

Updating Novel Foods Guidance: Products of Plant Breeding and Beyond

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Outline

- Context for new novel food guidance
- Novel Food Regulations: Current State to Future State
- Overview of Health Canada's new novel food guidance, focused on plant-derived foods
- Next Steps

Context

- *Novel Food Regulations* (Division 28, Part B of the *Food and Drug Regulations*) enacted in 1999.
- Guidance related to the safety assessment of novel foods last updated in 2006.
- Plant developers have expressed their need for greater clarity and predictability regarding the regulatory framework for Novel Foods (Report of Canada's Economic Strategy Tables: Agri-food, 2018; <https://www.ic.gc.ca/eic/site/098.nsf/eng/00022.html>).
- The Government of Canada has committed to modernize Canada's regulatory approach by providing greater clarity and predictability regarding the regulation of products derived from new technologies (Targeted Regulatory Review: Agri-food and Aquaculture Roadmap, 2019; <https://www.inspection.gc.ca/about-cfia/acts-and-regulations/forward-regulatory-plan/agri-food-and-aquaculture-roadmap/eng/1558026225581/1558026225797>).

The *Novel Food Regulations*

- Division 28, Part B of the *Food and Drug Regulations* (https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/page-91.html)
- No person shall sell or advertise for sale a novel food unless the manufacturer or importer of the novel food
 - (a) has notified the Minister in writing of their intention to sell or advertise for sale the novel food; and
 - (b) has received a written notice from the Minister.
- A Novel Food is:
 - A substance that does not have a history of safe use as a food;
 - A food that has been treated to a process that has not been previously applied to that food and causes that food to undergo a major change; and
 - **A food derived from a plant, animal or microorganism that has been genetically modified such that it has a characteristic new to that organism or has an existing characteristic that has been altered beyond the documented range for that organism.**

Past State to Current State for GM Plant-Derived Foods

- From 1999 to present, the Novel Food Regulations has pre-market oversight on foods derived from ALL GM plants that exhibit NEW characteristics to that plant. It is a product-based approach that is entirely based on the novelty (newness) of a product's characteristics.
- Applying 20 plus years of regulator experience assessing foods derived from GM plants and our understanding of current plant breeding practices, Health Canada is refining our interpretation of novelty to focus on GM plants with NEW characteristics that have a Potential Impact on Food Safety.
- The new guidance maintains our product-based approach while evolving our regulatory oversight to be more risk-based.
- Products subject to the Novel Food Regulations will be more clearly identified through the new guidance. This will provide developers with greater predictability regarding the regulatory status of their products with the aim of encouraging innovation, and at the same time helping to ensure the safety of the Canadian food supply.

Our timeline to date for guidance development

Event	Date
<u>Pre-development</u>	
CFIA-led Plant Breeding Seminar Series	June – July 2020
<u>Guidance development</u>	
Health Canada published Notice of Intent: To publish new guidance for the <i>Novel Food Regulations</i> , focussed on plant breeding	August 31, 2020
Health Canada-led Plant Breeding Expert Panel	October 16, 2020
Draft guidance presented to targeted stakeholders	December 8, 2020
Revision of guidance	December – January 2021
Revised guidance presented to targeted stakeholders	February 2021
<u>Public consultation of guidance</u>	March 25, 2021 – May 24, 2021

Scientific Opinion

- In support of the new guidance, Health Canada developed a scientific opinion (SO) on the regulation of gene-edited plant products within the context of the *Novel Food Regulations*
- The SO addresses:
 - The scientific basis for risk-based and product-based regulation
 - The advancement of plant breeding from selection to modern technologies
 - An overview of gene (genome) editing technologies
 - How gene editing technologies may be applied in plant breeding
 - Key considerations for regulators (including how products of gene-editing compare to other products of plant breeding)
 - Considerations for existing pre-market and post-market systems responsible for food safety

Scientific Opinion (cont'd)

- Overall, the SO supports the position that gene editing technologies do not pose any unique risks to food safety compared with other plant breeding practices.
- **Position:** Gene-edited plant products should be regulated like all other plant products – according to their characteristics and not the specific process used to introduce those characteristics
- The new guidance applies to food made from all products of plant breeding

The new guidance

- ***Guidance on the interpretation of Division 28 of Part B, of the Food and Drug Regulations (the Novel Food Regulations): When is a food that was derived from a plant developed through breeding a “novel food”?***
 - Novelty interpretation guidance
- ***Guidance on the pre-market assessment of foods derived from retransformants under Division 28 of Part B, of the Food and Drug Regulations (the Novel Food Regulations)***
 - Retransformants guidance

Public consultation and outcomes

- A public consultation for the new guidance was held from **March 25 to May 24, 2021**.
- Over **4600** comments were received.
 - **67** associations and organizations (provincial governments, industry associations, non-government organizations, and academia), as well as individuals of the general public.
- Comments were carefully analyzed and where relevant, revisions to the guidance and materials for the TI process have been made.

