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Te Mana Kounga Kai - Ahitereiria me Aotearoa

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Supporting document 1

Nutrient composition

Proposal P1066 – Review of young child formula

Executive summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements for young child formula under Proposal P1066 – Review of young child formula. Young child formula is currently regulated in the Australia New Zealand Food Standards Code (the Code) as formulated supplementary foods for young children (FSFYC) under Division 4 of Standard 2.9.3 *Formulated meal replacements and formulated supplementary foods*.

This Supporting Document (SD1) considers if the regulatory requirements for the nutrient composition of young child formula, for use as a supplementary product for children aged 1–3 years in Australia and New Zealand, remain fit for purpose. The assessment aligns with the main objectives of P1066: protecting young children's health and safety, relying on scientific evidence and supporting a globally competitive food industry.

Proposal P1066 also has regard to the *Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special purpose foods*, with this SD considering the policy principle that the composition of special purpose food should be consistent with the intended purpose. Young child formula is intended as a supplementary product for use in situations where usual dietary intakes of energy or specific nutrients may be inadequate. Accordingly, its composition has been considered in the context of consumption as part of a varied diet, rather than the sole source of nutrition.

FSANZ has considered whether compositional requirements for FSFYC in Standard 2.9.3 should be retained for the regulation of young child formula, or whether alignment with the provisions in the Codex *Standard for Follow-up Formula for Older Infants and Product for Young Children* (CXS 156-1987) is appropriate. This assessment was informed by the conclusions of the nutrition risk assessment (Attachment 1 to this SD), FSANZ's 2025/26 Market Survey, and population health information for Australian and New Zealand young children.

This assessment also compares the forms of vitamins and minerals permitted in the Code and currently applicable to young child formula, with those permitted in the Codex *Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979).

FSANZ proposes a compositional framework that distinguishes between mandatory and optional nutrients in young child formula, having regard to the provisions in CXS 156-1987, nutritional requirements of young children and the purpose of young child formula. In developing proposed compositional requirements, FSANZ has considered the use of

compositional limits, including minimum and maximum levels, and where appropriate, guidance upper levels (GUL). Full alignment with CXS 156-1987 is proposed for some nutrients, while for others partial alignment and retention of current Code requirements is proposed where these were considered more appropriate for the Australian and New Zealand context.

Mandatory nutrients aligned with those listed in CXS 156-1987 are proposed to support nutritional adequacy and safety based on nutrient requirements in the age group. Optional nutrients are those retained from current permissions in Standard 2.9.3, with compositional limits either retained from current permissions or reviewed having regard to CXS 156-1987. Other nutritive substances permitted through pre-market approval for optional use in FSFYC have been considered for permissions in young child formula.

FSANZ's proposed regulatory approach to the composition of young child formula is summarised below in Table 1. Proposed approaches are made with consideration to the objectives of the proposal and relevant risk management principles.

Table 1: Proposed nutrient composition for young child formula

Nutrient	Unit	Proposed permissions		Comment
		Min	Max	
Mandatory composition				
Energy	kJ/100 mL	251	293	Min and max adopted from Codex
Protein	g/100 kJ	0.43	-	Min adopted from Codex
Total fat	g/100 kJ	0.84	-	Min adopted from Codex
α-Linolenic acid	mg/100 kJ	12	-	Min adopted from Codex
Linoleic acid	mg/100 kJ	72	-	Min adopted from Codex
Carbohydrates	g/100 kJ	-	3.0	Max adopted from Codex
Vitamin A	µg RE/100 kJ	14	43	Min and max adopted from Codex
Vitamin D	µg/100 kJ	0.36	1.1	Min and max adopted from Codex
Riboflavin	µg/100 kJ	19	155*	Min and max adopted from Codex
Vitamin B_{12}	µg/100 kJ	0.02	0.48*	Min and max adopted from Codex
Vitamin C	mg/100 kJ	2.4	17*	Min and max adopted from Codex
Iron	mg/100 kJ	0.24	0.72	Min and max adopted from Codex
Calcium	mg/100 kJ	22	67*	Min and max adopted from Codex
Zinc	mg/100 kJ	0.12	0.36*	Min and max adopted from Codex
Optional composition				
Thiamin	µg/100 kJ	14	72*	Min and max adopted from Codex
Niacin	µg/100 kJ	72	758	Min adopted from Codex; max retained from Std 2.9.3
Folate	µg/100 kJ	2.4	12*	Min and max adopted from Codex
Vitamin B_6	µg/100 kJ	8	106	Min adopted from Codex; max retained from Std 2.9.3
Vitamin E	mg α-TE/100 kJ	0.12	1.2	Min and max adopted from Codex
Iodine	µg/100 kJ	2.4	14	Min and max adopted from Codex
Magnesium	mg/100 kJ	1.2	9.7	Min adopted from Codex; max retained from Std 2.9.3
Phosphorus	mg/100 kJ	6	76	Min adopted from Codex; max retained from Std 2.9.3

Other nutritive substance				
Lutein	µg/100 kJ	9	30	Min and max retained from Std 2.9.3
ITF/GOS	g/100 kJ	-	0.48	Max retained from Std 2.9.3

*Proposed as a GUL

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Abbreviations and glossary

Abbreviation or term	Meaning
α-TE	Alpha-tocopherol equivalent
BFD	Branded Food Database
CFS	Call for submissions
Codex	Refers to Codex Alimentarius
CXG 10-1979	Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children
CXS 156-1987	Codex Standard for Follow-Up Formula for Older Infants and Product for Young Children
DFE	Dietary folate equivalents
DHA	Docosahexaenoic acid
FOS	Fructo-oligosaccharides
FSANZ	Food Standards Australia New Zealand
FSFYC	Formulated supplementary food for young children
GOS	Galacto-oligosaccharides
GUL	Guidance upper level
ITF	Inulin-type fructans
NIP	Nutrition information panel
NNPAS	National Nutrition and Physical Activity Survey
NRV	Nutrient reference value
PDCAAS	Protein Digestibility Corrected Amino Acid Score
RDI	Recommended dietary intake
RE	Retinol equivalents
SD	Supporting document

1 Introduction

1.1 Scope

Young child formula is currently regulated by Division 4 of Standard 2.9.3 as “Formulated Supplementary Food for Young Children” (FSFYC). The main purpose of this Supporting Document 1 (SD1) is to consider if the regulatory requirements for the nutrient composition of young child formula in Australia and New Zealand remain fit for purpose or require amendment based on findings from risk assessment, market data, international regulations and policy guidance. This SD also considers the establishment of a discrete regulatory framework for the nutrient composition of young child formula in the Australia New Zealand Food Standards Code (the Code).

This SD to the 1st Call for submission (CFS) does not propose any drafting since the views presented are preliminary in nature. Amendments to the Code may be drafted after further assessment has been made and a decision taken for the purposes of sections 59 and 60 of the FSANZ Act. Any proposed amendments will be subject to further public consultation.

1.2 Background

1.2.1 Current Code requirements

Standard 2.9.3 – Division 4 sets out the mandatory energy and protein requirements for FSFYC per serve of that product. It is also stated that these products must contain 20% of the Recommended Daily Intake (RDI) of at least one permitted vitamin or mineral in a permitted form that is specified in Schedule 17. The Standard regulates the source and maximum amount of other permitted optional nutritive substances.

Section 29—15 lists the vitamins and minerals that may be used in FSFYC in units per serve. It is noted that the total of the naturally occurring and added vitamin or mineral in a serving is not more than the amount listed in S29—15. Absolute maximum limits are prescribed for some nutrients, which explicitly constrain nutrient content. In addition, maximum claimable amounts are listed for all permitted micronutrients. These amounts limit the quantity of a nutrient that may be declared or claimed per serving.

The compositional requirements in Standard 2.9.3 – Division 4 were based on the best scientific evidence available at the time of its development over two decades ago, for a range of products that meet the definition of FSFYC.

1.2.1.1 Proposal P199 – Formulated meal replacements and formulated supplementary foods

Proposal P199 established the compositional framework for FSFYC in Standard 2.9.3 – Division 4 (ANZFA 1999a; 1999b). This proposal initially developed compositional parameters on a per serve basis for formulated supplementary foods, as listed in Division 3 of Standard 2.9.3. These parameters were subsequently scaled to reflect the nutritional requirements of children aged 1–3 years and applied to FSFYC.

Minimum energy and protein requirements were set to ensure that formulated supplementary foods, including FSFYC, made significant nutritional contributions. Proposal P199 also established the requirement for the inclusion of at least one vitamin or mineral to be added based on evidence that generally only one micronutrient was inadequately consumed. A minimum inclusion level of 20% of the RDI was set to ensure sufficient nutrient density.

P199 established the list of nutrients in S29—15 by permitting any nutrient with an RDI for use in formulated supplementary foods. Maximum claimable amounts were set at 50% of the RDI to reflect that these products are not intended as the sole source of nutrition (ANZFA P1999b). This approach reflected the regulatory context at the time, under which controls on vitamin and mineral addition were considered sufficient, and absolute maximum amounts were only established where specific safety concerns were identified.

1.2.2 Codex

There are several Codex Standards and Guidelines that are relevant to the nutrient composition of young child formula.

The Codex Alimentarius Standard for Follow-Up Formula for Older Infants and Product for Young Children (CXS 156-1987) sets out the composition for follow-up formula for older infants in Section A (for infants aged 6–12 months) and for product for young children with added nutrients in Section B (for children aged 12–36 months) (Codex 2023b). This Standard guides member countries when establishing the composition of young child formula and considers safety, nutrient adequacy, bioavailability, levels of naturally occurring nutrients and the inherent variability of nutrients within ingredients and in water.

CXS 156-1987 was revised in 2023 to reflect more recent scientific understanding of nutritional needs of young children and to incorporate the provisions for product for young children into the Standard. As a result, Section B of CXS 156-1987 is informed by a more contemporary evidence base than that underpinning the existing requirements in Standard 2.9.3 – Division 4. This SD has therefore had regard to the nutrient requirements set out in Section B of CXS 156-1987, which is referred to throughout this report as CXS 156-1987.

The Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979) specifies permitted forms of nutrients for use in products for young children (Codex 2023a). This advisory list was last updated in 2010.

1.2.3 Ministerial Policy Guidance

Proposal P1066 has regard to the Australian and New Zealand *Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special purpose foods* (ANZFRMC 2009). This guideline specifies that ‘the composition of special purpose food should be consistent with the intended purpose’.

1.3 Approach

This assessment does not imply that young child formula is nutritionally required for children aged 1–3 years. Consistent with Australian and New Zealand dietary guidelines, the nutritional needs of most children in this age group can be met through a varied diet that includes appropriate foods from the 5 food groups. Young child formula is considered only in situations where usual dietary intakes of energy or specific nutrients may be inadequate to meet an individual child’s requirements.

The approach taken in this SD is to consider if the provisions for the nutrient composition in CXS 156-1987 are appropriate for the regulation of young child formula, and proposing alignment in the Code where suitable, while also having regard to the Australian and New Zealand regulatory context. This assessment primarily considers Codex requirements, is informed by risk assessment outcomes, and contextualises proposed amendments against current market practices and current Code provisions for FSFYC.

In undertaking this work, FSANZ has had regard to the intended purpose of young child formula as a supplementary product and not as a sole source of nutrition. This approach is consistent with Ministerial Policy Guidance, the definition of FSFYC in Standard 2.9.3 and the proposed definition of young child formula (see section 2.1 of the CFS Report).

As described in the nutrition assessment (Attachment 1 to this SD), whole cow's milk has been used as a reference product when considering the nutritional role of young child formula. It is used as a comparator for energy density, key macronutrients and selected micronutrients where cow's milk is a major dietary source. This reflects Australian and New Zealand dietary guidance and the role of these products as partial substitutes for milk in the diets of young children who require them. FSANZ has considered the extent to which the nutrient composition of young child formula compares with that of whole cow's milk, noting the fortified nature of the product.

Comparison with existing compositional permissions for infant formula products in Standard 2.9.1 has also been used to contextualise some levels observed in the domestic market. This has been done on the assumption that young child formula and infant formula products are typically manufactured from the same base milk powders.

As described in section 1.2.1.1 of this report, current Code requirements for FSFYC are expressed on a per serve basis. To enable comparison between the Code and Codex provisions for each nutrient, Code requirements have been converted to Codex-aligned units (per 100 kJ). These conversions were undertaken using the minimum energy requirement of 330 kJ per serve specified in Standard 2.9.3 for FSFYC. This approach enables a consistent comparison of compositional ranges across regulatory frameworks and supports assessment of the potential impact of the proposed approach on products currently available in the domestic market.

This SD is structured to discuss a proposed compositional framework for young child formula, followed by the consideration of proposed mandatory and optional nutrients, permitted forms of nutrients and other regulatory considerations.

1.3.1 Approach to setting minimum, maximum and guideline amounts

There are differences between the Code requirements for FSFYC and those set out in CXS 156-1987. Standard 2.9.3 prescribes minimum amounts only for required macronutrients and does not establish maximum amounts. Conversely, while the Code does not prescribe minimum amounts for permitted vitamins, minerals and other nutritive substances, it includes a maximum amount or a maximum claimable amount for these nutrients. In contrast, CXS 156-1987 prescribes either minimum or maximum amounts for macronutrients, and for each micronutrient specifies a minimum amount and either an absolute maximum or guidance upper level (GUL).

Where Codex has listed a minimum amount for micronutrients, FSANZ proposes that the minimum amount be adopted where appropriate. FSANZ considers that imposing a minimum composition level is important and justified to ensure young child formula appropriately contributes to the diets of young children when consumed as part of a varied diet. Moreover, imposing a minimum amount aligned with CXS 156-1987 will ensure that nutrient intakes from young child formula are either in alignment or higher than the average amount present in cow's milk, reflecting the fortified nature of the product.

In CXS 156-1987, maximum amounts are established where excessive intake is considered to pose a risk to young children. On the other hand, a GUL is used where there is insufficient information about adverse effects from excessive intakes for a science-based risk assessment to set a mandatory limit, but a reference upper point is considered appropriate to

manage potential risk.

The purpose of a GUL listed in CXS 156-1987 is to provide guidance to manufacturers and they should not be interpreted as goal values. They may be adjusted based on relevant scientific or technological progress. As noted in CXS 156-1987, nutrient contents in the product for young children with added nutrients should usually not exceed a GUL unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of the product, or due to technological reasons. When a product type or form has ordinarily contained lower levels than a GUL, manufacturers should not increase levels of nutrients to approach a GUL.

Where FSANZ is proposing to align compositional limits with Codex and the maximum amount for a nutrient is listed as a GUL, FSANZ proposes to adopt the GUL in the regulation of young child formula where risk assessment has concluded it to be safe. This approach is in alignment with FSANZ's preference for international alignment and is consistent with current regulatory practice under the Code. If adopted, a GUL should not be exceeded unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of young child formula due to technological reasons, consistent with CXS 156-1987.

1.3.2 Nutrition risk assessment

The nutrition risk assessment examined whether Codex minimum and maximum levels and GUL pose any risk of nutritional inadequacy or excess for children aged 1–3 years in Australia and New Zealand, with the objective of ensuring the protection of public health and safety. One serving of young child formula was defined as 250 mL, consistent with Australian and New Zealand dietary guidelines, which define one serve of milk as one cup (250 mL) and recommend that children aged 1–3 years consume 1–1½ serves of dairy foods per day (MoH 2021; NHMRC 2013).

Modelled intakes of one, 2 and 3 x 250 mL servings from young child formula were compared to Nutrient Reference Values for Australia and New Zealand (NRV) (NHMRC and MoH 2006) to evaluate their contribution to daily nutrient intake, as well as with existing compositional requirements in the Code. Whole cow's milk was used as a nutritional comparator. Consumption scenarios assumed that young child formula contributes approximately 15–25% of total daily energy intake, reflecting consumption of around 1–1½ serves per day, with the remainder of energy derived from other foods. The assessment assumes that young child formula is supplementarily consumed as part of a varied diet and does not rely on young child formula as a sole source of nutrition.

For further information please see Attachment 1 to this SD.

1.3.3 Market survey

To determine the potential impacts of the proposed nutrient composition outlined in this SD on current market practices, FSANZ completed a survey of young child formula on the Australian and New Zealand market. As described in the CFS Report, the 2025/26 Market Survey was collected from the Branded Food Database (BFD) in Australia and the GS1 On Pack Database in New Zealand, with both supplemented by online and in store retailers.

The 2025/26 Market Survey identified a total of 55 products: 35 in Australia, and 20 unique to the New Zealand market. Information collected included nutrients and their amounts listed on the Nutrition Information Panel (NIP). This SD has utilised the combined minimum and maximum nutrient values observed across both countries to represent current market practices, as the proposed nutrient composition would apply to both markets, if approved.

These minimum and maximum values have been used to comment on the potential impact of the proposed changes on the range of nutrient levels currently present on the market.

1.3.4 Dietary intake assessment

The objective of the dietary intake assessment was to estimate the mean consumption amount and number of consumers of young child formula in the most recently published Australian and New Zealand national nutrition surveys.

An estimation of nutrient intakes from young child formula could not be robustly determined due to there being too few consumers of young child formula aged 2–3 years in the 2011–12 National Nutrition and Physical Activity Survey (NNPAS) (ABS 2015) to provide reliable estimates.

Noting the above, the 2011–12 NNPAS showed that on day one 11 children aged 2–3 years consumed foods from the infant formula food group (which includes young child formula) (3.3% of survey respondents aged 2–3 years) and the mean consumption amount for these consumers was 428 g/day[1]. Assuming a specific gravity of 1.05 (FSANZ 2025) and a serve size of 230 mL, this mean consumption amount is equivalent to approximately 1.8 serves/day.

