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Dear FSANZ

Attached are the comments that the Australian Food and Grocery Council wishes to present on the first call for submissions to Proposal P1066 – Review of young child formula.

If you have any queries, please contact Anne-Marie Mackintosh anne-marie.mackintosh@afgc.org.au

Yours sincerely



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**FSANZ P1066 –
Review of Formulated Supplementary
Foods for Young Children**

21 July 2026



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector.

Our purpose is to bring Australia's fast-moving consumer goods industry together to champion growth.

With an annual turnover in the 2023-24 financial year of \$173 billion, Australia's food and grocery manufacturing sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity. Each business in the sector has contributed towards an industry-wide \$3.8 billion capital investment in 2023-24.

Food, beverage and grocery manufacturing together forms Australia's largest manufacturing sector, representing over 32% of total manufacturing turnover in Australia. The industry makes a large contribution to rural and regional Australia economies, with over 30 per cent of its 294,000 employees being in rural and regional Australia.

It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

The industry has a clear view, outlined in *Sustaining Australia: Food and Grocery Manufacturing 2030*, of its role in the expansion of domestic manufacturing, jobs growth, higher exports and enhancing the sovereign capability of the entire sector.

This submission has been prepared by the AFGC and reflects the collective views of the membership.

EXECUTIVE SUMMARY

AFGC does not support the proposed regulatory framework to young child formula (YCF) as presented in the first call for submissions to P1066 – Review of young child formula. The proposed restrictions on nutrition content claims, health claims, stage labelling and other representations would limit truthful and non-misleading information that may help caregivers understand product composition and make informed choices. These claims are already regulated under Standard 1.2.7 and must be substantiated, not misleading and consistent with the overall diet. The consultation material does not demonstrate that broad prohibitions are necessary, proportionate or the least restrictive way to address the issues identified.

The proposal also raises important trade and competitiveness concerns. Divergence from international approaches, particularly where other markets permit claims or manage comparable products through general food law, may increase compliance complexity, reduce label harmonisation, restrict cross-border e-commerce, and disadvantage Australian and New Zealand products in export markets. These impacts have not been adequately identified or quantified in the preliminary cost-benefit analysis.

Industry feedback indicates that the proposed framework may reduce incentives to invest in YCF science, product innovation and the ANZ market more broadly. Over time, this may reduce consumer access to advanced, science-based formulations and weaken the commercial case for future manufacturing, supply chain and employment investment in Australia and New Zealand.

However, AFGC is supportive a proportionate regulatory framework that improves caregiver understanding of the age suitability, intended purpose, composition and safe use of YCF. AFGC also supports regulatory clarity where it is evidence-based, practical for industry and consistent with the supplementary role of the product. Any additional requirements should be targeted to demonstrated risks and should not unnecessarily restrict lawful, truthful and substantiated information.

AFGC recommends that FSANZ refine Proposal P1066, so any new requirements are proportionate, evidence-based and targeted to demonstrated risks, while recognising the supplementary role of YCF. FSANZ should also use the next-stage CRIS to revise the cost-benefit analysis, so it better reflects the YCF market and the proposal's likely practical impacts.

SUMMARY OF AFGC RECOMMENDATIONS

AFGC recommends that FSANZ:

1. Regulatory framework

- 1.0 Not proceed with the proposed framework to YCF in its current form. Refine the proposal and adopt only those measures that address a clearly identified risk, are supported by category-specific evidence, and are proportionate to the supplementary role of the product.
- 1.1 Apply a proportionality and effectiveness assessment against each proposed YCF-specific measure. This assessment should clearly identify the risk each measure is intended to address, test whether the measure is necessary and likely to be effective and consider whether a less restrictive option would achieve the same outcome.
- 1.2 Include a detailed Part 2.9 comparator analysis in the next stage of the assessment. This analysis should explain why YCF requires more restrictive controls than other formulated supplementary foods, given its supplementary role and FSANZ's assessment that no public health or safety risks warrant restrictions on access for the general population
- 1.3 Strengthen its dietary exposure assessment and broaden its review of published evidence to distinguish demonstrated dietary risks from assumptions about YCF use.

2. Labelling

- 2.1 Retain regulated, substantiated claims under Standard 1.2.7, provided they are presented consistently with mandatory age suitability, intended purpose and safe use statements.
- 2.2 Permit truthful stage or age-segmentation information where it is clearly linked to the 1-to-3-year age range, does not imply use for infants or routine necessity, and supports product differentiation and international label harmonisation.

3. Food safety

- 3.1 Retain optional nutrient and ingredient permissions for YCF where those permissions are supported by a history of safe use, relevant scientific evidence, Codex alignment or recognition in key trading partner markets. Additionally, only remove existing permissions where it can identify new evidence of a safety, public health or technological concern, and should assess the likely impacts on reformulation, supply, trade, international harmonisation and future product innovation before finalising any changes.

4. FSANZ Act assessments requirements

- 4.1 Undertake more detailed international comparison and full trade impact assessment. This should consider impacts on imports, exports, cross-border e-commerce, Australia/New Zealand label harmonisation, product specification harmonisation, optional ingredient permissions and the competitiveness of Australian and New Zealand manufacturers.
Where a proposed measure diverges from Codex or comparable international approaches, FSANZ should explain why the measure is necessary and why a less trade-restrictive option would not achieve the same consumer protection outcome.
- 4.2 Revise the cost-benefit analysis before the next stage of assessment, so it more accurately reflects the YCF market, tests claimed benefits against evidence, captures direct and indirect industry costs, and assesses trade, e-commerce, label harmonisation, reformulation, relabelling, cumulative and transition impacts.

- 4.3 Complete a YCF-specific market assessment before finalising the CRIS. This should include domestic sales, affected SKUs, packaging formats, import and export exposure, online retail channels, shared packaging arrangements, product specification harmonisation and whether businesses may need separate Australia/New Zealand labels or formulations.
- 4.4 Test each claimed benefit in SD5 against the available evidence, including the expected behavioural change, affected population, likelihood and magnitude of benefit, and whether less restrictive measures could achieve the same outcome.
- 4.5 Assess the relative importance of labelling, claims and product presentation compared with other consumer drivers of use; explain the assumptions used to estimate consumer impacts and benefits, and the uncertainty associated with using non-representative datasets. This is important for determining whether the proposed restrictions are likely to deliver the claimed benefits, and whether targeted consumer information measures, education or clearer mandatory statements would be a more proportionate response.
- 4.6 Broaden the cost methodology to capture direct and indirect costs and reflect variation by business size, packaging format, supply chain, export exposure and rather than using single average per SKU estimates.
- 4.7 Assess the proposed claims prohibition as a distinct regulatory measure, including its impacts on consumer information, product comparison, product differentiation, packaging, online retail and export competitiveness.
- 4.8 Treat trade and cross-border e-commerce impacts as core elements of the CRIS and cost-benefit analysis and tested through targeted consultation with manufacturers, importers, exporters, retailers and e-commerce operators.
- 4.9 Use probabilistic modelling in the CRIS that captures regulatory and legal review, artwork development, packaging write-off, stock depletion, retailer transition, digital content updates, export market review and the cost of maintaining separate Australia/New Zealand labels.
- 4.10 Finalise reformulation assumptions only after targeted consultation with affected businesses, including testing whether proposed compositional changes would require separate Australia/New Zealand formulations, affect export market alignment or create cumulative costs when combined with relabelling and claims restrictions.

