8 November 2012
[26-12]

Call for submissions – Application A1074

Minimum L-histidine in Infant Formula Products

FSANZ has assessed an Application made by Nestlé Australia Limited and Nestlé New Zealand Limited to reduce the minimum required level of L-histidine in infant formula products, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 20 December 2012

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

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

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

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Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at:
http://www.foodstandards.govt.nz/foodstandards/applications/applicationa1074mini5583.cfm

SD1 Comparative Nutritional Safety Assessment

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Nestlé Australia Limited and Nestlé New Zealand Limited on 18 May 2012. The Application seeks to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ in the *Australia New Zealand Food Standards Code* (the Code). The request relates to all infant formula products regulated in Standard 2.9.1 – Infant Formula Products of the Code, specifically infant formula, follow-on formula and infant formula products for special dietary use.

FSANZ's assessment of the Application has involved a review of the best available scientific evidence to determine whether the proposed reduced minimum level for L-histidine protects the health and safety of formula-fed infants. FSANZ has also assessed whether the request meets its objectives under section 18 of the *Food Standards Australia New Zealand Act 1991*, and has given regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products.*

The Comparative Nutritional Safety Assessment used breast milk as the primary reference for the composition of infant formula products. It concluded that a minimum of L-histidine at 10 mg/100 kJ in infant formula products is comparable to the average amount of L-histidine present in breast milk. It also reported published evidence that showed growth of formula-fed infants consuming a formula containing a minimum of L-histidine at 10 mg/100 kJ is comparable with breastfed infants. These studies measured physiological outcomes (anthropometric measures) and biochemical outcomes (plasma amino acid concentration) of breastfed and formula-fed infants.

A minimum level for L-histidine in infant formula products of 10 mg/100 kJ is also consistent with requirements in the relevant Codex Alimentarius and European Commission standards. The current lack of harmonisation between the Code and international and overseas food standards, and its subsequent adverse effect on trade, was a key reason for the Applicant's request to amend the Code. A reduction in the requirement for L-histidine is expected to benefit trade, support business competitiveness and innovation, and improve the range of products available to Australian and New Zealand consumers.

Based on our assessment, FSANZ considers it is appropriate to reduce the minimum required level of L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ, as requested by the Applicant. The reduced minimum level is comparable to the *average* L-histidine content of breast milk and is considered adequate to support the growth of formula-fed infants. Amending the Code would provide consistency between the Code and international and overseas food standards, and overall, would provide a net benefit to the community.

FSANZ has prepared draft variations to amend the tables to clauses 22 and 32 of Standard 2.9.1 to require a minimum level of L-histidine in infant formula products of 10 mg/100 kJ.

2. Introduction

2.1 The Applicant

The Applicant is Nestlé Australia Limited and Nestlé New Zealand Limited. Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula products.

Nestlé currently imports and markets infant formula products, including paediatric speciality formulas for infants with specific nutritional needs, into Australia and New Zealand.

2.2 The Application

Application A1074 – Minimum L-histidine in Infant Formula Products was received on 18 May 2012. The Application seeks to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ in the *Australia New Zealand Food Standards Code* (the Code). The Applicant's request relates to all infant formula products, specifically infant formula, follow-on formula and infant formula products for special dietary use.

The Applicant states that a reduction in the current minimum requirement for L-histidine to 10 mg/100 kJ is safe and will promote normal growth and development in infants. In addition, it would reportedly promote consistency between the Code and international and overseas regulations, which would be beneficial for trade. The Applicant does not foresee any additional cost or burden for consumers, industry or regulators.

2.3 The current Standard

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products of the Code. Infant formula products comprise: infant formula (0 to 12 months); follow-on formula (6 to 12 months); and infant formula products for special dietary use (e.g. formulas for premature infants or those with metabolic or immunological conditions, which are specifically formulated for the intended use). An infant means a person under the age of 12 months.

Standard 2.9.1 specifically regulates the compositional and labelling of infant formula products, including requirements for minimum composition. Infant formula and follow-on formula must contain a minimum 0.45 g protein/100 kJ and a maximum 0.7 g/100 kJ for infant formula and 1.3 g/100 kJ for follow-on formula. To assure protein quality, the Standard also prescribes a minimum amino acid profile.