In the 2023 NNPAS, 6.6% of respondents aged 2–4 years consumed foods from the infant formulae and breast milk food group (which includes young child formula) (ABS 2025) suggesting an increase in the proportion of consumers over time.

FSANZ plans to complete a more comprehensive dietary intake assessment of the proposed composition of young child formula using food consumption data from the First Foods New Zealand and Young Foods New Zealand studies (Taylor et al. 2021; Haszard et al. 2024) at the 2nd CFS when these data are available in FSANZ's dietary exposure assessment computer program Harvest.

For a full explanation of the dietary intake assessment including the results, refer to Appendix 1.

[1] Survey sample weighting factors are used to adjust survey data to better reflect the results that would have been obtained if a truly representative sample had been able to be obtained (FSANZ 2024).

2 Compositional framework

2.1 Compositional framework in CXS 156-1987

CXS 156-1987 established a list of nutrients considered essential to the composition of the product for young children, as well as nutrients that may be added on an optional basis.

The mandatory composition for products for young children is listed in Section B of CXS 156-1987 and were developed based on a set of key principles. Codex identified nutrients as essential where they:

- Contribute to the nutritional needs of young children where the intakes of the nutrient is widely inadequate; and/or
- Contribute adequate amounts of key nutrients from milk, and if appropriate breast milk, where such nutrients are key contributors to the diet of young children; and/or
- Support the nutritional quality and integrity of the product to ensure nutritional safety.

In addition to the mandatory composition, CXS 156-1987 considers that additional ingredients and nutrients may be added to the product provided that these are:

- Selected from the essential composition of follow-up formula for older infants, as listed in Section A of CXS 156-1987, with levels consistent with the minimum, maximum and GUL specified for follow-up formula, and taking into account the levels of nutrients present in cow's milk; or
- Listed as optional ingredients for follow-up formula in Section A of CXS 156-1987, where the safety and suitability of the ingredient for a particular nutritional purpose, at the proposed level of use, has been evaluated and demonstrated by generally accepted scientific evidence.

2.2 Proposed compositional framework

The proposed framework for the nutrition composition of young child formula is at Figure 1, and depicts the considerations made in selecting proposed nutrient permissions in this report.

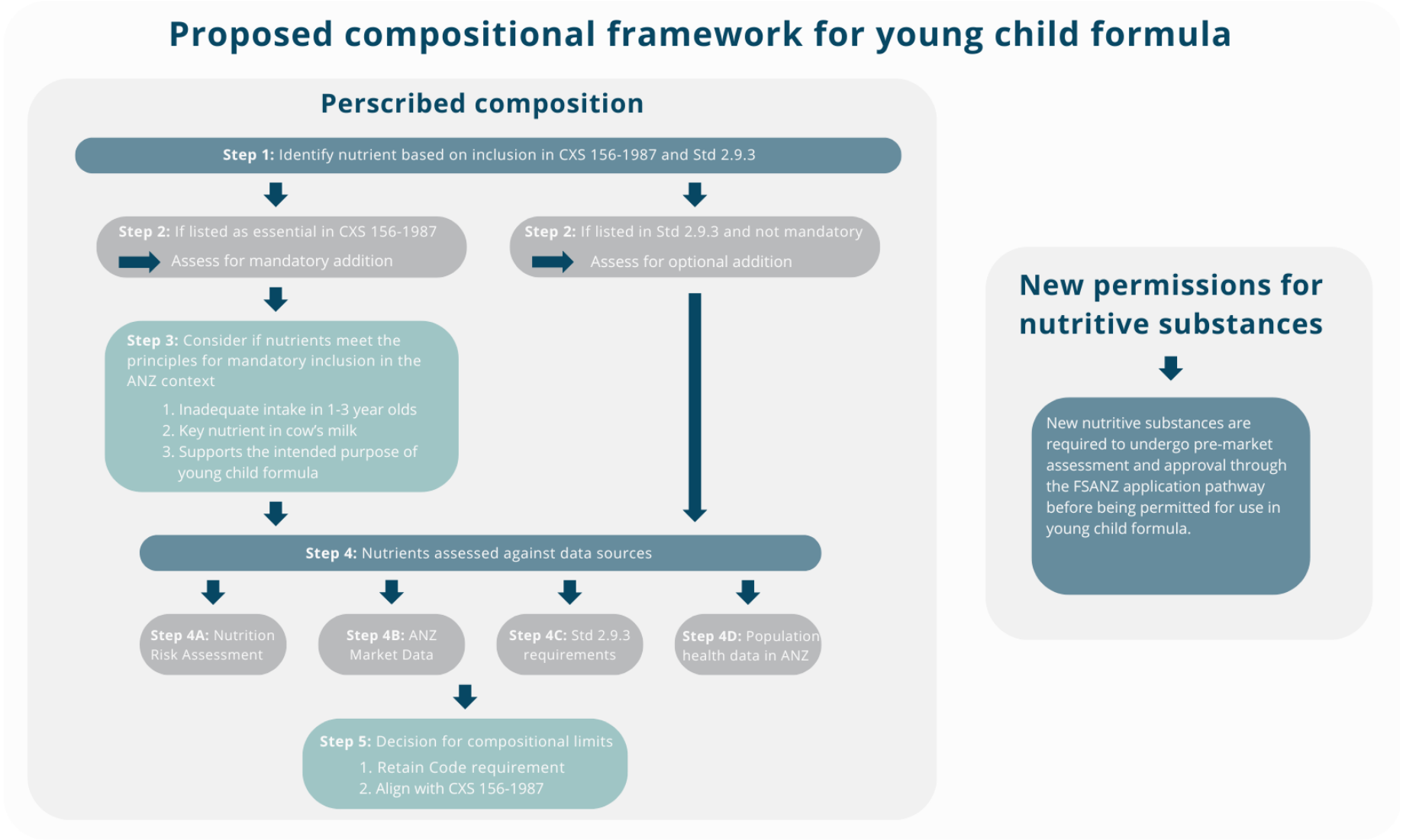

Figure 1: Proposed compositional framework for the nutrient composition of young child formula.

2.2.1 Mandatory nutrients

The establishment of a compositional framework for young child formula by FSANZ does not imply that young child formula is nutritionally necessary for healthy children but rather sets compositional requirements for products where they are consumed.

While CXS 156-1987 sets out recommended compositional requirements for products for young children, this Standard is intended to provide guidance to competent national and regional authorities. Accordingly, FSANZ is able to identify what is most appropriate to adopt in the Australian and New Zealand context, with regard to the domestic policy environment and nutrient needs of those aged 1–3 years.

FSANZ considers the principles set out for the selection of the mandatory composition listed in Section B of CXS 156-1987 to be broadly appropriate for the regulation of young child formula in Australia and New Zealand. In applying the Codex principles, FSANZ has had regard to the intended purpose of young child formula as a formulated supplementary food, rather than a sole source of nutrition or breast milk substitute. As young child formula is intended to be consumed as part of a varied diet that includes family foods, FSANZ considers that mandatory nutrients be limited to those necessary to fulfil the nutritional purpose of the product, having regard to dietary adequacy, potential substitution for cow's milk and the need to ensure nutritional safety.

Based on existing policy requirements and the purpose of the product, and noting the requirements of the FSANZ Act, FSANZ proposes the following principles to underpin the selection of the nutrients for the mandatory composition for young child formula:

- Contribute to the nutritional needs of young children where the nutrient is widely inadequate, and/or
- Contribute adequate amounts of key nutrients from cow milk, where such nutrients are key contributors to the diet of young children, and/or
- Support the nutritional quality and integrity of the product to ensure nutritional safety and fulfil its intended purpose for young children.

In considering these revised principles FSANZ is seeking to, where appropriate, adopt the mandatory composition for young child formula (see section 3 of this report).

2.2.2 Optional nutrients

As noted in section 2.1 of this report, CXS 156-1987 lists that optional nutrients for product for young children are to be selected from the essential and optional composition of follow-up formula for older infants, as listed in Section A of the Standard. As defined in CXS 156-1987, follow-up formula is intended to be a breast milk substitute, with the composition of breast milk informing the determination of its nutrient composition. However, given that young child formula is defined and intended as a supplementary milk drink, FSANZ does not consider it appropriate to directly align the optional composition of young child formula with the composition of follow-up formula for older infants (known as follow-on formula in Australia and New Zealand). It is expected that young children consume adequate amounts of non-essential nutrients through the consumption of a diverse diet.

FSANZ notes the existing permissions for vitamins and minerals listed in the table to section S29—15 that may be added to FSFYC under Standard 2.9.3. Where these nutrients are not proposed for inclusion in the essential composition (as listed in section 3) and have a corresponding permission in CXS 156-1987, FSANZ considers it appropriate to assess the

continued benefit of retaining these nutrients for voluntary addition to young child formula. This assessment will consider the most appropriate compositional limits for Australian and New Zealand children aged 1–3 years, having regard to both the current permissions in section S29—15 and those specified in CXS 156-1987.

This approach ensures no existing compositional permissions for current young child formula products are removed as part of the proposed regulatory outcomes for this proposal, while enabling compositional requirements to be revised where appropriate based on updated evidence.

Based on existing policy requirements and the purpose of the product, FSANZ proposes the following principles to underpin the selection of the nutrients for the optional composition for young child formula:

- Nutrients listed in S29—15 that are not considered essential may be added to young child formula.
- Compositional limits for these nutrients will be set with consideration to both current requirements listed in S29—15 and those listed in Section A of CXS 156-1987.

Consistent with these principles, FSANZ proposes to retain the nutrients listed in S29—15 for young child formula, while considering the compositional limits in both S29—15 and CXS 156-1987 (see section 4 of this report).

2.2.3 Other nutrients

As described in section 2.1 of this report, CXS 156-1987 considers that additional nutrients from the essential and optional composition of follow-up formula may be added to the product for young children. The nutrients listed as essential in Section A of CXS 156-1987 that are not listed in the table to S29—15 are vitamin K, pantothenic acid, biotin, sodium, chloride, potassium, manganese, selenium and copper. The nutrients listed as optional for follow-up formula are taurine, total nucleotides, docosahexaenoic acid (DHA), choline, myo-inositol and L-carnitine, as well as L (+) lactic acid-producing cultures.

In considering the purpose of young child formula and nutrient requirements in the 1–3 year age group, FSANZ has not identified any evidence for the including additional nutrients (or other substances) to those discussed in sections 3 and 4 of this report to young child formula. It is considered that children would consume sufficient amounts of these nutrients from a diverse diet.

2.2.3.1 Pre-market assessment for nutritive substances

Paragraph 1.1.1—10(6)(b) of the Code requires that, unless expressly permitted, a food for sale must not have as an ingredient or component a substance that was used as a nutritive substance (as defined in section 1.1.2—12). This requirement will apply to the regulation of young child formula, and pre-market assessment will be required for any nutritive substances not expressly permitted.

Several ingredients have received pre-market assessment for use in ‘toddler formulas’, with express permission granted for FSFYC. P1066 will consider the appropriateness of including a permission for that nutritive substance in young child formula (see section 4.9 of this report).

Based on existing regulatory requirements FSANZ proposes to not permit other nutrients (or substances) to be added to young child formula, where assessment has not identified a requirement, for the following reasons:

- Young child formula is not intended as a sole source of nutrition. It should not replicate the composition of infant formula products.
- The remaining nutrients permitted in CXS 156-1987 have not been identified to be required in a supplementary product, based on nutrient needs of 1–3 year olds.

3 Mandatory composition

3.1 Energy

Standard 2.9.3 requires that FSFYC must contain no less than 330 kJ/serve and does not specify a maximum energy level. Similarly, CXS 156-1987 lists energy as a mandatory nutrient and prescribes an energy density range of 251–293 kJ/100 mL. When converted to a 250 mL serve (consistent with the approach taken in the nutrition risk assessment), requirements in Standard 2.9.3 equate to 330 kJ/250 mL, and the range for Codex is 628–732 kJ/250 mL.

In establishing Standard 2.9.3, it was considered necessary to set a minimum energy requirement to ensure an appropriate macronutrient profile, while establishing a maximum was not required based on existing regulatory frameworks. In comparison, CXS 156-1987 specifies an energy density range to ensure the product has a nutritionally appropriate energy density profile. This range was set in alignment with the energy density of whole cow's milk and is consistent with the energy requirements for infant formula products in both Codex and Standard 2.9.1. The range also supports appropriate macronutrient and micronutrient profiles within a nutritionally appropriate energy density range (CCNFSDU 2016).

As discussed in section 1.3 of this report, FSANZ considers that young child formula is a supplementary food that is only intended to be consumed in situations where nutrient intakes are inadequate. As per the policy context in Australia and New Zealand, whole cow's milk is considered the reference product for young child formula. FSANZ considers that an energy density that aligns with the energy density of whole cow's milk is appropriate to meet the nutritional purpose of the product. Further, when modelling for a 250 mL serve size in line with domestic dietary guidance, the nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum levels would pose a low risk of both inadequate and excessive energy intake among the target population.

FSANZ's 2025/26 Market Survey found that the energy content in young child formula available in Australia and New Zealand ranges from 238–313 kJ/100 mL, with energy declared on 100% of products. This indicates that some products on the domestic market fall below the Codex minimum, while others exceed the upper end of the Codex range.

Adopting the Codex range technically increases regulations for energy, as there is currently no maximum energy prescribed for FSFYC. While this would require recipe adjustment and product reformulation, FSANZ considers these adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies, particularly given alignment with energy requirements for infant formula products in Standard 2.9.1. From a public health perspective, the introduction of a maximum amount has the potential to deliver benefits, given the well documented impact of excessive energy intake

across all population groups.

Further, alignment of the CXS 156-1987 minimum energy level would be deregulatory, as the Codex minimum is lower than the minimum energy requirement currently listed in the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require energy to be prescribed as a mandatory compositional requirement for young child formula
- Prescribe a minimum level of 251 kJ/100 mL
- Prescribe a maximum level of 293 kJ/100 mL.

3.2 Protein

Standard 2.9.3 requires that FSFYC must contain protein at no less than 2.5 grams serve (equivalent to 0.76 g/100 kJ). Similarly, CXS 156-1987 lists protein as a mandatory nutrient and requires a minimum level of 0.43 g/100 kJ. Neither standard specifies a maximum protein level.

In establishing both Standard 2.9.3 and CXS 156-1987, it was considered necessary to set a minimum protein amount to ensure an appropriate macronutrient profile. The minimum amount listed in the Code is set at approximately 20% higher than the protein in whole cow's milk based on a principle that a supplementary food should offer more in key macronutrients than similar, unmodified foods (ANZFA 1999b). In contrast, the minimum listed in CXS 156-1987 corresponds to the lower end of the protein content naturally present in cow's milk (CCNFSDU 2016).

As discussed in section 1.3 of this report, FSANZ considers that young child formula is a supplementary food that is only intended to be consumed in situations where nutrient intakes are inadequate. As per the policy context in Australia and New Zealand, whole cow's milk is considered the reference product for young child formula. FSANZ considers that a minimum protein level aligned with the lower end of the protein content of cow's milk is appropriate to meet the nutritional purpose of the product. Further, FSANZ's nutrition risk assessment concluded that the risk of inadequate protein intake is considered low if the Codex minimum amount was adopted.

Additionally, FSANZ's 2025/26 Market Survey found that protein content in young child formula available in Australia and New Zealand ranges from 0.43–1.29 g/100 kJ, with protein declared on 100% of products. This indicates that the domestic market aligns with the minimum level listed in CXS 156-1987. Therefore, adopting this standard would be deregulatory, and the effect on the domestic market would be minimal.

FSANZ considers that there is low risk associated with not setting a maximum protein level as the protein content in young child formula is inherently controlled by compositional constraints, such as the proposed maximum energy amount. Further, the nutrition risk assessment concluded that not setting a maximum level of protein in alignment with CXS 156-1987 poses a low risk of excessive intake.

In lieu of a maximum protein limit, Codex CXS 156-1987 manages protein quality through the Protein Digestibility Corrected Amino Acid Score (PDCAAS). Similarly, Standard 2.9.1 prescribes individual minimum amino acid requirements for infant formula products based on the amino acid composition of breast milk. These approaches represent stringent protein

quality controls appropriate for products intended to be consumed as a sole or primary source of nutrition. FSANZ considers that these requirements are not proportionate for young child formula given the product is intended to be consumed as a supplementary product as part of a varied diet rather than as a sole source of nutrition.

However, noting the risks recently explored for infant formula products in Proposal P1028 regarding new and novel protein sources (FSANZ 2023a), FSANZ does consider there to be merit in establishing protein sources for young child formula. P1028 concluded that only permitted protein sources could be used in the manufacture of infant formula products to mitigate potential safety risks associated with new proteins that have not been approved through the pre-market assessment process. The protein sources permitted for use in infant formula products were identified as being complete protein sources for human infants. As a similarly vulnerable population group, FSANZ considers that these conclusions are applicable for young children.

Based on the assessments completed in P1028, and in alignment with Code permissions listed in Standard 2.9.1 for infant formula products, FSANZ proposes to prescribe the protein sources for young child formula as cow milk, goat milk, sheep milk, soy protein isolate, and a partially hydrolysed protein of one or more of these.

FSANZ's 2025/26 Market Survey found that protein sources of young child formula available in Australia and New Zealand include predominantly cow milk, with goat and sheep milk products available. Plant-based protein sources include soy, pea, rice and oat milks. While the proposed approach would require recipe adjustment and product reformulation in some cases, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from optimisation of recipe reformulation based on the assumption that young child formula and infant formula products are typically manufactured from the same base milk powders.

