



13 February 2025

(25-1015)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English/French

NOTIFICATION

Addendum

The following communication, received on 13 February 2025, is being circulated at the request of the Delegation of Canada.

Modification to the *List of Permitted Supplemental Ingredients* to enable the use of milk thistle seed extract (silymarin)

The purpose of this Notice is to inform consumers and interested stakeholders that Health Canada's Food and Nutrition Directorate has completed a safety assessment of milk thistle seed extract. As a result of this safety assessment, Health Canada has permitted the use of milk thistle seed extract derived from the seeds of milk thistle, *Silybum marianum* (L.) Gaertn., and standardized according to the content of silymarin. The available toxicological and clinical evidence supports the safe consumption of milk thistle seed extract as a supplemental ingredient by the general population of healthy adults, up to the equivalent of 600 mg silymarin on a daily basis. Health Canada has concluded that milk thistle seed extract (silymarin), when used as a supplemental ingredient in accordance with the conditions of use outlined in Part IV of the *List of Permitted Supplemental Ingredients* does not pose any toxicological or nutritional concerns. 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 family. Therefore, cautionary labelling to alert individuals with allergies to plants in the aster family is warranted.

The above modification came into force 30 January 2025 the day it was published in the *List of Permitted Supplemental Ingredients*.

Health Canada's Food and Nutrition Directorate is committed to reviewing new scientific information on the safety of permitted supplemental ingredients, including milk thistle seed extract (silymarin). Anyone wishing to submit an inquiry or new scientific information on the use of this supplemental ingredient may do so by regular mail or email.

This addendum concerns a:

- ☐ Modification of final date for comments
- ☒ Notification of adoption, publication or entry into force of regulation
- ☐ Modification of content and/or scope of previously notified draft regulation
- ☐ Withdrawal of proposed regulation
- ☐ Change in proposed date of adoption, publication or date of entry into force
- ☐ Other:

Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)

[] Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Not applicable

Agency or authority designated to handle comments: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Text(s) available from: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

The Notice of "Modification to the List of Permitted Supplemental Ingredients to enable the use of milk thistle seed extract (silymarin)" is available through the following weblinks:

<https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/notices-proposal-notices-modification/list-permitted-supplemental-ingredients-enable-use-milk-thistle-seed-extract-silymarin.html> (English)

<https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/legislation-lignes-directrices/lois-reglements/avis-proposition-avis-modification/liste-ingredients-supplementaires-autorises-permettre-utilisation-extrait-graines-chardon-marie-silymarine.html> (French)

Or requested from:

Canada's Notification Authority and Enquiry Point

Technical Barriers and Regulations Division

Global Affairs Canada

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