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Notice of Modification to the *List of Permitted Colouring Agents* to Extend the Use of *Spirulina* Extract to Certain Unstandardized Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0160

February 8, 2021



Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (Regulations). Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on the Canada.ca website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada's Food Directorate received a food additive submission seeking approval for the use of *Spirulina* (*Arthrospira platensis*) extract as a colouring agent in various foods such as beverage dry mixes, unstandardized confectionery, custards, dessert coatings, frosting, frozen novelties, gelatin, ice cream, puddings, toppings, and yogurts. The requested maximum level of use, in all these foods, is 0.1%. For the beverage dry mixes, the requested maximum level of use applies to the beverage as consumed.

Spirulina extract is already permitted for use as a colouring agent in a variety of foods at a level consistent with Good Manufacturing Practice (GMP), including certain foods requested by the petitioner.

The results of the Food Directorate's evaluation of available scientific data support the safety of extending the use of *Spirulina* extract to the other foods of interest to the petitioner, namely custards, dessert coatings, non-alcoholic beverage dry mixes, puddings, toppings, and unstandardized chocolate confectionery, to be used at level consistent with GMP, as is already permitted for other uses of this colouring agent. Therefore, Health Canada has modified the [List of Permitted Colouring Agents](#) to extend the use of *Spirulina* extract to these foods by adding "Custards", "Dessert coatings", "Puddings", and "Toppings" to subitem (2); removing "unstandardized chocolate confectionery" as an exception in subitem (5), which has the effect of permitting *Spirulina* extract in unstandardized chocolate confectionery because it is a type of "Unstandardized confectionery"; and adding "Unstandardized non-alcoholic beverage dry mixes" to subitem (6). For clarity, these changes are shown in **bold** in the below table.

Modification to the *List of Permitted Colouring Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
15.	<i>Spirulina</i> extract	(2) Custards; Dessert coatings; Gelatin desserts; Puddings; Unstandardized frozen desserts; Toppings	(2) Good Manufacturing Practice
		(5) Unstandardized confectionery (except unstandardized chocolate confectionery)	(5) Good Manufacturing Practice
		(6) Unstandardized non-alcoholic beverages;	(6) Good Manufacturing Practice

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		Unstandardized non-alcoholic beverage concentrates; Unstandardized non-alcoholic beverage dry mixes	

Based on the safety evaluation, the entry for “unstandardized confectionery” was expanded to all include all types of unstandardized confectionery including those that contain chocolate. However, this entry excludes any chocolate product that meets one of the standards set out in [Division 4](#) of the *Food and Drug Regulations*.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of *Spirulina* extract for use as a colouring agent in the foods of interest to the petitioner that are not already permitted to be coloured with *Spirulina* extract. The assessment concluded that information related to allergenicity, chemistry, microbiology, nutrition and toxicology supports the safety of *Spirulina* extract for these new uses. Therefore, the Department has enabled these new uses of *Spirulina* extract by modifying the [List of Permitted Colouring Agents](#) with the changes shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as *Spirulina* extract that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. The *Combined Compendium of Food Additive Specifications*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations. Currently there are tentative specifications for *Spirulina* extract¹ established by JECFA.

Implementation and Enforcement

The above modification came into force **February 8, 2021**, the day it was published in the [List of Permitted Colouring Agents](#).

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

¹ SPIRULINA EXTRACT (TENTATIVE) – Residue Monograph prepared by the meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 86th Meeting 2018: <http://www.fao.org/3/ca3742en/ca3742en.pdf>

Contact Information

Health Canada's Food Directorate is committed to reviewing new scientific information on the safety in use of any permitted food additive, including *Spirulina* extract. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "***Spirulina* extract (NOM-0160)**" in the subject line of your e-mail.

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