26 May 2026
396-26

Call for submissions – Proposal P1066

Review of young child formula

FSANZ has assessed a proposal to revise and clarify provisions of the Australian New Zealand Food Standards Code as they apply to young child formula (1–3 years) including regulatory definitions, composition, labelling and representation of products. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the proposal.

Submissions on this proposal need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 7 July 2026

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting documents

The following documents which informed the assessment of this proposal are available on the Proposal P1066 page on the FSANZ website:

SD1 Nutrient composition
SD2 Labelling for young child formula
SD3 Safety and food technology assessment

SD4 Microbiological assessment
SD5 Preliminary consideration of costs and benefits

Executive summary

Young child formula is currently regulated under Standard 2.9.3 *Formulated meal replacements and formulated supplementary foods* as formulated supplementary foods for young children (FSFYC) in the Australia New Zealand Food Standards Code (the Code).

While these products are regulated as special purpose foods intended to supplement the diets of children aged 1–3 years in limited circumstances, they are widely marketed as 'toddler' or 'junior' milks and positioned as routine or beneficial components of healthy young children's diets. These developments have raised questions about whether the existing regulatory framework remains appropriate and fit for purpose.

Proposal P1066 – Review of young child formula considers whether the current regulation of young child formula under the Code continues to align with the product's intended purpose, the latest scientific evidence and contemporary international regulatory and market developments. Through this proposal, Food Standards Australia New Zealand (FSANZ) has assessed the regulatory framework applying to young child formula and, where appropriate, sought alignment with relevant international regulations, particularly Section B of the Codex Standard for Follow-Up Formula and Product for Young Children (CXS 156-1987).

This proposal is being assessed under FSANZ's major procedure, which requires two rounds of public consultation. This 1st Call for submissions (CFS) outlines FSANZ's assessment, key conclusions and proposed regulatory approaches, and seeks stakeholder views on whether FSANZ should proceed to preparing a draft variation to amend the Code.

FSANZ proposes a clearer and more targeted regulatory framework for young child formula that reflects its classification as a special purpose food. The proposed approach would introduce a specific product definition and establish a stand-alone division within Standard 2.9.3 to prescribe compositional and labelling requirements for young child formula. Consequential amendments to related Standards and Schedules are proposed to ensure alignment across provisions relating to composition, labelling, food additives, processing aids, contaminants and microbiological criteria.

Assessment of nutrient composition supports a framework that includes both mandatory and optional nutrients aligned with CXS 156-1987 and the nutrient requirements of children aged 1–3 years. Mandatory nutrients are limited to those supporting the product's intended supplementary purpose, while optional nutrients (including nutritive substances) are restricted to those currently permitted for FSFYC and assessed as suitable for this age group. Permitted forms of vitamins and minerals are proposed to align with those already permitted for other special purpose foods in the Code.

FSANZ has also reviewed current labelling requirements to ensure they support safe use and informed decision-making. Proposed measures include a prescribed product name, statements clarifying the product's supplementary purpose and age suitability, directions for preparation and storage, a tailored nutrition information panel, and restrictions on claims, stage numbering and representations that may contribute to consumer confusion or imply nutritional necessity.

Food safety and technology assessments informed proposed risk management measures for food additives, contaminants, processing aids and novel foods. FSANZ has proposed food additive permissions for young child formula are aligned with CXS 156-1987 through the establishment of a new food class in the Code. This includes not permitting colours and intense sweeteners to be consistent with Codex. The existing maximum levels for contaminants in infant formula products are proposed to apply to young child formula. No new requirements are proposed for processing aids, novel foods or container fill.

FSANZ now calls for stakeholder comments on the proposed approaches. Submissions received will inform FSANZ's decision on whether to proceed with preparing a draft variation to amend the Code and the nature of any such amendments. Further public consultation will occur if a draft variation is prepared.

Abbreviations and glossary

Abbreviation or term	Meaning
ADI	Acceptable Daily Intake
BFD	Branded food database
CFS	Call for submissions
Code	Australia New Zealand Food Standards Code
CRIS	Consultation Regulation Impact Statement
CXS 156-1987	Codex Standard for Follow-up formula for Older Infants and Product for Young Children
EFSA	European Food Safety Authority
EU	European Union
FMM	Food Ministers' Meeting
FSANZ	Food Standards Australia New Zealand
FSANZ Act	*Food Standards Australia New Zealand Act 1991*
FSFYC	Formulated supplementary foods for young children
GMP	Good Manufacturing Practice
GUL	Guidance upper level
HACCP	Hazard Analysis and Critical Control Points
INS	International Numbering System (for food additives)
JECFA	Joint WHO/FAO Expert Committee on Food Additives
ML	Maximum Limit
MPL	Maximum Permitted Levels
NHMRC	National Health and Medical Research Council
NIP	Nutrition information panel
NNPAS	National Nutrition and Physical Activity Survey
NRV	Nutrient Reference Values
NZMoH	New Zealand Ministry of Health
OIA	Office of Impact Analysis
RDI	Recommended daily intakes
SD	Supporting document
SPS	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

1.1. The Proposal

Young child formula (commonly known as toddler milk, junior milk, growing up milk or stage 3 formula) is a commercially produced, powdered or ready-to-consume formulated supplementary drink marketed to children aged 1–3 years. These products are often positioned as a continuation from infant and follow-on formula and promoted for convenience, as a transitional product or to address perceived dietary gaps.

Young child formula is currently regulated under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods. While not defined by the Australia New Zealand Food Standards Code (the Code), they are generally captured under Division 4 as formulated supplementary foods for young children (FSFYC), which includes basic compositional and labelling requirements for products intended to supplement a normal diet of children aged 1 to 3 years and may include added vitamins, minerals or other nutritive substances.

Since the implementation of FSFYC regulation, the market for young child formula has expanded considerably, with products increasingly positioned beyond their intended role as supplementary foods. In parallel, Proposal P1028 – Infant formula in Australia has been completed, creating a logical opportunity to examine the regulatory settings for young child formula.

Proposal P1066 – Review of young child formula will review the regulatory provisions applying to young child formula as special purpose foods. The proposal will consider whether current arrangements under the Code remain appropriate in light of market developments, with a focus on regulatory definitions, composition, labelling, product representation and safety. The review will be informed by the latest scientific evidence and reflect current international regulations, where appropriate.

1.2. Reasons for preparing the Proposal

FSANZ committed to considering the Code as it applies to the composition and labelling of young child formula following a recommendation from the Food Ministers' Meeting (FMM) in November 2024 to review regulatory provisions relating to 'toddler milks'. Proposal P1066 applies the term 'young child formula' to ensure the review considers the full regulatory framework and range of relevant products.

As outlined in section 1.1, the young child formula sector has evolved over time into a significant food category, with products frequently marketed as essential or beneficial for child development. This positioning contrasts with advice from public health authorities, including the World Health Organization (WHO), the Australian National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (NZMoH), which do not recommend their use by healthy toddlers.

These developments have raised concern that the current regulatory framework under Standard 2.9.3 may no longer be fit for purpose in managing risks associated with product composition, labelling and representation. Revision and clarification of the Code is therefore necessary to ensure it remains effective, enforceable and aligned with current evidence and international regulatory approaches.

The proposed outcomes of the proposal are to identify appropriate risk management strategies for young child formula, including consideration of definitions, composition, labelling and representation of products that:

- protect the health and safety of young children by specifying compositional requirements that adequately supplement a normal diet, where indicated, and limit nutrients of concern
- require adequate information about products to be available to parents/carers to make an informed choice
- are readily understood and able to be implemented by food manufacturers
- are enforceable by jurisdictions
- have regard to the Australian and New Zealand Feeding Guidelines and Nutrient Reference Values
- align with relevant international and overseas regulations, codes of practice and guidelines, as appropriate in the Australian and New Zealand context
- have regard to the Ministerial Policy Guideline on Intent of Part 2.9 – Special Purpose Foods (ANZFRMC 2009)
- support the desirability of an efficient and internationally competitive food industry and promote fair trading in food.

1.3. Scope

This paper summarises FSANZ's assessment for P1066 in accordance with the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The assessment focuses on how the provisions of Division 4 of Standard 2.9.3 apply to young child formula as a distinct food category. The review will clarify and revise relevant Code provisions, including definitions, composition, labelling and product representation. It will be informed by scientific evidence, international regulations, market developments, relevant Ministerial Policy Guidelines and the broader policy context in Australia and New Zealand.

This will determine:

1) the validity of young child formula as special purpose foods
2) whether the existing general compositional and labelling provisions in Division 4 of Standard 2.9.3 remain appropriate and what amendments to provisions may be required (if any) to ensure adequate protection of public health and safety.

Standard 2.9.3 provides appropriate regulation to a wide range of formulated supplementary foods. FSANZ has not been asked to review Standard 2.9.3 or Standard 2.9.3—Division 4, but rather the application of these provisions to young child formula. As these provisions apply to a broader range of products than young child formula alone, the Proposal will not amend provisions in Standard 2.9.3, except where consequential changes are required. Proposal P1066 will instead consider the need for new regulatory requirements specific to young child formula.

