

24 April 2012
[8-12]

Call for submissions – Proposal P1020

Ethyl Lauroyl Arginate as a Food Additive in Sausages

FSANZ has assessed a proposal prepared to permit the use of ethyl lauroyl arginate as a preservative for sausage and sausage meat containing raw, unprocessed meat, and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 14 May 2012

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

| | |
|--|----------|
| 1. EXECUTIVE SUMMARY | 2 |
| 2. INTRODUCTION..... | 3 |
| 2.1 THE PROPOSAL..... | 3 |
| 2.2 THE CURRENT STANDARD | 3 |
| 2.3 PROCEDURE FOR ASSESSMENT | 4 |
| 3. SUMMARY OF THE ASSESSMENT | 4 |
| 3.1 RISK ASSESSMENT | 4 |
| 3.2 RISK MANAGEMENT | 4 |
| 3.3 REGULATORY OPTIONS AND IMPACTS | 4 |
| 3.3.1 <i>Cost benefit analysis</i> | 4 |
| 3.3.2 <i>Other measures</i> | 5 |
| 3.3.3 <i>New Zealand standards</i> | 5 |
| 3.3.4 <i>Other relevant matters</i> | 6 |
| 3.3.5 <i>Addressing FSANZ's objectives for standards setting</i> | 6 |
| 3.4 RISK COMMUNICATION | 7 |
| 3.4.1 <i>World Trade Organization (WTO)</i> | 7 |
| 4. DRAFT VARIATION | 8 |
| 4.1 IMPLEMENTATION | 8 |
| ATTACHMENT A – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> | 9 |
| ATTACHMENT B – DRAFT EXPLANATORY STATEMENT | 11 |

Supporting documents

The following material relating to Application A1015 – Ethyl Lauroyl Arginate as a Food Additive, including the Approval and 1st Review Reports and various Risk Assessment Supporting Documents), used in the preparation of this report, are available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1015ethy4049.cfm>

1. Executive summary

A FSANZ assessment in 2009 of Application A1015 – Ethyl Lauroyl Arginate as a Food Additive concluded that it was a safe and suitable food additive preservative and should be permitted in the *Australia New Zealand Food Standards Code* for use in a variety of food categories.

The intent of the original drafting was to include permission for the use of ethyl lauroyl arginate for the subcategory sausage and sausage meat containing raw, unprocessed meat. However the final drafting did not contain this permission.

This proposal has been prepared to correct the drafting to include permission to use ethyl lauroyl arginate for sausage and sausage meat containing raw, unprocessed meat. The original risk assessment performed as part of Application A1015 included this food subcategory so a new risk assessment has not been undertaken.

2. Introduction

2.1 The Proposal

The Proposal was prepared to amend the *Australia New Zealand Food Standards Code* (the Code) to address the original intent of the assessment and variations for Application A1015 (Ethyl Lauroyl Arginate as a Food Additive). Specifically, the Code does not currently provide permission for the use of ethyl lauroyl arginate (ELA) as a food additive for sausage and sausage meat containing raw, unprocessed meat, as was intended by Application A1015.

2.2 The current Standard

The current permissions for ELA are listed in Schedule 1 of Standard 1.3.1 – Food Additives. There is permission for using ELA for the food category 8.3 (processed comminuted meat, poultry and game products). This food category includes the sub-category sausage and sausage meat containing raw, unprocessed meat. However there is a specific statement under this subcategory (which states ‘Additives must not be added to sausage and sausage meat containing raw, unprocessed meat, unless expressly permitted below’) which means the ELA permission does not carry through to this subcategory. The extract for food category 8.3 from Schedule 1 is copied below.

