



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

5-06

9 August 2006

INITIAL ASSESSMENT REPORT

APPLICATION A565

NISIN-EXTENSION OF USE AS A FOOD ADDITIVE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 September 2006

SUBMISSIONS RECEIVED AFTER THIS DEADLINE

WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

An Application (A565) was received on 23 June 2005 from Danisco Australia Pty Ltd, submitted by Axiome Pty Ltd, seeking to amend Schedule 1 of Standard 1.3.1 – Food Additives, of the *Australia New Zealand Food Standards Code* (the Code), to approve the extended use of nisin as an antimicrobial preservative in processed meat products to a maximum level of 12.5 mg/kg in the following food categories:

- 8.2 - Processed meat, poultry and game products in whole cuts or pieces.
- 8.3 - Processed comminuted meat, poultry and game products.

Nisin (INS 234) is a naturally occurring bacteriocin agent produced by certain strains of *Lactococcus lactis*, a food grade bacterium that occurs in milk.

Purpose

The purpose of the Application is to seek an amendment to the Code to Standard 1.3.1 – Food Additives, permitting the extension of use of nisin as an antimicrobial preservative in processed meat products.

This Initial Assessment Report is not a detailed assessment of the merits of the Application but rather an assessment of whether the Application should undergo further considerations according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for extension of use of nisin as a food additive. Such an approval, if accepted, would warrant a variation to Standard 1.3.1.
- There is currently no permission in the Code for the use of nisin in processed meat products.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

FSANZ seeks comments on this Initial Assessment Report. These submissions will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

Comments are particularly requested regarding the safety assessment on the extended use of nisin and the likelihood of development of antimicrobial resistance.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report based for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 20 September 2006.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

An Application (A565) was received on 23 June 2005 from Danisco Australia Pty Ltd, submitted by Axiome Pty Ltd, seeking to amend Schedule 1 of Standard 1.3.1 – Food Additives, of the Code, to approve the extended use of nisin as an antimicrobial preservative in processed meat products to a maximum level of 12.5 mg/kg in the following food categories:

- 8.2 - Processed meat, poultry and game products in whole cuts or pieces.
- 8.3 - Processed comminuted meat, poultry and game products.

The Applicant claims that although various antimicrobial preservatives are currently permitted for use in processed meat products (mainly nitrites/nitrates, and sorbic acid), they are not completely effective and spoilage is not uncommon. Processed meats are also prone to post-processing contamination during slicing and packaging operations, and in retail operations.

An Initial Assessment of the Application has been completed and public comment is now being sought to assist in the development of the Draft Assessment of the Application.

1. Background

1.1 Current Standard

Nisin is a naturally occurring bacteriocin agent produced by certain strains of *Lactococcus lactis*, a food grade bacterium that occurs in milk. Currently, nisin is permitted in the Code in a wide range of foods including cream products, cheese and cheese products, oil emulsions, tomato products, fruit and vegetable preparations, flour products, liquid egg products, tomato juices, beer and related products, dairy and fat based desserts, dips and snacks, and sauces and toppings including mayonnaises and salad dressings, at levels ranging from 10 mg/kg to GMP (Good Manufacturing Practice). The Applicant wishes to broaden the use of nisin as a food additive (antimicrobial preservative), which is a technological function listed in Schedule 5 to Standard 1.3.1 – Food Additives.

1.2 Technological Purpose

Nisin is a small heat stable peptide belonging to a group of bacteriocins known as lantibiotics, which are produced by different genera of Gram-positive bacteria. Nisin is active against a wide range of Gram-positive vegetative bacteria, and particularly bacterial spore-formers, including *Bacillus*, *Clostridium* and *Lactobacillus* as well as the highly significant Gram-positive pathogen *Listeria monocytogenes*. Nisin is however ineffective against Gram-negative bacteria, yeasts and moulds.