5. Other consideration

- 5.1 Provide an adequate transition period, stock-in-trade provisions and implementation flexibility for products manufactured or labelled before commencement.

GENERAL COMMENTS

The AFGC and its members appreciate the opportunity to respond to the Food Standards Australia New Zealand (FSANZ) **Proposal P1066 – Review of Formulated Supplementary Foods for Young Children**. In response to the consultation, the AFGC has had the opportunity to review the submissions by the Infant Nutrition Council (INC) and the New Zealand Food and Grocery Council. (NZFGC). The AFGC strongly supports the INC and NZFGC's positions as stated in their submissions and shares the concerns that they raise.

AFGC supports the continued application of general Code requirements to YCF (YCF) where those requirements are relevant to food safety, allergen declaration, date marking, ingredient information, nutrient and health claims, and general consumer protection. These requirements are well established across the food supply and provide a sound basis for ensuring consumers receive essential information.

Targeted YCF-specific measures would only be supported where FSANZ can demonstrate that they are necessary to address a clearly identified risk. This may include clearer age suitability statements, intended purpose statements, safe preparation directions and reasonable product differentiation requirements that reduce the risk of confusion with infant formula or follow-on formula.

However, AFGC does not support the definition, framework or the broad prohibition-based model that restricts otherwise lawful, truthful and non-misleading information without clear evidence that such restrictions are necessary and proportionate. The proposed approach would move YCF away from a supplementary food framework and towards a more restrictive model more commonly associated with higher-risk categories such as infant formula or foods for special medical purposes.

Recommendation 1.0

AFGC does not support the proposed regulatory approach to YCF in its current form. AFGC recommends that FSANZ refine the proposal and adopt only those measures that address a clearly identified risk, are supported by category-specific evidence, and are proportionate to the supplementary role of the product.

SPECIFIC COMMENTS

1.0 REGULATORY FRAMEWORK - SECTION 2

Intended purpose

YCF is described by FSANZ as a supplementary product for children aged 1 to 3 years. It is currently regulated under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods. It is not intended as a sole source of nutrition, is not suitable for infants under 12 months, is not a breast milk substitute and is not a food for special medical purposes.

FSANZ's own nutrition assessment models the product as contributing approximately 15–25% of total daily energy intake and being consumed as part of a varied diet. This characterisation should guide the regulatory response.

AFGC agrees that the current framework may benefit from clarification, particularly where clearer age and intended purpose information would assist caregivers. However, the product's supplementary role does not support the wholesale adoption of infant-formula-style controls unless FSANZ can demonstrate that the same level of regulatory restriction is required for this specific category.

AFGC considers that, as part of good regulatory practice and policy due diligence, each proposed measure should be assessed against four questions: what risk the measure is intended to address; what evidence shows that the risk exists for YCF; whether the measure is necessary and likely to be effective in addressing that risk; and whether a less trade-restrictive and less information-restrictive measure would achieve the same outcome.

This assessment is particularly important where the proposed measures would prohibit claims, restrict product representations, require significant label changes, affect export competitiveness, or limit information that may assist caregivers to compare products. In these cases, considering less restrictive alternatives is part of the due diligence expected before adopting policy or regulatory measures that impose costs or restrict truthful and substantiated information.

Recommendation 1.1

AFGC recommends that FSANZ apply a proportionality and effectiveness assessment against each proposed YCF-specific measure. This assessment should clearly identify the risk each measure is intended to address, test whether the measure is necessary and likely to be effective and consider whether a less restrictive option would achieve the same outcome.

Comparison with other Part 2.9 categories

Part 2.9 of the Code contains standards for foods for physiologically vulnerable individuals and population sub-groups. Requirements should be calibrated to the intended dietary use of the food, the level of nutritional dependence involved and the specific risk being managed. The issue is not whether YCF should be regulated, but whether the proposed regulatory intensity is justified.

Other formulated supplementary foods provide an important comparator for assessing the proportionality of Proposal P1066. Standard 2.9.3 already recognises that some foods may be formulated to supplement a normal diet where energy or nutrient intakes may not be adequate, without being regulated as infant formula or foods for special medical purposes. See Table 1 at the end of this submission.

By contrast, infant formula products under Standard 2.9.1 are subject to highly prescriptive controls because they may be the sole or principal source of nourishment for infants. Foods for special medical purposes under Standard 2.9.5 are also subject to a more medicalised framework because they are used for dietary management of diseases, disorders or medical conditions, often under medical supervision. YCF does not have the same risk basis. It is supplementary, is not intended as a sole source of nutrition, is not suitable for infants under 12 months, and is not used for disease management.

AFGC is concerned that Proposal P1066 would impose a level of prescription that is not clearly aligned with this lower level of nutritional dependence. The proposal would introduce a stand-alone division, prescribed name, product-specific compositional requirements, product-specific additive permissions, a microbiological criterion and extensive labelling prohibitions. This is a significant shift from the current formulated supplementary foods framework.

The proposal also creates an inconsistency within Part 2.9. Other formulated supplementary foods for young children would remain subject to broader requirements, while YCF would be singled out for a more restrictive regime, including prohibitions on claims and representations, without a clearly differentiated risk basis. FSANZ's Supporting Document 2 states that, because the scope of P1066 is limited to YCF products, it has not considered the labelling requirements for other formulated supplementary foods for young children regulated under Standard 2.9.3. This makes a fuller Part 2.9 comparator analysis important before finalising the proposal.

This is particularly important because nutrition content claims, health claims and relevant endorsements are already regulated under Standard 1.2.7. Claims must meet prescribed conditions, health claims must be supported by scientific evidence, and claims must not be false, misleading or deceptive. FSANZ should explain why the existing claims framework is insufficient for YCF but remains acceptable for other formulated supplementary foods or other foods that may also be purchased for young children.

AFGC considers that the regulatory response should reflect the specific risk profile and supplementary nutritional nature of YCF. The fact that young children are a relevant population group does not, of itself, justify treating all children aged 1–3 years as uniformly physiologically vulnerable for the purpose of broad product-specific prohibitions. This is particularly relevant given FSANZ's assessment that it "did not identify any public health or safety risks that would warrant restrictions on access to these products for the general population." [CFS Table 7(d), p 34.]

Recommendation 1.2

AFGC recommends that FSANZ include a detailed Part 2.9 comparator analysis in the next stage of the assessment. This analysis should explain why YCF requires more restrictive controls than other formulated supplementary foods, given its supplementary role and FSANZ's assessment that no public health or safety risks warrant restrictions on access for the general population.

Supporting nutritional need

YCF should be assessed considering its stated purpose as a formulated supplementary food. FSANZ acknowledges that YCF may have a legitimate role where energy or nutrient intakes may be inadequate. This confirms that the category can have a supplementary purpose in some dietary contexts.

AFGC is concerned that the consultation material risks overstating inappropriate use, overuse or dietary displacement without sufficient direct evidence. The available intake data are limited and should be interpreted cautiously, particularly where age groups differ between datasets or where infant formula and toddler milk are combined in national nutrition survey reporting. In these circumstances, it is difficult to draw robust conclusions about changes in YCF consumption or to attribute observed intake patterns specifically to YCF.

AFGC notes that FSANZ intends to complete further dietary exposure assessment at the second call for submissions. This work should be completed before FSANZ finalises broad prohibitions or highly prescriptive controls that may restrict information or constrain the practical role of YCF as a supplementary food.

