

13 June 2024

Approval Report – Proposal P1028 – Infant formula

Supporting Document 2 – Decision Regulation Impact Statement

Office of Impact Analysis ID 25089

Executive summary

FSANZ has developed a final set of regulatory decisions that would amend the regulation of infant formula products contained in the Australia New Zealand Food Standards Code (the Code).

This Decision Regulation Impact Statement (DRIS) has been developed and provided to decision makers to inform their decision to approve the amendments (collectively referred to as 'proposed changes' throughout this document).

The DRIS contains the impact analysis (including consideration of the costs and benefits) of the proposed changes.

FSANZ expects that the proposed changes to the Code will lead to a net benefit to society. It is likely that the societal costs (primarily the cost for industry to reformulate products and update labels) will be more than offset by the benefits (the key benefit being improved health outcomes for infants fed infant formula products).

The proposal achieves outcomes related to supporting public health and safety, ensuring appropriate information is provided to caregivers, increased international harmonisation and improved regulatory clarity.

What problems were identified with the infant formula standards?

FSANZ has reviewed the standards applying to infant formula products.

FSANZ found that, although the standards for infant formula products are, on the whole, functioning adequately, there is scope to make improvements.

At a high-level, the current standards for infant formula products are regarded as:

- not aligned to the most up-to-date scientific knowledge
- increasingly divergent with international standards
- difficult to interpret and enforce in some respects.

Why is government action needed to resolve the problems?

FSANZ is proposing to continue to maintain explicit government regulation and therefore maintain the standards. Other approaches to solving the problems identified were not considered within this review.

This is appropriate because infant formula products are the only safe and suitable substitute for breast milk for infants who are not breastfed.

What are the objectives of the proposal?

The objectives of P1028 are outlined below. The proposed changes to the standards are intended to address these objectives.

The objectives of P1028 are:

- the protection of infant health and safety
- the provision of information to enable informed choice and ensure caregivers are not misled
- consistency with advances in scientific knowledge
- industry innovation and/or trade is not unduly hindered.

This DRIS assesses the ability of the proposed changes to meet these objectives.

What options were considered to address the problems?

This DRIS analyses two options to address the identified problems:

1. Maintaining the status quo.
2. A series of amendments to Standard 2.9.1¹ that address the problems identified.

Option 2 is a substantial package of amendments that (at a high level):

- clarifies and strengthens the regulatory framework and its two-tiered framework:
 - a category for general formula (including infant formula and follow-on formula)
 - a category for Special Medical Purpose Products for infants (SMPPi), which replaces the previous regulations for Infant Formula Products for Special Dietary Use (IFPSDU)
- establishes new requirements for SMPPi, including:
 - labelling requirements
 - restricting sale to pharmacies and other responsible institutions
- amends and clarifies labelling requirements for all infant formula products
- makes updates that will result in improvements to the composition of infant formula products.

¹ This includes amendments to Schedule 29 (to which Standard 2.9.1 refers) and parts of Standards 1.1.2, 1.3.1 and 1.5.1 and Schedules 8, 15, 19 and 25 that are relevant to infant formula products.

What are the impacts of the amendments to the standards?

The most significant impacts of the proposal are summarised below.

The likely impacts on caregivers are:

- potentially improved health outcomes for infants fed infant formula products, due to:
 - improved composition
 - the potential for more health advice at the point of sale for specialty products
 - further reducing contaminants
 - reduced risk of negative health impacts, due to clearer preparation instructions
- improved information about infant formula products through clearer labels, including:
 - improved ability to compare products through a standardised nutrition information statement
 - removing misleading information.

Due to a lack of data and the technical complexity of calculating these sort of benefits the impacts on caregivers could not be quantified. However the benefits are expected to be significant when considered at a population level.

The likely impacts on the infant formula industry impacts are:

- benefits arising from:
 - greater alignment with international standards and resulting cost efficiencies
 - increased regulatory certainty
- costs due to:
 - reformulating infant formula products - A\$44m one off cost
 - relabelling infant formula products - A\$2–4m one off cost
 - restricting the of sale of SMPPi to pharmacies and other responsible institutions (unquantified in dollar terms).

The proposed changes are expected to lead to a net benefit

FSANZ expects that the changes to the standards will lead to a net benefit to society. It is likely that the societal costs (primarily the cost for industry to reformulate products and update labels) will be more than offset by the benefits (the key benefit being improved health outcomes for infants fed formula).

In order for Australian and New Zealand society to break-even on the quantified costs, for each infant fed infant formula (whether exclusively or in combination with breast milk), society will only need to receive a benefit of approximately A\$26 to A\$27 per infant.

FSANZ considers it likely that this benefit will be achieved, especially given the lifelong nature of the health benefits arising from the proposed changes.

Who was consulted and how was their feedback incorporated?

Potential changes to the regulation of infant formula products has been subject to extensive consultation, which began in 2012 and has involved eight consultation papers.

The proposed changes were developed iteratively—as each consultation paper was released the proposed changes to the standards were refined. The final version of the proposed changes was developed based on comments received in response to the 2nd Call for Submissions (CFS) and subsequent targeted consultations.

The high level outcomes of the 2nd CFS consultation were that:

- the review was supported by all stakeholders
- most of the proposed changes to the Code were supported
- there were some significant areas of disagreement with the proposed changes
- stakeholder views were often polarised—elements supported by some groups were opposed by others
- where there was disagreement, FSANZ either modified or maintained the proposed changes based on other factors in its assessment
- most of the comments on the impact analysis were from industry, with a significant number of comments disagreeing on the assessment of impacts arising from restricting the sale of SMPPi products.

FSANZ considered all comments and some significant aspects of the proposed changes have been amended as a result.

What is the best option considered and why?

FSANZ has concluded that Option 2 is best.

This consideration is broader than whether the proposed changes lead to a net benefit—it also considers if stakeholders have been appropriately consulted and whether the proposed changes achieve the objective of the proposal.

Option 2 is best because it:

- is expected to lead to a net benefit
- has been subject to comprehensive consultation with stakeholders
- is aligned with the objectives of the proposal.

How will the changes to the standards be implemented?

FSANZ does not expect there to be any significant challenges to successfully implementing the changes to the standards. While the changes are extensive, industry has been deeply involved in developing the standards and a relatively long transition period has been proposed.

