FOOD STANDARDS Australia • New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

26 May 2026
396-26

Attachment 1 – Nutrition risk assessment

Supporting Document 1 – Nutrient composition

Proposal P1066 – Review of young child formula

Executive summary

The Codex CXS 156-1987 Standard for Follow-up Formula for Older Infants and Product for Young Children (Codex) was revised in 2023 and reflects the best available scientific evidence on the composition of these products. In Australia and New Zealand, products for young children are regulated as formulated supplementary foods for young children under Division 4 of Standard 2.9.3 of the Australia New Zealand Food Standards Code (the Code). For this proposal and supporting assessment, products for young children are referred to as young child formula.

This nutrition risk assessment evaluated the compositional levels of nutrients specified in Codex to determine their suitability for adoption into Standard 2.9.3 of the Code. The assessment examines whether Codex minimum and maximum levels and guidance upper levels (GULs) 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.

Modelled intakes from young child formula were compared to Australian and New Zealand Nutrient Reference Values (NRVs) and with existing compositional requirements in the Code. Cow's milk was used as a nutritional comparator against modelled values, reflecting typical consumption of full-fat dairy products by children aged 1–3 years. Consumption scenarios assumed that young child formula contributes approximately 15–25% of total daily energy intake, replacing equivalent dairy serves as per dietary guidelines.

The assessment focuses on nutrients with mandatory compositional criteria in Codex as well as nutrients permitted under Standard 2.9.3 of the Code. Nutrients assessed include energy, protein, carbohydrates, fatty acids, vitamins, minerals and select nutritive substances. Nutrient exposure was assessed from young child formula only, total dietary intake from all food sources was not modelled.

At typical consumption levels, modelled intakes of energy, macronutrients, vitamins, minerals and nutritive substances generally meet requirements without exceeding Upper Limits (ULs). For nutrients where ULs have not been established, the risk of excessive intake from young child formula was considered low. Potential risks of excess intake were identified for some nutrients (vitamin A, zinc and iodine) under high consumption scenarios however, these risks

are considered low to moderate and are mitigated when intake is interpreted in the context of typical dietary patterns. For nutrients for which no compositional levels are specified in Codex, adopting a Codex aligned approach and not setting compositional levels is considered low risk. Similarly, for nutritive substances not specified in Codex, but permitted under the Code, retaining existing composition limits set out in Standard 2.9.3 is considered low risk.

Overall, the risk of nutritional inadequacy or excess consumption of young child formula as part of a varied diet is considered low if FSANZ adopts the Codex compositional criteria for products for young children into the Code.

Table of contents

1 Introduction

The purpose of this nutrition risk assessment is to evaluate the compositional levels for nutrients specified in Codex CXS 156-1987 Standard for Follow-up Formula for Older Infants and Product for Young Children (Codex) and to determine whether their adoption into Standard 2.9.3 of the Australia New Zealand Food Standards Code (the Code) would pose a risk of nutritional harm to children aged 1–3 years in Australia and New Zealand, in order to ensure the protection of public health and safety. For this proposal and supporting assessment, products for young children are referred to as young child formula.

1.1 Codex CXS 156-1987

CXS 156-1987 prescribes compositional criteria for follow-up formula for older infants (6 months to 12 months) and products for young children (12 months to 36 months), including minimum and maximum nutrient values, guidance upper levels (GULs), permitted nutrient sources and forms, ratios, conversion factors and other compositional restrictions. In addition to mandatory compositional requirements, Codex permits products for young children to include optional ingredients where their safety, suitability and nutritional purpose at the proposed level of use are supported by generally accepted scientific evidence. These listed substances are indicative rather than exhaustive and are intended to provide guidance to competent national and regional authorities (Codex, 2023).

1.2 Standard 2.9.3

Standard 2.9.3 of the Code establishes compositional requirements for formulated supplementary foods for young children. Standard 2.9.3 requires formulated supplementary foods for young children to provide a minimum amount of energy and protein per serving, and to contribute at least 20% of the Recommended Daily Intake (RDI) of at least one permitted vitamin or mineral per serving. Standard 2.9.3 also includes limits on optional ingredients and restricts the source and amount of certain nutritive substances. The addition of vitamins and minerals is restricted to those listed in section S29—15, subject to specified minimum amounts, maximum amounts and permitted forms. Section S29—15 also specifies maximum claimable amounts for certain vitamins and minerals in formulated supplementary foods for young children. These amounts limit the quantity of a nutrient that may be declared or claimed per serving, but do not place an upper limit on the amount that may be present in the product. This differs from nutrients that specify maximum compositional levels, which explicitly constrain nutrient content.

2 Scope

This nutrition assessment examines the nutritional adequacy and safety of young child formula. The scope of the assessment includes nutrients for which Codex Standard CXS 156-1987 specifies mandatory compositional criteria, as well as vitamins and minerals currently permitted to be added to formulated supplementary foods for young children under Schedule 29— 5 of the Code. The nutrients considered in this risk assessment include energy, protein, carbohydrates, total fat, fatty acids, vitamins, minerals and selected nutritive substances. Nutrient exposure was assessed from young child formula only; total dietary intake from all food sources was not modelled.

2.1 Approach

Codex specifies minimum and maximum compositional levels and GULs per 100 kJ and 100 kcal. These values were assessed against Australia and New Zealand Nutrient Reference Values (NRVs) (NHMRC and MoH, 2006) to evaluate their contribution to daily nutrient intake. Codex compositional values were modelled using a 250 mL serving size, using the energy density assumptions specified in the Codex Standard. The minimum energy value of 251 kJ per 100 mL was used to convert Codex minimum compositional values to a 250 mL serving, while the maximum energy value of 293 kJ per 100 mL was used to convert Codex maximum compositional levels and GULs. This approach was applied to account for the lowest and highest plausible nutrient exposure and their percentage contribution to the relevant NRVs.

Section S29—15 to Standard 2.9.3 sets out minimum amounts, maximum amounts and maximum claimable amounts for specified nutrients. These values are provided for a serving and are expressed as a proportion of the RDI. The minimum energy requirement set in Standard 2.9.3 (330 kJ) was used to convert these values into Codex aligned values (/100 kJ).

A comparative assessment was undertaken based on serving size between the compositional values specified in Codex Standard Codex and those set out in Standard 2.9.3 of the Code. As Standard 2.9.3 specifies compositional requirements per serving. The reference serving size of 250 mL was used, and nutrient amounts per serving were directly compared with the relevant NRVs to determine their percentage contribution to daily intake.

2.2 Comparison with nutrient reference values

The Australia and New Zealand NRVs are intake based reference values used to assess nutrient adequacy and the risk of excess intake in individuals and population groups and are not intended to be used directly to derive minimum or maximum compositional levels for foods. For the purposes of this assessment, NRVs were used as reference points to assess potential nutrient inadequacy and excess intake. The proposed composition of young child formula was compared against the NRVs by modelling nutrient intake values for minimum compositional levels, maximum compositional levels and GULs in one, 2 and 3 serves of young child formula against the NRVs. Minimum compositional levels were assessed against Estimated Average Requirements (EARs) to evaluate the risk of nutritional inadequacy. Where EARs were not available, Adequate Intakes (AIs) were used. Maximum compositional levels and GULs were assessed against Upper Limits (ULs) to evaluate the potential risk of excessive intake. Where EARs, AIs or ULs were not available, Acceptable Macronutrient Distribution Ranges (AMDRs) were considered. Definitions for AI, EAR, UL and AMDR are provided in Table 1. As energy requirements for children differ based on age and sex, the average EAR for energy was used for this assessment. The average energy EAR for children aged 1-3 years is 4,700 kJ.

Table 1: Nutrient reference values and their definitions

Nutrient Reference Value	Definition
Adequate Intake (AI)	The average daily nutrient intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
Estimated average requirement (EAR)	A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.

Recommended daily intake (RDI)	The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97‑98 per cent) healthy individuals in a particular life stage and gender group.
Upper Limit (UL)	The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.
Acceptable macronutrient distribution range (AMDR)	The AMDR is an estimate of the range of intake for each macronutrient for individuals (expressed as percent contribution to energy), which would allow for an adequate intake of all the other nutrients whilst maximising general health outcome.

Source: NHMRC and MoH. (2006).

2.2.1 Guidance Upper Levels

In some instances, Codex does not set a maximum permitted level and instead specifies a guidance upper level. GULs are established for nutrients without sufficient information to support a science-based maximum level. These levels are derived based on meeting the nutritional requirements of young children and an established history of apparent safe use. Codex states that GULs may be adjusted based on relevant scientific or technological progress. GULs provide guidance to manufacturers and should not be interpreted as goal values. Nutrient content in young child formula should generally not exceed GULs unless higher levels cannot be avoided due to high or variable contents in constituents of the product or due to technological reasons. Where a product has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs (Codex, 2023). For the purpose of this assessment, GULs are treated as equivalent to maximum amounts and are assessed for the risk of excess nutrient intake against the ULs.

