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[14-09]

APPLICATION A1015

ETHYL LAUROYL ARGINATE AS A FOOD ADDITIVE

APPROVAL REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from Laboratorios Miret SA (LAMIRSA) on 28 August 2008. This Application seeks to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to include a new food preservative, ethyl lauroyl arginate.

Ethyl lauroyl arginate is a synthetically produced cationic surfactant¹ that is intended to be used to protect food against microbial growth and thus spoilage. Cationic surfactants such as ethyl-N^α-lauroyl-L-arginate·HCl (active ingredient), can be used as food preservatives because they are able to disrupt the integrity of cell membranes in a broad spectrum of bacteria, yeasts and moulds. It is proposed to be used in a wide range of food groups.

Ethyl lauroyl arginate has been evaluated by other international agencies in recent years. In 2005, the US Food and Drug Administration (FDA) issued a Letter of No Objection regarding a submission that ethyl lauroyl arginate is Generally Recognised as Safe (GRAS, Notice No. GRN 000164) for use as an antimicrobial at levels up to 200 mg ethyl-N^α-lauroyl-L-arginate·HCl /kg in a wide range of foods. In April 2007, the European Food Safety Authority (EFSA) issued the opinion of the Scientific Committee on ethyl lauroyl arginate as a new food preservative for use in a range of food categories. An Acceptable Daily Intake (ADI) of 0-0.5 mg/kg body weight (bw) was established by EFSA. Most recently, in June 2008, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered ethyl lauroyl arginate as a food additive and allocated an ADI of 0-4 mg/kg bw for the active ingredient, ethyl-N^α-lauroyl-L-arginate·HCl. The large difference in the ADIs established by EFSA and JECFA is due to a difference in the interpretation of haematology data obtained in animal toxicity studies.

Based on the availability of an adequate range of suitable studies, FSANZ has independently completed a safety assessment for ethyl lauroyl arginate and established an ADI of 0-5 mg/kg bw, equivalent to the ADI set by JECFA for the active ingredient. The safety assessment reports that only minimal amounts of unchanged ethyl lauroyl arginate enter the bloodstream because the compound is rapidly metabolised by enzymes in the upper intestine before substantial absorption can occur.

¹ Surfactants are wetting agents that lower the surface tension of a liquid, allowing easier spreading, and lower the interfacial tension between two liquids.

In the intestine, ethyl lauroyl arginate is rapidly degraded to compounds normally present in the diet such as the amino acid L-arginine and the fatty acid lauric acid.

In animal toxicity studies of up to one year duration, ethyl lauroyl arginate was well tolerated even at high concentrations in the diet. Ethyl lauroyl arginate and its major metabolites showed no evidence of genotoxic activity. In reproductive and developmental toxicity studies, the only notable and consistent finding was delayed onset of puberty in female rats. The ADI for ethyl lauroyl arginate established by FSANZ derived from this study was 0-5 mg/kg bw.

The ADI of 0-4 mg/kg bw published by JECFA was derived from this same study, however JECFA applied a correction factor for the content of active ingredient in the batch used in the study (88%) to arrive at an ADI expressed as the active ingredient, ethyl-N^α-lauroyl-L-arginate-HCl.

The dietary exposure assessment assumed the addition of ethyl lauroyl arginate at the proposed maximum use level for all food types proposed by the Applicant, i.e. assuming 100% uptake by food manufacturers. This scenario is highly protective of consumers as such complete uptake of ethyl lauroyl arginate is considered unlikely and actual use levels may be lower than maximum permitted levels. All estimated dietary exposures to ethyl lauroyl arginate for the population groups assessed were within the range of the ADI.

Estimated dietary exposure for high consumers of ethyl lauroyl arginate (90th percentile) for Australian children aged 2-6 years approached 80% of the ADI, 90th percentile dietary exposure for the whole population of Australians aged 2+ years was 30% of the ADI and for New Zealanders aged 15+ years 20% of the ADI. The major contributor to mean ethyl lauroyl arginate dietary exposure for Australians aged 2+ years and for New Zealanders aged 15+ years would be comminuted meat products and whole pieces of processed meat, assuming use in all requested food groups. For Australian children aged 2-6 years, the major contributor would be cordials.

Non-dietary sources of exposure to ethyl lauroyl arginate were evaluated as part of the Approval report. Systemic exposure arising from the dermal application and inhalation of cosmetic and personal care products was considered to be negligible because of its poor absorption through biological membranes. Non-food oral exposure from lipstick, toothpaste and mouthwash was estimated based on worst-case scenarios that assumed partial ingestion for adults and complete ingestion of toothpaste only in children. The oral exposure from dietary sources was below 2 mg/kg bw/day for the Australian population and non-dietary sources for adults was less than 1 mg/kg bw/day. For Australian children, the total estimated oral exposure combining exposure from food at the 90th percentile and personal care use was estimated to be below the ADI. Therefore, the additional oral exposure from the use of cosmetics and personal care products is unlikely to exceed the ADI for any population group.

The unpublished data provided by the Applicant and supplemented with published scientific journal reports indicate that ethyl lauroyl arginate is an effective food preservative in the food categories proposed. This new antimicrobial agent is stable during storage in a range of food matrices and provides protection against microbial spoilage in these foods to extend their shelf life. Use of ethyl lauroyl arginate as a preservative in the specified food categories and at the maximum permitted level is technologically justified and it could be potentially a useful component of food preservation systems.

Based on the conservative assumptions in the dietary exposure calculations, FSANZ concludes that there are no public health and safety concerns for ethyl lauroyl arginate when used as a food additive at the maximum levels proposed by the Applicant.

Assessing the Application

The Application is being assessed under the General Procedure.

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from the amendments of the Code to permit the use of the antimicrobial agent, ethyl lauroyl arginate, as a food additive would outweigh the direct and indirect benefits to the community, Government or industry.
- 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.
- There are no relevant New Zealand standards.
- There are no other relevant matters.

Decision

FSANZ approves the proposed draft variations to Standard 1.3.1, Schedule 1 – Food Additives, to include permissions for ethyl lauroyl arginate in the food types at the specified maximum limits for the active ingredient, ethyl-N^α-lauroyl-L-arginate·HCl, in the list of intended uses of ethyl lauroyl arginate.

List of intended uses of ethyl lauroyl arginate

Food types*		Ethyl lauroyl arginate** (mg/kg; maximum)
0.1	Preparations of food additives	200
1.6	Cheese - soft/cream/processed and mozzarella	400 except for mozzarella at 200
1.6	Cheese – Hard/Semi-hard	1 mg/cm ² of surface area of cheese (taken to a depth of 3 mm and not more than 5 mm)
4.1.3	Peeled and/or cut fruits and vegetables	200
4.3.8	Processed fruits and vegetables—rehydrated legumes only	200
6.3	Processed cereal and meal products- cooked rice only	200
6.4	Flour products (including noodles and pasta) – cooked pasta and noodles only	200
8.2	Processed meat, poultry and meat products in whole cuts or pieces	200
8.3	Processed comminuted meat and poultry products	315
9.3	Semi preserved fish and fish products	400

Food types*		Ethyl lauroyl arginate** (mg/kg; maximum)
14.1.2	Fruit and vegetable juices and fruit and vegetable juice products	50
14.1.3	Water based flavoured drinks	50
20.2	Savoury toppings or fillings - essentially sauces such as tomato paste used in ready to eat pizzas, etc.	200
20.2	Dairy and fat based desserts, dips and snacks	400

*the code number and food types are as listed in the Code, Standard 1.3.1, Schedule 1.

