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Supporting document 5

Preliminary consideration of costs and benefits

P1066 – Review of young child formula

Executive summary

This supporting document outlines assumptions that will be used to inform the consultation Regulation Impact Statement that will accompany the 2nd CFS.

As stated in the 1st call for submissions (CFS), FSANZ's preliminary conclusion is that the costs of the proposed regulatory approach are likely to be outweighed by the benefits, including:

- ensuring caregivers are informed about the intended purpose of young child formula
- mitigate the likelihood that young child formula is used in ways that do not align with its intended purpose
- improved nutrition composition of young child formula
- improved international regulatory alignment.

FSANZ estimates 35 and 34 differently packaged young child formula products with their own barcode (stock keeping units; SKUs) are available in Australia and New Zealand, respectively, with a total of 55 SKUs when accounting for those available in both markets.

The costs to industry include reformulation to meet proposed nutrition composition requirements and labelling changes.

Feedback provided by submitters in response to this CFS will contribute to FSANZ's determination regarding potential amendments to the Code. Additionally, such input may assist FSANZ in enhancing its assessment of associated costs and benefits.

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1. Introduction

This supporting document (SD) contains the consideration of costs and benefits and should be read in conjunction with the 1st Call for submissions (CFS) for Proposal P1066 – Review of young child formula.

The *Food Standards Australia New Zealand Act 1991* requires FSANZ to have regard to whether the costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the proposed changes to standards (paragraph 59(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considers the revisions of standards related to young child formula in the Australia New Zealand Food Standards Code (the Code) that preferred options will require, if approved.

The consideration of the costs and benefits in this SD 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.

Submitter feedback from the 1st CFS will inform FSANZ's decision on whether to amend the Code and how. A consultation Regulation Impact Statement (CRIS) and a more comprehensive consideration of costs and benefits will be prepared if, after consideration of submissions received in response to this 1st CFS, FSANZ decides to proceed and prepare a draft variation. The Office of Impact Analysis will be consulted to confirm the adequacy of the analysis for consultation purposes.

2. Young child formula

The CFS provides an introduction to young child formula products and how they are regulated.

Table 1 presents the domestic sales for young child formula in 2024.

Table 1: Domestic sales of young child formula in 2024 (inflation adjusted to September 2025)

Product type	Country	AUD million
Toddler milk	Australia	53.12
	New Zealand	4.94
Junior milk	Australia	73.0
	New Zealand	14.22

Source: Euromonitor (2024)

Note: Data used is from 'Growing-Up Milk Formula' category using 1-3 years to represent toddler milk and 3+ years to represent junior milks. The junior milk category may over represent the foods within the scope of this proposal.

FSANZ's microbiological risk assessment for this proposal estimated 20% of Australian and New Zealand 1-3 year olds consume young child formula.¹

¹ This was not based existing national consumption datasets because young children are not adequately represented which would lead to underestimating microbiological risk. Instead, an approach was used, consistent with international guidance, that combined the total number of 1-3 year olds in Australia and New Zealand (from official population statistics) and used various best available evidence to make assumptions about the proportion consuming and amount consumed.

Young child formula and infant formula products share several important compositional and manufacturing similarities. Both product types are typically manufactured using similar base powders and are usually produced within the same manufacturing facilities and production lines.

As a category, infant formula product exports in 2024 were valued at:

- \$1.81 billion (NZD) for New Zealand exports (MPI 2025a)
- \$361.31 million (AUD) for Australian exports (DAFF 2025).

Infant formula products comprised 8% of New Zealand’s total dairy exports revenue in 2024-25, with China being the top infant formula product export market (67% of infant formula product export revenue) (MPI 2025b).

3. What is the likely net benefit of each option?

Detail of the preliminary regulatory approach discussed in this section can be found in the CFS.

This section outlines assumptions that will be used to inform the CRIS that will accompany the 2nd CFS.

3.1. Preliminary regulatory approach against status quo

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.

Table 2 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 3 presents whether FSANZ expects these impacts to be quantifiable and which impacts are expected to be qualitatively analysed.

Table 2: Impact on different stakeholder groups arising from the preliminary regulatory approach

Stakeholder group	Impact
<p>Young children consuming young child formula and their caregivers</p>	<p>Improved composition of young child formula to reflect its intended purpose as a special purpose food</p> <ul style="list-style-type: none"> • Greater health outcomes for young children consuming young child formula <p>Reduced unnecessary use of young child formula by clarifying its intended purpose as a special purpose food via labelling</p> <ul style="list-style-type: none"> • Savings for caregivers of young children <p>Improved provision of information</p> <ul style="list-style-type: none"> • Correct preparation leading to reduced risk of unsafe preparation

