - Ensure /include potential to audit for completion of PD process and retention of documentation
    - Ensure transfer of accountability for conditions of registration /stewardship
  - Specify necessary actions including determining inventory/sales/returns, disposition of remaining seed, last date of seed sale, and documentation for reconstruction of PD process
    - Compare licensee's reported seed volumes with data on licensee's inventory to ensure accounting of all materials
    - Specify appropriate means of destruction
- Monitor with detection method as part of Seed Quality Management Program, confirming declining presence of discontinued products in materials
  - Establish duration of monitoring period
  - Consider frequency of reporting and recipient(s) of report
- Where appropriate, transfer authorizations to licensees (licenses extend beyond patent expiration)

**Internal Activities (e.g., research, breeding, production, seed quality testing labs)**

- Inform all functions of discontinuation/phase out - provide timelines and requirements
- Include counter season activities, if applicable

- Individual functional groups develop plans to meet timelines and requirements and provide information to Product Discontinuation Team:
  - Determine inventory and its disposition
  - Required documentation to be retained to support the reconstructability of the process
  - If applicable, ensure product replacement(s) in place for future development
  - Monitor with detection method as part of Seed Quality Management Program, confirming declining presence of discontinued products in materials
    - Establish duration of monitoring period
    - Consider frequency of reporting and recipient(s) of report

**Timeline: Implementation of PD Plan**



**After PD / PPO Plan**

**Additional Stewardship Considerations:**

- Seed piracy
- External/internal databases and website listings updated
- Grower compliance in year(s) after discontinuation (crop dependent)
- Changes to chemistry labels?
- How are inquiries regarding discontinued products handled?
  - Report possible use of discontinued product(s)
  - Additional seed stock identified after discontinuation
- Maintain the Product Discontinuation Team “on-call” to support ongoing discussions/inquiries

**Retention of documentation:**

- Regulatory documents
- Third party agreements and termination documentation
- Detection methods
- Archive records; include Inventory depletion, Date of last sale, Disposal records, Decisions, Seed Quality Control records, Verifications
- Verification/Audit – i.e., product discontinued and process documented
- Prepare a report of the Product Discontinuation Process

**CANADIAN REGULATORY DEPARTMENTS:**

Canadian Food Inspection Agency <http://www.inspection.gc.ca/>

Health Canada <http://www.hc-sc.gc.ca>

Agriculture and Agri-Food Canada <http://www.agr.gc.ca>