The Table to clause 22 in Standard 2.9.1 prescribes the minimum amino acid profile for 11 essential amino acids. One of these, L-histidine, is currently required to be present at a minimum of 12 mg/100 kJ.

Provisions for infant formula products for special dietary use (IFPSDU) are provided in Division 3 of Standard 2.9.1. Subclause 32(2) requires IFPSDU to contain minimum levels of the same amino acids as prescribed for infant formula and follow-on formula in the Table to clause 22. The Code also allows IFPSDU to be specially formulated for a particular use, such as for metabolic or immunological medical conditions, and therefore the composition of these products may vary from the mandatory compositional requirements.

2.3.1 Relevant international and overseas regulations

The most relevant Codex Alimentarius standard is *STAN 72-1981 – Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*; revised 2007 and amended 2011 (Codex 2011). The Codex infant formula standard adopted the same approach as the Code in specifying a minimum amino acid profile for infant formula, based on the average content of each essential amino acid in breast milk. The Codex minimum requirement for L-histidine in infant formula is 41 mg/100 kcal, which is equivalent to approximately 10 mg/100 kJ.

Similarly, 10 mg/100 kJ is the minimum requirement for L-histidine in infant formula and follow-on formula under the *European Commission Directive 2006/141/EC – Infant Formula and Follow-on Formulae and amending Directive 1999/21/EC*; published in 2006 (European Commission 2006).

A difference to note between the Code and the Codex and European Commission (EC) regulations is that different nitrogen conversion factors are prescribed to calculate protein content, which subsequently affects the results of the calculated amino acid content of a product. Both the Codex and European protein and amino acid requirements are based on a nitrogen conversion factor of 6.25. However, the Code currently prescribes two nitrogen conversion factors depending on the type of protein in the product: a factor of 6.38 for milk proteins and their partial protein hydrolysates; and 6.25 for any other protein source. The absolute difference in protein content calculated using a nitrogen conversion factor of 6.25 compared to 6.38 is relatively small. For the purposes of this report, a nitrogen conversion factor of 6.38 will be used where appropriate, to be consistent with the current requirements for milk-based infant formula products in the Code.

2.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act); and
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application is being assessed under the General Procedure and will include one round of public consultation within the 9 month statutory timeframe for assessment.

3. Summary of the assessment

3.1 Nutritional safety assessment

A Comparative Nutritional Safety Assessment (CNSA) (Supporting Document (SD) 1) was undertaken for this Application.

The objectives of the CNSA were to confirm that a reduced level of L-histidine of 10 mg/100 kJ is consistent with reported levels in breast milk and that it will support normal growth in formula-fed infants. The CNSA addressed three questions:

1. Is a reduction in the minimum required amount of L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ supported by current available studies on breast milk composition?
2. Is plasma/serum level of L-histidine a marker of dietary intake? If so, is a minimum level of 10 mg/100 kJ of L-histidine in infant formula products adequate to meet the physiological requirements of formula-fed infants compared to breastfed infants?
3. If not, would a minimum level of 10 mg/100 kJ of L-histidine in infant formula products support adequate growth of formula-fed infants compared to breastfed infants?

The CNSA concluded that a minimum level of 10 mg/100 kJ of L-histidine in an infant formula product is comparable to the average amount of L-histidine present in breast milk. This conclusion is based on the best evidence of breast milk composition currently available.

The average level of L-histidine in breast milk, measured against crude protein content was calculated from analysis of selected studies and ranged from 18-40 mg L-histidine/g crude protein with an average of 24 mg L-histidine/g crude protein (based on a nitrogen conversion factor of 6.25). This value is consistent with recent international reports (Life Sciences Research Office 1998; EC Scientific Committee on Food 2003; Koletzko et al. 2005; WHO/FAO/UNU Expert Consultation 2007) that have conducted similar analyses (but using different studies). Converting the average L-histidine content to a per kJ value (using data for protein, carbohydrate and fat compositional data for breast milk and energy conversion data) indicates that this level is equivalent to 10 mg L-histidine/100 kJ (using either 6.25 or 6.38 as the nitrogen conversion factor). Reduction of L-histidine content to 10 mg/100 kJ is equivalent to a reduction in the protein content of less than 0.1 mg protein/100 kJ.