Published evidence on formulated supplementary products for young children should also be considered. Brooker et al. (2022) undertook a systematic review and meta-analysis of randomised controlled trials comparing fortified milk beverages with cow's milk or unfortified comparator formula in young children. The review included 19 articles from 12 studies and 4,795 participants and found improvements in haemoglobin and ferritin among children consuming fortified milk.

The authors concluded that fortified milk beverages appear to offer a safe and acceptable source of complementary nutrition as a short-term strategy for addressing nutritional deficits, particularly iron status. While AFGC notes that the review was partly industry-funded, it was conducted by researchers affiliated with CSIRO, prospectively registered, limited to randomised controlled trials and reported in accordance with PRISMA. These factors support its relevance to FSANZ's assessment of product purpose, use and proportionality.

Industry continues to invest in scientific research and product development for YCF in Australia and New Zealand. This investment supports the development of formulations designed to supplement dietary intake where energy or nutrient intakes may be insufficient. A regulatory framework that is more restrictive than necessary may reduce incentives to invest in this category, limit the introduction of new scientific developments and constrain future innovation pipelines.

Overall, the evidence supports a more balanced assessment of YCF use. It does not support assuming that current use is necessarily inappropriate or excessive, or that broad restrictions on truthful and substantiated product information are justified before the further dietary exposure assessment is complete.

Use patterns and dietary impact

AFGC notes that FSANZ considers YCF to be intended to supplement diets "in limited circumstances" and is concerned that products are widely marketed as "routine or beneficial" for healthy young children's diets [CFS Executive summary p 3]. FSANZ also notes that the market has expanded, with products "increasingly positioned beyond their intended role as supplementary foods" [CFS Section 1.1, p 6].

These concerns should be tested against direct evidence rather than assumed from product presence, marketing or caregiver use. AFGC does not consider that the CFS presents strong direct evidence that YCF is causing dietary displacement in practice.

The available evidence is mixed and incomplete. A randomised controlled trial in Australia and New Zealand by Lovell et al. (2019) found that consumption of a growing-up milk did not affect broader dietary patterns, although it changed nutrient intakes, including higher intakes of iron, vitamin D, vitamin C and zinc. A related analysis found higher nutrient adequacy scores among children consuming growing-up milk, while noting that effects on dietary diversity require further evaluation.

AFGC accepts that caregiver perceptions and product presentation can influence use. Studies have reported that caregivers may use toddler milk for convenience, perceived nutritional value and perceived benefits associated with claims, and that some caregivers may have difficulty distinguishing toddler milk from infant formula. These findings support targeted measures to improve product differentiation, age suitability and intended purpose information.

However, the evidence does not establish that use of YCF necessarily displaces meals, reduces dietary variety or results in inappropriate feeding behaviour. FSANZ should complete its further dietary exposure assessment and distinguish demonstrated displacement risks from assumptions about use before finalising broad restrictions.

Recommendation 1.3

AFGC recommends that FSANZ strengthen its dietary exposure assessment and broaden its review of published evidence to distinguish demonstrated dietary risks from assumptions about YCF use.

2.0 LABELLING – SECTION 4

Product differentiation

AFGC recognises the importance of distinguishing YCF from infant formula and follow-on formula. Clear age labelling and product differentiation can support appropriate use and reduce confusion. However, several elements of Proposal P1066 resemble controls applied to infant formula, including restrictions on claims, stage labelling, proxy advertising and product representations. Those controls may be justified in the infant formula context because infant formula may be the sole or principal source of nutrition for a highly vulnerable group. YCF does not have that role.

Informed consumer choice

i) nutrition content and health claims

FSANZ evidence from its social science assessment states “Nutrition and health claims on packaging were found to increase perceptions of the product’s overall health benefits.” [CFS section 4.1 p 22]. AFGC understands that FSANZ’s rationale for prohibiting nutrition content and health claims is that such claims may lead caregivers to view YCF as routine, necessary or beneficial for healthy young children, rather than as a supplementary food for use where dietary intakes may be inadequate.

AFGC also understands that FSANZ considers the claims prohibition to form part of a broader package of labelling controls intended to reduce confusion with infant formula and reinforce the product’s intended purpose

While the evidence presented by FSANZ indicates that claims may influence caregiver perceptions of YCF, this does not, of itself, establish that regulated claims cause harm. The consultation material does not demonstrate that the presence of regulated, substantiated and non-misleading claims leads to unsafe use, inappropriate feeding practices, displacement of a varied diet, or other outcomes that would justify a broad prohibition.

AFGC is concerned that the proposed prohibition on nutrition content and health claims would remove a legitimate and regulated source of information for caregivers. When appropriately regulated, claims can help consumers identify product attributes, compare products, understand nutrient composition and make choices that align with their needs and preferences. Standard 1.2.7 already imposes strict requirements on nutrition content and health claims, including conditions for use and substantiation requirements.

Removing regulated claims may also weaken the link between scientific development and consumer information. Where formulations are developed to address specific nutrient intake issues, industry needs a lawful and proportionate way to communicate relevant, substantiated product attributes. A blanket prohibition may reduce incentives to invest in improved formulations if those improvements cannot be clearly communicated to caregivers.

Claims must not be false, misleading or deceptive, and they operate within the broader protections of food law and Australian and New Zealand Consumer Law.

AFGC submits that FSANZ has not demonstrated why this existing regulatory framework is inadequate for YCF, particularly where the product is supplementary and not a sole-source food. AFGC does not support a blanket prohibition on nutrition content and health claims for YCF. AFGC accepts that claims should not undermine required statements about age suitability, intended purpose or the supplementary role of the product. However, that concern can be addressed through targeted controls, presentation requirements or limitations on specific types of claims rather than a blanket prohibition. For example, an appropriately substantiated iron or vitamin D claim may help caregivers identify relevant product attributes, provided it is presented consistently with required statements and does not imply that the product is necessary for all children.

A more proportionate approach would retain truthful and substantiated information, provided it is presented consistently with the product's intended use. Mandatory age suitability, intended purpose, and safe use statements should be clear and prominent, and claims should not contradict or undermine them. Where a claim is substantiated, complies with Standard 1.2.7 and reflects the product's supplementary role, it should not be prohibited simply because it may influence consumer perception.

Recommendation 2.1

AFGC recommends that FSANZ retain regulated, substantiated claims under Standard 1.2.7, provided they are presented consistently with mandatory age suitability, intended purpose and safe use statements.

ii) Age suitability and stage information

AFGC supports FSANZ's proposal to require a clear front-of-pack statement that YCF is suitable for children aged 1 to 3 years. This would help caregivers quickly identify who the product is for and support clearer use of the product.

However, AFGC does not support using this requirement to prohibit all stage numbers or narrower age-related product information. A clear 1-to-3-year statement can be the primary mandatory information on the front of pack, while still allowing truthful and non-misleading stage or age-segmentation information where it is consistent with that statement.

AFGC submits that FSANZ has not demonstrated that all stage numbers or age-segmentation information are inherently misleading. Removing this information may reduce product clarity, limit product differentiation and create trade and export implications, including for Stage 4 products and labels designed for use across multiple markets.

Recommendation 2.2

AFGC recommends that FSANZ permit truthful stage or age-segmentation information where it is clearly linked to the 1-to-3-year age range, does not imply use for infants or routine necessity, and supports product differentiation and international label harmonisation.