The standards will primarily be implemented by industry, with food regulatory authorities playing a monitoring and enforcement role. FSANZ will support the implementation with communication materials.

A five year transition period has been proposed, which is longer than the default one year period provided by the Code.

A five year transition period balances several considerations:

- reformulating infant formula products is complex; specialist knowledge is required
- most infant formula products are impacted
 - there is not likely to be enough specialists within the industry to reformulate every product at the same time
 - therefore, a shorter timeframe would increase costs or risk supply issues, with a potential flow on impact to caregivers
- infant formula products currently on the market are safe and suitable
 - there is no safety risk to mitigate by shortening the transition period
 - however, delays beyond what is needed to minimise costs will delay all identified benefits of the proposed changes being realised.

How will the changes to the standards be evaluated?

The primary responsibility for actively monitoring and evaluating food standards lies with jurisdictional bodies that enforce the Code.

The results of any concerns identified through monitoring and evaluation will ultimately be communicated through the food regulatory system to FSANZ for potential action.

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1 Introduction to the DRIS and the proposed changes to infant formula standards

1.1 Impact analysis for the proposed changes to the infant formula standards

Food Standards Australia New Zealand (FSANZ) has assessed a proposal to review the standards applying to infant formula products under proposal P1028 – Infant formula.

The DRIS contains the impact analysis (including consideration of the costs and benefits) FSANZ has undertaken on the proposed changes, which will be provided to decision makers.

The DRIS has been prepared to meet the requirements of:

- The Office of Impact Analysis (OIA)
- Section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

1.1.1 *The DRIS has been assessed as meeting OIA guidelines*

This DRIS has been prepared in line with OIA guidance.²

The OIA guidance requires FSANZ to answer the following impact analysis questions when developing a DRIS:

- What is the policy problem?
- Why is government action needed?
- What are the objectives of government action?
- What policy options are to be considered?
- What is the likely net benefit of each option?
- Who was consulted and how was their feedback incorporated?
- What is the best option from those considered?
- How will the chosen option be implemented and evaluated?

These questions have been answered in the sections that follow.

The OIA has assessed the DRIS as being compliant with the requirements.³

1.1.2 *The DRIS contains an assessment of costs and benefits under the FSANZ Act*

In assessing P1028 and in making its decision to prepare the amendments to the standards, FSANZ was also required by Section 59 of the FSANZ Act to have regard to whether the costs that would arise from the proposed measure outweigh its direct or indirect benefits.

As explained, FSANZ has decided to prepare a set of proposed amendments to the standards.

This decision reflects in part FSANZ's assessment that the costs that would arise from these proposed amendments will not outweigh the direct or indirect benefits of those proposed amendments. This DRIS sets out the reasons for that assessment, in section 6.

² [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies](#)

³ Refer to letter dated 22 February 2024. The letter is available on the OIA website, reference number OIA22-02958.

The assessment was based on the best available information at the time the decision was made to prepare the amendments. That included submissions received from stakeholders in response to the 1st and 2nd Calls for Submissions (CFS).

1.2 The current infant formula standards and why they were reviewed

This section outlines the scope of proposal P1028 and discusses why the standards applying to infant formula products were reviewed and the objectives of the review.

1.2.1 How infant formula products are currently regulated

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products and Schedule 29 – Special Purpose Foods in the Australia New Zealand Food Standards Code (the Code). The standards (the collective term this DRIS uses for Standard 2.9.1 and Schedule 29) apply to products sold in Australia and New Zealand.

The standards contain requirements for the composition and labelling of infant formula products.

Standard 2.9.1 covers infant formula products including:

- infant formula, for use from birth to 12 months of age
- follow-on formula, for use from 6 months to 12 months of age
- infant formula for special dietary use (IFPSDU).

This DRIS uses the term ‘infant formula products’ when referring to these products as a group.

1.2.2 Why FSANZ reviewed the standards

FSANZ commenced a preliminary review of the standards in 2012. Three primary reasons were cited for commencing the review:

- updates to international standards⁴
- concerns about interpreting the standards⁵
- new guidance from food ministers on how infant formula products should be regulated (see below discussion).

When the current standards were developed in the late 1990s and early 2000s, they were based on the best available scientific evidence, as well as alignment with the Codex infant formula standards and European regulations of the time.

Only minor amendments have been made to the standards since 2002, including changes made through successful applications to FSANZ.⁶

⁴ See section 2.2.1 for discussion on why international standards are important.

⁵ See section 2.3 for discussion on why clear interpretation of the standards is important.

⁶ For example, permitting additional optional substances including lutein, inulin-type fructans and galacto-oligosaccharides, 2'-Fucosyllactose, bovine lactoferrin and a review of requirements for other substances such as medium chain triglycerides and minimum protein in follow-on formula.

1.2.3 *The objectives of the review*

In reviewing the standards FSANZ had the following objectives in mind:

- protection of infant health and safety
- provision of information to enable informed choice and ensure caregivers are not misled
- consistency with advances in scientific knowledge
- industry innovation and/or trade is not unduly hindered.

These objectives provided a framework for determining what was (or what was not) a problem within the standards.

2 What problems have been identified with the infant formula product standards?

In 2013 FSANZ formally created a proposal (referred to as P1028) that would review the standards. The review process was extensive—all provisions within the infant formula product standards were in scope. It was also iterative and conducted in consultation with stakeholders (refer to Appendix B for a detailed discussion).

The review process found that while the standards in the Code that regulate infant formula products are working well, there is scope to make improvements.

The review identified problems at the micro-level. However this DRIS considers the problems within three high-level categories.

At a high level, the problems with the standards are that they:

- are not aligned with the most up-to-date scientific knowledge
- have scope to improve harmonisation with international standards
- are not achieving their intended purpose in some respects.

These problems are discussed in more detail in the following sections.

2.1 The current standards are not aligned with the most up-to-date scientific knowledge

The review identified parts of the standards that are not consistent with the latest scientific knowledge of infant nutrition. This section explores some examples.

The impact of this is primarily felt by infants and their caregivers⁷. In the short term, the magnitude of the impacts is small. The products on the market are safe and suitable for infants, however they could be improved. The long-term magnitude of this issue could be medium to large, due to the long-term impacts of infant nutrition.