Accordingly, the following matters are out of scope for Proposal P1066:

- Other formulated supplementary foods regulated under Standard 2.9.3, including other FSFYC regulated under Division 4 of this Standard
- Regulatory provisions for commercial foods for infants (regulated by Standard 2.9.2) and young children
- Marketing and advertising outside of the label of young child formula
- Categorisation as a breast milk substitute and infant formula product regulations
- Permissions for new optional ingredients (nutritive substances and novel foods)
- Review of nutrient definitions
- Other Code requirements, such as significant figures or definitions.

1.4. Procedure for assessment

The proposal is being assessed under the Major Procedure of the FSANZ Act, which requires 2 rounds of public consultation.

Any draft variation of the Code will be provided for comment at the next round of public consultation. Following this, FSANZ will consider a final draft variation of the Code and, if approved, provide the variation to the Food Ministers' Meeting for consideration.

Questions to submitters are included in the supporting documents (SD) and collated in Appendix 1. Please consider these questions in your submission.

1.5. The current regulatory environment

1.5.1 Australian and New Zealand Standards

Standard 2.9.3 was finalised in 2000 through Proposal P199 during the development of the joint food standards code (ANZFA 1999). The standard regulates the compositional and labelling requirements for formulated meal replacements and formulated supplementary foods in any form. Standard 2.9.3 has not been reviewed since the introduction of the joint Code in 2000.

Division 4 of Standard 2.9.3 lists provisions specific to FSFYC, with the generic provisions applying to many foods specifically formulated as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements. For FSFYC, they are products which must be suitable for the population aged 1–3 years. Requirements for the regulation of FSFYC are contained in 4 Standards and 7 Schedules across the Code, these include:

- Standard 2.9.3 – Formulated meal replacements and formulated supplementary foods
- Schedule 29 – Special purpose foods
- Standard 1.1.1 – Structure of the Code and general provisions
- Standard 1.1.2 – Definitions used throughout the Code
- Standard 1.2.1 – Requirements to have labels or otherwise provide information
- Schedule 15 – Substances that may be used as food additives
- Schedule 17 – Vitamins and minerals
- Schedule 18 – Processing aids
- Schedule 19 – Maximum levels of contaminants and natural toxicants
- Schedule 25 – Permitted novel foods
- Schedule 27 – Microbiological limits in food.

1.5.2 Ministerial Policy Guidance

FSANZ must have regard to the Australian and New Zealand Ministerial Policy Guideline – *Intent of Part 2.9 of the Food Standards Code – Special purpose foods* (ANZFRMC 2009) and the Ministerial Policy Guideline – *Nutrition, Health and Related Claims* (ANZFRMC 2018) in the assessment and proposed regulatory approaches in P1066.

This Guideline on special purpose foods states that Part 2.9 – Special Purpose Foods of the Code is intended to contain food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups. It is noted that physiological vulnerability related only to situations where there is a risk of dietary inadequacy to support physical and physiological need arising from specific life stages, physical disease, disorder and disability; or physical and physiological conditions that require altered energy intake.

The specific policy principles included in this guideline all relate to the regulation of young child formula as a special purpose food. These are:

- Special purpose foods should be targeted only to those population groups satisfying the definition of physiologically vulnerable.
- The composition of special purpose food should be consistent with the intended purpose.
- Adequate information should be provided, including through labelling and advertising of special purpose foods, to:
  - assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food
  - provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.
- Consideration, where appropriate, should be given to the application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

The Guideline on claims allows for nutrition content and health claims to be made on food provided they meet a set of policy principles. It states that health claims are prohibited on alcohol, 'infant foods' and 'baby foods'. It does not provide specific comment on how nutrition content or health claims are to be used in the context of special purpose foods such as young child formula.

The Guideline on claims includes the following principles relating to health claims that are most relevant to young child formula:

- Claims that a food or component manages, influences, inhibits or modifies a physiological process may only be made in the context of the appropriate total diet (that must be described)
- Claims about a food or component can describe a health benefit for the population but must not:
  - imply or state a health benefit for the population if the claimed benefit applies only to a particular subgroup of the population, unless the population subgroup is stated
  - lead a consumer to self-diagnose or self-manage a condition or disease that should be medically diagnosed and/or managed
  - Claims that refer to the dietary management of a biomarker, condition or disease that may require the supervision of an appropriate health care practitioner must have an advisory statement to the effect that a health care practitioner's advice is required.

1.5.3 International Standards

Requirements for young child formula vary internationally, ranging from unique standards developed specifically to regulate this product category to regulation as general foods. To assist trade, it is preferable for regulations to be harmonised as much as possible between countries and consistent with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization (WTO). Support for this is provided in both the FSANZ Act and Ministerial Policy Guidelines.

The Codex Standard for Follow-up Formula for Older Infants and Product for Young Children Section B (CXS 156-1987) captures drinks and products for young children aged 12 months to 3 years with or without added nutrients. This standard was revised in 2023 and is reflective

of the best available scientific evidence and international market developments (Codex 2023).

CXS 156-1987 establishes essential and optional composition requirements, requirements for labelling and specific permissions for flavourings for these products. The compositional and labelling requirements included in CXS 156-1987 are more comprehensive than those prescribed for FSFYC in Division 4 of Standard 2.9.3. FSANZ is aware that the following international jurisdictions have either adopted CXS 156-1987 in full or are at various stages of adopting the provisions: Philippines, Draft East Africa Standard (Burundi, Kenya, Rwanda, Tanzania and Uganda) and the Gulf Cooperation Council (the Kingdom of Bahrain, the State of Kuwait, Qatar, the Kingdom of Saudi Arabia, United Arab Emirates and Yemen).

The People's Republic of China implemented *The Formula for Young Children Standard* in 2023 for the regulation of young child formula (NHC 2023). Provisions in this standard closely align with provisions in CXS 156-1987, however differences include the minimum and maximum for some nutrients and nutrients that are classified as essential. This standard has not been updated since the revision of CXS 156-1987 in 2023.

Canada currently permits young child formula as "nutritional supplements" which do not define a specific age category for relevant products. However, Canada is in the process of reviewing regulations for foods for special dietary use and infant foods, which includes a defined product category for "formulated nutritional foods for children", with a subcategory for children aged 1 to 3 years. The proposed regulations would specify compositional and labelling requirements for this product category. Canada completed a third round of consultation on these proposed regulations in 2024 (Health Canada 2024).

The European Union (EU) and the United States of America (USA) currently regulate young child formula as general foods, with these products not covered by a specific legislative measure.

1.6. Assessment and consideration of the evidence

- FSANZ's assessment of this proposal included the following: Nutrition risk assessment (Attachment 1 to SD1)
- Dietary Intake Assessment (Appendix 1 to SD1)
- Rapid scoping review on young child formula use and understanding, stage labelling and proxy advertising (Attachment 1 to SD2)
- Safety and food technology assessment (SD3)
- Microbiological assessment (SD4)
- Preliminary consideration of costs and benefits (SD5)
- FSANZ 2025/26 Market Survey (section 1.7 of this report)

1.7. FSANZ 2025/26 Market Survey

FSANZ undertook a market survey to provide information on the composition and labelling of foods sold as FSFYC, in particular, products represented as toddler milks or junior milks. The information was collected to inform an analysis of market developments, current market trends, the similarities and differences between current regulatory requirements in the Code and CXS 156-1987.

Data in Australia was collected from the Branded Food Database (BFD) and was supplemented with information from selected in-store retailers. Data in New Zealand was collected from the GS1 On Pack Database and supplemented with information from selected online retailers.

Products in scope for this survey included formulated milk-based drinks represented for children aged 1 to 3 years and labelled with either ‘formulated supplementary food for young children’, or the marketing terms ‘toddler milk’ and ‘junior milk’. A total of 35 products were identified within scope in Australia. The New Zealand survey identified 34 products within scope, with 20 products unique to New Zealand.

Information collected from the products included nutrients listed on the Nutrition Information Panel (NIP) and on-pack labelling elements, however not all labelling information collected in Australia was available in the New Zealand dataset. The nutrient composition (SD1) and labelling (SD2) assessments utilised information from both the Australian and New Zealand market data. The dietary exposure assessment will consider information from the market survey in the 2nd CFS, where modelling can be undertaken once the proposed regulatory framework and relevant consumption scenarios are further developed.

2 Regulatory Framework

Young child formula is currently regulated under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods, within which FSFYC are defined. These provisions establish compositional and labelling requirements and permit a wider range of food additives than some international regulatory frameworks, including Codex and EU regulations.

Over time, the market for young child formula has expanded beyond the original intent of FSFYC raising concerns that the existing regulatory framework may no longer be fully fit for purpose in relation to the intended use of these products. In response, FSANZ proposes to modernise the regulatory requirements for young child formula to better reflect contemporary market practices and current international regulatory developments.

While FSFYC are categorised as a special purpose food, there is scope to strengthen alignment between this classification and the proposed regulatory approach for young child formula. This is particularly relevant given widespread domestic marketing practices that increasingly present these products as essential components of healthy toddlers' diets, rather than as foods intended for individuals with specific physiological or nutritional needs. Accordingly, a key objective of the proposed reforms is to clarify and reaffirm the purpose of young child formula as a special purpose product.

