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**CODEX COMMITTEE ON FOOD ADDITIVES**

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**USE OF NISIN (INS 234) IN FOOD CATEGORY 08.3.2 IN GENERAL, AND SPECIFICALLY IN PRODUCTS CONFORMING TO THE CORRESPONDING COMMODITY STANDARDS**

Prepared by the United States of America with the assistance of Brazil, China, European Union, Iran, Japan, Malaysia, Russian Federation, Singapore, Spain, Calorie Control Council (CCC), Federation of European Specialty Food Ingredients Industries (ELC), and International Food Additives Council (IFAC)

**Introduction**

1. The 44<sup>th</sup> Session of the Codex Committee on Food Additives (CCFA44) discontinued work on an existing draft provision for the use of nisin (INS 234) in food category 08.0 (*Meat and meat products, including poultry and game*) of the *General Standard for Food Additives* (GSFA; CODEX STAN 192-1995) due to questions on the reporting basis of the maximum use level and the Joint Expert Committee on Food Additives (JECFA) Acceptable Daily Intake (ADI) for nisin.<sup>1</sup> CCFA44 also issued a request (CL 2012/5-FA Part B) for proposals for the use of nisin in the subcategories of food category 08.0. CCFA45 noted that nisin was scheduled for re-evaluation by the 77<sup>th</sup> JECFA meeting and agreed to postpone consideration of new proposals for the use of nisin until CCFA46.<sup>2</sup> CCFA46 considered the proposals for the use of nisin provided in response to CL 2012/5-FA Part B and agreed to include in the GSFA a proposed draft provision for the use nisin in food category 08.3.2 (*Heat-treated processed comminuted meat, poultry, and game products*).<sup>3</sup> CCFA46 also circulated the provision at step 3 for comment (CL 2014/8-FA Part B). The current proposed draft provision for the use nisin in food category 08.3.2 is presented below:

Nisin	INS 234	Functional Class:	Preservative	
Food Cat No	Food Category	ML (mg/kg)	Notes	Step
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	25	233	3

Note 233: As nisin

2. CCFA47 considered comments submitted in response to CL 2014/8-FA Part B on the proposed draft provision for nisin in food category 08.3.2. During this discussion, it was noted that the commodity standards corresponding to food category 08.3.2 (*i.e.* the standards for *Corned Beef* (CODEX STAN 88-1981), for *Luncheon Meat* (CODEX STAN 89-1981), and for *Cooked Cured Chopped Meat* (CODEX STAN 98-1981)) do not contain provisions for the use of nisin in products conforming to those standards. However, comments provided in response to CL-2014-FA, Part B indicated that nisin is currently used in internationally traded products that would fall under some of those standards.<sup>4</sup> During the physical Working Group (pWG) to CCFA47, the Codex Secretariat noted that, as there is no active commodity committee for these standards, the use of food additives in food conforming to these standards would fall within the mandate of the CCFA.<sup>5</sup> At the CCFA47 plenary, it was clarified that there was no specific provision in the Procedural Manual that prevented CCFA from revising and updating food additive provisions in commodity standards or their corresponding provisions in the GSFA.<sup>6</sup>

<sup>1</sup> REP12/FA, paras 75-80.

<sup>2</sup> REP 13/FA, para 99.

<sup>3</sup> REP 14/FA, para 90.

<sup>4</sup> Comments provided in response to CL-2014-FA Part B were compiled in CX/FA 15/4/11, CX/FA 15/4/11 Add. 1, and CX/FA 15/4/11 Add. 2.

<sup>5</sup> FA/47 CRD2.

<sup>6</sup> REP 15/FA, para 83.