2.3 Assumptions

2.3.1 Consumption Assumptions

This nutrition risk is undertaken to characterise potential nutritional risk and does not imply that young child formula is necessary or recommended for children aged 1–3 years. For the purposes of this nutrition risk assessment, one serving of young child formula was defined as 250 mL. This definition is 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 to 1½ serves of dairy foods per day (Ministry of Health, 2021; National Health and Medical Research Council, 2013).

For modelling purposes, where young child formula is consumed, it was assumed to replace other dairy foods in the diet, providing an equivalent number of dairy serves to those recommended for children aged 1–3 years. For interpreting nutrient adequacy and excess, young child formula was assumed to contribute approximately 15–25% of total daily energy intake, reflecting consumption of around 1 to 1½ serves per day, with the remainder of energy derived from other foods. To represent expected and higher end consumption scenarios, the assessment modelled one (250 mL), 2 (500 mL) and 3 (750 mL) servings of young child formula per day. These intake scenarios were selected to characterise reported patterns of use, as well as upper levels of consumption.

Modelled intakes are assessed on the basis that young child formula is consumed alongside a varied diet and contributes a proportion of total daily energy intake. The assessment does not assume reliance on young child formula as a sole source of nutrition.

2.4 Cow's milk comparator

Regular (full) fat cow's milk was used as a comparator in this assessment under the assumption that it would be replaced by young child formula in the diets of some children aged 1–3 years. Cow's milk therefore provides an appropriate reference point for evaluating the relative nutritional contribution of young child formula, particularly in relation to energy, macronutrients and key micronutrients.

Although dietary guidelines generally recommend a transition to reduced-fat milk from around 2 years of age for the general population, regular fat cow's milk remains a relevant comparator for the purposes of nutritional risk assessment. Its use reflects its ongoing consumption in this age group and supports evaluation of whether young child formula meaningfully modifies nutrient intakes or addresses potential nutritional gaps relative to regular milk consumption. The nutritional profile of 250 mL of young child formula at the proposed compositional levels was compared with the nutritional profile of 250 mL of regular cow's milk (National Health and Medical Research Council, 2013).

3 Mandatory Nutrients

3.1 Energy

Table 3.1: Comparison of energy compositional values

	Minimum (kJ/100 mL)	Maximum (kJ/100 mL)
Codex 156-1987	251	293
Standard 2.9.3	132	—
Cow milk (average)	270	—

Note: The minimum energy requirement specified in Standard 2.9.3 (330 kJ per serving) was expressed on a per 100 mL basis using a mean serving size of 250 mL, based on Australian and New Zealand dietary guidelines.

Table 3.2: Comparison of dietary intakes with nutrient reference values

Estimated average requirement (EAR) for energy (average) 1–3 years = 4,700 kJ/day; Upper Limit (UL): not set.

Scenario (kJ/100 mL basis)	1 serve (kJ)	%EAR	%UL	2 serves (kJ)	%EAR	%UL	3 serves (kJ)	%EAR	%UL
Minimum intakes									
Codex minimum (251)	628	13%	—	1,255	27%	—	1,883	40%	—

Standard 2.9.3 minimum (132)	330	7%	—	660	14%	—	990	21%	—
Maximum intakes									
Codex maximum (293)	732	16%	—	1,465	31%	—	2,198	47%	—
Comparator intake *(based on average composition)*									
Cow's milk (270)	674	14%	—	1,348	29%	—	2,022	43%	—

3.1.1 Minimum

At the Codex minimum compositional level, modelled intake of energy from one 250 mL serve of young child formula provides approximately 13% of the EAR for energy intake when considered in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate energy intake. The Codex minimum energy value, when modelled in a 250 mL serving, is aligned with the energy value of cow's milk. On this basis, the risk of inadequate energy intake is considered low if FSANZ adopted the Codex minimum amount (251 kJ/100 mL).

3.1.2 Maximum

No UL has been set for energy for children aged 1–3 years. At the Codex maximum compositional level, modelled intake of energy from one 250 mL serve of young child formula accounts for approximately 16% of the EAR for energy intake when considered in isolation. No UL has been set for energy for children aged 1–3 years. The Codex maximum energy value, when modelled in a 250 mL serving, is only slightly higher than the energy value of cow's milk. In the absence of an established UL for energy, the risk of excessive energy intake from consumption of young child formula is therefore considered low if FSANZ adopted the Codex maximum amount (293 kJ/100 mL).

3.1.3 Conclusion

Under both the Codex minimum and maximum energy scenarios, modelled intakes are comparable to the energy in cow's milk. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake, comparisons with the EAR do not indicate a risk of energy inadequacy or excess.

3.2 Protein

Table 3.3: Comparison of protein compositional values

	Minimum (g/100 kJ)	Maximum (g/100 kJ)
Codex 156-1987	0.43	—
Standard 2.9.3	0.76	—

Note: Conversion of the minimum protein requirement specified in Standard 2.9.3 (2.5 g per serving) to Codex units (g/100 kJ) was based on the minimum energy requirement of 330 kJ per serving, resulting in an upper bound estimate of the minimum protein concentration under the Code.

Table 3.4: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 12 g/day; No UL has been set for protein; Acceptable Macronutrient Distribution Ranges (AMDR) of 25% protein per day is used as a prudent reference point.

Scenario (g/100 kJ basis)	1 serve (g)	%EAR	2 serves (g)	%EAR	3 serves (g)	%EAR
Minimum intakes						
Codex minimum (0.43)	2.70	23%	5.40	45%	8.09	68%
Standard 2.9.3 minimum (0.76)	2.5	21%	5	42%	7.5	63%
Comparator intake *(based on average composition)*						
Cow's milk (1.28)	8.63	72%	17.3	144%	25.9	216%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.2.1 Minimum

At the Codex minimum compositional level, modelled protein intake from one 250 mL serving of young child formula provides approximately 23% of the EAR for protein when considered in isolation. This contribution is lower than that provided by an equivalent volume of cow's milk. The Standard 2.9.3 minimum protein value is closely aligned to the Codex value. At the Standard minimum, modelled protein intake from one 250 mL serving of young child formula contains 21% of the EAR for protein. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate protein intake. On this basis, the risk of inadequate protein intake is considered low if FSANZ adopted the Codex minimum amount (0.43g/100 kJ).

3.2.2 Maximum

Neither Codex nor Standard 2.9.3 specify a maximum compositional level for protein, and no UL has been established. In the absence of a UL an AMDR upper boundary for protein of 25% of total energy is used as a prudent reference point for characterising potential excess. Compositional constraints, including minimum total fat requirements, inherently limit protein density, such that protein intakes remain constrained even at higher consumption scenarios of up to 3 servings per day. On this basis, the risk of excessive protein intake from consumption of young child formula is considered low if FSANZ adopts a Codex consistent approach and does not set a maximum compositional level for protein.

3.2.3 Conclusion

At the Codex minimum compositional level, modelled intakes of protein from young child formula are consistent with meeting protein requirements without indicating a risk of inadequacy when consumed as part of a varied diet. In the absence of an established UL, and consistent with Codex, the risk of excessive protein intake from consumption of young child formula is considered low.

3.3 Total fat

Table 3.5: Comparison of total fat compositional values

	Minimum (g/100 kJ)	Maximum (g/100 kJ)
Codex 156-1987	0.84	—
Standard 2.9.3	—	—

Table 3.6: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): AMDR for total fat = 20–35% of energy; No EAR or UL has been set for total fat.

Scenario (g/100 kJ basis)	1 serve (g)	%AMDR*	%UL	2 serves (g)	%AMDR	%UL	3 serves (g)	%AMDR	%UL
Minimum intakes									
Codex minimum (0.84)	5.27	4.2%	—	10.5	8.4%	—	15.8	13%	—
Comparator intake *(based on average composition)*									
Cow's milk (1.26)	8.5	6.7%	—	17	13%	—	25.5	20%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.3.1 Calculations

Grams of fat were converted to kilojoules (kJ) using a conversion factor of 37 kJ per gram of fat. The resulting energy from fat was expressed as a percentage of assumed total daily energy intake (4,700 kJ/day) to allow comparison with the Acceptable Macronutrient Distribution Range (AMDR) for total fat (20–35% of energy) for children aged 1–3 years.