It is assumed that levels of L-histidine in breast milk are adequate for normal growth, and this proposed reduction falls well within the range for mature breast milk. There is also published evidence that growth of formula-fed infants consuming a formula containing L-histidine at 10 mg/100 kJ is comparable with breastfed infants. These studies measured physiological outcomes (anthropometric measures) and biochemical measures (plasma amino acid concentration) of breastfed and formula-fed infants.

3.2 Risk management

Infants are a vulnerable population group and although breastfeeding is the recommended way to feed a baby, a safe and nutritious substitute for breast milk is needed for infants that are not breastfed.

For formula-fed infants, infant formula products provide the sole source of nutrition during the first months of life and continue to act as the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months. For this reason, infant formula products are regulated as special purpose foods in the Code with highly prescriptive provisions for the composition and labelling of these products.

3.2.1 Cost/benefit analysis

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

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

Two regulatory options are considered for this Application:

- Option 1 – to prepare draft variations to Standard 2.9.1 to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ; or
- Option 2 – to reject the Application and maintain the current minimum requirement for L-histidine in infant formula products of 12 mg/100 kJ.

There are no other measures (available to FSANZ or not) that would be more cost-effective than a food regulatory measure varied as a result of this Application.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 12 October 2012 (reference 14346), confirmed that a Regulation Impact Statement (RIS) was not required for this Application. The proposed variation to the Code is considered minor and machinery in nature. However, FSANZ has performed a summary impact assessment.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Rather, the analysis seeks to highlight the qualitative effects of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

3.2.1.1 Option 1 – Prepare draft variations to Standard 2.9.1

Consumers

A minimum requirement for L-histidine of 10 mg/100 kJ of infant formula product is considered adequate to support the growth of formula-fed infants compared to breastfed infants.

Harmonisation with international and overseas regulations means there would be potential for a larger product range, particularly of special dietary use products, to be available in Australia and New Zealand. It is expected that the range of products would be similar to that available in larger markets such as the European Union (EU), which are reformulated regularly based on the latest research and development. Therefore, consumers would potentially have greater choice of infant formula products, and in the case of special dietary use formulas these may be more suited to the dietary management of the infant's medical condition.

Use of the same formulation for multiple markets should help ensure a regular supply of products for Australian and New Zealand consumers, which is particularly important as infant formula products provide either the sole source or principal source of nutrition for formula-fed infants.

It is not foreseen that this change would mean consumers pay a higher price for products.

Government

A benefit of the proposed change for government is that it would promote consistency between domestic and international regulations.

It is not expected that there would be any costs for government if the minimum required level of L-histidine was reduced. Enforcement agencies would continue to enforce the minimum requirement for L-histidine in infant formula products as done in the past.

Industry

The proposed reduction in the minimum required L-histidine level would benefit local and overseas infant formula manufacturers. It would potentially allow manufacturers, assuming all other regulatory requirements are the same, to use the same product formulation for products for larger markets, such as the EU, and for products destined for Australia and New Zealand.

Importers may then be able to provide a larger product range, particularly for infant formula products for special dietary use. It may also allow Australian and New Zealand manufacturers to be more competitive internationally and to be more innovative.

As the requirement for L-histidine is a minimum requirement and it is proposed that this level be reduced, manufacturers would not be required to reformulate existing products (that meet current requirements) to meet the lower minimum requirement. However, some manufacturers may choose to reformulate products for potential business and trade advantages, as outlined previously, and there would be a cost associated with doing so.

Similarly, there would be no required labelling changes for existing products. Costs to change labels would only be incurred if a product was reformulated and no longer needed L-histidine added as a single amino acid to meet the minimum required level. In this situation, L-histidine would need to be removed from the statement of ingredients on the product label.

3.2.1.2 Option 2 – Reject the Application

Consumers

It is unlikely that Australian and New Zealand consumers/purchasers of infant formula products would notice any change if the current minimum requirement for L-histidine of 12 mg/100 kJ was maintained. It would be expected that, in general, the product choice and accessibility to products would remain the same.

However, there is potential for the range of products available for Australian and New Zealand consumers to be limited compared to that available for consumers in larger markets, such as the EU. In the case of formula-fed infants that require special dietary use products, this may be disadvantageous from a health perspective if the most suitable product to manage their condition is not available in Australia and New Zealand.

Government

It is not expected that there would be any financial costs or benefits to government if the current minimum requirement for L-histidine was maintained.

