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

4 April 2022
196-22

Supporting document 5

Consideration of costs and benefits

Proposal P1028 – Infant Formula

Executive summary

As stated in the Call for Submissions, FSANZ currently concludes that the costs of this Proposal are likely to be outweighed by the following benefits:

- further ensuring that Infant Formula Products (IFP) and Special Medical Purpose Products for infants (SMPPi) remain safe and suitable into the foreseeable future for almost 3 million infants a decade
- regulatory clarity for producers and enforcement agencies
- greater international alignment and fewer trade barriers, enabling longer-term production-cost savings, and improved supply. Fewer trade barriers will particularly benefit the infants that depend on continued access to special formula products for uncommon health conditions.

During the transition to revised standards, the main production costs to industry resulting from the Proposal are likely to be:

- reformulation costs between AU $80,000 and AU $200,000 per affected product line
- one-off label change costs that average AU $8,000 and generally vary +/- 20% per product line.

Actual production costs will vary by individual circumstances with some products experiencing markedly different production costs than the estimates above.

FSANZ would seek to minimise production costs to industry by providing an adequate transition for making changes under Proposal P1028 and permitting carried-over additives in any product that meet the following criteria:

- are confirmed by a formal risk- assessment as being safe, and
- are present as a result of carryover only.

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Abbreviations and glossary

FSANZ	Food Standards Australia New Zealand
Infant formula product (IFP)	A product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants; as defined in Standard 1.1.1 of the Code.
Special Medical Purpose Products for infants (SMPPi)	Proposed new Division 4 name and definition to be created within Standard 2.9.1 to replace IFPSDU for infants that require specialised medical purpose products.
Stock Keeping Unit (SKU)	An identical product line of an infant formula product. For instance, all units produced of the same brand, product and container.

1. Introduction

This short Supporting Document (SD) 5 should be read in conjunction with the 2022 Call for Submissions (CFS) for Proposal P1028 – Infant Formula.

When assessing this Proposal, FSANZ gave regard to whether the costs that would arise from the Proposal outweigh the direct or indirect benefits as per section 59 of the FSANZ Act.

This supporting document provides further details to the CFS section on consideration of costs and benefits. Those details include how the following were estimated:

1. numbers of infants fed Infant Formula Products (IFP) and Special Medical Purpose Products for infants (SMPPi)
2. transitional costs of reformulating products to meet proposed standard amendments
3. transitional costs of relabelling products.

It should be noted that other information on costs and benefits from the Proposal have not been quantified, so are included in the 2022 Call for Submissions for Proposal P1028 but not included in this Supporting Document 5.

2. Estimated numbers of infants fed IFP and SMPPi

The Australian Bureau of Statistics estimated an annual average of 305,993 live births in the ten years 2011-20, using relevant census statistics.

Statistics New Zealand estimated live births of 59,385 in the ten years 2011-20, also using relevant census statistics.

The Australian National Infant Feeding Survey in 2010-2011 (the only edition so far) found that in the day before the survey, about 40% of infants aged 1 month old received non-human milk or infant formula. That rate gradually rose to 55% at 6 months. Nearly 80% of children aged 12 months received non-human milk or infant formula.

A similar pattern was discernible from New Zealand statistics. In 2007, 41% of infants were fed infant formula at six months old.

Therefore, approximately 168,000 Australian and 24,000 New Zealand infants are likely fed infant formula by six months of age, i.e. between 40% and 55% of all infants.

This may increase to approximately 245,000 Australian and 48,000 New Zealand infants 6 – 12 months and toddlers aged 12 months and above, i.e. 80% of all infants and toddlers.

3. Estimated transitional costs of reformulating products to meet Proposed Standard amendments

Throughout this SD5 and in the accompanying CFS, FSANZ expresses a “stock keeping unit” or SKU as a “product line”. In this context, a SKU is the same as a product line.

It is currently estimated that reformulation costs may generally range between AU $80,000

and AU $200,000 per affected product line, based on information received during consultations. FSANZ notes, there will be large variations depending on circumstances of individual products.

Although some submitters previously provided useful information on numbers of their product lines affected, FSANZ does not currently have the information needed to estimate total numbers of product lines in the whole market that would need to reformulate to meet proposed composition requirements. Further information on this would be gratefully received to further improve cost estimates.

FSANZ also seeks to minimise reformulation costs to industry by permitting the carried-over additives in any product that meet the following criteria:

- are confirmed by a formal risk-assessment as being safe, and
- are present as a result of carryover only.

4. Estimated transitional costs of relabelling products

Label change costs will greatly vary between product lines, depending on circumstances, including but not limited to: available space on the existing label, printing and packaging dimensions and technology.

