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Health Canada's Proposal to Enable the Use of Grape Seed Extract (oligomeric proanthocyanidins) as a Supplemental Ingredient in Foods

Notice of Proposal – List of Permitted Supplemental Ingredients

Reference Number: NOP/ADP SI-002

August 16, 2022



Canada

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 grape 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.

Grape seed extract has a history of safe use as a flavouring in food. The continued use of grape seed extract as a food flavouring ingredient is the responsibility of the food seller to ensure that the sale of a food containing grape seed extract does not contravene section 4 of the *Food and Drugs Act*.

For food sellers who choose to use grape seed extract as a supplemental ingredient, the Food Directorate concluded that information related to the safety of standardized grape seed extract supports its safe use in supplemented foods provided levels of use do not exceed intakes equivalent to 100 mg oligomeric proanthocyanidins¹ per day, do not exceed 100 mg oligomeric proanthocyanidins 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 grape seed extract (oligomeric proanthocyanidins)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	Grape seed extract (oligomeric proanthocyanidins)	Foods belonging to a category listed in the <i>List of Permitted</i>	100 mg oligomeric proanthocyanidins	(a) All products containing Grape seed extract (oligomeric proanthocyanidins) require the cautionary statements: i. “For Adults only (18 years of age or older)”;	Grape seed extract (oligomeric proanthocyanidins) is an extract of <i>Vitis vinifera</i> L. including, dry extract, fluid extract, tincture, decoction and infusion obtained via water and/or food grade organic

¹ The primary constituent of grape seed extract is oligomeric proanthocyanidins.

² This naming convention denotes that grape seed extracts used as a supplemental ingredient, be a standardized preparation of oligomeric proanthocyanidins.

		<i>Supplemented Food Categories</i>		<p>ii. "Not recommended for pregnant or breastfeeding women"; and</p> <p>iii. "Do not consume [eat/drink] on the same day as any other supplemented foods or supplements with [the same supplemental ingredients/(name specific ingredients)]".</p> <p>(b) Products containing Grape seed extract (oligomeric proanthocyanidins) providing more than 20 mg of oligomeric proanthocyanidins 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 oligomeric proanthocyanidins that does not exceed 100 mg.</p>	<p>solvent extraction techniques that is standardized to an oligomeric proanthocyanidins content of 70% – 90%. Any organic solvents used must 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 grape seed extract. The assessment concluded that information related to chemistry, nutrition, microbiology, toxicology, and allergenicity supports the safety of grape seed extract for its use as a supplemental ingredient.

Grape seed extract is derived from the seeds of grapes, *Vitis vinifera* L. (family: *Vitaceae*). Grape seed extract is standardized according to the content of oligomeric proanthocyanidins. Proanthocyanidins are naturally present in a wide variety of commonly consumed foods. Grape seed extract (oligomeric proanthocyanidins) is well tolerated in clinical studies, is not associated with reports of allergic reactions, and does not pose any toxicological or nutritional concerns when used as a supplemental ingredient in accordance with the conditions of use outlined in the table above.

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

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

Other Relevant Information

Part B of the Regulations do not set out specifications for the use of grape seed extract (oligomeric proanthocyanidins) 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 grape seed extract (oligomeric proanthocyanidins) is safe for use as a supplemental ingredient.

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 SFs 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 "**Grape Seed Extract (NOP/ADP SI-002)**" in the subject line of your e-mail. Health Canada is able to consider information received by **October 29, 2022**, 75 days from the date of this posting.