3.0 SAFETY AND FOOD TECHNOLOGY - SECTION 5**Mandatory composition and optional permissions**

AFGC supports a framework for YCF that sets clear minimum compositional requirements, while also allowing optional nutrients and ingredients where they are safe, suitable and appropriately regulated.

Minimum composition requirements are important because they establish the baseline for products in the category. They help ensure that all young child formula products meet core safety and nutritional expectations. However, optional permissions serve a separate purpose. They allow products to reflect advances in nutrition science, different formulation approaches and changing consumer or dietary needs, without requiring the Code to be amended each time a safe and suitable ingredient is supported by new or emerging evidence.

For this reason, AFGC considers that optional permissions should not be treated as unnecessary additions or exceptions. They are an important way of building flexibility into the regulatory framework while maintaining safety controls. This is especially important for YCF, which is intended to supplement the diet of children over one year of age and is not a sole source of nutrition.

AFGC is concerned that Proposal P1066 appears to narrow the range of optional permissions available for YCF. This is not clearly justified in the consultation material. FSANZ has not consistently identified evidence that the current permissions have resulted in food safety issues, inappropriate use or adverse public health outcomes.

Where an optional nutrient, ingredient or substance has an established history of safe use and is recognised in Codex or by key trading partners, AFGC considers that permission should generally be retained unless there is new evidence to justify its removal. A more restrictive approach may reduce international alignment, create avoidable reformulation impacts and limit the ability of businesses to innovate within a safe and regulated framework.

This is particularly relevant to proposed changes affecting DHA, L+ lactic acid producing cultures, and ALA and LA requirements. These changes may affect existing products and could require reformulation, create supply complexity and reduce alignment with international product specifications.

AFGC considers that FSANZ should focus on whether there is a clear reason to remove an existing permission, rather than whether every permitted nutrient or ingredient must be used in every product. Optional permissions do not require use; they simply allow safe and suitable ingredients to be used where appropriate.

Recommendation 3.1

AFGC recommends that FSANZ retain optional nutrient and ingredient permissions for YCF where those permissions are supported by a history of safe use, relevant scientific evidence, Codex alignment or recognition in key trading partner markets.

FSANZ should only remove existing permissions where it can identify new evidence of a safety, public health or technological concern, and should assess the likely impacts on reformulation, supply, trade, international harmonisation and future product innovation before finalising any changes.

4.0 FSANZ ACT ASSESSMENT REQUIREMENTS - SECTION 7**International regulatory approaches**

International approaches provide a useful benchmark for assessing whether FSANZ's proposed model is proportionate and trade compatible. Where comparable markets manage YCF or similar products through general food law, or permit claims subject to general claims rules, this indicates that consumer protection can be achieved without broad product-specific prohibitions. These examples should be used to test whether FSANZ's proposed restrictions are the least restrictive way to achieve the regulatory objective.

AFGC considers that FSANZ should use international comparisons to test whether a more targeted and trade-compatible model would achieve the same consumer protection outcomes. On the current evidence, a model focused on age clarity, intended purpose, safe preparation and permitted claims appears more proportionate than the broad prohibition-based approach proposed in P1066. Table 2 at the end of this submission illustrates international regulatory approaches to YCF and relevance to P1066.

For example, FSANZ's supporting material notes that Canada has proposed age range statements for formulated nutritional foods for children but has not proposed prescriptive requirements about where or how those statements must appear on the label. The EU and UK also demonstrate that products broadly comparable to YCF can be managed through general food law, with claims permitted where they comply with applicable nutrition and health claims rules and are not misleading. These examples show that age suitability, intended use and consumer protection can be addressed through clearer information and existing claims rules, without necessarily adopting highly prescriptive presentation requirements or broad prohibitions.

Fair trade and harmonisation

AFGC considers that Proposal P1066 may create practical trade and competitiveness impacts and may miss an opportunity to improve trade harmonisation. These impacts require fuller assessment, including impacts on imports, exports, cross-border e-commerce, label harmonisation, product specification harmonisation, optional ingredient permissions and the ability of Australian and New Zealand manufacturers to compete in export markets.

FSANZ should also assess whether the proposed approach aligns with Codex and key trading partners on permitted optional vitamins, minerals and other substances. This includes the practical implications of removing existing permissions for substances such as DHA and L+ lactic acid producing cultures, and of

focusing on mandatory ALA and LA requirements where products may be formulated without added vegetable oils.

Cross-border e-commerce is a particular concern. Consumers can access comparable products through overseas websites and online marketplaces where different claims, descriptors and product presentation requirements may apply. If domestic suppliers are prevented from using equivalent regulated and substantiated information, the proposal may create competitive asymmetry without necessarily improving consumer understanding. It may also result in consumers seeing inconsistent product information across domestic and overseas channels.

The trade implications are not limited to technical compliance costs. Claims and product information can be important tools for explaining product composition, demonstrating alignment with recognised standards and supporting product differentiation in export markets. Removing or narrowing these permissions may reduce the ability of Australian and New Zealand suppliers to compete effectively where consumers, retailers and regulators expect this information to be available.

AFGC submits that FSANZ should avoid unnecessary trade restrictiveness or competitive asymmetry unless it can clearly demonstrate that a restriction is necessary to address a defined public health risk and that no less restrictive option is available. Where FSANZ proposes measures that diverge from Codex or comparable international approaches, it should explain why those measures are necessary to achieve a legitimate public health objective and why less trade-restrictive options would not achieve the same outcome.

Recommendation 4.1

AFGC recommends that FSANZ undertake more detailed international comparison and full trade impact assessment. This should consider impacts on imports, exports, cross-border e-commerce, Australia/New Zealand label harmonisation, product specification harmonisation, optional ingredient permissions and the competitiveness of Australian and New Zealand manufacturers.

Where a proposed measure diverges from Codex or comparable international approaches, FSANZ should explain why the measure is necessary and why a less trade-restrictive option would not achieve the same consumer protection outcome.

Preliminary consideration of costs and benefits

AFGC understands that Supporting Document 5 (SD5) is a preliminary consideration of costs and benefits that sets out assumptions intended to inform the Consultation Regulation Impact Statement (CRIS) accompanying the second call for submissions. AFGC considers it important that the next-stage CRIS and cost-benefit analysis address the additional impacts identified below.

While the current analysis recognises some direct industry costs, including reformulation and relabelling, it does not sufficiently assess broader commercial, trade, consumer information and competitiveness impacts. These impacts are central to assessing whether the proposal is proportionate.

SD5 refers to infant formula export data and notes manufacturing similarities between infant formula products and YCF. While this context may be relevant, it does not substitute for a targeted assessment of the YCF market, including domestic sales, export exposure, affected businesses, SKUs and label or formulation harmonisation across markets.

AFGC supports FSANZ using the second call for submissions and CRIS process to undertake a fuller cost-benefit analysis that addresses direct, indirect, trade, consumer information and competitiveness impacts.

Recommendation 4.2

AFGC recommends that FSANZ revise the cost-benefit analysis before the next stage of assessment, so it more accurately reflects the YCF market, tests claimed benefits against evidence, captures direct and indirect industry costs, and assesses trade, e-commerce, label harmonisation, reformulation, relabelling, cumulative and transition impacts.

