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Approval report – Application A1173

Minimum protein in follow-on formula

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Nestlé Nutrition Oceania, prepared by Intertek Scientific & Regulatory Consultancy to vary the minimum protein requirement in follow-on formula.

On Thursday 16 May 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received ten (10) submissions.

FSANZ approved the draft variation on 11 September 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 25 September 2019.

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

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Supporting documents

The [following documents](#) which informed the assessment of this Application are available on the FSANZ website:

- SD1 Nutritional safety assessment report
- 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 (Nestlé Oceania) Limited in January 2019. The application sought to reduce the minimum protein requirement for all types of follow-on formula subject to paragraph 2.9.1—9(2)(b) of the Australia New Zealand Food Standards Code (the Code) from 0.45 g/100 kJ to 0.38 g/100 kJ. The application did not seek to amend any other protein specifications in Standard 2.9.1 – Infant Formula Products including paragraph 2.9.1—15(2)(b) relating to infant formula products for special dietary use.

FSANZ reviewed the best available scientific evidence to determine whether the proposed reduced protein minimum would protect the health and safety of older formula-fed infants from 6 months of age. The Nutritional Safety Assessment (SD1) reviewed protein levels in human milk from 5 to 12 months post-partum and considered impacts on older infant growth of consuming formula with a lower protein content together with complementary foods. The proposed reduced minimum was found to be within the range of protein content of mature human milk and as such, protein intakes of Australian and New Zealand older infants would remain adequate. In addition, published studies reported no adverse effects on growth rates of older infants fed a lower protein follow-on formula.

FSANZ understands that follow-on formulas currently on the market use the following protein sources: milk, soy, and hydrolysed protein. FSANZ assessed the risk of applying the protein reduction to soy-based follow-on formulas, and concluded there was insufficient evidence to reduce the protein minimum in soy-based formulas. FSANZ therefore concluded that reducing the minimum protein from 0.45 g/100 kJ to 0.38 g/100 kJ is appropriate and safe for milk-based follow-on formulas only. This is consistent with requirements in the European Union (EU) and is expected to benefit Australian and New Zealand trade, and support business competitiveness and innovation.

FSANZ also assessed whether its assessment met the objectives under Section 18 of the *Food Standards Australia New Zealand Act 1991*, including having regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (SD2).

FSANZ has prepared a draft variation (Attachment A) 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 and to retain the existing requirement of no less than 0.45 g/100 kJ for all other follow-on formulas that comply with that paragraph. The protein requirements for follow-on formula for special dietary use based on a protein substitute regulated by paragraph 2.9.1—15(2)(b) are also retained.

1 Introduction

1.1 The Applicant

The applicants are Nestlé Australia Limited and Nestlé New Zealand Limited (Nestlé Nutrition Oceania). 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 including paediatric speciality formulas for infants with specific nutritional needs.

1.2 The Application

Application A1173 – Minimum protein in follow-on formula was received on 3 January 2019. The application sought to amend the Code to reduce the minimum protein requirement in all follow-on formula products subject to paragraph 2.9.1—9(2)(b) of the Code from 0.45 g/100 kJ to 0.38 g/100 kJ for the following reasons:

- to harmonise Australia and New Zealand standards for follow-on formula with those proposed internationally
- to more closely align protein levels in follow-on formula with those found in human milk for older infants
- to achieve growth rates (measured by infants' length, weight, and head circumference) of formula-fed older infants that are more comparable to those of breastfed infants.

Infants are physiologically and developmentally ready for complementary foods from around 6 months of age (NHMRC, 2012). Parents are advised to introduce complementary foods (including protein foods) to infants from around 6 months of age. Follow-on formula is designed for older infants from 6 months to less than 12 months of age and is not intended as a sole source of nutrition. The application does not seek to amend any other protein specifications in the Code for infant formula products.