This approach is consistent with the *Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods* (ANZFRMC 2009). Part 2.9 of the Code is intended to contain standards for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups, with regulatory requirements proportionate to their intended dietary use.

Under the policy guidance, physiological vulnerability is limited to circumstances where there is a risk of dietary inadequacy arising from specific life stages, disease, disorder, disability or conditions requiring altered energy intake. A specific policy principle is that special purpose foods should be targeted exclusively to population groups that meet this definition and have a demonstrable need for such products. This distinction is intended to maintain a clear separation between special purpose foods and other foods regulated elsewhere in the Code.

The proposed regulatory framework seeks to reinforce the purpose and intent of young child formula as special purpose foods and to introduce appropriate risk management measures aligned with ministerial policy guidance, national dietary guidance and the objectives of this proposal.

From a regulatory framework perspective, FSANZ considers it most appropriate to regulate young child formula within a stand-alone division of Standard 2.9.3. While young child formula will, by definition, remain a sub-category of formulated supplementary foods, it will be positioned adjacent to, rather than within, FSFYC. This approach allows the definition of formulated supplementary foods to provide appropriate regulatory context for young child formula, without conferring the specific regulatory attributes applicable to FSFYC.

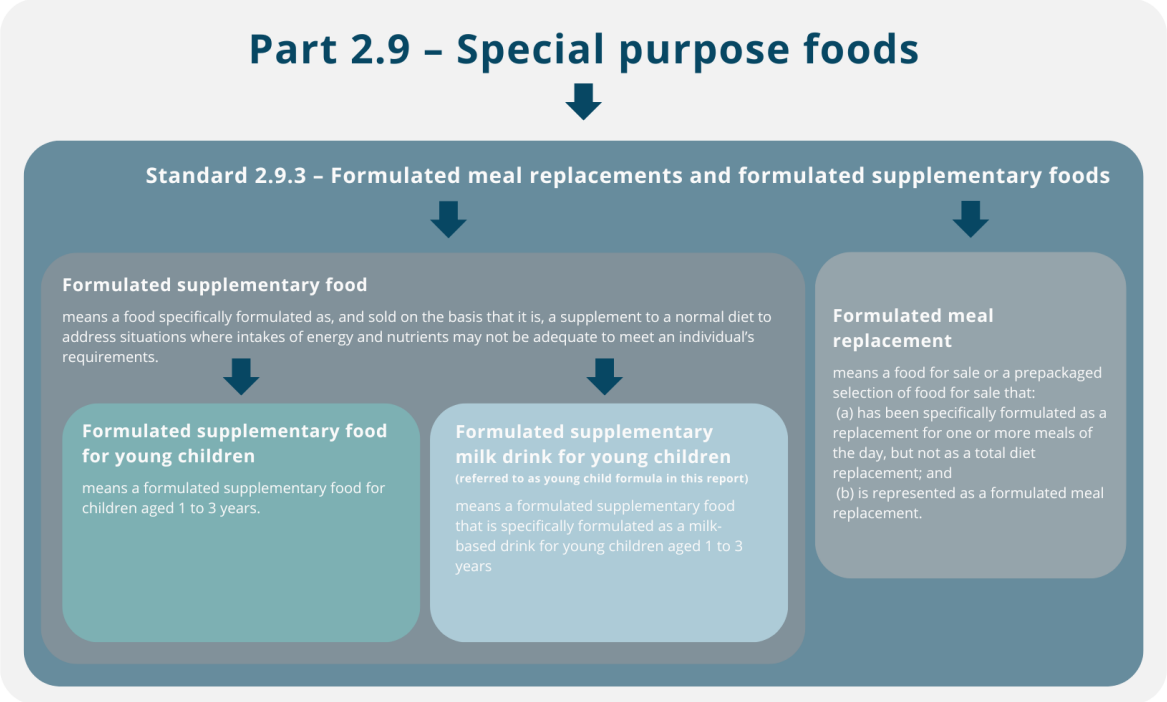

Figure 1: The proposed regulatory framework for Standard 2.9.3

Constructing the Standard in this manner enables regulatory requirements for young child formula to be established without impacting FSFYC and vice versa.

While young child formula remains a sub-category of formulated supplementary foods, it will not be subject to the provisions in Division 3. Instead, all compositional and labelling requirements applicable to young child formula will be prescribed within a stand-alone division, supporting regulatory clarity and certainty.

The new division for young child formula will be named in accordance with the finalised product name used in the regulatory definition. It will contain provisions relating to compositional requirements and associated interpretation, as well as labelling requirements.

In addition, amendments will be made to Standard 2.9.3, where required, to exclude young child formula from the application of requirements in other divisions of the Standard.

Consequential amendments will be fully considered at the next stage of the assessment. It is expected that amendments will also be made to an additional 3 Standards and 7 Schedules within the Code. These amendments would aim to align requirements relating to product definition, labelling, composition, food additive and processing aid permissions, contaminants and microbiological criteria.

Nutrition composition

As part of the stand-alone division, regulatory requirements for nutrient composition will be prescribed, including clearly defined mandatory and optional nutrient permissions. The proposed compositional framework provides a clear basis for regulating nutrient composition, aligned with the product's intended purpose and the nutritional requirements of children aged 1–3 years.

The framework aligns with the mandatory nutrient permissions set out in CXS 156-1987 and

retains optional nutrient permissions already permitted under Standard 2.9.3. All nutrient permissions, including minimum, maximum and guideline maximum levels have been assessed for adequacy and safety against the Nutrient Reference Values for Australia and New Zealand to ensure suitability for the target population. The assessment also incorporates considerations specific to the Australian and New Zealand context, including domestic market characteristics, population health data and the role of cow's milk as a comparator relative to intended dietary use.

Cow's milk has been used as a comparator because it is commonly consumed by young children in Australia and New Zealand and has a well-characterised nutrient profile. Comparison with full-fat cow's milk provides a relevant reference point for assessing how supplementary milk products modify energy, macronutrient and micronutrient intakes relative to usual dietary patterns. This approach supports evaluation of whether such products meaningfully address potential nutritional gaps relative to standard milk consumption.

The compositional framework and associated regulatory risk-management decisions uphold the intended purpose of young child formula as a fortified supplementary product and ensures that its nutrient composition consistent with its formulated, supplementary role.

This framework is underpinned by the classification of young child formula as a formulated supplementary food and clearly distinguishes these products from infant formula products regulated under Standard 2.9.1. Consistent with this purpose, the framework differs from both CXS 156-1987 and Standard 2.9.1 in that young child formula is not categorised as a breast milk substitute.

Establishing compositional requirements does not imply that young child formula is nutritionally necessary for young children. Rather, it provides a regulatory framework for products where they are consumed, with the objective of protecting public health and safety. This approach enables FSANZ to adopt requirements that are appropriate to the Australian and New Zealand context, taking into account domestic policy settings and the nutrient needs of children aged 1–3 years.

Further information on the nutrition compositional framework and proposed regulatory decisions can be found in section 3 below and SD1.

Labelling

The stand-alone division will prescribe tailored labelling requirements relating to general labelling requirements, safety-related labelling and labelling for the provision of information.

The framework proposes prescribed labelling elements to clearly identify the product's true nature and intended age range, and to distinguish young child formula from both infant formula products and other foods regulated by part 2.9 of the Code. The labelling requirements are designed to reduce the risk of consumer confusion, including proxy advertising of infant formula products and to ensure representations are consistent with the product's supplementary role rather than implying nutritional necessity.

The proposed requirements strengthen the regulation as they support appropriate product selection, preparation and use by end users. Consistent with the treatment of young child formula as a powdered formula product, the stand-alone Division will also prescribe directions for preparation and use, including information necessary to support safe handling and consumption.

The proposed approach draws on current domestic requirements, relevant international standards and evidence on consumer understanding and market practices. It establishes clear boundaries around claims, imagery and other representations to ensure labelling

remains fit-for-purpose in the Australian and New Zealand context and appropriately reflects the regulatory classification of young child formula.

Further information on the labelling framework and proposed regulatory decisions can be found in section 3 below and SD2.

Food class

To establish individual food additive requirements for young child formula, the framework introduces a new, stand-alone food class listed in the table to section S15—5 to prescribe food additive permissions specific to young child formula. This approach seeks to align food additive permissions for young child formula with those set out in CXS 156-1987, while providing regulatory clarity and ensuring permissions are appropriate for the product's intended purpose.

FSANZ assessed a range of regulatory options to achieve this alignment.

Incorporating CXS 156-1987 into existing food classes was not supported, due to the hierarchical classification of food additives in the Code.

Establishing a sub-class within the existing food class of 13.3 Formulated meal replacements and formulated supplementary foods listed in the table to section S15—5 was not preferred, as it would either grant permission for food additives used in Formulated meal replacements and formulated supplementary foods to be used in young child formula or would rely on exclusions and accompanying notes that may create ambiguity and undermine the hierarchical structure of Schedule 15.