YCF market assessment

SD5 reports 2024 domestic sales of toddler milk of AUD \$53.12 million in Australia and AUD \$4.94 million in New Zealand, and junior milk sales of AUD \$73.0 million in Australia and AUD \$14.22 million in New Zealand. However, SD5 also notes that the junior milk category may over-represent foods within the scope of P1066. This reinforces the need for a clearly defined YCF-specific market assessment before relying on market size or impact estimates.

SD5 identifies 55 SKUs across Australia and New Zealand, including 20 SKUs unique to New Zealand. It also notes that most products are sold in aluminium or steel tins, with a smaller number of sachet products. These packaging differences should be reflected in any relabelling cost model, as costs are unlikely to be uniform across packaging formats or markets.

FSANZ should undertake a targeted market assessment that clearly defines the size and structure of the YCF sector. This should include affected businesses and SKUs, import and export exposure, domestic and export market roles, shared regional or global packaging, product specification harmonisation, online retail channels and whether businesses may need separate Australia/New Zealand labels or formulations.

Recommendation 4.3

AFGC recommends that FSANZ complete a YCF-specific market assessment before finalising the CRIS. This should include domestic sales, affected SKUs, packaging formats, import and export exposure, online retail channels, shared packaging arrangements, product specification harmonisation and whether businesses may need separate Australia/New Zealand labels or formulations.

Expected benefits assessment

AFGC notes that SD5 identifies expected benefits including improved caregiver understanding of YCF's intended purpose, reduced use inconsistent with that purpose, improved nutritional composition and improved international regulatory alignment. AFGC considers that each claimed benefit should be separately tested against the evidence, including the expected behavioural change, affected population, magnitude of benefit and availability of less restrictive alternatives.

The Australian Government Guide to Policy Impact Analysis emphasises the need to assess the likelihood that an intervention will achieve its intended outcomes or benefits. FSANZ should therefore more clearly explain how the proposed labelling, claims and representation restrictions are expected to change behaviour, how likely those changes are, and whether less restrictive measures could achieve similar outcomes.

This is particularly important because the proposed benefits appear to rely on a chain of assumptions: that on-pack information is a key driver of unnecessary use; that the proposed restrictions will materially change caregiver understanding; that this will materially change purchasing or consumption behaviour; and that those changes will generate measurable consumer savings or public health benefits. Each step in that chain should be tested and transparently assessed.

SD5 also identifies potential industry benefits, including regulatory clarity, international alignment, further harmonisation of base powders and possible recipe, manufacturing and formulation efficiencies. AFGC considers these claimed benefits should not be assumed. They should be tested with affected businesses, particularly where other elements of the proposal may require Australia/New Zealand-specific labels, specifications or formulations.

Industry feedback indicates that potential industry benefits should not be assumed where the proposal may reduce category profitability, competitiveness and the ability to communicate substantiated product attributes. If the framework reduces incentives for ongoing scientific research, product development and market investment, this should be counted as a potential cost rather than treated as a neutral or beneficial outcome.

Recommendation 4.4

AFGC recommends that FSANZ test each claimed benefit in SD5 against the available evidence, including the expected behavioural change, affected population, likelihood and magnitude of benefit, and whether less restrictive measures could achieve the same outcome.

Consumer assessment

i) Behaviour

AFGC considers that the assessment should also recognise that consumption of YCF is influenced by multiple factors, not solely by on-pack information. FSANZ's supporting material identifies reasons for use such as convenience, transition from breastmilk or infant formula to cow's milk and solid foods. These drivers suggest that labelling changes may not, by themselves, materially alter purchasing or consumption patterns. A clearer understanding of consumer behaviour would also help identify whether non-regulatory or less restrictive measures could achieve the intended outcome more effectively and at lower cost.

ii) Impact

AFGC notes that in the preliminary cost-benefit assessment (SD5), FSANZ references a figure from the microbiological risk assessment (SD4) that an estimated that 20% of Australian and New Zealand children aged 1 to 3 years consume YCF. FSANZ states that this estimate was not based on existing national consumption datasets, because young children are not adequately represented in those datasets. This reinforces the need for the cost-benefit analysis to clearly explain the assumptions used when estimating likely consumer impacts and benefits. This uncertainty should be reflected clearly in the cost-benefit analysis.

FSANZ should also consider whether the proposal may have unintended consumer impacts by reducing access to advanced, science-based formulations. If regulatory settings reduce incentives for industry to invest in ANZ-specific research, innovation or new product development, consumers may have fewer

options available where YCF is used as a supplementary food to support energy or nutrient intake in specific dietary circumstances.

Recommendation 4.5

AFGC recommends that FSANZ assess the relative importance of labelling, claims and product presentation compared with other consumer drivers of use; explain the assumptions used to estimate consumer impacts and benefits, and the uncertainty associated with using non-representative datasets. This is important for determining whether the proposed restrictions are likely to deliver the claimed benefits, and whether targeted consumer information measures, education or clearer mandatory statements would be a more proportionate response

Cost assessment methodology

AFGC is concerned that FSANZ's approach to estimating reformulation and relabelling costs may underestimate the true cost to industry. Previous FSANZ cost-benefit assessments have relied on single-point per-SKU estimates, which do not adequately reflect the variability of costs across product categories, business sizes, economies of scale, internal capability, packaging types, printing methods, supply chains and export market arrangements.

Single average per-SKU estimates can oversimplify the complexity and diversity of the affected sector. Industry feedback indicates that, in practice, relabelling and reformulation costs vary significantly depending on the nature of the change, the number of markets affected, whether packaging is shared across countries, the extent of retailer and digital content changes, and the need for regulatory, legal, technical or export market review.

The cost assessment should also consider broader dynamic impacts that may not be captured through per-SKU relabelling or reformulation estimates. These include impacts on future science investment, innovation pipelines, category profitability, manufacturing and supply chain investment, regional employment and contractor networks.

Recommendation 4.6

AFGC recommends that the FSANZ broaden the cost methodology to capture direct and indirect costs and reflect variation by business size, packaging format, supply chain, export exposure and rather than using single average per SKU estimates.

Impacts of prohibiting claims

AFGC considers that the proposed prohibition on nutrition content and health claims should not be treated only as a labelling compliance issue. It has broader commercial and consumer information impacts.

Claims can support product comparison, communicate compositional attributes, and help consumers understand the role of nutrients in the product. Removing regulated claims may reduce the information available to caregivers and may require businesses to redesign packaging, marketing materials, online product pages and retailer content. Industry feedback indicates it may also reduce the ability of Australian and New Zealand products to compete with products in jurisdictions where equivalent claims remain permitted.

AFGC considers that FSANZ should separately assess the costs and benefits of prohibiting claims, including the likely effect on consumer information, product differentiation, competitiveness, online retail, export markets and packaging harmonisation. These impacts should be assessed against less restrictive alternatives, such as conditions on claim presentation, additional contextual statements, or targeted restrictions on specific claim types.

Recommendation 4.7

AFGC recommends that FSANZ assess the proposed claims prohibition as a distinct regulatory measure, including its impacts on consumer information, product comparison, product differentiation, packaging, online retail and export competitiveness.

Trade and cross-border e-commerce impacts

AFGC considers that the cost-benefit analysis should expressly include trade and cross-border e-commerce impacts. While SD5 identifies improved international regulatory alignment as a potential benefit, this should be assessed measure by measure. Some compositional or base powder changes may improve alignment, while labelling, claims or presentation restrictions may increase divergence from key markets and reduce label harmonisation.