The Applicant has claimed that nisin is very effective at low use levels in preventing or delaying the growth of Gram-positive bacteria in processed meat products. These bacteria associated with processed meat products (unlike many Gram-negative bacteria) have a relatively high tolerance to reduced water activity, refrigeration temperatures, low pH and the presence of nitrate and phosphate emulsifying salts. Furthermore, while the temperatures

used in processing are sufficient to kill most bacteria, they are not effective against heat resistant spores.

Processed meats are also prone to post-processing contamination during slicing and packaging operations, and in retail operations (delicatessen). Growth of spoilage organisms shortens the shelf-life of processed meat products, even at refrigerated temperatures, and makes them particularly prone to rapid spoilage as a result of temperature abuse.

1.3 History of Use

Nisin has been used for over 50 years as an antimicrobial food preservative and is currently approved in more than 70 other countries for use in a wide range of foods. First established use was as a preservative in processed cheese products and since then numerous other applications in food and beverage have been identified.

1.4 Regulatory Status

1.4.1 Codex Standards

Nisin is currently used as an antimicrobial preservative in the following Codex Standards:

- Codex General Standard for Named Variety Processed Cheese and Spreadable Processed Cheese (Ref: Codex Standard A-8(a))¹;
- Codex General Standard for Processed Cheese and Spreadable Processed Cheese (Ref: Codex Standard A-8(b))²;
- Codex General Standard for Processed Cheese Preparations, Processed Cheese Food and Processed Cheese Spread (Ref: Codex Standard A-8(c))³; and
- Codex General Standard for Cheese (Ref: Codex Standard A-6)⁴.

The maximum level of nisin permitted in all of these standards is 12.5 mg/kg.

The Applicant claims that nisin is also under consideration for inclusion in the Codex General Standard for Food Additives for use in a wide range of other foods including meat and meat products including poultry and game at a maximum level of 12.5 mg/kg.

1.4.2 International Legislation

Nisin is approved as an antimicrobial preservative in more than 70 countries including major jurisdictions such as the European Union, USA, China and MERCOSUR (Argentina, Brazil, Paraguay, Venezuela and Uruguay).

In USA, nisin has been accepted as GRAS (generally recognised as safe) as an antimicrobial agent for use on casings for frankfurters and on cooked meat and poultry products.

¹ <http://www.codexalimentarius.net/download/standards/177/CXSA08ae.pdf> *

² <http://www.codexalimentarius.net/download/standards/178/CXSA08be.pdf> *

³ <http://www.codexalimentarius.net/download/standards/179/CXSA08ce.pdf> *

⁴ http://www.codexalimentarius.net/download/standards/175/CXS_A06e.pdf *

* accessed on 28 July 2006.

2. The Issue

Under Standard 1.3.1 food additives, including preservatives, are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand.

Nisin (INS 234) is an approved food additive (preservative) currently permitted in Schedule 1 of Standard 1.3.1 for use on numerous foods. This Application is to broaden the use of nisin and therefore a safety assessment considering these proposed new uses will be required.

3. Objectives

The objective of this assessment is to determine whether it is appropriate to amend the Code to allow the extension of use of nisin, an antimicrobial preservative, in processed meat products. This assessment is carried out in order to ensure that the amendment to the standard protects public health and safety to the appropriate level as included in s.10 of the FSANZ Act.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Questions

Does the extension of use of nisin pose any public health and safety issues regarding an increase in the intake of food preservative agents?

If the Application is approved, is the increase of ingestion of nisin likely to produce antimicrobial resistance in humans?

Is the maximum level of nisin proposed for use in processed meat products acceptable?

Is there a technological justification for seeking the approval of an extension of use of nisin in processed meat products?

RISK ASSESSMENT

5. Safety Assessment

JECFA (Joint FAO/WHO Expert Committee on Food Additives) evaluated the safety of nisin as an antimicrobial preservative in 1968 and assigned an ADI (Acceptable Daily Intake) of 0-33,000 IU/kg bw.