From a public health perspective, prescribing protein sources ensures that the protein used in young child formula is nutritionally adequate and safe for vulnerable consumers. While this approach differs from CXS 156-1987, which manages protein quality through PDCAAS, these differences reflect the variances in product definition, and the regulatory contexts and purposes of the Codex standard as a guidance document and the Code as a legislative instrument. However, both the protein quality requirements in CXS 156-1987 and the proposed permitted protein sources for young child formula operate to prevent the use of novel or low-quality proteins. Manufacturers may apply for permission to amend the Code to add other mammalian or plant-based protein sources to young child formula through the pre-market assessment process.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require protein as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.43 g/100 kJ
- Not prescribe a maximum level
- Require young child formula must be derived from one or more of cow milk, goat milk, sheep milk, soy protein isolate, or a partially hydrolysed protein of one or more of these.

3.3 Total fat

Standard 2.9.3 does not prescribe any compositional limits for total fat in FSFYC. In contrast, CXS 156-1987 lists the total fat as a mandatory nutrient and requires a minimum level of

0.84 g/100 kJ.

In establishing Standard 2.9.3, it was not considered appropriate to restrict the fat content due to the varied purpose and intended consumers of products categorised as FSFYC (ANZFA 1999a). In contrast, a minimum fat amount was established for CXS 156-1987 to ensure an appropriate macronutrient profile. The minimum listed in CXS 156-1987 corresponds to the usual fat content in reduced fat cow's milk (CCNFSDU 2017).

As discussed in section 1.3 of this report, FSANZ considers that young child formula is a supplementary food that is only intended to be consumed in situations where nutrient intakes are inadequate. As per the policy context in Australia and New Zealand, whole cow's milk is considered the reference product for young child formula, with the consumption of reduced fat milk not recommended before 24 months. However, FSANZ's nutrition risk assessment concluded that the adoption of the CXS 156-1987 minimum would pose a low risk of inadequate fat intake among the target population. Further, setting a minimum below the reference product allows for formulation flexibility given the differences in total fat requirements within the 1–3 year age group.

FSANZ's 2025/26 Market Survey found that fat content in young child formula available in Australia and New Zealand ranges from 0.66 – 1.31 g/100 kJ, with fat declared on 100% of products. This indicates that only the upper end of the domestic market aligns with the CXS 156-1987 minimum.

Adopting the Codex minimum technically increases regulations for total fat, as there are currently no fat requirements prescribed in the Code for FSFYC. While this would result in an effect on the domestic market, require recipe adjustment and product reformulation, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing a minimum total fat level in young child formula has the potential to deliver benefits associated with ensuring young child formula provides sufficient amounts of fat in line with Australian and New Zealand dietary guidance. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

FSANZ considers there is low risk associated with not setting a maximum fat level as the fat content in young child formula is inherently controlled by compositional constraints, such as the proposed maximum energy amount. Further, the nutrition risk assessment concluded that not setting a maximum limit of total fat in alignment with CXS 156-1987 poses a low risk of excessive intake.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require fat as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.84 g/100 kJ
- Not set a maximum total fat level.

3.4 α-Linolenic Acid

Standard 2.9.3 does not prescribe any compositional limits for α-linolenic acid in FSFYC. In

contrast, CXS 156-1987 lists α-linolenic acid as a mandatory nutrient and requires a minimum level of 12 mg/100 kJ.

As described in section 3.3 of this report, in establishing Standard 2.9.3, it was not considered appropriate to restrict the fat content of FSFYC, and similarly, requirements for fatty acids were not set. In contrast, the mandatory addition of α-linolenic acid was established for CXS 156-1987 based on establishing compositional requirements for essential fatty acids. Further, α-linolenic acid was identified to be limited in the diets of young children.

FSANZ considers it important to establish fatty acid requirements in alignment with CXS 156-1987 to support the nutritional quality of fats used in young child formula by ensuring it provides an appropriate fatty acid profile, including essential fatty acids. As α-linolenic acid cannot be synthesised by the body, NRV have been established for its intake, supporting its inclusion in a supplementary product. Consistent with the role of young child formula as a supplementary product intended to be consumed when nutrient intakes are inadequate, the level in CXS 156-1987 is higher than the level typically found in cow's milk. FSANZ's nutrition risk assessment concluded that the adoption of the CXS 156-1987 minimum would pose a low risk of inadequate α-linolenic acid intake among the target population.

FSANZ's 2025/26 Market Survey found that α-linolenic acid content in young child formula available in Australia and New Zealand ranges from 5–136 mg/100 kJ, with α-linolenic acid declared on 76% of products. This indicates that the lower end of the domestic market does not align with the CXS 156-1987 minimum level.

Adopting the Codex minimum technically increases regulations for α-linolenic acid, as there are currently no α-linolenic acid requirements prescribed in the Code for FSFYC. While this would have an impact on the domestic market, require recipe adjustment and product reformulation, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing a minimum α-linolenic acid level in young child formula has the potential to deliver benefits associated the nature of α-linolenic acid being an essential fatty acid. This will ensure young child formula provides sufficient amounts of α-linolenic acid in line with Australian and New Zealand dietary guidance. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children, with the minimum set above the average amount present in cow's milk to reflect the fortified nature of the product

FSANZ considers that there is low risk associated with not setting a maximum α-linolenic acid level, based on α-linolenic acid being a component of total fat, which is inherently controlled by compositional constraints, such as the proposed maximum energy amount. Further, the nutrition risk assessment concluded that not setting a maximum limit of α-linolenic acid in alignment with CXS 156-1987 poses a low risk of excessive intake.

FSANZ acknowledges that in infant formula products, a similarly formulated and fortified food, there is a ratio between α-linolenic acid and linoleic acid. This requirement is also listed in Section A of CXS 156-1987 for the composition of follow-up formula for older infants and ensures the balance of fatty acids. FSANZ considers that this ratio is not needed for young child formula as this product is not intended to be a sole source of nutrition, so does not require as much extensive composition as infant formula products. Further, when young child formula is not consumed as the sole source of nutrition, the α-linolenic acid:linoleic acid ratio in the total diet cannot be controlled through the composition of young child formula alone.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require α-linolenic acid as a mandatory nutrient in young child formula
- Prescribe a minimum level of 12 mg/100 kJ
- Not set a maximum α-linolenic acid level.

3.5 Linoleic acid

Standard 2.9.3 does not prescribe any compositional limits for linoleic acid in FSFYC. In contrast, CXS 156-1987 lists linoleic acid as a mandatory nutrient and requires a minimum level of 72 mg/100 kJ.

As described in section 3.3 of this report, in establishing Standard 2.9.3, it was not considered appropriate to restrict the fat content of FSFYC, and similarly, requirements for fatty acids were not set. In contrast, the mandatory addition of linoleic acid was established for CXS 156-1987 based on establishing compositional requirements for essential fatty acids.

As discussed in section 3.4, FSANZ considers it important to establish fatty acid requirements in alignment with CXS 156-1987 to support the nutritional quality of fats used in young child formula by ensuring it provides an appropriate fatty acid profile, including essential fatty acids. As linoleic acid cannot be synthesised by the body, NRV have been established for its intake, supporting its inclusion in a supplementary product. Consistent with the role of young child formula as a supplementary product intended to be consumed when nutrient intakes are inadequate, the level in CXS 156-1987 is higher than the level typically found in cow's milk. FSANZ's nutrition risk assessment concluded that the adoption of the CXS 156-1987 minimum would pose a low risk of inadequate linoleic acid intake among the target population.

FSANZ's 2025/26 Market Survey found that linoleic acid content in young child formula available in Australia and New Zealand ranges from 16–268 mg/100 kJ, with linoleic acid declared on 13% of products. This indicates that the lower end of the domestic market falls below the CXS 156-1987 minimum level.

Adopting the Codex minimum technically increases regulations for linoleic acid, as there is currently no linoleic acid requirements prescribed in the Code for FSFYC. Based on the low levels of young child formula on the domestic market that currently include this nutrient, adopting the Codex minimum would have an impact on the domestic market. FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing a minimum linoleic acid level in young child formula has the potential to deliver benefits associated with the nature of linoleic acid being an essential fatty acid. This will ensure young child formula provides sufficient amounts of linoleic acid in line with Australian and New Zealand dietary guidance. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children, with the minimum set above the average amount present in cow's milk to reflect the fortified nature of the product.

FSANZ considers that there is low risk associated with not setting a maximum linoleic acid

level, based on linoleic acid being a component of total fat, which is inherently controlled by compositional constraints, such as the proposed maximum energy amount. Further, the nutrition risk assessment concluded that not setting a maximum limit of linoleic acid in alignment with CXS 156-1987 poses a low risk of excessive intake.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require linoleic acid as a mandatory nutrient in young child formula
- Prescribe a minimum level of 72 mg/100 kJ
- Not set a maximum linoleic acid level.

3.6 Available carbohydrates

Standard 2.9.3 does not prescribe any compositional limits for carbohydrates in FSFYC. In contrast, CXS 156-1987 lists the carbohydrates as a mandatory nutrient and requires a maximum level of 3.0 g/100 kJ.

In establishing Standard 2.9.3, setting carbohydrate requirements was not considered. However, it was noted that it was not necessary to establish dietary fibre requirements, as the supplementary product would not replace the total diet (ANZFA 1999a). Similarly, no minimum was established for CXS 156-1987 based on carbohydrates not being limited in the general diet. However, a maximum was considered appropriate to limit the addition of free sugar and was set at a level that incorporates the average level of carbohydrates in cow's milk (CCNFSDU 2017).

As discussed in section 1.3 of this report, FSANZ considers that young child formula is a supplementary food that is only intended to be consumed in situations where nutrient intakes are inadequate. The energy needs and intakes of carbohydrates for young children are achieved by a diversified diet. Further, FSANZ's nutrition risk assessment concluded that the adoption of the CXS 156-1987 maximum would pose a low risk of inadequate carbohydrate intake among the target population. As such, based on the low risk to public health, FSANZ does not consider it necessary to set a minimum carbohydrate level for young child formula.

FSANZ's 2025/26 Market Survey found that carbohydrates content in young child formula available in Australia and New Zealand ranges from 1.85–3.65 g/100 kJ, with carbohydrates declared on 100% of products. This indicates that only the upper end of the domestic market exceeds the CXS 156-1987 maximum. Therefore, while adopting this standard would increase regulations, in practice there would be minimal impacts on products or reformulation requirements.

Adopting the Codex maximum technically increases regulations for carbohydrates, as there are currently no carbohydrate requirements prescribed in the Code for FSFYC. While this would require recipe adjustment and product reformulation, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing a maximum carbohydrate level in young child formula has the potential to deliver benefits associated with appropriate sugar intake in line with international and domestic dietary guidance. The World Health Organization recommend that the intake of free sugars is limited to 10% of energy (WHO 2015). Similarly, Australian and New Zealand dietary guidance recommends the limited intake of foods and drinks

containing added sugars. Adopting a maximum would inherently limit the amount of total sugars consumed in a serve of young child formula.

As such, and on the basis of minimum effective regulation, FSANZ does not deem it necessary to set a list of permitted carbohydrate sources. Rather, in alignment with CXS 156-1987, FSANZ considers it appropriate to limit the sugar content of young child formula to that naturally occurring in the milk source. Lactose should be the preferred carbohydrate in young child formula based on the naturally occurring levels in cow's milk, and sucrose and fructose must not be added. Further, as noted in CXS 156-1987, mono- and disaccharides other than lactose should not exceed 0.60 g/100 kJ (no more than 20% of carbohydrates). Restrictions on these carbohydrate sources also relate to reducing the cariogenic risk of these sugars, as described in Proposal P1028 (FSANZ 2023a).

CXS 156-1987 notes that for products based on non-milk protein, carbohydrate sources that have no contribution to sweet taste should be preferred. As noted in section 3.2 of this report, soy protein isolate is proposed as the only plant-based protein source permitted for use in young child formula. FSANZ considers it appropriate to align with this requirement. Section 3.2 also proposes partially hydrolysed proteins as a permitted protein source. In the interest of Code consistency, FSANZ proposes that young child formula manufactured using partially hydrolysed proteins may add fructose and/or sucrose as a carbohydrate source, ensuring that the sum of the fructose and/or sucrose does not exceed 20% of available carbohydrates in the formula. Further, the restriction on the addition of fructose and/or sucrose would not apply to the presence of these sugars that are the result of the addition of inulin-type fructans (ITF) or processing aids in young child formula.

In this context, the carbohydrate source refers to available carbohydrates that are a primary energy source for young child formula. While the definition of *available carbohydrates* provided at Standard 1.1.2—2(3) in the Code includes both total available sugars and available oligosaccharides, references to the source of carbohydrate are not intended to capture oligosaccharides or other carbohydrates that may have physiological functions other than as an energy source. The definition of *available carbohydrates* in the Code would apply to the regulation of young child formula and incorporate any permitted non-digestible carbohydrates. See section 4.9.2 of this report for discussion of the oligosaccharides proposed for addition to young child formula.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and the overarching principles of the regulatory framework, FSANZ proposes to:

- Require available carbohydrates as a mandatory nutrient in young child formula
- Not set a minimum level for available carbohydrates
- Prescribe a maximum level of 3.0 g/100 kJ
- Not prescribe carbohydrate sources for young child formula, but note lactose is the preferred sugar and restrict the addition of fructose and/or sucrose.

3.7 Vitamin A

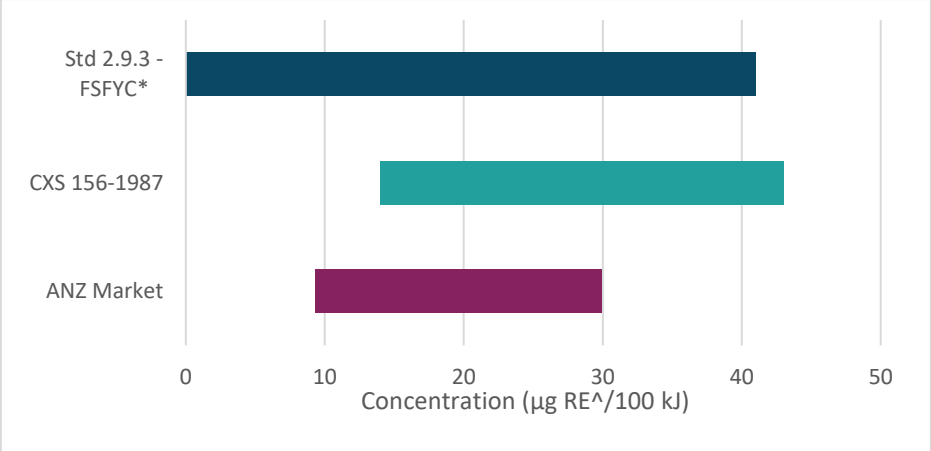

Figure 2: Comparison of Vitamin A regulatory requirements and market levels
*The Code does not prescribe a minimum amount of vitamin A for FSFYC.
^Expressed as retinol equivalents (RE).

As per Figure 2, Standard 2.9.3 permits FSFYC to contain vitamin A at no more than 135 µg/serve (equivalent to 41 µg RE/100 kJ), representing 45% of the RDI. A maximum claimable amount is also listed as 105 µg/serve (35% of the RDI). In contrast, CXS 156-1987 identifies vitamin A as an essential nutrient and prescribes a compositional range of 14–43 µg RE/100 kJ.

FSANZ's 2025/26 Market Survey found that vitamin A content in young child formula available in Australia and New Zealand ranges from 9.34–29.9 µg RE/100 kJ (Figure 2), with vitamin A declared on 98% of products. This indicates that the domestic market sits below the CXS 156-1987 minimum but aligns with both the maximum and the current permission in Standard 2.9.3.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum level would pose a low risk of inadequate vitamin A intake among the target population. Adopting the Codex minimum technically increases regulations for vitamin A, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level mostly accounts for the levels on the domestic market, in practice there would be minimal impacts on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing vitamin A as a mandatory nutrient in young child formula has the potential to deliver benefits, given that vitamin A has been identified globally as a nutrient of concern for the target population. As the purpose of young child formula is as a supplementary product for use where usual dietary intakes of specific nutrients may be inadequate, it is important that its composition reflects the nutrient needs of 1–3 year olds. Based on the importance of young child formula in achieving a supplementary role for nutrients with inadequate intake, FSANZ considers that requiring vitamin A is justified. Additionally, adopting the Codex minimum ensures that young child formula appropriately contributes levels of vitamin A, with the minimum comparable to levels in cow's milk.

Adopting the CXS 156-1987 maximum for vitamin A in young child formula would result in a decrease in regulation, as the current Code requirement is lower than the Codex maximum, with levels present in the domestic market already within the proposed maximum level. FSANZ's nutrition risk assessment concluded that, at typical consumption levels, the risk of

excessive vitamin A intake under the CXS 156-1987 maximum is low, but that exceedances may occur under chronic high consumption scenarios. However, as noted in the nutrition assessment, FSANZ considers the UL for vitamin A for 1–3 year olds to be conservative due to it being extrapolated from adult data. In addition, the modelled exceedances are likely to overstate risk in typical dietary patterns, particularly where higher intakes are not sustained. FSANZ also notes that the modelling assumptions used in the nutrition risk assessment (i.e. total daily intake of up to 750 mL) differ from those applied by Codex in establishing CXS 156-1987, where total daily intakes of up to 500 mL were considered (CCNFSDU 2016).

As described in the proposed regulatory framework for young child formula in the CFS report, young child formula is intended to be consumed under the guidance of a healthcare professional in situations where energy and/or nutrient intakes are inadequate. In this context, multiple serves of young child formula with higher vitamin A content represent a high intake scenario and would typically be accompanied by a diet that is otherwise not rich in vitamin A, which would reduce the likelihood of exceeding the UL. Further, use of young child formula is expected to be for an acute period of time and these products are not intended to be consumed on a long-term basis. In addition, CXS 156-1987 specifies an absolute maximum rather than a GUL for vitamin A, meaning manufacturers would not be able to exceed this limit.

