16 May 2019
[80–19]

Call for submissions – Application A1173

Minimum protein in follow-on formula

FSANZ has assessed an application made by Nestlé Australia Ltd and Nestlé New Zealand Limited to lower the protein minimum in follow on formula 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 that we accept as confidential, 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 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) 13 June 2019

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 are available on the FSANZ website:

SD1 Nutritional safety assessment
SD2 Regard to the Ministerial Policy Guideline

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Nestlé Australia Limited and Nestlé New Zealand Limited in January 2019. The application seeks to reduce the minimum protein requirement for follow-on formula from 0.45 g/100 kJ to 0.38 g/100 kJ in the Australia New Zealand Food Standards Code (the Code). The request relates to all follow-on formula products regulated by Standard 2.9.1 – Infant Formula Products.

FSANZ's assessment reviewed the best available scientific evidence to determine whether the proposed reduced protein minimum 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 in so doing has given regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products.*

The nutritional safety assessment reviewed protein levels in human milk from 5 to 12 months post-partum and considered impact on infant growth of consuming formula with a lower protein content. The assessment also investigated the impact of a lower protein follow-on formula on the dietary protein intakes of infants consuming such a follow-on formula and complementary foods.

The assessment concluded that the requested minimum protein requirement (0.38 g/100 kJ) is appropriate and safe. This requirement falls within the range of human milk protein content established by FSANZ's assessment. Also, from published studies, the growth rates of infants fed a lower protein formula reported no adverse effects. The dietary intake assessment indicates that protein intakes of Australian and New Zealand infants would remain adequate if the minimum protein requirement for follow-on formula was lowered to 0.38 g/100 kJ.

Reducing the minimum protein requirement in follow-on formula is consistent with requirements in the relevant European Commission standards. A reduction in the minimum protein requirement is expected to benefit trade, support business competitiveness and innovation.

Based on our assessment, FSANZ considers it is appropriate to reduce the minimum protein requirement in follow-on formula products from 0.45 g/100 kJ to 0.38 g/100 kJ, as requested by the applicant. FSANZ has prepared a draft variation to amend paragraph 2.9.1–9(2)(b) to reduce the minimum protein requirement for milk-based follow-on formula to no less than 0.38 g/100 kJ. However, as there is no evidence to support the safety and suitability of a lower minimum protein requirement in soy-based follow-on formula, the current minimum requirement of no less than 0.45 g/100 kJ is retained.

1 Introduction

1.1 The applicant

The applicants are 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.

1.2 The application

Application A1173 – Minimum protein in follow-on formula was received on 3 January 2019. The application seeks to amend the Australia New Zealand Food Standards Code (the Code) to reduce the minimum protein requirement in follow-on formula products from 0.45 g/100kJ to 0.38 g/100kJ. Follow-on formula is suitable for infants aged 6 to less than 12 months, and as such, is intended to be consumed with complementary food and not as a sole source of nutrition.

The applicant states that a reduction in the minimum protein requirement (while meeting protein quality requirements) is safe and will promote normal growth and development in infants. In addition, it will reportedly promote consistency between the Code and the European Regulations.

The application does not seek to amend any other protein specifications in the Code.

1.3 The current standards

1.3.1 Australia and New Zealand

1.3.1.1 Definitions

Standard 1.1.2 in the Code defines

Follow-on formula as an infant formula product that:

> *(a) is represented as either a breast-milk substitute or replacement for infant formula; and*
> *(b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.*

and

Soy-based formula as an infant formula product in which soy protein isolate is the sole source of protein.

1.3.1.2 Protein content, calculation and quality

Follow-on formula products are currently regulated by Standard 2.9.1 – Infant Formula Products[1] and Schedule 29–Special purpose foods[2]. There are several inter-related requirements for protein: content, calculation and quality.

[1] http://www.comlaw.gov.au/Series/F2015L00409
[2] http://www.comlaw.gov.au/Series/F2015L00463

Currently all follow-on formula must have protein content between 0.45 g/100 kJ and 1.3 g/100 kJ (paragraph 2.9.1—9(2)); protein quality is regulated by mandating minimum amounts of 11 essential and semi-essential amino acids as listed in the table to section S29—6 (paragraph 2.9.1—10(2)).

Section S29—3 prescribes the equation and two nitrogen conversion factors for calculating the protein content of infant formula products depending on the protein source. For milk proteins and their partial hydrolysates, a conversion factor of 6.38 is prescribed whereas a factor of 6.25 is prescribed for all other protein sources.