1.3 The current Standards

1.3.1 Australia and New Zealand

1.3.1.1 Definitions

Standard 1.1.2 – Definitions, defines the following terms:

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.*

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 and Schedule 29 – Special purpose foods. There are several inter-related requirements for protein set out in the Code: content, calculation, and quality.

Currently all follow-on formula products – with the exception of follow-on formula for special dietary use based on a protein substitute – must have a protein content between 0.45 g/100 kJ and 1.3 g/100 kJ (paragraph 2.9.1—9(2)(b)). Protein quality for all follow-on formula is regulated by the minimum presence of L-amino acids listed in the table to section S29—6 (subsections 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](#)¹. 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, the proposal's 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 156–1987²), 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)³. 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 Codex Standard specifies a protein content between 0.7 g/100 kJ and no more than 1.3 g/100 kJ. However, protein quality is related to casein composition instead of using 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.

The draft revised Codex standard for follow-up formula has revised the approach for essential composition and quality factors (CCNFSDU, 2018) by specifying a protein minimum 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 indicates that a lower minimum level 0.38 g/100 kJ in formula based on non-

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

² For further information, search for CXS 156-1987 on the Codex Alimentarius 'standards' page: <http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/>

³ For further information, search on the [Codex Alimentarius website](#) (accessed 20 July 2019). <http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCNFSDU>

hydrolysed milk protein can be accepted, noting that such formula 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

The relevant regulations are shown in Table 1 noting that EU legislation is currently in transition.

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, foods for special medical purposes, 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 for 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.

Table 2 details the differences between the current and incoming European regulations.

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
Follow-on formula manufactured from cows' milk proteins	0.45 g/100kJ	0.8 g/100kJ	0.43 g/100kJ	0.6 g/100kJ
Follow-on formula 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

Min = minimum protein level; Max = maximum protein level

Both regulations specify that protein content shall be determined using the nitrogen conversion factor of 6.25. All follow-on formulas are required to contain an available quantity of key L-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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments. The variation takes effect on gazettal. The approved draft variation, as varied after consideration of submissions, is at Attachment A.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

FSANZ sought public comments on the draft variation between 6 May 2019 and 13 June 2019.

Ten (10) submissions were received from government agencies, industry or industry associations and one from health care professionals. Individual issues raised in submissions and FSANZ's responses are detailed in Table 3.

2.1 Summary of issues raised in submissions

Table 3: Summary of issues

Issue	Raised by	FSANZ response
Minimum protein level for non-milk and soy-based follow-on formulas		
<p>By only mentioning milk-based and soy-based follow-on formula, there is a regulatory gap for any other potential protein sources. This creates uncertainty and confusion for stakeholders and limits the capacity for innovation within the industry. This does not ‘future proof’ the Code and may result in the need to review Standard 2.9.1 in the future.</p> <p>FSANZ should not knowingly create uncertainty in the Code. In doing so, FSANZ may be required to undertake further work to review standards (submitter highlights P1024 – Nuts and Novels as an example).</p>	<p>Multiple industry submitters</p>	<p>FSANZ acknowledged that specifying a protein minimum for milk and soy-based follow-on formula, without specifying requirements for other protein sources has the potential to create confusion and may not be appropriate for future innovations in novel protein sources for follow-on formula.</p> <p>FSANZ has amended the draft variation for Standard 2.9.1—9. See Attachment A.</p> <p>See section 2.3.1.</p>
Suggested alternative amendments to minimum protein levels in follow-on formulas		
<p>Currently Standard 2.9.1—9 permits a single protein level to cover all protein sources, except for protein substitutes. Alternative drafting options were proposed to improve the clarity.</p>	<p>Multiple industry submitters</p>	<p>FSANZ appreciated the time and effort submitters have put in to developing alternative options for the variation of Standard 2.9.1—9. See Attachment A.</p>
Implications of P1028 outcomes on A1173		
<p>‘Baby nuts and novels’ are discussed as part of P1028 Infant Formula. It is important that any potential changes to the Code from P1028 are not pre-empted in the drafting for this application.</p>	<p>Dairy Goat Co-operative</p>	<p>Noted. P1028 excludes follow-on formula as outlined above in section 1.3.1.3 and thus there are no conflicting outcomes between the two projects.</p>
Energy sources, energy density and other macronutrient profiles in follow-on formula		
<p>Permitted energy density of follow-on formula [in Australia and New Zealand] is wider than revised EU Standards and the draft revised Codex standards.</p> <p>As with protein, fat has a permitted range in the Code. If the protein minimum is lowered, energy would have to come from carbohydrate sources. It is suggested that the energy content of follow-on formula be limited to a maximum 315 kJ/100mL or 3150 kJ/L (aligning with the energy maximum in infant formula).</p>	<p>NZ Ministry for Primary Industries (NZ MPI); Victorian Department of Health and Human Services (VIC DHHS)</p>	<p>The Applicant has specifically applied to lower the protein minimum in follow-on formula. To maintain energy density, any energy deficit would need to be made up by either fat and/or carbohydrate. Assuming the deficit was made up by only carbohydrate, FSANZ calculated the additional small amount required to meet the minimum energy level. See section 2.3.2.</p>