3. CCFA47 agreed to establish an electronic working group (eWG) to:<sup>7</sup>

*“Request information and justification on the use of nisin (INS 234) in food category 08.3.2 (Heat-treated processed comminuted meat, poultry, and game products) in general, and specifically in products conforming to the corresponding commodity standards, and to prepare proposals based on the information received.”*

### Background

4. The commodity standards that correspond to food category 08.3.2 do not cover all foods that fall under that food category. Food category 08.3.2 includes both standardized foods (*i.e.* foods covered by a commodity standard) and non-standardized foods. All of the commodity standards<sup>8</sup> that correspond to food category 08.3.2 have a section that includes food additives that are permitted in that commodity (Section 4). Prior to 2014, all of these commodity standards had a subsection (*4.1 Preservatives*) that listed the following for use as preservatives:

- Potassium chloride (INS 508) – use level: Good Manufacturing Practice (GMP)
- Nitrites (INS 249, 250) – use level: 125 mg/kg total nitrite (CODEX STANs 89-1981, 98-1981), 50 mg/kg total nitrite (CODEX STAN 88-1981)<sup>9</sup>

5. In 2014, CCFA46 replaced the food additive section of all three corresponding commodity standards with a general reference to the GSFA<sup>10</sup>. As such, the following wording (or similar wording) now appears in the food additive section of all three corresponding commodity standards:

#### 4. FOOD ADDITIVES

*4.1 Preservatives used in accordance with Tables 1 and 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in food category 08.3.2 “Heat-treated processed comminuted meat, poultry, and game products” and its parent food categories are acceptable for use in foods conforming to this Standard.*

### Procedure of the eWG

6. A first circular was distributed to the eWG, requesting information on the use of nisin in foods covered by the specific commodity standards that correspond to food category 08.3.2, as well as in non-standardized foods that correspond to that food category. This request for information was made in the context of the requirements for the justification of the use of a food additive as per Section 3.2 of the Preamble to the GSFA. To inform the eWG, the first circular also included a compilation of the comments submitted in response to CL 2014/8-FA Part B, as well as an analysis of those comments. This analysis of comments submitted in response to CL 2014/8-FA Part B was conducted in the context of Section 3.2 of the Preamble to the GSFA. Nine eWG Members provided comments on the first circular.

7. Comments on the first circular were collated and became the basis for a proposed revision to the current Step 3 provision for the use of nisin in food category 08.3.2. The proposed revision was distributed to the eWG in a second circular with a request for comment on the proposed revision. To inform the eWG on the reasoning used to formulate the proposed revision, the second circular also presented an analysis of the comments submitted to the first circular. The second circular also requested comment on specific issues raised by eWG members in comments submitted to the first circular. Ten eWG Members provided comments on the second circular.

### eWG Analysis

8. The discussion of the eWG is presented below in the context of whether the use of nisin in compliance with: (i) Section 3.2 of the Preamble to the GSFA; and (ii) Section 2 of the corresponding commodity standards (CODEX STANs 98-1981, 89-1981, 88-1981). This discussion takes into account comments submitted in response to both the first and second circulars of the eWG.

#### Section 3.2 of the Preamble to the GSFA

9. When discussing whether the use of nisin is in compliance with Section 3.2 of the Preamble to the GSFA, the eWG considered the use of nisin in standardized and non-standardized foods. This discussion did not identify factors specific to standardized foods that were not addressed in the discussion of the general use of nisin in food category 08.3.2.

<sup>7</sup> REP 15/FA, para. 116.

<sup>8</sup> The standards for *Corned Beef* (CODEX STAN 88-1981), for *Luncheon Meat* (CODEX STAN 89-1981) and for *Cooked Cured Chopped Meat* (CODEX STAN 98-1981).

<sup>9</sup> This level was expressed as sodium nitrite in all three commodity standards.

<sup>10</sup> REP 14/FA, para 43, Appendix VII.

### Use

10. The eWG requested information on the use of nisin in products conforming to food category 08.3.2. Some comments submitted to the eWG stated that certain Members do not allow for the use of nisin in products conforming to food category 08.3.2. However, other comments confirmed that other Members do allow the use of nisin in these products. These comments also confirmed that nisin is used in products conforming to food category 08.3.2 that are internationally traded. Most comments in favour of the use of nisin indicated use levels of 25 mg/kg, although one indicated use at 5.5 mg/kg and another at 12.5 mg/kg.

- a. Standardized foods: All comments in favour of the use of nisin reported that nisin is used in products conforming to the *Standards for Luncheon Meat* (CODEX STAN 89-1981) and *for Cooked Cured Chopped Meat* (CODEX STAN 98-1981). There was disagreement within the eWG on the use of nisin in products conforming to the *Standard for Corned Beef* (CODEX STAN 88-1981): two eWG members stated that nisin is used in products conforming to this standard, while other eWG members stated that it is not.