Potential impacts include increased compliance costs for imported products, reduced ability to use common regional or global packaging, additional artwork and packaging change costs, write-off of existing stock, complexity in managing Australia/New Zealand-specific SKUs, increased barriers for smaller suppliers, and reduced competitiveness for domestic manufacturers in export markets.

Cross-border e-commerce creates additional complexity. Consumers may be able to purchase comparable products from overseas websites where claims and product descriptors remain permitted. This may create competitive asymmetry across sales channels, particularly where domestic and overseas online products are viewed side by side. It may also increase the risk of inconsistent consumer information across physical and digital retail channels.

Recommendation 4.8

AFGC recommends that FSANZ treat trade and cross-border e-commerce impacts as core elements of the CRIS and cost-benefit analysis and tested through targeted consultation with manufacturers, importers, exporters, retailers and e-commerce operators.

Impacts of relabelling costs

AFGC is concerned that relabelling costs may be underestimated if they are treated primarily as artwork or packaging changes. For many businesses, relabelling involves regulatory assessment, legal review, translation or export market review, packaging redesign, retailer approval, inventory management, depletion of old stock, system updates, online content updates and coordination across multiple markets.

Where a change affects claims, stage labelling, product names, product differentiation or other representations, the cost is likely to extend beyond a simple label edit. Businesses may need to revisit brand architecture, packaging hierarchies, consumer communication strategies, digital assets and export market consistency.

AFGC recommends that FSANZ adopt a broader relabelling cost methodology that captures internal and external regulatory review, artwork development, packaging write-off, stock depletion, retailer transition, online content changes and the cost of maintaining separate labels for Australia and New Zealand.

Similarly, if FSANZ applies relabelling assumptions similar to those used in Proposal P1028, relabelling costs for 55 SKUs may be estimated at around \$440,000 using an \$8,000 per-SKU estimate, or around \$880,000 using a \$16,000 per-SKU estimate. AFGC considers that these figures are likely to understate the real cost burden because they focus on direct label change costs and do not adequately capture indirect, cumulative and market-specific costs.

AFGC notes that in SD5, FSANZ is updating its cost of label change model and expects updated figures to be available in the CRIS accompanying the second call for submissions. AFGC welcomes this but considers that the model should capture more than direct artwork or label change costs.

AFGC preliminary estimate

AFGC proposes an alternative methodology for estimating total industry costs using a Monte Carlo simulation rather than relying on a single-point estimate.

In contrast to an approach based on a single average per-SKU cost, Monte Carlo simulations produce a range of possible total cost outcomes that reflects the distribution of costs businesses are likely to face. This allows policymakers to consider not only a central estimate but also the likelihood and magnitude of higher-cost outcomes.

Based on preliminary member feedback and 55 SKUs, the model estimates a 90 per cent probability that total relabelling costs alone would fall between around \$0.8 million and \$1.3 million, with a mean estimate of around \$1.1 million. This is materially higher than the \$440,000 to \$880,000 range that may result if FSANZ applies relabelling assumptions similar to those used in Proposal P1028. This suggests that the cost range is likely to be wider and higher than a single average per-SKU estimate indicates. FSANZ should use sensitivity or probabilistic modelling in the final cost-benefit analysis, including for any associated reformulation costs. **See Appendix 1.**

Recommendation 4.9

AFGC recommends that FSANZ use probabilistic modelling in the CRIS that captures regulatory and legal review, artwork development, packaging write-off, stock depletion, retailer transition, digital content updates, export market review and the cost of maintaining separate Australia/New Zealand labels.

Reformulation assumptions

AFGC notes SD5 proposes to use the P1028 reformulation estimate of AUD \$200,000 per SKU, because of similarities between infant formula products and YCF. Applied to 55 SKUs, this would imply a potential reformulation cost of around AUD \$11 million before any sensitivity analysis or market-specific adjustment.

AFGC considers that these assumptions should be treated cautiously. While there may be similarities in manufacturing processes or ingredients, YCF is a distinct supplementary product and the regulatory rationale for changes should not be derived from infant formula by analogy. This would be a material one-

off cost to industry and should be tested with affected businesses before being relied on in the final assessment.

Reformulation costs may vary significantly depending on the number of SKUs affected, the nature of the compositional change, ingredient availability, stability testing, validation requirements, packaging changes, export market implications and timing. Even where reformulation is technically possible, the commercial impact may be significant if it reduces alignment with international product specifications or requires separate Australia/New Zealand formulations.

Recommendation 4.10

AFGC recommends that FSANZ finalise reformulation assumptions only after targeted consultation with affected businesses, including testing whether proposed compositional changes would require separate Australia/New Zealand formulations, affect export market alignment or create cumulative costs when combined with relabelling and claims restrictions.

5.0 OTHER CONSIDERATIONS

Transition arrangements

If FSANZ proceeds with changes that require relabelling, reformulation or changes to claims and product representations, adequate transition arrangements will be essential. These should include a realistic transition period, stock-in-trade provisions and flexibility for products manufactured or labelled before commencement to move through the supply chain.

Transition timing should also be aligned, as far as practicable, with normal label change cycles and export market planning. This would reduce avoidable packaging waste, stock write-off, retailer disruption and compliance costs, while still allowing the regulatory objective to be achieved.

5.1 Recommendation

AFGC recommends that FSANZ provide an adequate transition period, stock-in-trade provisions and implementation flexibility for products manufactured or labelled before commencement.

CONCLUSION

AFGC supports proportionate reform that improves caregiver understanding, supports safe and appropriate use, and gives industry clear and workable regulatory requirements.

However, Proposal P1066 should be refined so that any new controls are targeted, evidence-based and proportionate to the supplementary role of YCF. Restrictions on truthful and substantiated information, infant-formula-style controls and trade-impacting measures should only proceed where FSANZ can demonstrate a clearly identified risk and explain why a less restrictive option would not achieve the same objective.

AFGC recommends that FSANZ revise the proposal and the supporting cost-benefit analysis before the next stage of assessment. This should include a targeted YCF market assessment, clearer testing of claimed benefits, a more transparent cost methodology, assessment of trade and e-commerce impacts, and adequate transition arrangements, including stock-in-trade provisions and implementation flexibility.

The final assessment should also consider whether the proposal may unintentionally reduce consumer access to future science-based product innovation and weaken incentives for broader business investment in Australia and New Zealand.