1.3.1.3 Proposal P1028 – Infant formula

FSANZ is currently reviewing the regulation of infant formula under Proposal P1028 – Infant Formula[3]. The purpose of this proposal is to revise and clarify standards relating to infant formula and infant formula products for special dietary use. This proposal is considering the issues related to category definitions, composition, labelling and representation of products.

The composition of follow-on formula is outside the scope of the proposal. However some of the consideration of regulation of protein in infant formula is relevant to this application and is further discussed in section 2.3 below.

1.3.2 Relevant international regulations

1.3.2.1 Codex standards

The current Codex Alimentarius Standard for Follow-up Formula (Codex Standard 156-1987[4]), applies to infants and young children aged from the 6th month (5 months) to 36 months. This standard is currently under revision by the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)[5]. Codex defines follow-up formula as:

> *a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.*

The current *Codex Standard 156-1987* specifies a minimum protein content of 0.7 g/100 kJ (3.0 g/100 kcal) and total protein no more than 1.3 g/100 kJ (5.5 g/100 kcal). Protein quality is related to casein composition rather than through application of a nitrogen conversion factor as indicated below.

> *…of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality of the protein shall not be less than 85% of that of casein*.

A footnote also states:

> *Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.*

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3 http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx
4 http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BSTAN%2B156-1987%252FCXS_156e.pdf
5 For further information, search on the Codex Alimentarius website (accessed 25 October 2018). http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BSTAN%2B156-1987%252FCXS_156e.pdf

The draft revised Codex standard for follow-up formula has taken a different approach for essential composition and quality factors (CCNFSDU, 2017). The draft revised standard specifies a protein minimum level of 0.43 g/100 kJ and a maximum of 0.72 g/100 kJ for formula based on cows' and goats' milk. A footnote also notes that a lower minimum level between 0.38 and 0.43 g/100 kJ in formula based on non-hydrolysed milk protein can be accepted, noting that the lower minimum should be *evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence*.

1.3.2.2 European Union

EU legislation is currently in transition from old to new regulation. Table 1 summarises the relevant regulations.

Table 1: EU laws for follow-on formula

Legislation/Regulation	Description	Note/Comment
CURRENT		
Regulation (EU) No 609/2013 on food intended for infants and young children, FSMP, and total diet replacement for weight control	The overarching Regulation	Repeals Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009)
Commission Directive 2006/141/EC on infant formulae and follow-on formulae.	Establishes detailed and complete compositional and labelling rules for products intended to infants from birth up to 12 months of age.	Rules remain applicable until 22 February 2020
INCOMING		
Commission Delegated Regulation (EU) 2016/127	Outlines the specific compositional and information requirements for infant formula and follow-on formula and requirements on information relating to infant and young child feeding. This supplements EC Regulation No 609/2013.	Adopted 25 September 2015 to apply on 22 February 2020

EU Regulation No 609/2013 includes the following definition of follow-on formula:

> *'Follow-on formula' means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants*

There are some differences between the current and incoming regulations as summarised in Table 2 below.

Table 2: Protein requirements in the European regulations

	Commission Directive 2006/141/EC on infant formulae and follow-on formulae		Commission Regulation 2016/127	
	Min	**Max**	**Min**	**Max**
FoF manufactured from cows milk proteins	0.45g/100kJ	0.8g/100kJ	0.43 g/100kJ	0.6g/100kJ
FoF manufactured from soy protein isolates (alone or in combination with cow's milk protein)	0.56 g/100kJ	0.8 g/100kJ	0.54 g/100kJ	0.67 g/100 kJ

Abbreviation:
FoF = Follow-on formula
Min = minimum protein level
Max = maximum protein content

Both regulations specify that protein content shall be determined using the nitrogen conversion factor of 6.25. All follow-on formula are required to contain an available quantity of 11 amino acids (based on the reference protein for human milk).

1.4 Reasons for accepting 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.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

A nutritional safety assessment was undertaken for this application and is found at Supporting Document 1 (SD 1). The assessment examined the average protein levels in human milk from 5 to 12 months post-partum reported in the scientific literature. The Code does not specify a method to establish human milk protein concentrations, but prescribes the protein content in infant formula products to be determined from nitrogen-based methods. Therefore, to facilitate comparisons between protein levels in human milk and follow-on formula, the range of crude[6] and true[7] protein concentrations were determined for this assessment.

