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Modification to the List of permitted preservatives to enable the use of chitosan

Notice of Modification - Lists of permitted food additives

Reference Number: M-FAA-24-05

May 30, 2024

Background

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (Regulations). Authorized 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 authorize a new additive, or a new source or a new condition of use for an already permitted food additive by filing a food additive submission with the Department's Food and Nutrition Directorate. Health Canada uses this premarket authorization process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Issue

Health Canada's Food and Nutrition Directorate received a food additive submission seeking authorization for the use of chitosan from white button mushrooms (*Agaricus bisporus*) as a preservative in numerous foods at maximum levels of use ranging from 150 parts per million (ppm) to 1,500 ppm. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published the Notice of Proposal titled Health Canada's Proposal to Enable the Use of Chitosan from White Button Mushrooms (*Agaricus bisporus*) as a Preservative in Various Foods (Reference number: NOP/ADP-0042). The Notice of Proposal was published on November 20, 2023, and was open to the public for comment for 75 days. The petitioner provided examples of products that would be included in the requested food categories. For example, by toppings, the petitioner refers to glaze, maple butter, marshmallow cream and fruit-based toppings. Chitosan is proposed for use in the requested foods to prevent the growth of microorganisms and subsequent spoilage.

Rationale for Action

Health Canada's Food and Nutrition Directorate completed a premarket safety assessment of chitosan from white button mushrooms (*A. bisporus*) as a preservative in numerous foods. The Department considered allergenicity, chemistry, microbiology, nutrition, and toxicology in the assessment. The results of the assessment support the safety and efficacy of chitosan from *A. bisporus* for its requested uses. Therefore, Health Canada has authorized the use of chitosan having an average molecular weight 90 to 120 kDa and degree of deacetylation not less than 80%, obtained from *Agaricus bisporus*, by adding the new item and its corresponding entries shown in the table below to Part 2 and Part 3 of the List of permitted preservatives.

To clarify, the "Rationale" section of the Notice of Proposal had, by error, included "molecular biology" in the types of information that support the safety of chitosan from *A. bisporus* for its requested uses. In fact, molecular biology was not taken into consideration in the evaluation of chitosan from this source because *A. bisporus* is a mushroom that has not been genetically modified.

Consultation - Summary of Stakeholder Comments and Health Canada's Responses

Health Canada's Proposal to Enable the Use of Chitosan from White Button Mushrooms (*Agaricus bisporus*) as a Preservative in Various Foods was published on November 20, 2023. The consultation ended on February 2, 2024.

One stakeholder responded to the Notice of Proposal, asking for clarification on the common name of chitosan that would appear in the list of ingredients of foods sold in Canada. In response, Health Canada indicated that chitosan from *Agaricus bisporus* will appear as "chitosan" in the List of permitted preservatives, and therefore "chitosan" would be an acceptable common name for use in the lists of ingredients of foods sold in Canada.

Since the conclusions of the evaluation otherwise remain as described in the Notice of Proposal, and no new scientific information was submitted to the Department as a result of this Notice of Proposal, the list is modified as shown below.

Modifications to Part 2 and Part 3 of the List of permitted preservatives

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
C.3	Chitosan from <i>Agaricus bisporus</i> (average molecular weight 90 to 120 kDa and degree of deacetylation not less than 80%)	(1) Apricot nectar; Concentrated (naming the fruit) juice; Concentrates for unstandardized beverages containing fruit juice; Fruit-based or dairy-based smoothie beverages; Fruit-flavoured drinks; (naming the fruit) Juice; (naming the fruits) Juice; Peach nectar; Pear nectar; Unstandardized beverages containing fruit juice	(1) 600 p.p.m.
		(2) Bread; Unstandardized bakery products	(2) 1,000 p.p.m.
		(3) Caffeinated energy drinks; Unstandardized alcoholic beverages; Unstandardized fermented tea beverages; Unstandardized non-alcoholic water-based beverages; Unstandardized tea beverages; Unstandardized vegetable juices; Water-based beverages with vitamin and mineral nutrients added, except beverages with vitamins added in accordance with Part D of the <i>Food and Drug Regulations</i>	(3) 400 p.p.m.

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		(4) Cheddar cheese; (naming the variety) Cheese; Cold-pack (naming the variety) cheese; Cold-pack cheese food; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food with (naming the added ingredients); Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); Unstandardized cheese-based sauces; Unstandardized processed cheese products; Unstandardized shredded cheese products	(4) 1,500 p.p.m.
		(5) Egg-based desserts; Fruit-based desserts	(5) 800 p.p.m.
		(6) Fillings; Toppings; Unstandardized table syrups	(6) 1,000 p.p.m.
		(7) Fresh pasta; Fresh noodles	(7) 200 p.p.m.
		(8) Frostings; Icings	(8) 400 p.p.m.

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		(9) Liquid plant protein isolate-based products that resemble egg products	(9) 1,500 p.p.m.
		(10) Liquid soup bases; Liquid soup mixes; Soups	(10) 400 p.p.m.
		(11) Liquid table-top sweeteners	(11) 1,000 p.p.m.
		(12) Meal replacement bars; Nutritional supplement bars	(12) 200 p.p.m.
		(13) Plant-based products that resemble cheese	(13) 1,500 p.p.m.
		(14) Relishes	(14) 800 p.p.m.
		(15) Simulated meat products; Simulated poultry products	(15) 1,500 p.p.m.
		(16) Unstandardized coffee beverages	(16) 150 p.p.m.
		(17) Unstandardized confectionery coatings	(17) 1,000 p.p.m.
		(18) Unstandardized fruit spreads	(18) 1,000 p.p.m.
		(19) Unstandardized salad dressings	(19) 1,000 p.p.m.
		(20) Unstandardized sauces	(20) 1,000 p.p.m.

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		(21) Unstandardized snack bars	(21) 200 p.p.m.
		(22) Unstandardized vegetable purées	(22) 400 p.p.m.
		(23) Yogurt	(23) 1,000 p.p.m.

Other Relevant Information

Food additives are required to meet food-grade specifications set out in Part B of the Regulations, where such specifications exist, or those set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications* where there are no specifications in Part B and there are specifications in one of these compendia. The *Food Chemicals Codex* is a compendium of food-grade specifications for food ingredients, including food additives, published by the United States Pharmacopeial Convention. Specifications in the *Combined Compendium of Food Additive Specifications* are prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The *Combined Compendium of Food Additive Specifications* is published by the Food and Agriculture Organization of the United Nations. There are no specifications for chitosan from *A. bisporus* in Part B, the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. However, the petitioner's specifications for chitosan from *A. bisporus* are consistent with those for chitosan from crustacean sources set out in the

Food Chemicals Codex with respect to the mineral content (i.e., chromium, iron, and nickel) and concentrations of trace elements of most concern to human health (i.e., arsenic, cadmium, lead, and mercury).

Implementation and Enforcement

The above modification came into force **May 30, 2024**, the day it was published in Part 2 and Part 3 of the List of permitted preservatives.

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

Contact Information

Health Canada's Food and Nutrition Directorate is committed to reviewing new scientific information on the safety in use of any permitted food additive. Anyone wishing to submit an inquiry or new scientific information on the use of a permitted food additive may do so in writing, by regular mail or e-mail. If you wish to contact the Food and Nutrition Directorate by e-mail about chitosan from *A. bisporus*, please use the words "**chitosan(M-FAA-24-05)**" in the subject line of your e-mail.

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