Section S29—15 lists the vitamin A maximum for FSFYC as vitamin A without reference to units of RE or applicable conversion factors. Paragraph 1.1.2—14(3)(a) lists that vitamin A should calculated in terms of RE and, for provitamin A forms of vitamin A, calculated using the RE conversion factors in section S1—4. This indicates that vitamin A requirements in Standard 2.9.3 for FSFYC and those in CXS 156-1987 are in equivalent units.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require vitamin A as a mandatory nutrient in young child formula
- Prescribe a minimum level of 14 µg RE/100 kJ
- Prescribe a maximum level of 43 µg RE/100 kJ.

3.8 Vitamin D

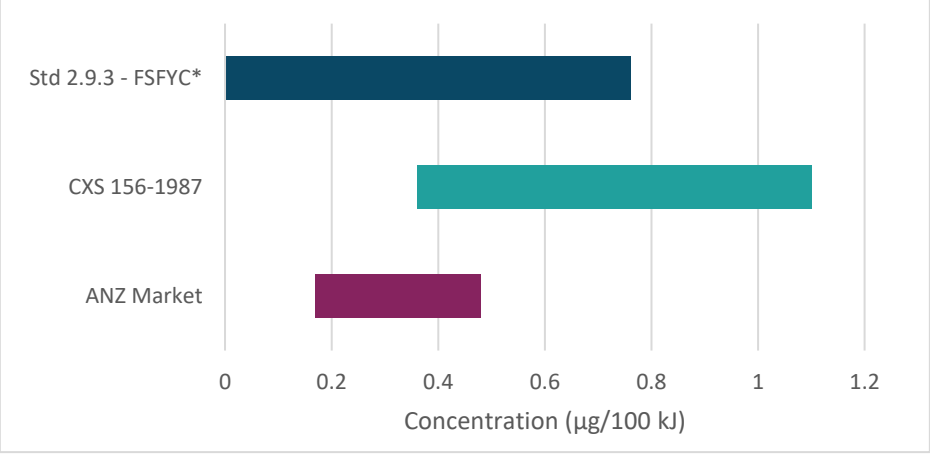

Figure 3: Comparison of Vitamin D regulatory requirements and market levels
*The Code does not prescribe a minimum amount of vitamin D for FSFYC.

As per Figure 3, Standard 2.9.3 permits FSFYC to contain vitamin D at no more than 2.5 µg/serve (equivalent to 0.76 µg/100 kJ), representing 50% of the RDI. The same amount is

specified as the maximum claimable amount. In contrast, CXS 156-1987 identifies vitamin D as an essential nutrient and prescribes a compositional range of 0.36–1.1 µg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum levels would pose a low risk of both inadequate and excessive vitamin D intake among the target population.

FSANZ's 2025/26 Market Survey found that vitamin D content in young child formula available in Australia and New Zealand ranges from 0.17–0.48 µg/100 kJ (Figure 3), with vitamin D declared on 98% of products. This indicates that the domestic market currently aligns with the lower end of the CXS 156-1987 range, despite greater overlap between Standard 2.9.3 and CXS 156-1987 at the higher end of their respective requirements. Interestingly, the range present in young child formula is reflective of the vitamin D levels prescribed for infant formula by the Code (0.24–0.63 µg/100 kJ).

Adopting the Codex range technically increases regulations for vitamin D, as there is currently no minimum prescribed. While this would require recipe adjustment and product reformulation, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing vitamin D as a mandatory nutrient in young child formula has the potential to deliver benefits, given the well documented prevalence of vitamin D insufficiency among young children, including in countries with high sunlight exposure (NHMRC and MoH 2006; CCNFSDU 2016). Vitamin D also enhances the absorption of dietary calcium, another nutrient of concern for this age group (NHMRC and MoH 2006). Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children, with the minimum set above the average amount present in cow's milk to reflect the fortified nature of the product.

FSANZ also considers it to be appropriate for young child formula to align with the compositional range prescribed by CXS 156-1987, as it was intentionally set for the vulnerable population and product type at hand. Further, alignment of the CXS 156-1987 maximum amount would be deregulatory, as the maximum level of vitamin D in Codex is higher than the maximum listed in the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require vitamin D as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.36 µg/100 kJ
- Prescribe a maximum level of 1.1 µg/100 kJ.

3.9 Riboflavin

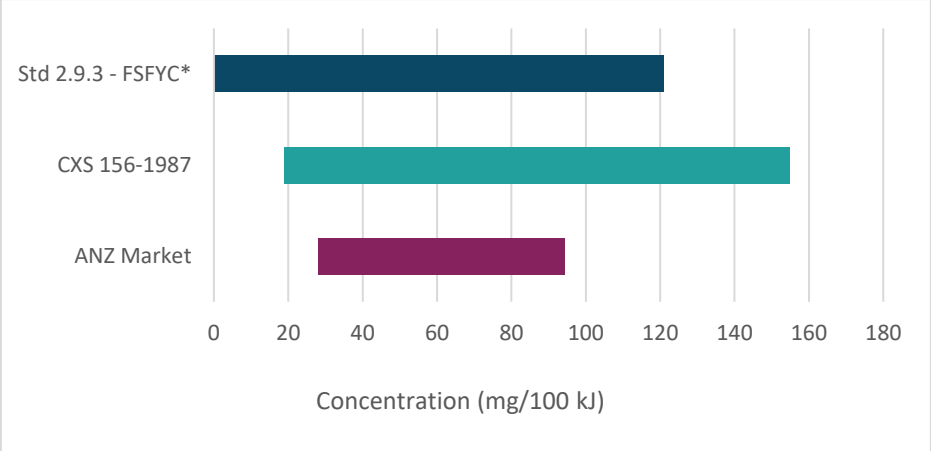

Figure 4: Comparison of Riboflavin regulatory requirements and market levels
*The Code does not prescribe a minimum amount of riboflavin for FSFYC.

As per Figure 4, Standard 2.9.3 permits FSFYC to contain riboflavin at a maximum claimable amount of no more than 0.4 mg/serve (equivalent to 121 µg/100 kJ), representing 50% of the RDI. In contrast, CXS 156-1987 identifies riboflavin as an essential nutrient and prescribes a compositional range of 19–155 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum levels would pose a low risk of both inadequate and excessive riboflavin intake among the target population.

FSANZ's 2025/26 Market Survey found that riboflavin content in young child formula available in Australia and New Zealand ranges from 28–94 µg/100 kJ (Figure 4), with riboflavin declared on 95% of products. This indicates that the domestic market aligns with the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex minimum technically increases regulations for riboflavin, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing riboflavin as a mandatory nutrient in young child formula has the potential to deliver benefits. As the purpose of young child formula is as a supplementary product to be consumed in place of cow's milk, it is important that young child formula provides a significant contribution of the key nutrients from cow's milk. Given the well documented contribution of riboflavin from cow's milk, FSANZ considers that requiring this nutrient is justified. Additionally, adopting the Codex minimum ensures that young child formula appropriately contributes levels of riboflavin, with the minimum set to accommodate levels in cow's milk.

CXS 156-1987 prescribes a GUL for riboflavin. As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As there is no UL set for riboflavin in the NRV for Australia and New Zealand and no adverse effects have been identified from usual dietary intakes from food, regulation of the riboflavin maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require riboflavin as a mandatory nutrient in young child formula
- Prescribe a minimum level of 19 µg/100 kJ
- Prescribe a GUL of 155 µg/100 kJ.

3.10 Vitamin B_{12}

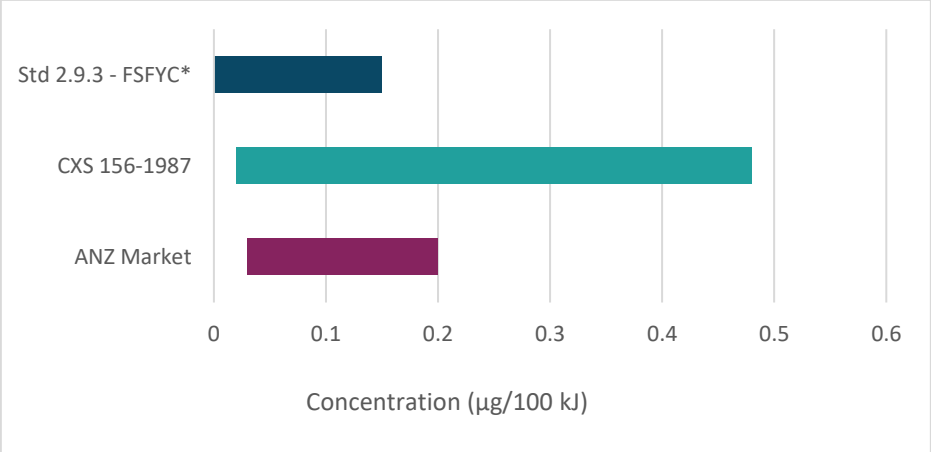

Figure 5: Comparison of Vitamin B_{12} regulatory requirements and market levels
*The Code does not prescribe a minimum amount of vitamin B_{12} for FSFYC.

As per Figure 5, Standard 2.9.3 permits FSFYC to contain vitamin B_{12} at a maximum claimable amount of no more than 0.5 µg /serve (equivalent to 0.15 µg/100 kJ), representing 50% of the RDI. In contrast, CXS 156-1987 identifies vitamin B_{12} as an essential nutrient and prescribes a compositional range of 0.02–0.48 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum levels would pose a low risk of both inadequate and excessive vitamin B_{12} intake among the target population.

FSANZ's 2025/26 Market Survey found that vitamin B_{12} content in young child formula available in Australia and New Zealand ranges from 0.03–0.2 µg/100 kJ (Figure 5), with vitamin B_{12} declared on 98% of products. This indicates that the domestic market aligns with the CXS 156-1987 range but exceeds the current permission in Standard 2.9.3.

Adopting the Codex minimum technically increases regulations for vitamin B_{12}, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing vitamin B_{12} as a mandatory nutrient in young child formula has the potential to deliver benefits. As the purpose of young child formula is as a supplementary product to be consumed in place of cow's milk, it is important that young child formula provides a significant contribution of the key nutrients from cow's milk. Given the well documented contribution of vitamin B_{12} from cow's milk, FSANZ considers that requiring this nutrient is justified. Additionally, adopting the Codex minimum ensures that young child formula appropriately contributes levels of vitamin B_{12}, with the minimum set to

accommodate levels in cow's milk.

CXS 156-1987 prescribes a GUL for vitamin B_{12}, which represents the upper range of variable amounts of vitamin B_{12} in cow's milk, and allows for potential for shelf life losses (CCNFSDU 2016). As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As there is no UL set for vitamin B_{12} in the NRV for Australia and New Zealand and no adverse effects have been identified from usual dietary intakes from food, regulation of the vitamin B_{12} maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require vitamin B_{12} as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.02 µg/100 kJ
- Prescribe a GUL of 0.48 µg/100 kJ.

3.11 Iron

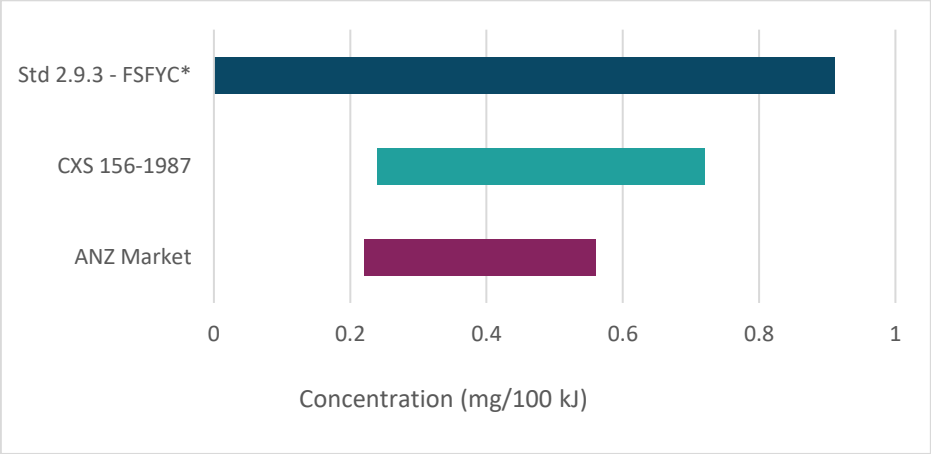

Figure 6: Comparison of Iron regulatory requirements and market levels
*The Code does not prescribe a minimum amount of iron for FSFYC.

As per Figure 6, Standard 2.9.3 permits FSFYC to contain iron a maximum claimable amount of no more than 3.0 mg/serve (equivalent to 0.91 mg/100 kJ), representing 50% of the RDI. In contrast, CXS 156-1987 identifies iron as an essential nutrient and prescribes a compositional range of 0.24–0.72 mg/100 kJ. CXS 156-1987 also requires a minimum amount of 0.36 mg/100 kJ applies for products for young children that are based on soy protein isolate.

FSANZ's nutrition risk assessment found that each modelled iron scenario of both the Standard 2.9.3 maximum claimable amount and the Codex maximum fell below the UL. It was concluded that the risk of excessive iron intake from consumption of young child formula is considered low if FSANZ adopted the Codex maximum (0.72 mg/100 kJ) or retained the Standard 2.9.3 maximum (equivalent to 0.91 mg/100 kJ). Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive iron intake among the target population.

The nutrition risk assessment concluded that adopting the CXS 156-1987 minimum iron level for products based on soy protein isolate would pose a low risk of inadequate iron intake

among the target population. As noted in section 3.2 of this report, soy protein isolate is proposed as the only plant-based protein source permitted for use in young child formula. With consideration of the lower bioavailability of iron from plant-based sources, FSANZ considers it appropriate to adopt this minimum level for young child formula based on soy protein isolate.

FSANZ's 2025/26 Market Survey found that iron content in young child formula available in Australia and New Zealand ranges from 0.22–0.56 mg/100 kJ (Figure 6), with iron declared on 100% of products. This indicates that the domestic market aligns with both the current permission in Standard 2.9.3 and the CXS 156-1987 maximum but is slightly lower than the minimum amount.

Adopting the Codex minimum technically increases regulations for iron, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level mostly accounts for the levels on the domestic market, in practice there would be minimal impacts on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing iron as a mandatory nutrient in young child formula has the potential to deliver benefits, based on the well documented prevalence of iron insufficiency among young children (CCNFSDU 2016). As the purpose of young child formula is as a supplementary product for use where usual dietary intakes of specific nutrients may be inadequate, it is important that its composition reflects the nutrient needs of 1–3 year olds. Based on the importance of young child formula in achieving a supplementary role for nutrients with inadequate intake, FSANZ considers that requiring iron is justified. Additionally, adopting the Codex minimum helps ensure young child formula provides a meaningful contribution to iron intake, noting that cow's milk is not a good source of iron.

Adopting the CXS 156-1987 maximum for young child formula would result in an increase in regulation based on the Codex maximum being lower than current requirements for FSFYC in the Code. However, levels present in the domestic market are already within the maximum level and impacts on reformulation requirements are not anticipated. The range in CXS 156-1987 represents amounts at which fortification has been demonstrated to improve the iron status of young children and also allows for higher levels of fortification in situations that require higher intakes. Codex also set a maximum level to manage the potential impact of excessive iron intakes on the absorption of zinc and copper. By contrast, the maximum claimable amount listed in Standard 2.9.3 is based on 50% of the RDI for 1–3 year olds. FSANZ therefore considers that setting a maximum amount that was established due to minimising risk of adverse nutrient interactions is more fit for purpose than a maximum derived from an RDI based labelling claim. For these reasons, and consistent with FSANZ's preference for international alignment, FSANZ considers it appropriate to adopt the CXS 156-1987 maximum level.

Based on the conclusions of the nutrition risk assessment, consideration of the domestic market and age appropriate nutritional requirements, FSANZ proposes to:

- Require iron as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.24 mg/100 kJ and maximum of 0.72 mg/100 kJ for young child formula based on mammalian protein sources
- Prescribe a minimum level of 0.36 mg/100 kJ and maximum of 0.72 mg/100 kJ for young child formula based on soy protein isolate.

3.12 Vitamin C

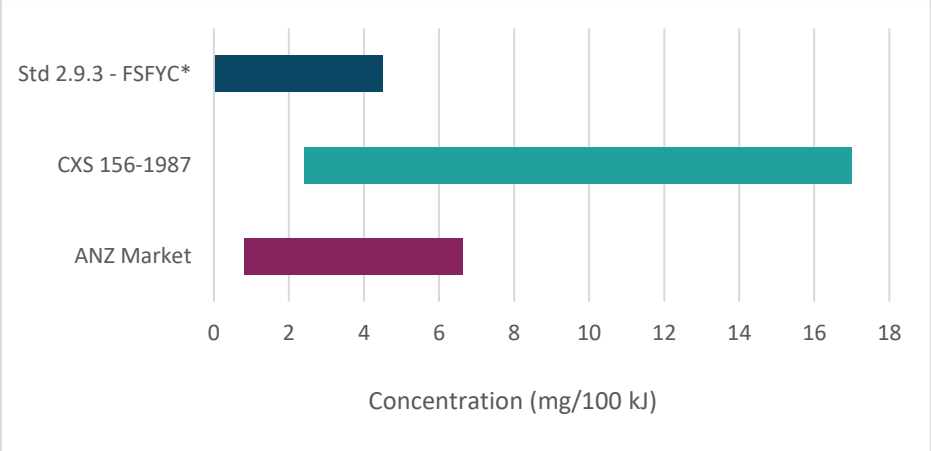

Figure 7: Comparison of Vitamin C regulatory requirements and market levels
*The Code does not prescribe a minimum amount of vitamin C for FSFYC.