** Ethyl lauroyl arginate shall be calculated as ethyl-N^a-lauroyl-L-arginate·HCl.

Reasons for Preferred Approach

Amendments to the Code to include ethyl lauroyl arginate as a food preservative in Australia and New Zealand is proposed on the basis of the available scientific evidence for the following reasons:

- A detailed safety assessment has concluded the permission for the use of ethyl lauroyl arginate does not raise any public health and safety concerns, including considering development of antimicrobial resistance.
- Use of ethyl lauroyl arginate as a preservative in the specified food categories up to the maximum permitted level is technologically justified and it could potentially be a useful component of food preservation systems. Based on data provided by the Applicant, ethyl lauroyl arginate could possibly replace some approved food grade preservatives such as benzoates, sulphites and sorbates, which have some inherent limitations.
- The regulatory impact assessment concluded that the benefits of the potential use of ethyl lauroyl arginate in the specified food categories outweigh any costs associated with its use.
- The proposed variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

Consultation

This Application is being assessed under the General Procedure and the Assessment Report was released for public comment from 6 May to 17 June 2009. Three submissions were received; they were all from government agencies. Two of these submitters support FSANZ's preferred option of including ethyl lauroyl arginate as a food additive in the food types at the specified maximum limits as stated in Table 1 of the Assessment Report, with one of these requesting further information and clarification. The third submitter reflected mixed opinions from different agencies within a jurisdiction on FSANZ's preferred approach. Issues raised by the submitters are summarised (Attachment 2) and have been taken into account in preparing the Approval Report for this Application. The issues raised in the submissions are addressed in Section 9.1.

Amendments to the Draft Variation after Consultation

The draft variation in the Assessment Report circulated for public comment excluded apple juice as a food type permitted to have ethyl lauroyl arginate as a food additive. Following consideration of submitters' comments and further assessment as described below, it was decided to allow the addition of ethyl lauroyl arginate to apple juice. Therefore 'not apple juice' was removed from the proposed variation [2.12].

Apple juice had been excluded from the list of intended uses in the Assessment Report because the Applicant believed it had the potential for ethyl lauroyl arginate exposure to exceed the ADI for children (2-6 years old). However, there is no technological reason for not using ethyl lauroyl arginate in apple juice.

Further dietary modelling has shown that the addition of ethyl lauroyl arginate in apple juice does not lead to a significant increase in the total exposure of ethyl lauroyl arginate in the Australian population, New Zealanders 15 years and above and Australians 2-6 years old (Supporting Document 2).

If the initial draft had been approved, it could lead to practical and regulatory complexity of monitoring its use in fruit juice blends that may contain up to 90% apple juice. Therefore, FSANZ has now permitted apple juice in the list of intended uses.

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SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Approval Report, are available on the FSANZ website at <http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa1015ethy4049.cfm>

- SD1: Hazard Assessment
- SD2: Dietary Exposure Assessment
- SD3: Food Technology Report
- SD4: Antimicrobial Resistance Assessment Report

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received an Application from Laboratorios Miret SA on 28 August 2008. The Application seeks to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to include ethyl lauroyl arginate as a preservative for a wide range of food categories at specified maximum levels.

Ethyl lauroyl arginate is a new synthetically produced chemical preservative. The Applicant claims that because of the effectiveness of ethyl lauroyl arginate in a wide range of food matrices and over a broad antimicrobial spectrum, some sectors of the food industry might prefer the use of ethyl lauroyl arginate over the other commonly used and approved antimicrobials. The Applicant has provided experimental data to demonstrate the relative effectiveness of ethyl lauroyl arginate.

In the original dossier submitted by the Applicant, their product is referred to as lauric arginate. However, FSANZ has referred to the product as ethyl lauroyl arginate throughout this assessment, in order to be consistent with international naming. Codex has proposed the name of the product as ethyl lauroyl arginate (INS 243). The abbreviation, ELA, will be used in Tables in this Approval Report because of spacing limitations.

1. The Issue / Problem

Food additives, including preservatives, are required to undergo a pre-market safety assessment before they are included in Standard 1.3.1. There is currently no permission for ethyl lauroyl arginate in the Code. Maximum limits for ethyl lauroyl arginate have to be established for all food types considered. The limits are established through consideration of:

- the safety assessment for ethyl lauroyl arginate
- the technological justification for and effectiveness of ethyl lauroyl arginate in the range of food groups requested.

2. Background

2.1 Current Standard

A food additive, as stated in the Purpose clause of Standard 1.3.1, 'is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions as specified in Schedule 5. Preservation is one of the functions specified in Schedule 5 and a preservative is defined as an additive that 'retards or prevents the deterioration of a food by micro organisms'. Sub-classes of preservative are anti-microbial preservative, anti-mycotic agent, bacteriophage control agent, chemosterilant and disinfection agent.

This Standard regulates the use of food additives in the production and processing of food. A food additive may only be added to food where expressly permitted in this Standard. Additives may only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice.

Currently, Standard 1.3.1, Schedule 1 permits one or more of the following preservatives for use in the food types, with the exception of precooked rice, in which the Applicant has proposed to use ethyl lauroyl arginate: sorbates, benzoates, parabens, sulphites, nisin, pimaricin, nitrates, nitrites, dimethyl dicarbonate and propionates. No preservative is permitted in precooked rice.

2.2 Technological Purpose

The active component of ethyl lauroyl arginate, ethyl-N^α-lauroyl-L-arginate·HCl, is a cationic surfactant with a broad spectrum of activity against bacteria, yeasts and moulds. Ethyl lauroyl arginate is stable in relatively acidic product formulations (for example, pH 4). It is effective as an antimicrobial in a wide range of food categories at the proposed usage limits and thus provides the food industry with a flexible tool to control shelf life of foods. However, ethyl lauroyl arginate binds to proteins and therefore a higher limit of usage is proposed in protein-based foods.

The Applicant has provided information to demonstrate ethyl lauroyl arginate could be used as a potential alternative to the currently approved preservatives, which have some inherent limitations. For example, sulphite consumption exceeds the ADI for some high-level consumers in Australia².

2.3 International Regulatory Status

The WHO Joint Expert Committee on Food Additives (JECFA) first considered ethyl lauroyl arginate at its 69th meeting in June 2008 (FAO/WHO 2008). The Committee established an ADI of 0–4 mg/kg bw for ethyl lauroyl arginate, expressed as the active ingredient ethyl-N^α-lauroyl-L-arginate·HCl.

The specification for ethyl lauroyl arginate was revised at JECFA's 71st meeting in July 2009. There is no change in the main product specification. The revision is in the analysis of two impurities (L-arginine·HCl and Ethyl arginate·2HCl), where quantification procedures were modified.

The European Food Safety Authority (EFSA) published its opinion on ethyl lauroyl arginate in April 2007 and established an ADI for ethyl lauroyl arginate of 0-0.5 mg/kg bw³. EFSA has listed ethyl lauroyl arginate in their Working Document for discussion in July 2009.

