19 March 2013
[04-13]

Approval Report – Application A1074

Minimum L-histidine in Infant Formula Products

Food Standards Australia New Zealand (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.

On 8 November 2012, FSANZ sought submissions on a draft variation to Standard 2.9.1 – Infant Formula Products and published an associated report. FSANZ received eight submissions.

FSANZ approved the draft variation on 7 March 2013. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 18 March 2013.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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

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Supporting documents

The following documents used to prepare this Report are available on the FSANZ website at http://www.foodstandards.govt.nz/foodstandards/applications/applicationa1074mini5583.cfm

SD1 Comparative Nutritional Safety Assessment (Approval)
SD2 Assessment of the Application in relation to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (Approval)

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 sought 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 related to all infant formula products regulated in Standard 2.9.1 – Infant Formula Products, specifically infant formula, follow-on formula and infant formula products for special dietary use.

FSANZ's assessment of the Application 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 also assessed whether the request meets its objectives under section 18 of the *Food Standards Australia New Zealand Act 1991*, and gave 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 growth outcomes (anthropometric measures) and physiological 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 level is comparable to the 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 approved 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 was accepted on 7 June 2012 and commenced on 5 July 2012. The Application sought 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 related to all infant formula products, specifically infant formula, follow-on formula and infant formula products for special dietary use.

The Applicant stated 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 if the minimum level was reduced.

2.3 The current Standard

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products. 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 composition 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 of product.

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) standards 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)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

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

The draft variation is at Attachment A and the Explanatory Statement at Attachment B.

3. Summary of the findings

3.1 Comparative Nutritional Safety Assessment

A Comparative Nutritional Safety Assessment (CNSA) 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 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 infant formula products is appropriate and safe. A minimum level of 10 mg/100 kJ 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 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 the minimum L-histidine content to 10 mg/100 kJ is equivalent to a reduction in the protein content of less than 0.1 g protein/100 kJ. Note that the minimum amount of protein in infant formula products is also prescribed in Standard 2.9.1.

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 growth outcomes (anthropometric measures) and physiological measures (plasma amino acid concentration) of breastfed and formula-fed infants.

The full CNSA report is provided as Supporting Document 1 (SD1).

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.

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 Summary of submissions

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

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

Public submissions were invited on the draft variation to Standard 2.9.1, which was released for public comment between 8 November and 20 December 2012.

Eight submissions were received from jurisdictions, infant formula product manufacturers and industry representative groups; as listed below. All submitters supported the preparation of a variation 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. Submitters agreed there are no public health and safety concerns with the proposed variation and that the reduced level would promote consistency with international and overseas standards. FSANZ's response to specific issues raised in submissions is provided in Table 1.

The eight submitters to the consultation were:

- Australian Food and Grocery Council
- H.J. Heinz Company Australia Limited and Heinz Wattie's Limited (Heinz)
- Infant Nutrition Council
- Ministry for Primary Industries, New Zealand (MPI)
- New Zealand Food & Grocery Council
- Nutricia Australia Pty Ltd
- Pfizer Australia Pty Limited
- Victorian Departments of Health and Primary Industries

Table 1: Specific issues raised in submissions

Issue	Raised by	FSANZ response
Justification for selected studies to derive the average content of L-histidine in breast milk	MPI	The CNSA is FSANZ's independent analysis of scientific studies that have measured L-histidine concentration in breast milk. The 10 selected studies for the CNSA were chosen based on comparable analytical technique, sampling protocols, protein determinations and availability of the study in the peer reviewed scientific literature (see section 3.3 of SD1). In applying these criteria, there is considerable overlap with the previous reports. Only two additional studies were included in the CNSA; noting that Harzer et al. (1986) and Yamawaki et al. (2005) are English publications of studies considered in previous reports. Additional discussion on this issue has been incorporated into SD1. The approach for selecting relevant studies was similar to that used for previous reports published by international scientific advisory groups, although it is noted that there is little consistency in the studies selected between the reports (as shown in Table 2 of SD1).
Variation in the L-histidine concentrations found in breast milk	MPI	Further explanation about the variation in the reported values for L-histidine content in breast milk was requested, particularly in relation to the study by Harzer et al. (1986). The study by Harzer et al. (1986) reported amino acid concentrations of breast milk for three time points – Day 2, Day 8 and Day 36. Only the last time point is considered mature breast milk and although the reported concentration of L-histidine at 40 mg/g protein (as shown in Table 3 of SD1) appears to be an outlier, the paper met the study selection criteria for the CNSA and was therefore included. However, if Harzer et al. (1986) and those studies published prior to 1985 are excluded from the analysis, there is only a minor change in the average L-histidine concentration in breast milk; as discussed in section 3.3 of SD1. An additional figure showing the mean and range of values of L-histidine concentration in breast milk as determined by analysis of the 10 selected studies was suggested – this information is already presented as 'FSANZ 2012' in Figure 1 of SD1.