FSANZ therefore proposes to establish a new, dedicated food class for young child formula in Schedule 15. This approach provides a clear and transparent regulatory pathway and ensures that food additive permissions are fit for purpose, internationally aligned and reflective of the regulatory classification of young child formula.

Further information can be found in section 5 below and SD3.

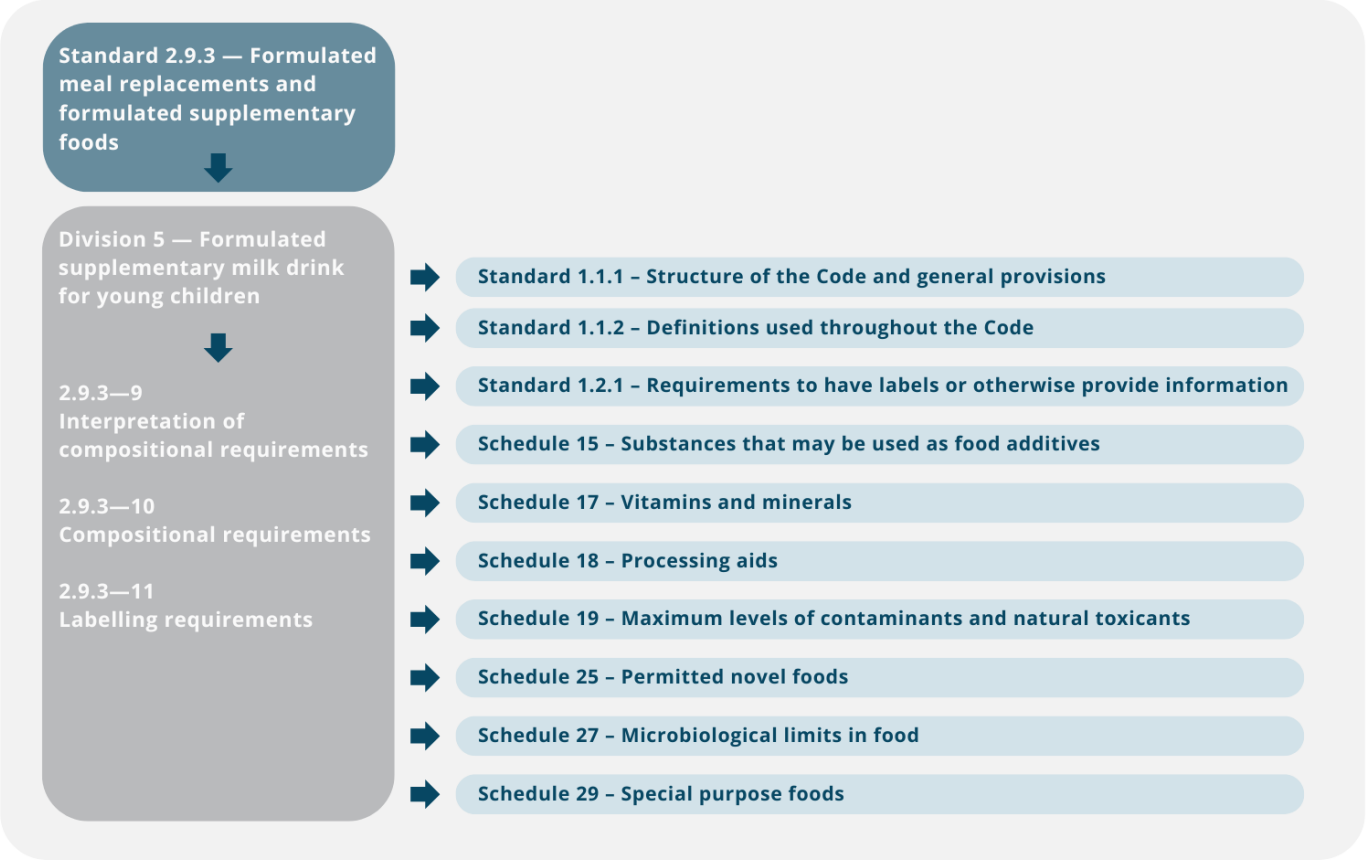

Figure 2: The proposed regulatory framework for young child formula
* Example illustration of how the proposed regulatory provisions may be accommodated within the Code. The final structure, including division subsections and affected standards, will be determined during drafting and informed by submissions received.

2.1 Product name and regulatory definition

As a general rule, regulatory definitions should be descriptive rather than prescriptive. They should identify the essential characteristics of a food without imposing obligations or stating regulatory requirements, which are more appropriately addressed elsewhere within the standard.

The product name used within the regulatory definition, which is often also used as the prescribed name, provides legal and regulatory precision around the true nature of the food. It anchors the product to an agreed definition in the Code, enabling regulators to assess compliance with compositional, safety and identity requirements. The proposed product name and definition are intended for inclusion in the Code and to operate as a defined term for regulatory purposes.

In the case of young child formula, the key identifying characteristics are that it is:

- a formulated supplementary food
- a formulated milk-based drink
- intended to supplement the normal diet in circumstances where intakes of energy and nutrients may not be adequate
- specifically formulated for young children aged 1 to 3 years.

Given the similarities between FSFYC and young child formula, clear differentiation between these products is required, including through their respective names and definitions to ensure

certainty of regulatory classification and enforceability.

Establishing a clear, coherent and enforceable standalone regulatory framework therefore requires explicit delineation between each product type and its intended purpose. This includes alignment with the overarching definition of *formulated supplementary foods*, while clearly distinguishing young child formula as a discrete product category within the Code.

To reflect these defining elements, FSANZ is proposing that the product name be "*formulated supplementary milk drink for young children*". This nomenclature aligns with the formulated supplementary food framework, while clearly identifying the product as a milk-based product specifically formulated for young children.

Importantly, the proposed name and definition are intended to capture a single product type under a single prescribed name for the purposes of the Code. This supports regulatory clarity and reduces the potential for market fragmentation or alternative classification.

The proposed name also ensures that products are readily identifiable and cannot be confused with infant formula or follow-on formula, nor represented as a continued "step", transitional product or necessary food for healthy young children. This is consistent with the intent of distinguishing special purpose foods both from each other and from foods for general consumption.

A clear and comprehensive definition is critical to ensuring that the product is captured beyond reasonable doubt by the regulatory provisions of the proposed new Division and, therefore, cannot vary from the prescribed requirements. The definition specifies the product's form and target population, thereby reinforcing its categorisation as a special purpose food.

In support of this approach, FSANZ is proposing the following definition for inclusion in the Code:

Formulated supplementary milk drink for young children means a formulated supplementary food that is specifically formulated as a milk-based drink for young children aged 1 to 3 years.

FSANZ has considered the proposed definition in the context of other formulated supplementary foods including FSFYC and is satisfied that it does not unintentionally capture products that are not young child formula. This reflects the inclusion of clearly distinguishing characteristics, including specification as a milk-based drink and the targeted age range of 1 to 3 years.

FSANZ also considers that all products meeting the characteristics of young child formula would be captured by this definition. Accordingly, such products would not be able to self-select regulation as a FSFYC in place of regulation as a formulated supplementary milk drink for young children.

Question to submitters:

Q1 Do you agree that the proposed definition does not unintentionally capture products that are not young child formula?

2.2 Age range

As per the FSFYC definition, young child formula is formulated specifically for children aged

1 to 3 years. The specification of this age range is informed by the regulatory and scientific considerations underpinning the development of requirements for FSFYC and the Nutrient Reference Values for Australia and New Zealand (NRV).

The requirements for FSFYC were established through Proposal P199 – Formulated Foods, which concluded that nutritional composition assessments for this product category should be informed by the recommended daily intakes (RDI) for children aged 1 to 3 years, as defined by the NRV (ANZFA 1999).

Accordingly, the age range for these products was defined as extending from the day of a child's first birthday to the day before the child's fourth birthday (≥1 to <4 years). This approach ensured continuity in nutritional coverage and avoided the creation of a regulatory or dietary gap for children aged 3–4 years, for whom RDI are not separately specified.

While the definition for FSFYC includes the intended age range of 1 to 3 years, the Code does not set requirements for what age information must appear on FSFYC labels.

FSANZ's 2025/26 Market Survey indicates that manufacturers have increasingly segmented the intended age range and marketed multiple age-differentiated product lines. This practice appears to be driven primarily by commercial considerations, rather than by a clear nutritional rationale aligned with the product's intended purpose.

The proliferation of age-segmented product lines has weakened the nutritional justification for these products and undermined their positioning as discrete special purpose foods, while also blurring distinctions between overlapping subcategories (e.g., "toddler" and "junior" milks marketed from 2 years of age). Accordingly, FSANZ proposes a regulatory framework that ensures young child formula can only be formulated and represented for young children aged 1 to 3 years, thereby preventing the splitting and sub-dividing of the age range.

Clear articulation of the age range within the definition is critical for regulatory certainty, as it reinforces the intended target population, supports consistent product formulation and labelling, and limits the potential for inappropriate extension of use beyond the population group for whom the product is designed.