The US Food and Drug Administration has issued a Letter of No Objection regarding the submission that ethyl lauroyl arginate is Generally Recognised as Safe (GRAS) for use as an antimicrobial at levels up to 225 mg/kg of ethyl lauroyl arginate in the food categories specified (USFDA 2005).

3. Objectives

The objective of this assessment is to determine whether it is appropriate to amend the Code to include ethyl lauroyl arginate in the specified food categories and to establish maximum allowable limits. In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

² FSANZ 2005, 21st Australian Total Diet Study: a total diet study of sulphites, benzoates and sorbates.

³ Reason for discrepancy between JECFA and EFSA is given in Supporting Document 1.

- the protection of public health and safety; and
- 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 Council⁴.

4. Questions to be answered

For this Application, FSANZ has considered the following key questions:

- What would the potential dietary exposure to ethyl lauroyl arginate be for mean and high consumers of foods containing the preservative?
- Are there any public health and safety issues as a consequence of approving the use of ethyl lauroyl arginate at the levels proposed in the range of food types applied for?
- Are the requested levels of ethyl lauroyl arginate technologically justified in the food categories applied for?

RISK ASSESSMENT

5. Risk Assessment Summary

5.1 Hazard Assessment

FSANZ has assessed the submitted evidence on the safety of ethyl lauroyl arginate including studies on absorption, metabolism, acute toxicity, repeat-dose toxicity, genotoxicity and reproductive toxicity. The submitted data were considered suitable for hazard assessment and assignment of an ADI for ethyl lauroyl arginate. For the full Hazard Assessment Report see Supporting Document 1.

JECFA first assessed the toxicity of ethyl lauroyl arginate in 2008 and established an ADI of 0-4 mg/kg bodyweight expressed as the active ingredient.

⁴ In May 2008, the Australia and New Zealand Food Regulation Ministerial Council endorsed the Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals. This includes policy principles in regard to substances added for technological purposes such as food additives and processing aids.

The ADI was based on the No Observed Adverse Effect Level (NOAEL) of 502 mg/kg bw/day (expressed as ethyl lauroyl arginate) established in a reproductive toxicity study. This NOAEL was corrected for the active ingredient content (88% w/w) to give a NOAEL for the active ingredient of 442 mg/kg bw/day. The ADI of 0-4 mg/kg bodyweight for the active ingredient was derived by applying a 100-fold safety factor (10-fold for inter-species differences and 10-fold to account for differences between individuals).

After assessing all of the available data, FSANZ has used the same NOAEL of 502 mg/kg bw/day obtained in the reproductive toxicity study and applied a 100-fold safety factor to establish an ADI of 0-5 mg/kg bodyweight for ethyl lauroyl arginate. Thus, the only difference between the ADIs derived by JECFA and FSANZ was the correction for active ingredient content by JECFA. FSANZ did not correct for active ingredient content because the batch used in the relevant study conformed to the approved JECFA specifications for ethyl lauroyl arginate.

In the submitted studies, systemic exposure to orally administered ethyl lauroyl arginate was low because most of the compound is rapidly metabolised in the intestines before absorption occurs. Ethyl lauroyl arginate is rapidly degraded to endogenous compounds and compounds normally present in the diet such as the amino acid L-arginine and the fatty acid lauric acid. In animal toxicity studies of up to one year duration, ethyl lauroyl arginate was well tolerated even at relatively high doses. Ethyl lauroyl arginate had a slight local irritant effect on the rat forestomach probably due to its surfactant activity. However, the rodent forestomach is not protected by mucus and has no anatomical equivalent in humans. The forestomach findings were therefore not considered to be relevant for a risk assessment in humans.

Ethyl lauroyl arginate and its major metabolite showed no evidence of genotoxic activity. 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). No other effects on reproduction or development attributable to ethyl lauroyl arginate were observed.

Ethyl lauroyl arginate has been approved for use and commercialised in the USA since 2005 with no published reports of intolerance associated with consumption. Ethyl lauroyl arginate is rapidly metabolised to compounds which have not been associated with intolerance reactions.

5.2 Dietary Exposure

FSANZ conducted a dietary exposure assessment for the food additive ethyl lauroyl arginate based on the information provided by the Applicant. For the full Dietary Exposure Assessment Report see Supporting Document 2.

Food consumption data from the 1995 Australian and 1997 New Zealand National Nutrition Surveys were used for the exposure assessments. The population groups assessed were the Australian population (2 years and above), the New Zealand population (15 years and above) and children (2 to 6 years for Australia only).

The Applicant provided FSANZ with information on proposed levels of use for ethyl lauroyl arginate for specific food groups and the expected foods within each food group that may contain it.

Based on this information, dietary exposure was estimated assuming that ethyl lauroyl arginate was present in foods at the maximum permitted level suggested by the applicant, expressed as ethyl lauroyl arginate. This scenario is highly protective of consumers.

Estimated mean exposures for consumers of ethyl lauroyl arginate for all population groups assessed were 38 mg/day (0.7 mg/kg bw/day) for the Australian population 2 years and above; 38 mg/day (2.1 mg/kg bw/day) for Australian children 2-6 years; and 32 mg/day (0.4 mg/kg bw/day) for the New Zealand population aged 15 years and above. Estimated 90th percentile exposures for consumers of ethyl lauroyl arginate were 83 mg/day (1.6 mg/kg bw/day) for the Australian population 2 years and above; 73 mg/day (4.0 mg/kg bw/day) for Australian children 2-6 years; and 76 mg/day (1.0 mg/kg bw/day) for the New Zealand population aged 15 years and above.

Based on the food groups proposed by the Applicant, the major contributor to the estimated ethyl lauroyl arginate dietary exposure for Australians aged 2 years and above and for New Zealanders aged 15 years and above would be comminuted meat products and whole pieces of processed meat. For Australian children aged 2-6 years, the major contributor would be cordials.

5.3 Risk Characterisation

Comparisons of the dietary exposure to ethyl lauroyl arginate with the ADI of 0-5 mg/kg bw indicated that for all groups of Australian and New Zealand consumers assessed (including children), estimated dietary exposures were below this safe level of exposure. The estimated mean dietary exposures for consumers of ethyl lauroyl arginate correspond to 15% of the ADI for Australians aged 2 years and above, 40% of the ADI for Australian children aged 2-6 years, and 10% of the ADI for New Zealanders aged 15 years and above. The estimated 90th percentile dietary exposures for consumers of ethyl lauroyl arginate correspond to 30% of the ADI for Australians aged 2 years and above, 80% of the ADI for Australian children aged 2-6 years, and 21% of the ADI for New Zealanders aged 15 years and above. These comparisons raise no public health and safety concerns for the addition of ethyl lauroyl arginate at the proposed levels of use.

Non-dietary sources of oral exposure may occur if ethyl lauroyl arginate is used as a preservative in lipsticks, toothpaste and mouthwash. The additional oral exposure arising from the use of such products is unlikely to result in the ADI being exceeded for any population group.

5.4 Antimicrobial Resistance

While there is a potential for resistance of microorganisms to antimicrobial agents, such as ethyl lauroyl arginate and other preservatives used in food production, this can be minimised through proper management and monitoring of their use. These measures include the setting of appropriate maximum limits and following the principles of GMP i.e. the quantity of additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.