The safety of the extended use of nisin will be assessed in the context of the proposed new food uses at Draft Assessment.

6 Dietary Exposure Assessment

Dietary modelling will be required in the Draft Assessment Report for the product categories in which nisin is requested for use in this Application.

7. Antimicrobial Properties

The Applicant claims that the use of nisin as an antimicrobial preservative is particularly suited in foods and beverages that are by their nature, pasteurized but not fully sterilized. More recently, the effectiveness of nisin against *Listeria monocytogenes* has become of particular interest to food manufacturers and regulatory agencies, due to public health and safety concerns from potential contamination of foods with this pathogen.

The Applicant claims the suitability of nisin for use in food as an antibacterial preservative is based on the following:

- it is non-toxic;
- it is produced from certain strains of food-grade lactic acid bacteria (*Lactococcus lactis* subsp. *Lactis*) which are regarded as safe;
- it is not used therapeutically as an antibiotic;
- there is no apparent cross-resistance in bacteria that might affect antibiotic therapeutics;
- it is digested immediately;
- it is heat-stable at a low pH and
- activity against a wide range of food spoilage bacteria, food pathogens and bacterial spores.

An assessment of these claims will be made at Draft Assessment.

RISK MANAGEMENT

8. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and government agencies in Australia and New Zealand.

There are no other options other than a variation to Standard 1.3.1 for this Application. Therefore the regulatory options available for this application are:

Option 1: maintain the *status quo* approach; no change to Standard 1.3.1

Option 2: vary Standard 1.3.1 to approve a broader use of nisin.

Under this option, the proposed amendments to Standard 1.3.1 of the Code would be made.

9. Impact Analysis

9.1 Affected Parties

The parties affected by this Application include the following:

- consumers, particularly those who have concerns about food preservatives;
- the manufacturing and retail sectors of the food industry;
- food exporters of processed meat products;
- public health professionals and
- Australian Government, State and Territory agencies and government agencies in New Zealand.

9.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To develop the analysis of the cost and benefits of the regulatory options proposed, FSANZ seeks comments on the following:

- As a stakeholder, which is the potential cost and benefit of the implementation of this Application?
- Are there potential exporters of processed meat products that will be advantaged if this application is approved?
- As a consumer, from a public health and safety point of view, will there be cost or benefits from the implementation of this Application?
- For Australian Government, State and Territory agencies, will the adoption or rejection of this Application result in a potential cost or benefit?

COMMUNICATION

10. Communication and Consultation Strategy

This Application is for approval of extension of use of an antimicrobial preservative that is approved under an existing Standard, being Standard 1.3.1. As a result, FSANZ has applied a basic communication strategy to Application A565. This involves advertising the availability of the Initial Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and stakeholders, including the public, will be notified on the gazettal of changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

11. Consultation

11.1 Public consultation

The Initial Assessment Report is not a detailed assessment of this Application but rather an assessment of whether the Application should undergo further consideration. At this stage FSANZ is seeking public comment in order to assist in assessing this Application at Draft Assessment. A further round of public comment will occur after the Draft Assessment Report is completed to assist in the development of the Final Assessment.

FSANZ is seeking public comment to assist in assessing the Application. Comments on, but not limited to, the following would be useful:

- technological justification for extending the use of nisin;
- which food products are likely to be affected;
- if there are any safety considerations with its proposed use;
- dietary intake might be substantially affected beyond the ADI;
- arguments in support or opposition to permitting the extension of use of nisin in food;
- likely costs and benefits of extending the use of nisin; and
- parties that might be affected by having this Application approved or rejected.

All stakeholders must observe the relevant due date for submissions.

11.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

12. Conclusion and Recommendation

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for extension of use of nisin as a food additive. Such an approval, if accepted, would warrant a variation to Standard 1.3.1.
- There is currently no permission in the Code for the use of nisin in processed meat products.
- The Application is not so similar to any previous application that it ought not to be accepted.
- There are no other measures that would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.