As per Figure 7, Standard 2.9.3 permits FSFYC to contain vitamin C at a maximum claimable amount of no more than 15 mg/serve (equivalent to 4.5 mg/100 kJ), representing 50% of the RDI. In contrast, CXS 156-1987 identifies vitamin C as an essential nutrient and prescribes a compositional range of 2.4–17 (GUL) mg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum levels would pose a low risk of both inadequate and excessive Vitamin C intake among the target population.

FSANZ's 2025/26 Market Survey found that vitamin C content in young child formula available in Australia and New Zealand ranges from 0.82–6.64 mg/100 kJ (Figure 7), with vitamin C declared on 100% of products. This indicates that the domestic market currently aligns with the lower end of the CXS 156-1987 range, but some products sit below the minimum.

Adopting the Codex range technically increases regulations for vitamin C, as there is currently no minimum prescribed. While this would require recipe adjustment and product reformulation, FSANZ considers these one-off adjustments are outweighed by the long-term benefits for both industry and public health. Industry will benefit from international harmonisation, optimisation of recipe formulation and overall manufacturing efficiencies.

From a public health perspective, establishing vitamin C as a mandatory nutrient in young child formula has the potential to deliver benefits, based the role of vitamin C in enhancing the absorption of iron. As discussed in section 3.11 of this report, iron intake is noted to be inadequate in the target population. As the purpose of young child formula is as a supplementary product for use where usual dietary intakes of specific nutrients may be inadequate, it is important that its composition reflects the nutrient needs of 1–3 year olds. Based on the importance of young child formula in achieving a supplementary role for nutrients with inadequate intake, and the functionality of vitamin C enhancing the absorption of iron, FSANZ considers that requiring vitamin C is justified. Additionally, adopting the Codex minimum helps ensure young child formula provides a meaningful contribution to vitamin C intake, noting that cow's milk is not a good source of vitamin C.

CXS 156-1987 prescribes a GUL for vitamin C, which has been set in alignment with the GUL listed in Section A for follow-up formula. A footnote in Section A states that 'this GUL has been set to account for possible high losses over shelf-life in liquid products; for

powdered products lower upper levels should be aimed for'. As noted in Proposal P1028, an estimated vitamin C loss of 20–50% in powdered products and up to 75% in liquid products can occur before the product is consumed based on losses that can occur during shelf life and preparation (FSANZ 2021). While P1028 considered infant formula products, young child formula is a similarly formulated and fortified product, and similar vitamin C losses may occur. FSANZ's Market Survey did not identify any products that were in a liquid form. However, setting requirements that accommodate liquid formulations supports future product innovation and provides regulatory clarity.

As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. There is no UL set for vitamin C in the NRV for Australia and New Zealand and no adverse effects have been identified from usual dietary intakes from food. On this basis, and considering the potential for shelf life losses, regulation of the vitamin C maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require vitamin C as a mandatory nutrient in young child formula
- Prescribe a minimum level of 2.4 mg/100 kJ
- Prescribe a GUL of 17 mg/100 kJ.

3.13 Calcium

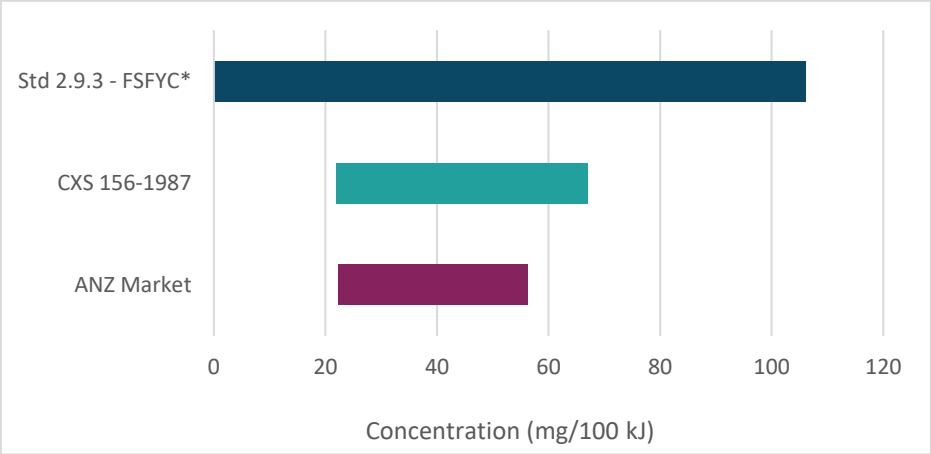

Figure 8: Comparison of Calcium regulatory requirements and market levels

*The Code does not prescribe a minimum amount of calcium for FSFYC.

As per Figure 8, Standard 2.9.3 permits FSFYC to contain calcium at a maximum claimable amount of no more than 350 mg/serve (equivalent to 106 mg/100 kJ), representing 50% of the RDI. In contrast, CXS 156-1987 identifies calcium as an essential nutrient and prescribes a compositional range of 22–67 (GUL) mg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled calcium scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive calcium intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL (67 mg/100 kJ) or retained the Standard 2.9.3 maximum (equivalent to 106 mg/100 kJ). Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive calcium intake among the target population.

FSANZ's 2025/26 Market Survey found that calcium content in young child formula available in Australia and New Zealand ranges from 22–56 mg/100 kJ (Figure 8), with calcium declared on 100% of products. This indicates that the domestic market aligns with both the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex minimum technically increases regulations for calcium, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing calcium as a mandatory nutrient in young child formula has the potential to deliver benefits, based on the significant role of calcium in bone development. As the purpose of young child formula is as a supplementary product to be consumed in place of cow's milk, it is important that young child formula provides a significant contribution of the key nutrients from cow's milk. Given the well documented contribution of calcium from cow's milk, FSANZ considers that requiring this nutrient is justified. Additionally, adopting the Codex minimum ensures that young child formula appropriately contributes levels of calcium, with the minimum set to accommodate levels in cow's milk.

Adopting the CXS 156-1987 maximum for young child formula would result in an increase in regulation due to deceasing the permitted level of calcium. However, levels present in the domestic market are already within the maximum level and impacts on reformulation requirements are not anticipated. The range in CXS 156-1987 reflects the range of calcium naturally occurring in cow's milk, incorporating amounts in both whole and reduced fat milk, aligning with the reference product for young child formula. By contrast, the maximum claimable amount listed in Standard 2.9.3 is based on 50% of the RDI for 1–3 year olds. FSANZ considers that setting a maximum amount in line with the reference product to reflect the supplementary nature of the product is more fit for purpose than a maximum derived from an RDI based labelling claim. For these reasons, and consistent with FSANZ's preference for international alignment, FSANZ considers it appropriate to adopt the CXS 156-1987 maximum as a GUL.

FSANZ acknowledges that in infant formula products, a similarly formulated and fortified powdered food, there is a ratio between calcium:phosphorus. This requirement is also listed in Section A of CXS 156-1987 for the composition of follow-up formula for older infants and ensures adequate mineral balance and bone mineralisation. FSANZ considers that this ratio is not needed for young child formula as this product is not intended to be a sole source of nutrition, so does not require as much extensive composition as infant formula products. Further, phosphorus is not being proposed as a mandatory nutrient (see section 4.8 of this report), and so requiring a ratio would be difficult and setting this regulation would result in regulatory confusion. Further, when young child formula is not consumed as the sole source of nutrition, the calcium:phosphorus ratio in the total diet cannot be controlled through the composition of young child formula alone.

Based on the conclusions of the nutrition risk assessment, consideration of the domestic market and age appropriate nutritional requirements, FSANZ proposes to:

- Require calcium as a mandatory nutrient in young child formula
- Prescribe a minimum level of 22 mg/100 kJ
- Prescribe a GUL of 67 mg/100 kJ.

3.14 Zinc

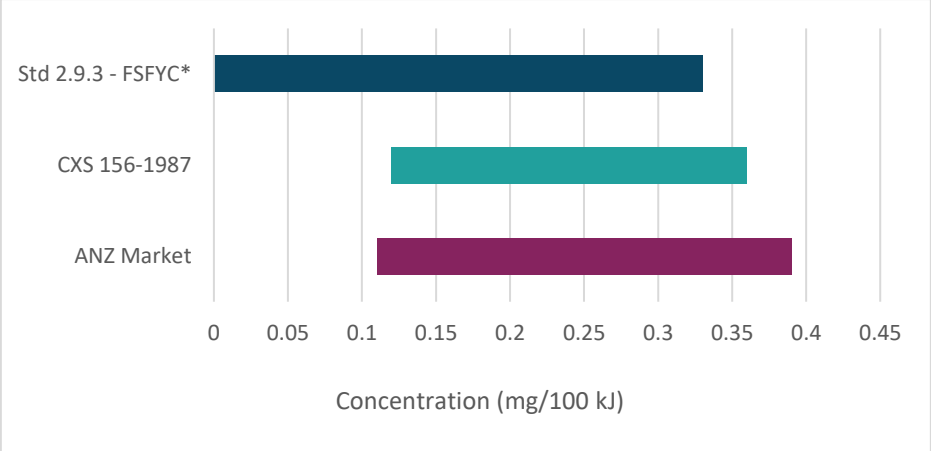

Figure 9: Comparison of Zinc regulatory requirements and market levels
*The Code does not prescribe a minimum amount of zinc for FSFYC.

As per Figure 9, Standard 2.9.3 permits FSFYC to contain zinc a maximum claimable amount of no more than 1.1 mg/serve (equivalent to 0.33 mg/100 kJ), representing 25% of the RDI. In contrast, CXS 156-1987 identifies zinc as an essential nutrient and prescribes a compositional range of 0.12–0.36 (GUL) mg/100 kJ.

FSANZ's 2025/26 Market Survey found that zinc content in young child formula available in Australia and New Zealand ranges from 0.11–0.39 mg/100 kJ (Figure 9), with zinc declared on 100% of products. This indicates that the domestic market exceeds the CXS 156-1987 range and the current permission in Standard 2.9.3.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum level would pose a low risk of inadequate zinc intake among the target population. Adopting the Codex minimum technically increases regulations for zinc, as there currently no minimum prescribed. However, as the minimum CXS 156-1987 level mostly accounts for the levels on the domestic market, in practice there would be minimal impacts on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation.

From a public health perspective, establishing zinc as a mandatory nutrient in young child formula has the potential to deliver benefits, given that zinc has been identified globally as a nutrient of concern for the target population. In addition, since zinc deficiency can negatively affect vitamin A status, another nutrient of global concern, zinc was considered as a mandatory nutrient in the establishment of CXS 156-1987. As the purpose of young child formula is as a supplementary product for use where usual dietary intakes of specific nutrients may be inadequate, it is important that its composition reflects the nutrient needs of 1 - 3 year olds. Based on the importance of young child formula in achieving a supplementary role for nutrients with inadequate intake, FSANZ considers that requiring zinc is justified. Adopting the Codex minimum also ensures that young child formula appropriately contributes levels of zinc, with the minimum set to accommodate levels in cow's milk.

Adopting the CXS 156-1987 GUL for zinc in young child formula would result in a decrease in regulation, as the current Code requirement is lower than the Codex GUL. While the domestic market exceeds this GUL, overages could be due to the natural variation that is allowed with a GUL and may not require reformulation. FSANZ's nutrition risk assessment concluded that, at typical consumption levels, the risk of excessive zinc intake under the CXS 156-1987 GUL is low, but that exceedances may occur under chronic high consumption

scenarios. However, as noted in the nutrition assessment, FSANZ considers the UL for zinc for 1–3 year olds to be conservative due to being extrapolated from adult data, and also incorporates the intake of supplements. In addition, the modelled exceedances are likely to overstate risk in typical dietary patterns, particularly where higher intakes are not sustained. FSANZ also notes that the modelling assumptions used in the nutrition risk assessment (i.e. total daily intake of up to 750 mL) differs from those applied by Codex in establishing CXS 156-1987, where total daily intakes of up to 500 mL were considered (CCNFSDU 2016).

As described in the proposed regulatory framework for young child formula in the CFS report, young child formula is intended to be consumed under the guidance of a healthcare professional in situations where energy and/or nutrient intakes are inadequate. In this context, multiple serves of young child formula with higher zinc content represent a high intake scenario and would typically be accompanied by a diet that is otherwise not rich in zinc, which would reduce the likelihood of exceeding the UL. Further, use of young child formula is expected to be for an acute period of time and these products are not intended to be consumed on a long-term basis.

As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As FSANZ considers the UL for zinc to be conservative based on it incorporating intakes from supplements, and no adverse effects have been identified from usual dietary intakes from food, regulation of the zinc maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Require zinc as a mandatory nutrient in young child formula
- Prescribe a minimum level of 0.12 mg/100 kJ
- Prescribe a GUL of 0.36 mg/100 kJ.

4 Optional composition

4.1 Thiamin

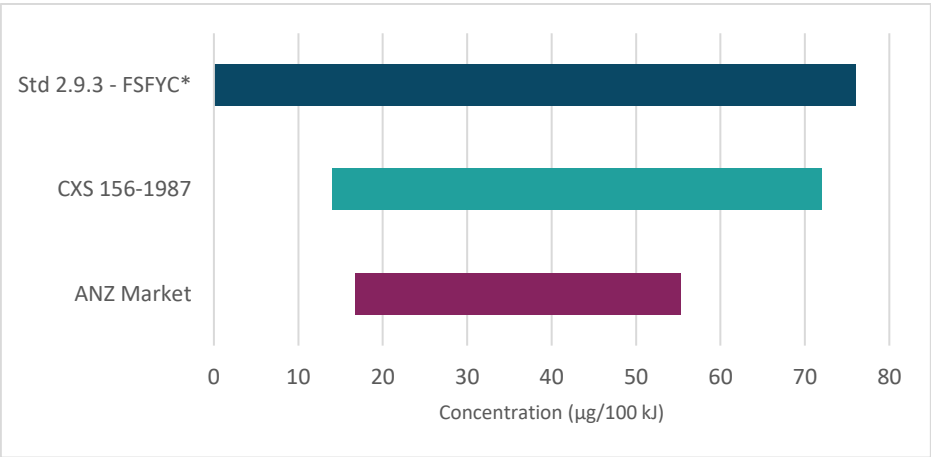

Figure 10: Comparison of Thiamin regulatory requirements and market levels
*The Code does not prescribe a minimum amount of thiamin for FSFYC.

As per Figure 10, Standard 2.9.3 permits FSFYC to contain thiamin at a maximum claimable

amount of no more than 0.25 mg/serve (equivalent to 76 µg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies thiamin as an optional nutrient and prescribes a compositional range of 14–72 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled thiamin scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive thiamin intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL or retained the Standard 2.9.3 maximum claimable amount. Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive thiamin intake among the target population.

FSANZ's 2025/26 Market Survey found that thiamin content in young child formula available in Australia and New Zealand ranges from 17–55 µg/100 kJ (Figure 10), with thiamin declared on 98% of products. This indicates that the domestic market aligns with both the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex range technically increases regulations for thiamin, as there is currently no minimum prescribed. However, as the levels present in the domestic market already fall neatly within the Codex range, FSANZ considers there would be minimal impact on the industry and recipe reformulation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children, with the minimum set above the average amount present in cow's milk to reflect the fortified nature of the product.

Adopting the CXS 156-1987 maximum as a GUL for young child formula would result in an increase in regulation based on the Codex maximum being lower than current requirements for FSFYC in the Code. However, levels present in the domestic market are already within the maximum level and impacts on reformulation are not anticipated. As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As there is no UL set for thiamin in the NRV for Australia and New Zealand and no adverse effects have been identified from usual dietary intakes from food, regulation of the thiamin maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit thiamin as an optional nutrient in young child formula
- Where thiamin is added, require a minimum level of 14 µg/100 kJ
- Where thiamin is added, require a GUL of 72 µg/100 kJ.

4.2 Niacin

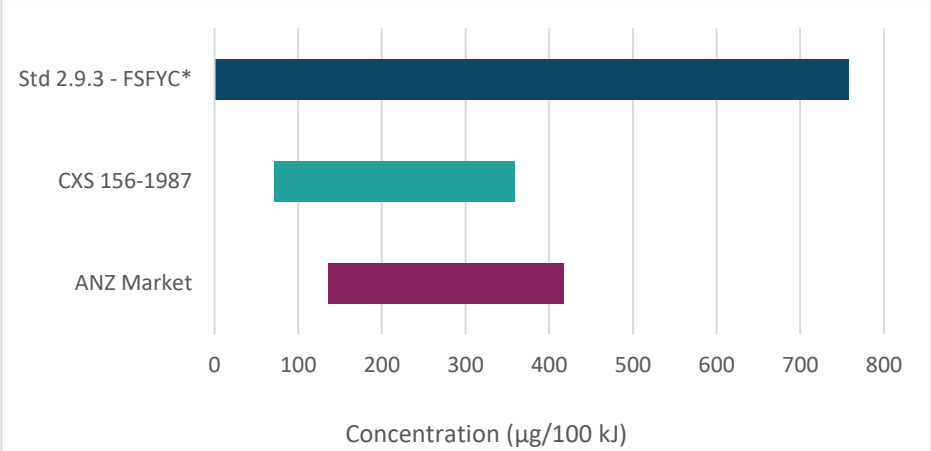

Figure 11: Comparison of Niacin regulatory requirements and market levels
*The Code does not prescribe a minimum amount of niacin for FSFYC.