[6] **Crude protein** is based on all nitrogen-containing substances in human milk and calculated from the total nitrogen content of a food multiplied by a conversion factor

[7] **True protein** is based on the all nitrogen-containing substances minus NPN multiplied by an appropriate conversion factor (e.g. 6.38 for milk proteins). Therefore, the calculation excludes nitrogen that may be metabolically available, e.g. amino acids, small peptides, urea, amino sugars, nucleotides, carnitine, and choline.

The assessment concluded that the requested minimum protein requirement in follow-on formula is comparable to the mean protein level in human milk from 5 to 12 months post-partum based on calculated crude protein values in selected studies ranging from 0.34 g/100 kJ to 0.40 g/100 kJ. It is assumed that protein levels in human milk are adequate for normal growth for older infants, in addition to protein intakes from complementary foods.

The potential effect of lowering the minimum protein requirement from 0.45 g/100 kJ to 0.38 g/100 kJ on infant growth was assessed. Two randomised controlled trials were examined, which compared weight gain from 3 to 12 months of age, in infants fed a lower protein formula (0.39 g crude protein/100 kJ) compared with higher protein formula (study 1: 0.65 g/100 kJ; study 2: 0.51 g/100 kJ), and with breastfed infants. Both studies indicated slower weight gain between 3 and 12 months for infants fed the lower protein formula compared with the higher protein group. However, the differences only reached statistical significance between 3 and 6 months in study 1. Compared with breastfed infants, study 2 reported higher weight gain in infants fed either formula, whereas study 1 reported greater weight gain in the higher protein group and no difference in the lower protein group.

The dietary intake assessment found no risk of inadequate protein intake for Australian or New Zealand infants consuming a lower protein formula and complementary foods. Therefore, protein intakes of Australian and New Zealand infants would remain adequate if the minimum protein requirement for follow-on formula was lowered to 0.38 g/100 kJ.

On the basis of assessed growth rate and dietary protein intake, the requested minimum protein requirement in follow-on formula reduced from 0.45 g/100 kJ to 0.38 g/100 kJ is appropriate and safe. Published research studies have shown the crude protein value of 0.38 g/100 kJ falls within the mean levels found in human milk from 5 to 12 months post-partum. In addition, randomised, controlled trials reported no adverse effects on growth in infants consuming the lower protein formula from 3 months to 12 months of age. Finally, the dietary intake assessment indicates that protein intakes of Australian and New Zealand infants would remain adequate if the minimum protein level for follow-on formula was lowered to 0.38 g/100 kJ

2.2 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants who are not breastfed. As infants are a vulnerable population group, follow-on formula is regulated by prescriptive provisions for the composition of these products. Any changes to the composition must be established as safe prior to being permitted.

FSANZ also had regard to the matters covered in the Ministerial policy guideline on the regulation of infant formula products (ANZFRMC 2011) (see SD2). The policy guideline refers to the need for follow-on formula to be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development of healthy full term breastfed infants at the appropriate age, taking into account the levels in human milk.

2.2.1 Minimum protein requirement

FSANZ has considered the requested minimum protein requirement in the context of the nutritional safety assessment which concluded no risk to infants if minimum protein requirement of follow-on formula is lowered to 0.38 g/100kJ, based on comparison of protein content (both crude and true protein) in human milk, growth studies using milk-based follow-on formula and dietary intake estimates.

2.2.1.1 Soy-based follow-on formula

The applicant sought to amend the minimum protein for *all* follow-on formula. As discussed in section 1.3.1.2, the Code defines soy-based formula and specifies the use of nitrogen-to-protein conversion factors to determine protein content. Currently a factor of 6.25 is specified for all protein other than milk proteins and their partial protein hydrolysates. As noted in SD1, soy protein has different digestibility and amino acid availability compared to dairy protein sources. Because of this soy-based follow-on formula has higher minimum protein requirements in the European regulation and in the draft revised Codex follow-up formula standard.

The nutritional safety assessment found no evidence assessing the suitability of a lower protein minimum for soy-based formula. Thus the conclusion of the nutritional safety assessment (SD1) is relevant only to milk-based follow-on formula. Taking into consideration the potential difference between milk protein and soy protein and consistency with international approaches, FSANZ proposes to retain the current minimum protein requirement of 0.45 g/100 kJ for soy-based follow-on formula. Thus the minimum requirement will be reduced only for milk-based[8] follow-on formula.