2.1.1 *Specific examples of where the standards are not up-to-date with scientific knowledge*

The table below summarises just some of the scientific advances since 2002, which are not reflected in the standards.

For more information, refer to section 2.2 of the approval report which provides information on the assessments FSANZ has undertaken. These documents explain why proposed changes to the standards are made, including where the change is being made due to advancements in scientific knowledge.

⁷ For brevity, this DRIS uses the term 'caregivers' to refer to anyone who feeds an infant under their care. Caregivers therefore encompasses a broad range of people, including parents, members of the infant's household, other family members or relatives, friends and professional caregivers like baby-sitters.

Table 2-1 Examples of scientific advances not reflected in the standards

Area of research	Examples of new evidence	Link between the study and the standards
Adequate intake of essential nutrients	Review of evidence by National Health and Medical Research Council (NHMRC) and resulting update to reference values (NRV) in 2017	The NRVs are a set of recommendations for nutritional intake based on currently available scientific knowledge. Therefore, the standards should reflect the NRVs. FSANZ identified some areas where the standards do not meet the NRVs. One example is choline, which is now listed as essential in the NRVs, but not in the standards.
Composition of breast milk	A number of studies, referenced in the 2013 and 2014 European Food Safety Authority studies on the essential composition of infant formula	Ministerial guidance is that the composition of infant formula products should mirror breast milk as closely as possible. Over time, the knowledge of the composition of breast milk has improved. In some areas, the standards do not reflect this knowledge.
Understanding of caregiver behaviour	Several studies, summarised in FSANZ's literature reviews	The effectiveness of labelling regulations in the standards are dependent on how caregivers interpret them. Studies of caregivers have shown: <ul style="list-style-type: none"> • some caregivers provide infants (under 6 months) with formula for older children, which is not safe⁸ • the majority of caregivers find reading the nutrition information panel on infant formula difficult⁹
Analytical testing methods	Several research and development (R&D) studies	Analytical and testing methodologies, as well as equipment, have advanced beyond what was possible when the standards were developed. For example, lactose is now detectable in lower amounts than what was possible in 2002.
Minimising contaminants through manufacturing processes	Industry R&D	The intent of the standards is that permitted contaminant levels are to be set as low as reasonably achievable. Industry has indicated that they have the ability to cost effectively achieve lower contaminant levels than what is currently permitted, including for lead. ¹⁰

⁸ 2nd CFS – Supporting Document 3 – Attachment 1 – Rapid Systematic Evidence Summary on Infant Formula Stage Labelling and Proxy Advertising

⁹ 1st CFS – Supporting Document 3 – Attachment 1 – Consumer research on infant formula labelling

¹⁰ Refer to the summary of industry responses provided in Consultation Paper 1 – Food technology for Infant Formula Products (2021).

2.1.2 The lack of alignment with up-to-date knowledge primarily impacts infants and their caregivers

In the short term, the magnitude of the problem is small for individual infants and caregivers. The infant formula products on the market are safe and suitable for infants, therefore any changes based on the latest science will only be small with marginal benefits. However, there is an opportunity cost of cumulative small changes to infant health.

The long-term magnitude of this issue could be medium to large. The impacts of infant nutrition are long lasting, therefore, over the long term the marginal impact of products not adhering to the latest science will add up on a population-wide basis.

The long-term impacts could be significant enough to appreciably increase governments' healthcare expenditure.

There are also likely to be minor impacts on industry. They are unable to produce products composed in accordance with the latest science, which could impact on demand. The impact on industry is limited because:

- breast milk is the only safe and suitable substitute to infant formula (for infants under 6 months of age), limiting the ability of caregivers to change behaviour if they are not satisfied with the composition of current products
- marketing restrictions prevent manufacturers from highlighting improvements and some features of products.

The consequence of inaction is an opportunity cost to make very minor improvements to individual products that on a population-wide, long-term basis, could add up to material improvements in public health.

2.2 There is scope to increase alignment with international standards

FSANZ is required to align the infant formula product standards with relevant international standards (in this case Codex and European regulations) as far as possible.

The review found that there is significant scope to improve alignment with international standards. This is because, over time, Codex standards and European regulations have been updated more frequently than the Code.¹¹

This section covers:

- why FSANZ must align with international standards (as far as possible)
- what limits FSANZ achieving full alignment
- why Codex standards and the EU regulations have been selected for alignment
- the impact of standards that are not aligned to the greatest extent possible.

2.2.1 Requirement for consistency with international standards, as far as possible

The FSANZ Act and policy guidance from ministers states that the infant formula product standards should be consistent with international standards as far as is possible.¹²

¹¹ The Codex standard for infant formula (including specialised formula) was last amended in 2020 and the follow-up formula standard was last amended in 2017. The relevant EU regulations were last updated in 2016.

¹² Section 13(d) of the FSANZ Act states the functions of the Authority (FSANZ) is to “promote consistency between standards in Australia and New Zealand with those used internationally, based on the best available scientific evidence”.

Other government policies and initiatives encourage standards-setting bodies in Australia and New Zealand to align standards as closely as possible to international standards.¹³

Full alignment with international standards is not possible for a number of reasons.

One reason is that the Codex standards do not contain all the necessary regulation. For example, some nutrient maximum levels have not been set by Codex, these are to be determined by national authorities (such as FSANZ)¹⁴. Another example is the Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997). This guideline states that nutrition claims and health claims on infant formula product labels should be consistent with national nutrition policy and national health policies. Therefore, the Codex provisions for labelling health claims need to be adapted to Australian and New Zealand health policies.

However, the most significant reason is that FSANZ's independent process means that sometimes different decisions are made to international bodies such as Codex.

The FSANZ Act requires FSANZ to perform a scientific assessment for each individual change to the Code. In performing this assessment, FSANZ considers data and other factors that are specific to the Australian and New Zealand context.

For example, the composition of infant formula products must be as close as possible to breast milk.¹⁵ FSANZ's reference for the composition of breast milk is based on a number of studies, including some studies conducted specifically on Australian and New Zealand mothers.¹⁶

The composition of breast milk varies from population to population—where FSANZ has used Australian and New Zealand specific data, the outcomes of the assessment may be different to an assessment using data collected on other populations.