2.3 Intended purpose

Consistent with the definition of a *formulated supplementary food* and relevant ministerial policy guidance, the intended purpose of young child formula is to supplement a normal diet in circumstances where intakes of energy and nutrients may be insufficient to meet the individual requirements of young children aged 1–3 years. Young child formula is therefore designed to address specific dietary gaps and inadequacies, rather than function as a routine or necessary component of the diets of healthy young children.

Young child formula is appropriately characterised and regulated as a special purpose food, reflecting its fortified and supplementary nature and its targeted use in defined circumstances. It is intended for use where dietary intake from family foods does not adequately meet nutritional requirements and where additional nutritional support may be required. Accordingly, its role is supplementary and conditional, and distinct from foods for general consumption.

This regulatory intent is consistent with national dietary guidance in both Australia and New Zealand. The Australian Infant Feeding Guidelines state that special complementary foods or milks for toddlers are not required for healthy children and emphasise the importance of a varied family diet. Similarly, the Healthy Eating Guidelines for New Zealand Babies and Toddlers (0–2 years) recommends breast milk, whole-fat pasteurised cow's milk and water as appropriate drinks from one year of age, noting that toddler milks generally confer no

added benefit where a toddler consumes a varied diet. Collectively, these guidelines reinforce that young child formula is not intended for the general population of healthy young children.

Evidence does indicate that, in circumstances where young children have inadequate intakes of certain micronutrients, young child formula can assist in improving nutrient adequacy. This supports the continued recognition of a legitimate supplementary role for these products. However, this evidence also underscores the importance of maintaining a clear distinction between targeted dietary supplementation and general dietary advice. The existence of a supplementary role does not support positioning young child formula as universally beneficial or required for optimal growth and development.

In practice, circumstances where use may be appropriate include situations such as persistent poor dietary intake, selective eating patterns or food aversions that result in inadequate intakes of energy or nutrients. In such cases, young child formula may be used as a targeted dietary intervention to support nutritional inadequacy. Where feeding difficulties or nutritional concerns are present, assessment and management by an appropriately qualified healthcare professional may be required to determine the suitability, duration and frequency of use in the context of the child's usual diet.

While young child formula may be used as part of dietary management, it is not a food for special medical purposes as regulated under Standard 2.9.5. These products are not intended for the treatment or management of a disease, disorder or medical condition. Accordingly, FSANZ proposes retain young child formula within the regulatory framework for formulated supplementary foods.

Young child formula is frequently marketed using staged or sequential positioning that implies a linear progression from infant formula and follow-on formula. However, this positioning is not supported by its distinct regulatory purpose and nutritional role. Infant formula and follow on formula are regulated as breast milk substitutes for infants and are intended to meet the nutritional requirements of infants as a sole or principal source of nourishment. In contrast, young child formula is regulated as a formulated supplementary food for children aged 1 to 3 years, with a limited role to supplement the diet only where usual intake may be insufficient to meet individual energy or nutrient requirements. It is not designed or formulated as a routine continuation of infant formula or follow on formula, is not recommended for healthy young children and is not suitable for infants under 12 months of age. Clear regulatory and market distinction between these product categories is therefore necessary to prevent consumer confusion and avoid inappropriate use.

Consistent with the intended purpose of young child formula and national dietary guidance, FSANZ's proposed approach is to strengthen and clarify the regulatory framework so that it explicitly reflects the product's limited and conditional role.

Under this proposed approach, regulatory requirements would clearly establish that young child formula is:

- A special purpose product formulated to supplement the diets of young children aged 1 to 3 years where nutritional intakes may be inadequate
- Not recommended for healthy young children
- Not suitable for infants under 12 months of age
- Not intended to be positioned or represented as a routine, transitional or next-stage milk.

This clarity is necessary to ensure that definitions, conditions of use, labelling and product representation align with public health objectives and appropriately position young child

formula as a special purpose food within the broader regulatory framework.

3 Nutrient Composition

FSANZ has reviewed the current nutrient composition requirements for young child formula in the Code and is proposing amendments to ensure they remain fit for purpose. The following sections detail the risk assessment that has informed the proposed nutrient composition requirements for young child formula, followed by a summary of the proposed approaches to the nutrient composition. Further details on these assessments and proposed approaches are provided in SD1.

3.1 Dietary exposure 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) 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). The mean consumption amount for these consumers was 428 g/day, which 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), 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 at the 2nd CFS when these data are available in FSANZ's dietary exposure assessment computer program Harvest.

3.2 Nutrition risk assessment

The nutrition risk assessment examines whether the adoption of Codex minimum and maximum compositional levels and guidance upper levels (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.

Modelled intakes based on a 250 mL serving of young child formula were compared with the NRV for Australia and New Zealand, as well as with existing compositional requirements as per the current regulations in the Code for FSFYC. Cow's milk was used as a nutritional comparator. For modelling purposes, young child formula was assumed to replace all recommended dairy serves in the diets of young children and to contribute 15-25% of total daily energy intake, as per dietary guidance.

Under expected consumption scenarios, modelled intakes of energy, macronutrients, vitamins, minerals and nutritive substances generally contributed to daily nutrient requirements without exceeding the upper level of intake. Potential risks of excess intake were identified for some nutrients (vitamin A, zinc and iodine) under high consumption scenarios however, the risk of excessive intake from young child formula at typical consumption levels was considered low.

Overall, the risk of nutritional inadequacy or excess associated with consumption of young

child formula as part of a varied diet is considered low where Codex-aligned compositional requirements for young child formula are adopted into the Code.

3.3 Risk management and proposed composition

FSANZ's nutrition risk management approach considered the nutrient composition of young child formula, as set out in SD1. This approach involved examining whether the existing nutrient composition for FSFYC in Standard 2.9.3 remain appropriate for the regulation of young child formula and whether alignment with the provisions in CXS 156-1987 is suitable, having regard to the Australian and New Zealand regulatory context. The assessment considered findings from the nutrition risk assessment, market data, international regulatory approaches and Ministerial Policy Guidelines.

Based on this assessment, FSANZ proposes a compositional framework for the mandatory and optional addition of nutrients to young child formula. A summary of the proposed nutrient composition, including whether individual values are adopted from CXS 156-1987 or retained from the Code, is provided in Table 1.

Nutrients included in the mandatory framework were selected based on the principles that they are either nutrients for which intakes may be inadequate in the diets of children aged 1-3 years, key nutrients naturally present in cow's milk or nutrients that support the intended purpose of the product. Optional nutrients include those for which there are existing permissions in FSFYC, with the compositional limits reviewed as part of this Proposal. FSANZ also proposes that the permitted forms of vitamins and minerals in young child formula align with the forms permitted in the Code for FSFYC and other special purpose foods. For further details, see SD1 to this CFS.

Table 1: Summary of the 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

4 Labelling

FSANZ has reviewed the current labelling requirements for young child formula in the Code and proposes amendments to ensure they remain fit for purpose. The following sections detail the risk assessment that has informed the proposed labelling requirements for young child formula, followed by a summary of the proposed approaches to labelling requirements. Further details on these assessments and proposed approaches are provided in SD2.

4.1 Social science assessment

FSANZ conducted a scoping review on caregivers' use and understanding of young child formula, including the role of stage labelling and the influence of proxy advertising of other formula stages on caregivers' perceptions and purchasing decisions. Evidence indicates that caregivers in Australia and New Zealand generally use young child formula as a supplement for convenience or to aid dietary transitions, with international evidence suggesting some view it as essential after infant formula or breastfeeding. Nutrition and health claims on packaging were found to increase perceptions of the product's overall health benefits.

Caregivers in Australian and New Zealand are familiar with product stages but depend more on age statements to guide purchasing decisions. Internationally, evidence indicates some confusion in caregivers about what stage numbers mean. Similar branding or packaging across formula can blur the distinction between infant formula products and young child formula. However, direct evidence on the impact of on-pack references on caregiver perceptions and purchasing behaviour for young child formula itself remains limited.

4.2 Food safety assessment

FSANZ undertook a microbiological assessment to examine the food-safety risks associated with *Cronobacter* and *Salmonella* in powdered young child formula consumed in Australia and New Zealand, see section 6 below and SD4.

The assessment identified that microbiological safety of young child formula is strongly influenced by preparation and handling practices prior to feeding. Preparation of each drink individually, reconstitution using previously boiled and cooled potable water, immediate consumption following preparation or refrigeration at controlled temperatures for limited periods and disposal of leftover prepared product within prescribed timeframes, were associated with substantially reduced risk of exposure to both *Cronobacter* and *Salmonella*.

These findings support that preparation and handling practices equivalent to that for infant

formula products are important measures for reducing the risk from *Cronobacter* and *Salmonella* in young child formula. These findings have informed the risk management considerations for directions for use and storage on young child formula labels.

Other microbiological hazards such as spore forming bacteria, *Bacillus cereus* and *Clostridium botulinum*, as well as toxins such as cereulide were identified. However, they were not included in the semi quantitative assessment. This reflects differences in exposure pathways and limited hazard characterisation data. Suitable data are not currently available to support robust modelling in the Australia and New Zealand context.