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Issue	Raised by	FSANZ response
Quality of evidence assessing follow-on formula with protein levels as proposed		
There are limited studies of moderate quality that have assessed formula with protein levels as proposed.	VIC DHHS	FSANZ acknowledged the small number of studies that directly investigate the safety of a lower protein level in follow on formula. However, FSANZ considered evidence to inform the decision from the levels in human milk, international safety assessments and permissions, estimated protein intakes of older infants, and public health advice to feed them complementary foods. Australian Infant Feeding Guidelines (NHMRC, 2012) suggest carers look for lower protein content when choosing a formula product.
Maximum protein levels permitted in follow-on formula		
The maximum protein levels currently permitted in the Code are higher than revised EU and draft revised Codex standard. Recent European and Codex reviews suggest there is no physiological need for infants to consume follow up formula containing protein above 0.72 g/100 kJ. While the maximum protein is out of scope, it was noted that addressing that level would align the Code with the Australian Infant Feeding Guidelines (NHMRC, 2012) and Ministerial Policy Guidelines on infant formula products (Australia and New Zealand Food Regulation Ministerial Council, 2011).	NZ MPI	FSANZ noted the maximum protein level for follow-on formula in the Code is higher than the revised EU and draft revised Codex standards. We also noted evidence suggesting that Australian and New Zealand older infants may consume more than an adequate amount of protein. Reducing the maximum protein is beyond the scope of the current application however it can be considered in a subsequent application or future proposal.
Dietary intake assessment for New Zealand infants		
Although support was provided for FSANZ's nutrition assessment, FSANZ could consider constructing a theoretical infant diet for the New Zealand population consistent with the recently published 26 th New Zealand <i>Total Diet Study</i> (New Zealand Food Safety, 2018). This study obtained and utilised published data from the New Zealand Baby Led Introduction to Solids (BLISS) study.	NZ MPI	FSANZ acknowledged this feedback and undertook further assessment based on a number of publications focusing on the 26 th New Zealand Total Diet Study to consider the relevance of this data on the risk management of A1173. See section 2.2.1.
Future implications for reduced protein minimum in follow-on formula		