3.3.2 Minimum

Standard 2.9.3 does not specify a minimum compositional value for total fat, and no EAR or AI has been established. In the absence of an EAR or AI, the AMDR lower boundary of 20% of total energy from fat provides a relevant reference point for assessing adequacy. At the Codex minimum compositional level, modelled intakes of total fat from one 250 mL serving of young child formula provide approximately 4% of the mean total daily energy intake when considered in isolation. This contribution is lower than that provided by an equivalent volume of cow's milk. However, when interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, modelled intakes do not indicate a risk of inadequate intake from total fat. On this basis, the risk of inadequate total fat intake is considered low if FSANZ adopts the Codex minimum amount (0.84 g/100 kJ).

3.3.3 Maximum

Neither Codex nor Standard 2.9.3 specify a maximum compositional value for total fat, and no UL has been established. In the absence of a UL, the AMDR upper boundary of 35% of total energy from fat provides a prudent reference point for characterising potential excess. Compositional constraints, including minimum protein requirements would inherently limit the amount of total fat, such that total fat intakes remain constrained even at higher consumption levels of up to three servings per day. On this basis, the risk of excessive total fat intake from consumption of young child formula is considered low if FSANZ adopts a Codex consistent approach and does not set a maximum compositional level for total fat.

3.3.4 Conclusion

At the Codex minimum compositional level, modelled intakes of total fat from young child formula contributes to overall dietary fat without indicating a risk of inadequacy when consumed as part of a varied diet. In the absence of an established UL, and consistent with Codex and Standard 2.9.3, the risk of excessive total fat intake from consumption of young child formula is considered low.

3.4 α-linolenic acid

Table 3.7: Comparison of α-linolenic acid compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	12	
Standard 2.9.3	—	

Table 3.8: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): Adequate Intake (AI) = 500 mg/day; UL: not set.

Scenario (mg/100 kJ basis)	1 serve (mg)	%AI	%UL	2 serves (mg)	%AI	%UL	3 serves (mg)	%AI	%UL
Minimum intakes									
Codex minimum (12)	75.3	15%	—	151	30%	—	226	45%	—
Comparator intake *(based on average composition)*									

Cow's milk (7.05)	47.5	9.5%	—	95	19%	—	143	29%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.4.1 Minimum

At the Codex minimum compositional level, modelled intakes provide from one 250 mL serving of young child formula provide approximately 15% of the AI for α-linolenic acid and 3 servings provide close to half of the AI. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate α-linolenic acid intake. When modelled at the minimum proposed compositional level, one serving of young child formula contains a higher amount of α-linolenic acid than cow's milk. On this basis, the risk of inadequate α-linolenic acid intake is considered low if FSANZ adopts the Codex minimum amount (12 mg/100 kJ).

3.4.2 Maximum

Neither Codex nor Standard 2.9.3 specify a maximum compositional level for α-linolenic acid. No UL has been established for α-linolenic acid and there is no known level at which adverse effects may occur. In the absence of an established UL and given that young child formula contributes only a portion of total daily intake, the risk of excessive α-linolenic acid intake from consumption of young child formula is considered low if FSANZ adopts a Codex consistent approach and does not set a maximum compositional level for α-linolenic acid.

3.4.3 Conclusion

Under the Codex minimum compositional level, modelled intakes of α-linolenic acid from young child formula contribute to overall dietary α-linolenic acid requirements without indicating a risk of inadequacy, when consumed as part of a varied diet. In the absence of an established UL and consistent with Codex, the risk of excessive α-linolenic acid intake is considered low.

3.5 Linoleic acid

Table 3.9: Comparison of linoleic acid compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex 156-1987	72	—
Standard 2.9.3	—	—

Table 3.10: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): AI = 5,000 mg/day; UL: not set.

Scenario (mg/100 kJ basis)	1 serve (mg)	%AI	%UL	2 serves (mg)	%AI	%UL	3 serves (mg)	%AI	%UL

Minimum intakes									
Codex minimum (72)	452	9%	—	904	18%	—	1,355	27%	
Comparator intake *(based on average composition)*									
Cow's milk (22.1)	149	3%	—	298	6%	—	447	8.9%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.5.1 Minimum

At the Codex minimum compositional level, modelled intakes from one 250 mL serving of young child formula provides approximately 9% of the AI for linoleic acid and 3 servings provides approximately 27% of the AI. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate linoleic acid intake. At the minimum compositional level, young child formula contains a higher level of linoleic acid than cow's milk. On this basis, the risk of inadequate linoleic acid intake is considered low if FSANZ adopted the Codex minimum amount (72 mg/100 kJ).

3.5.2 Maximum

Neither Codex nor Standard 2.9.3 specify a maximum compositional level for linoleic acid. No UL has been established and there is no known level at which adverse effects may occur. In the absence of an established UL, the risk of excess linoleic acid intake from consumption of young child formula is considered low if FSANZ adopts a Codex-consistent approach and does not set a maximum compositional level for linoleic acid.

3.5.3 Conclusion

Under the Codex minimum compositional level, modelled intakes of linoleic acid from young child formula contribute to overall dietary linoleic acid requirements without indicating a risk of inadequacy, when consumed as part of a varied diet. In the absence of an established UL and consistent with Codex, the risk of excessive linoleic acid intake is considered low.

3.6 Available carbohydrates

Table 3.11: Comparison of available carbohydrate compositional values

	Minimum (g/100 kJ)	Maximum (g/100 kJ)
Codex 156-1987	—	3
Standard 2.9.3	—	—

Table 3.12: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): AMDR for carbohydrate = 45-65% of energy; No EAR or UL has been set for carbohydrates.

Scenario (g/100 kJ basis)	1 serve (g)	%Energy	%UL	2 serves (g)	%Energy	%UL	3 serves (g)	%EAR	%UL
Maximum intakes									
Codex maximum (3)	22	8%	—	44	16%	—	65.9	24%	—
Comparator intake *(based on average composition)*									
Cow's milk (1.81)	12.3	4.4%	—	24.5	8.9%	—	37	13%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.6.1 Calculations

Grams of carbohydrate were converted to kilojoules (kJ) using a conversion factor of 17 kJ per gram of carbohydrate, to enable assessment of carbohydrate intake against the EAR for energy. Carbohydrate intake was evaluated against total energy intake, this value was then assessed against the AMDR (45%-65%) For children aged 1–3 years, an average daily energy intake of 4,700 kJ was assumed.

3.6.2 Minimum

Neither Codex nor Standard 2.9.3 specify a minimum compositional level for available carbohydrates. Young child formula is assumed to contribute approximately 15–25% of total daily energy intake and to be consumed alongside a varied diet. Carbohydrates are widely consumed in the usual diets of young children through staple foods. On this basis, the risk of inadequate carbohydrates intake is considered low if FSANZ were to adopt the same approach as Codex and not set a minimum compositional level for available carbohydrates.

3.6.3 Maximum

At the Codex maximum compositional level, modelled intakes from one 250 mL serving of young child formula contribute approximately 8% of total daily energy requirements and modelled intakes from 3 servings remain well below the AMDR for carbohydrate (45%-65%). No UL has been set for available carbohydrates. Therefore, the risk of excessive carbohydrate intake from consumption of young child formula is considered low if FSANZ adopts the Codex maximum amount (3 g/100 kJ).

3.6.4 Conclusion

Under the Codex maximum compositional level, modelled carbohydrate intakes are below the recommended AMDR ranges. No UL has been set for carbohydrates. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparison with the recommended intake ranges does not indicate a risk of nutritional inadequacy or excess.

3.7 Vitamin A

Table 3.13: Comparison of vitamin A compositional values

	Minimum (µg RE*/100 kJ)	Maximum (µg RE*/100 kJ)
Codex CXS 156-1987	14	43
Standard 2.9.3	—	41

* Expressed as retinol equivalents (RE).

Note: The maximum Vitamin A amount specified in Schedule 29 (135 µg RE/serve) was converted to Codex aligned units (µg RE/100 kJ) using the minimum energy requirement of 330 kJ per serving, the maximum Vitamin A concentration permitted under the Code on a per energy basis.

Table 3.14: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 210 µg RE/day; UL= 600 µg RE/day.

Scenario (RE/µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (14)	87.9	42%	—	176	84%	—	264	126%	—
Maximum intakes									
Codex maximum (43)	315	—	53%	623	—	105%	945	—	158%
Standard 2.9.3 maximum (41)	135	—	23%	270	—	45%	405	—	68%
Comparator intake *(based on average composition)*									
Cow's milk (43.5)	109	52%	18%	218	104%	36%	327	156%	55%

Note: Nutrient amounts per serve are calculated on an energy equivalent basis, see Table 3.1.

The amount of vitamin A in a food is calculated as retinol equivalents (RE) using the internationally accepted conversion:1 µg RE = 3.33 International Units (IU) vitamin A = 1 µg all-trans retinol.