These hazards are the subject of ongoing international risk assessment work. The fifty fifth session of the Codex Committee on Food Hygiene requested the FAO/WHO Joint Expert Meetings on Microbiological Risk Assessment (JEMRA) to undertake risk assessment of spore forming pathogens, including *B. cereus* and *C. botulinum* in powdered formula for infants and young children. JEMRA was also requested to update the scientific advice for *Salmonella* and *Cronobacter*. Additional advice on control measures across the production and preparation continuum has also been requested.

The outcomes of this work will be monitored and considered in future risk management considerations for powdered formula products as new evidence becomes available.

4.3 Risk management and proposed labelling

FSANZ's labelling risk management approach, as set out in SD2, has considered the latest scientific evidence, market developments, international regulatory approaches, ministerial policy guidelines and national infant and toddler feeding and healthy eating guidance for Australia and New Zealand. This work considered 2 types of labelling for young child formula:

1. Safety-related labelling requirements
2. Labelling for the provision of information

FSANZ is seeking stakeholder views and comments on the proposed labelling approaches informed by this risk management, which are summarised in Table 2. A set of consultation questions relating to FSANZ's proposed approaches to labelling is provided in Appendix 1 of this document.

Table 2: Summary of FSANZ's proposed approach for the labelling of young child formula.

Labelling issue	FSANZ's proposed approach
Prescribed name	The prescribed name for young child formula will be *Formulated supplementary milk drink for young children.* The prescribed name must be used on the front of pack of the label, to act as an identifier for the true nature of the product.
Age-related information	Require an age statement on the front of pack, co-located with the prescribed name, indicating that the product is suitable for children aged 1 to 3 years. Any other voluntary age range statements on the label must indicate the product is intended for children aged 1 to 3 years.

Labelling issue	FSANZ's proposed approach
Required statements	The following statements will be required on the label of young child formula: • A description that the food is to be used as a supplement to the diet of a 1 to 3 year old child, to address situations where intakes of energy and nutrients may not be adequate to meet the child's requirements, and that caregivers should consult an appropriately qualified health professional before using this product. • Words to the effect that the food is not suitable for children less than one year of age.
Directions for use and storage	Directions for use and storage of young child formula must include the following, in words and pictures: • each drink must be prepared individually • if a prepared drink will be stored prior to use, it must be refrigerated and used within 24 hours • previously boiled and cooled potable water must be used • if a package contains a measuring scoop – only the enclosed scoop must be used • do not change proportions of the powder or add other food except on medical advice • leftover prepared drink must be discarded within 2 hours • storage instructions must cover the period after the package is opened.
Nutrition information requirements	Retain the requirement for nutrition information for young child formula to be provided in a NIP. In addition to standard NIP nutrient declarations, the NIP for young child formula must declare all other nutritive substances or other substances permitted to be added to young child formula (whether as part of its mandatory composition or voluntarily added, where permitted), in a prescribed order under a separate heading in the NIP of 'Composition Information'.
Statement of ingredients	Permit the voluntary use of a separate format for declaring vitamins and minerals, with separate lists and their own headings 'Vitamins' and 'Minerals', placed adjacent to the statement of ingredients. Within these groupings, the vitamins and minerals would not be required to be listed in descending order of ingoing weight.
Nutrition content and health claims	Prohibit nutrition content and health claims on young child formula. Prohibit endorsements which are nutrition content and health claims made with permission of an endorsing body on young child formula.
Stage labelling	Prohibit the use of stage numbers on the label of young child formula.
Product differentiation	Require that young child formula is differentiated from infant formula, follow-on formula, special medical purpose product for infants, other formulated supplementary foods for young children, and other foods by the use of text, pictures and/or colour.

Labelling issue	FSANZ's proposed approach
Proxy advertising	Prohibit proxy advertising of all other food products, by means of a name, a number, a picture, an image, a word or words, on the label of young child formula.
Other representations	Prohibit the following representations on young child formula: • pictures of feeding bottles, infants, older infants, young children and adults; • the terms 'humanised', 'maternalised' or other similar terms; • any other picture, text or representation that: – undermines or discourages breastfeeding; – makes a comparison to milk or breast milk, including suggesting that the product is similar, equivalent, or superior to milk or breast milk; – might convey or be construed as endorsement or approval by an individual or organisation.

5 Safety and Food Technology

This section outlines FSANZ's approach to the assessment and proposed risk management of food additives, contaminants, processing aids, novel foods and container fill in relation to young child formula.

Comprehensive information on the safety and food technology assessment is provided in SD3. The following sections summarise the assessment findings relevant to food additive and contaminants for young child formula and set out the proposed regulatory approaches. FSANZ is seeking stakeholder feedback on the proposed approaches outlined below through this CFS.

5.1 Food technology assessment

The food technology assessment reviewed current permissions for food additives and contaminants applicable to young child formula under the Code In undertaking this assessment, FSANZ considered alignment with CXS 156-1987 as well as related assessments and regulatory approaches adopted in the European Union.

FSANZ's assessment concluded food class 13.3 listed in the table to section S15—13.3, under which FSFYC is currently regulated, is not fit for purpose for young child formula due to the wide variety of foods captured within this class. FSANZ therefore compared the food additives permitted in CXS 156-1987 for use in young child formula with those permitted under the Code. While food class 13.3 permits a wide range of food additives, largely on the basis of good manufacturing practice (GMP), CXS 156-1987 permits a more limited number of food additives and generally specifies maximum permitted levels (MPLs). The comparison identified 7 food additives that are permitted under CXS 156-1987 (Table 3) but not permitted under the Code. FSANZ's assessment confirmed that these food additives are safe for use in young child formula at the levels specified in CXS 156-1987 (section 5.2). The assessment also considered the need for permissions for food additives that function as flavourings, colours and intense sweeteners, having regard to the intended purpose of young child formula proposed in this CFS.

Permissions for contaminants were considered in the context of recent work completed by FSANZ for Proposal P1028, which established maximum levels (MLs) for contaminants

where justified to protect infant health while remaining technologically achievable. These assessments represent the most recent evaluation of contaminant risks associated with formula products in Australia and New Zealand.

The assessment also considered whether the existing regulatory approaches for processing aids and novel foods, as well as the Codex requirements relating to container fill where appropriate for young child formula. FSANZ did not identify any safety concerns with the current approaches and therefore proposes to retain the status quo.

5.2 Food additive safety assessment

Seven food additives permitted by CXS 156-1987 but not currently permitted under Schedule 15 of the Code were assessed to determine their safety for use in young child formula (Table 3). The assessment considered existing safety evaluations conducted by Joint FAO/WHO Expert Committee on Food Additives (JECFA) and included an extensive review of the scientific literature using PubMed and EBSCO databases. The detailed safety evaluation is provided in section 2.7 of SD3.

FSANZ concluded that there are no toxicological concerns associated with the use of these 7 food additives in young child formula.

Table 3: Assessment of food additives for alignment proposes

Food Additive	INS number	CXS 156-1987 Permission & proposed usage level in the Code	Acceptable Daily Intake (ADI)	Toxicological concerns
Ascorbyl palmitate	304	50 mg/kg	Not specified for ascorbyl palmitate, ascorbyl stearate, or their combined total	No toxicological concerns identified
Ascorbyl stearate	305			
Potassium hydroxide	525	GMP	Not limited	
Sodium hydroxide	524			
d-alpha-Tocopherol	307a	30 mg/kg	0.15-2 mg/kg body weight where used separately or together	No toxicological concerns identified No evidence indicating the group ADI should be reduced
Tocopherol concentrate mixed	307b			
dl-alpha-Tocopherol	307c			

5.3 Risk management and conclusion

The safety and food technology assessment described in SD3 considered the best available scientific evidence, market developments and updated international regulatory approaches. The assessment examined whether the existing Code requirements for FSFYC, including those relating to food additives, processing aids, novel foods, contaminants and container fill are appropriate for young child formula and whether alignment with CXS 156-1987 is warranted.

Based on this assessment and as summarised in Table 4, FSANZ proposes establishing a

new food class in the Code for food additives permitted for use in young child formula to align with CXS 156-1987. FSANZ also proposes that requirements for contaminants, processing aids and novel foods remain aligned with existing provisions in the Code. No new regulatory requirements are proposed in relation to the fill of containers.

Table 4: Summary of the proposed safety and food technology requirements for young child formula.

Safety and food technology	FSANZ's proposed approach
Food additives	A new food class would be inserted into the table to section S15—5. This food class would retain food additive permissions in the Code which are listed in CXS 156-1987, at the Codex levels; and may adopt 7 new food additives from CXS 156-1987. This approach would result in the removal of some existing food additive permissions that currently apply to young child formula as a consequence of its regulation under the broader FSFYC food class. Existing permissions for flavourings are proposed to be retained for young child formula. Permissions for colourings and intense sweeteners are not proposed to be added to the new food class for young child formula.
Contaminants	Apply the established MLs for infant formula products to young child formula, based on similarities between the formulation and manufacture of the products.
Processing aids	Apply the permitted processing aids in Schedule 18, as well as the food additives listed in section 16—2 that are permitted to be used as processing aids to young child formula.
Novel foods	Unless expressly permitted, novel foods may not be added to young child formula. The addition of new novel foods would be subject to pre-market assessment.
Fill of containers	Not require any specific requirements relating to fill of containers.