While there is an absence of data in the peer-reviewed literature on the selection and/or development of microorganisms resistant to ethyl lauroyl arginate, resistance to other cationic surfactants, such as quaternary ammonium compounds, has been reported. Unpublished laboratory data provided by the Applicant showed that when test organisms were exposed to sub-lethal concentrations of ethyl lauroyl arginate, an increased resistance to the antimicrobial was observed over time. This adaptation was temporary, however, as resistant cultures quickly became susceptible following growth in ethyl lauroyl arginate-free media. See Supporting Document 4 for the full review of antimicrobial resistance by FSANZ.

5.5 Food Technology Assessment

FSANZ conducted a review of the technological justification of ethyl lauroyl arginate as a preservative based on the information provided by the Applicant and on published information. For the full Food Technology Assessment Report see Supporting Document 3.

The Application requested ethyl lauroyl arginate as a preservative in a wide range of food groups as listed below:

- food additive preparations
- cheeses – soft, cream, processed, mozzarella, hard and semi hard
- peeled and/or cut fruit and vegetables – rehydrated legumes
- cereal products – cooked rice, noodles and pasta
- semi-processed fish and fish products – salted fish and roe
- processed meat, poultry and meat products in whole or cut pieces or comminuted products
- non-alcoholic beverages – fruit and vegetable juices and juice products, water based flavoured drinks and high energy drinks and soft drinks
- savoury toppings or fillings, dairy based desserts, dips and snacks

Within these foods, the Applicant proposed ethyl lauroyl arginate, expressed as the active ingredient ethyl-N^α-lauroyl-L-arginate·HCl, be used in levels ranging between 50 mg/kg (e.g. beverages) and 400 mg/kg (in protein based foods, e.g. cheese and fish products).

The Applicant provided 36 experimental studies to support their claims that ethyl lauroyl arginate effectively suppresses a broad spectrum of microorganisms in a wide range of food matrices. The Applicant provided information to demonstrate ethyl lauroyl arginate may be a potential alternative for some of the currently approved preservatives such as sulphites, benzoates and sorbates, which have some inherent limitations.

The data provided by the Applicant supplemented with published scientific journal information indicate that ethyl lauroyl arginate is an effective food preservative to extend shelf life of foods in the food groups proposed above and that it also reduces the levels of certain pathogenic bacteria. This new antimicrobial agent is stable in storage and processing of a range of food groups.

Use of ethyl lauroyl arginate as a preservative in the specified food types up to the maximum requested level is technologically justified based on consideration of stability and effectiveness. Along with good manufacturing practice, ethyl lauroyl arginate could be a useful component of food preservation systems.

RISK MANAGEMENT

6. Regulatory Options

There are no non-regulatory options for this Application. Two regulatory options have been identified for this Application:

Option 1 Reject the Application, thus maintaining the *status quo*.

Option 2 Amend Schedule 1 of Standard 1.3.1 to permit maximum limits for ethyl lauroyl arginate as a food additive in the range of food types specified in Table 1.

Ethyl lauroyl arginate will be added to the list of food additive code numbers in Standard 1.2.4 – Labelling of Ingredients. As ethyl lauroyl arginate complies with Monograph 5 published in the FAO Combined Compendium of Food Additive Specifications (Monograph 5) (JECFA, 2008), Monograph 5 will be a primary source of specification, as required in Clause 2 of Standard 1.3.4.

Table 1: Intended uses of ethyl lauroyl arginate

Food types*		Ethyl lauroyl arginate** (mg/kg; maximum)
0.1	Preparations of food additives	200
1.6	Cheese - soft/cream/processed and mozzarella	400 except for mozzarella at 200
1.6	Cheese – Hard/Semi-hard	1 mg/cm ² of surface area of cheese (taken to a depth of 3 mm and not more than 5 mm)
4.1.3	Peeled and/or cut fruits and vegetables	200
4.3.8	Processed fruits and vegetables— rehydrated legumes only	200
6.3	Processed cereal and meal products- cooked rice only	200
6.4	Flour products (including noodles and pasta) – cooked pasta and noodles only	200
8.2	Processed meat, poultry and meat products in whole cuts or pieces	200
8.3	Processed comminuted meat and poultry products	315
9.3	Semi preserved fish and fish products	400
14.1.2	Fruit and vegetable juices and fruit and vegetable juice products	50
14.1.3	Water based flavoured drinks	50
20.2	Savoury toppings or fillings - essentially sauces such as tomato paste used in ready to eat pizzas, etc.	200
20.2	Dairy and fat based desserts, dips and snacks	400

* the code number and food types are as listed in the Code, Standard 1.3.1, Schedule 1.

**Ethyl lauroyl arginate shall be calculated as ethyl-N^o-lauroyl-L-arginate·HCl.

7. Impact Analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

In accordance with the Best Practice Regulation Guidelines the preliminary assessment for this application indicated low or negligible impacts. The Office of Best Practice Regulation has advised that the analysis is adequate and approved the preliminary assessment (RIS ID 10222).

7.1 Affected Parties

The affected parties may include the following:

1. Those sectors of the food industry wishing to use this new food preservative.
2. Consumers who may be affected, either negatively or positively, as a result of a new preservative becoming available in processed foods.
3. Government agencies with responsibility for compliance and enforcement of the Code.

7.2 Benefit Cost Analysis

7.2.1 Option 1 – Reject Application

- Food industries may be disadvantaged as they would be unable to capture the potential benefits of the new food preservative. Some sectors of the food industry are under pressure to reduce their levels of benzoates and sulphites. These sectors face increasing costs if alternatives are not permitted.
- There is no perceived impact on consumers.
- There is no perceived impact on government agencies.

7.2.2 Option 2 – Permit maximum limits for ethyl lauroyl arginate as a food additive in the range of foods specified in Table 1

- Food industries may benefit as they may be able to include ethyl lauroyl arginate in their products as part of their food preservation systems with consequent market advantages from reduced spoilage losses and extended shelf life. However, the food industries would incur the cost of labelling changes if they chose to use the new preservative.
- Consumers may benefit from foods containing ethyl lauroyl arginate through reduction in losses associated with food spoilage and potential for lowered consumption of some of the currently approved preservatives. However, some consumers may object to having a new chemical preservative added to foods.
- Government agencies may incur an increase in the cost of monitoring compliance, but this is expected to be minor as the method of analysis is published and uses typical laboratory apparatus.

7.3 Comparison of Options

Option 1 appears to provide no apparent benefits to industry, consumers or government. Option 1 denies industry access to a flexible preservative in a wide range of food products.

Option 2 does not appear to impose any significant costs on industry, consumers or government. Option 2 provides benefits to industry in terms of product innovation and potential benefits for industry and consumers in reducing the losses associated with food spoilage and to reduce the level of usage of some of the current approved preservatives.

An assessment of the costs and benefits of Option 1 and 2 indicates that there would be a net benefit in permitting the use of ethyl lauroyl arginate in the food categories listed in Table 1 at the specified maximum level of usage. Therefore Option 2 is the preferred option.

