

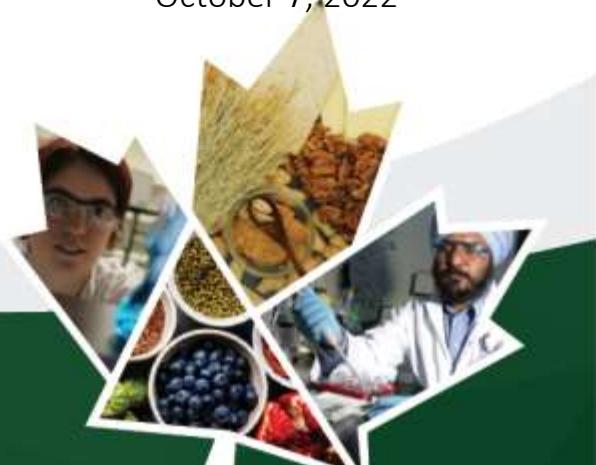


Health Canada's Proposal to Enable the Use of Milk Thistle Seed Extract (silymarin) as a Supplemental Ingredient in Foods

Notice of Proposal – List of Permitted Supplemental Ingredients

Reference Number: NOP/ADP SI-004

October 7, 2022



Summary

Supplemental ingredients are regulated in Canada under the *Supplemented Foods Regulations*, which are set out in Division 29, Part B of the *Food and Drug Regulations* (Regulations). The *List of Permitted Supplemental Ingredients* is incorporated by reference in the Regulations through the definition of “supplemental ingredient” set out in Division 1, Part B of the Regulations and captures substances that may be added to a specified food as a supplemental ingredient. This list also sets out the detailed conditions of use for each supplemental ingredient such that the supplemented food may be sold in Canada. A petitioner can request that Health Canada approve a new supplemental ingredient or a new condition of use for an already approved supplemental ingredient by [filing a supplemental ingredient submission](#) with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of supplemental ingredients in foods sold in Canada.

Health Canada's Food Directorate has assessed milk thistle seed extract for use as a supplemental ingredient. This is one of the ingredients the Food Directorate previously identified for further assessment since it was an ingredient that was present in product(s) that were previously eligible to transition to the food regulatory framework under Temporary Marketing Authorizations.

The Food Directorate concluded that information related to the safety of standardized milk thistle seed extract supports its safe use in supplemented foods provided levels of use do not exceed intakes equivalent to 600 mg silymarin¹ per day, do not exceed 200 mg silymarin per serving, and that certain other compositional and labelling requirements are met; as set out in the table below. Therefore, Health Canada proposes to enable the use of milk thistle seed extract (silymarin)² by adding the entry shown in the table below to the *List of Permitted Supplemental Ingredients*.

Proposed Modification to the *List of Permitted Supplemental Ingredients*

Supplemental Ingredient		Conditions of Use			
Item No.	Column 1 Description	Column 2 Permitted in	Column 3 Maximum Amounts and Units Per Serving of Stated Size	Column 4 Cautionary Statements Required on the Label	Column 5 Other
Part IV: Other Supplemental Ingredients					
1.2	Milk Thistle Seed Extract (silymarin)	Foods belonging to a category listed in the <i>List of Permitted Supplemented Food Categories</i>	200 mg silymarin	(a) All products containing Milk Thistle Seed Extract (silymarin) require the cautionary statements: i. “For Adults only (18 years of age or older)”; ii. “Not recommended for pregnant or breastfeeding women”; iii. “Do not consume [eat/drink] on the same day as any other supplemented foods or supplements with [the same	Milk Thistle Seed Extract (silymarin) is an extract of <i>Silybum marianum</i> (L.) Gaertn. seeds, including, dry extract, fluid extract, tincture, decoction, and infusion obtained via water and/or food grade organic solvent extraction techniques, that is standardized to a silymarin content of 65% – 80%. Any organic solvents used must

¹ The primary constituent of milk thistle seed extract is silymarin.

² This naming convention denotes that milk thistle seed extracts be a standardized preparation of silymarin.

				<p>supplemental ingredients/(name specific ingredients)]”; and</p> <p>iv. “Not recommended for individuals with allergy to plants in the aster family.”</p> <p>(b) Products containing Milk Thistle Seed Extract (silymarin) providing more than 120 mg of silymarin per serving require the additional cautionary statement:</p> <p>i. “Do not eat/drink more than X container(s)/serving(s) daily”, where X is a number of servings that provides a daily amount of silymarin that does not exceed 600 mg.</p>	<p>be in accordance with the <i>List of Permitted Carrier or Extraction Solvents</i>.</p>
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Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of milk thistle seed extract. The assessment concluded that information related to chemistry, nutrition, microbiology, toxicology, and allergenicity supports the safety of milk thistle seed extract for its use as a supplemental ingredient.

Milk thistle seed extract is derived from the seeds of milk thistle, *Silybum marianum* (L.) Gaertn. Milk thistle seed extract is standardized according to the content of silymarin. Sources of exposure to silymarin and/or milk thistle seed extract in the diet are not common. Milk thistle seed extract (silymarin) is well tolerated in clinical studies and does not pose any toxicological or nutritional concerns when used as a supplemental ingredient in accordance with the conditions of use outline in the table above. Adverse effects are rare and generally considered mild; however, there is a potential for sensitization and/or allergic reactions associated with the ingestion of silymarin by individuals who have allergies to members of the aster (Asteraceae) plant family³. Therefore, cautionary labelling to alert individuals with allergies to plants in the aster family is warranted.

Health Canada is therefore proposing to enable the use of this supplemental ingredient as shown in the table above.

To obtain an electronic copy of Health Canada’s summary of the safety assessment for the use of milk thistle seed extract as a supplemental ingredient, please contact our publications office or send an e-mail to publications-publications@hc-sc.gc.ca with the subject heading “**HPFB BNS Milk Thistle Seed Extract_EN**”.

Other Relevant Information

Part B of the Regulations do not set out specifications for the use of milk thistle seed extract (silymarin) as a supplemental ingredient; however, the proposed conditions of use as set out in Column 5 of the table above identify compositional requirements that must be met, and which, in part, form the basis of Health Canada’s determination that milk thistle seed extract (silymarin) is safe for use as a supplemental ingredient.

³ The aster (Asteraceae) family includes, but is not limited to, artichokes and common thistle.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in the *List of Permitted Supplemental Ingredients*. This will be announced via a Notice of Modification that will be published on the [Government of Canada's website](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Under the transitional provisions of the [*Regulations Amending the Food and Drug Regulations and the Cannabis Regulations \(Supplemented Foods\)*](#), products that have a valid authorization for market access will be allowed a transition period after the coming into force of the regulations until December 31, 2025. The transition period allows manufacturers or distributors of supplemented foods continued market access and provides time to make the necessary changes to comply with the requirements of the Supplemented Foods Regulations.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

Supplemented Foods:

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If communicating by e-mail, please use the words “**Milk Thistle Seed Extract (NOP/ADP SI-004)**” in the subject line of your e-mail. Health Canada is able to consider information received by **December 20, 2022**, 75 days from the date of this posting.