

29 June 2012
[14-12]

Approval Report – Proposal P1020

Ethyl Lauroyl Arginate as a Food Additive in Sausages

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to permit the use of ethyl lauroyl arginate as a preservative food additive for sausage and sausage meat containing raw, unprocessed meat.

On 24 April 2012, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 20 June 2012. The COAG Legislative and Governance Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 27 June 2012.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents used to prepare this Report are available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1015ethy4049.cfm>:

Application A1015 – Ethyl Lauroyl Arginate as a Food Additive (including the Approval and Review Reports and various risk assessment supporting documents)

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 preservative food additive 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 (ELA) for the subcategory sausage and sausage meat containing raw, unprocessed meat. This food group is a subcategory of the category 8.3 – processed comminuted meat, poultry and game products. However, the final drafting for Application A1015 did not contain this permission.

This Proposal was prepared to correct the drafting to include permission to use ELA 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 was not undertaken, nor were there any new issues to manage. No new issues were raised that required amending the draft variation when the Call for Submissions was released for public comment between 24 April 2012 and 15 May 2012. Four submissions were received, with three supporting the approach taken and one raising an issue that has been addressed in this Report.

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.

2.2 The current Standard

The current permissions for ethyl lauroyl arginate (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 Reasons for preparing the Proposal

The Proposal was prepared on the basis that the Code does not currently provide permission for the use of ELA as a food additive for sausage and sausage meat containing raw, unprocessed meat, as was intended by Application A1015.

2.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

2.5 Decision

The draft variation, as proposed following assessment, was approved without change.

3. Summary of the findings

3.1 Risk assessment

The risk assessment conclusions for Application A1015 remain valid for this Proposal and therefore do not need to be reassessed since they were finalised in 2009. No new evidence has been provided indicating they need to be reviewed (refer to the Approval Report for A1015 and the relevant supporting documents on FSANZ's website).

A stakeholder (though not an official submitter) raised two issues relating to FSANZ's earlier risk assessment for A1015.

The first point was a request that any new risk assessment information performed since FSANZ completed its risk assessment in 2009 should be made available. FSANZ can confirm that no new toxicity studies related to ELA have been published since FSANZ completed its risk assessment.

The stakeholder also reiterated a concern raised during FSANZ's consideration of A1015. The issue was that only female rats showed the effect that was used to determine the acceptable daily intake (ADI). It believed FSANZ ignored this issue and did not explain it as part of the risk assessment performed for A1015 and so asked FSANZ to re-examine this matter now.

FSANZ can confirm that it did consider this specific issue as part of the Approval Report for A1015 and the relevant passage is:

In reproductive and developmental toxicity studies the only notable and consistent finding was delayed onset of puberty in female rats. There was no information to indicate that this effect may not be relevant to humans. The finding was therefore considered suitable for deriving an ADI. Because of uncertainties regarding the mechanism of delayed puberty in female rats and the relevant exposure period for the effect, a conservative dose was chosen on which to base the ADI as discussed in the Hazard Assessment Report (Supporting Document 1).

The dietary exposure assessment performed for A1015 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. Although the term 'sausage and sausage meat' was not explicitly used in the A1015 documents, this subcategory was covered by category 8.3. FSANZ has confirmed that the dietary modelling performed for A1015 included sausage and sausage meat.

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 were no new risk assessment conclusions to manage, there were 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 that apply to 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 ELA are required to comply with this standard.

3.2.1 Summary of submissions

Consultation is a key part of FSANZ’s standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public comments were invited on the Call for Submissions from 24 April – 15 May 2012. Three submissions (New Zealand Ministry for Primary Industries, New Zealand Food and Grocery Council and the Australian Department of Agriculture, Fisheries and Forestry) supported the proposed draft variation and raised no issues. One submission raised an issue which FSANZ has addressed in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The Ministerial Council requested FSANZ address a risk assessment issue as part of the 1st review for A1015. The issue was that the delayed onset of puberty in female rats was the only notable finding used to determine the ADI. There was no information to indicate this effect was not relevant to humans so the Ministerial Council suggested further research may be required.</p> <p>Because the Ministerial Council raised issues related to the risk assessment for A1015 the submitter requests FSANZ conduct a comprehensive literature review of any pertinent research related to the risk assessment of ELA since FSANZ completed the original risk assessment three years ago.</p>	<p>Department of Health Victoria</p>	<p>FSANZ provided a detailed response in the 1st Review Report for A1015 that explained the conservative approach taken to determine the ADI. Since FSANZ was unable to conclude the delayed onset of puberty in female rats was not relevant for humans it used a conservative basis to derive the ADI by using a safety factor of 100. If studies are available that demonstrates the endpoint in the rat study is not relevant for humans, then the ADI may be raised, not lowered (i.e. even less of a safety concern).</p> <p>FSANZ maintains the earlier view that since the original risk assessment was performed three years ago, and no new evidence has been provided indicating any new safety concern, a literature review of recent studies is not required for this Proposal. However, FSANZ performed a search on Medline and did</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
		not locate any new hazard assessment studies on ELA.

3.3 Risk communication

A basic communication strategy had 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 were sought to obtain the views of interested parties on the issues raised by the Proposal and the impacts of regulatory options.

Individuals and organisations who made submissions on this Proposal are notified at each stage of assessment.

4. Reasons for decision

FSANZ decided to include a specific draft variation to the Code to implement the original intention of the earlier ELA Application A1015 permitting the use of ELA as a preservative food additive for sausage and sausage meat containing raw, unprocessed meat. This drafting implements the original conclusions of the risk assessment i.e. that ELA was safe and suitable to treat these products. No new risk assessment was required and no new risk management options were needed. No new issues were raised in submissions to the Call for Submissions that required amendments to the drafting.

FSANZ had regard to the following matters under 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*

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 performed a limited impact analysis below and the conclusions are as follows:

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 agencies may need to 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.

The manufacturers of sausages may 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.

- *whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal*

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

- *any relevant New Zealand standards*

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

- *any other relevant matters.*

No other relevant matters were identified.

4.1 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Proposal as follows.

4.1.1 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.

4.1.2 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.

4.1.3 The prevention of misleading or deceptive conduct

There are no relevant issues identified.

4.1.4 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 Council².

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.

4.2 Implementation

The variation takes effect on gazettal.

Attachments

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

² Now known as the COAG Legislative and Governance Forum on Food Regulation, and abbreviated as the Forum.

Attachment A – Approved 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
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Attachment B – 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 food additive 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.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation³, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The Authority has approved the use of ELA as a preservative food additive 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 has included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 24 April 2012 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

³ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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 amends Schedule 1 of Standard 1.3.1 to allow the preservative food additive ELA to be added to sausage and sausage meat containing raw, unprocessed meat. The maximum level of ELA that can be added to this food type subcategory is 315 mg/kg. This is the same maximum permitted level of ELA as for the main category of processed comminuted meat, poultry and game products.