<p>Young child formula industry</p>	<p>Costs related to reformulating products to meet changes to the Code</p> <p>Costs related to relabelling products to meet changes in the Code</p> <p>Costs related to introducing <i>Salmonella</i> microbiological criteria</p> <p>Regulatory clarity regarding young child formula as its own subcategory of formulated supplementary foods</p> <p>International regulatory alignment (opportunity for manufacturing efficiencies)</p> <p>Further harmonisation of base powders, leading to recipe, manufacturing and formulation efficiencies</p> <p>Consistent Code requirements for young child formula with infant formula (base milk powder provisions)</p> <p>Loss of profits from sales of young child formula products due to intended purpose being clarified</p>
<p>Government</p>	<p>Benefits in enforceability of young child formula products</p> <p>Savings in healthcare costs avoided</p> <p>Small cost to adjust to new standards</p>

Table 3: Quantified and unquantified impacts arising from the preliminary regulatory approach

	Stakeholder group	Impact
<p>Quantified cost</p>	<p>Young child formula industry</p>	<p>Costs related to relabelling products to meet changes in the Code</p> <p>Costs related to reformulating products to meet changes to the Code</p>
<p>Unquantified cost</p>	<p>Young child formula industry</p>	<p>Costs related to introducing <i>Salmonella</i> microbiological criteria</p> <p>Loss of profits from sales of young child formula products</p>
<p>Quantified benefit</p>	<p>Young children consuming young child formula and their caregivers</p>	<p>Reduced unnecessary use of young child formula</p>
<p>Unquantified benefit</p>	<p>Young children consuming young child formula and their caregivers</p>	<p>Improved composition of young child formula</p> <p>Improved provision of information</p> <p>Reduced foodborne illness</p>

	Young child formula industry	<p>Regulatory clarity regarding young child formula as its own subcategory of formulated supplementary foods</p> <p>International regulatory alignment (opportunity for manufacturing efficiencies)</p> <p>Further harmonisation of base powders, leading to recipe, manufacturing and formulation efficiencies</p> <p>Code requirements for young child formula is consistent with infant formula (base milk powder provisions)</p>
	Government	<p>Enforceability of young child formula products</p> <p>Savings in healthcare costs avoided</p> <p>Small cost to adjust to new standards</p>

Question to submitters:

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.

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.

3.2. Impacts on young children and their caregivers

Young children and their caregivers will be impacted by changes to the provisions related to young child formula by:

- ensuring caregivers are informed about the intended purpose of young child formula
- mitigate the likelihood that young child formula is used in ways that do not align with its intended purpose
- improving the nutrition composition of young child formula
- requiring the provision of preparation requirements to ensure safe preparation of young child formula.

FSANZ’s review of the consumer evidence (Attachment 1 to SD2) found internationally that some caregivers believed young child formula was a necessary next step from infant formula or breastfeeding, while other caregivers regarded young child formula as unnecessary. The review noted some confusion for caregivers around stage labelling (e.g. what the numerals

'2' or '4' meant) and the impact of product similarity, a form of proxy advertising, on caregivers' perceptions of young child formula.

Caregivers of young children might benefit from the proposed labelling approach for young child formula that aims to provide clarity for caregivers, support informed choice and mitigate the likelihood that young child formula is used in ways that do not align with its intended purpose.

For example, health claims that have been observed on the market have the potential to make caregivers think these products are necessary to support specific biological functions even when diets may be adequate. Prohibition of health claims might mean consumers are less likely to be misled regarding the intended purpose of young child formula. For full detail of the proposed approach to labelling at the 1st CFS see SD2.

Young children consuming young child formula will directly benefit from the improved nutrition composition of these products. Reviewing the nutrition composition requirements would bring the Code in line with the latest scientific evidence, given the requirements in the current standard were introduced over two decades ago.

There are currently no specific labelling requirements for directions of use and storage of young child formula listed in Standard 2.9.3 – Formulated meal replacements and formulated supplementary foods. FSANZ completed a market survey of young child formula on the Australian and New Zealand markets. Further information of the survey can be found in the 1st CFS. While young child formula products were found to typically emulate most requirements applied to infant formula products, the survey found the majority of products omitted instructions that are important for managing microbiological risk.

Young children (under five years) represent a vulnerable population for foodborne illness due to their higher susceptibility and increased risk of severe outcomes. FSANZ's microbiological risk assessment (SD4) indicates that aligning preparation, storage and use instructions for young child formula products with those currently required for infant formula products would reduce microbiological risk by minimising opportunities for contamination and bacterial growth during preparation, storage and use.

The assessment further indicates that applying an infant-formula equivalent *Salmonella* microbiological criterion to young child formula would support equivalent and proportionate safety controls at manufacture for young child formula. When combined with infant-formula-equivalent preparation practices, these measures are estimated to support a level of health protection for children aged 1-3 years that is comparable to the modelled baseline level of protection for infants.

Taken together, the proposed labelling requirements and *Salmonella* criterion target a high-risk population, act at multiple points in the supply and use chain, and are expected to deliver meaningful public health benefits by reducing the likelihood of foodborne illness in young children.

Providing clarification of young child formula as a special purpose food via labelling may benefit caregivers in the form of cost savings. Savings could be made where caregivers of children with an adequate dietary intake are unnecessarily purchasing young child formula.