Potential variations are highlighted by Vitamin D levels in breast milk. Because vitamin D levels in breast milk are influenced by sun exposure (which is related to climate, season, latitude, skin colour and lifestyle) as well as the maternal diet, (Kim SY, Yi DY, 2020).

2.2.2 The primary international standards are Codex

The international benchmark for infant formula regulations is primarily the *Codex Alimentarius Standard*...

- for *Infant Formula and Formulas for Special Medical Purposes Intended for Infants*¹⁷
- for *Follow-up formula*¹⁸

Codex Alimentarius is used as a benchmark because it is the most widely-accepted set of international food standards. In 2023 the Codex Alimentarius Commission had 188 member countries (plus the European Union).

The Codex standards are considered guidelines for developing standards. Typically the Codex standards are not adopted in full by its members. They are adopted as much as possible within a jurisdiction's standards. In doing so, differences in standards between members is minimised.

¹³ For example, for Australian Government bodies, refer to the [Australian Government Guide to Policy Impact Analysis](#) (2023).

¹⁴ Refer to Codex CXS 72-1981

¹⁵ [Policy guideline on infant formula products](#).

¹⁶ To view the studies FSANZ referenced when determining the composition of breast milk, refer to the nutrition assessments in Consultation Paper 1 (2021) and in the 2016 Infant Formula consultation paper, available on the [P1028 webpage](#).

¹⁷ Codex CXS 72-1981.

¹⁸ Codex CXS 156-1987. Note that follow-up formula is referred to as follow-on formula in the Code.

The following table shows the extent of mis-alignment of permissions under the current standards with Codex, using the example of composition permissions.¹⁹

Table 2-2 Extent of alignment of permissions with Codex under the status quo

	Infant formula	Follow-on formula
Total number of permissions aligned to Codex	30	31
Total number of permissions	68	68
Proportion of permissions not aligned to Codex	56%	54%

2.2.3 FSANZ also considers alignment with European regulations

An additional international benchmark is the European Union (EU) infant formula regulations. While Codex is a primary benchmark (for the reasons listed above), the EU regulations are adopted as far as possible because the EU is:

- a major producer of infant formula products and infant formula product ingredients
- the sole supplier of a number of highly-specialised infant formula products for medical purposes
- home to a significant number of global dairy companies that invest in production facilities in Australia and New Zealand.²⁰

Approximately 50% of all imports of finished infant formula product to Australia are from the EU.²¹ Similar data has not been found for New Zealand.

FSANZ is able to consider two sets of international standards because:

- in some respects, EU regulations are aligned with Codex
- alignment with both the EU regulations and Codex standards can be achieved through regulating ranges
- there are some areas regulated by one set of standards or regulations but not the other
- FSANZ’s assessment may mean it is unable to support alignment with one set of standards or regulations, but can align with the other.

2.2.4 The infant formula industry is global and divergent standards decreases manufacturing efficiency

The impact of the divergence is primarily experienced by the infant formula industry. The infant formula products industry is global. Products sold in Australia and New Zealand can be manufactured overseas, or made with ingredients sourced from overseas. In addition to

¹⁹ ‘Permissions’ to refer to a broad collection of regulatory permissions relating to infant formula composition, including energy (kJ) ranges, ranges for macronutrients and micronutrient values (which can be minimums, maximums or ranges depending on the micronutrient).

²⁰ This includes Nestlé, Lactalis and Danone, who all participate in the Australian and New Zealand infant formula markets.

²¹ Excluding imports from New Zealand. Data for the year-to-November 2023, on a volume basis. Source: Department of Agriculture, Fisheries and Forestry – [Australian agriculture trade – reference tables](#) (January, 2024).

finished products, Australian and New Zealand companies also export ingredients to use used by manufacturers overseas to make finished products.²²

The INC stated that:

- 20 to 40% of infant formula products and inputs are imported
- a significant proportion of base powder is exported
- a significant proportion of finished products are exported.²³

Having fewer points of difference between the standards increases efficiency. For example, products manufactured in and exported from the EU can be produced to the standards at lower cost where there are fewer modifications required to adapt EU-compliant products to the standards. Another example is base powder. Local manufacturers export base powder; the greater the number of differences in regulations between importing nations, the greater the number of adjustments that need to be made to this powder.

This cost impact could flow through to caregivers and could also limit product range and availability.

Not resolving this issue results in an opportunity cost; infant formula products could be produced at lower cost while maintaining their safety and suitability as a source of nutrition.

The magnitude of impacts arising from this issue is not likely to be large. The issue identified is the scope for increased international alignment, which is the shift from current level of alignment to the level of alignment to what can be justified by FSANZ's scientific assessment. If complete alignment were possible, then the magnitude of the issue would be more significant.

2.3 Parts of the standards are not achieving their intended purpose

FSANZ found aspects of the infant formula standards were not clear or specific enough to achieve their intended purpose.

This section discusses:

- three examples of this issue, which are:
 - the unrestricted sale of specialised infant formula products
 - a lack of specificity on what can be used as a protein source
 - the absence of a specific prohibition on marketing infant formula through statements about ingredients
- the impacts of this issue, which are that:
 - governments find it difficult to use the standards to achieve their policy purpose
 - caregivers do not receive the benefits of the standards to the greatest extent possible
 - businesses experience increased compliance costs.

This has resulted in developments within the infant formula market which jurisdictions view as being outside of what the standards are intended to allow, where there is no effective mechanism within the standards to resolve these issues. From an industry perspective, their products are fully compliant with the standards as they are drafted.

²² For more background on the industry, refer to section 6.5.1.

²³ INC submission to the 2nd CFS

The following table provides three examples of where the standards are not clear or specific. the table includes the intent of the standards, an example of where this intent is not achieved and a description.