### Advantage

11. Most comments noted that nisin is used as a preservative in meat and that meat is susceptible to microbial contamination. The majority of comments submitted that were in favour of the use of nisin referenced information on the effectiveness of nisin as a preservative that was provided in response to CL 2014/8-FA Part B. However, two eWG members questioned the effectiveness of nisin as a preservative in heat-treated meat products. Another eWG member questioned whether the use of nisin could “disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques” or if the intended technical effect of nisin could be achieved by other means that are economically and technologically practicable. However, other comments stated that the proposed use levels are only adequate to prevent further growth of existing microbial loads and cannot disguise faulty raw materials, improper slaughter and processing hygiene, or heat treatment that is not sufficient to achieve commercial sterility of the packaged food. Several eWG members noted that meat processing facilities are inspected by national authorities, which acts as an added safeguard against unhygienic or inadequate processing conditions or the use of faulty raw materials.

12. A large portion of the discussion of the eWG focused on the use of nisin in the context of storage requirements of the packaged food:

- a. Refrigerated foods: All comments submitted in favour of the use of nisin supported its use in ready-to-eat products that are refrigerated during storage. These comments indicated that nisin has an advantage in developing nations where access to stable refrigeration may be limited, or in developed countries where the final consumer may not adhere to storage instructions. However, one eWG member questioned if nisin is effective against meat spoiling microorganisms.
- b. Shelf-stable foods<sup>11, 12</sup>: The majority of eWG members in favour of the use of nisin supported its use in shelf-stable products. These comments indicated that nisin is effective against heat resistant bacterial spores and that spores damaged by heat have heightened sensitivity to nisin. Several comments stated that the use of nisin allows for milder thermal processing of shelf-stable foods to protect the organoleptic property of the food while still ensuring that the processing is sufficient to achieve commercial sterility. However, one eWG member expressed concern that nisin may be used to compromise thermal processing requirements for meat products.

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<sup>11</sup> The eWG did not use the term “shelf-stable,” rather it used the term “canned.” However, the term “canned” is not defined in Codex, and implies characteristics of the packaging material (*i.e.* that the food is packaged in metal cans or tins). The current document uses the term “shelf-stable,” which indicates that the product does not require refrigeration but does not imply that the product is packaged in a specific type of packaging material.

<sup>12</sup> Shelf –stable foods can be considered products that meet the definition of “Commercial sterility of thermally processed food” as defined in Section 2.9 of the *Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods* (CAC/RCP 23-1979). Commercial sterility is the “condition achieved by application of heat, sufficient, alone or in combination with other appropriate treatments, to render the food free from microorganisms capable of growing in the food at normal non-refrigerated conditions at which the food is likely to be held during distribution and storage.”

### Safety

13. The eWG noted the JECFA review of nisin as well as safety reviews by various national and international bodies. One comment noted the difference in the acceptable daily intakes (ADIs) set by various authoritative regulatory bodies. One member of the eWG asserted that the use of nisin in meat products could result in antimicrobial resistance.<sup>13</sup> However, comments submitted by other eWG members appeared to address many of the concerns raised on this issue.

### Dietary Assessment

14. The eWG noted that JECFA's exposure assessment for nisin included the use of nisin in food category 08.3.2. One comment stated that if "new and current uses" were taken into account, the ADI for nisin could be exceeded for toddlers and children. However, no information was provided on these "new and current uses," and the ADI cited was not the JECFA ADI.

### Mislead the Consumer

15. No comments were received indicating that the use of nisin in products corresponding to food category 08.3.2 would mislead the consumer. The majority of comments in favor of the use of nisin noted that nisin would be declared on the label to inform the consumer of its use. Several comments asserted that at the proposed use levels nisin only prevents further growth of existing microbial loads; all nisin-containing meat products must still be produced following good manufacturing practice and therefore the use of nisin cannot deceive the consumer by allowing the marketing of inferior or unwholesome products.

### Section 2 of the corresponding commodity standards

16. During discussion of the use of nisin in standardized products, the question was raised if the use of nisin in standardized meat products was in compliance with Section 2 of the corresponding commodity standards.

