

Novel Food Notification Submission Cover Letter

Health Canada, Food and Nutrition Directorate

Canadian Novel Foods Regulatory Resource | Phase 2 — Safety Dossier Preparation

*When to use: Attach this cover letter as the first document in your Novel Food Notification (NFN) submission package to Health Canada's Food and Nutrition Directorate.
Submit via the online application form: healthycanadians.gc.ca/radar/FD-DA-0001.08.html
Regulatory basis: Division 28, Part B, Food and Drug Regulations; SMIU submission requirements.*

Note: The tables in this template are worksheets to help you organize information before drafting your cover letter. **Do not include the tables in the cover letter itself.**

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

Sender Information

Company / Organization	
Mailing Address	
Primary Contact Name	
Title / Role	
Email	
Phone	
Regulatory Representative	[Name, Firm - if submission prepared by external consultant]
Date of Submission	

Recipient

To	Food and Nutrition Directorate, Health Products and Food Branch, Health Canada
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Attention	Submission Management and Information Unit (SMIU)
Email	smiu-ugdi@hc-sc.gc.ca
HC Case Number	[Insert if a pre-submission consultation was held and a case number was assigned]

Product Summary

Product / Ingredient Name	[Common name or working title]
Product Category	☐ Cultivated meat/seafood ☐ Precision fermentation ingredient ☐ Whole microbial food ☐ Other: _____
Source Organism	[Genus, species, strain]
Intended Use	[e.g., protein ingredient in consumer food products for the general adult population]
Novelty Basis	☐ No history of safe use in Canada ☐ Major change (novel process) ☐ Genetic modification
GM Organism Involved?	☐ Yes ☐ No

Mandatory Submission Content Disclosure

The following questions are required by the Submission Management and Information Unit (SMIU) and must be answered in the cover letter of every Novel Food Notification submission.

⚠ These three questions are mandatory per SMIU requirements. All three must be answered regardless of product type. A missing or incomplete answer may delay intake of your submission.

Required Question (SMIU)	Answer	Guidance Note
Does your submission contain nutritional data?	☐ Yes ☐ No	<i>Include if your dossier contains any proximate composition, amino acid profiles, vitamin/mineral analysis, or dietary exposure data.</i>
Does your submission contain a microbiological analysis?	☐ Yes	<i>Include if your dossier contains any pathogen</i>

Required Question (SMIU)	Answer	Guidance Note
	☐ No	<i>testing, microbial limits data, contamination risk assessments, or sterility testing relevant to the novel food.</i>
Does your submission contain any food additives or contaminants data?	☐ Yes ☐ No	<i>Include if your dossier contains data on process-related contaminants, residual solvents, heavy metals, mycotoxins, pesticide residues, or any substances used as food additives.</i>

Cover Letter Body

[City], [Province], [Date]

Submission Management and Information Unit (SMIU)
Food and Nutrition Directorate, Health Products and Food Branch
Health Canada

Dear SMIU,

On behalf of [Company Name], I am pleased to submit a Novel Food Notification (NFN) for [product/ingredient name], pursuant to Division 28, Part B of the Food and Drug Regulations.

Product Description

[Provide a 2–3 sentence description of the product: what it is, how it is produced, what it will be used for, and who will consume it. Example: 'The subject of this notification is a fermentation-derived whey protein produced by a genetically modified strain of *Trichoderma reesei*. The ingredient is intended for use as a protein source in consumer food products including beverages, protein bars, and dairy alternatives, targeting the general adult population in Canada.']

Basis for Novel Food Notification

[Explain briefly why this product requires an NFN — i.e., which novelty trigger applies. Example: 'This product is considered novel under B.28.001 of the Food and Drug Regulations on the basis that it has no history of safe use as food in Canada and is produced by a genetically modified microorganism.']

Mandatory Content Disclosure

In accordance with SMIU submission requirements, we confirm the following regarding the content of this submission:

Nutritional data:

- ☐ Yes — this submission contains nutritional data (see [Section/Appendix reference])
☐ No

Microbiological analysis:

- ☐ Yes — this submission contains microbiological analysis data (see [Section/Appendix reference])
☐ No

Food additives or contaminants data:

- ☐ Yes — this submission contains food additive or contaminant data (see [Section/Appendix reference])
☐ No

Pre-Submission Consultation

- ☐ A pre-submission consultation with the Food Directorate was held on [date]. HC Case Number: [number]. Key guidance received during the consultation has been incorporated into this submission package.
☐ No pre-submission consultation was held prior to this submission.

Submission Package Contents

List all sections and appendices included in your submission package.

#	Document / Section Title	Notes
1	Cover Letter	<i>If applicable</i>
2	Executive Summary	<i>If applicable</i>
3	Product Characterization	<i>If applicable</i>
4	Production Process Description	<i>If applicable</i>
5	Compositional / Nutritional Data	<i>If applicable</i>
6	Dietary Exposure Assessment	<i>If applicable</i>
7	Toxicology Data	<i>If applicable</i>
8	Allergenicity Assessment	<i>If applicable</i>
9	Microbiological Analysis	<i>If applicable</i>

#	Document / Section Title	Notes
10	Chemical Contaminants Data	<i>If applicable</i>
11	International Regulatory Assessments	<i>If applicable</i>
12	Supporting References / Bibliography	<i>If applicable</i>

Confidentiality

All information contained in this submission package is submitted as confidential business information. We request that it not be disclosed to individuals outside the Government of Canada without prior written consent from [Company Name].

We look forward to Health Canada's assessment and are available to provide any clarifications or additional information required. Please direct any correspondence to the primary contact listed above.

Respectfully submitted,

[Full Name]

[Title]

[Company Name]

[Email] | [Phone]

Pre-Submission Checklist

Complete before sending. Do not submit until all mandatory items are confirmed.

Item	Confirmed ✓
All three SMIU mandatory questions answered in the cover letter body (nutritional data / microbiological analysis / food additives or contaminants) [MANDATORY]	☐
HC Case Number included (if a pre-submission consultation was held)	☐
All sections listed in the submission package contents table are attached [MANDATORY]	☐
Novelty basis clearly stated in the cover letter [MANDATORY]	☐
GM organism status disclosed [MANDATORY]	☐
Confidentiality statement included [MANDATORY]	☐

Item	Confirmed ✓
Submission sent to correct address: smiu-ugdi@hc-sc.gc.ca [MANDATORY]	☐
Cover letter dated and signed by an authorized company representative [MANDATORY]	☐