FSANZ considers the nitrogen conversion factor requirements for follow-on formula are out of scope of this application. However, *Proposal P1028 – Review of the Regulation of infant formula*[9] has considered the appropriate nitrogen conversion factor for infant formula products. Based on scientific evidence, it is proposed to introduce the nitrogen conversion factor of 5.71 for soy-based products (FSANZ 2016). This scientific conclusion is re-iterated in the nutritional safety assessment of this application (section 2.3 of SD1). However there is no international regulatory consistency in the use of the nitrogen conversion factor for soy protein. In 2017, CCNFSDU sought scientific advice from the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU) on the appropriate nitrogen to protein conversion factor for use when determining the protein content of milk-based and soy-based ingredients (CCNFSDU 2017). This work is currently in progress.

2.2.2 Labelling requirements

No changes to labelling requirements for follow-on formula have been proposed. Existing requirements for declaring nutrition information on follow-on formula will apply.

2.2.2.1 Mandatory nutrition information

Nutrition information, including the protein content, must be declared on the label of packaged follow-on formula. Paragraph 2.9.1—21(1)(a)(ii) requires the average amount of protein expressed in g/100 mL to be declared. A change to the average amount of protein present in the follow-on formula product (as a result of a lower minimum compositional limit) would be reflected in the nutrition information statement.

Consumers can use the nutrition information statement to compare different follow-on formula products and make an informed choice. Average protein content already varies between different follow-on formulas, and consumers expect the products to be formulated to meet the nutritional requirements of infants, and are used to seeing different values on the label. In accordance with the warning statement required by paragraph 2.9.1—19(1)(d), consumers are instructed to consult their doctor or health worker for advice about using a follow-on formula. Consumers can also seek more information from manufacturers, as follow-on formula products must include the name and address of the supplier and most manufacturers provide Careline contact information on the label.

[8] Milk-based formula is not a defined term in the Code but is already used in Standard 2.9.1
[9] http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

2.2.2.2 Voluntary representations

The applicant stated the compositional change is intended to align follow-on formula more closely with total protein levels in breast milk at the same age stage, and therefore more closely match the growth outcomes of infants fed follow-on formula with that of breastfed infants. However, the applicant has not proposed a change to the existing prohibition on nutrition and health claims.

Paragraph 1.2.7—4(b) states that a nutrition content claim or health claim must not be made about an infant formula product. The prohibition for claims is also set out in section 2.9.1—24 (1)(f), which prohibits a reference to the presence of a nutrient or substance that may be used as a nutritive substance, except for a statement relating to lactose, a statement of ingredients or a declaration of nutrition information.

2.2.3 Risk management conclusion

Following consideration of the objectives of the FSANZ Act (see section 2.4) and relevant Ministerial policy guidelines (see SD2), FSANZ's preferred approach is to lower the minimum protein requirement for milk-based follow-on formula but not for soy-based formula.

Soy-based formula is defined in the Code and is shown with an asterisk in the draft variation whereas *milk-based formula* is used in Standard 2.9.1 but is not a defined term. The draft variation at Attachment A maintains this approach.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ has developed a communication strategy for this application. Subscribers and interested parties have been notified about this call for submissions via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to consider this application. All comments are valued and contribute to the rigour of our assessment. Comments received will be taken into account when deciding whether to develop draft variation(s) at the next stage of assessment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 lower the minimum protein requirement to 0.38 g/100 kJ for milk-based follow-on formula is unlikely to have a significant adverse effect on international trade as the lower range will align with recent decisions in the European Union and the draft revised Codex standard. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The OBPR exempted FSANZ from the need to undertake a formal Regulation Impact Statement in relation to the regulatory change proposed in response to this application (OBPR reference number: 25142). This was due to OPBR being satisfied that this appears likely to have only a minor economic impact and would not substantially alter existing arrangements.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. Section 29(2)(a) of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure.

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers the option to reduce the minimum protein requirement in follow-on formula from 0.45g/100 kJ to 0.38g/100 kJ. FSANZ's preliminary view is that that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo to the option described above.

Industry and business in general
Because the maximum protein requirement for follow-on formula is not changing, producers and importers would have a wider range of protein levels across different products. This may provide some flexibility and efficiency gains for businesses, particularly for those already producing lower protein follow-on formula in the European Union. Any change to the formulation of products would be voluntary and the change can be appropriately characterised as deregulatory in nature.

Consumers
There are no anticipated costs to consumers from the proposed change. Current scientific evidence suggests there are no health or safety risks from the lower minimum protein requirement. If there are any cost-efficiency gains to businesses from the extra flexibility of wider protein ranges, some of this may be passed on to consumers as lower prices. Consumers may also have a greater choice of protein content in follow-on formula.