17. Section 2 of the *Standards for Luncheon Meat* (CODEX STAN 89-1981) and *for Cooked Cured Chopped Meat* (CODEX STAN 98-1981) states:

*"The heat treatment to which the product has been subjected and the type of cure and packaging shall be sufficient to ensure that the product presents no public health hazard and remains wholesome under the conditions of storage, transport and sale as indicated in Sub-sections 6.4 and 6.5."*

18. Section 2 of the *Standard for Corned Beef* (CODEX STAN 88-1981) states:

*"The heat treatment shall be applied after the container is sealed and shall be sufficient to ensure that the product is shelf-stable and that it presents no public health hazard."*

19. The second circular requested comment from the eWG on whether the use of nisin was in compliance with Section 2 of the corresponding commodity standards.<sup>14</sup>

- a. Commercial sterility: The majority of the discussion focused on the use of nisin to achieve "commercial sterility."<sup>12</sup> Two eWG members asserted that the text of Section 2 of the corresponding commodity standards dictates that the heat treatment and packaging (and curing in the case of CODEX STANs 89-1981 and 98-1981) of the product should be sufficient to guarantee the preservation of the product under conditions of transport, distribution, and storage. These eWG members noted that these commodity standards referred to Guidelines and other Codes of Practice that must be followed, and questioned why additional sterility measures such as the use of nisin would be needed.<sup>15</sup> Other eWG members asserted that the intent of Section 2 of these commodity standards is not to be prescriptive as to the technology or approach used, but rather to ensure that the final product is wholesome. These eWG members stated that the use of nisin could be considered part of the heat treatment of these meat products; that products treated with nisin would still be required to comply with any Guidelines or Codes of Practice listed in the commodity standards; and that those Guidelines or Codes of Practice do not exclude the use of nisin.

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<sup>13</sup> There was a general discussion on the "microbiological effect" of nisin at CCFA47 (REP 15/FA, para 79). At that time, the JECFA Secretariat noted that JECFA had considered a literature review on the development of acquired nisin resistance in various bacteria during its safety assessment.

<sup>14</sup> The second circular specifically asked for comments on whether the use of nisin was in compliance with Section 2 of CODEX STANs 89-1981 and 98-1981. However, the generalities of the resultant discussion around thermal treatment can also be applied to CODEX STAN 88-1981.

<sup>15</sup> Section 6 (*Hygiene*) of CODEX STANs 88-1981, 89-1981, and 98-1981 refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Hygienic Practice for Meat* (CAC/RCP 58-2005), the *Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods* (CAC/RCP 23-1979), the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods* (CAC/GL 61-2007), the

- b. Curing vs preservative: The eWG noted that the commodity standards allow the use of preservatives. It was also noted that the preservatives that were historically listed in these commodity standards act to both preserve the product and to provide other organoleptic properties to the product.
- c. Refrigerated foods: Several eWG members noted that Section 2 of CODEX STANs 89-1981 and 98-1981 refers to Section 6.5 of those standards. Section 6.5 of both standards states that the product should “*withstand spoilage and present no public health hazard under the conditions... indicated on the label*”. These members noted that products requiring refrigeration would have the directive “keep refrigerated” or other similar instructions on their label. These members asserted that the use of nisin to protect refrigerated products when access to stable refrigeration may be limited would not be in conflict with the literal reading of Section 2 of CODEX STANs 89-1981 and 98-1981.

### Recommendation

20. The eWG was tasked by CCFA47 to request information and justification on the use of nisin in food category 08.3.2 and to prepare proposals based on the information received. Information submitted to the eWG indicates that nisin is used in food category 08.3.2 on a general basis at levels up to 25 mg/kg; that is nisin is used in shelf-stable and refrigerated products that are non-standardized, and in shelf-stable and refrigerated products that conform to all three commodity standards that correspond to food category 08.3.2. This supports the proposed draft provision for the use of nisin in food category that is currently in the GSFA at Step 3.

21. The eWG recommends that CCFA48 discuss the current proposed draft provision for the use nisin in food category 08.3.2:

Nisin		INS 234		Functional Class:	Preservative
Food Cat No	Food Category	ML (mg/kg)	Notes	Step	
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	25	233	3	

Note 233: As nisin