



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 5(f)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES
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PROPOSALS FOR PROVISIONS OF NISIN (INS 234) IN FOOD CATEGORY 08.0 “MEAT AND MEAT PRODUCT, INCLUDING POULTRY AND GAME” AND ITS SUB-CATEGORIES (REPLIES TO CL 2012/5-FA, PART B, POINT 8) - OUTSTANDING FROM 45TH CCFA

Prepared by the Codex Secretariat

BACKGROUND

1. The 44th Session of the Codex Committee on Food Additives (CCFA) agreed to discontinue work on the provision for nisin (INS 234) in food category 08.0 (Meat and meat products, including poultry and game).¹ The Committee also agreed to request specific proposals for the use of nisin in food category 08.0 and its sub-categories for consideration at its next session.² The United States of America (USA) was requested to compile, in a structured form, the proposals submitted for the use of nisin (INS 234) in food category 08.0 and its sub-categories³ in response to CL 2012/5-FA, Part B, Point 8 by Colombia, Costa Rica, European Union, Japan, New Zealand, USA, and International Council of Grocery Manufacturer Associations (ICGMA). The document, prepared by the USA, was distributed under reference CX/FA 13/45/10.
2. The 45th CCFA noted that nisin (INS 234) was scheduled for re-evaluation by the 77th JECFA Meeting in June 2013 and agreed to postpone consideration of new proposals on the use of nisin (INS 234) in food category 08.0 (Meat and meat products, including poultry and game) and its sub-categories until its next Session to take into consideration the JECFA report⁴.
3. The present document compiles the information that was included in document CX/FA 13/45/10.

SUMMARY OF COMMENTS AND RECOMMENDATION

| Food Category No. | Food or Food Category | Max Level (mg/kg) | Notes | Comment Summary |
|--------------------------|---|--------------------------|--------------|--|
| 08.0 | Meat and meat products, including poultry and game | 12.5 | Note 233 | New Zealand Colombia, European Union: Do not support |
| 08.2.2 | Heat-treated processed meat, poultry, and game products in whole pieces or cuts | 25 | Note 233 | Costa Rica, ICGMA: 25 mg/kg Japan: 6 mg/kg USA: 5.5 mg/kg |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 25 | Note 233 | Costa Rica, ICGMA: 25 mg/kg Japan: 7 mg/kg USA: 5.5 mg/kg |
| 08.4 | Edible casings (e.g., sausage casings) | 7 | Note 233 | USA |

Note 233: As nisin.

¹ REP 12/FA, Appendix VIII.

² REP 12/FA, para. 80.

³ REP 12/FA, para. 134.

⁴ REP 13/FA, para. 99.

Based on this summary, **the following provisions for nisin (INS 234) are proposed for inclusion in the GSFA at Step 3:**

| Food Category No. | Food or Food Category | Max Level (mg/kg) | Notes |
|-------------------|---|-------------------|----------|
| 08.2.2 | Heat-treated processed meat, poultry, and game products in whole pieces or cuts | 25 | Note 233 |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 25 | Note 233 |
| 08.4 | Edible casings (e.g., sausage casings) | 7 | Note 233 |

Note 233: As nisin.

TECHNOLOGICAL JUSTIFICATION IN SUPPORT OF COMMENTS

Colombia

With respect to these two points, Colombia suggests that, before making new proposals for provisions for nisin (INS 234) in the sub-categories of 08.0 "Meat and meat products, including poultry and game," the maximum permitted level should be reevaluated, because the study data used to make the calculation of the maximum level are outdated.

Costa Rica

First Comment:

Costa Rica does not have new proposals in response to the request in this section.

Second Comment:

Costa Rica appreciates the opportunity to provide comments on proposals for new provisions for **nisin** (INS 234) in the sub-categories of 08.0 "Meat and meat products, including poultry and game" in the GSFA, on which the following is provided:

Nisin is an antimicrobial that is widely used in meat products, such as sausages. It is very effective against *Listeria monocytogenes*, as well as other gram-positive bacteria, such as *Clostridium botulinum* and *Bacillus cereus*.

The inclusion of Nisin in the GSFA for the following categories at a level of 25 ppm is requested:

08.2.2 Heat-treated processed meat, poultry, and game products in whole pieces or cuts

08.3.2 Heat-treated processed comminuted meat, poultry, and game products

European Union

The EU takes note of the unresolved issue of the ADI for nisin which needs a further consideration by JECFA. In light of the very low ADI for nisin in the EU (0.13 mg/kg bw/day) the EU generally does not support the use of nisin in 08.0 sub-categories.