As per Figure 11, Standard 2.9.3 permits FSFYC to contain niacin at a maximum claimable amount of no more than 0.25 mg/serve (equivalent to 758 µg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies niacin as an optional nutrient and prescribes a compositional range of 72–359 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled niacin scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive niacin intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL or retained the Standard 2.9.3 maximum. Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive niacin intake among the target population.

FSANZ's 2025/26 Market Survey found that niacin content in young child formula available in Australia and New Zealand ranges from 136 – 418 µg/100 kJ (Figure 11), with niacin declared on 98% of products. This indicates that the domestic market aligns with the CXS 156-1987 minimum but slightly exceeds the maximum amount.

Adopting the Codex minimum technically increases regulations for niacin, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

As noted in section 2.1 of this report, the Codex framework for Section B of CXS 156-1987 permits the addition of nutrients as listed in the essential composition of follow-up formula for older infants and levels are as per the prescribed minimum, maximum and GUL. Codex considered these levels account for the inherent levels of nutrients in cows' milk and where required may be amended by national authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

Given that the maximum level in CXS 156-1987 is derived from follow-up formula, the observed differences between Codex and Standard 2.9.3 are understandable.

Adopting the CXS 156-1987 maximum for young child formula within the domestic market would require industry to reformulate products. Additionally, while the level set in CXS 156-1987 does not pose risk to the health of young children it was not specifically set or developed to meet the requirements of young children agreed 1–3 years. The level set in CXS 156-1987 is reflective of requirements for 6–12 month olds and levels in breast milk.

Due to these key differences and on the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Additionally, as the level in Standard 2.9.3 is higher than that prescribed by CXS 156-1987 and there is a UL set for niacin, FSANZ does not consider the level is needed as a GUL. A GUL is applied in the Code when there are no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements and an established history of apparent safe use. Therefore, FSANZ considers a maximum level is a more appropriate regulatory measure.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit niacin as an optional nutrient in young child formula
- Where niacin is added, require a minimum level of 72 µg/100 kJ
- Where niacin is added, require a maximum level of 758 µg/100 kJ.

4.3 Folate

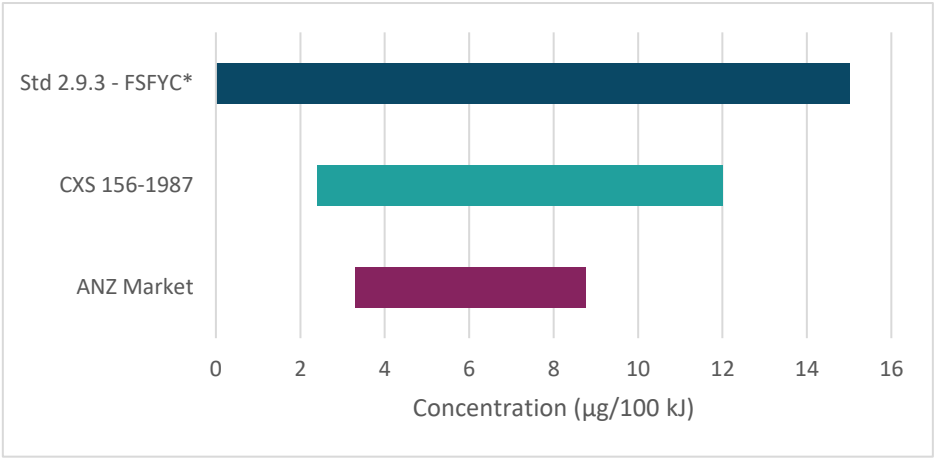

Figure 12: Comparison of Folate regulatory requirements and market levels
*The Code does not prescribe a minimum amount of folate for FSFYC.

As per Figure 12, Standard 2.9.3 permits FSFYC to contain folate at a maximum claimable amount of no more than 50 µg/serve (equivalent to 15 µg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies folic acid as an optional nutrient and prescribes a compositional range of 2.4–12 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum (GUL) levels would pose a low risk of both inadequate and excessive folate intake among the target population.

FSANZ's 2025/26 Market Survey found that folate content in young child formula available in Australia and New Zealand ranges from 3 – 9 µg/100 kJ (Figure 12), with folate declared on 96% of products. This indicates that the domestic market aligns with both the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex minimum technically increases regulations for folate, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

Adopting the CXS 156-1987 maximum as a GUL for young child formula would result in an increase in regulation based on the Codex maximum being lower than current requirements for FSFYC in the Code. However, levels present in the domestic market are already within the maximum level and impacts on reformulation are not anticipated. As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. While there is a UL set for folate in the NRV for Australia and New Zealand, no adverse effects have been identified from usual dietary intakes from food. Considering this, and the conclusions of the nutrition risk assessment, regulation of the folate maximum as a GUL is considered appropriate and consistent with current regulatory practice under the Code.

It is important to note that folate is the naturally occurring form of the vitamin found in foods, while folic acid is the synthetic form added to foods and supplements, with higher bioavailability than folate. Codex expresses minimum and maximum levels as folic acid, whereas Schedule 29 specifies requirements FSFYC as folate. Because cow's milk naturally contains folate, young child formula made from milk contains both naturally occurring folate and added folic acid. Therefore, expressing requirements only as folic acid would exclude the natural contribution. Dietary folate equivalents (DFE) were introduced to account for differences in bioavailability and are used for NRV, but they have not been incorporated into the Code. The Code currently treats folate and folic acid as having equivalent bioavailability, with values for folate and folic acid considered equal (FSANZ 2016). FSANZ has previously supported moving to DFE, however this is not under active consideration. As neither Standard 2.9.3 nor CXS 156-1987 use DFE, the proposed approach is to retain 'folate' as the nutrient name and 'µg folate' as the unit to maintain Code consistency.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit folate as an optional nutrient in young child formula
- Where folate is added, require a minimum level of 2.4 µg/100 kJ
- Where folate is added, require a GUL of 12 µg/100 kJ.

4.4 Vitamin B_6

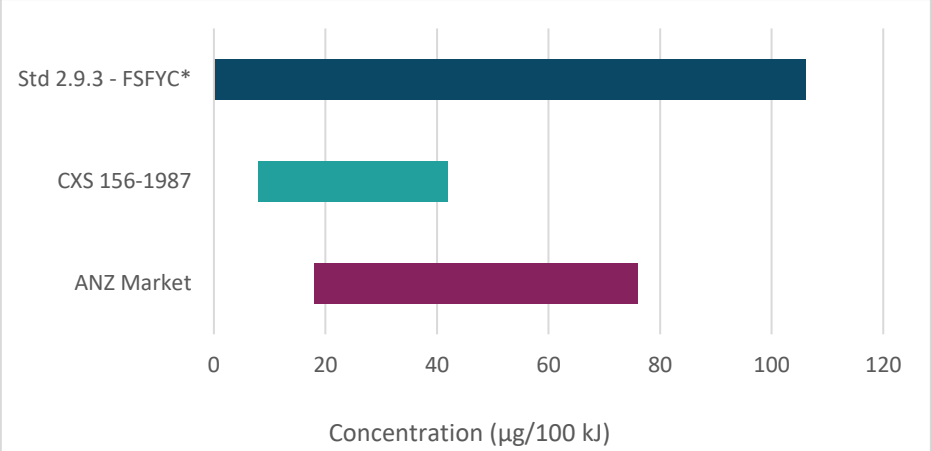

Figure 13: Comparison of Vitamin B_6 regulatory requirements and market levels
*The Code does not prescribe a minimum amount of vitamin B_6 for FSFYC.

As per Figure 13, Standard 2.9.3 permits FSFYC to contain vitamin B_6 at a maximum claimable amount of no more than 0.35 mg/serve (equivalent to 106 µg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies vitamin B_6 as an optional nutrient and prescribes a compositional range of 8–42 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled vitamin B_6 scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive vitamin B_6 consumption from young child is considered low if FSANZ adopted the Codex GUL or retained the Standard 2.9.3 maximum. Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive vitamin B_6 intake among the target population.

FSANZ's 2025/26 Market Survey found that vitamin B_6 content in young child formula available in Australia and New Zealand ranges from 18–76 µg/100 kJ (Figure 13), with vitamin B_6 declared on 96% of products. This indicates that the domestic market aligns with the current permission in Standard 2.9.3 and the CXS 156-1987 minimum but exceeds the maximum amount.

Adopting the Codex minimum technically increases regulations for vitamin B_6, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

As noted in section 2.1, the Codex framework for Section B of CXS 156-1987 permits the addition of nutrients as listed in the essential composition of follow-up formula for older infants and levels account for the inherent levels of nutrients in cow's milk and where required may be amended by national authorities if the nutritional needs of the local population and scientific justification warrants such deviation. Given the maximum level in CXS 156-1987 is derived from follow-up formula, the observed differences between Codex and Standard 2.9.3 are understandable.

Adopting the CXS 156-1987 maximum for young child formula within the domestic market would require industry to reformulate products. Additionally, while the level set in CXS 156-

1987 does not pose risk to the health of young children it was not specifically set or developed to meet the requirements of young children agreed 1–3 years. The level set in CXS 156-1987 is reflective of requirements for 6–12 month olds and levels in breast milk.

Due to these key differences and on the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Additionally, as the level set in Standard 2.9.3 is higher than that prescribed by CXS 156-1987 and there is a UL set for vitamin B_6, FSANZ does not consider the level is needed as a GUL. A GUL is applied in the Code when there are no significant risks on the basis of current scientific knowledge. These levels are values derived on the basis of meeting nutritional requirements and an established history of apparent safe use. Therefore, FSANZ considers a maximum level is a more appropriate regulatory measure.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit vitamin B_6 as an optional nutrient in young child formula
- Where vitamin B_6 is added, require a minimum level of 8 µg/100 kJ
- Where vitamin B_6 is added, require a maximum of 106 µg/100 kJ.

4.5 Vitamin E

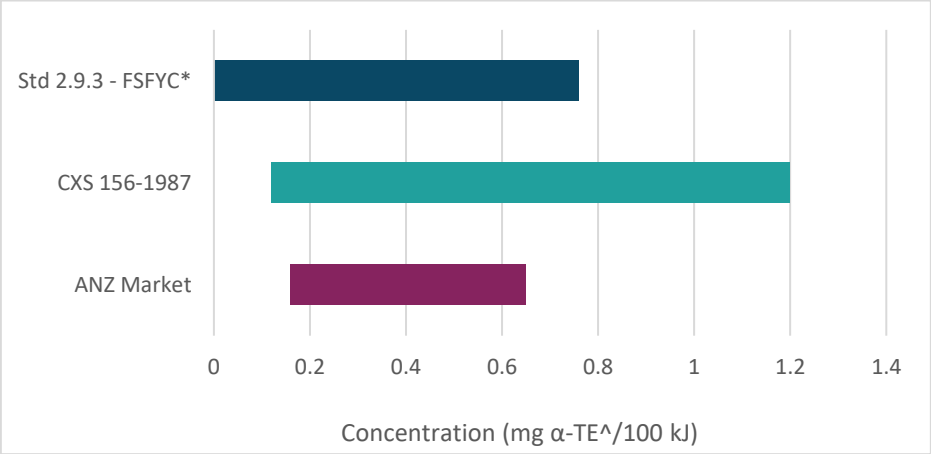

Figure 14: Comparison of Vitamin E regulatory requirements and market levels

*The Code does not prescribe a minimum amount of vitamin E for FSFYC.
^Expressed as alpha-tocopherol equivalents (α-TE).

As per Figure 14, Standard 2.9.3 permits FSFYC to contain vitamin E at a maximum claimable amount of no more than 2.5 mg/serve (equivalent to 0.76 mg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies vitamin E as an optional nutrient and prescribes a compositional range of 0.12 – 1.2 (GUL) mg α-TE/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum and maximum (GUL) levels would pose a low risk of both inadequate and excessive vitamin E intake among the target population.

FSANZ's 2025/26 Market Survey found that vitamin E content in young child formula available in Australia and New Zealand ranges from 0.16–0.65 mg α-TE/100 kJ (Figure 14), with vitamin E declared on 98% of products. This indicates that the domestic market aligns with both the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex range technically increases regulations for vitamin E, as there is currently no minimum prescribed. However, as the levels present in the domestic market already fall within the Codex range, FSANZ considers there would be minimal impact on the industry and recipe reformulation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children, with the minimum set above the average amount present in cow's milk to reflect the fortified nature of the product.

CXS 156-1987 prescribes a GUL for vitamin E. As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As there is a UL set for vitamin E in the NRV for Australia and New Zealand, regulation of the vitamin E maximum as a GUL is not considered appropriate. In consistency with current regulatory practice under the Code, and based on established safety requirements for 1–3 year olds, FSANZ proposes to adopt the Codex GUL as a maximum.

Section S29—15 lists the vitamin E maximum for FSFYC as vitamin E without reference to units of α-TE or applicable conversion factors. Paragraph 1.1.2—14(3)(e) lists that vitamin E must be calculated in terms of α-TE using the conversion factors in section S1—5. This indicates that vitamin E requirements in Standard 2.9.3 for FSFYC and those in CXS 156-1987 are in equivalent units.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit vitamin E as an optional nutrient in young child formula
- Where vitamin E is added, require a minimum level of 0.12 mg α-TE/100 kJ
- Where vitamin E is added, require a maximum of 1.2 mg α-TE/100 kJ.

4.6 Iodine

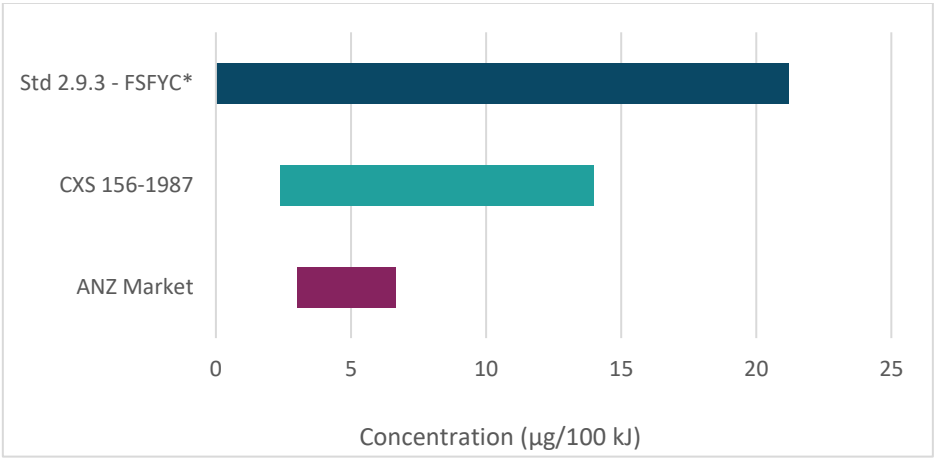

Figure 15: Comparison of Iodine regulatory requirements and market levels

*The Code does not prescribe a minimum amount of iodine for FSFYC.

As per Figure 15, Standard 2.9.3 permits FSFYC to contain iodine at no more than 70 µg/serve (equivalent to 21.2 µg/100 kJ), representing 100% of the RDI. A maximum claimable amount is also listed as 35 µg/serve (equivalent to 10.6 µg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies iodine as an optional nutrient and prescribes a compositional range of 2.4–14 (GUL) µg/100 kJ.

FSANZ's nutrition risk assessment concluded that adoption of the CXS 156-1987 minimum levels would pose a low risk of both inadequate and excessive iodine intake among the target population.

FSANZ's 2025/26 Market Survey found that iodine content in young child formula available in Australia and New Zealand ranges from 3–6.7 µg /100 kJ (Figure 15), with iodine declared on 98% of products. This indicates that the domestic market aligns with both the CXS 156-1987 range and the current permission in Standard 2.9.3.

Adopting the Codex minimum technically increases regulations for iodine, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

While P199 prescribed a maximum amount of 50% for iodine when added to FSFYC based on known toxicities, Application A528 sought to increase the maximum permitted amount of iodine from 50% of the RDI to 100% (70 µg/serve) (FSANZ 2005). This was to accommodate for normal fluctuations in the level of iodine present in milk, noted to be a key base ingredient for the applicant's FSFYC, referred to as 'toddler formula'. This was approved by FSANZ based on evidence that the proposed increase was unlikely to result in public health and safety risks. In conjunction, FSANZ retained the claimable level of 50% of the RDI, noting this would discourage unnecessary fortification, improve regulatory compliance and provide industry flexibility without compromising safety.

Having regard to this regulatory history, FSANZ considers it appropriate to adopt the CXS 156-1987 GUL for young child formula to support international alignment and reflect the updated evidence underpinning CXS 156-1987. As described in section 1.3.1 of this report, FSANZ considers a GUL will be implemented for young child formula where it poses no significant risks on the basis of current scientific knowledge. As there is a UL set for iodine in the NRV for Australia and New Zealand, regulation of the iodine maximum as a GUL is not considered appropriate. In consistency with current regulatory practice under the Code, and based on established safety requirements for 1–3 year olds, FSANZ proposes to adopt the Codex GUL as a maximum.

Adopting the Codex GUL as a maximum would result in an increase in regulation due to decreasing the permitted level of iodine. However, levels within the domestic market are already within this maximum level and impacts on reformulation requirements are not anticipated. FSANZ's nutrition risk assessment concluded that, at typical consumption levels, the risk of excessive iodine under the CXS 156-1987 GUL is low, but that exceedances may occur under chronic high consumption scenarios. However, as noted in the nutrition assessment, FSANZ considers the UL for iodine for 1–3 year olds to be conservative due to being extrapolated from adult data. In addition, the modelled exceedances are likely to overstate risk in typical dietary patterns, particularly where higher intakes are not sustained.