The Code would continue to be inconsistent with international and overseas food standards for L-histidine content in infant formula products. In turn, this may adversely impact on the efficiency and competitiveness of infant formula manufacturers and importers. This situation is in contrast to the section 18(2) objectives of the FSANZ Act, which support the promotion of consistency between domestic and international food standards, and the desirability of an efficient and internationally competitive food industry.

Industry

If the minimum requirement for L-histidine in infant formula products was to remain at 12 mg/100 kJ then this may limit the ability of manufacturers to innovate and readily reformulate products for the Australian and New Zealand market. If the same product formulation cannot be used to meet the regulatory requirements for multiple markets, then manufacturers are more likely to formulate the product for the largest market. This is particularly relevant for small volume, specialised products, in which Australia and New Zealand would be at a disadvantage with its small market for these products.

In addition, to maintain the minimum required level of L-histidine at 12 mg/100 kJ would require some manufacturers to continue to 'top up' naturally occurring levels of L-histidine in products. The addition of L-histidine as a single amino acid to products adds cost for the manufacturer. Alternatively, the manufacturer/importer may decide not to supply infant formula products to the Australian and New Zealand market.

3.2.2 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the matters addressed by the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application.

3.2.2.1 Protection of public health and safety

The protection of the health and safety of formula-fed infants is paramount. This vulnerable population relies on infant formula products as either its sole source or principal liquid source of nutrition. Infant formula products must be safe for consumption and must also provide all the essential nutrients, in the right amounts, to support the growth and development of formula-fed infants.

L-histidine, an essential amino acid, is found in breast milk. Essential amino acids cannot be synthesised by the body and therefore need to be provided in the diet. Amino acids are the building blocks of proteins. Proteins have a key role in infant nutrition since adequate protein is needed to support normal growth and development of the infant.

For this reason, the protein content of infant formula products is mandated at no less than 0.45 g/100 kJ and no more than 0.7 g/100 kJ and 1.3 g/100 kJ for infant formula and follow-on formula respectively, within a controlled energy density. Similarly, it is a mandatory requirement for 11 essential amino acids, including L-histidine, to be present in infant formula products in minimum amounts to ensure a high quality of protein in products.

L-histidine is also naturally present in mammalian milk such as cows' and goats' milk, which is a key ingredient in most regular infant formula products. The amino acid content of milk varies across the season, with highest levels in early season when the protein and fat content of the milk is highest. To account for this seasonal variability, manufacturers typically adjust the whey to casein fractions of the base milk ingredient to at least meet the minimum level for each essential amino acid in the final product. However, when this is not possible, amino acids are added as single amino acids to raise the levels in the product to at least meet the minimum requirements.

Comparison with breast milk

The CNSA considered whether the proposed minimum level for L-histidine in infant formula products of 10 mg/100 kJ is consistent with reported levels in breast milk. This approach aligns with the Ministerial Policy Guideline on the *Regulation of Infant Formula Products,* which recommends the composition of breast milk is used as a primary reference for determining the composition of infant formula and follow-on formula. The CNSA found that the level of L-histidine in breast milk is variable with the average level equating to 10 mg/100 kJ, which is the same level the Applicant has proposed as the new minimum requirement for L-histidine in infant formula products.

While the level of a nutrient may be comparable between breast milk and an infant formula product, the bioavailability of the nutrient may differ. The CNSA considered this issue for L-histidine and noted that the amino acid bioavailability, as determined by its concentration in plasma, corresponds to the amino acid content of the ingested protein.

Given that a reduction in L-histidine content from 12 mg/100 kJ to 10 mg/100 kJ is minor relative to the natural variability in total protein content for breast milk, a small difference in protein digestibility is unlikely to have any physiological importance.

Adequacy to support growth

Sufficient dietary energy and a range of nutrients are required to support the normal growth and development of infants. L-histidine is one of these nutrients and it is internationally accepted that its presence should be mandated in infant formula products.

The minimum level at which L-histidine should be present in infant formula products is the basis for this Application. The CNSA evaluated current scientific evidence to determine whether the proposed minimum level of L-histidine of 10 mg/100 kJ is adequate to support the normal growth of formula-fed infants. It was found that anthropometric measures were comparable between formula-fed infants consuming formula with L-histidine content of either 12 mg/100 kJ or 10 mg/100 kJ, and with breastfed infants.