Table 2-3 Examples where the standards do not achieve their intention

Intention of the standards ²⁴	Issue	Description of the issue
Products for infants with special dietary or medical needs (that deviate from the general compositional requirements) should be used under the supervision of a specialist.	Standards do not contain any provisions that connect the sale of specialised products to the provision of advice.	Specialised products should be used under medical supervision. Without this supervision, there is an increased risk of negative impacts to an infant's health or development. This could be due to the product being unsuitable for the condition the infant has, or the product is not necessary and leads to the infant missing out on nutrition that otherwise would be provided by non-specialised formula. However, there is no provision within the standards that achieve this intention. This is unlike all other food for special medical purposes, where the Code restricts sales of these products such that caregivers are more likely to receive advice.
The essential composition of infant formula should be prescribed in regulation and must satisfy the nutritional requirements of infant. The composition of infant formula must be safe, suitable.	Protein sources.	Protein is important for normal growth and development of an infant. Some protein sources have limiting amino acids, allergen risks and can interfere with the absorption of other essential nutrients. The standards do not specify what can be used as a protein source. There is a general requirement for all food to be safe and suitable and novel foods must have pre-market assessment. However, it is more difficult for enforcement agencies to use these requirements, compared to a specific prohibition. ²⁵
The labelling of infant formula products should be consistent with the World Health Organization (WHO) International Code of Marketing of Breast Milk Substitutes.	Statements about ingredients.	The WHO code restricts the marketing of infant formula products, so that breastfeeding is continued to be considered the normal way to feed an infant. The standards explicitly prohibit infant formula products carrying nutrition content claims and health claims. There is no specific restriction about making statements about ingredients, like "contains ingredient X". Some stakeholders view these statements as promotional tools. ²⁶ Some stakeholders believe these statements are clearly prohibited ²⁷ , others have stated that there is confusion about how the standards apply. ²⁸

²⁴ The intention of the standards has been interpreted using the [Policy guideline on infant formula products](#).

²⁵ NSW Food Authority submission to 2nd CFS.

²⁶ Submission by the New Zealand Ministry of Health the 1st CFS.

²⁷ Submission by the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions to the 1st CFS.

²⁸ Submission by Nestlé to the 1st CFS.

The impacts of this issue are primarily experienced by government, with flow-on impacts to caregivers and infants. A lack of clarity or specificity reduces the ability of governments to enforce the standards. There is also an impact on industry.

Jurisdictions have had some past challenges establishing a clear shared understanding of the infant formula provisions with industry. As a result they have asked that the standards be made as clear and as understandable as possible to increase the efficiency and effectiveness of their implementation and enforcement activity.

The NSW Food Authority stated that the absence of a specific prohibition clause in the standards can cause “*a significant and unusual shift in the burden of proof required*” to take enforcement action where products are deemed unsafe, which is especially problematic “*considering infants are a highly vulnerable sub-population*”.²⁹

This impact flows through to broader society, as the standards are not achieving their objectives of maximising infant health.

Reduced clarity can also lead to increased compliance costs for industry. Clarity and understandability of provisions reduce ‘regulatory transaction’ costs between regulators and industry.

The short-term impact of this issue is relatively small. The majority of provisions in the standards are clear and achieve their objective. FSANZ is not aware of any significant or immediate negative outcomes to infant health linked to this issue. However, some aspects of the problem have a very small risk of serious consequences, for example, unsafe protein sources.

The longer term impact may be more significant. The impacts of any minor negative health consequences (for example, low-level marketing of infant formula products) due to ambiguities in the standards may accumulate at a population level due to the lifelong impacts of infant nutrition.

²⁹ Submission by NSW Food Authority to the 2nd CFS.

3 Why is government action needed to resolve the problems?

Impact analysis guidance requires a DRIS to clearly identify why there is a legitimate reason for government to intervene to resolve an identified problem.³⁰

This section covers the consensus that explicit regulation is appropriate for infant formula products and the reason why (infant nutrition is a high-risk issue; poor nutrition has severe consequences).

3.1 Explicit government regulation is appropriate for high risk situations

Explicit government regulation (like the standards) is appropriate to be used as a regulatory tool where there is a perceived high risk and achieving compliance is seen as critically important.³¹

As demonstrated below, poor infant nutrition introduces high risk and compliance with the standards is critically important for the health and safety of infants.

Therefore maintaining the standards is commensurate with this level of risk, which is managed with the support of other features of the food regulatory system (including industry self-regulation and the food enforcement agencies).

Maintaining explicit regulation is consistent with the expectation of food ministers in Australia and New Zealand that infant formula products will be regulated, as described in the *Policy guideline on infant formula products*.

It is also the approach taken internationally where strict standards are in place for infant formula products, including all major infant formula product markets like China, the USA, Canada and Europe.

In addition to the above, government-developed food standards benefit industry and consumers, where they are designed to achieve their objectives in a way that maximises net benefit.

Industry benefits from the trust standards create, because:

- consumers trust that manufacturers make products that are safe and comply with government standards³², increasing demand
- credible standards enable products to be exported into markets that otherwise would not accept them.

Where standards exist and are adequately enforced, consumers can trust that all products are safe and suitable. Without this trust consumers experience search costs. For example, if there was no approval process for infant formula ingredients and consumers did not trust manufacturers, then to confidently select a safe and suitable product for their infant, caregivers would have to do their own research for every unfamiliar ingredient advertised on a product label for every product they are considering buying.

³⁰ Refer to the [Australian Government Guide to Policy Impact Analysis](#) for further information on why it is important to establish a case for government intervention to resolve problems.

³¹ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies (2023).

³² 1st Call for Submissions - Supporting Document 3 – Attachment 1 – Consumer research on infant formula labelling.

3.2 High risk of serious consequences of poor infant nutrition

Poor nutrition of infants is a significant risk, due to the significant consequences that can occur if an infant not provided with food that is safe and suitable.

Nutrition has both short-term impacts on an infant's health, as well as lifelong impacts. Infants are a vulnerable population group because they have immature immune systems and organs and are dependent on adults for feeding.

Poor nutrition can cause illness and sometimes lead to death in an infant. This can be due to issues such as:

- inadequate (or excessive) intake of micronutrients (vitamins and minerals)
- inadequate (or excessive) intake of macronutrients (carbohydrates, fat and protein).