6 Microbiological assessment

FSANZ undertook a microbiological assessment, detailed in SD4, to inform risk-management decisions under Proposal P1066. SD4 presents the detailed technical assessment. A summary of the assessment approach and key findings is provided below to support risk managers and non-technical readers.

6.1 Purpose of this assessment

The assessment compared estimated risks under different microbiological criteria at the end of manufacture and under different consumer preparation scenarios for young child formula consumed by Australian and New Zealand children aged 1–3 years.

6.2 What was assessed

FSANZ conducted a semi-quantitative microbiological risk assessment, consistent with international guidance. The assessment focused on two key pathogens of relevance for powdered formula products:

- *Cronobacter* - an opportunistic pathogen associated with rare but severe illness in very young infants with declining incidence and severity with age, and
- *Salmonella* - a pathogen of high public-health relevance in Australia and New Zealand causing gastrointestinal illness across infancy and early childhood.

Risks were evaluated for infants (0–6 months and 6–12 months) and young children (1–3 years). Infants aged 0–6 months were used as the baseline population, reflecting the high level of protection currently modelled under existing Code requirements. Estimated risks for young children were then compared against this infant benchmark.

The microbiological assessment combined information on:

- estimated concentrations of microbiological hazards in the powdered formula under different microbiological criteria scenarios at the end of manufacture
- consumption amounts and consumption frequency across the age groups
- preparation, storage and feeding practices that influence exposure
- age-related differences in susceptibility and illness severity.

Scenarios were assessed under best-practice and suboptimal preparation and handling conditions to evaluate the relative impact of microbiological criteria and consumer behaviour and risk.

6.3 Key findings for *Cronobacter*

The assessment found that:

- severe illness associated with *Cronobacter* is primarily reported in very young infants, particularly those under six months of age,
- both the likelihood and severity of illness decline substantially with age, and
- for children aged 1–3 years, estimated *Cronobacter* risk remained well below the infant reference level across all modelled scenarios, including scenarios without infant formula-equivalent microbiological criteria

While microbiological criteria equivalent to infant formula (n = 30, not detected) was not identified as a primary risk-reduction measure for *Cronobacter* in young child formula based on risk, appropriate preparation, storage and handling practices were identified as important controls to minimise exposure.

6.4 Key findings for *Salmonella*

The assessment found that:

- there is less evidence of a marked decline in susceptibility and severity of illness from *Salmonella* across early childhood,
- estimated risk for children aged 1–3 years increases when contamination levels are higher or preparation practices are suboptimal, and
- application of infant-formula-equivalent microbiological criteria (n = 60, not detected), together with equivalent preparation practices, resulted in the most robust level of protection comparable to that modelled for infants.

Scenarios without microbiological criteria resulted in estimated risks exceeding the infant baseline for young children when preparation practices deviated from best practice.

6.5 Broader risk-management considerations

FSANZ reviewed the existing infant formula product guidance in the FSANZ Compendium of Microbiological Criteria for Food for its applicability to young child formula. This review considered whether the Compendium's process hygiene criteria, indicator organisms and verification testing guidance used for other powdered formulas are applicable to young child formula, given shared manufacturing processes and contamination risks. On this basis, extension of the non-regulatory framework to young child formula was considered appropriate.

The assessment reinforces that end-product testing alone cannot ensure microbiological safety. Powdered formula products are not sterile and microbiological safety is achieved primarily by though-chain preventive controls across ingredients, manufacture and preparation. These are supported by good hygienic practices, Hazard Analysis and Critical Control Points (HACCP) based systems, and effective consumer preparation and handling informed by clear instructions and risk communication.

6.6 Risk management and conclusion

The microbiology assessment described in SD4 considered the best available scientific evidence and international regulatory approaches. The assessment considered preparation and storage practices as well as microbiological testing of FSFYC. Safety-related labelling requirements, based on SD4, are discussed in Section 4.2 and SD2. FSANZ proposes establishing microbiological limits for *Salmonella* only (not detected in 25g, n = 60) for FSFYC.

A set of consultation questions relating to FSANZ's proposed approaches to labelling and microbiological limits is provided in Appendix 1 of this document.

7 FSANZ Act assessment requirements

When assessing this Proposal, FSANZ had regard to the following matters prescribed in section 59 of the FSANZ Act:

7.1 Section 59 of the FSANZ Act considerations

7.1.1 Consideration of costs and benefits

FSANZ has considered the costs and benefits that may arise from the preliminary approach summarised above for the purposes of meeting FSANZ Act considerations (see SD5). The FSANZ Act requires FSANZ to have regard to whether the costs that would arise from a proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from a proposed measure.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered, particularly benefits, cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo and determine whether, on balance, the community government, and industry as a whole is likely to benefit from that move.

The *status quo* must be considered by FSANZ in any proposal to change the Code. Under this option, there would be no change to how young child formula is regulated under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods. Concerns will remain that the current regulatory framework for young child formula may not

be fit for purpose in managing risks associated with product composition, labelling and representation.

Submissions received will be used to inform a Consultation Regulation Impact Statement and a more comprehensive consideration of costs and benefits if, after consideration of submissions received in response to this 1st CFS, should FSANZ determine to prepare a draft measure. The Office of Impact Analysis will be consulted to confirm the adequacy of the analysis for consultation purposes.

For the full analysis, refer to SD5.

Table 5 presents the potential impacts on stakeholder groups by a potential shift away from status quo to the preliminary regulatory approach presented in the CFS. Table 6 presents whether FSANZ expects these impacts to be quantifiable and which impacts are expected to be qualitatively analysed.

Table 5: Impact on different stakeholder groups arising from the preliminary regulatory approach

Stakeholder group	Impact
Young children consuming young child formula and their caregivers	Improved composition of young child formula to reflect its intended purpose as a special purpose food • Greater health outcomes for young children consuming young child formula Reduced unnecessary use of young child formula by clarifying its intended purpose as a special purpose food via labelling • Savings for caregivers of young children Improved provision of information • Correct preparation leading to reduced risk of unsafe preparation
Young child formula industry	Costs related to reformulating products to meet changes to the Code Costs related to relabelling products to meet changes in the Code Costs related to introducing *Salmonella* microbiological criteria International regulatory alignment (opportunity for manufacturing efficiencies) Consistent Code requirements for young child formula with infant formula (base milk powder provisions) Loss of profits from sales of young child formula products due to intended purpose being clarified
Government	Benefits in enforceability of young child formula products Savings in healthcare costs avoided Small cost to adjust to new standards

Table 6: Quantified and unquantified impacts arising from the preliminary regulatory approach

	Stakeholder group	Impact
Quantified cost	Young child formula industry	Costs related to relabelling products to meet changes in the Code Costs related to reformulating products to meet changes to the Code
Unquantified cost	Young child formula industry	Costs related to introducing *Salmonella* microbiological criteria Loss of sales of young child formula products
Quantified benefit	Young children consuming young child formula and their caregivers	Reduced unnecessary use of young child formula
Unquantified benefit	Young children consuming young child formula and their caregivers	Improved composition of young child formula Improved provision of information Reduced foodborne illness
	Young child formula industry	International regulatory alignment (opportunity for manufacturing efficiencies) Code requirements for young child formula is consistent with infant formula (base milk powder provisions)
	Government	Enforceability of young child formula products Savings in healthcare costs avoided Small cost to adjust to new standards

Preliminary conclusion from consideration of costs and benefits in SD4

FSANZ's preliminary conclusion from its consideration of costs and benefits, as set out in SD4, is that the unquantified benefits associated with clarifying young child formula as a special purpose food, and improving the nutrition composition and information available to caregivers, are likely to outweigh the associated costs of relabelling, reformulation and potential loss of profits that may result from the proposed changes.

7.1.2 Other measures

FSANZ has not identified other measures that would be more cost-effective than varying the Code as proposed, to address the identified issues and risks.

7.1.3 Any relevant New Zealand standards

The standards relevant to this proposal apply in both Australia and New Zealand. FSANZ is not aware of any relevant New Zealand only standards.

7.1.4 Any other relevant matters

Other relevant matters are considered below.

7.2 Subsection 18(1)

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

7.2.1 Protection of public health and safety

Standard 2.9.3 and its related standards establish compositional and labelling requirements to ensure FSFYC are safe and suitable. This proposal reviews these provisions as they apply to young child formula. FSANZ has assessed the available scientific evidence on the health and safety of children aged 1–3 years who consume these products. Of which, the assessment indicates the proposed measures set out in this CFS would better protect public health and safety and ensure products are safe and appropriate for their intended purpose.

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

Labelling requirements intended to ensure that adequate information is provided to caregivers for FSFYC are set out in Division 4 of Standard 2.9.3. As part of Proposal P1066, these requirements have been reviewed as they apply to young child formula, with a focus on ensuring they support informed caregiver choice and appropriate use. The assessment of labelling issues relating to this objective is provided in SD2.

