



## Supplemented food submission checklist – food category

### Instructions

This checklist is divided into several main sections, each with a specific set of requirements:

- Section 1: Administrative
- Section 2: Description
- Section 3: Food consumption information
- Section 4: Special conditions proposed for the food category
- Section 5: General safety information

As you work through each section, check off each completed item. If you have any questions concerning the items in this checklist, please contact the Submission Management and Information Unit (SMIU) via the following email address: [smiu-ugdi@hc-sc.gc.ca](mailto:smiu-ugdi@hc-sc.gc.ca). For information on how to prepare a submission to request a modification to the List of Permitted Supplemented Food Categories, please refer to Health Canada's [Guidance Document: Pre-market Submission Process for Supplemented Foods](#). If further guidance is required, it is strongly recommended to request a [pre-submission consultation](#) with the Food Directorate.

### How to submit

The submission should be sent electronically through the [Online Application Form for Pre-Market Submissions to the Food Directorate](#). Please review the guidance document, titled [How to Complete the Online Application and Transport Form for Pre-Market Submissions to the Food Directorate](#).

**Note:** Your submission must be organized following the order and titles of the main sections (Sections 1 – 5) set out above. Failure to do so will result in the closure of your submission.

If you cannot provide each piece of information required by the checklist (i.e., if you do not check off one of the boxes in the checklist), you must provide a written explanation to justify why each piece of missing information is not provided to support the safety assessment of the supplemented food category.

Your explanation must be provided in the corresponding section of your submission, not in the checklist.

All fields are mandatory, unless otherwise indicated.

Section 1: Administrative	
1.1 Name of petitioner (manufacturer, company, consultant, importer, etc.):	
1.2 Name of supplemented food category:	
1.3 Cover letter	
The dated and signed Cover Letter must include the following information:	
	Title of submission <sup>1</sup>
	Submission type (i.e., supplemented foods)
	Submission sub-type (i.e., food category)
	Supplemented Food (SF) category name, as it appears or is proposed to appear in the <a href="#">List of Permitted Supplemented Food Categories</a>
	Comment on eligibility of the food category for inclusion in the <a href="#">List of Permitted Supplemented Food Categories</a> (i.e., does the category include excluded foods: foods requiring or permitted addition of vitamins, minerals or amino acids as per the table to D.03.002 of the <a href="#">Food and Drug Regulations</a> (FDR); foods for special dietary use other than gluten-free foods (FDR, Part B, Division 24); infant formulas (FDR, Part B, Division 25); foods targeted towards children under 4 years of age, or pregnant or breastfeeding individuals; prepackaged unprocessed foods or minimally processed foods; beverages containing more than 0.5% alcohol?)
	Executive summary explaining the proposed name and description of the food category (including any differences compared to a food category already set out in the <a href="#">List of Permitted Supplemented Food Categories</a> ), supplemental ingredients requested to be permitted in the food category, and special conditions of use (e.g., special packaging considerations)
	Reference to related submission number(s) (or titles if a submission number is not yet available), where applicable (e.g., pre-submission, closed submission, cross-linked supplemental ingredient submission)
1.4 Authorization forms	
<b>Note:</b> A signed DPA form need only be provided if the primary contact is a designated party (e.g., consultant) authorized to act on behalf of the petitioner. The primary contact serves as the individual to which all correspondence from the Food Directorate will be sent.	
	Signed <a href="#">Designated Party Authorization (DPA) Form</a>

<sup>1</sup> Please follow the naming convention for the title: [Food category name] as an SF category containing [all SI] OR [specify supplemental ingredients(s) (SI) (from [source] when applicable)] OR [Food sub-category name] in SF category [X] containing [all SI] OR [specify SI(s) (from [source] when applicable)]. E.g., Pudding as an SF category containing L-leucine; Pudding as an SF category containing all SI; Ground coffee in bulk format in SF category 4, containing Vitamins and Mineral Nutrients.

<b>Section 2: Description</b>	
	Proposed name of the food category
	Description of the requested food category
	Comprehensive list of food commodities under the requested food category
	Information on any applicable exclusions
	Information on supplemental ingredients requested to be permitted in the food category
	Proposed use (e.g., intended for use as a finished product; comment on potential use in the preparation of other foods)

<b>Section 3: Food consumption information</b>	
	Canadian data regarding the estimated consumption of foods within the requested food category across life-stage and gender groups (e.g., data from the Canadian Community Health Survey (CCHS) – Nutrition); otherwise, data regarding the estimated consumption of foods within the requested food category across life-stage and gender groups in similar countries (e.g., U.S. data from the National Health and Nutrition Examination Survey)
	Scientific rationale that supports that the supplementation of the requested food category with the proposed supplemental ingredients does not present an increased health or safety risk relative to the existing list of permitted supplemented food categories

<b>Section 4: Special conditions proposed for the food category</b>	
	Special packaging conditions, or other conditions of use, and impact on safety for the consumer

<b>Section 5: General safety information</b>	
	Safety narrative based on the conclusions of Sections 3 and 4 of this checklist (regarding the overall safety of the requested modification to the List of Permitted Supplemented Food Categories, considering the food category, food commodities, and/or exclusions).