Overall, it is considered that the proposed reduction in minimum level of L-histidine to 10 mg/100 kJ will continue to support the growth of formula-fed infants compared to breastfed infants.

Use of a minimum requirement

In relation to this Application, the proposed *minimum* level for L-histidine in infant formula products of 10 mg/100 kJ has been shown to be equivalent to the *average* L-histidine content of breast milk (24 mg/g crude protein, which is equivalent to 10 mg/100 kJ). Therefore, a *minimum* level in infant formula that equates to the *average* level in breast milk provides a 'safety net' to account for any potential differences in bioavailability of L-histidine from breast milk versus formula (although this is considered negligible) and for any losses over the shelf-life of the product.

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

FSANZ does not consider that current labelling provisions for infant formula products would need to be amended if the minimum level for L-histidine was reduced to 10 mg/100 kJ. The CNSA does not identify any new risks that could be managed through provision of additional information on the product label. Also, labelling information for L-histidine is unlikely to influence product choice, as the mandatory minimum L-histidine requirement means that this information shows little comparative difference between products. Instead, it is more likely that purchasers would compare nutritional factors that differ such as total protein content and the presence of 'optional' ingredients (e.g. omega 3 fatty acids and lutein) when choosing a product, both of which must be declared in the nutrition information statement on the product label. The Applicant noted that it is not aware of any consumer enquiries about L-histidine to its consumer care line in the last three years.

3.2.2.3 The prevention of misleading or deceptive conduct

No issues were identified in relation to the potential for misleading or deceptive conduct with the proposed reduction in minimum requirement for L-histidine in infant formula products.

L-histidine is unlikely to be used to differentiate products for marketing purposes, particularly as it is a mandatory requirement and must not be added in amounts more than necessary to improve protein quality.

In addition, under current labelling provisions, information relating to L-histidine on product labels is limited. As no labelling changes would be required if the proposed amendment was approved, it is unlikely that consumers would be aware of the change.

3.2.2.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2) of the FSANZ Act:

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

  As the composition of breast milk is the most appropriate reference for determining the composition of infant formula products, a comparative nutritional safety assessment using best available scientific evidence has been used. As well as scientific studies provided by the Applicant, FSANZ sourced additional information to complement this evidence base and to address any gaps in the information. The CNSA outlines the evidence base to support the Applicant's request to reduce the minimum required level of L-histidine in infant formula products (refer to section 3.1 and SD1).

- *The promotion of consistency between domestic and international food standards*

  The proposed variation to reduce the minimum required level of L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ would promote consistency between the Code and international and overseas regulations.

  The Applicant notes that although this is a company-specific application, there is general support from the majority of the infant formula food industry for the principle of harmonisation with Codex.

  It is advantageous for manufacturers to use the same formulation for products for the Australia/New Zealand market that they do for larger overseas markets, such as the EU. The Applicant states this is particularly relevant for infant formula products for special dietary use, which are small volume specialty products. Harmonisation for L-histidine requirements is expected to improve the variety of available products since those products available in the EU should also meet the Australia/New Zealand requirements. In turn, this should improve the ability of companies to ensure a regular supply of products for Australian and New Zealand consumers.

  Codex and European regulations permit the addition of amino acids only if the naturally occurring levels are insufficient to meet the minimum requirements. Therefore, a European manufactured product with a naturally occurring L-histidine level between 10 and 12 mg/100 kJ could not meet the higher Code requirement of 12 mg/100 kJ and be lawfully sold on both the EU and Australia/New Zealand markets.

- *The desirability of an efficient and internationally competitive food industry*

  Trade is an important consideration for regulatory matters relating to infant formula products as these products are traded globally. Infant formula products available for sale in Australia and New Zealand are a combination of locally manufactured and imported products. In addition, a number of products manufactured locally, particularly in New Zealand, are produced for export only.

  Consistency with international and overseas regulations helps to support local infant formula manufacturers to be efficient and internationally competitive.

Currently, locally produced infant formula products for export must comply with the compositional requirements in the Code as well as any additional requirements of the importing country. The New Zealand Government may issue product- and country-specific exemptions from the Code requirements although a similar process for exemptions does not currently exist in Australia.

- *The promotion of fair trading in food*

  The proposed variation is not expected to have any effect on fair trading in food.