Issue	Raised by	FSANZ response
Calculation of change in protein content if L-histidine content is reduced	MPI	The proposed reduction in L-histidine from 12 mg/100 kJ to 10 mg/100 kJ represents a reduction in the crude protein content of less than 0.1 g protein/100 kJ. The calculation to support this statement has been included in section 3.4 of SD1).
New paper on composition requirements of follow-up formula	MPI and Heinz	A paper titled 'Compositional requirements for follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early nutrition Academy' authored by Koletzko et al. (2012) was published following the release of the assessment report for this Application. The paper is a review article that includes recommendations for minimum amino acid levels for follow-up formula. The paper did not contain new experimental data and minimum amino acid levels cited are based on the approach described by Koletzko et al. in 2005 (as cited in SD1). The paper recommends 2.3 g histidine/100 g protein as the minimum content for follow-up formula which is consistent with the average value calculated from the 10 selected studies in Table 3 of SD1. A comment about the minimum L-histidine concentration in follow-up formula recommended by this paper has been added to section 3.4 of SD1

3.2.2 Public health, trade and other relevant issues

3.2.2.1 Protecting the health and safety of formula-fed infants

The protection of the health and safety of formula-fed infants is paramount. 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. 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 proposed as the new minimum requirement for L-histidine in infant formula products.

Although 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 of 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 was 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

The proposed *minimum* level for L-histidine in infant formula products of 10 mg/100 kJ has been shown in the CNSA 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 Consistency with ministerial policy guidance

FSANZ had regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* in its 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.

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- (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 levels of L-histidine in 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.

Supporting Document 2 (SD2) provides further details of our assessment of the Application in relation to the Policy Guideline, particularly the specific policy principles related to composition. SD2 is available at:
http://www.foodstandards.govt.nz/foodstandards/applications/applicationa1074mini5583.cfm

3.2.2.3 Efficiencies for trade of infant formula products

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.

It is advantageous for manufacturers to use the same formulation for products for the Australia/New Zealand market as 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, as the majority of these products is manufactured overseas and imported to Australia and New Zealand. 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 product manufactured in Europe 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.

3.2.2.4 Labelling provisions for amino acids

FSANZ considered that current labelling provisions for infant formula products are appropriate for a minimum required level of L-histidine of 10 mg/100 kJ.

The CNSA did not identify any new risks that could be managed through provision of additional information 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.

3.3 Risk communication

FSANZ applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the Food Standards News. Subscribers and interested parties were also notified 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 issues raised in the public submissions were evaluated and addressed in this Report.

The variation was approved by the FSANZ Board taking into account public comments received from the call for submissions.

The FSANZ Board decision has been notified to the Forum. If the decision is not subject to a request for a review, 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.

4. Reasons for decision

The variation to Standard 2.9.1, as proposed following assessment, was approved without change on the basis of the available evidence and for the following reasons:

- No public health or safety issues were identified; FSANZ's assessment determined that a minimum L-histidine level of 10 mg/100 kJ is safe and adequate to support normal growth in formula-fed infants.
- A *minimum* level of 10 mg/100 kJ corresponds to the *average* L-histidine content of breast milk. Ministerial policy guidance recommends that breast milk be used as the primary reference for the composition of infant formula products.
- The reduced minimum level promotes consistency with international and overseas food standards, and overall, provides a net benefit to the community.