3.7.1 Minimum

At the Codex minimum compositional level, modelled vitamin A intakes from one and 2 x 250 mL servings contribute substantially to the EAR, while 3 servings exceed the EAR when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin A intake. On this basis, the risk of inadequate vitamin A intake is considered low if FSANZ adopts the Codex minimum amount (14 µg RE/100 kJ).

3.7.2 Maximum

At the Codex maximum compositional levels, modelled vitamin A intakes from 2 servings at 250 mL of young child formula slightly exceed the UL (105%), with 3 servings exceeding the UL to a greater extent (158%). In contrast, intakes modelled at the maximum levels permitted under

Standard 2.9.3 remain below the UL across all consumption scenarios assessed (up to 68% of UL).

This modelling suggests a potential for exceeding the vitamin A UL under scenarios involving multiple servings consumed at the Codex maximum compositional level. At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ serves per day), modelled vitamin A intakes remain below the UL.

Exceedance of the UL under higher-intake scenarios may pose a low to moderate risk, particularly where intake is chronic. While the risk of excessive vitamin A intake is considered low with consumption of one serving, regular consumption of multiple servings at the Codex maximum level could pose a risk of excessive vitamin A intake if FSANZ were to adopt the Codex maximum amount (43 µg RE/100 kJ).

In further characterising risk, it is important to note that the Australia and New Zealand UL for vitamin A for children aged 1–3 years (600 µg RE/day) was derived by extrapolation from adult data due to limited direct evidence in children and is therefore conservative. In 2024, EFSA retained an adult UL of 3,000 µg RE/day for preformed vitamin A and using allometric scaling to derive age specific values, reaffirmed the UL for the 1–3 year age group at 800 µg RE/day. Taken together, these considerations indicate that modelled exceedances against the Australia and New Zealand UL are likely to overstate risk under typical dietary patterns, particularly where exposures are not sustained.

3.7.3 Conclusion

At the Codex minimum compositional level, modelled vitamin A intakes do not indicate a risk of inadequacy. At the Codex maximum compositional level, modelled intakes from multiple servings of young child formula exceed the UL. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet and not as a sole source of nutrition, the risk of excessive vitamin A intake is considered low at typical consumption levels. However, frequent consumption of multiple serves at the Codex maximum compositional level could pose a risk of excessive vitamin A intake, particularly if exposures were to be chronic.

3.8 Vitamin D

Table 3.15: Comparison of vitamin D compositional values

	Minimum (µg*/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	0.36	1.1
Standard 2.9.3	—	0.76

* Calciferol. 1 µg calciferol = 40 International Units (IU) vitamin D.

The maximum vitamin D amount specified in Schedule 29 (2.5 µg per serving) was converted to Codex aligned units (µg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum vitamin D concentration permitted under the Code on a per energy basis.

Table 3.16: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): AI = 5 µg/day; UL = 80 µg/day.

Scenario (µg/100 kJ basis)	1 serve (µg)	%AI	%UL	2 serves (µg)	%AI	%UL	3 serves (µg)	%AI	%UL
Minimum intakes									
Codex minimum (0.36)	2.26	45%	—	4.52	90%	—	6.77	136%	—
Maximum intakes									
Codex maximum (1.1)	8.06	—	10%	16.1	—	20%	24.2	—	30%
Standard 2.9.3 maximum (0.76)	2.5	—	3.1%	5	—	6.3%	7.5	—	9.4%
Comparator intake *(based on average composition)*									
Cow's milk (0.04)	0.25	5%	—	0.5	10%	—	0.75	15%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.8.1 Minimum

At the Codex minimum compositional level, modelled vitamin D intake from 3 x 250 mL servings of young child formula exceed the AI when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin D intake. At the minimum compositional level proposed level, young child formula contains a higher amount of vitamin D than cow's milk. On this basis, the risk of inadequate vitamin D intake is considered low if FSANZ adopts the Codex minimum amount (0.36 µg/100 kJ).

3.8.2 Maximum

Under both the Standard 2.9.3 and the Codex maximum compositional scenarios, modelled vitamin D intakes from up to 3 x 250 mL servings remain well below the UL. At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ servings per day), intakes represent a small proportion of the UL. The risk of excessive vitamin D intake from consumption of young child formula is therefore considered low if FSANZ adopts the Codex maximum amount (1.1 µg/100 kJ).

3.8.3 Conclusion

Under all intake scenarios, modelled intakes of vitamin D are higher than the average amount present in cow's milk, reflecting the fortified nature of young child formula. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparisons with the AI and UL do not indicate a risk of nutritional inadequacy or excess.

3.9 Riboflavin

Table 3.17: Comparison of riboflavin compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	19	155 (GUL*)
Standard 2.9.3	n/a	121 (maximum claimable amount)

The maximum claimable amount for riboflavin specified in Schedule 29 (0.4 mg per serving) was converted to Codex aligned units (µg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum riboflavin concentration that could be declared under the Code on an energy basis.

*Guidance Upper Level (GUL).

Table 3.18: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 400 µg/day; UL: not set.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (19)	119	30%	—	238	60%	—	358	89%	—
Maximum intakes									
Codex GUL (155)	1,135	—	—	2,271	—	—	3,406	—	—
Standard 2.9.3 maximum (121)	400	—	—	800	—	—	1,200	—	—
Comparator intake *(based on average composition)*									
Cow's milk (83.7)	560	140%	—	1,120	280%	—	1,680	560%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.9.1 Minimum

At the Codex minimum compositional level, modelled riboflavin intake from one 250 mL serving provides approximately 30% of the EAR, while intakes from 2 and 3 servings approach or exceed the EAR when assessed in isolation. At the Codex minimum compositional level, young child formula contains a lower amount of riboflavin than cow's milk. However, when interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate riboflavin intake. On this basis, the risk of riboflavin inadequacy is considered low if FSANZ adopts the Codex minimum amount (19 µg/100 kJ).

3.9.2 Maximum

No UL has been established for riboflavin. Under the Codex GUL scenarios, modelled riboflavin intakes exceed the EAR; however, in the absence of an established UL and given the well-established safety profile of riboflavin, these intakes do not raise safety concerns. On this basis, the risk of excessive riboflavin intake due to consumption of young child formula is considered low if FSANZ adopts the Codex GUL (155 µg/100 kJ).

3.9.3 Conclusion

Under the Codex minimum compositional level, modelled intakes of riboflavin from young child formula, when compared with the EAR, contribute to overall riboflavin requirements without indicating a risk of inadequacy when consumed as part of a varied diet. In the absence of an established UL, the risk of excessive riboflavin intake is considered low under the Codex GUL.

3.10 Vitamin B12

Table 3.19: Comparison of vitamin B12 compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	0.02	0.48 (GUL)
Standard 2.9.3	—	0.15 (maximum claimable amount)

The maximum claimable amount for vitamin B12 specified in Schedule 29 (0.5 µg per serving) was converted to Codex aligned units (µg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum vitamin B12 concentration that could be declared under the Code on an energy basis.

Table 3.20: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 0.7 µg/day; RDI = 0.9 µg/day; UL: not set.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (0.02)	0.13	18%	—	0.25	36%	—	0.38	54%	—
Maximum intakes									
Codex GUL (0.48)	3.52	—	—	7.03	—	—	10.55	—	—
Standard 2.9.3 maximum (0.15)	0.5	—	—	1	—	—	1.5	—	—
Comparator intake *(based on average composition)*									

Cow's milk (0.12)	0.81	116%	—	1.62	232%	—	2.44	348%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.10.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 18% of the EAR for vitamin B12, and intake from 3 x 250 mL servings provides over half of the EAR. At the Codex minimum compositional level, modelled intake for one serving of young child formula contains less vitamin B12 than cow's milk. However, when interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin B12 intake. On this basis, the risk of vitamin B12 inadequacy is considered low if FSANZ adopts the Codex minimum amount (0.02 µg/100 kJ).

3.10.2 Maximum

No UL has been set for vitamin B12. In the absence of a UL and given that no adverse effects are associated with high vitamin B12 intake from foods in healthy individuals, the risk of excessive vitamin B12 intake due to consumption of young child formula is considered low if FSANZ adopts the Codex GUL (0.48 µg/100 kJ).

3.10.3 Conclusion

Under the Codex minimum compositional level, modelled vitamin B12 intakes from young child formula contribute to overall vitamin B12 requirements without indicating a risk of inadequacy when consumed as part of a varied diet. In the absence of an established UL, the risk of excessive vitamin B12 intake is considered low under the Codex GUL.

3.11 Vitamin C

Table 3.21: Comparison of vitamin C* compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	2.4	
Standard 2.9.3	—	4.5 (maximum claimable amount)

* Expressed as L-ascorbic acid.

The maximum claimable amount for vitamin C specified in Schedule 29 (15 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum vitamin C concentration that could be declared under the Code on an energy basis.

