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Notice of Modification to the *List of Permitted Colouring Agents* to Enable the Use of Lycopene Extract from Tomato in Certain Non-Carbonated Sweetened Flavoured Water-Based Beverages with Vitamins and Mineral Nutrients Added and in Sports Drinks

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0143

March 12, 2020



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 lycopene extract from tomato as a food colouring agent in sports drinks and certain non-carbonated sweetened flavoured water-based beverages to which vitamins have been added. The requested maximum level of use is 3 ppm. Lycopene extract from tomato has been permitted as a colouring agent in a few other beverage categories since 2017; however, sports drinks and certain non-carbonated sweetened flavoured water-based beverages to which vitamins have been added did not fall within the permitted beverage categories.

Lycopene extract from tomato is already permitted for use in Canada as a colouring agent in a number of foods including the following beverage categories: non-alcoholic carbonated water-based flavoured and sweetened beverages; unstandardized dairy-based beverages; and non-carbonated unsweetened flavoured coloured water beverages.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of lycopene extract from tomato when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Colouring Agents](#) to extend the use of lycopene extract from tomato by adding the entry shown below to the List.

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	(16) Non-carbonated sweetened flavoured water-based beverages with vitamin and mineral nutrients added, except beverages with vitamins added in accordance with Part D of the Food and Drug Regulations; Sports drinks	(16) 3 p.p.m. calculated as lycopene

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of lycopene extract from tomato for use as a food colouring agent. The assessment concluded that information related to chemistry, microbiology, nutrition, toxicology, and allergenicity supports the safety of lycopene extract from tomato for its requested uses. Therefore, the Department has enabled the requested uses of lycopene extract from tomato by adding to the [List of Permitted Colouring Agents](#) the new entry shown in the above table.

Other Relevant Information

The CODEX General Standard for Food Additives provides for the use of lycopene extract from tomato, with the functional class "colour", in a number of food categories including "water-based flavoured drinks including 'sport', 'energy', or 'electrolyte' drinks and particulated drinks, at a maximum use level of good manufacturing practice. Major trading partners such as the United States, Europe, and Australia and New Zealand all appear to permit the use of lycopene extract from tomato in these types of beverages, with the exception that the European Union allows for its use in flavoured drinks, but not "dilutable drinks".

The *Food and Drug Regulations* require that food additives such as lycopene extract from tomato that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade 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 above modification came into force **March 12, 2020**, 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.

Contact Information

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including lycopene extract from tomato. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**lycopene extract from tomato (NOM-0143)**" in the subject line of your e-mail.

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

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