- *Any written policy guidelines formulated by the Ministerial Council[1].*

  FSANZ has had regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* in our assessment of this Application. The specific policy principles for composition were particularly relevant, specifically the principles that intend that:

  - (d) and (e): Infant formula and follow-on formula should strive to achieve the normal growth and development of healthy, full term, breastfed infants in the same age group as those for whom the product is intended. Normal growth and development should be determined by appropriate and measurable physiological, biochemical and functional outcomes.
  - (f) and (g):The essential (mandated) composition must satisfy the nutritional requirements of infants and be shown to be essential for normal growth and development.
  - (h): Breast milk composition should be a primary reference for formula composition.

  Specific policy principles (i) and (j) are not applicable to this Application as L-histidine is not a new substance to be regulated.

  FSANZ considers that the proposed reduction in the minimum level of L-histidine in infant formula products meets all of the applicable Policy Guideline principles. Specifically, FSANZ's assessment of this Application has:

  - used the average L-histidine content of breast milk as the primary reference to determine the appropriate amount that should be required in infant formula products.
  - noted that a minimum level of L-histidine is already mandated to provide for the nutritional requirements of infants.
  - determined that the plasma levels of L-histidine in breastfed infants and those fed infant formula products with a lower amount of L-histidine are physiologically equivalent. In combination with other amino acids, L-histidine is required for protein synthesis and therefore plays an important role in infant nutrition as this is a period of rapid growth.
  - Determined that a minimum L-histidine level of 10 mg/100 kJ is adequate to support the growth of formula-fed infants compared to breastfed infants.

  Attachment C provides further details of our assessment of the Application in relation to the Policy Guideline, specifically the specific policy principles for composition.

[1] Now known as the COAG Legislative and Governance Forum on Food Regulation

3.2.3 Proposed regulatory approach

FSANZ supports the proposed request to reduce the existing minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ. The lower level of 10 mg/100 kJ corresponds to the average L-histidine content of breast milk, which policy guidance recommends is used as the primary reference for the composition of infant formula products. FSANZ's assessment has determined that a minimum L-histidine level of 10 mg/100 kJ is safe and adequate to support normal growth in formula-fed infants. In addition, a reduction in the minimum level promotes consistency with international and overseas food standards, and overall, is expected to provide a net benefit to the community.

3.3 Risk communication

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and *Food Standards News*. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

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

The Applicant and individuals and organisations that make submissions on this Application, will be notified at each stage of the assessment.

Documents relating to A1074 are available on the FSANZ website at:
http://www.foodstandards.govt.nz/foodstandards/applications/applicationa1074mini5583.cfm

The draft variations will be considered for approval by the FSANZ Board, taking into account any public comments received.

If the draft variations to the Code are approved by the FSANZ Board, that decision will be notified to COAG Legislative and Governance Forum on Food Regulation (the Forum). If the decision is not subject to a request for a review by the Forum, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.3.1 World Trade Organization (WTO)

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

There are relevant international standards and amending the Code to reduce the minimum level of L-histidine in infant formula products is unlikely to have a significant effect on international trade as this amendment would promote harmonisation between domestic and international regulations. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variations

The draft variations to Standard 2.9.1 are at Attachment A and the draft Explanatory Statement at Attachment B.

5. References

Codex (2011) Standard for infant formula and formulas for special medical purposes intended for infants. Codex Alimentarius STAN 72-1981 (revision 2007; amended 2011). Codex Alimentarius Commission, Rome.

European Commission (2006) Infant formula and follow-on formulae and amending Directive 1999/21/EC. European Commission Directive 2006/141/EC. European Commission, Brussels.

European Commission Scientific Committee on Food (2003) report on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae. European Commission Health and Consumer Protection Directorate-General, European Commissions, Brussels.

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Attachments

A. Draft variations to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement
C. Assessment of the Application in relation to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*

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

Food Standards (Application A 1074 – Minimum L-histidine in Infant Formula Products) 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 *(Application A 1074 – Minimum L-histidine in Infant Formula Products) 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

These variations commence on the date of gazettal.

SCHEDULE

[1] **Standard 2.9.1** is varied by

[1.1] omitting from the Table to clause 22 “12 mg” and substituting “10 mg”

[1.2] omitting from the Table to clause 32 “12 mg” and substituting “10 mg”

Attachment B – Draft Explanatory Statement

1. Authority

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

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1074 which seeks to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 2.9.1 – Infant Formula Products.