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Issue	Raised by	FSANZ response
<p>Although the lower minimum protein level in follow-on formula appears safe from the nutritional perspective, FSANZ should consider closely any future implications on infant wellbeing.</p> <p>There are many potential confounders and it is simplistic to single out a link between protein intake and obesity.</p>	<p>Royal Australasian College of Physicians (RACP)</p>	<p>FSANZ has not assessed the relationship between higher protein intakes and childhood obesity for this application, but agree there are complex factors contributing to this condition. In 2016, FSANZ reviewed the evidence linking high protein-containing formulas and obesity in older infants as part of Proposal P1028 (see P1028 SD1 attachment A1.1 - nutrition assessment). At that time, FSANZ concluded the evidence linking high protein-containing formulas to obesity was not sufficiently strong to warrant an amendment to the Standard.</p>
<p>Concern about promotion, labelling and claims on follow-on formula</p>		
<p>Concerns that reducing protein minimum in follow-on formula may be used by manufacturers for marketing purposes to imply that lower protein follow-on formulas are more like breastmilk and contribute to consumer belief that follow-on formula is comparable to human milk. Concern was expressed that this will further segment and differentiate an already overcrowded market.</p>	<p>RACP</p>	<p>There are existing provisions in the Code which prevent marketing of follow-on formula as suggested.</p> <p>Section 2.9.1—24(1) prohibits certain representations on the label of follow-on formula, including: <i>the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; and information relating to the nutritional content of human milk.</i></p> <p>Nutrition content claims and health claims are also prohibited. See section 2.3.3. These existing labelling requirements support the Policy Guideline for the Regulation of Infant Formula Products, which reflects the WHO Code of Marketing of Breastmilk Substitutes.</p>

2.2 Risk assessment

The [nutritional safety assessment report \(SD1\)](#) concluded that the requested lower minimum protein level in milk-based follow-on formula of 0.38 g/100 kJ is appropriate and safe.

To facilitate comparisons between protein levels in human milk and follow-on formula, the range of crude and true protein concentrations were determined and findings indicated that the requested lower minimum protein content for follow-on formula of 0.38 g/100 kJ falls within the ranges of crude and true protein levels reported for human milk from 5 to 12 months post-partum.

Formula-fed infants show faster weight gain compared to breastfed infants (Koletzko et al. 2009). As breastfed infants are the benchmark, some reduction in growth rates of lower protein formula-fed infants compared to higher protein formula-fed infants is not an adverse effect (providing growth is not less than that of breastfed infants). SD1 considered two randomised control trials, one examining growth trajectories and the other examining weight gain of infants fed lower protein formula (1.61 or 1.65 g/100 kcal, equivalent to 0.39 and 0.40 g/100 kJ, respectively). These were compared to those fed higher protein formula (2.2 or 2.7 g/100 kcal, equivalent to 0.51 or 0.65 g/100 kJ) (Ziegler et al. 2015; Inostroza et al. 2014). No adverse effects were recorded on growth or weight gain in infants who consumed lower protein formulas. The infant age range in these studies was 3 to 12 months.

The nutritional safety assessment identified only studies which tested milk-based formula in the intervention. No evidence was identified that assessed any other protein sources, including protein substitutes as defined in Standard 1.1.2 (which were considered out of scope for the purposes of this Application). The assessment considered the protein levels for soy-based formula products because soy protein has different digestibility and amino acid availability compared to dairy protein sources (Koletzko et al. 2013). 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. FSANZ reviewed the evidence and concluded that maintaining the current, higher minimum protein amount of 0.45 g/100 kJ in soy-based follow-on formulas is scientifically justified to ensure infants are obtaining adequate protein and amino acids.

2.2.1 Dietary intakes for Australian and New Zealand Infants

FSANZ considered two scenarios for infants aged 6 months to less than 12 months as part of the dietary intake assessment for protein as presented in SD1. In considering these, FSANZ compared age-specific protein intakes from each scenario to the Adequate Intake (AI) of protein from the Australian and New Zealand Nutrient Reference Values (NRVs) (NHMRC, 2006). The AIs for infants are based on the average protein content and average consumption of human milk relevant to infants at the same ages (NHMRC, 2006), with an additional allowance of protein from complementary foods in the AI for infants aged 7 to 12 months. The AI for protein for infants 0-6 months is 10 g/day and for 7-12 months is 14 g/day.

The proportion of infants not introduced to complementary foods by 7 months is low. The 2010 Australian National Infant Feeding Survey (AIHW, 2011) indicated that only 8.4% of Australian infants had not been introduced to solids by 6 months of age. The Infant Feeding in New Zealand report (NZ Ministry of Social Development, 2018) indicated that only 3.8% of New Zealand infants had not been introduced to solids by 7 months of age.