Nutrition in an infant's early days of life has the potential to affect their health and wellbeing over their lifetime. Appropriate feeding of an infant is central their health and wellbeing, growth and development post-infant life stage.³³

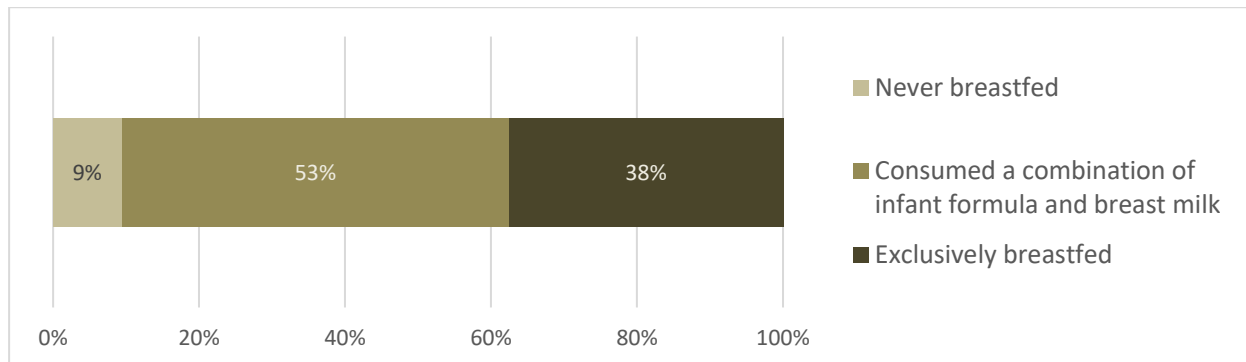
Poor nutrition can also have negative health impacts throughout the infant's life, including increased incidence of:

- morbidity and mortality
- chronic disease
- underdevelopment physically and mentally.³⁴

The potential scale of this risk is large. The majority of infants consume infant formula at some point over their first 6 months of life, as the charts below demonstrate.³⁵

The below chart shows what Australian infants were fed from birth to 6 months of age.

Figure 3-1 Australian infants' (0–6 months old) consumption of breast milk and infant formula (2022)



Source: ABS: Breastfeeding (2023)

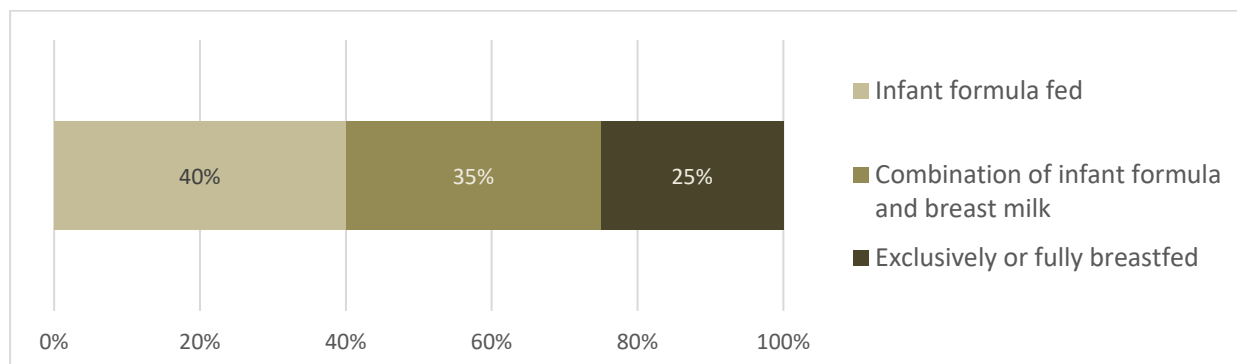
The next chart shows what New Zealand infants were fed at 6 months of age, according to data collected in 2006 (the latest available data).

³³ [Healthy Eating Guidelines for New Zealand Babies and Toddlers \(0-2 years old\)](#)

³⁴ World Health Organisation, [Infant Nutrition](#)

³⁵ FSANZ was unable to find similar data for New Zealand.

Figure 3-2 New Zealand infants' (at 6 months) consumption of breast milk and infant formula (2006)



Source: Ministry of Health: Protecting, Promoting and Supporting Breastfeeding in New Zealand - Background report (2008). Data from Table 1.

These impacts on infants have consequences at a population level, through increased healthcare expenditure and lost economic productivity.

4 Objectives of the Proposal

Impact analysis guidance requires a DRIS to clearly identify what the objectives are of government action.³⁶ This enables options proposed to be assessed against their ability to achieve the objectives.

This section discusses the objectives the proposal are intended to achieve and how they relate to the problems identified.

The objectives are forward looking, they describe the future state FSANZ is trying move the infant formula market towards after the proposed standards have taken effect.

This is different to the problems identified (in the previous section). The problems describe the negative aspects of the current state FSANZ that is trying to resolve through the proposed standards.

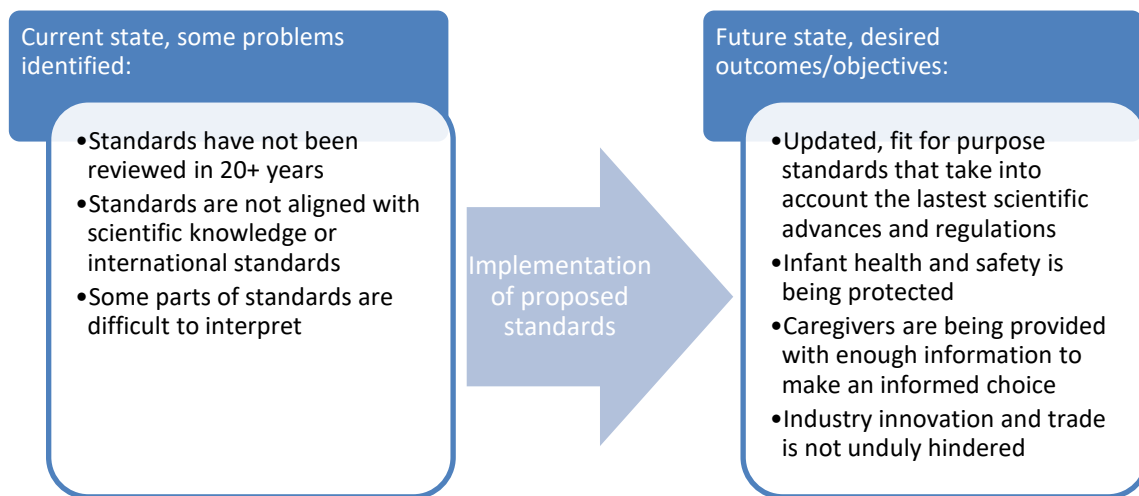
The objectives of P1028 are:

- the protection of infant health and safety
- the provision of information to enable informed choice and ensure caregivers are not misled
- consistency with advances in scientific knowledge
- industry innovation and/or trade is not unduly hindered.

