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Notice of Modification to the *List of Permitted Preservatives* to Enable the Use of Nisin as an Antimicrobial Preservative in or on Various Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0110]

February 9, 2018

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* (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 received two food additive submissions that together sought approval for the use of nisin as an antimicrobial preservative in assorted standardized and unstandardized foods. The proposed maximum levels of use, on the basis of the finished food or beverage, range from 2.5 parts per million (p.p.m.) to 30 p.p.m., depending on the product.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of nisin when used as set out in the table below. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a notice of the Department's intent to enable the use of nisin, titled [Health Canada's Proposal to Enable the Use of a New Food Additive, Nisin, as an Antimicrobial Preservative in or on Various Foods – Reference Number: NOP/ADP-0028](#).

The proposal was published on September 20, 2017, and was open for public comment for 75 days. No new scientific information was submitted to the Department as a result of this publication. Since the conclusions of the evaluation remain as described in the publication, Health Canada has modified Part 2 of the [List of Permitted Preservatives](#) as indicated below, with two minor modifications to the listings in response to comments received. This is further described in the section "Notification – Summary of Comments".

Modification to Part 2 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
N.1	Nisin	(1) Baking mixes containing egg; Brine for hard-boiled egg; Liquid whole egg; Liquid whole egg mix	(1) 15 p.p.m.
		(2) Concentrated (naming the fruit) juice; (naming the fruit) Juice; (naming the	(2) 2.5 p.p.m. in products as consumed

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Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		fruits) Juice; Unstandardized beverages containing fruit juice; Unstandardized beverage concentrates containing fruit juice	
		(3) Meat Loaf; Ready-to-eat prepared meat (Division 14); Ready-to-eat prepared meat by-product; Ready-to-eat prepared poultry meat; Ready-to-eat prepared poultry meat by-product; Ready-to-eat preserved meat (Division 14); Ready-to-eat preserved meat by-product; Ready-to-eat preserved poultry meat; Ready-to-eat preserved poultry meat by-product; Ready-to-eat smoked fish; Sausage	(3) 25 p.p.m.
		(4) Refrigerated cooked potato-based products	(4) 12.5 p.p.m.
		(5) Unstandardized heat-treated low-acid sauces	(5) 6.25 p.p.m.
		(6) Unstandardized processed cheese products	(6) 30 p.p.m.

Certain foods identified in sub-item (3) in the table shown above are meat products for which there are standards of identity and composition set out in Division 14 of Part B of the Regulations. The terminology “prepared meat” and “preserved meat” is used both in Division 14 (“Meat, Its Preparations and Products”) and in Division 21 (“Marine and Fresh Water Animal Products”). Therefore, “Division 14” is indicated after these terms in order to be clear that they do not refer to marine or freshwater animal products.

Rationale

Health Canada’s Food Directorate completed a premarket safety and efficacy assessment of the requested uses of nisin. The assessment considered information related to chemistry, microbiology, nutrition, and toxicology, as well as the efficacy of nisin as an antimicrobial preservative, and found that the available data supported the uses of this preservative as shown in the table above. Health Canada has therefore enabled these requested uses of nisin by modifying Part 2 of the [*List of Permitted Preservatives*](#) as shown in the above table.

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Other Relevant Information

The *Food and Drug Regulations* require that food additives such as nisin 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.

Notification – Summary of Comments

During the comment period, Health Canada received comments from one industry association and one member of the food industry. The association expressed support for the use of nisin in beverages; requested confirmation that the maximum level of use would be applied to concentrated juice on an “as consumed” basis; and requested that “Unstandardized beverage concentrates containing (naming the fruit/fruits) juice” be added to sub item (2). The food industry member requested clarification on the definition and scope of products covered by the food category “unstandardized processed cheese products.”

To ensure clarity in how the maximum level of use should be applied to juice concentrates and to beverage concentrates containing juice, wording has been added, as shown in the table above, to the maximum level of use for sub item (2) indicating that the concentration is to be applied on an “as consumed” basis. With respect to the second request, since the use of nisin is acceptable in “unstandardized beverages containing fruit juice”, it is also acceptable in “unstandardized beverage concentrates containing fruit juice”. Therefore, the latter food category has also been included in sub item (2). The term “fruit juice” accommodates the use of both standardized and unstandardized fruit juices.

With respect to the question regarding “unstandardized processed cheese products”, this food category covers processed cheese products that: (1) are made by comminuting or mixing one or more varieties of cheese into a homogeneous mass with the aid of heat; and (2) do not meet and are not being represented as one of the various standards for processed cheese products that are set out in sections B.08.040(1)[S] through to B.08.041.4(1)[S], Part B, of the *Food and Drug Regulations*.

Implementation and Enforcement

The above modification came into force **February 9, 2018**, the day it was published in Part 2 of the [*List of Permitted Preservatives*](#).

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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 nisin. Anyone wishing to submit new scientific information on the use of this food 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 "**nisin (NOM-0110)**" in the subject line of your e-mail.

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