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- (1) Brooker PG, Rebuli MA, Williams G, Muhlhausler BS. Effect of Fortified Formula on Growth and Nutritional Status in Young Children: A Systematic Review and Meta-Analysis. *Nutrients*. 2022; 14(23):5060. <https://doi.org/10.3390/nu14235060>
- (2) Lovell AL, Milne T, Jiang Y, Chen RX, Grant CC, Wall CR. Evaluation of the Effect of a Growing up Milk Lite vs. Cow's Milk on Diet Quality and Dietary Intakes in Early Childhood: The Growing up Milk Lite (GUMLi) Randomised Controlled Trial. *Nutrients*. 2019 Jan 20;11(1):203 <https://www.mdpi.com/2072-6643/11/1/203>

Table 1: Comparison of YCF with other Part 2.9 categories

Product category	Intended use	Level of nutritional dependence	Indicative risk basis	Regulatory controls	Implication for P1066
Infant formula products	For infants, including products represented as suitable as the sole or principal liquid source of nourishment.	High. May be the sole or principal source of nutrition for a physiologically vulnerable group.	Heightened vulnerability of infants, including immature immune systems and organs, and reliance on the product for nutrition.	Highly prescriptive framework, including compositional requirements, claim restrictions, product differentiation requirements and specific information requirements.	Infant-formula-style controls should not be imported into the YCF framework unless FSANZ demonstrates a comparable risk basis.
Food for special medical purposes	For dietary management of people with diseases, disorders or medical conditions, under medical supervision.	Variable but potentially high, depending on the clinical use. Some products may be used as a sole source of nutrition or as a medically supervised supplement.	Medical or clinical need, with use linked to disease, disorder or medical condition management.	Medicalised framework, including mandatory statements, sale restrictions and medical supervision requirements.	Medicalised controls require a medical-purpose rationale and should not be applied to YCF without a comparable risk basis.
YCF	Supplementary product for children aged 1 to 3 years.	Lower. Not intended as a sole source of nutrition and not suitable for infants under 12 months.	Potential risks relate to inappropriate use, caregiver perception, labelling clarity, food safety and composition.	Proposal P1066 would introduce a stand-alone division, prescribed name, product-specific compositional and additive requirements, microbiological criterion, and extensive labelling prohibitions.	Targeted controls may be justified, but blanket prohibitions require stronger category-specific evidence.
Other formulated supplementary foods for young children	Supplementary foods for young children within the broader Standard 2.9.3 framework.	Generally lower. Intended to supplement, not replace, a varied diet.	Risks are managed through general and category-specific requirements relevant to intended use.	Broader framework with less extensive product-specific prohibitions than proposed for YCF.	A clearer comparator analysis is needed before singling out YCF for a materially more restrictive regime.

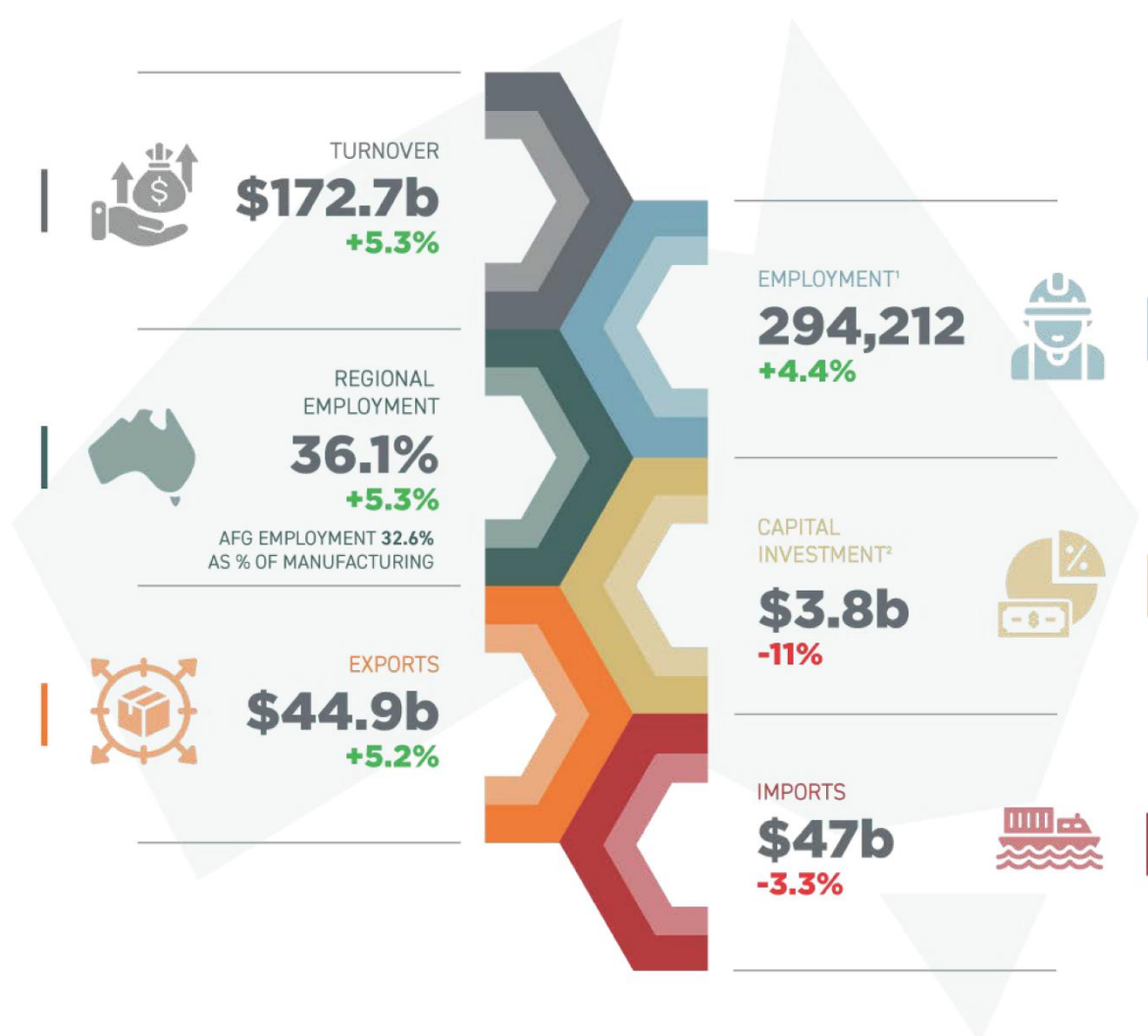
Table 2: Selected international regulatory approaches to YCF and similar products

Jurisdiction or framework	Regulatory treatment	Approach to claims and consumer information	Strategic relevance for P1066
Codex	The revised Codex Standard for Follow-up Formula for Older Infants and Product for Young Children recognise a distinct category for products for young children aged more than 12 months up to 3 years.	Codex provides a harmonising reference point for composition and labelling, while recognising that implementation should be consistent with national and regional health and nutrition policies.	Demonstrates Codex alignment can support regulatory consistency, but it should not be used to justify more restrictive local measures unless those measures are supported by a clear risk basis.
European Union and United Kingdom	Products broadly comparable to YCF are generally subject to broader food law and general claims controls, rather than a product-specific prohibition equivalent to that proposed by FSANZ.	Claims may be permitted where they comply with applicable nutrition and health claims rules and are not misleading.	Demonstrates that regulated claims can coexist with consumer protection and that broad product-specific claim prohibitions are not the only available regulatory model.
United States	Toddler milk and similar products are generally managed through broader food law and general labelling requirements, rather than through a YCF standard equivalent to infant formula.	Product information and claims are managed through general labelling and misleading conduct requirements.	Demonstrates that risks can be addressed through existing consumer protection and labelling frameworks without imposing a broad prohibition model.
Canada	A proposed a modernised framework is in process that includes formulated nutritional foods for children as products for self-selection by consumers, rather than treating them as foods for special dietary purpose requiring the same level of oversight as sole-source or medically supervised products.	Proposed age range statements for formulated nutritional foods for children but has not proposed prescriptive requirements for where or how those age-related statements must appear on the label.	Demonstrates a more targeted model focused on age suitability and consumer information, rather than broad restrictions on presentation or claims.
China	One of the more prescriptive jurisdictions and has specific standards applying to YCF or similar products.	More product-specific than the general food law approach used in many other markets.	Demonstrates that more prescriptive models exist, but these should not be treated as the default international benchmark where most comparable markets rely on broader food law or less restrictive approaches.
Japan and India	Products in these markets are broadly equivalent to YCF are regulated as general foods rather than through product-specific YCF standards.	Claims and representations are generally managed through broader food labelling and consumer protection frameworks.	Reinforces the need for FSANZ to justify why Australia and New Zealand require a materially more restrictive model than many comparable trading partners.