The scenarios for the dietary intake assessment based on model diets were:

1. follow-on formula as the single source of protein in the diet

2. a mixed diet of follow-on formula and other solid foods and beverages.

For intake scenario 1, follow-on formula was assumed to be the sole source of protein for infants aged 6 to less than 12 months. As outlined in Table 4 in SD1, infants aged 6 months have an estimated intake of protein from follow-on formula based on the lower proposed protein level that is equivalent to their AI and infants aged 9 and 12 months have estimated intakes that are between 1-3 g/day lower than the AI (depending on age and sex). As AIs are based on averages, FSANZ considers that intakes of protein slightly below the AI (as a result of follow-on formula being the sole source of protein) would still be within the distribution of normal daily protein intakes of this population group. FSANZ noted that the proposed minimum protein in follow-on formula aligns more closely to the protein content in human milk. As such, the same percentage of breastfed infants would have protein intakes lower than the AI in scenario 1.

FSANZ considered that older infants are not at risk of inadequate protein intake as a result of reducing the protein minimum in follow-on formula.

In scenario 2, a model diet for 9 month olds was developed using consumption data extrapolated from 2 year olds from the 2011-12 Australian National Nutrition and Physical Activity Survey (ABS, 2014) with adjustments made to account for the proportion of solid foods to milk and the type of milk consumed. Based on the AI's outlined above, FSANZ concluded that protein intakes for infants aged 9 and 12 months consuming follow-on formula and complementary foods was higher than the protein AI for 7 to 12 month olds (14 g/day). A reduced protein minimum is therefore unlikely to pose a risk of inadequate protein intake for infants aged 7 to 12 months.

One submission drew attention to the 2016 26th New Zealand Total Diet Study (NZ MPI, 2018). FSANZ located and reviewed publications discussing the study (Erikson et al. 2018; Daniels et al. 2018; Fu et al. 2018), including the BLISS Study Protocol (Daniels et al. 2015). The New Zealand Total Diet Study included a simulated (model) diet for 6-12 month old New Zealand infants. FSANZ further assessed these data to consider their appropriate application to the risk assessment, and considered the simulated diet together with protein concentration data from The Concise New Zealand Food Composition Tables (Plant and Food Research, 2016) and AUSNUT 2011-13 (FSANZ 2014) for follow-on formula. FSANZ then estimated the baseline mean protein intake for New Zealand infants aged 6-12 months to be approximately 34 g/day. The equivalent mean protein intake of 24 g/day was estimated for infants aged 9 months using the model diet based on Australian consumption data. Since consumption data for Australian infants aged 7 to 12 months resulted in lower estimates of protein intakes than New Zealand infants of the same age, conclusions that lowering the protein minimum if follow-on formula is suitable for infants in Australia would also apply to infants in New Zealand.

In conclusion, the dietary intake assessment indicated that protein intakes of Australian and New Zealand older infants would remain adequate if the minimum protein level for follow-on formula was lowered to 0.38 g/100 kJ.

2.3 Risk management

In keeping with the [Ministerial Policy Guideline \(SD2\)](#), breastfeeding is the recommended way to feed infants. As infants are a vulnerable population group, a safe and nutritious substitute is necessary when breastfeeding is not possible. Follow-on formula composition is regulated by prescriptive provisions. Any changes to the composition must be established as

safe prior to being permitted.

Following consideration of the objectives of the FSANZ Act (see section 2.5), relevant Ministerial policy guidelines (SD2), and issues raised and considered at the call for submissions, FSANZ's approach is to lower the minimum protein requirement for milk-based follow-on formula from 0.45 g/100 kJ to 0.38 g/100 kJ, but not to reduce the minimum protein requirement for any other follow-on formula.