7.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements in Standard 2.9.3 include provisions intended to prevent misleading or deceptive conduct in relation to FSFYC. As part of Proposal P1066, FSANZ has reviewed these requirements as they apply to young child formula. Of which, the assessment indicates the proposed measures set out in SD2 would better prevent misleading or deceptive conduct relating to young child formula. The assessment of these issues is provided in SD2.

7.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence in assessing this Proposal. This evidence has primarily informed the assessment of nutrients, food additives and other compositional requirements. Where evidence was limited, particularly in relation to consumer behaviour, FSANZ undertook targeted literature and research reviews and drew on this evidence as part of the assessment (Attachment to SD2).

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

FSANZ's assessment had regard to international standards, particularly Codex standards such as CXS 156-1987. Other international regulatory approaches have also been considered and are referenced throughout the assessment.

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

The proposed approaches in this assessment, if adopted, would provide greater regulatory clarity for young child formula and promote alignment with relevant international standards, where appropriate. This is expected to support regulatory efficiency and contribute to the competitiveness of the domestic food industry.

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

The regulation of young child formula has implications for domestically manufactured products supplied to domestic and international markets, as well as for internationally manufactured products supplied to the domestic market. In assessing this Proposal, FSANZ has sought to ensure regulatory approaches are protective of public health and safety, while not unduly disadvantaging any sector or trade circumstance.

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

The *Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods* is most relevant to this Proposal.

The specific policy principles that FSANZ must have regard to when reviewing young child formula and considerations from this assessment are outlined in Table 7.

Table 7: Assessment against Policy Guideline on the Intent of Part 2.9 of the Food Standards Code.

Specific Policy Principles	Assessment
a) Special purpose foods should be targeted to specific population groups who meet the criteria outlined in the policy guideline.	This Proposal does not amend the range of special purpose foods in Part 2.9 of the Code. It focuses on the regulation of young child formula within the existing special purpose food framework, alongside FSFYC. Both product categories are targeted to a defined population group, that is young children aged 1–3 years, consistent with the criteria set out in the policy guideline.
b) The composition of special purpose food should be consistent with the intended purpose.	The compositional requirements for young child formula have been developed to be consistent with the product's intended purpose as a supplementary food. They are based on the assumption that young child formula is consumed as part of a balanced diet for children aged 1–3 years, and not as a sole source of nutrition.
c) Adequate information should be provided, including through labelling and advertising of special purpose foods.	The proposed labelling requirements for young child formula are set out in SD2. These requirements are intended to ensure that adequate, clear and accurate information is provided to caregivers, including through labelling, to support informed purchasing decisions consistent with the product's intended supplementary purpose.

d) Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.	Access to young child formula is not currently restricted. The assessment undertaken for Proposal P1066 did not identify any public health or safety risks that would warrant restrictions on access to these products for the general population. Accordingly, the proposed regulatory approach does not include controls to restrict the sale or availability of young child formula, as such measures are not considered necessary on public health and safety grounds.

The Ministerial Policy Guideline – *Nutrition, Health and Related Claims* is also of relevance and has been considered in FSANZ's evaluation of labelling, as detailed in SD2.

Based on its assessment, FSANZ is satisfied that this Proposal is consistent with, and has had regard to, the relevant Ministerial Policy Guidelines.

8 Risk Communication

8.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. All submissions received are considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

Consultation with interested parties will include the statutory consultation processes specified in the FSANZ Act, including a second CFS, should FSANZ prepare a draft variation to the Code.

The release of the 1st CFS will be notified via the FSANZ Notification Circular, media release and Food Standards News, and supported by updated website information. Following the release of the 1st CFS, FSANZ will host targeted webinars to further engage interested parties.

8.2 World Trade Organization (WTO)

Australia and New Zealand are members of the World Trade Organization (WTO) and therefore are legally obliged to follow the rules of WTO trade related agreements. The Technical Barriers to Trade (TBT) Agreement recognises countries' rights to adopt standards for the protection of human health at the level it considers appropriate provided that such measures are in accordance with that Agreement (WTO 1995).

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at the next stage of the assessment, should FSANZ determine to prepare a draft measure. Submissions received in response to this CFS will inform that decision. If FSANZ decides to prepare a proposed measure, public consultation must occur in relation to that measure, once prepared. If necessary, notification will be made at that point in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on any proposed amendments.

9 References

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OIA (2023). Regulatory Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies. Office of Impact Analysis, Canberra. Available online at: https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national

WTO (1995) Agreement on the Technical Barriers to Trade. World Trade Organization. Available online at: https://wtocenter.vn/file/18398/tbt3rd_e.pdf

Appendix 1: Consultation Questions

FSANZ invites stakeholders to provide comments on the proposed approaches outlined in this first call for submissions. To support stakeholder engagement, a series of consultation questions has been included within each SD. As noted in relevant sections, some questions address information gaps that may be needed to further support proposed options at the 2nd call for submissions.

In addition, certain questions are intended to inform the development of a Cost-Benefit Analysis (CRIS), should one be required. Information relating to costs and benefits would assist FSANZ in considering regulatory impacts in accordance with the FSANZ Act.

Stakeholders are invited to consider and respond to the consultation questions below as part of their submission to this CFS.

Table A1: Consultation questions for Proposal P1066 1st CFS

Question number	Question	Section of the CFS
CFS Report		
Q1	Do you agree that the proposed definition does not unintentionally capture products that are not young child formula?	2.1, page 17.
Supporting Document 1: Nutrient composition		
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?	4.6, page 39.
Supporting Document 2: Labelling for young child formula		
Q2.1	Are there other overseas labelling regulations relevant to young child formula that FSANZ should be aware of when considering this proposal?	1.3.3, page 12.
Q2.2	Do you support FSANZ's proposed approach that general Code requirements, including requirements for warning and advisory statements, allergen declarations, date marking, characterising ingredients and components of foods and foods requiring pre-market approval, should apply to young child formula? Please provide justification and any supporting evidence to support your response.	2.1, page 13.
Q2.3	Do you support FSANZ's proposed approach to safety-related labelling for young child formula in relation to: • Prescribed name • Required statements • Directions for use and storage.	3.4.6, page 24.

Question number	Question	Section of the CFS
	Please organise your response by issue and provide justification and any supporting evidence.	
Q2.4	Do you support FSANZ's proposed approach to the labelling for provision of information for young child formula in relation to: • Nutrition information requirements • Statement of ingredients • Nutrition content and health claims • Stage labelling • Product differentiation • Proxy advertising • Other representations. Please organise your response by issue and provide justification and any supporting evidence.	4.7.5, page 45.
Supporting Document 3: Safety and food technology assessment		
Q3.1	Do you support FSANZ preferred option (option 3) which proposes establishing a new food class in in the table to section S15—5 for young child formula, which would list food additive permissions for young child formula separate to provisions for formulated meal replacements and formulated supplementary foods. Please provide justification and any supporting evidence.	2.6.1, page 8.
Q3.2	FSANZ seeks stakeholder comment, supported by data or other evidence where available, on whether young child formula currently on the Australia and New Zealand market would be disadvantaged from a food technology perspective by alignment with CXS 156-1987 food additive permissions (refer to Table 4 below).	2.6.1, page 8.
Q3.3	FSANZ seeks stakeholder comment, supported by data or other evidence where available, on whether the 7 food additives assessed for young child formula (Ascorbyl palmitate (INS 304), Ascorbyl stearate (INS 305), Potassium hydroxide (INS 525), Sodium hydroxide (INS 524), d-alpha-Tocopherol (INS 307a), Tocopherol concentrate mixed (INS 307b) and dl-alpha-Tocopherol (INS 307c)) require permissions in the new proposed food class.	2.9.2, page 11.
Supporting Document 4: Microbiology assessment		
Q4.1	FSANZ seeks stakeholder comment, supported by data or other evidence where available, on the need for microbiological	5.3, page 55.

Question number	Question	Section of the CFS
	criteria in Schedule 27 for young child formula, specifically: (a) criteria for *Salmonella*; and (b) criteria for *Cronobacter*.	
Q4.2	FSANZ seeks comment on the need to extend the Compendium of Microbiological Criteria for Food to include young child formula.	6.2, page 57.
Q4.3	FSANZ seeks comment on aligning or retaining the Standard Plate Count for all powdered formula in the Compendium of Microbiological Criteria for Food.	6.3, page 57.
Supporting Document 5: Preliminary consideration of costs and benefits		
Q5.1	Have all the major impacts to industry, consumers and government from the proposed options been identified in Table 2 of SD5? Please provide evidence (where possible) to support the inclusion and magnitude of these or other impacts.	3.1, page 5.
Q5.2	Do you have information which may assist FSANZ in quantifying the costs and benefits currently identified as unquantified in Table 3 of SD5? Please provide data and evidence to support the inclusion of such information.	3.1, page 5.
Q5.3	Do you agree with the assumptions proposed to be used to estimate the cost of reformulation in SD5? Please provide data and evidence to support the inclusion of alternative assumptions.	3.5, page 8.
Q5.4	Do you agree with the assumptions proposed to be used to estimate the cost of re-labelling in SD5? Please provide data and evidence to support the inclusion of alternative assumptions.	3.6, page 9.