Government
Minimal additional costs will be incurred by government.

International Trade
The proposed change would ensure greater regulatory consistency with trading partners. Trade impacts are uncertain, and this food regulatory measure may allow a greater range of imports of follow-on formula.

In summary, FSANZ's preliminary view that the direct and indirect benefits that would arise from a food regulatory measure, developed or varied as a result of the application, outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

The standard being amended applies in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has completed a risk and technical assessment (SD1) which is summarised in section 2.1. The assessment concluded that there are no public health and safety concerns associated with the lower protein minimum requirement for follow-on formula.

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

Existing requirements for the declaration of nutrition information described in section 2.2.2 ensure consumers have information about the protein content of follow-on formula.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues have been identified.

2.4.3 Subsection 18(2)

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to assess this application. The applicant submitted a dossier of scientific studies as part of its application. Other relevant information including scientific literature was also used in assessing the application.

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

The incoming EU Regulations and draft Codex follow-up formula standard allow milk-based formula to have a lower protein minimum consistent with FSANZ's proposed amendment. Permitting the lower minimum requirement will promote consistency of food regulations between Australia and New Zealand and international standards.

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

The proposed amendment would support an internationally competitive food industry for follow-on formula products.

- **the promotion of fair trading in food**

No negative impact is anticipated on fair trading.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial policy guideline on the regulation of infant formula products applies to this application. FSANZ considers that this policy guideline has been met. Our assessment against these policy guidelines is provided at SD2.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

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

4 References

ANZFRMC (2011) Policy Guideline on the Regulation of Infant Formula Products. Australia New Zealand Food Regulation Ministerial Council http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines

Codex (1987) Standard for follow-up formula. Codex Alimentarius CXS 156-1987. Codex Alimentarius Commission, Rome http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BSTAN%2B156-1987%252FCXS_156e.pdf

Codex Committee On Nutrition And Foods For Special Dietary Uses (CCNFSDU) (2018) Report of the Thirty ninth Session of the Codex Committee On Nutrition And Foods For Special Dietary Uses (REP19/NFSDU). Codex Alimentarius Commission, Rome. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-720-40%252FREPORT%252FREP19_NFSDUe.pdf

FSANZ (2016) Consultation paper: Supporting document 1 – Comparative nutritional safety assessment. Proposal P1028 – Review of the regulation of infant formula. Food Standards Australia New Zealand, Canberra http://www.foodstandards.gov.au/code/proposals/Documents/P1028-Consult-SD1.pdf

Inostroza, J.; Haschke, F.; Steenhout, P.; Grathwohl, D.; Nelson, S. E.; Ziegler, EE. (2014): Low-protein formula slows weight gain in infants of overweight mothers. In *Journal of Pediatric Gastroenterology and Nutrition* 59 (1), pp. 70–77. DOI: 10.1097/MPG.0000000000000349.

Ziegler, Ekhard E.; Fields, David A.; Chernausek, Steven D.; Steenhout, Philippe; Grathwohl, Dominik; Jeter, Janice M. et al. (2015): Adequacy of Infant Formula With Protein Content of 1.6 g/100 kcal for Infants Between 3 and 12 Months. In *Journal of Pediatric Gastroenterology and Nutrition* 61 (5), pp. 596–603. DOI: 10.1097/MPG.0000000000000881.

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

Food Standards (Application A1173 – Minimum protein in follow-on formula) Variation

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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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert delegate's details]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1173 – Minimum protein in follow-on formula) Variation.*

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 2.9.1 is varied by omitting paragraph 2.9.1—9(2)(b), substituting

(b) the following protein content:

(i) for a milk-based formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; and

(ii) for a *soy-based formula—a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;

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 A1173 which seeks to lower the minimum protein requirement in all follow-on formula. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose

The Authority has prepared a draft amendment to paragraph 2.9.1—9(2)(b) in Standard 2.9.1 to permit a lower protein minimum in milk-based follow-on formula and retain the current minimum for soy-based formula.

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 A1173 will include one round of public consultation (4 weeks) following an assessment and the preparation of a draft variation Standard and associated assessment summary.

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

5. Statement of compatibility with human rights

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

6. Variation

Item [1] varies paragraph 2.9.1—9(2)(b) of Standard 2.9.1 by omitting the existing paragraph and substituting a new paragraph. The new paragraph will require: milk-based follow-on formula to have a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; and soy-based formula to have a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ.