

Novelty Determination Self-Assessment Checklist

Health Canada: Novel Food Regulations (Division 28, Food and Drug Regulations)

Canadian Cellular Agriculture Regulatory Resource

Purpose: Use this checklist before engaging Health Canada to determine whether your product qualifies as a “novel food” and requires a pre-market notification (NFN).

Disclaimer: This is not an official government document. It does not constitute legal or regulatory advice. Always verify requirements with the regulatory entities involved.

SECTION A: Company & Product Identification

Company Name	
Product Name / Working Title	
Product Type	<input type="checkbox"/> Cultivated meat/seafood (e.g., cultivated chicken or salmon) <input type="checkbox"/> Precision fermentation ingredient (e.g., dairy or heme) <input type="checkbox"/> Whole microbial food (e.g., fungal mycelium meat alternatives or whole microalgae) <input type="checkbox"/> Other (e.g., Novel scaffolding materials, cell-culture media components):
Source Organism(s) (Genus and species) of the original cell source or microbial host)	
Production Method Summary A high-level, 2–3 sentence overview of the bioprocess. Mention the bioreactor phase, the inputs (media/feedstock), and the harvesting/purification method.	
Intended Use / Application Is it a standalone consumer food, an ingredient mixed into other foods, a processing aid, or a flavoring agent?	

Completed by Internal tracking for accountability	
Today's Date	

SECTION B: Novelty Trigger Assessment

Answer each question. A single YES may trigger a novel food notification requirement. Review all questions before concluding.

B1. History of Safe Use in Canada

Question	YES	NO	UNCERTAIN
Does this food or food ingredient have a documented history of safe use as food in Canada?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Has this product been previously sold or widely consumed in Canada without safety concerns?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is there a well-established history of safe use as food in another country that is directly analogous to Canadian dietary patterns?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B2. Production Process Novelty

Question	YES	NO	UNCERTAIN
Does the production process involve cell culture techniques not previously used in food production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does it involve precision fermentation with a genetically modified microorganism?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Could the process result in significant changes to the food's composition, nutritional profile, or presence of new compounds?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the process been demonstrated to cause a 'major change' as defined in B.28.001 (alteration of molecular structure, biological activity, nutrient content, allergenicity, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B3. Genetic Modification

Question	YES	NO	UNCERTAIN
Does your product or any ingredient involve genetic modification of a microorganism, plant, or animal cell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does it involve gene editing (CRISPR, TALENs, etc.) that results in heritable trait changes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the source organism not on Health Canada's list of completed novel food safety assessments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B4. Source Organism

Question	YES	NO	UNCERTAIN
Is the source organism species not previously used as human food in Canada?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the source organism have a known history of producing toxins, allergens, or other hazardous compounds?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the organism a non-pathogenic strain of a species that has pathogenic relatives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B5. International Regulatory Status

Question	YES	NO	UNCERTAIN
Has this product been approved as a novel food by another jurisdiction (EFSA, US FDA, Singapore SFA, etc.)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Note: Approval elsewhere does NOT exempt from Canadian requirements. A Canadian novel food notification is still required.	—	—	—

SECTION C: Determination Outcome

Select	Determination	Recommended Next Step
<input type="checkbox"/>	NOVEL: One or more YES answers in Section B	Proceed to pre-submission consultation request with Health Canada SMIU. Begin compiling NFN dossier.

Select	Determination	Recommended Next Step
<input checked="" type="checkbox"/>	LIKELY NOT NOVEL: All NO answers, no UNCERTAIN	Document your rationale fully. Retain this checklist on file. Consider a novelty determination consultation with Health Canada to confirm before market entry.
<input type="checkbox"/>	UNCERTAIN: One or more UNCERTAIN answers	Request a novelty determination pre-consultation with Health Canada SMIU to seek official guidance before proceeding.

IMPORTANT: Even if your product is determined non-novel under the Food and Drug Regulations, other requirements may still apply: ECCC New Substances Notification (Organisms) under CEPA if a new living organism is involved; CFIA requirements for labelling, licensing, and preventive controls; and Good Manufacturing Practices (GMP) and HACCP under the Safe Food for Canadians Act.

SECTION D: Notes & Supporting Documentation

Supporting rationale / notes:

Key Reference Documents

- Health Canada: Guidelines for the Safety Assessment of Novel Foods (2006, updated 2022)
- Division 28, Part B, Food and Drug Regulations (B.28.001 — Definitions)
- Health Canada: Guidance on Novelty Interpretation of Products of Plant Breeding (2022)
- Health Canada: Cellular Agriculture page:
canada.ca/en/health-canada/services/food-nutrition/cellular-agriculture
- Health Canada list of completed novel food safety assessments (approved products)

Reviewer Sign-Off

Role	Name	Date
Prepared by		
Reviewed by		
Approved by		