In the short run, some manufacturers might pass on some (or all) of the increased cost of meeting new requirements to caregivers through higher prices of young child formula products. However, any potential price increase per product would likely be very small.

In the longer run, greater alignment with the international regulations might reduce

production costs and caregivers may then benefit from price reductions. The benefit of international regulatory harmonisation is discussed in the following section.

3.3. Impacts on young child formula industry

Proposed changes to the regulatory framework of young child formula are expected to impact manufacturers of young child formula by:

- clarifying young child formula as its own subcategory of formulated supplementary foods
- setting nutrition composition limits and permission for use of certain food additives for young child formula
- updating labelling requirements for young child formula, including the prohibition of certain labelling elements.

Table 4 presents young child formula products with unique barcodes, or stock keeping units (SKUs), that were identified in the market survey.

Table 4: Young child formula SKUs identified in Australian and New Zealand markets

SKUs	Australia	New Zealand
Toddler milk	29	31
Junior milk	6	3

Of the 34 SKUs identified in New Zealand, 20 were unique to the New Zealand market. There is an estimated total of 55 young child formula SKUs across the Australian and New Zealand markets.

One SKU identified in the Australian market was sold in sachet packaging. Three were identified in the New Zealand market. The remaining SKUs were packaged in aluminium/steel tins.

An intended outcome of this proposal is to ensure that caregivers are provided with adequate information to make informed decisions and understand the intended purpose of young child formula. This may result in decreased profits on the sale of young child formula products.

The proposed *Salmonella* microbiological criteria for young child formula align with existing infant and follow-on formula requirements. Given the similarities and sometimes shared processes for infant, follow-on and young child formula industry is not expected to incur significant additional costs as a result of this change.

3.4. Benefits to industry

Clarifying young child formula as a subcategory of formulated supplementary food will provide regulatory certainty to industry. Standard 2.9.3 has not been reviewed since it was introduced into the Code in 2000. Young child formula has rapidly evolved into its own food category rather than a discrete supplementary food. Overall, industry will benefit from the review of the Standard as the Code will be updated to set up appropriate regulation for the innovations that have occurred within the category since its introduction to the Code.

Industry may also benefit where alignments in the Code are made with international and overseas standards. Many producers of young child formula are multi-national companies. Where alignment is made between countries, this might provide efficiencies to industry where products can be made for multiple markets, with fewer differences in product composition between Australia and New Zealand and overseas markets.

Industry might also benefit from regulatory consistency with recent changes made in Australia from Proposal P1028.² As described earlier, young child formula products are typically manufactured by the same businesses as infant formula products and use the same or similar ingredients. Consistency with some changes made in P1028 might provide certainty and efficiencies for manufacturers of both infant formula products and young child formula.

3.5. Cost of reformulation

Industry will incur costs to reformulate impacted young child formula products to meet the proposed nutrition composition limits and proposed prohibition of colourings and sweeteners. This is considered to be a one-off cost.

For P1028, the estimated cost to reformulate one SKU was \$200,000 (AUD). A number of submitters for that proposal supported these estimations. A further submitter noted that their cost to reformulate would be higher but supported this cost as a general indication.

Given the similarities of infant formula products and young child formula, FSANZ proposes to use this same figure to estimate the cost of reformulation for young child formula.

Question to submitters:

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.

3.6. Cost of label change

Industry will incur costs to update young child formula product labels to align with the proposed labelling approach (see SD2).

Consistent with the regulatory approach at 1st CFS, this would include the prohibition of labelling elements such as health claims and proxy advertising (i.e. references made about another product within a product range on the label).

Required label changes to meet the proposed regulatory approach are considered to be a one-off cost.

FSANZ's market survey indicated that most young child formula products bear at least one health claim and many have some form of proxy advertising.

Along with other proposed labelling requirements, such as introducing and updating required statements, it is likely most SKUs will be impacted by proposed changes. Table 4 above presents the SKUs that have been identified in the Australia and New Zealand markets.

FSANZ is currently in the process of updating its cost of label change model. Updated costing figures are expected to be available in the CRIS accompanying the 2nd CFS.

² <https://www.foodstandards.gov.au/food-standards-code/proposals/P1028>

Question to submitters:

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.

3.7. Impacts on government

The proposed changes will impact state and territory governments in Australia and New Zealand.

Improved health outcomes for young children that consume young child formula due to improved nutritional composition of young child formula, or minimised microbiological risk from improved preparation instructions will potentially reduce burden on healthcare by an unquantifiable amount.

There may be small one-off costs to jurisdictions for adjusting monitoring and enforcement systems to reflect updated standards for young child formula products.

Proposed changes will also improve regulatory certainty for monitoring and enforcement agencies, leading to longer-term effectiveness and efficiency. For example, introducing a prescribed name for young child formula will assist with enforcement by clarifying the products as their own identifiable category.

3.8. Preliminary conclusion of consideration of costs and benefits

FSANZ's preliminary conclusion of the consideration of costs and benefits is that the unquantified benefits of 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 might result from the proposal.

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