8. Other considerations

8.1 Non-food use

Based on use information provided by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for cosmetics and personal care products likely to contain ethyl lauroyl arginate, FSANZ has estimated the additional exposure arising from these products. The calculations for the exposure of cosmetics and personal care products including mean dietary exposure for the Australian population and Australian children are shown in Table 2 and discussed in Section 9.1.1.

8.2 Policy Guidance on Addition of Substances other than Vitamins and Minerals

In developing or reviewing food regulatory measures and variations of food regulatory measures FSANZ must have regard to any relevant written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

The *Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals* (the Guideline) provides guidance on the addition to food of substances other than vitamins and minerals. This includes substances intentionally added solely for a technological purpose, such as food additives and processing aids.

The Guideline states that the addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where the substance meets a number of safety and technological objectives.

Having given due regard to the Guideline, FSANZ concluded that the addition of ELA should be permitted as proposed for the following reasons:

- the purpose for adding ELA to food is as a preservative. This has been articulated clearly by the manufacturer (see Section 2.2 and Supporting Document 3)
- the proposed addition of ELA to food is safe for human consumption (see Sections 5.1, 5.2 and 5.3; Supporting Documents 1 and 2)
- the proposed amounts of ELA added are consistent with achieving the technological function (see Section 5.5 and Supporting Document 3)
- ELA would be added in a quantity and a form which is consistent with delivering the stated purpose (see Section 5.5 and Supporting Document 3)
- no nutrition, health or related claims are to be made in regard to ELA.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication and Consultation

FSANZ has developed a communication strategy for Application A1015 that involved advertising the availability of the assessment report for public comment in the national press and placing the reports on the FSANZ website. In addition, FSANZ will issue a media release drawing journalists' attention to the matter.

The aim of the communication strategy is to inform the food industry and consumers about the issues raised in the Application and to communicate with health professionals about the proposed change to the standard and provide them with information for their clients if this should become necessary.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ assessment reports.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. The FSANZ Board's decision to approve the draft variation to the Code has been notified to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the notification to the Ministerial Council as well as any gazettal of amendments to the Code in the national press and on the website.

9.1 Consultation

This Application is being assessed under a general procedure and was published for a round of public comment from 6 May to 17 June 2009. Three submissions were received; they were all from government agencies. Two of these submitters support FSANZ's preferred option of including ethyl lauroyl arginate as a food additive in the food types at the specified maximum limits as stated in Table 1 of the Assessment Report, with one of these requesting further information and clarification. The third submitter reflected mixed opinions from different agencies within a jurisdiction on FSANZ's preferred approach. Issues raised by the submitters are summarised (Attachment 2) and have been taken into account in preparing the Approval Report of this Application. The issues raised in the submissions are addressed in this Section.

9.1.1 Consider potential exposure from non-food sources

Two submitters commented that it is appropriate to consider the contribution of cosmetics and personal care products to total exposure for different age groups.

9.1.1.1 FSANZ response

An application for ethyl lauroyl arginate as a preservative to be used in cosmetics and personal care products is currently under consideration by NICNAS. Information provided by NICNAS has allowed FSANZ to consider additional exposure to ethyl lauroyl arginate from the use of cosmetics and personal care products. Routes of exposure from such products include dermal (for example, from deodorant, body lotion, soap, shampoo and shaving cream), inhalation (from deodorant sprays and hairsprays), and oral (from lipstick, toothpaste and mouthwash).

Experimental data to estimate dermal exposure indicate that systemic exposure to ethyl lauroyl arginate is likely to be negligible. An *in vitro* study using pig skin resulted in only 3.9% penetration of the applied ethyl lauroyl arginate dose into the epidermis, 1.5% into the dermis and undetectable transfer into the receptor solution (SCCP, 2008)⁵. Pig skin is generally a good model for human skin permeability (see for example Barbero & Frasc, 2009⁶). It is therefore likely that the systemic bioavailability of dermally applied ethyl lauroyl arginate in humans will be negligible or zero.

⁵ SCCP (Scientific Committee on Consumer Products, 2008). Opinion on ethyl lauroyl arginate HCl.

⁶ Barbero AM & Frasc HF (2009). Pig and guinea pig skin as surrogates for human *in vitro* penetration studies: a quantitative review. *Toxicol In Vitro*. **23**, 1-13.

Inhalation exposure from the use of cosmetic and personal care products that form aerosols, such as anti-perspirant /deodorant sprays and hairsprays was considered by FSANZ, even though the use of ethyl lauroyl arginate in such products is not recommended by NICNAS. The inhalation bioavailability of ethyl lauroyl arginate in aerosol form is not known but is also likely to be negligible because only a small percentage of such aerosol droplets are respirable. However, even assuming an inhalation bioavailability of 10% the upper estimate of inhalation systemic exposure is only several micrograms/kg bw/day. Inhalation can also lead to oral exposure, however this contribution is also expected to be minimal. The dermal and inhalation routes of exposure to ethyl lauroyl arginate are therefore considered to contribute negligibly to overall exposure and are not considered further.

Non-food oral exposure to ethyl lauroyl arginate from cosmetic and personal care products may also occur by inadvertent ingestion of products such as toothpaste, mouthwash and lipstick. The estimated oral exposure to ethyl lauroyl arginate from non-food and dietary sources for the Australian population and Australian children is shown in Table 2 below.

For non-food oral exposure in adults it was assumed that mouthwash (10 mL) is used three times daily with 10% swallowed each time, that toothpaste (1 g) is used twice daily with 17% swallowed and that lipstick (10 mg) is applied 4 times daily with 100% swallowed. The only source of non-food oral exposure for children was from the use of toothpaste (twice daily) with the worst case assumption that 100% is swallowed. The concentrations of ethyl lauroyl arginate proposed for lipstick, toothpaste and mouthwash are 0.4%, 0.8% and 0.8%, respectively. For children, a toothpaste amount of 0.5 g per brushing was assumed, the same amount used to calculate the amount of fluoride consumed by children for Application 588: Fluoride in packaged water. This results in an estimated intake of 0.9 mg/kg bw/day for non-food oral exposure in 18 month old children. While the level of consumption of 0.5 g was assumed based on the recommendation for young children to use a “pea sized” amount of toothpaste, recent studies indicate this amount is what is actually used by young children (Institute of Medicine, 1997; Table 8-4)⁷. The recommended level of toothpaste used is the same for all ages 18 months to 6 years, therefore the dietary exposure for children older than 18 months would be lower than that estimated for 18 month olds given their higher body weights. The Australian Dental Association (ADA, 2007)⁸ recommends that children under the age of 18 months do not need to use toothpaste. Therefore non-food oral exposure does not need to be considered for this age group.

Table 2: Estimated oral exposure (non-food and dietary) to ethyl lauroyl arginate by population group.

Population Group	Exposure Source (mg/kg bw/day)		
	Oral (non-food)	Dietary	
		Mean	90th Percentile
Australian Adults	0.4**		
Australian population 2+ years	-	0.7	1.6
Australian children (2 – 6 years)	0.4*	2.1	4.0
Children (18 months)	0.9*	-	-

* Calculation based on the assumptions of concentration of 0.8% ethyl lauroyl arginate, 0.5 g of toothpaste, 2 brushings/day and 9 kg bodyweight (18 months old) or 19 kg (2-6 years).

** Provided by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

⁷ Institute of Medicine (1997). Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride. Washington DC.

