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FSIS Docket Clerk
US Department of Agriculture
Food Safety and Inspection Service
Room 102 – Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

02-047N
02-047N-1
Michael H. Auerbach

RE: Docket # 02-047N

Dear Sir:

The following comments are submitted for the US Delegation to the 35th meeting of the Codex Committee on Food Additives and Contaminants (CCFAC).

The Working Group on the Codex General Standard for Food Additives at the 33rd CCFAC meeting was asked to consider that a) the suggested use level of 250 mg/kg for **nisin** use in processed cheese (01.6.4) and fine bakery wares (07.2) is too high; and b) the proposed use of **nisin** in canned/bottled/retorted vegetables (04.2.2.4) and ready to eat soups and broths (12.5.1) is unjustified and should be dropped.

As nisin status in the GSFA was not discussed at the 33rd or 34th meetings of the Working Group, Danisco re-submits the following comments for the 35th meeting. Supporting information is given below.

1. We agree that the 250 mg/kg use level in processed cheese and fine bakery wares is too high. Our technical and commercial experience indicates that the maximum level required to produce the desired preservative effect in these products is 15 mg/kg for processed cheese and 6.25 mg/kg for fine bakery wares.
2. While it is true that canned vegetables and ready to eat soups can be pasteurized, we respectfully submit that pasteurization does not kill certain bacterial spores. It is the prime function of nisin to control the outgrowth of heat resistant bacterial spores that survive pasteurization. Accordingly, we respectfully submit that use of nisin in both product categories is justified.

Fine Bakery Wares

The use of nisin in fine bakery wares at a level of 250 mg/kg is limited to Australia and New Zealand where the specific products and level of nisin are defined as follows: "Crumpets, flapjacks and pikelets with a water activity greater than 0.95 which are prepared on a hot plate or any similar appliance may contain nisin to a maximum level of 250 mg/kg" (1). Practical levels of nisin used in these products in the industry fall in the range of 3.75 to 6.25 mg nisin per kg of product.

Processed Vegetables and Soups

The use of nisin in certain processed (canned, bottled and retort pouch) vegetables is permitted in several countries including Australia, China, New Zealand, Cyprus, Gibraltar, Malta, Slovak Republic, Guyana, Trinidad & Tobago, Hong Kong, Malaysia, Singapore, Mauritius, and Bahrain.

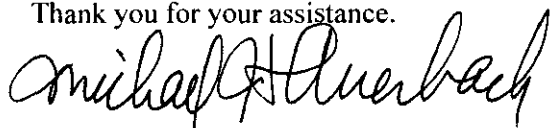
Many bacteria can be present on raw vegetables and other raw foods including the heat resistant spores of *Bacillus* and *Clostridium spp.* In canned vegetables, higher heat processes are used and most mesophilic spores are destroyed. However, heat resistant thermophilic spores can still survive this process and cause spoilage of canned vegetables particularly if stored under warm ambient conditions.

Soups and similar products often contain raw vegetables in their ingredients. Pasteurization or retorting of vegetable and soup products under GMP conditions will often leave viable heat resistant bacterial spores that can potentially outgrow and cause spoilage during shelf life. For example, relatively low temperature pasteurized soups rely heavily on effective chilled temperature distribution and storage during their limited shelf life to prevent outgrowth and spoilage by spore forming bacterial species that survive pasteurization.

Numerous studies have demonstrated that nisin is particularly effective at inhibiting the outgrowth of these surviving bacterial spores following heat treatment. This sporostatic property of nisin has been very successfully applied in the food industry for many years to help prevent spoilage during distribution of ambient and chilled vegetables and other food products that are heat processed but not fully sterilized during their normal manufacturing process (2-12). Many of these vegetable and soup products cannot be processed under full heat sterilization regimes without destroying their organoleptic and nutritive qualities.

Accordingly, we respectfully submit that the use of nisin in pasteurized ready to eat soups and canned vegetables is justified. We would be grateful for your support for retaining these food categories for nisin in the Codex GSFA.

Thank you for your assistance.



M. H. Auerbach

Cc: J Delves-Broughton
J Thestrup

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