2.3.1 Minimum protein requirement

The nutritional safety assessment (SD1) concluded there was no risk to infants if the minimum protein requirement of milk-based follow-on formula were lowered to 0.38 g/100 kJ. This was 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. FSANZ also conducted dietary modelling which indicated a reduced protein minimum in follow-on formula would still be sufficient to allow older infants to meet their Adequate Intake for protein. Therefore, reducing the minimum protein in milk-based⁴ follow-on formula does not pose a risk to the nutrition of older infants.

2.3.1.1 Soy-based follow-on formula

The applicant sought to amend the minimum protein for all follow-on formula that are subject to paragraph 2.9.1—9(2)(b). The Code defines soy-based formula and specifies the use of nitrogen-to-protein conversion factors to determine protein content (see 1.3.1.1 above). Currently a factor of 6.25 is specified for all protein other than milk proteins and their partial protein hydrolysates. At this time, there is no international regulatory consistency in the use of the nitrogen conversion factor specifically for soy protein (see section 2.3 of SD1).

FSANZ found no evidence that assessed 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 has retained the current minimum protein requirement of 0.45 g/100 kJ for soy-based follow-on formula.

2.3.1.2 Other protein sources in follow-on formula

Submissions highlighted that the proposed drafting specified a minimum protein requirement only for milk- and soy-based follow-on formula, noting this does not provide clarity for any other protein sources. This was considered to create potential regulatory gaps for manufacturers looking at innovative or novel protein sources, and so did not future-proof the Code.

FSANZ considered the different protein sources used in follow-on formula currently on the market in Australia and New Zealand, and internationally. Only milk- and soy-based protein sources were used in follow-on formula on the local market. Consequently, without scientific evidence to suggest otherwise, FSANZ concluded it was appropriate to maintain the current minimum protein amount of 0.45 g/100 kJ for all other protein sources. The proposed drafting has been amended to extend the proposed exclusion from the reduced protein minimum of milk-based follow-on formula to any other potential protein source used in follow-on formulas.

⁴ Milk-based formula is not a defined term in the Code but is already used in Standard 2.9.1.

2.3.2 Energy deficit and carbohydrate

In response to comments made in submissions, FSANZ calculated the potential increase in carbohydrate per day to maintain product energy density when the protein content was lowered. The protein content was assumed to be lowered from 0.45 g/100 kJ to 0.38 g/100 kJ, a difference of 0.7 g protein/100 kJ. Since protein and carbohydrate have the same energy density, this equated to 0.07 g carbohydrate/100 kJ formula. A 9-month old infant is expected to consume 550 mL of follow-on formula in a day. From Standard 2.9.1, the energy content of this volume is 1375 kJ – 1925 kJ therefore the difference in carbohydrate intake from this volume is 1.0 – 1.3 g/day. FSANZ considers this to be a minor difference.

2.3.3 Labelling requirements

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

2.3.3.1 Mandatory nutrition information

Nutrition information, including the protein content, must be declared on the label of packaged follow-on formula. Subparagraph 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 familiar with 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 product. 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 Care-line contact information on the label.

2.3.3.2 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 (for example, about protein) must not be made about an infant formula product. The prohibition for claims is also set out in paragraph 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.

Paragraph 2.9.1—24(1)(e) prohibits information relating to the nutritional content of human milk. Representations that the protein level is equivalent or similar to breastmilk could not be made.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. 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. FSANZ developed and applied a basic communication strategy for this application. Public submissions were invited on a draft variation which was released for public comment between 16 May and 13 June 2019. Subscribers and interested parties were notified about the call for submissions through the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News.

All stakeholders who submitted at the call for submission received a recognition of receipt email, which thanked them for their valued input. Stakeholders that raised significant issues, of which FSANZ took an opposing position, were contacted by the project manager with an explanatory email as a matter of courtesy.

Every submission on this application was considered by the FSANZ Board. Documents relating to Application A1173, including submissions received, are available on the FSANZ website.

2.4.2 World Trade Organization (WTO)

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

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.