Table 3.22: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 25 mg/day; RDI 1–3 years = 35 mg/day; UL: 1,000 mg/day*

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL*	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									
Codex minimum (2.4)	15.1	60%	—	30.1	121%	—	45.2	181%	—
Maximum intakes									
Codex GUL (17)	125	—	13%	249	—	25%	374	—	37%
Standard 2.9.3 maximum (4.5)	15	—	1.5%	30	—	3%	45	—	4.5%
Comparator intake *(based on average composition)*									
Cow's milk (0)	0	—	—	0	—	—	0	—	—

*It is not possible to establish a UL for vitamin C, but 1,000 mg/day is a prudent limit.

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.11.1 Minimum

At the Codex minimum compositional level, modelled vitamin C intake from one 250 mL serving of young child formula provides over half of the EAR, and intake from 2 x 250 mL servings exceed the EAR for vitamin C when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin C intake. On this basis, the risk of inadequate vitamin C intake is considered low if FSANZ adopts the Codex minimum amount (2.4 mg/100 kJ).

3.11.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex GUL, modelled intakes at up to 3 x 250 mL servings remain below the prudent UL (1,000 mg/day). At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ servings per day), intakes represent a small proportion of the prudent UL. The risk of excess intake of vitamin C from consumption of young child formula is therefore considered low if FSANZ adopts the Codex GUL (17 mg/100 kJ).

3.11.3 Conclusion

Cow's milk does not contain vitamin C and therefore, under all scenarios, modelled intakes of vitamin C are higher than the average amount present in cow's milk, reflecting the fortified nature of young child formula. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparisons with the EAR and UL do not indicate a risk of nutritional inadequacy or excess.

3.12 Iron

Table 3.23: Comparison of iron compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	0.24	0.72
Codex CXS 156-1987(Product based on soy protein isolate)	0.36	—
Standard 2.9.3	—	0.91 (maximum claimable amount)

Product based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

The maximum claimable amount for iron specified in Schedule 29 (3 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum iron concentration that could be declared under the Code on an energy basis.

Table 3.24: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years) EAR = 4 mg/day; RDI = 9 mg/day; UL = 20 mg/day.

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									
Codex minimum (0.24)	1.51	38%	—	3.01	75%	—	4.52	113%	—
Codex minimum (0.36) (Product based on soy protein isolate)	2.26	56%	—	4.52	113%	—	6.78	169%	—
Maximum intakes									
Codex maximum (0.72)	5.27	—	26%	10.6	—	53%	15.8	—	79%
Standard 2.9.3 maximum (0.91)	3.0	—	15%	6.0	—	30%	9.0	—	45%
Comparator intake *(based on average composition)*									
Cow's milk (0.01)	0.05	1.3%	0.25%	0.10	2.5%	0.5%	0.15	3.8%	0.75%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.12.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 38% of the EAR for iron, while intake from 3 x 250 mL servings exceeds the EAR when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate iron intake. On this basis, the risk of inadequate iron intake is considered low if FSANZ adopted the Codex minimum amount (0.24 mg/100 kJ).

3.12.1.1 Soy based products

Products based on soy protein isolate typically have higher minimum iron permissions because iron from plant sources has lower bioavailability than iron from animal-based proteins, largely due to the presence of anti-nutrients such as phytates. Typically, higher minimum levels help ensure that products formulated with soy protein can still meet iron nutritional requirements and support adequate iron status.

For products based on soy protein isolate, at the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately half the EAR for iron and intake from 2 and 3 250 mL servings exceeds the EAR when assessed in isolation. When interpreted in the context that young child formula is assumed to contribute approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate iron intake. On this basis, the risk of inadequate iron intake is considered low if FSANZ adopts the Codex minimum amount (0.36 mg/100 kJ).

3.12.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex maximum compositional scenarios, modelled iron intakes at up to 3 x 250 mL servings remain below the UL. Under the highest consumption scenario, which represents a conservative modelling assumption, iron intakes provide up to approximately 80% of the UL. On this basis, the risk of excessive iron intake from consumption of young child formula is considered low if FSANZ adopts the Codex maximum amount (0.72 mg/100 kJ).

3.12.3 Conclusion

Under all scenarios, modelled intakes of iron are higher than the average amount present in cow's milk, reflecting the fortified nature of young child formula. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparisons with the EAR and UL do not indicate a risk of nutritional inadequacy or excess.

3.13 Calcium

Table 3.25: Comparison of calcium compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	22	67 (GUL)
Standard 2.9.3	—	106 (maximum claimable amount)

The maximum claimable amount for calcium specified in Schedule 29 (350 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum calcium concentration that could be declared under the Code on an energy basis.

Table 3.26: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR= 360 mg/day; RDI = 500 mg/day; UL = 2,500 mg/day.

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									
Codex minimum (22)	138	38%	—	276	77%	—	414	115%	—
Maximum intakes									
Codex GUL (67)	491	—	20%	982	—	39%	1,472	—	60%
Standard 2.9.3 maximum (106)	350	—	14%	700	—	28%	1,050	—	42%
Comparator intake *(based on average composition)*									
Cow's milk (42.6)	286	79%	11%	572	159%	23%	858	238%	34%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.13.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 38% of the EAR for calcium, while intake from 3 x 250 mL servings slightly exceed the EAR. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate calcium intake. On this basis, the risk of inadequate calcium intake is considered low if FSANZ adopted the Codex minimum amount (22 mg/100 kJ).

3.13.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex GUL scenarios, modelled calcium intakes at up to 3 x 250 mL serves remain below the UL. At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ servings per day), intakes represent a small proportion of the UL. The risk of excessive calcium intake from consumption of young child formula is therefore considered low if FSANZ adopts the Codex GUL (67 mg/100 kJ).

3.13.3 Conclusion

Under the Codex minimum compositional level, modelled calcium intakes from young child formula contribute to overall calcium requirements without indicating a risk of inadequacy when consumed as part of a varied diet. Under the Codex maximum, modelled intakes remain below the UL and do not indicate a risk of excess.

3.14 Zinc

Table 3.27: Comparison of zinc compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	0.12	0.36 (GUL)
Standard 2.9.3	—	0.33 (maximum claimable amount)

The maximum claimable amount for zinc specified in Schedule 29 (1.1 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum zinc concentration that could be declared under the Code on an energy basis.

Table 3.28: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR= 2.5 mg/day; RDI = 3 mg/day; UL = 7 mg/day.

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									
Codex minimum (0.12)	0.75	30%	—	1.51	60%	—	2.26	90%	—
Maximum intakes									
Codex GUL (0.36)	2.64	—	38%	5.27	—	75%	7.91	—	113%
Standard 2.9.3 maximum (0.33)	1.1	—	16%	2.2	—	31%	3.3	—	47%
Comparator intake (based on average composition)									
Cow's milk (0.13)	0.85	34%	12%	1.70	68%	24%	2.55	102%	36%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

3.14.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 30% of the EAR for zinc, while intake from 3 x 250 mL servings provides approximately 90% of the EAR when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate zinc intake. On this basis, the risk of inadequate zinc intake is considered low if FSANZ adopts the Codex minimum amount (0.12 mg/100 kJ).

3.14.2 Maximum

Under the Codex GUL, modelled zinc intakes from one 250 mL serving of young child formula provides approximately 38% of the UL for zinc, while intake from the highest consumption scenario (3 x 250 mL servings) slightly exceeds the UL (113%). In contrast, intakes modelled at the maximum claimable amount under Standard 2.9.3 remain below the UL across all consumption scenarios assessed (up to 47% of UL). This modelling indicates a potential for exceeding the UL for zinc under scenarios involving multiple servings consumed at the Codex GUL.

At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ serves per day), modelled zinc intakes remain below the UL. Exceedance of the UL under higher-intake scenarios is considered to pose a low risk, particularly where intake is not chronic and where zinc intakes from the remainder of the diet are moderate. While the risk of excessive zinc intake is considered low with consumption of up to 2 servings, regular consumption of 3 or more servings could pose a risk of excessive zinc intake if FSANZ adopts the Codex GUL (0.36 mg /100 kJ).

In further characterising the risk, it is important to note that the UL for zinc was established in the absence of evidence of adverse effects from naturally occurring zinc in foods. The UL applies to total zinc intake from food, water and supplements, including fortified foods, and is based on the critical effect of excess zinc on copper metabolism. Due to limited data for older children and adolescents, ULs for these age groups were derived by extrapolation on a body-weight basis and rounded down, resulting in conservative values. Reported adverse effects of zinc, including reduced copper status, immune suppression and decreased HDL cholesterol, have been associated primarily with chronic high-dose supplemental intakes. These considerations indicate that modelled exceedances of the UL are likely to overstate risk under typical dietary patterns, particularly where exposures are not sustained.