⁸ Australian Dental Association (2007). Policy Statement 1.2.1, Community Oral Health Promotion Fluoride Use.

The oral exposure from dietary sources is less than 2 mg/kg bw/day for the Australian population 2 years and above and exposure from non-dietary sources for adults is less than 1 mg/kg bw/day. For Australian children, the total estimated oral exposure would not exceed the ADI of 0-5 mg/kg bw, based on dietary exposure at the 90th percentile.

A separate analysis was not done for the New Zealand population – it was assumed that similar exposure levels would apply.

9.1.2 Current International approval for use of ethyl lauroyl arginate

A submitter questioned the number of countries that have given the approval for ethyl lauroyl arginate and if the ADI proposed by EFSA in 2007 has changed.

9.1.2.1 FSANZ response

In September 2005, FDA issued a GRAS notice recognising the safety of ethyl lauroyl arginate when used as an antimicrobial ingredient in a wide range of food types at a maximum level of 200 ppm ethyl-N^o-lauroyl-L-arginate·HCl. This determination was based on an ADI of 9 mg/kg bw of ethyl lauroyl arginate. The intended uses of ethyl lauroyl arginate in foods are listed in Appendix 1 of the Food Technology Report (Supporting Document 3).

The Ministry of Health of Mexico published in its Official Journal on 17 July 2006 a list of substances allowed as additives or processing aids in food, beverages and food supplements and ethyl lauroyl arginate is included. No maximum level was specified.

The 69th Joint Expert Committee on Food Additives (JECFA) held in June 2008 considered information available on ethyl lauroyl arginate. The Committee noted that EFSA had established an ADI of 0-0.5 mg/kg bw in 2007 and acknowledged that new information not available to EFSA enabled JECFA to conclude that the effects of ethyl lauroyl arginate on some white blood cell parameters in rodents were not relevant for a human risk assessment. Based on their evaluation, JECFA established an ADI of 0 – 4 mg/kg bw expressed as the active ingredient. JECFA has published a proposed use level for ethyl lauroyl arginate in a wide range of foods (except carbonated drinks) at 200 ppm (Appendix 2 of Supporting Document 2).

EFSA has not yet amended their ADI but has listed ethyl lauroyl arginate for consideration in July 2009.

In the EU, the Working Group of government experts on additives recently adopted the Working Document that will amend the EU Directive 95/2/EC by the end of 2009. This Working Document includes the statement “list of uses of ethyl lauroyl arginate should be restricted in order to bring the estimated intake within the limit of the ADI. Ethyl lauroyl arginate can under certain conditions be used as an efficient alternative to the currently authorised preservatives. It is therefore appropriate to permit these uses at Community level and to assign E243 as E number for ethyl lauroyl arginate”. (The Working Group’s list is included in Appendix 3 in the Food Technology Report – Supporting Document 3)

9.1.3 Levels of ethyl lauroyl arginate and food types

A submitter asked why the levels of ethyl lauroyl arginate appear higher and more food types are proposed in this application compared to the US and Europe.

9.1.3.1 FSANZ response

The proposed levels of ethyl lauroyl arginate in different countries reflect the ADI and food consumption pattern adopted by individual countries. Each country provides permissions in certain food types to ensure that sufficient ethyl lauroyl arginate level is used to justify its technological function while not exceeding their ADI.

The lists of intended uses of ethyl lauroyl arginate reported by the US FDA and JECFA (Appendices 1 and 2 in Food Technology Report – Supporting Document 3) have adopted a standard usage level of 200 ppm ethyl-N^α-lauroyl-L-arginate·HCl in a wide range of food types, with limited exceptions. On the other hand, the proposed applications of ethyl lauroyl arginate by the EC (Appendix 3 in Food Technology Report – Supporting Document 3) and FSANZ suggest specific usage levels depending on the type of food, e.g. 50 ppm ethyl-N^α-lauroyl-L-arginate·HCl in juices and drinks. A higher level, 400 mg ethyl-N^α-lauroyl-L-arginate·HCl, is proposed by FSANZ in certain foods such as fish and dairy based products. This is because ethyl lauroyl arginate reacts with protein-based foods and the higher amount of ethyl lauroyl arginate is required for effective preservation of the products.

9.1.4 Exclusion of apple juice

Submitters asked why apple juice was being excluded in this application and raised queries over the impact this would have on juice blends containing apple juice.

9.1.4.1 FSANZ response

Apple juice had been excluded from the list of intended uses initially because the Applicant believed it had the potential for ethyl lauroyl arginate exposure to exceed the ADI for children. There is no technological reason for not using ethyl lauroyl arginate in apple juice.

Additional dietary modelling has shown that the addition of ethyl lauroyl arginate to apple juice does not lead to a significant increase in the total exposure of ethyl lauroyl arginate in the Australian population, New Zealanders 15 years and above and Australians 2-6 years old (Supporting Document 2).

Therefore, FSANZ has now included apple juice in the list of intended uses. This will result in a simpler regulatory outcome.

9.1.5 Dietary exposure

A request was made to include the use of survey data from both New Zealand's 2002 National Children's Nutrition Survey and Australia's 2007 Children's Nutrition and Physical Activity Survey, which were not available during the assessment of A1015.

9.1.5.1 FSANZ response

The current situation with both of the children's surveys is that only the consumption data is uploaded into FSANZ's modelling program DIAMOND and available for use. For food additive modelling additional data sets need to be uploaded. These data sets are nearing completion, but some work still remains to incorporate the data into DIAMOND before it is ready for use. Therefore, the estimates of ethyl lauroyl arginate exposure will not be able to be conducted with the Australian and New Zealand children's survey data within the statutory time frame for this Application.

As the 2007 Australian consumption data are available, it was possible to estimate 2007 consumption of the major contributors as food groups identified in the Assessment Report for Application 1015 for the population group Australians 2 to 6 years. These consumption figures can be compared to the consumption figures extracted for the same population group from the 1995 Australian National Nutrition Survey. These data are presented in Table 3.

It should be noted that the comparison of consumption figures can only give an indication of differences between the surveys or changes in consumption patterns, due to differences in survey methodology.

Table 3: Consumption data from the 1995 National Nutrition Survey and the 2007* Australian Children’s Nutrition and Physical Activity Survey for Australians 2 to 6 years.

Children 2 - 6 years				
Food Group	Survey	No. of consumers	No. of consumers as % of all respondents	Mean g/day
Comminuted meat products	1995	231	23.4	56
	2007	395	21.9	54
Fruit and vegetables juice and fruit drinks	1995	447	45.2	320
	2007	834	46.6	251
Cordials 'made up'	1995*	264	26.7	472
	2007	7	0.4	143
Cordial bases	1995	176	17.8	66
	2007**	350	19.5	49

*Both 1995 & 2007 data are unweighted

** The majority of cordial consumption is recorded under cordial bases for the 2007 NNS and cordials 'made-up' for the 1995 NNS.

The consumption data for the major contributors to ethyl lauroyl arginate exposure from the 1995 and 2007 nutrition surveys indicate potential for estimated dietary exposures of ethyl lauroyl arginate to be somewhat lower based on more recent consumption data. The exposures would need to be estimated using data for all foods and beverages consumed in the 2007 survey before this could be confirmed. However, from the conservative calculation using 1995 data there is limited evidence for potential overexposure.