Below is a diagram, intended to illustrate the difference between the concept of problems and objectives and how they relate to each other in this proposal.

³⁶ Refer to the [Australian Government Guide to Policy Impact Analysis](#) for further information.

Figure 4-1 P1028 flowchart – from problems identified, to proposal development, to desired outcomes/objectives



The proposed standards are designed to achieve the objectives by solving the problems. Solving some problems will achieve more than one objective. For example, aligning the standards with the most up-to-date scientific knowledge will result in:

- infant health and safety being better protected
- caregivers having informed choices (and not being misled)
- improvements in international trade.

5 What options are being considered to achieve the objectives?

This DRIS has considered just two options to address the identified problems.

This section explains why there are only two options presented.

It also discusses the options, which are:

1. Maintaining the status quo
2. A package of amendments to the infant formula products standards³⁷

5.1 Why only two options are presented in this DRIS

Impact analysis guidance states a DRIS “*should canvass a range of viable options, ranging from non-regulatory to explicit government regulation.*”

FSANZ only considered explicit government regulation (amending the standards), for the reasons discussed in section 3.

However, FSANZ did canvass options to resolve each individual problem identified within the standards. FSANZ presented these options (and its preferred option for each problem) to stakeholders at the 1st CFS and again at the 2nd CFS. Section 2.2 of the approval report lists the assessments FSANZ has undertaken, where further information can be found on

³⁷ This includes amendments to Standard 2.9.1, Schedule 29 (which Standard 2.9.1 refers) and parts of standards 1.1.2, 1.3.1 and 1.5.1 and schedules 8, 15, 19 and 25 that are relevant to infant formula products.

every individual problem identified, with a discussion on the alternatives considered (including maintaining the status quo).

As the approval report (as well as 1st and 2nd CFS) demonstrates, P1028 has a large number of issues being considered, resulting in a large number of amendments.

The DRIS considers the amendments as a package, because considering them individually would:

- be problematic from an analytical point of view as it is unlikely that the impact of the separate interventions could be sensibly considered individually
- disregard the fact that a number of the interventions are likely to have additional cumulative benefits when implemented together
- potentially inappropriately discount the significant work that has been undertaken with stakeholders over many years to develop a workable group of interrelated interventions.

5.2 Option 1 – Maintaining the status quo

In any consideration of changes to regulation, the status quo must be a part of FSANZ's assessment.

The status quo would leave the standards unchanged. As a result, the problems identified above will continue.

FSANZ has completed an extensive review of the standards as part of proposal P1028 and found that most parts of the standards are working as intended. Therefore, in regards to these aspects of the standards, FSANZ has decided to maintain the status quo.

More information on previous assessment reports (where decisions to make no change to aspects of the standards were made) can be found in section 2.2 of the approval report.

5.3 Option 2 – A package of amendments to the standards

The multitude of changes to the standards are analysed as a package (Option 2) within this DRIS.

The following table summarises the entire set of proposed changes by providing:

- high level categories of changes to the regulation of infant formula products
- summaries of each category
- explanation of how the problems are managed by the changes in each category
- references to relevant sections of the approval report.

All impacts arising from the proposed changes analysed by this Decision RIS relate to the categories identified.

More information on the changes are provided in the approval report for P1028, along with the full text of the proposed changes to the standards.

Table 5-1 High level summary of proposed amendments to the standards

Category of proposed change to the standards	Description of the changes within this category	Purpose of the changes in this category and how they relate to the objectives of the proposal	Approval report reference
<p>Clarifying the regulatory framework, by providing clear differentiation of the two categories:</p> <ul style="list-style-type: none"> • formula for healthy infants • specialised formula for infants with specific diseases, disorders or conditions (see below) 	<p>The regulations within the two categories are intended to be identical, except where differences are required to achieve the purpose of specialised formula.</p> <p>The two categories are largely based on existing parts of the Code. Some definitions within the standards have been amended, for clarity of interpreting the new framework.</p> <p>The significant modifications to the existing parts of the Code are listed below.</p>	<p>The new framework more clearly differentiates the various types of products.</p> <p>This arrangement is designed to make the standards clearer and easier to interpret, particularly in light of the proposed changes.</p>	<p>Section 4.1</p>
<p>Creating the <i>Special Medical Purpose Products for infants (SMPPi)</i> category of infant formula products</p> <p>Removing the Infant Formula Products for Special Dietary Use (IFPSDU) category (and subcategories)</p>	<p>The SMPPi category and captures products formulated for medical conditions.</p> <p>Products in this category must now be designed for a specific condition. Products formulated for lactose intolerance will be categorised as SMPPi.</p> <p>The category replicates all IFPSDU provisions.</p>	<p>This category contains products that are formulated for infants with a medical disease, disorder or condition and must be used under medical supervision.</p> <p>The category allows for compositional deviation to achieve the products medical purpose. This facilitates the continued importation of products from the EU and US (which is where the majority of Australia and New Zealand’s SMPPi come from).</p>	<p>Section 4.1 – creating the category</p> <p>Section 4.2 – compositional requirements for the category</p> <p>Section 4.4 – including low lactose and lactose free in the category</p>
<p>Creating mandatory labelling requirements for SMPPi</p>	<p>Requirements include (amongst others):</p> <ul style="list-style-type: none"> • statements that the food must be used under medical supervision • medical purpose of the food • the properties or characteristics which make the food appropriate for the medical purpose. 	<p>The labelling requirements provide information necessary for proper use to treat medical conditions and to prevent inappropriate/unsafe use.</p> <p>They also differentiate SMPPi products from infant formula products for healthy infants.</p> <p>The changes maintain consistency with international standards.</p>	<p>Section 4.19 to Section 4.22</p>