3.14.3 Conclusion

At the Codex minimum compositional level, modelled zinc intakes do not indicate a risk of nutritional inadequacy. Modelled intakes of zinc at the Codex GUL exceed the UL under the highest consumption scenario (3 x 250 mL servings), while intakes from up to 2 servings remain below the UL. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet and not as a sole source of nutrition, the risk of excessive zinc intake is considered low at typical consumption levels and when consumed alongside a varied diet. However, frequent consumption of multiple serves at the Codex GUL could pose a risk of excessive zinc intake, particularly if exposures were to be chronic.

4 Optional Nutrients

4.1 Thiamin

Table 4.1: Comparison of thiamin compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	14	72 (GUL)
Standard 2.9.3	—	75.8 (maximum claimable amount)

Note: The maximum thiamin amount specified in Schedule 29 (250 µg RE/serve) was converted to Codex aligned units (µg RE/100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum thiamin concentration that could be declared under the Code on a per energy basis.

Table 4.2: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 400 µg/day; UL: not set.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (14)	87.9	22%	—	176	44%	—	264	66%	—
Maximum intakes									
Codex GUL (72)	527	—	—	1,055	—	—	1,582	—	—
Standard 2.9.3 maximum (75.8)	250	—	—	500	—	—	750	—	—
Comparator intake (based on average composition)									
Cow's milk (11.8)	78.8	20%	—	157	40%	—	236	59%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.1.1 Minimum

At the Codex minimum compositional level, modelled thiamin intake from one 250 mL serving of young child formula provides approximately 22% of the EAR, and intake from 3 x 250 mL servings provides about two thirds of the EAR for thiamin when assessed in isolation. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate thiamin intake. On this basis, the risk of inadequate thiamin intake is considered low if FSANZ adopted the Codex minimum amount (14 µg/100 kJ).

4.1.2 Maximum

No UL has been set for thiamin. In the absence of an established UL and given that no adverse effects have been identified from usual dietary intakes from food, these intakes do not raise safety concerns. The risk of excessive thiamin intake due to consumption of young child formula is therefore considered low if FSANZ adopted the Codex GUL (72 µg/100 kJ).

4.1.3 Conclusion

Under all modelled scenarios, thiamin intakes from young child formula are higher than the average amount present in cow's milk, reflecting the fortified nature of the product. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake, comparisons with the EAR do not indicate a risk of nutritional inadequacy. In the absence of an established UL, the risk of excessive thiamin intake is considered low under the Codex GUL.

4.2 Niacin

Table 4.3: Comparison of Niacin Compositional Values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	72	359 (GUL)
Standard 2.9.3	—	758 (maximum claimable amount)

Note: The maximum niacin amount specified in Schedule 29 (2,500 µg RE/serve) was converted to Codex aligned units (µg RE/100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum niacin concentration that could be declared under the Code on a per energy basis.

Table 4.4: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 5,000 µg/day; UL = 10,000 µg/day.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (72)	452	9%	—	904	18%	—	1,355	27%	—
Maximum intakes									
Codex GUL (359)	2,630	—	29%	5,259	—	53%	7,889	—	79%
Standard 2.9.3 maximum (758)	2,500	—	25%	5,000	—	50%	7,500	—	75%
Comparator intake (based on average composition)									
Cow's milk (85.1)	575	12%	5.7%	1,150	23%	12%	1,725	35%	17%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.2.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 9% of the EAR for niacin, while intake from 3 x 250 mL servings provides approximately 27% of the EAR when considered in isolation. At this minimum level, niacin intake from a serving of young child formula is slightly lower than that from a serving of cow's milk. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate niacin intake at the population level. This is supported by national dietary intake data showing a low prevalence of inadequate niacin intakes among young children (ABS 2015). While young child formula at the Codex minimum level makes a modest contribution to total niacin intake, this does not raise a public health concern when the remainder of the diet is considered. On this basis the risk of inadequate niacin intake is considered low if FSANZ adopts the Codex minimum amount (72 µg/100 kJ).

4.2.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex GUL scenarios, modelled niacin intakes at up to 3 x 250 mL servings remain below the UL. Under the highest consumption scenario, which represents a conservative modelling assumption, niacin intakes provide up to approximately 79% of the UL. On this basis, the risk of excessive niacin intake from consumption of young child formula is considered low if FSANZ adopted the Codex GUL (359 µg/100 kJ).

4.2.3 Conclusion

At the Codex minimum compositional level, modelled intakes of niacin from one 250 mL serving of young child formula are slightly lower than those from cow's milk and contribute approximately 9% of the EAR. For children with lower dietary niacin intake, reliance on young child formula could increase the likelihood of niacin intakes falling below requirements if not offset by the remainder of the diet. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparisons with the EAR do not indicate a risk of nutritional inadequacy. Under the Codex GUL, modelled intakes remain below the UL and do not indicate a risk of excess.

4.3 Folate

Table 4.5: Comparison of folate/folic acid compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987 *(folic acid)*	2.4	12 (GUL)
Standard 2.9.3 *(folate)*	—	15 (maximum claimable amount)

Note: The maximum folate amount specified in Schedule 29 (50 µg RE/serve) was converted to Codex aligned units (µg RE/100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum folate concentration that could be declared under the Code on a per energy basis.

Table 4.6: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years) folic acid: EAR = 120 µg/day; UL = 300 µg/day. When converted to Dietary Folate Equivalents (DFE) EAR= 72 µg/day.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR*	%UL#	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									

Codex minimum (2.4)	15	21%	—	30.1	42%	—	45.2	63%	—
Maximum intakes									
Codex GUL (12)	87.9	—	29%	176	—	59%	264	—	88%
Standard 2.9.3 maximum (15) ***(folate)***	50	—	17%	100	—	33.%	150	—	50%
Comparator intake (based on average composition)									
Cow's milk (3.40) ***(total folates)***	22.5	31%	7.5%	45	63%	15%	67.5	94%	23%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.
**Expressed as Dietary Folate Equivalents*

#Percentages against the UL are based on folic acid.

4.3.1 Minimum

To assess the Codex minimum, the EAR was converted to Dietary Folate Equivalents (DFE) values. Standard equivalence factors provide an internationally recognised approach for addressing this conversion. The following conversion factors were used; 1 µg of DFE is equivalent to 1 µg food folate, 0.5 µg folic acid on an empty stomach and/or 0.6 µg folic acid with meals or as a fortified food (NHMRC and NZ MOH, 2006). Based on these equivalence factors, the EAR of 120 µg/day DFE corresponds to approximately 72 µg/day of folic acid.

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 21% of the EAR, and intake from 3 x 250 mL servings provides approximately 63% of the EAR on a DFE-equivalent basis. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate folate intake. On this basis, the risk of inadequate folate intake is considered low if FSANZ adopted the Codex minimum amount (2.4 µg/100 kJ).

4.3.2 Maximum

The UL for folate in young children applies to folic acid intake from fortified foods and supplements and does not include naturally occurring food folate. Accordingly, modelled folic acid intakes from young child formula were assessed directly against the UL. Under both the Standard 2.9.3 maximum claimable amount (expressed as folate) and the Codex GUL (expressed as folic acid) scenarios, modelled intakes up to 3 x 250 mL servings remain below the UL; however, 3 servings at the Codex GUL approach the UL (88%), which represents a high intake scenario. At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ servings per day), the risk of excessive folic acid intake due to consumption of young child formula is considered low if FSANZ adopted the Codex GUL (12 µg/100 kJ).

4.3.3 Conclusion

Under the Codex minimum compositional level, modelled intakes of folate (as DFE) from young child formula, when compared with the EAR, contribute to overall folate requirements without indicating a risk of inadequacy when consumed as part of a varied diet. Under the Codex GUL, modelled intakes remain below the UL and do not indicate a risk of excess.

4.4 Vitamin B6

Table 4.7: Comparison of vitamin B6 compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	8	42 (GUL)
Standard 2.9.3	—	106 (maximum claimable amount)

The maximum claimable amount for vitamin B6 specified in Schedule 29 (0.35 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum vitamin B6 concentration that could be declared under the Code on an energy basis.

Table 4.8: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 400 µg/day UL = 15,000 µg/day.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (8)	50.2	13%	—	100	25%	—	151	38%	—
Maximum intakes									
Codex GUL (42)	308	—	2.1%	615	—	4.1%	923	—	6.2%
Standard 2.9.3 maximum (106)	350	—	2.3%	700	—	4.7%	1,050	—	7%
Comparator intake (based on average composition)									
Cow's milk (13.2)	87.5	22%	0.58%	175	44%	1.2%	263	66%	1.8%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.4.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 13% of the EAR for vitamin B6, and intake from 3 x 250 mL servings provides approximately 38% of the EAR when assessed in isolation. At this minimum level, vitamin B6 intake from a serving of young child formula is slightly lower than that from a serving of cow's milk. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin B6 intake. On this basis, the risk of inadequate vitamin B6 intake is considered low if FSANZ adopted the Codex minimum amount (8 µg/100 kJ).