9.1.6 Limited published literature supporting the effectiveness of ethyl lauroyl arginate

A submitter requested further evidence to be provided with respect to the effectiveness of ethyl lauroyl arginate and suggested that the internal studies provided by the Applicant be reviewed by one or two independent food microbiologists.

9.1.6.1 FSANZ response

FSANZ has required that the Applicant produce data for at least one representative food in each of the food types assessed in this Application.

The Applicant provided data from an independent laboratory study that demonstrated the activity of ethyl lauroyl arginate against a broad range of Gram-negative and Gram-positive bacteria, yeasts and moulds, with reported minimal inhibitory concentrations of 4-128 µg/mL.

There have been limited published scientific journal reports describing the use of ethyl lauroyl arginate in food products, due largely to the novelty and originality of the food preservative. However, the Applicant submitted 35 internal laboratory studies gathered using standardised techniques to demonstrate the activity of ethyl lauroyl arginate in a wide range of food products.

FSANZ microbiology experts reviewed all the data provided and in some cases, further information and clarification was sought.

FSANZ confirmed ethyl lauroyl arginate performed its stated technological function (i.e. retard or prevent the deterioration of foods by microorganisms) when applied to specific foods at the required concentration and stored under test conditions. As for any preservative, the extent of inhibition will vary depending on the physical and chemical nature of the food, type of microorganism, and the conditions of application, including the environment (e.g. temperature of storage).

FSANZ does not believe further review is required.

9.2 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.

Amending the Code to include ethyl lauroyl arginate as a food additive is unlikely to have a significant effect on trade. The ethyl lauroyl arginate preparation is consistent with the international specifications for ethyl lauroyl arginate. For these reasons FSANZ did not notify the WTO under either the Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements.

CONCLUSION

10. Conclusion and Preferred Option

The Applicant has sought to amend Schedule 1 of Standard 1.3.1 – Food Additives, of the Code to permit maximum limits for the use of ethyl lauroyl arginate as a preservative in food types as listed in Table 3.

Decision

FSANZ approves the proposed draft variations to Standard 1.3.1, Schedule 1 – Food Additives, to include ethyl lauroyl arginate in the food types at the specified maximum limits as listed in Table 1 with subsequent amendments to Standard 1.2.4 – Labelling of Ingredients and Standard 1.3.4 – Identity and Purity.

10.1 Reasons for Preferred Approach

Amendments to the Code to include ethyl lauroyl arginate as a food preservative in Australia and New Zealand is proposed on the basis of the available scientific evidence for the following reasons:

- A detailed safety assessment has concluded the permission for the use of ethyl lauroyl arginate does not raise any public health and safety concerns, including considering development of antimicrobial resistance and exposure from cosmetics and personal care products. The relevant assessments are based on the best available scientific evidence.
- Use of ethyl lauroyl arginate as a preservative in the specified food categories and at the maximum permitted level is technologically justified and it could potentially be a useful component of food preservation systems. Based on data provided by the Applicant, ethyl lauroyl arginate could potentially replace some approved food grade preservatives, such as benzoates, sulphites and sorbates.
- The regulatory impact assessment concluded that the benefits of the potential use of ethyl lauroyl arginate in the specified food categories outweigh any costs associated with its use.
- The proposed variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

11. Implementation and Review

The FSANZ Board's decision on this Approval Report has been notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

- 1A. Draft variation to the *Australia New Zealand Food Standards Code* (at Approval)
- 1B. Draft variations to the *Australia New Zealand Food Standards Code* (Indicating Changes from Drafting at Assessment)
- 1C. Draft variations to the *Australia New Zealand Food Standards Code* (at Assessment)
2. Summary of issues from Assessment Submissions

Draft variations to the Australia New Zealand Food Standards Code (at Approval)

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence on gazettal:

[1] **Standard 1.2.4** of the Australia New Zealand Food Standards Code is varied by –

[1.1] *inserting in Part 1 of Schedule 2 –*

Ethyl lauroyl arginate	243
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[1.2] *inserting in Part 2 of Schedule 2 –*

Ethyl lauroyl arginate	243
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[2] **Standard 1.3.1** of the Australia New Zealand Food Standards Code is varied by –

[2.1] *inserting in subclause 5(2) –*

ethyl lauroyl arginate shall be calculated as ethyl-N^α-lauroyl-L-arginate·HCl

[2.2] *inserting in Schedule 1, under item 0.1 Preparations of food additives –*

243	Ethyl lauroyl arginate	200	mg/kg
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[2.3] *inserting in Schedule 1, under item 1.6 Cheese and cheese products, immediately following the last additive entry –*

1.6.1 Soft cheese, cream cheese and processed cheese

243	Ethyl lauroyl arginate	400	mg/kg
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Mozzarella cheese

243	Ethyl lauroyl arginate	200	mg/kg
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1.6.2 Hard cheese and semi-hard cheese

243	Ethyl lauroyl arginate	1	mg/cm ²	applied to the surface of food; maximum level determined in a surface sample taken to a depth of not less than 3 mm and not more than 5 mm.
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[2.4] *inserting in Schedule 1, under item 4.1.3 Peeled and/or cut fruits and vegetables –*

	243	Ethyl lauroyl arginate	200	mg/kg	
[2.5] <i>inserting in</i> Schedule 1, <i>under item</i> 4.3.8 Other fruit and vegetable based products* –					
Rehydrated legumes					
	243	Ethyl lauroyl arginate	200	mg/kg	
[2.6] <i>inserting in</i> Schedule 1, <i>under item</i> 6.3 Processed cereal and meal products, <i>immediately following the last additive entry</i> –					
6.3.1 Cooked rice					
	243	Ethyl lauroyl arginate	200	mg/kg	
[2.7] <i>inserting in</i> Schedule 1, <i>under item</i> 6.4 Flour products (including noodles and pasta)* –					
	243	Ethyl lauroyl arginate	200	mg/kg	cooked pasta and noodles only
[2.8] <i>inserting in</i> Schedule 1, <i>under item</i> 8.2 Processed meat, poultry and meat products in whole cuts or pieces –					
	243	Ethyl lauroyl arginate	200	mg/kg	
[2.9] <i>inserting in</i> Schedule 1, <i>under item</i> 8.3 Processed comminuted meat, poultry and game products –					
	243	Ethyl lauroyl arginate	315	mg/kg	
[2.10] <i>inserting in</i> Schedule 1, <i>under item</i> 9.3 Semi preserved fish and fish products –					
	243	Ethyl lauroyl arginate	400	mg/kg	
[2.11] <i>inserting in</i> Schedule 1, <i>under item</i> 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products* –					
	243	Ethyl lauroyl arginate	50	mg/kg	
[2.12] <i>inserting in</i> Schedule 1, <i>under item</i> 14.1.3 Water based flavoured drinks* –					
	243	Ethyl lauroyl arginate	50	mg/kg	
[2.13] <i>inserting in</i> Schedule 1, <i>under item</i> 20.2 Food other than beverages*, <i>sub-item</i> dairy and fat based desserts, dips and snacks –					
	243	Ethyl lauroyl arginate	400	mg/kg	
[2.14] <i>inserting in</i> Schedule 1, <i>under item</i> 20.2 Food other than beverages*, <i>sub-item</i> sauces and toppings (including mayonnaises and salad dressings) –					
	243	Ethyl lauroyl arginate	200	mg/kg	