Public consultation and outcomes (cont'd)

- Comments were diverse, detailed, and grouped into 5 general themes:
 1. Clarity and predictability
 2. Government oversight
 3. Safety of products of plant breeding
 4. Transparency
 5. Other topics related to other dimensions of biotechnology
- ***A What We Heard report***, summarizing the outcomes of the consultation will be published at the same time as the new guidance on the Health Canada website.
- As some comments expressed criticism regarding the length and content of the primer on gene editing technologies, Health Canada will publish the full-length **Scientific Opinion on the Regulation of Gene-edited Plant Products within the Context of the *Novel Food Regulations***

What foods derived from products of plant breeding will NOT require pre-market notification and assessment as novel foods under the new guidance?

- Foods derived from plants:
 1. Foods derived from plants with genetic modifications that do not alter an endogenous protein in a way that introduces or increases similarity with a known allergen or toxin relevant to human health;
 2. Foods derived from plants with genetic modifications that do not increase levels of a known endogenous allergen, a known endogenous toxin, or a known endogenous anti-nutrient beyond the documented ranges observed for these analytes in the plant species;
 3. Foods derived from plants with genetic modifications that do not have an impact on key nutritional composition and/or metabolism;
 4. Foods derived from plants with genetic modifications that do not intentionally change the food use of the plant; and
 5. Foods derived from plants with genetic modifications that do not result in the presence of foreign DNA in the final plant product.
- **If a plant does not meet all 5 criteria, foods derived from that plant are considered novel foods and require pre-market assessment.**

Retransformants guidance

1. Introduction

- Explains the reasoning for the new guidance.
- Defines what Health Canada considers a “retransformant” product.

2. Assessment Criteria

- Indicates what data is required for the safety assessment of a product meeting this definition.

3. Pre-market assessment with an expedited service standard for foods derived from retransformants

- Describes the process, service standard (i.e., 120 calendar days), and outcome for retransformants.

Transparency Initiative

- Under the new guidance, many foods derived from gene-edited plants will not be considered novel.
- The TI allows plant developers to voluntarily provide Health Canada with a set of information regarding their non-novel gene-edited plant products.
- This information will be published on the Health Canada website for public access to increase transparency regarding gene-edited plant products in the Canadian market.
- Under the TI, developers are encouraged to provide information about their product at least 90 calendar days prior to commercialization.
- Health Canada will review the information provided and, upon concurring with the “non-novel” status of the product, will publish the information within 60 calendar days of receipt.
- Publication will contain no Confidential Business Information (CBI).

Developing materials for the TI process

- Based on the comments received during the consultation, the following materials have been developed for the TI process:
 1. A **landing page** that describes the purpose of the TI and the voluntary process. The page also explains how the TI process differs from Health Canada's Novelty Determination process.
 2. A **TI Product Information Form** that clearly indicates what information (data and/or rationale(s)) should be provided by the product developer.
 3. A **list of non-novel products of plant breeding** that will contain information about non-novel products of plant breeding that have either been:
 - determined to be not novel by Health Canada through the Novelty Determination process; or
 - determined to be not novel by the developer who has notified the Department about their gene-edited plant product.

List of non-novel products of plant breeding

Date of Receipt	Product Name	Plant	Developer	Technology	Characteristic(s)	Mechanism(s) of Action	Food Use(s)	Earliest Entry to Market Date
YYYY-MM-DD	Variety Name	Common name (Genus species)	Developer name	e.g., conventional breeding, genome editing - oligonucleotide-directed mutagenesis, genome editing - CRISPR-Cas9, etc.	e.g., herbicide tolerance, insect resistance, modified nutritional composition, etc.	e.g., deletion of [gene] encoding [protein] involved in [cellular process]	e.g., oil, starch, produce, etc.	YYYY

Next steps

- Notice of Intent to Propose Amendments to Division 28 of the *Food and Drug Regulations (Novel Foods)*
 - Develop and propose amendments that will provide clarity, predictability, and transparency for stakeholders.
 - Reduce the need for future amendments as new guidance is developed.
- Proposed amendments will maintain the health and safety of Canadians and the Canadian food supply, while also:
 - Supporting innovation and the introduction of new technologies, which result in the production of safe food.
 - Maintaining the product-based regulatory framework.
 - Facilitating a risk-based approach where oversight is commensurate to the level of risk posed by a product.
- Health Canada will seek engagement from stakeholders to identify where Division 28 might benefit from amendments and key issues that need to be considered as part of the development of the proposed amendments.