4.4.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex GUL scenarios, modelled intakes at up to 3 x 250 mL servings of young child formula remain well below the UL. The risk of excessive vitamin B6 intake from consumption of young child formula is therefore considered low if FSANZ adopted the Codex GUL (42 µg/100 kJ).

4.4.3 Conclusion

Under the Codex minimum compositional level, modelled intakes of vitamin B6 from young child formula, when compared with the EAR, contribute to overall vitamin B6 requirements without indicating a risk of inadequacy when consumed as part of a varied diet. Under the Codex GUL, modelled intakes remain below the UL and do not indicate a risk of excess.

4.5 Vitamin E

Table 4.9: Comparison of vitamin E compositional values

	Minimum (mg α-TE*/100 kJ)	Maximum (mg αTE*/100 kJ)
Codex CXS 156-1987	0.12	1.2 (GUL)
Standard 2.9.3	—	0.76 (maximum claimable amount)

The maximum claimable amount for vitamin E specified in Schedule 29 (2.5 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum vitamin E concentration that could be declared under the Code on an energy basis.

* Expressed as alpha-tocopherol equivalents.

Table 4.10: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): AI = 5 mg α-TE/day; UL = 70 mg α-TE/day

Scenario (mg α-TE/100 kJ basis)	1 serve (mg)	%AI	%UL	2 serves (mg)	%AI	%UL	3 serves (mg)	%AI	%UL
Minimum intakes									
Codex minimum (0.12)	0.75	15%	—	1.51	30%	—	2.26	45%	—
Maximum intakes									
Codex GUL (1.2)	8.79	—	13%	17.6	—	25%	24.4	—	38%
Standard 2.9.3 maximum (0.76)	2.5	—	3.6%	5	—	7.1%	7.5	—	11%

Comparator intake (based on average composition)									
Cow's milk (0.03)	0.23	4.6%	0.33%	0.45	9%	0.64%	0.68	14%	0.97%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

Vitamin E is expressed in terms of α-tocopherol equivalents (α-TE). T1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol.

4.5.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 15% of the AI, and intake from 3 x 250 mL servings provides approximately 45% of the AI for vitamin E. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate vitamin E intake. On this basis, the risk of inadequate vitamin E intake is considered low if FSANZ adopted the Codex minimum amount (0.12 mg α-TE/100 kJ).

4.5.2 Maximum

Under both the Standard 2.9.3 maximum claimable amount and the Codex GUL scenarios, modelled intakes at up to 3 x 250 mL servings remain well below the UL. The risk of excessive vitamin E intake from consumption of young child formula is therefore considered low if FSANZ adopted the Codex GUL (1.2 mg α-TE/100 kJ).

4.5.3 Conclusion

Under all modelled scenarios, Vitamin E intakes from young child formula are higher than the average amount present in cow's milk, reflecting the fortified nature of the product. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake, comparisons with the AI and UL do not indicate a risk of nutritional inadequacy or excess.

4.6 Iodine

Table 4.11: Comparison of iodine compositional values

	Minimum (µg/100 kJ)	Maximum (µg/100 kJ)
Codex CXS 156-1987	2.4	14 (GUL)
Standard 2.9.3	—	21.2

Note: The maximum iodine amount specified in Schedule 29 (35 µg/serve) was converted to Codex aligned units (µg /100 kJ) using the minimum energy requirement of 330 kJ per serving, the maximum iodine concentration permitted under the Code on a per energy basis.

Table 4.12: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 65 µg/day; UL = 200 µg/day.

Scenario (µg/100 kJ basis)	1 serve (µg)	%EAR	%UL	2 serves (µg)	%EAR	%UL	3 serves (µg)	%EAR	%UL
Minimum intakes									
Codex minimum (2.4)	15.1	23%	—	30.1	46%	—	45.2	70%	—
Maximum intakes									
Codex GUL (14)	103	—	51%	205	—	103%	308	—	154%
Standard 2.9.3 maximum (21.2)	70	—	35%	140	—	70%	210	—	105%
Comparator intake (based on average composition)									
Cow's milk (5.73)	39.3	60%	20%	78.6	121%	39%	118	182%	59%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.6.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 23% of the EAR for iodine, and intake from 3 x 250 mL servings provides approximately 70% of the EAR. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate iodine intake. On this basis, the risk of inadequate iodine intake is considered low if FSANZ adopted the Codex minimum amount (2.4 µg/100 kJ).

4.6.2 Maximum

At the Codex GUL, modelled iodine intakes from 2 x 250 mL servings of young child formula slightly exceed the UL (103%) for iodine, with 3 servings exceeding the UL to a greater extent (154%). Under the Standard 2.9.3 maximum amount, modelled iodine intakes from 3 serves only slightly exceed the UL (105%). This modelling suggests a potential for exceeding the iodine UL under scenarios involving multiple servings consumed at the Codex GUL. At consumption levels consistent with young child formula contributing approximately 15-25% of total daily energy intake (around 1–1½ serves per day) modelled iodine intakes remains below the UL.

Exceedance of the UL under higher-intake scenarios would be expected to pose a low to moderate risk, particularly where intake is chronic. While the risk of excessive iodine intake is considered low with one serving, regular consumption of multiple servings at the Codex maximum level could pose a risk of excessive iodine intake if FSANZ adopts the Codex maximum amount (14 µg/100 kJ).

In further characterising risk, it is important to note that the UL for iodine for children aged 1-3 was extrapolated from adult values. Disruption of thyroid function, as reflected by elevated TSH concentrations, is the critical adverse effect underpinning the UL. A Lowest Observed Adverse Effect Level (LOAEL) of 1,700 µg/day was established with application of an uncertainty factor of 1.5 resulting in a No Observed Adverse Effect Level (NOAEL) that forms the basis of the adult UL. ULs were extrapolated from the adult value using metabolic body-weight scaling. As a result, these ULs may be considered conservative.

4.6.3 Conclusion

At the Codex minimum compositional level, modelled iodine intakes do not indicate a risk of inadequacy. At the Codex maximum compositional level, modelled intakes from multiple servings of young child formula exceed the UL. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet and not as a sole source of nutrition, the risk of excessive iodine intake is considered low at typical consumption levels. However, frequent consumption of multiple serves at the Codex GUL could pose a risk of excessive iodine intake, particularly if exposures were to be chronic.

4.7 Magnesium

Table 4.13: Comparison of magnesium compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	1.2	3.6 (GUL)
Standard 2.9.3	—	9.7 (maximum claimable amount)

The maximum claimable amount for magnesium specified in Schedule 29 (32 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum magnesium concentration that could be declared under the Code on an energy basis.

Table 4.14: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 65 mg/day; UL: not set

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									
Codex minimum (1.2)	7.53	12%	—	15.1	23%	—	22.6	35%	—
Maximum intakes									
Codex GUL (3.6)	26.4	—	—	52.7	—	—	79.1	—	—
Standard 2.9.3 maximum (9.7)	32	—	—	64	—	—	96	—	—
Comparator intake (based on average composition)									
Cow's milk (3.91)	26.3	40%	—	52.6	81%	—	78.9	121%	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1

4.7.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving of young child formula provides approximately 12% of the EAR for magnesium, and intake from 3 x 250 mL servings provides approximately 35% of the EAR when assessed in isolation. At this minimum level, magnesium intake from a serving of young child formula is lower than that from a serving of cow's milk. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate magnesium intake. On this basis, the risk of inadequate magnesium intake is considered low if FSANZ adopts the Codex minimum amount (1.2 mg/100 kJ).

4.7.2 Maximum

No UL has been set for magnesium. In the absence of a UL and given that magnesium has not been shown to produce toxic effects when consumed as naturally occurring magnesium in food, these intakes do not raise safety concerns. On this basis, the risk of excessive magnesium intake due to consumption of young child formula is considered low if FSANZ adopts the Codex GUL (3.6 mg/100 kJ).

4.7.3 Conclusion

Under the Codex minimum compositional level, modelled magnesium intakes from young child formula contribute to overall magnesium requirements without indicating a risk of inadequacy when consumed as part of a varied diet. In the absence of an established UL, the risk of excessive magnesium intake is considered low under the Codex GUL.

4.8 Phosphorus

Table 4.15: Comparison of phosphorus compositional values

	Minimum (mg/100 kJ)	Maximum (mg/100 kJ)
Codex CXS 156-1987	6	24 (GUL)
Standard 2.9.3	—	76 (maximum claimable amount)

The maximum claimable amount for phosphorus specified in Schedule 29 (250 mg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum phosphorus concentration that could be declared under the Code on an energy basis.