STATE OF THE INDUSTRY

2023-24



The figures on this page exclude the fresh food sector and are based on 2023-24 ABS data.

1: This is total number of employees, head count basis and does not include seasonal employees.

2: Gross fixed capital formation for food, beverage and tobacco manufacturing subsector is taken as indicator of capital investment.

APPENDIX 1

P1066 – YOUNG CHILD FORMULA

ASSESSMENT OF SUPPORTING DOCUMENT 5 – PRELIMINARY CONSIDERATION OF COSTS AND BENEFITS

Previous P1028 - Infant formula cost estimates

FSANZ undertook a cost-benefit analysis as part of proposal P1028 that was seeking to modernise the compositional, labelling and regulatory framework for infant formula products, aligning requirements with current scientific evidence and international standards. FSANZ applied a break-even methodology to assess whether the benefits of the regulatory change outweighed the total cost to industry through product reformulation and label changes.¹

To estimate the number of affected products, FSANZ built a dataset to identify the number of infant formula products on sale in Australia and New Zealand by searching across retail outlets, pharmacies and online channels. Each product was assessed against the proposed requirements to determine whether it would need reformulation, relabelling or both.

Reformulation costs were estimated at \$200,000 per-SKU based on industry feedback. Relabelling costs were initially set at \$8,000 per-SKU drawing on the PriceWaterhouseCoopers study used in P1050 and the pregnancy warning label survey data.² However, industry indicated the estimates were underestimated. Following further consultation and data from a Marsden Jacob survey of relabelling costs by packaging type, the estimate was revised to \$16,000 per-SKU. Total industry costs were estimated at \$44m in one-off reformulation costs, plus \$2-4m in relabelling costs.

Table 1 Summary of cost estimates. Proposal P1028.

	# SKUs	Average per-SKU cost	Total cost
Reformulation	220	\$ 200,000	\$ 44,000,000
Relabelling	243	\$ 8,000	\$ 1,944,000
		\$ 16,000	\$ 3,888,000

Limitations in FSANZ's cost assessment

- FSANZ's average per-SKU estimates have focused on direct costs, such as packaging type, printing method, and the scale of change, while often excluding indirect costs such as product testing, legal fees, marketing, logistics, digital assets, and the disposal of old stock. This means that estimates by design have captured only a portion of the total compliance burden.

¹ (FSANZ, 2023)

² (PricewaterhouseCoopers, 2014)

- Studies that have been used in the past to inform cost benefit analysis have drawn insights from a small pool of sources. For example, (PricewaterhouseCoopers, 2014) assessed labelling costs including design, proofing, and production, which varied based on packaging type. The study cited lack and variability of data as one of its limitations, given that a small number of responses could disproportionately influence the average, producing estimates that may not be representative of the broader industry.
- FSANZ has also previously relied on single-point estimates to characterise total industry costs, treating all businesses within a category as if they face the same per-SKU cost. In practice, costs vary significantly by product category, business size, economies of scale, internal capability, packaging type, printing method, and supply chain structure. FSANZ usually acknowledges this complexity but is not considered in the cost modelling.

Assessment of P1066

As indicated in SD5, if FSANZ uses the same methodology and per-SKU cost estimates as P1028, its cost-benefit assessment would likely estimate total industry costs at around \$11 million in one-off reformulation costs, and relabelling costs at between \$400,000 and \$900,000. The AFGC understands FSANZ is in the process of updating its cost of label change model which will be presented at the 2nd call for submission.

Table 2. Table 1 FSANZ's likely cost estimates following P1028 assumptions

	# SKUs	Average per-SKU cost	Total cost
Reformulation	55	\$200,000	\$11,000,000
Relabelling	55	\$8,000	\$440,000
		\$16,000	\$880,000

Preliminary AFGC labelling cost assessment

The AFGC proposes an alternative methodology for estimating total industry costs using a Monte Carlo simulation rather than relying on single-point estimates. The method assigns a probability distribution to each uncertain input – in this case, per-SKU relabelling cost – and runs the model repeatedly, each time drawing a random value from that distribution. After a large number of iterations, the outputs converge on a full distribution of possible total cost outcomes, from which expected values, confidence intervals, and the probability of exceeding any given cost threshold can be derived.

In contrast to an approach based on a single average per-SKU cost, Monte Carlo simulations produce a range of possible total cost outcomes that reflects the distribution of costs businesses are likely to face. This allows policymakers to consider not only a central estimate but also the likelihood and magnitude of higher-cost outcomes.

Data inputs

The AFGC is demonstrating this approach with labelling costs only. The same would apply to reformulation costs, however it would require further data collection and analysis.

Per-SKU relabelling costs

The AFGC has consulted member companies to obtain preliminary per-SKU cost estimates for modelling purposes. These estimates provide an initial evidence base, but additional data from a broader set of companies, including information on packaging type, print method, stock run-out, design, approval and implementation costs, would improve the robustness of the model.

- \$11,380 - \$28,000 AUD

SKU Counts

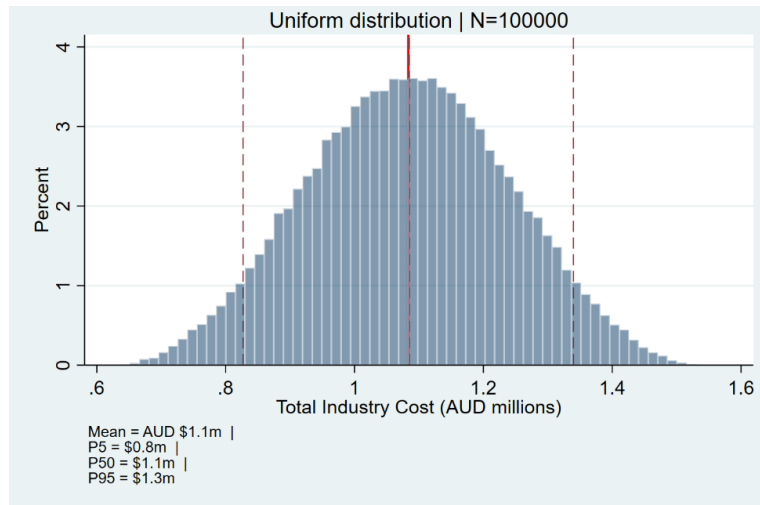
- 55 SKUs identified by FSANZ.
 - 21 unique SKUs – AU
 - 20 unique SKUs – NZ
 - 14 both markets

For simplification all 55 SKUs are assumed to face the same preliminary per-SKU relabelling cost range in Australian dollars. This provides an initial basis for estimating total industry costs, but further industry data on how costs vary by product, market, packaging type would improve the robustness of the model.

Preliminary results

AFGC's preliminary results suggest a 90 per cent probability that total uncoordinated relabelling costs between \$0.8 million and \$1.3 million with a mean estimate of \$1.1 million. This is 48 to 82 per cent above what FSANZ would estimate if following the same approach as used for P1028.

The breadth of this range shows that even within a structured, transparent model, the choice of data source, the assumption about business-size cost variability, and the underlying per-SKU cost range all materially affect the headline number.



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