4.1 Addressing section 29 of the FSANZ Act

FSANZ had regard to the following matters under 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
- any other relevant matters.

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 variation to the Code was considered minor and machinery in nature. However, FSANZ performed a summary cost benefit analysis. FSANZ concluded that:

- The cost benefit analysis identifies an overall net benefit to the community, with no additional cost for consumers, government or industry if the minimum requirement for L-histidine in infant formula products was reduced to 10 mg/100 kJ.
- There were no measures other than a variation to Standard 2.9.1 that would achieve the same end.
- Standard 2.9.1 applies to New Zealand and there are no other relevant New Zealand only standards that need to be considered.
- There are no other relevant matters than those considered in section 4.2.

4.2 Addressing FSANZ's objectives for standards-setting

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

4.2.1 Protection of public health and safety

The CNSA concluded that a minimum level of 10 mg/100 kJ of L-histidine in infant formula products is appropriate and safe. A minimum level of 10 mg/100 kJ is comparable to the average amount of L-histidine present in breast milk. In addition, there is published evidence that growth of formula-fed infants consuming a formula containing L-histidine at 10 mg/100 kJ is comparable with breastfed infants (see section 3.1).

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

FSANZ considered that current labelling provisions for infant formula products are appropriate for a minimum required level of L-histidine of 10 mg/100 kJ. The CNSA did not identify any new risks that could be managed through provision of additional information on the product label (see section 3.2.2.4).

4.2.3 The prevention of misleading or deceptive conduct

No issues were identified in relation to the potential for misleading or deceptive conduct with a reduction in the 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.

4.2.4 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*

  A comparative nutritional safety assessment using best available scientific evidence was undertaken as part of the assessment of this Application. 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 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 (see section 3.2.2.3).

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

  Trade is an important consideration for regulatory matters relating to infant formula products because 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. It also helps support the maintenance of supply of imported products, particularly infant formula products for special dietary use, given the smaller Australia and New Zealand market for these specialty products.

- *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[2].*

  The assessment of this Application fully aligns with the relevant principles in the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (see section 3.2.2.2).

4.3 Implementation

The variation to Standard 2.9.1 will commence on the date of gazettal.

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.

Koletzko B, Baker S, Cleghorn G, Neto UF, Gopalan S, Hernell O, Hock QS, Jirapinyo P, Lonnerdal B, Pencharz P, Pzyrembel H, Ramirez-Mayans J, Shamir R, Turck D, Yamashiro Y, Zong-Yi D (2005) Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. J Pediatr Gastroenterol Nutr 41(5):584-599.

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

Koletzko B, Bhutta ZA, Cai W, Cruchet S, El Guindi M, Fuchs GJ, Goddard EA, van Goudoever JB, Hock Quak S, Kulkarni B, Makrides M, Ribeiro H, Walker A (2012) Composition requirements of follow-on formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. Annals of Nutrition and Metabolism 62(1):44-54.

Life Sciences Research Office (1998) Assessment of nutrient requirements for infant formulas. J Nutr 128(11S):2059S-2294S.

WHO/FAO/UNU Expert Consultation (2007) Protein and amino acid requirements in human nutrition. WHO technical report series No 935. World Health Organization, Geneva.

Attachments

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

Attachment A – Approved variation 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 – 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.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation[3], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose

The Authority has approved a draft variation to Standard 2.9.1 to require the presence of L-histidine in infant formula products, specifically infant formula, follow-on formula and infant formula products for special dietary use, at a reduced minimum level of 10 mg/100 kJ.

A minimum requirement for L-histidine of 10 mg/100 kJ is safe and supports adequate growth in formula-fed infants. The reduced level also 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 included one round of public consultation following an assessment and the preparation of a draft variation to Standard 2.9.1 and an associated report. Submissions were called for on 8 November 2012 for a six-week consultation period.

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

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

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

6.1 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.

6.2 Item [1.2]

Item [1.2] replaces the existing minimum requirement for L-histidine in infant formula products for special dietary use 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.