2.5 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:

2.5.1 Section 29

2.5.1.1 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). OPBR was satisfied that the proposed approach 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 was to determine if the community, government, and industry as a whole would likely benefit, on balance, from a move from the status quo. This analysis considered whether to approve or reject the application (retain the status quo). No further information has been received in the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

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 will not change, 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.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from lowering the minimum protein requirement, outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The approved amendment applies in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ concluded that there are no public health and safety concerns associated with the lower protein minimum requirement for milk-based follow-on formula. Formulas made from other protein sources (such as soy) will retain the current protein minimum of 0.45 g/100 kJ as FSANZ considered the current evidence on safety and benefit to be insufficient to warrant a similar reduction.

2.5.2.2 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.

2.5.2.3 The prevention of misleading or deceptive conduct

There were no issues identified relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ 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 identified and 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 the expected changes in international standards.

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

The approved amendment supports an internationally competitive food industry for follow-on formula products.

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

No negative impacts were identified relevant to this objective.

- **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 determined that this policy guideline has been met (see SD2).

Attachments

- A. Approved draft variations to the Australia New Zealand Food Standards Code
- B. Explanatory Statement
- C. Draft variation/s to the Australia New Zealand Food Standards Code (call for submissions)

References

ABS (2014) National Nutrition and Physical Activity Survey, 2011-12, Basic CURF, CD-ROM. Findings based on ABS CURF data. Australian Bureau of Statistics, Canberra.

AIHW (2011) 2010 Australian National Infant Feeding Survey: indicator results. Australian Institute of Health and Welfare, Canberra.

ANZFRMC (2011) Policy Guideline on the Regulation of Infant Formula Products. Australia and New Zealand Food Regulation Ministerial Council
<https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Infant-Formula-Products>. Accessed 18 June 2019

Codex Alimentarius Commission (1987) Standard for follow-up formula. Codex Alimentarius CXS 156-1987. Codex Alimentarius Commission, Rome. <http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/>. Accessed 20 July 2019

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 (REP18/NFSDU). Codex Alimentarius Commission, Rome.
https://www.ccnfsdu.de/fileadmin/SITE_MASTER/content/Downloads2017/REP18_NFSDUe.pdf. Accessed 20 July 2019

Erickson LW, Taylor RW, Haszard JJ, Fleming EA, Daniels L, Morison BJ, Leong C, Fangupo LJ, Wheeler BJ, Taylor BJ, Te Morenga L, McLean RM, Heath AM (2018) Impact of a Modified Version of Baby-Led Weaning on Infant Food and Nutrient Intakes: The BLISS Randomized Controlled Trial. *Nutrients* 10: 740. doi:10.3390/nu10060740

Daniels, L, Heath AM, Williams SM, Cameron SL, Fleming EL, Taylor BJ, Wheeler BJ, Gibson RS, Taylor RW (2015) Baby-Led Introduction to Solids (BLISS) study: a randomised controlled trial of a baby-led approach to complementary Feeding. *BMC Pediatrics* 15:179. doi:10.1186/s12887-015-0491-8

Daniels L, Taylor RW, Williams SM, Gibson RS, Samman S, Wheeler BJ, Taylor BJ, Fleming EA, Hartley NK, Heath AH (2018) Modified Version of Baby-Led Weaning Does Not Result in Lower Zinc Intake or Status in Infants: A Randomized Controlled Trial (2018). *Journal of the Academy of Nutrition and Dietetics* 118(6); 1006–1016.e1. doi:10.1016/j.jand.2018.02.005

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>. Accessed on 18 June 2019

Fu X, Conlon CA, Haszard JJ, Beck KL, von Hurst PR, Taylor RW, Heath AM (2018) Food fussiness and early feeding characteristics of infants following Baby-Led Weaning and traditional spoon-feeding in New Zealand: An internet survey. *Appetite* 130: 110–116. doi: 10.1016/j.appet.2018.07.033

Koletzko B, von Kries R, Closa R, Escribano J, Scaflioni S, Giovannini M, Beyer J, Demmelmair H, Anton B, Gruszfeld D, Dobrzanska A, Senquier A, Langhendries JP, Rolland Cachera MF, Grote V (2009) Can infant feeding choices modulate later obesity risk? *American Journal of Clinical Nutrition* 89 (5), 1502S–1508S. DOI: 10.3945/ajcn.2009.27113D.