Table 4.16: Comparison of dietary intakes with nutrient reference values

NHMRC NRVs used for comparison (1–3 years): EAR = 380 mg/day; UL = 3,000 mg/day.

Scenario (mg/100 kJ basis)	1 serve (mg)	%EAR	%UL	2 serves (mg)	%EAR	%UL	3 serves (mg)	%EAR	%UL
Minimum intakes									

Codex minimum (6)	37.7	9.9%	—	75.3	20%	—	113	30%	—
Maximum intakes									
Codex GUL (24)	176	—	5.9%	352	—	12%	572	—	18%
Standard 2.9.3 maximum (76)	250	—	8.3%	500	—	17%	750	—	25%
Comparator intake (based on average composition)									
Cow's milk (34)	229	60%	7.6%	458	120%	15%	687	181%	23%

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.8.1 Minimum

At the Codex minimum compositional level, modelled intake from one 250 mL serving provides approximately 10% of the EAR for phosphorous, and intake from 3 x 250 mL servings provides approximately 30% of the EAR when assessed in isolation. At this minimum level, phosphorus intake from a serving of young child formula is considerably lower than that from a serving of cow's milk. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet, the modelled intake does not indicate a risk of inadequate phosphorus intake. This is supported by national dietary intake data showing low prevalence of inadequate phosphorus intakes in young children (ABS 2015). While young child formula at the Codex minimum level makes a modest contribution to total phosphorus intake, this does not raise a public health concern when the remainder of the diet is considered. On this basis, the risk of inadequate phosphorus intake is considered low if FSANZ adopts the Codex minimum amount (6 mg/100 kJ).

4.8.2 Maximum

Under both the Standard 2.9.3 maximum and the Codex GUL scenarios, modelled phosphorus intakes from up to 3 x 250 mL servings of young child formula remain well below the UL. The risk of excessive phosphorus intake is considered low if FSANZ adopted the Codex GUL (24 mg/100 kJ).

4.8.3 Conclusion

At the Codex minimum compositional level, modelled phosphorus intakes from one 250 mL serving of young child formula are considerably lower than those from cow's milk and contribute approximately 10% of the EAR. When interpreted in the context of young child formula contributing approximately 15–25% of total daily energy intake as part of a varied diet, comparisons with the EAR do not indicate a risk of nutritional inadequacy. Under the Codex GUL, modelled intakes remain below the UL and do not indicate a risk of excess.

4.9 Lutein

Table 4.17: Lutein compositional values

	Minimum (μg /100 kJ)	Maximum (μg /100 kJ)
Standard 2.9.3	—	30

The maximum claimable amount for lutein specified in Schedule 29 (100 μg per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum lutein concentration that could be declared under the Code on an energy basis.

Table 4.18: Modelled dietary intakes

Scenario (mg/100 kJ basis)	1 serve (μg)	%EAR	%UL	2 serves (μg)	%EAR	%UL	3 serves (μg)	%EAR	%UL
Maximum intakes									
Standard 2.9.3 maximum (30)	100	—	—	200	—	—	300	—	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.9.1 Minimum

Neither Codex nor Standard 2.9.3 specify a minimum compositional value for lutein. As lutein is not an essential nutrient and there is no evidence of a deficiency syndrome or toxicity at levels relevant to dietary intake, no EAR or UL has been established, and risk characterisation is appropriately based on permitted use levels rather than nutrient reference values. Accordingly, the absence of a minimum compositional requirement does not indicate a nutritional risk, and the consumption of young child formula without added lutein does not raise concerns regarding inadequate intake if FSANZ adopts a Codex-consistent approach and does not set a minimum compositional level.

4.9.2 Maximum

Codex does not specify a maximum compositional value for lutein, however Standard 2.9.3 specifies that lutein may be used as a nutritive substance in a formulated supplementary food for young children only if the lutein is derived from *Tagetes erecta L.*, and where the total amount of lutein, both added and naturally occurring does not exceed 100 μg/serving.

Application A597 concluded that lutein added to formulated supplementary foods for young children at a maximum concentration of 100 μg/serve is unlikely to pose any health and safety concerns for young children who consume these products (FSANZ, 2009). In the absence of a UL, and given the existing compositional restriction, the risk of excessive lutein intake from consumption of young child formula is considered low if the current maximum amount specified in Standard 2.9.3 is retained (equivalent to 30 μg/100 kJ).

4.9.3 Conclusion

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 considered low.

4.10 Inulin-Type Fructans / Galacto-Oligosaccharides

Table 4.19: ITF/GOS compositional values

	Minimum (g/100 kJ)	Maximum (g/100 kJ)
Standard 2.9.3	—	0.48

The maximum claimable amount for ITF/GOS specified in Schedule 29 (1.6 g per serving) was converted to Codex aligned units (mg /100 kJ) using the minimum energy requirement of 330 kJ per serving. This represents the maximum ITF/GOS concentration that could be declared under the Code on an energy basis.

Table 4.20: Modelled dietary intakes

Scenario (mg/100 kJ basis)	1 serve (g)	%EAR	%UL	2 serves (g)	%EAR	%UL	3 serves (g)	%EAR	%UL
Maximum intakes									
Standard 2.9.3 maximum (30)	1.6	—	—	3.2	—	—	4.8	—	—

Note: Nutrient amounts per serve are calculated on an energy-equivalent basis, see Table 3.1.

4.10.1 Minimum

Neither Codex nor Standard 2.9.3 specify a minimum compositional value for inulin-type fructans (ITF) or galacto-oligosaccharides (GOS), and no EAR has been established for these substances. ITF and GOS are non-essential dietary components with no defined requirement for adequacy but are important non-digestible oligosaccharides which benefit the gut microbiota. Accordingly, the absence of a minimum compositional requirement does not indicate a nutritional risk, and the consumption of young child formula without added ITF or GOS does not raise concerns regarding inadequate intake if FSANZ adopts a Codex-consistent approach and does not set a minimum compositional level.

4.10.2 Maximum

Codex does not specify a maximum compositional value for ITF/GOS, however Standard 2.9.3 specifies that if *inulin-type fructans or *galacto-oligosaccharides are added to a formulated supplementary food for young children, the total amount of those substances, both added and naturally occurring, must not exceed 1.6 g/serving.

Proposal P306 concluded that ITF/GOS added to formulated supplementary foods for young children at a maximum concentration of 1.6 g/serving is unlikely to pose any health and safety concerns for young children who consume these products (FSANZ, 2008). In the absence of a UL, and given the existing compositional restriction, the risk of excessive ITF/GOS intake due to consumption of young child formula is considered low if the current maximum amount specified in Standard 2.9.3 is retained (equivalent to 0.48g/100 kJ).

4.10.3 Conclusion

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 considered low.

5 References

ABS (2015) Australian Health Survey: Usual Nutrient Intakes (Reference period 2011-12 financial year). Australian Bureau of Statistics, Canberra. Available online at: https://www.abs.gov.au/statistics/health/food-and-nutrition/usual-nutrient-intakes/2011-12. Accessed 31 March 2026

Codex (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. Codex CXS 156-1987. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

EFSA (2024) Scientific opinion on the tolerable upper intake level for preformed vitamin A and β-carotene. EFSA Journal, 22(6):e8814.
doi:10.2903/j.efsa.2024.8814

FSANZ (2008) Proposal P306: Addition of Inulin/FOS & GOS to Food. First Review Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/proposals/Documents/P306%20FOS%20_%20GOS%20FRR%20FINAL.pdf

FSANZ (2009) Application A597: Addition of Lutein to Formulated Supplementary Foods for Young Children. Final Assessment Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A597%20Lutein%20FAR%20FINAL1.pdf

FSANZ (2019) Application A1155: 2′-FL and LNnT in infant formula and other products. Approval Report. Food Standards Australia New Zealand, Canberra. Available online at: https://www.foodstandards.gov.au/sites/default/files/food-standards-code/applications/Documents/A1155%20Approval%20Report%20for%20web.pdf

MoH (2021) Healthy Eating Guidelines for New Zealand Babies and Toddlers (0–2 years old). Ministry of Health, Wellington. Available at online: https://www.health.govt.nz/system/files/2021-09/healthy-eating-guidelines-for-new-zealand-babies-and-toddlers-nov21-v3.pdf

NHMRC (2013) Australian Dietary-Guidelines. National Health and Medical Research Council, Canberra. Available online at: https://www.health.gov.au/sites/default/files/australian-dietary-guidelines.pdf

NHMRC and MoH (2006) Nutrient Reference Values for Australia and New Zealand. National Health and Medical Research Council and New Zealand Ministry of Health, Canberra. Available online at: https://www.eatforhealth.gov.au/nutrient-reference-values