FSANZ is using two models to estimate costs of changing product labels:

Model	Estimates average cost per product line
2021 cost survey of changing labels for alcoholic beverage cans	AU $7,632
2014 PricewaterhouseCoopers Cost Schedule for Food Labelling Changes – steel cans of general foods and beverages.	AU $8,254 (adjusted for Producer Price Inflation to 2021).

The more recent 2021 cost survey of changing labels for alcoholic beverage cans was used as a source of the estimates. Although the 2021 survey looked at a different food sector, there are similarities in printing technology to infant formula and 2021 is significantly more recent than the general 2014 survey. Both surveys also produced relatively similar results for average costs per product line of changing labels.

An average of the two independent estimates is AU $7,943. For simplicity, FSANZ has rounded this estimate up to AU $8,000 per product line, and estimates average label change costs of AU $8,000 and with general variations of +/- 20% per product line. FSANZ expects a large amount of variation from that average among different product lines that will have their own unique circumstances.

The estimate of AU $8,000 +/- 20% per product line assumes:

- most label change costs will involve changing the text and/or layout without changes needed to the shape or size of the label or package. Up to three colours may need to be changed
- businesses only do the minimum necessary to comply with the new labelling requirements under this proposal and do not go over and above label change requirements

- all necessary label changes only need to be done once for each product line, i.e. costs are one-off
- an adequate transition period to change labels and to run-down stocks of packaging and labels
- there are no lost stocks of cans, boxes, other packaging or labels due to an adequate transition time and stock-in-trade provisions.

The estimated average of AU $8,000 +/- 20% per product line accounts for:
- administration activities, including internal company discussions and approvals
- label redesign
- market testing
- developing proofs and film/files,
- engraving plates/cylinders and colour match
- reviewing label samples.

The above costs did not take into account the following: associated staff and other resourcing needed for education and communication to healthcare professionals, customers, consumers and patients. Such costs may be additional to the AU $8,000 +/- 20% average estimate.

In 2018, FSANZ conducted an online search of IFP sold in the main supermarkets of both Australia and New Zealand.

	Products sold in Australia and/or New Zealand				
	Australia and NZ	Australia only	NZ only	Total	Total plus 50%
Standard Infant Formula product lines	11	8	10	**29**	**44**
Currently defined special formula products for low-risk / temporary conditions (e.g. acid reflux, colic, sleepy baby)	2	6	0	**8**	**12**
Special formula products for higher risk conditions (classed as SMPPi under the Proposal)	1	1	0	**2**	**3**

FSANZ assumes there are 50% more IFP than we were able to find through the online search that was time-limited. See the last column of the above table. Therefore, FSANZ assumes 44 standard infant formula product line are sold in Australia and/or New Zealand and a similar number of follow-on formula product lines (SKUs).

The number of product lines (SKUs) that would need to change labels under the Proposal is therefore assumed as 44 Infant product lines, plus 44 follow-on formula products, plus 12 currently defined products for low-risk conditions. That totals **100** IFP products lines.

It is assumed that special formula products for higher-risk conditions (SMPPi) will not require any label changes under the Proposal.

Therefore, a starting estimate of total one-off label change costs to businesses affected by the proposal is AU $8,000 generally varying by +/-20% multiplied by 100 product lines = **AU $800,000 +/- 20%.**

These one-off cost estimates exclude label change-related staff and other resourcing needed for education and communication to healthcare professionals, customers, consumers and patients and follow the assumptions above.

5. Minimising production costs to industry

FSANZ would seek to minimise production costs to industry by providing an adequate transition for making changes under Proposal P1028 and permitting the carried-over additives in any product that meet the following criteria:

- are confirmed by a formal risk-assessment as being safe, and
- are present as a result of carryover only.

6. Unquantified benefits outweighing costs

FSANZ currently concludes that the following unquantified benefits are likely to outweigh the costs of this Proposal:

- further ensuring that IFP and SMPPi remain safe and suitable into the foreseeable future for almost 3 million infants a decade
- regulatory clarity for producers and enforcement agencies
- greater international alignment and fewer trade barriers enabling longer-term production-cost savings, and improving sustainability of supply. Fewer trade barriers will particularly benefit the most vulnerable infants that depend on continued access to special formula products for high-risk health conditions.

7. References

Australian Bureau of Statistics – annual live births: https://www.abs.gov.au/statistics/people/population/births-australia/latest-release

Statistics New Zealand – annual live births: https://www.stats.govt.nz/topics/births-and-deaths

The Australian National Infant Feeding Survey in 2010-2011: https://www.aihw.gov.au/reports/mothers-babies/2010-australian-national-infant-feeding-survey/summary

2014 PricewaterhouseCoopers Cost Schedule for Food Labelling Changes – steel cans of general foods and beverages: http://teams/Sections/BRAS/Shared%20Documents/Proposals/Models/LC%20model/2014%20PWC%20Cost%20Schedule%20for%20Food%20Labelling%20Changes.pdf