Koletzko B, Bhutta ZA, Cai W, Cruchet S, Guindi ME, Fuchs GJ, Goddard EA, van Goudoever JB, Quak SH, Kulkarni B, Makrides M, Ribeiro H, Walker A (2013) Compositional Requirements of Follow-Up Formula for Use in Infancy. Recommendations of an

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

International Expert Group Coordinated by the Early Nutrition Academy. *Annals of Nutrition and Metabolism* 62(1):44–54. doi.10.1159/000345906

NHMRC (2006): Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes. Version 1.2. Edited by National Health and Medical Research Council. Canberra.

NHMRC (2012) Infant Feeding Guidelines: Summary. National Health and Medical Research Council, Canberra.

NZ MPI (2018) 2016 New Zealand Total Diet Study. New Zealand Ministry for Primary Industries, Wellington. <https://www.mpi.govt.nz/dmsdocument/28976-2016-nz-total-diet-study-with-appendices-report>. Accessed 24 June 2019

Plant and Food Research (2016) The Concise New Zealand Food Composition Tables 12th edition. The New Zealand Institute for Plant & Food Research Limited and the ministry of Health (New Zealand) on behalf of the Crown, Auckland. <https://www.foodcomposition.co.nz/downloads/concise-12-edition.xlsx>. Accessed 24 June 2019

Ziegler EE, Fields DA, Chernausek, SD, Steenhout P, Grathwohl D, Jeter JM, Nelson SE, Haschke F (2015): Adequacy of Infant Formula With Protein Content of 1.6 g/100 kcal for Infants Between 3 and 12 Months. *Journal of Pediatric Gastroenterology and Nutrition* 61 (5), pp. 596–603. DOI: 10.1097/MPG.0000000000000881.

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

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

[1.1] omitting paragraph 2.9.1—9(2)(b), substituting

(b) the following protein content:

(i) for a milk-based follow-on 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 all other follow-on formulas—a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;

[1.2] inserting after subsection 2.9.1—9(2)

Note Section 2.9.1—15 sets the protein content for infant formula and follow-on formula that are for special dietary use based on a *protein substitute.

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.

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

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose

The Authority has approved 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 all other follow-on formulas with the exception of follow-on formula for special dietary use based on a protein substitute. The protein compositional requirements for an infant formula product for special dietary use based on a protein substitute are imposed by section 2.9.1—15 and not by paragraph 2.9.1—9(2)(b).

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 included one round of public consultation following an assessment and the preparation of a draft variation Standard and associated assessment summary and report. Submissions were called for on Thursday 16 May 2019 for a four-week consultation period.

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 [1.1] 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: a 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 all other follow-on formulas – with the exception of follow-on formula for special dietary use based on a protein substitute – to have a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ.

The new paragraph will not prescribe the protein content for follow-on formula for special dietary use based on a protein substitute. This is because section 2.9.1—9(2) does not set the protein content for the latter. Instead, section 2.9.1—15 currently sets the compositional requirements for infant formula products, including follow-on formula, that are for special dietary use based on a protein substitute. Paragraph 2.9.1—15(2)(c) currently requires these products to have a protein content of no less than 0.45g/100kJ and no more than 1.4g/100kJ.

Item [1.2] inserts a note after section 2.9.1—9(2) of Standard 2.9.1. This note is to assist the reader and advises that section 2.9.1—15 – as opposed to section 2.9.1—9(2) – sets the protein content for infant formula and follow-on formula that are for special dietary use based on a *protein substitute.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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