As described in the proposed regulatory framework, young child formula is intended to be consumed under the guidance of a healthcare professional in situations where energy and/or

nutrient intakes are inadequate. In this context, multiple serves of young child formula with higher iodine content represent a high intake scenario and would typically be accompanied by a diet that is otherwise not rich in iodine, which would reduce the likelihood of exceeding the UL. Further, use of young child formula is expected to be for an acute period of time and these products are not intended to be consumed on a long-term basis.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit iodine as an optional nutrient in young child formula
- Where iodine is added, require a minimum level of 2.4 µg/100 kJ
- Where iodine is added, require a maximum of 14 µg/100 kJ.

Question to submitters:

Q1.1 FSANZ recognises that the maximum level for iodine for FSFYC in the Code was established through Application A528 and considered its application to young child formula. Do you support FSANZ's proposed approach to adopt the Codex GUL as a maximum regulatory limit for iodine in young child formula?

4.7 Magnesium

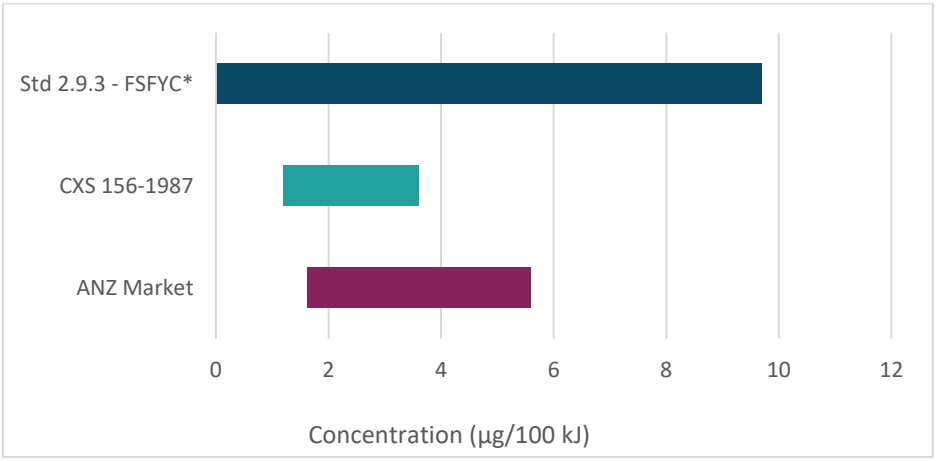

Figure 16: Comparison of Magnesium regulatory requirements and market levels
*The Code does not prescribe a minimum amount of magnesium for FSFYC.

As per Figure 16, Standard 2.9.3 permits FSFYC to contain magnesium at a maximum claimable amount of no more than 32 mg/serve (equivalent to 9.7 mg/100 kJ), representing 40% of the RDI. Similarly, CXS 156-1987 identifies magnesium as an optional nutrient and prescribes a compositional range of 1.2 – 3.6 (GUL) mg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled magnesium scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive magnesium intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL or retained the Standard 2.9.3 maximum. Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive magnesium intake among the target population.

FSANZ's 2025/26 Market Survey found that magnesium content in young child formula available in Australia and New Zealand ranges from 1.6 – 5.6 mg/100 kJ (Figure 16), with magnesium declared on 100% of products. This indicates that the domestic market aligns with the current permission in Standard 2.9.3 and the CXS 156-1987 minimum but exceeds the maximum amount.

Adopting the Codex minimum technically increases regulations for magnesium, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

As noted in section 2.1, the Codex framework for Section B of CXS 156-1987 permits the addition of nutrients as listed in the essential composition of follow-up formula for older infants and levels are as per the prescribed minimum, maximum and GUL. Codex considered these levels account for the inherent levels of nutrients in cows' milk and where required may be amended by national authorities if the nutritional needs of the local population and scientific justification warrants such deviation. Given that the maximum level in CXS 156-1987 is derived from follow-up formula, the observed differences between Codex and Standard 2.9.3 are understandable.

Adopting the CXS 156-1987 maximum for young child formula within the domestic market would require industry to reformulate products. Additionally, while the level set in CXS 156-1987 does not pose risk to the health of young children it was not specifically set or developed to meet the requirements of young children agreed 1–3 years. The level set in CXS 156-1987 is reflective of requirements for 6–12 month olds and levels in breast milk.

Due to these key differences and on the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit magnesium as an optional nutrient in young child formula
- Where magnesium is added, require a minimum level of 1.2 mg/100 kJ
- Where magnesium is added, require a maximum of 9.7 mg/100 kJ.

4.8 Phosphorus

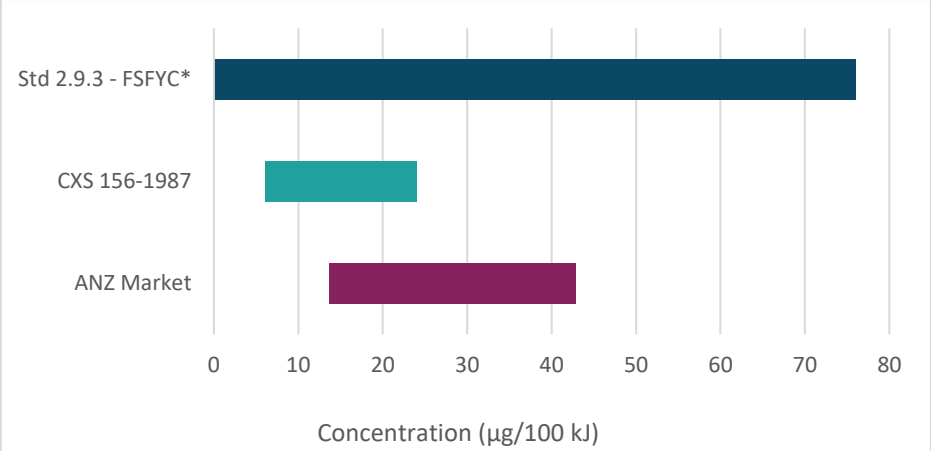

Figure 17: Comparison of Phosphorous regulatory requirements and market levels
*The Code does not prescribe a minimum amount of phosphorous for FSFYC.

As per Figure 17, Standard 2.9.3 permits FSFYC to contain phosphorus at a maximum claimable amount of no more than 250 mg/serve (equivalent to 76 mg/100 kJ), representing 50% of the RDI. Similarly, CXS 156-1987 identifies phosphorus as an optional nutrient and prescribes a compositional range of 6–24 (GUL) mg/100 kJ.

FSANZ's nutrition risk assessment found that each modelled phosphorus scenario of the Standard 2.9.3 maximum claimable amount and the Codex GUL fell below the UL. It was concluded that the risk of excessive phosphorus intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL or retained the Standard 2.9.3 maximum. Additionally, the risk assessment found that the adoption of the CXS 156-1987 minimum would pose a low risk of both inadequate and excessive phosphorus intake among the target population.

FSANZ's 2025/26 Market Survey found that phosphorus content in young child formula available in Australia and New Zealand ranges from 14 – 41 mg/100 kJ (Figure 17), with phosphorus declared on 100% of products. This indicates that the domestic market aligns with the current permission in Standard 2.9.3 and the CXS 156-1987 minimum but exceeds the maximum amount.

Adopting the Codex minimum technically increases regulations for phosphorus, as there is currently no minimum prescribed. However, as the minimum CXS 156-1987 level accounts for the levels already present on the domestic market in practice there would be no impact on products or reformulation requirements. FSANZ considers that the industry will benefit from this international harmonisation. Additionally, as described in section 1.3.1 of this report, FSANZ considers that imposing a minimum composition level is important and justified. This ensures young child formula appropriately contributes to the diets of young children.

As noted in section 2.1, the Codex framework for Section B of CXS 156-1987 permits the addition of nutrients as listed in the essential composition of follow-up formula for older infants and levels are as per the prescribed minimum, maximum and GUL. Codex considered these levels account for the inherent levels of nutrients in cows' milk and where required may be amended by national authorities if the nutritional needs of the local population and scientific justification warrants such deviation. Given that the maximum level in CXS 156-1987 is derived from follow-up formula, the observed differences between Codex and Standard 2.9.3 are understandable.

Adopting the CXS 156-1987 maximum for young child formula within the domestic market would require industry to reformulate products. Additionally, while the level set in CXS 156-1987 does not pose risk to the health of young children it was not specifically set or developed to meet the requirements of young children agreed 1–3 years. The level set in CXS 156-1987 is reflective of requirements for 6–12 month olds and levels in breast milk.

Due to these key differences and on the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Based on the conclusions of the nutrition risk assessment, alignment with CXS 156-1987 and age appropriate nutritional requirements, FSANZ proposes to:

- Permit phosphorus as an optional nutrient in young child formula
- Where phosphorus is added, require a minimum level of 6 mg/100 kJ
- Where phosphorus is added, require a maximum of 76 mg/100 kJ.

4.9 Other nutritive substances

4.9.1 Lutein

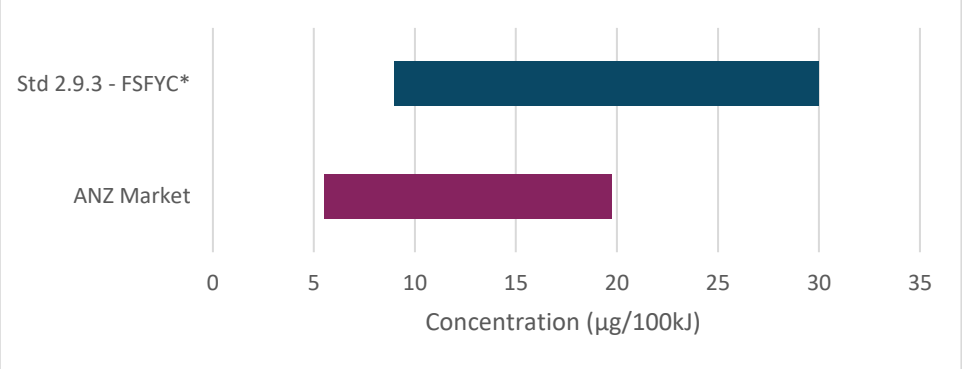

Figure 18: Comparison of lutein regulatory requirements and market levels
*The Code requires a minimum claimable amount of lutein for FSFYC.

As per Figure 18, Standard 2.9.3 permits FSFYC to contain lutein at a maximum level of 100 µg/serve (equivalent to 30 µg/100 kJ), including both added and naturally occurring lutein. Standard 2.9.3 does not specify a minimum compositional amount for lutein but lists a minimum claimable amount of 30 µg/serve (equivalent to 9 µg/100 kJ). CXS 156-1987 does not include a permission for lutein.

As described in Table 4.17 of the nutrition risk assessment, the maximum claimable amount for lutein specified in Standard 2.9.3 (100 µg per serve) was converted to Codex aligned units (µg /100 kJ) using the minimum energy requirement of 330 kJ per serve. This represents the maximum lutein concentration that could be declared under the Code on an energy basis. The minimum claimable amount was also converted using this methodology.

The approval of Application A597 (FSANZ 2009) resulted in the permission for the voluntary addition of lutein as a nutritive substance to FSFYC up to a maximum concentration of 100 µg/serve (equivalent to 30 µg/100 kJ). A minimum claimable amount of 30 µg/serve

(equivalent to 9 µg/100 kJ) was also established to ensure where lutein was added, it provided at least 10% of a child's estimated lutein intake from other foods. The permission was based on a conclusion that lutein from marigold flowers (*Tagetes erecta L.)* added to FSFYC at the maximum concentration is unlikely to pose any public health and safety concerns for young children who consume these products. This permission has established a history of safe use of lutein in these products.

FSANZ's nutrition risk assessment concluded that in the absence of an established EAR and consistent with Codex, the risk of inadequate lutein intake associated with consumption of young child formula is considered low. Similarly, in the absence of an established UL, and under the existing compositional limit specified in Standard 2.9.3, the risk of excessive lutein intake from consumption of young child formula is also considered low.

FSANZ's 2025/2026 Market Survey found that lutein content in young child formula available in Australia and New Zealand ranges from 6–20 µg/100 kJ (Figure 18), with lutein declared on 27% of products. This indicates that the domestic market is below the current permission in Standard 2.9.3.

On the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of safe use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Based on the conclusions of the nutrition risk assessment, consideration of the domestic market and age appropriate nutritional requirements, FSANZ proposes to:

- Permit lutein as an optional nutrient in young child formula
- Where lutein is added, it must be derived from *Tagetes erecta L.*
- Where lutein is added, require a minimum level of 9 µg/100 kJ
- Where lutein is added, require a maximum level of 30 µg/100 kJ

4.9.2 Inulin-type fructans / galacto-oligosaccharides

Standard 2.9.3 permits FSFYC to contain ITF and/or galacto-oligosaccharides (GOS) at a maximum concentration of no more than 1.6 g/serve (equivalent to 0.48 g/100 kJ), including both added and naturally occurring. Standard 2.9.3 does not specify a minimum compositional amount for ITF/GOS. CXS 156-1987 does not include a permission for ITF/GOS.

As described in Table 4.19 of the nutrition risk assessment, the maximum claimable amount for ITF/GOS specified in Standard 2.9.3 (1.6 g per serve) was converted to Codex aligned units (g /100 kJ) using the minimum energy requirement of 330 kJ per serve. This represents the maximum ITF/GOS concentration that could be declared under the Code on an energy basis.

ITF/GOS in FSFYC was considered in Proposal P306 (FSANZ 2008) and Application A1055 (FSANZ 2013). P306 permitted the voluntary addition of inulin-derived substances and GOS to FSFYC up to a maximum concentration of 1.6 g/serve (equivalent to 0.48 g/100 kJ). The permission was for short chain fructo-oligosaccharides (FOS) derived from inulin and expressly excluded polymers of fructose produced from sucrose. The permission was based on a conclusion that inulin derived substances and GOS added to FSFYC at a maximum concentration of 1.6 g/serve is unlikely to pose any health and safety concern for young

children who consume these products. This permission has resulted in a permitted history of safe use in these products.

Following this, Application A1055 amended the Code to permit the optional addition of short chain FOS derived from sucrose. This resulted in the term 'inulin-derived substances' in the Code being replaced by the term ITF with the definition being broadened to include both short chain FOS derived from sucrose and from insulin.

FSANZ's nutrition risk assessment concluded that in the absence of an established EAR and consistent with Codex, the risk of inadequate ITF/GOS intake associated with consumption of young child formula is considered low. Similarly, in the absence of an established UL, and under the existing compositional limits specified in Standard 2.9.3, the risk of excessive ITF/GOS intake from consumption of young child formula is also considered low.

FSANZ's 2025/26 Market Survey was not able to determine either the number of products that include ITF and/or GOS on the NIP, or the range of ITF/GOS amounts declared on the NIP for young child formula. This is because the Code permits ITF/GOS to be added in combination up to a total maximum amount, and products may declare one or multiple types of ITF/GOS. In addition, data confidentiality restricts the ability to determine which products list which types of ITF/GOS and in which combinations. Where declared, types of ITF and/or GOS included GOS, including short and long chain GOS, and FOS, including long chain types. Despite these limitations, the proposed maximum concentration is not a change to the regulation and therefore should not affect the domestic market.

On the basis of minimally effective regulation FSANZ considers it appropriate to retain the Standard 2.9.3 maximum level. This level has been present on the domestic market for over 20 years demonstrating a history of safe use and the nutrition assessment found it would pose low risk to young children. Retaining this level would meet the nutritional needs of young children while also having minimal impact on the industry.

Based on the conclusions of the nutrition risk assessment, consideration of the domestic market and age appropriate nutritional requirements, FSANZ proposes to:

- Permit ITF/GOS as an optional nutrient in young child formula
- Where ITF/GOS is added, require a combined maximum of 0.48 g/100 kJ.

5 Permitted forms

Standard 2.9.3 states that FSFYC may contain a vitamin or mineral (that is listed in Column 1 of the table to section S29—15), so long as it is a permitted form specified in S17—2 or S17—3. Products regulated by Standard 2.9.3 (formulated meal replacements, formulated supplementary foods and FSFYC) are permitted to use the forms in Schedule 17. Whereas all other special purpose foods (including formulated meal replacements) are permitted to use the forms as specified in S29—23.

The equivalent regulation for permitted forms in Codex Alimentarius is the Codex advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10–1979). Within this list there are 150 permitted forms for infant formula, follow-up formula and product for young children. The three product categories share identical permitted forms, unlike young child formula, infant formula and follow-on formula in the Code.

Young child formula and infant formula products share a number of important compositional

and manufacturing similarities. Both product types are typically manufactured using similar base milk powders and produced within the same manufacturing facilities and production lines. As commercially produced powdered or ready-to-consume formulations, they also share many technological properties, including similar ingredient matrices and nutrient formulations. Therefore, it is fair to assume that the base milk powders and complete recipes utilise the same permitted forms. Additionally, forms permitted for infant formula product have been considered for the most vulnerable population group, with no evidence to suggest any concerns pertaining to safety and suitability for young children. Alignment between the product categories would also produce trade and formulation efficiencies. Given the benefits of alignment and no known public health or safety risks, FSANZ considers it appropriate for young child formula to have the same permitted forms as infant formula products.

To achieve this intent in the proposed regulation, three elements need to be considered:

- Retainment of Schedule 17 permitted forms
- Adoption of Schedule 29 permitted forms, and
- Alignment with CXG 10–1979 permitted forms (where appropriate).

5.1 Retainment of Schedule 17 (S17–2 and S17–3) permitted forms

As the forms prescribed in S17—2 and S17—3 have an established history of safe use in young child formula and are supported by safety assessments, FSANZ considers it appropriate to retain these permitted forms in young child formula. This decision does not pose risk to public health and safety of young child formula and aligns with the principles of minimally effective regulation.