**Draft variations to the *Australia New Zealand Food Standards Code*
(Indicating Changes from Drafting at Assessment)**

1. Item [2.11]

1.1 At Assessment

[2.11] *inserting in* Schedule 1, *under item* 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products* –

243	Ethyl lauroyl arginate	50	mg/kg	not apple juice
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1.2 At Approval

[2.11] *inserting in* Schedule 1, *under item* 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products* –

243	Ethyl lauroyl arginate	50	mg/kg	
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Draft variations to the Australia New Zealand Food Standards Code (At Assessment)

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

To commence on gazettal:

[1] **Standard 1.2.4** of the Australia New Zealand Food Standards Code is varied by –

[1.1] *inserting in Part 1 of Schedule 2 –*

Ethyl lauroyl arginate	243
------------------------	-----

[1.2] *inserting in Part 2 of Schedule 2 –*

Ethyl lauroyl arginate	243
------------------------	-----

[2] **Standard 1.3.1** of the Australia New Zealand Food Standards Code is varied by –

[2.1] *inserting in subclause 5(2) –*

ethyl lauroyl arginate shall be calculated as ethyl-N^o-lauroyl-L-arginate·HCl

[2.2] *inserting in Schedule 1, under item 0.1 Preparations of food additives –*

243	Ethyl lauroyl arginate	200	mg/kg
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[2.3] *inserting in Schedule 1, under item 1.6 Cheese and cheese products, immediately following the last additive entry –*

1.6.1 Soft cheese, cream cheese and processed cheese

243	Ethyl lauroyl arginate	400	mg/kg
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Mozzarella cheese

243	Ethyl lauroyl arginate	200	mg/kg
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1.6.2 Hard cheese and semi-hard cheese

243	Ethyl lauroyl arginate	1	mg/ cm ²	applied to the surface of food; maximum level determined in a surface sample taken to a depth of not less than 3 mm and not more than 5 mm.
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[2.4] *inserting in Schedule 1, under item 4.1.3 Peeled and/or cut fruits and vegetables –*

243	Ethyl lauroyl arginate	200	mg/kg
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[2.5] *inserting in Schedule 1, under item 4.3.8 Other fruit and vegetable based products* –*

Rehydrated legumes

243	Ethyl lauroyl arginate	200	mg/kg
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[2.6] *inserting in Schedule 1, under item 6.3 Processed cereal and meal products, immediately following the last additive entry –*

6.3.1 Cooked rice

243	Ethyl lauroyl arginate	200	mg/kg
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[2.7] *inserting in Schedule 1, under item 6.4 Flour products (including noodles and pasta)* –*

243	Ethyl lauroyl arginate	200	mg/kg	cooked pasta and noodles only
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[2.8] *inserting in Schedule 1, under item 8.2 Processed meat, poultry and meat products in whole cuts or pieces –*

243	Ethyl lauroyl arginate	200	mg/kg
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[2.9] *inserting in Schedule 1, under item 8.3 Processed comminuted meat, poultry and game products –*

243	Ethyl lauroyl arginate	315	mg/kg
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[2.10] *inserting in Schedule 1, under item 9.3 Semi preserved fish and fish products –*

243	Ethyl lauroyl arginate	400	mg/kg
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[2.11] *inserting in Schedule 1, under item 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products* –*

243	Ethyl lauroyl arginate	50	mg/kg	not apple juice
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[2.12] *inserting in Schedule 1, under item 14.1.3 Water based flavoured drinks* –*

243	Ethyl lauroyl arginate	50	mg/kg
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[2.13] *inserting in Schedule 1, under item 20.2 Food other than beverages*, sub-item dairy and fat based desserts, dips and snacks –*

243	Ethyl lauroyl arginate	400	mg/kg
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[2.14] *inserting in Schedule 1, under item 20.2 Food other than beverages*, sub-item sauces and toppings (including mayonnaises and salad dressings) –*

243	Ethyl lauroyl arginate	200	mg/kg
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[3] **Standard 1.3.4** of the Australia New Zealand Food Standards Code is varied by omitting paragraph 2(a), substituting –

- (a) Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005) as superseded by specifications published in FAO JECFA Monographs 3 (2006) and FAO JECFA Monographs 4 (2007) and FAO JECFA Monographs 5 (2008), Food and Agriculture Organisation of the United Nations, Rome; or

Summary of issues in Assessment submissions

ISSUES	PROPOSED ACTION/INFORMATION REQUIRED
New Zealand Food Safety Authority	Support Option 2
New South Wales Food Authority	Satisfied with the justification of the use of ELA. Support progression of this Application
Need clarification on why the levels proposed by this Application are higher than levels allowed by US FDA	The higher levels are required only in foods that contain protein, for effective use of ELA. As this does not result in the exceedance of the ADI for any consumer groups, it does not cause public health concern.
Potential exposure through non-food source such as cosmetics	With advice from NICNAS regarding personal care products likely to contain ELA, FSANZ has estimated the potential dermal, inhalation and oral exposure arising from the use of such products. The potential additional exposure to ELA from cosmetics and personal care products is so low that it is unlikely to be of concern.
Queensland Government	
- Health Department	Does not support either option
- Department of Employment, Economic Development and Innovation	Indication of supporting Option 2
Has EFSA revised its position on the ADI?	EFSA has not yet amended its ADI but has listed ethyl lauroyl arginate for consideration in July 2009
Should dietary modelling with data from 2002 NZ and 2007 Australia's children survey be included since they have now become available?	The estimates of ethyl lauroyl arginate exposure will not be able to be conducted with the Australian and New Zealand children's survey data within the statutory time frame for this Application. Work still remains to incorporate the additional datasets into DIAMOND before food additive modelling can be conducted. However, food consumption data is available to be used. The consumption data for the major contributors to ethyl lauroyl arginate exposure for Australian children aged 2 to 6 years from the 1995 and 2007 nutrition surveys may indicate a potential for estimated dietary exposures to be lower based on more recent consumption data.
Application in cosmetics - additional potential exposure in non-foods	See response to NSWFA above.
Status of international permissions for use of ELA	No change since the Assessment Report was published in May 2009

ISSUES	PROPOSED ACTION/INFORMATION REQUIRED
<p>Requested further and more convincing evidence be provided for microbial effectiveness and that these results be reviewed by independent food microbiologists.</p>	<p>The Food Technology Report has been expanded to provide more information on the conditions of the studies.</p> <p>FSANZ has reviewed the data again and concluded that no further review by external microbiologists is required.</p>
<p>Why was ELA excluded for its use in apple juice? Regulatory clarification needed for juice blends that may contain apple juice.</p>	<p>There was no technological reason for excluding the use in apple juice. It was the Applicant's initial view that inclusion of apple juice may potentially exceed the ADI.</p> <p>Since the apple juice makes a minor difference in the dietary exposure in the high consumption group (2-6 year olds), it does not change the risk assessment conclusion.</p> <p>FSANZ acknowledges that this exclusion could lead to practical and regulatory complexity.</p> <p>FSANZ has now recommended to remove 'NOT apple juice' from Food type 14.1.2. in Standard 1.3.1.</p>