



13 October 2022

(22-7703)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English/French

NOTIFICATION

1. Notifying Member: <u>CANADA</u> If applicable, name of local government involved:
2. Agency responsible: Health Canada
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Milk thistle seed extract (silymarin) as a supplemental ingredient in foods
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Health Canada's proposal to enable the use of milk thistle seed extract (silymarin) as a supplemental ingredient in foods. Language(s): English and French. Number of pages: 4 and 5
6. Description of content: Health Canada's Food Directorate completed a detailed premarket safety assessment of milk thistle seed extract for use as a supplemental ingredient in foods, under the Supplemented Foods regulatory framework. The results of the premarket assessment support the safety of standardized milk thistle seed extracts based on the silymarin content. Consequently, Health Canada intends to enable the use of milk thistle seed extract (silymarin) by modifying the <i>List of Permitted Supplemental Ingredients</i> as described in the Notice of Proposal information document. The purpose of this communication is to publicly announce the Department's intention in this regard and to provide the appropriate contact information for any inquiries or for those wishing to submit new scientific information relevant to the safety of milk thistle seed extract (silymarin) when used as a supplemental ingredient in foods.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None Does this proposed regulation conform to the relevant international standard?

<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>	
9.	<p>Other relevant documents and language(s) in which these are available: Health Canada's Food and Nutrition – "Public Involvement and Partnerships" Website, posted 7 October 2022 (available in English and French): https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships.html https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats.html</p>
10.	<p>Proposed date of adoption (dd/mm/yy): The proposed supplemental ingredient will be legally enabled once published in Health Canada's <i>List of permitted supplemental ingredients</i> (https://www.canada.ca/en/health-canada/services/food-nutrition/supplemented-foods/technical-documents/list-permitted-food-ingredients.html).</p> <p>Proposed date of publication (dd/mm/yy):</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): The supplemental ingredient modification noted in this document come into force the day they are made to the <i>List of permitted supplemental ingredients</i> (https://www.canada.ca/en/health-canada/services/food-nutrition/supplemented-foods/technical-documents/list-permitted-food-ingredients.html).</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 20 December 2022</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p>
13.	<p>Text(s) available from: <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>The "Health Canada's Proposal to enable the use of milk thistle seed extract (silymarin) as a supplemental ingredient in foods" is available through the following weblink: https://canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-proposal-enable-use-milk-thistle-seed-extract-supplemental-ingredient-foods/document.html (English) https://canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats/avis-proposition-utilisation-extrait-graines-chardon-marie-ingredient-supplementaire-aliments/document.html (French)</p> <p>Canada's Notification Authority and Enquiry Point Technical Barriers and Regulations Division Global Affairs Canada 111 Sussex Drive Ottawa, Ontario, K1A 0G2 Canada Tel: +(343) 203 4273 Fax: +(613) 943 0346 E-mail: enquiry@international.gc.ca</p>