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Health Canada's Proposal to Enable the Use of a New Food Additive, Nisin, as an Antimicrobial Preservative in or on Various Foods

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/ADP-0028]

September 20, 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* (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 two food additive submissions seeking 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 ranges from 2.5 ppm to 30 ppm.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of nisin as an antimicrobial preservative. Therefore, it is the intention of Health Canada to modify the [List of Permitted Preservatives](#) by adding the following entries to the List:

Proposed 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 fruits) Juice; Unstandardized beverages containing fruit juice	(2) 2.5 p.p.m.
		(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	(3) 25 p.p.m.

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Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
		poultry meat; Ready-to-eat preserved poultry meat by-product; Ready-to-eat smoked fish; Sausage	
		(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.

Rationale

Health Canada's Food Directorate assessed nisin for use as an antimicrobial preservative. The assessment considered information related to chemistry, microbiology, nutrition, and toxicology, as well as the efficacy of nisin as an antimicrobial preservative.

Nisin is a mixture of structurally-related bacteriocin peptides with antimicrobial activity and are isolated from certain strains of *Lactococcus lactis* subsp. *lactis*. Commercial preparations are comprised of a blend of concentrated nisin and sodium chloride, standardized for nisin activity.

Nisin is a normal dietary constituent since many lactic acid bacteria, including *Lactococcus lactis* subsp. *lactis*., are found in fermented dairy and meat products.¹ When consumed as part of these foods, nisin is inactivated by digestive enzymes and then hydrolyzed to small peptides in the small intestine which, in turn, are further broken down into to their constituent amino acids. Like other amino acids in the diet, they will be absorbed into the bloodstream and then enter normal metabolic pathways. Any small peptides not totally degraded to individual amino acids in the small intestine are expected to pass into the colon where they will either be metabolized by gut bacteria or excreted. There have been no known cases where nisin was identified as the trigger for an allergic reaction.

Nisin can be effective in controlling certain microorganisms, particularly when used in combination with other antimicrobial technologies. Food manufacturers who use nisin or any other antimicrobial technologies are responsible for ensuring that the food products they offer for sale are microbiologically safe.

¹ Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to The use of nisin (E 234) as a food additive. Question number EFSA-Q-2005-031. Adopted on 26 January 2006. *The EFSA Journal* (2006) 314:1-16 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/314.pdf

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

Other Relevant Information

Nisin is permitted for use as a food preservative in Australia and New Zealand, Europe, and the United States, and it has international recognition for use as a food additive under the *Codex General Standard for Food Additives*.

The Canadian *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.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in Part 2 of the *List of Permitted Preservatives*. This will be announced via a Notice of Modification and will be published on the [Government of 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:

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If communicating by e-mail, please use the word “**nisin**” in the subject line of your e-mail. Health Canada is able to consider information received by **December 3, 2017**, 75 days from the date of this posting.