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Health Canada's Proposal to Enable the Use of a New Food Additive, Lycopene Extract from Tomato, as a Food Colouring Agent in Various Foods

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0024]

March 24, 2017

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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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 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 lycopene extract from tomato as a food colouring agent. The maximum level of use on the basis of the finished food or beverage ranges from 3 ppm to 100 ppm.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of lycopene extract from tomato as a food colouring agent. Therefore, it is the intention of Health Canada to modify the [List of Permitted Colouring Agents](#) by adding the following entries to the list.

Proposed 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
13.	Lycopene Extract from Tomato	(1) Dry beverage mixes except fruit-flavoured dry beverage mixes; Non-alcoholic carbonated water-based flavoured and sweetened beverages; Unstandardized coffee beverages; Unstandardized tea beverages; Unstandardized vegetable-based beverages	(1) 12 p.p.m. calculated as lycopene, in beverages as consumed
		(2) Frostings; Unstandardized confectionery	(2) 40 p.p.m. calculated as lycopene
		(3) Chewing gum; Unstandardized confectionery coatings	(3) 100 p.p.m. calculated as lycopene
		(4) Apple (or rhubarb) and (naming the fruit) jam; (naming	(4) 10 p.p.m. calculated as lycopene

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	the fruit) Jam with pectin; Pineapple marmalade with pectin; Unstandardized fruit spreads	
	(5) Mashed fruit for use in yogurt; Mashed fruit for use in yogurt-based beverages	(5) 30 p.p.m. calculated as lycopene
	(6) Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Unstandardized dairy-based dips; Unstandardized dairy-based spreads	(6) 20 p.p.m. calculated as lycopene
	(7) Unstandardized dairy-based beverages; Unstandardized dairy-based dry beverage mixes	(7) 20 p.p.m. calculated as lycopene, in beverages as consumed
	(8) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(8) 20 p.p.m. calculated as lycopene
	(9) Simulated meat products	(9) 30 p.p.m. calculated as lycopene
	(10) Unstandardized desserts; Sherbet	(10) 20 p.p.m. calculated as lycopene
	(11) Fillings; Filling mixes	(11) 20 p.p.m. calculated as lycopene, in fillings as consumed
	(12) Unstandardized dry sauce mixes; Unstandardized sauces	(12) 15 p.p.m. calculated as lycopene, in sauces as consumed
	(13) Ice cream mix	(13) 20 p.p.m. calculated as lycopene, in the ice cream made from the mix
	(14) Ice milk mix	(14) 20 p.p.m. calculated as lycopene, in the ice milk made from the mix
	(15) Non-carbonated unsweetened flavoured coloured water beverages	(15) 3 p.p.m. calculated as lycopene

Rationale

Health Canada's Food Directorate assessed lycopene extract from tomato for use as a food colouring agent. The assessment considered information related to chemistry, microbiology, toxicology, nutrition and to the efficacy of the extract as a food colouring agent.

Lycopene is a red carotenoid pigment that naturally occurs in ripe tomatoes and other fruits such as papaya, watermelon and guava. The petitioner who filed the food additive submission extracts lycopene from specially-bred lycopene-rich tomatoes to manufacture a red, crystalline powdered oleoresin that is composed of fatty acids (60-75%), lycopene (at least 5%) and other constituents of tomatoes. Product quality data demonstrated that the product can consistently meet acceptable microbiological and chemical specifications. Data was provided demonstrating the stability of the lycopene from the extract over a five day period in different food matrices.

The toxicological data on lycopene include the results of safety tests conducted with lycopene from natural sources, including tomato, and lycopene made synthetically. Lycopene was not determined to be mutagenic, genotoxic, carcinogenic or to cause systemic toxicity or to produce harmful reproductive or developmental effects. Studies with human volunteers showed high daily doses of lycopene to be well tolerated. The non-lycopene constituents present in the lycopene extract from tomato are normal constituents of the diet and at the levels of consumption are not considered toxicologically significant.

Tomatoes can trigger oral allergy syndrome in some individuals. However, the lycopene extract that is derived from tomato is unlikely to trigger this sensitivity reaction since the manufacturing process for the extract is expected to remove much of the tomato protein. There were no data indicating that lycopene is a food allergen.

No nutritional concerns were identified with any of the constituents of lycopene extract from tomato, including lycopene, fatty acids, phytosterols, tocopherols, beta-carotene, phosphorous and the carotenoid precursors phytofluene and phytoene, when the extract is used as proposed.

The results of the premarket assessment support the safety of lycopene extract from tomato when used under the conditions set out in the table above. The Department is therefore proposing to enable the uses of lycopene extract from tomato as shown in the table.

Other Relevant Information

Lycopene extract from tomato is permitted for use as a food colour in the United States, Europe, and Australia and New Zealand. It is also included in Table 3 of the Codex Alimentarius Commission's General Standard for Food Additives (GSFA), indicating its acceptance at the international level for use in foods in general, with some exceptions, in accordance with good manufacturing practice.

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The Canadian *Food and Drug Regulations* require that food additives, such as lycopene extract from tomato, which do not have specifications set out in the Regulations meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC) or the most recent edition of the *Combined Compendium on Food Additive Specifications*. The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention. The *Combined Compendium on Food Additive Specifications* is prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and is published by the Food and Agriculture Organization of the United Nations. The current specifications in the FCC and the *Combined Compendium on Food Additive Specifications* for lycopene extract from tomato are for a liquid form of the extract. However, the petitioner intends to sell lycopene extract from tomato in a dried powder form. This must also meet the specifications set out in the FCC or by JECFA, with specification test results being expressed, where appropriate, on the basis of the liquid from which the dried powder was obtained.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the [List of Permitted Colouring Agents](#). This will be announced via a Notice of Modification which will be published on [Health 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.

Contact Information

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

[Bureau of Chemical Safety, Food Directorate](#)

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If communicating by e-mail, please use the words “**lycopene extract from tomato**” in the subject line of your e-mail. The comment period for this proposal is open until **June 06, 2017**, 75 days from the date of this posting.