2. Purpose and operation

There is an existing requirement in Standard 2.9.1 for L-histidine to be present in infant formula products, specifically infant formula, follow-on formula and infant formula products for special dietary use, at a minimum level of 12 mg/100 kJ of product.

The draft variations are intended to require the presence of L-histidine in infant formula products at a reduced minimum level of 10 mg/100 kJ; a level that is safe and supports adequate growth in formula-fed infants. A minimum requirement for L-histidine of 10 mg/100 kJ promotes consistency between domestic and international regulations and supports global trade of infant formula products with an overall net benefit to the community.

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 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1074 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (which includes the draft variation) will be released for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 2.9.1 are likely to have minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variations

Item [1.1]

Item [1.1] replaces the existing minimum requirement for L-histidine in infant formula products of 12 mg/100 kJ, as it appears in the Table to clause 22, with a reduced level of 10 mg/100 kJ in the same Table. The minimum requirement will continue to apply to infant formula products currently regulated under Division 2 of Standard 2.9.1, specifically infant formula and follow-on formula.

Item [1.2]

Item [1.2] replaces the existing minimum requirement for L-histidine in infant formula products for special dietary uses of 12 mg/100 kJ, as it appears in the Table to clause 32, with a reduced level of 10 mg/100 kJ in the same Table. The amended requirement will continue to apply to infant formula products for special dietary use, as currently regulated under Division 3 of Standard 2.9.1.

Attachment C – Assessment of the Application in relation to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products*

FSANZ has had regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline) in our assessment of this Application. The Policy Guideline includes specific policy principles relating to composition, labelling and advertising, as well as overarching principles. The table below summarises our assessment in relation to these specific policy principles, with particular focus on the principles for composition.

Specific Policy Principles	**Approach**	**Does the assessment meet the Policy Principles?**
Overarching		
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	Not applicable to this Application. FSANZ acknowledges in this report that breastfeeding is the recommended way to feed an infant.	Not applicable
(b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.	Not applicable to this Application. The proposed change to the minimum requirement for L-histidine is not inconsistent with current national nutrition polices and guidelines for infant feeding. There is no deviation proposed from the current nutrient reference value for infants for protein; the minimum total protein content is unchanged.	Not applicable
(c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.	A comparative nutritional safety assessment approach was taken for the assessment of this Application.	Yes
Composition		
(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as	Toxicological data has not been considered in the assessment of this Application. A minimum level of L-histidine is already	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.	required in infant formula products and the Applicant's request is to reduce this level. L-histidine is an essential amino acid and is required (along with other essential amino acids) in infant formula products for protein quality purposes. The assessment has determined that a minimum L-histidine level of 10 mg/100 kJ is adequate to support the growth of formula-fed infants compared to breastfed infants. Also, that the plasma levels of L-histidine in breastfed infants and those fed infant formula products with a lower amount of L-histidine are physiologically equivalent.	
(e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.	See comments for specific policy principle (d).	Yes
(f) The essential composition of infant formula and follow on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	L-histidine is an essential amino acid and a minimum level of L-histidine is already mandated in Standard 2.9.1 to provide for the nutritional requirements of formula-fed infants. It is proposed that this existing requirement is amended.	Yes
(g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.	The safety of L-histidine and its role in infant nutrition is internationally recognised, and there is an existing mandatory requirement for a minimum level to be present in infant formula products.	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
(h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula.	The average L-histidine content of breast milk was used as the primary reference to determine the appropriate amount that should be required in infant formula products. The Comparative Nutritional Safety Assessment found that the level of L-histidine in breast milk is variable with an *average* level of 10 mg/100 kJ; the same as the proposed *minimum* required level.	Yes
(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.	Not applicable to this Application as L-histidine is not a new substance to be regulated.	Not applicable
(j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.	Not applicable to this Application as L-histidine is not a new substance to be regulated.	Not applicable

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
Labelling and advertising		
(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand.	Not applicable to this Application. Amendments to current labelling requirements for L-histidine in infant formula products are not proposed as part of this Application. No issues were identified in relation to the potential for misleading or deceptive conduct with the proposed reduction in minimum requirement for L-histidine in infant formula products.	Not applicable
(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better than, breast milk.		
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.		
(n) The Authority should: i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and ii. consider whether the current labelling regime is leading to consumers being mislead about the quality or effectiveness of an infant formula product.		