8.3 Processed comminuted meat, poultry and game products*

| | | | | |
|--------------------------------|--|------|-------|--|
| 160b | Annatto extracts | 100 | mg/kg | |
| 220 221 222 223 224 225 228 | Sulphur dioxide and sodium and potassium sulphites | 500 | mg/kg | |
| 234 | Nisin | 12.5 | mg/kg | |
| 243 | Ethyl lauroyl arginate | 315 | mg/kg | |
| 249 250 | Nitrites (potassium and sodium salts) | 125 | mg/kg | total of nitrates and nitrites, calculated as sodium nitrite |

fermented, uncooked processed comminuted meat products

| | | | | |
|-----------------|--|------|--------------------|---|
| 200 201 202 203 | Sorbic acid and sodium, potassium and calcium sorbates | 1500 | mg/kg | |
| 235 | Pimaricin (natamycin) | 1.2 | mg/dm ² | when determined in a surface sample taken to a depth of not less than 3 mm and not more than 5 mm including the casing, applied to the surface of food. |
| 251 252 | Nitrates (potassium and sodium salts) | 500 | mg/kg | total of nitrates and nitrites, calculated as sodium nitrite |

sausage and sausage meat containing raw, unprocessed meat

Additives must not be added to sausage and sausage meat containing raw, unprocessed meat, unless expressly permitted below

| | | | | |
|--------------------------------|--|-----|-------|--|
| - | Additives in Schedule 2 | | | |
| 220 221 222 223 224 225 228 | Sulphur dioxide and sodium and potassium sulphites | 500 | mg/kg | |

2.3 Procedure for assessment

The Proposal is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The risk assessment conclusions of the original ELA application (A1015) remain valid and therefore do not need to be reassessed (refer to the Approval Report for A1015 and the relevant supporting documents on FSANZ's website - refer to the link under the Table of Contents). The dietary exposure assessment performed included sausage and sausage meat in the food category of processed comminuted meat, poultry and game products as listed in the food categories of Schedule 1 of Standard 1.3.1. Consistency with stated purpose (i.e. as a preservative in sausages and sausage meat) was also assessed in A1015. The conclusion of the risk assessment was that ELA was both safe and suitable as a preservative food additive to be added to specific foods, including sausages and sausage meats, with various maximum permitted levels.

3.2 Risk management

Since there are no new risk assessment conclusions to manage, there are no risk management options required except to address the lack of permission to use ELA to treat sausage and sausage meat containing raw, unprocessed meat.

The Code includes labelling requirements applicable to the use of food additives for manufactured foods such as sausages. These are detailed in clause 8 of Standard 1.2.4 – Labelling of Ingredients. Sausage manufacturers who decide to use ethyl lauroyl arginate are required to comply with this standard.

3.3 Regulatory options and impacts

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal
- any relevant New Zealand standards
- any other relevant matters.

3.3.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) provides a standing exemption (RIS ID: 12065) from the need to assess if a Regulation Impact Statement is required for applications and proposals relating to food additives as they are minor or machinery in nature and their use would be voluntary. However, FSANZ has performed a short impact analysis below.

Two regulatory options were considered:

- (1) prepare a draft variation to Standard 1.3.1 to permit ELA to treat sausage and sausage meat containing raw, unprocessed meat.
- (2) abandon the proposal.

3.3.1.1 Option 1 – Prepare a draft variation to Standard 1.3.1

Consumers

Consumers may benefit from purchasing sausages that contain added ELA through reduced food waste due to food spoilage. However, some consumers may object to having a new chemical food additive preservative added to their sausages.

Government

Government agencies may need undertake work related to new analytical method development along with monitoring and surveillance for Code compliance as directed or required.

However, it is unlikely that government agencies will be affected by this Proposal since the impact arising from possible development of methods of analysis for foods permitted to contain ELA, including processed comminuted meat products, was already considered as part of the earlier Application, A1015.

Industry

The manufacturers of sausages will benefit as they have access to a new food additive preservative which may provide advantages with reduced spoilage losses and extended shelf life. The permission may allow sausage producers to reduce the levels of sulphites they add to sausages. However using the preservative will require labelling changes to the ingredients list of treated sausages.

3.3.1.2 Option 2 – Abandon the proposal

Consumers

There are no perceived impacts on consumers.

Government

There are no perceived impacts on government agencies.

Industry

Sausage producers would be at a disadvantage as they would not be able to access the potential benefits of the new food additive preservative.

3.3.2 Other measures

There are no other measures that would be more cost effective to achieve the same aim than a variation to Standard 1.3.1.

3.3.3 New Zealand standards

There are no relevant New Zealand only standards, since Standard 1.3.1 applies to New Zealand.