Retention of these forms maintains a stable and evidence based regulatory baseline in the absence of any identified public health or safety concerns. This approach facilitates a high degree of alignment with CXG 10–1979 while avoiding unnecessary regulatory change where suitable and well characterised forms are already permitted under the Code.

5.2 Adoption of Schedule 29 (S29–23) permitted forms

Across Sections S17—2, S17—3 and S29—23, the Code currently lists 134 permitted forms of vitamins and minerals. Of these, 43 forms are currently permitted under Section S29—23 for use in infant formula products and other special purpose foods but are not permitted under Sections S17—2 and S17—3 for FSFYC.

FSANZ proposes to adopt these 43 forms as permitted forms of vitamins and minerals for use in young child formula. The safety and suitability for inclusion of these vitamins and minerals as permitted forms for young child formula is based on previous assessments that concluded their suitability in section S29—23 originally. When assessed for use within infant formula there was no evidence to suggest any concerns pertaining to safety and suitability. Due to similarities between the products and population group, FSANZ considers use of these food additives in young child formula will pose low risk to the health and safety of young children.

It is also important to note that inclusion of young child formula in 29—23 does not, of itself, allow the addition of that form in a food, rather it provides acceptable forms should addition otherwise be permitted under Standard 2.9.3.

5.3 Alignment with CXG 10–1979 permitted forms

As noted above, CXG 10–1979 lists 150 permitted forms for infant formula, follow-up formula and product for young children. Of these, there are 15 permitted forms not included in S29—

23, S17—2 or S17—3. These are detailed below in Table 2.

Table 2: Permitted forms listed in CXG 10–1979 that are not permitted in relevant sections of the Code (S17—2, S17—3 and S29—23)

Nutrient	Form
Chromium	Chromium (III) chloride
Iron	Carbonyl iron
	Electrolytic iron
	Ferric orthophosphate
	Ferric saccharate
Magnesium	Magnesium acetate
	Magnesium glycerophosphate
	Magnesium lactate
Molybdenum	Ammonium molybdate
Pantothenic acid	Dl-panthenol
Selenium	Sodium hydrogen selenite
Vitamin A	All trans retinol
Vitamin E	D-alpha-Tocopherol
	DL-alpha-Tocopheryl polyethylene glycol 1000 succinate
Zinc	Zinc carbonate

This high amount of alignment is due to the harmonisation work complete through Proposal P1028, which aimed to align the Code with CXG 10–1979 where appropriate for infant formula products. Where permitted forms where not adopted, there were either other permitted forms of that vitamin or mineral for industry to utilise or there were technological or safety concerns.

In the absence of any substantiated public health, safety or technological need to permit the remaining 15 permitted forms listed in CXG 10–1979, FSANZ considers it unnecessary to include these forms, noting that the relevant vitamins and minerals are permitted (or proposed to be) in other forms across S17—2, S17—3 and S29—23 of the Code.

Based on the above considerations, FSANZ proposes to permit the forms currently listed in S17—2, S17—3 and S29—23 of the Code for use in young child formula. These forms are listed in Appendix 2.

6 Other requirements

6.1 Interpretation of compositional requirements

FSFYC may be presented in a variety of forms, including solid, liquid or powdered products that require reconstituted with milk or water. As such, there are no specific requirements in the Code on directions for their use and storage.

In SD2, FSANZ has proposed a series of requirement for young child formula labels including a direction for use and storage that previously boiled and cooled potable water must be used.

FSANZ's 2025/2026 Market Survey was not able to identify any products equivalent to a young child formula that are ready to drink or in a concentrated form, therefore the requirement applies to powdered forms.

For regulatory clarity, compositional requirements set out in the regulation of young child formula apply to a powdered form of young child formula that has been reconstituted with water according to directions. Unless otherwise expressly stated, this will incorporate the naturally occurring amounts of the nutrients present in the base ingredients.

6.2 Scoop size

P1066 aims to provide set compositional requirements for young child formula and due to the proposed compositional ranges discussed above, differentiation between products is possible. Products will differ further based on individual formulation (within the proposed compositional limits) and through the prescribed 'directions of use' which are determined by manufacturers. The reconstitution of young child formula products is also determined by manufacturers based on the product's specific requirements, in conjunction with appropriate feeding guides based on the nutrient density of their product.

FSANZ considers that the requirement for the package of a multi-serve can of young child formula in powdered form to contain a scoop specific to that young child formula is necessary due to the risk of over or under nutrition from using a different measure. Single serve sachets for young child formula would not be required to contain a scoop. Proposed labelling provisions (see section 3.4.6 of SD2 to this CFS) address this risk, including the requirement for a direction instructing that if a package contains a measuring scoop, only the enclosed scoop must be used and a warning statement to not change the proportions of powder (or concentrate) except on medical advice. Declaring the weight of the scoop and the amount of water needed to prepare the formula is important information for the general population to aid correct interpretation. This information, and information about the proportion of powder or concentrate, is also useful for health professionals when calculating the nutritional value of the formula when reconstituted according to the directions on the label. FSANZ does not propose to prescribe the size of the scoop due to the variety of powder densities across products.

Based on the above considerations, FSANZ proposes to require a package of a multi-serve can of young child formula in powdered form to contain a scoop specific to that young child formula to enable to its use in accordance with the directions contained in the label on the package.

6.3 Lactic Acid Producing Microorganisms

Standard 2.9.3 does not include a permission for the addition of L(+) lactic acid producing microorganisms (LAM) in FSFYC. CXS 156-1987 identifies that LAM may be used for the purpose of producing acidified follow-up formula for older infants.

LAM is permitted to be added to infant formula products for acidification purposes as per Standard 2.9.1. Proposal P1028 concluded that formula fermented with LAM, where no viable bacteria are present in the final product, satisfies a technological function and does not present a risk to public health and safety in full term infants. FSANZ considers that the safety assessment of LAM for acidification purposes undertaken as part of Proposal P1028 is relevant to the consideration of its safety of young children.

FSANZ proposes to include a permission for LAM for the technological purpose of

acidification in young child formula. In alignment with existing requirements in Standard 2.9.1, only microorganisms producing the L(+) form of lactic acid would be permitted to be used. The addition of specific strains for any other purpose, such as probiotics would be considered as new permissions for addition and require pre-market safety assessment by FSANZ.

Based on the above considerations, FSANZ proposes to:

- Permit LAM as an optional substance for acidification purposes in young child formula
- Where LAM is added, only permit microorganisms producing the L(+) form of lactic acid

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Appendix 1: Dietary intake assessment

The objective of the dietary intake assessment is to estimate the mean consumption amount and number of consumers of young child formula in the most recently published Australian and New Zealand national nutrition surveys.

The dietary intake assessment was undertaken using FSANZ's dietary modelling computer program Harvest[2]. A summary of the FSANZ approach to conducting the dietary intake assessment for this CFS is outlined below. A detailed discussion of the FSANZ methodology and approach to conducting dietary intake assessments is set out in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024).

Population group assessed

Formulated Supplementary Food for Young Children is defined in the Standard 2.9.3—2 of the Code as a formulated supplementary food for children aged 1–3 years. Food consumption data used in dietary intake assessments is preferably obtained from national nutrition surveys. The scope of the most recently published Australian and New Zealand national nutrition surveys did not include children younger than two years of age, and five years of age respectively. Therefore, only Australian national nutrition survey data for children aged 2–3 years were used for this assessment.

Food consumption data used

The food consumption data used for the dietary intake assessment were from the 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), a one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (Australian Bureau of Statistics (ABS) 2015). There were 317 respondents aged 2–3 years.

Whilst data from the 2023 Australian National Nutrition and Physical Activity Survey (2023 NNPAS) have been released by the ABS, only summary consumption statistics at the food group level have been published to date (ABS 2025). At the time of this assessment the raw data from the survey that allows extraction of consumption for specific foods is not available to FSANZ, therefore the 2023 NNPAS data are not able to be used for this assessment. The published summary data relating to the proportion of consumers has been presented in Section 1.3.4.

Assumptions and limitations of the dietary intake assessment

The aim of the dietary intake assessment was to make the best estimate of young child formula consumption. Where significant uncertainties in the data existed, FSANZ used conservative assumptions to ensure that the results were not an underestimate. These included:

- The estimated consumption of young child formula also included consumers of infant formula. There is evidence that caregivers may not always provide the correct formula product for their child's age (FSANZ 2023b) and therefore all formulas consumed by children aged 2–3 years were included.
- The consumption of young child formula in Australia is the same as for New Zealand.
- 1 serve of young child formula is 230 mL (maximum serve size from the Market Survey Summary Report for P1066).

[2] https://www.foodstandards.gov.au/science-data/exposure/fsanzdietaryexposur

- Mean consumption of young child formula on day one of the 2011-12 NNPAS reflects longer term daily consumption.

In addition to the specific assumptions made in relation to this dietary intake assessment, there are several limitations, including those associated with the nutrition surveys per se. A discussion of these limitations is included in Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes (FSANZ 2024). The limitations of this dietary intake assessment and how these are addressed are detailed below:

- Due to the scope of the surveys, no food consumption data from the most recent New Zealand national nutrition surveys could be included in this dietary intake assessment, and only food consumption data for children aged 2–3 years could be included from the Australian 2011-12 NNPAS.
- An estimation of nutrient intakes from young child formula was considered for this dietary intake assessment however this could not be conducted due to there being too few consumers of young child formula (including consumers of infant formula) aged 2–3 years in the 2011-12 NNPAS to provide reliable estimates of nutrient intake. FSANZ plans to complete a more comprehensive dietary intake assessment of the proposed composition of young child formula using food consumption data from the First Foods New Zealand and Young Foods New Zealand studies (Taylor et al. 2021, Haszard et al. 2024) at the 2nd CFS when these data are available in Harvest.
- Food consumption data from the 2011-12 NNPAS are 15 years old and consumption patterns may have changed over time. Recently published summary data from the 2023 NNPAS (ABS 2025) are included to supplement the results of this dietary intake assessment.

Estimated number of consumers and mean consumption of young child formula

In the 2011-12 NNPAS, two infant formulas and three young child formulas (all prepared with water) were reported consumed by survey respondents (Table A.1).

Table A.1: Infant formula and young child formula foods in the 2011-12 NNPAS

Survey food code	Survey food name
32101001	Infant formula, 6–12 months, prepared with water
32101002	Infant formula, 6–12 months, added omega 3 fatty acids, prepared with water
32103001	Toddler milk, regular, prepared with water
32103002	Toddler milk, S26 Gold, prepared with water
32103003	Toddler milk, added omega 3 fatty acids, prepared with water

On day one of the 2011-12 NNPAS, 11 children aged 2–3 years consumed young child formula (3.3 % of survey respondents aged 2–3 years). The mean consumption amount of young child formula for these consumers was 428 g/day[3]. Assuming a specific gravity of 1.05 (FSANZ 2025) and a serve size of 230 mL, this mean consumption amount is equivalent to approximately 1.8 serves/day.

In the 2023 NNPAS, 6.6% of respondents aged 2–4 years consumed foods from the infant formulae and breast milk food group (which includes young child formula) (ABS 2025) suggesting an increase in the proportion of consumers over time. The median consumption amount for consumers aged 2–4 years of foods from the infant formulae and human breast

[3] Survey sample weighting factors are used to adjust survey data to better reflect the results that would have been obtained if a truly representative sample had been able to be obtained (FSANZ 2024).

milk food group on day one of the survey is 349.5 g/day, however this estimate has a relative standard error of 25% to 50% and should be used with caution (ABS 2025).

In New Zealand, the recent First Foods New Zealand and Young Foods New Zealand studies included children aged from 6 months to 3.9 years of age (Taylor et al. 2021, Haszard et al. 2024). These data include two days of food consumption information from 934 individual respondents (Haszard et al. 2024). These data are currently being incorporated in Harvest and will be included in the dietary intake assessment at the 2nd CFS to provide further information about young child formula consumption.

Appendix 2: Permitted forms

Table A2.1: Proposed forms of vitamins and minerals permitted in young child formula

Nutrient	Permitted form	Code provision
Vitamin A (Retinol forms)	Vitamin A palmitate (retinyl palmitate)	S17—2; S29—23
	Vitamin A (retinol)	S17—2; S29—23
	Vitamin A propionate (retinyl propionate)	S17—2; S29—23
Vitamin A (Provitamin A forms)	beta-apo-8′-carotenal	S17—2
	beta-apo-8′-carotenoic acid ethyl ester	S17—2
	beta-carotene	S29—23
	beta-carotene-synthetic	S17—2
	Carotenes-natural	S17—2
Vitamin C	L-ascorbic acid	S17—2; S29—23
	Ascorbyl palmitate	S17—2; S29—23
	Calcium ascorbate	S17—2; S29—23
	Potassium ascorbate	S17—2; S29—23
	Sodium ascorbate	S17—2; S29—23
Vitamin D	Vitamin D_2 (ergocalciferol)	S17—2; S29—23
	Vitamin D_3 (cholecalciferol)	S17—2; S29—23
	Vitamin D (cholecalciferol-cholesterol)	S29—23
Thiamin	Thiamin hydrochloride	S17—2; S29—23
	Thiamin mononitrate	S17—2; S29—23
	Thiamin monophosphate	S17—2
Riboflavin	Riboflavin	S17—2; S29—23
	Riboflavin-5′-phosphate sodium	S17—2; S29—23
Niacin	Niacinamide (nicotinamide)	S17—2; S29—23
	Nicotinic acid	S17—2
Vitamin B_6	Pyridoxine hydrochloride	S17—2; S29—23
	Pyridoxine-5′-phosphate	S29—23
Folate	Folic acid	S17—2; S29—23
	L-methyltetrahydrofolate, calcium	S17—2

Vitamin B_{12}	Cyanocobalamin	S17—2; S29—23
	Hydroxocobalamin	S17—2; S29—23
Vitamin E	dl- α -tocopherol	S17—2; S29—23
	d- α -tocopherol concentrate	S17—2; S29—23
	d-α-tocopheryl acetate	S17—2; S29—23
	dl-α-tocopheryl acetate	S17—2; S29—23
	Tocopherols concentrate, mixed	S17—2; S29—23
	d-alpha-tocopheryl acetate concentrate	S17—2
	d-alpha-tocopheryl acid succinate	S17—2; S29—23
	dl-α-tocopheryl succinate	S29—23
Calcium	Calcium carbonate	S17—3; S29—23
	Calcium chloride	S17—3; S29—23
	Calcium chloride, anhydrous	S17—3
	Calcium chloride solution	S17—3
	Calcium citrate	S17—3; S29—23
	Calcium gluconate	S17—3; S29—23
	Calcium glycerophosphate	S17—3; S29—23
	Calcium hydroxide	S29—23
	Calcium lactate	S17—3; S29—23
	Calcium oxide	S17—3; S29—23
	Calcium phosphate, dibasic	S17—3; S29—23
	Calcium phosphate, monobasic	S17—3; S29—23
	Calcium phosphate, tribasic	S17—3; S29—23
	Calcium sodium lactate	S17—3
	Calcium sulphate	S17—3; S29—23
Iodine	Potassium iodate	S17—3; S29—23
	Potassium iodide	S17—3; S29—23
	Sodium iodate	S17—3
	Sodium iodide	S17—3; S29—23
Iron	Ferric ammonium citrate, brown or green	S17—3
	Ferric ammonium citrate	S29—23

	Ferric ammonium phosphate	S17—3
	Ferric citrate	S17—3; S29—23
	Ferric hydroxide	S17—3
	Ferric phosphate	S17—3
	Ferric pyrophosphate	S17—3; S29—23
	Ferric sodium edetate	S17—3
	Ferric sulphate	S17—3
	Ferrous bisglycinate	S29—23
	Ferrous carbonate	S17—3
	Ferrous citrate	S17—3; S29—23
	Ferrous fumarate	S17—3; S29—23
	Ferrous gluconate	S17—3; S29—23
	Ferrous lactate	S17—3; S29—23
	Ferrous succinate	S17—3; S29—23
	Ferrous sulphate	S17—3; S29—23
	Ferrous sulphate, dried	S17—3
	Iron, reduced (ferrum reductum)	S17—3
Magnesium	Magnesium carbonate	S17—3; S29—23
	Magnesium chloride	S17—3; S29—23
	Magnesium gluconate	S17—3; S29—23
	Magnesium oxide	S17—3; S29—23
	Magnesium phosphate, dibasic	S17—3; S29—23
	Magnesium phosphate, tribasic	S17—3; S29—23
	Magnesium sulphate	S17—3; S29—23
	Magnesium hydroxide carbonate	S29—23
	Magnesium hydroxide	S29—23
	Magnesium salts of citric acid	S29—23
Phosphorus	Bone phosphate	S17—3
	Calcium glycerophosphate	S17—3; S29—23
	Calcium phosphate, dibasic	S17—3; S29—23
	Calcium phosphate, monobasic	S17—3; S29—23
	Calcium phosphate, tribasic	S17—3; S29—23
	Magnesium phosphate, dibasic	S17—3; S29—23
	Magnesium phosphate, tribasic	S17—3
	Phosphoric acid	S17—3

	Potassium glycerophosphate	S17—3
	Potassium phosphate, dibasic	S17—3; S29—23
	Potassium phosphate, monobasic	S17—3; S29—23
	Potassium phosphate, tribasic	S29—23
	Sodium phosphate, dibasic	S17—3; S29—23
	Sodium phosphate, monobasic	S29—23
	Sodium phosphate, tribasic	S29—23
Zinc	Zinc acetate	S17—3; S29—23
	Zinc chloride	S17—3; S29—23
	zinc citrate	S29—23
	Zinc gluconate	S17—3; S29—23
	Zinc lactate	S17—3; S29—23
	Zinc oxide	S17—3; S29—23
	Zinc sulphate	S17—3; S29—23