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Health Canada's Proposal to Enable the Use of Tara Gum as an Emulsifying, Gelling, Stabilizing and Thickening Agent in Unstandardized Foods and Certain Standardized Foods

Notice of Proposal – ***Lists of Permitted Food Additives***

Reference Number: [NOP/ADP-0027]

August 23, 2017

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

Summary

Food additives are regulated in Canada under Marketing Authorizations (MAs) issued by the Minister of Health and the *Food and Drug 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 Health Canada's website. A petitioner can request that Health Canada approve a new food 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 received a food additive submission seeking approval for the use of tara gum as an emulsifying, gelling, stabilizing and thickening agent. The foods in which it is intended to be used are bread as well as the same foods, or foods that fall within the same food categories, as those to which carob bean gum (locust bean gum) may be added.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of tara gum for its requested uses. Therefore, Health Canada intends to modify the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* by adding the entries to the list as set out in the table below.

Proposed Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
T.2B	Tara gum	(1) Bread; Cream; French dressing; Mustard pickles; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids; Relishes; Salad dressing	(1) Good Manufacturing Practice
		(2) Cottage cheese; Creamed cottage cheese	(2) 0.5% in accordance with the requirements of sections

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
			B.08.051 and B.08.052
		(3) Ice cream mix	(3) 0.5%. If used in combination with microcrystalline cellulose, other stabilizing agents, or both, the total amount not to exceed 0.5%
		(4) Ice milk mix	(4) 0.5%. If used in combination with other stabilizing agents, the total amount not to exceed 0.5%
		(5) Calorie-reduced margarine	(5) 0.5%. If used in combination with other food additives from this list except gelatin and lecithin, the total amount not to exceed 0.5%
		(6) Sherbet	(6) 0.75%. If used in combination with other stabilizing agents, the total amount not to exceed 0.75%
		(7) Sour cream	(7) 0.5%. If used in combination with other food additives from this list except monoglycerides, mono- and diglycerides and sodium phosphate dibasic, the total amount not to exceed 0.5%
		(8) Unstandardized foods	(8) Good Manufacturing Practice
		(9) Cold-pack cheese food; Cold-pack cheese food with (naming the added ingredients); Cold-pack (naming the variety) cheese with (naming the added ingredients); Cream cheese; Cream cheese with (naming the	(9) 0.5% singly or in combination in accordance with the same conditions of use as prescribed for those food additives referred to in subparagraphs or clauses B.08.035.(1)(*b*)(iv), B.08.037.(1)(*b*)(v),

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients)	B.08.038.(1)(*b*)(v)(A), B.08.039.(1)(*b*)(v)(A), B.08.041.3.(1)(*b*)(v)(A), B.08.041.4.(1)(*b*)(v)(A), B.08.041.6.(1)(*b*)(v), B.08.041.7.(1)(*b*)(v) and B.08.041.8.(1)(*b*)(v)

Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of tara gum when used as described in the table above. The assessment considered information related to chemistry, microbiology, nutrition, toxicology, and the efficacy of tara gum for its requested uses.

Tara gum, also referred to as "Peruvian carob", is a white to yellowish powder obtained by grinding the endosperm of seeds of the tara tree (*Tara spinosa* (Molina) Britton & Rose, synonym *Caesalpinia spinosa* (Molina) Kuntze, family Fabaceae).

Tara gum is a polysaccharide composed mainly of galactomannans, as is the case for carob bean gum and guar gum. Tara gum's structure consists of a linear main chain of (1→4)-β-D-mannopyranose (mannose) units with side units of α-D-galactopyranose (galactose) attached by (1→6) linkages. The galactose side units are distributed non-uniformly along the main chain. The presence of galactose side units tends to inhibit aggregation so gums with more side chains (e.g., carob bean gum) are harder to dissolve in water than tara gum.

Tara gum galactomannans are structurally similar to several gums that are approved food additives, namely guar gum, partially hydrolyzed guar gum (PHGG) and carob bean gum, differing primarily in the mannose to galactose ratio. The ratio of these sugar residues is approximately 3:1. The ratios of mannose to galactose in guar gum, PHGG and carob bean gum are approximately 2:1, (1.5-2):1, and 4:1, respectively.

Submitted data show that tara gum has an intermediate acid solubility between carob bean gum and guar gum. It resists the depolymerization effect of organic acids down to a pH of 3.5 whereas carob bean gum is stable to a pH of 3.0 and guar gum to a pH of 4.0. Tara gum is stable to high temperature heat treatment and has synergistic effects when used in combination with other gums. These data support the conclusion that tara gum is as effective as carob bean gum or guar gum, and in some respects more effective. Data was also provided demonstrating shelf-life stability of tara gum itself.

In experimental animal feeding studies, tara gum showed negligible evidence of being broken down by digestive enzymes. It passed essentially unchanged into the intestinal tract. There it was shown to be almost entirely hydrolyzed (98%) by the microflora of the intestine into mannose and galactose, two simple sugars commonly found in the diet. These can be further degraded into short-chain fatty acids that are used in normal metabolism. The findings are similar to those observed with other structurally-related gums. The fact that tara gum is broken down to constituents that are commonly found in the diet is consistent with the fact that an extensive toxicological database shows that tara gum is not a systemic toxin, carcinogen, teratogen, reproductive toxin or genotoxic substance under standard study conditions.

No nutritional or microbiological concerns were identified for the requested uses of tara gum. There have been no reports in the literature of tara gum, which has been used in the United States, Europe and elsewhere for decades as an ingredient in food, triggering an allergic response.

Tara gum is to be used as a replacement for, or in combination with, other permitted gums such as carob bean gum, guar gum, acacia gum, karaya gum, tragacanth gum and xanthan gum. For many of the standardized foods in which the use of tara gum was requested, a numerical maximum level of use is proposed in order that the requirements of the relevant compositional standards are respected. However, for some of the standardized foods and for unstandardized foods, allowing tara gum at a maximum use level of good manufacturing practice (GMP) as indicated in the table will provide the same flexibility in levels of use afforded to these other gums, all of which are permitted in unstandardized foods and some of the requested standardized foods at GMP.

Health Canada's Food Directorate considers that the outcome of the safety assessment supports the safety of tara gum when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of tara gum as described in the table above.

Other Relevant Information

As indicated by the petitioner, in the United States of America, tara gum is "self-affirmed" GRAS (Generally Recognized as Safe) when used as a thickener, stabilizer, emulsifier and gelling agent in foods.[1]

Tara gum is recognized internationally as acceptable for use in various foods at levels of use consistent with good manufacturing practice. In this regard, it is listed in the Codex Alimentarius Commission's General Standard for Food Additives, and is a permitted food additive in the European Union and in Australia and New Zealand.

1 As stated by the petitioner, the "self-affirmed" GRAS affirmation was not submitted to the Food and Drug Administration as it is not a mandatory requirement.

The *Food and Drug Regulations* require that food additives such as tara gum that do not have specifications set out in Part B of the Regulations meet the most recent specifications set out in 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.

Implementation and enforcement

The proposed changes to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* will be effective the day on which they are published in this List on Health Canada's website. This will be announced via a Notice of Modification that will also be published on Health Canada's website.

The Canadian Food Inspection Agency is responsible for the enforcement of the food-related aspects of the *Food and Drugs Act* and its associated regulations.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

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If communicating by e-mail, please use the words "**Tara gum**" in the subject line of your e-mail. Health Canada is able to consider information received by **December 3, 2017**.