3.3.4 Other relevant matters

There are no other relevant matters identified.

3.3.5 Addressing FSANZ's objectives for standards setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.3.5.1 Protection of public health and safety

The assessment undertaken for Application A1015 concluded that there are no public health and safety concerns with approving ELA at the proposed levels to treat sausages.

3.3.5.2 The provision of adequate information relating to food to enable consumers to make informed choices

There are ingredient labelling requirements for sausages that have been prepared using the food additive ELA (as noted in Section 3.2), which ensures consumers have adequate information to make informed choices.

3.3.5.3 The prevention of misleading or deceptive conduct

There are no relevant issues identified.

3.3.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2) as addressed below:

- the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ's risk analysis performed as part of the assessment of Application A1015 was based on the best available scientific evidence.

- the promotion of consistency between domestic and international food standards

ELA is approved and permitted for use as a food additive preservative in a number of other countries, so permitting its use to treat sausages will promote international consistency in food standards.

- the desirability of an efficient and internationally competitive food industry

Permitting the use of ELA to treat sausages may improve the efficiency and competitiveness of the Australian and New Zealand sausage industry though it is unlikely there is a large export market for these products.

- the promotion of fair trading in food

Permitting the use of ELA to treat sausages ensures these products are considered consistently with other processed comminuted meat products that currently can be treated with the preservative.

- any written policy guidelines formulated by the Ministerial Council¹.

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals* includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the ‘stated purpose’),
- the addition of the substance to food is safe for human consumption,
- the amounts added are consistent with achieving the technological function; and
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of ELA as a food additive in the manufacture of sausage and sausage meat containing raw, unprocessed meat is consistent with the above policy principles.

3.4 Risk communication

A basic communication strategy has been applied to this Proposal.

All calls for submissions are notified through the FSANZ Notification Circular, a media release and through FSANZ’s social media tools and *Food Standards News*.

The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent. Public submissions are sought to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options.

Individuals and organisations making submissions on this Proposal will be notified at each stage of assessment.

3.4.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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.

Amending the Code to permit the use of ELA as a food additive for sausage and sausage meat containing raw, unprocessed meat is unlikely to have a significant effect on trade. The ELA preparation is consistent with the international specifications for ELA. Furthermore, the purpose of the Proposal is to ensure the intent of the original Application A1015 is achieved, but not to go beyond the conclusions of that assessment. Therefore, a notification to the WTO under Australia’s and New Zealand’s obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

¹ Now known as the COAG Legislative and Governance Forum on Food Regulation, and abbreviated as the Forum.

4. Draft variation

The draft Standard to Standard 1.3.1 is at Attachment A.

The draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variation takes effect on gazettal.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1020 – Ethyl Lauroyl Arginate as a Food Additive in Sausages) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is *the Food Standards (Proposal P1020 – Ethyl Lauroyl Arginate as a Food Additive in Sausages) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences **on the date of gazettal**.

SCHEDULE

[1] **Standard 1.3.1** is varied by inserting in numerical order in Schedule 1, under item 8.3 sausage and sausage meat containing raw, unprocessed meat –

| | | | |
|-----|------------------------|-----|-------|
| 243 | Ethyl lauroyl arginate | 315 | mg/kg |
|-----|------------------------|-----|-------|

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1020 to permit the use of ethyl lauroyl arginate (ELA) as a preservative for sausage and sausage meat containing raw, unprocessed meat. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation to the Standards.

2. Purpose and operation

The Authority has approved the use of ELA as a food additive preservative to treat sausage and sausage meat containing raw, unprocessed meat. Currently the permission to treat the food category 8.3 – Processed comminuted meat, poultry and game products with ELA does not include the subcategory sausage and sausage meat containing raw, unprocessed meat.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1020 will include one round of public consultation following an assessment and the preparation of a draft variation and associated report. A Call for Submissions (which includes the draft variation) will be released for a three-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.3.1 is likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

The variation permits the use of the food additive preservative ELA for the subcategory of sausage and sausage meat containing raw, unprocessed meat to the same maximum permitted level as for the main category of processed comminuted meat, poultry and game products.