Japan

Japan is pleased to provide the following comments in response to part B point 8 of CL 2012/5 FA.

| Food category No | Food category title | Maximum use level (mg/kg as nisin) | Name of foods/Justification |
|------------------|---|------------------------------------|---|
| 8.2.2 | Heat-treated processed meat, poultry, and game products in whole pieces or cuts | 6 | 1. Name of foods Cooked cured pork belly, Pastrami 2. Justification To inhibit bacterial growth during shelf-life. |
| 8.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 7 | 1. Name of foods Sausages 2. Justification To inhibit bacterial growth during shelf-life. |

New Zealand

New Zealand would like to propose an ML of 12.5 mg/kg as nisin for this category (08.0 "Meat and meat products, including poultry and game").

United States of America

The United States appreciates this opportunity, and provides proposals for the inclusion of new provisions for nisin (INS 234) as proposed draft provisions in the GSFA for consideration at the forthcoming 45th Session of the Codex Committee on Food Additives (CCFA). This proposal is submitted according to the *Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives* in the Procedural Manual, and the following information is being provided in accordance with these requirements.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated nisin at its 12th Meeting (1968), and established an acceptable daily intake (ADI) of 0-33,000 units/kg bw. Specifications for nisin were prepared at the 71st JECFA (2009) and published in FAO JECFA Monographs 7 (2009). The International Numbering System (INS; CAC/GL 36-1989) associates the technological purpose of “preservative” and INS No. 234 with nisin.

The following uses of nisin as a preservative are requested for inclusion as proposed draft provisions in Tables 1 and 2 of the GSFA:

| Food Cat. No. | Food Category | Max Level |
|----------------------|---|--------------------|
| 08.2.2 | Heat-treated processed meat, poultry, and game products in whole pieces or cuts | 5.5 mg/kg as nisin |
| 08.3.2 | Heat-treated processed comminuted meat, poultry, and game products | 5.5 mg/kg as nisin |
| 08.4 | Edible casings (e.g., sausage casings) | 7 mg/kg as nisin |

Nisin has been determined to be safe and suitable for use as an antimicrobial preservative for the control of the bacteria *Listeria monocytogenes*. Nisin is an effective antimicrobial, and is typically applied to the outside of the meat product immediately prior to packaging.

Nisin is effective primarily against Gram positive bacteria, such as *Clostridium botulinum*, *Bacillus cereus*, and *L. monocytogenes*. Nisin has limited effectiveness vs. *L. monocytogenes* when added to meat before thermal processing. It appears that undenatured meat proteins bind nisin, and thus inhibit its activity. Nisin is not particularly effective by itself against Gram negative bacteria, such as *Salmonella* spp. and *Escherichia coli*. Because different pathogens are associated with different meats products, nisin is used in ready-to-eat meat products where growth inhibition is critical.

Nisin is applied to meat products in commercial preparations that usually consist of 2.5 % nisin. The use level is typically 5 - 25mg/kg (as pure nisin). Low levels can also inhibit some spoilage microbes, such as certain lactic acid bacteria.

The use of nisin as a preservative in processed meat and poultry products is technological justified according to Section 3.2(c) of the Preamble to the GSFA, "to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer."

The use of this additive meets the general principles for food additive safety in Section 3.1 of the Preamble to the GSFA. The additive has been evaluated by JECFA, the ADI is taken into account, and the quantity of the additive used in the food is at the appropriate level to achieve the intended technical effect.

The consumer would not be deceived by the use of nisin in the proposed products. The name of the additive would be included in the list of ingredients on the food label. Further, consumers are familiar with the use of preservatives in foods to maintain their quality and stability.

International Council of Grocery Manufacturer Associations

Nisin is used on a few meat products at the retail level, predominantly in RTE products (hot dogs, smoked sausages, etc.). It has been used extensively for a *Listeria monocytogenes* (Lm) intervention. Nisin is an effective antimicrobial when used appropriately. It works primarily against Gram positive bacteria such as *Clostridium botulinum*, *Bacillus cereus* and Lm. Because different pathogens are associated with different meats products, it is used in RTE products where growth inhibition is critical. It is being used at the maximum allowable level of 100 ppm on a pure nisin basis. A level of 50 ppm can actually reduce some populations of Lm in a model meat system, but additional barriers (such as lactate/diacetate or other antimicrobial systems) are needed to prevent recovery of resistant populations. Low levels can also inhibit some spoilage microbes, such as certain lactic acid bacteria. Nisin functions as a microbial inhibitor, and is most effective when used as an additional “hurdle” to pathogen survival. A primary challenge to wider-spread usage of nisin is that:

- Since it is applied to the outside of the product immediately prior to packaging, manufacturers must have the equipment and technology to effectively apply it.

Nisin is applied to meat products in commercial preparations. Nisin provisions of 25 ppm on a pure nisin basis are being requested for the following meat sub-categories:

08.2.2 Heat-treated processed meat, poultry, and game products in whole pieces or cuts

08.3.2 Heat-treated processed comminuted meat, poultry, and game products