Category of proposed change to the standards	Description of the changes within this category	Purpose of the changes in this category and how they relate to the objectives of the proposal	Approval report reference
<p>Limiting the sale of SMPPi to specialised settings, including pharmacies</p>	<p>The sale of SMPPi will be restricted to the following:</p> <ul style="list-style-type: none"> • a pharmacy, medical practice or responsible institution • a medical practitioner or dietitian • a majority seller of that food for special medical purposes. <p>Currently there is no restriction on where any infant formula products can be sold.</p>	<p>SMPPi products should be used under medical supervision. All other medical purpose foods regulated by the Code are subject to restricted sale.</p> <p>This arrangement improves the information provided to caregivers, to enable them to make informed decisions and not be misled.</p> <p>Consumption of these medical products by healthy infants could lead to serious negative health outcomes.</p>	<p>Section 4.3</p>
<p>Updating requirements and permissions for:</p> <ul style="list-style-type: none"> • macronutrients • micronutrients • nutritive substances <p>This applies to all products, except where SMPPi deviate for medical reasons</p>	<p>This impacts provisions for nutrient ranges, sources, equivalents, permitted forms, conversion factors and ratios for macronutrients, micronutrients and nutritive substances.</p> <p>Changes have also been made to units of measurement, definitions for Guidance Upper Levels, vitamin and mineral supplementation.</p>	<p>Changes to these permissions:</p> <ul style="list-style-type: none"> • update permissions based on the latest scientific data • have a positive impact on infant health • achieve greater international alignment. <p>Some previously optional nutrients have been made mandatory.</p>	<p>Appendix 1 Tables 10 to 12</p>
<p>Specifying what can be used as a protein source, for infant formula products</p>	<p>The protein source must be:</p> <ul style="list-style-type: none"> • cow, goat, or sheep milk, or • soy protein isolate. <p>New requirements apply for declaring the protein source on infant formula products.</p>	<p>Some protein sources have limiting amino acids, allergen risks and can interfere with the absorption of other essential nutrients.</p> <p>Other protein sources will be permitted, where an application is submitted and approved by FSANZ³⁸</p> <p>This protects infant health and safety.</p>	<p>Section 4.7</p>

³⁸ Under general provisions of the Food Standards Code that are out-of-scope for this proposal. The application will need to demonstrate the protein source is safe and suitable and meet other criteria.

Category of proposed change to the standards	Description of the changes within this category	Purpose of the changes in this category and how they relate to the objectives of the proposal	Approval report reference
Updating food additive permissions	<p>A number of permissions are being updated. These permissions specify what can be added and/or in what quantity.</p> <p>Food additives perform a range of functions, including for improving taste, appearance, quality, stability and extending shelf life.</p>	<p>These changes are based on more current science on infant nutrition.</p> <p>Where possible they align with relevant international regulations, improving trade.</p>	Section 4.12.1
Removing the permission for the automatic carry-over of food additives	<p>The current permission allows food additives to 'carry-over' to a final food, where they have been added (as permitted) to ingredients used in the production of a final food.</p> <p>This will no longer be permitted. All additives must have a specific permission to be used in final foods, including when added to an ingredient of a final food.</p> <p>New additive permissions have been created (see above) in response to this change.</p>	<p>This protects infant health and safety, by minimising the use of additives in products for infants.</p> <p>Where possible, these changes align with relevant international regulations, improving trade.</p> <p>New additive permissions were created to eliminate potential impacts on the supply of infant formula products.</p>	<p>Removal of automatic carry over – not discussed in approval report.</p> <p>Refer to 2nd CFS, Supporting Document 3, section 3.2</p> <p>New permissions – section 4.12.1 of the approval report</p>
Reducing the permitted maximum level of some contaminants	<p>The maximum level of aluminium (except in soy-based products) and lead will be reduced.</p> <p>Where possible they align with relevant international regulations,</p>	<p>This ensures public health is protected by keeping exposure levels as low as technically possible.</p> <p>This aligns the standards with the most up to date science and improves alignment with international regulations.</p>	Section 4.12.2
Updating labelling requirements – new and amended protein source statement requirements	<p>Products must state the specific animal or plant source of protein (for example, cow, goat, sheep, soy) and whether it is partially hydrolysed.</p> <p>The protein source statement must be co-located with the name of the food on the front of the pack.</p>	<p>These changes provide more information in a more accessible location for caregivers, so that they can make informed choices.</p> <p>They align the standards with the latest studies on caregiver understanding of labels.</p> <p>They support infant health by providing clearer information to caregivers that assists them to select products suitable for their infant.</p>	Section 4.13

Category of proposed change to the standards	Description of the changes within this category	Purpose of the changes in this category and how they relate to the objectives of the proposal	Approval report reference
Updating labelling requirements – additional prohibitions on what can be represented on labels	<p>The changes expand what cannot be represented on infant formula products, unless expressly permitted or required by other areas of the Code.</p> <p>Notable prohibitions are references to:</p> <ul style="list-style-type: none"> • any ingredients (outside the ingredient list or nutrition information panel) • additional information about protein sources (for example, preventing references to protein fractions like ‘alpha-lactalbumin’). 	<p>The changes align the standards with the objectives of:</p> <ul style="list-style-type: none"> • providing caregivers with the information needed for them to make an informed choice • preventing misleading information. 	Section 4.17
Updating labelling requirements – greater differentiation with and preventing advertising of, products similar to infant formula products	<p>Infant formula products will not be able to reference other products (for example products designed for toddlers).</p> <p>Labels must differentiate that product from other foods by the use of text, pictures and/or colour.</p>	<p>The changes support infant health by reducing the risk of infants under 6 months being fed products that are not safe and suitable for them.</p> <p>They align the standards with the latest studies on caregiver understanding of product labels.</p>	<p>Not discussed in approval report.</p> <p>Refer to 2nd CFS, Supporting Document 3, section 9.</p>
Updating labelling requirements – improving information provided to caregivers	<p>The proposed changes:</p> <p>prescribes a standard format for the NIS updates the existing required instructions for preparation and use</p> <p>permits voluntary stage labelling of infant formula with the number ‘1’ and follow-on formula as ‘2’, with conditions.</p>	<p>These changes:</p> <p>improve information provided to caregivers by improving the comparability of products</p> <p>reduce the risk of improper preparation which can have serious health consequences.</p>	<p>Standard NIS format – refer to 1st CFS, Supporting Document 3, section 3</p> <p>Preparation instructions – refer to 2nd CFS, Supporting Document 3, section 1 and 2</p> <p>Stage labelling – section 4.18 of the approval report</p>

Category of proposed change to the standards	Description of the changes within this category	Purpose of the changes in this category and how they relate to the objectives of the proposal	Approval report reference
Making other minor changes	A number of other minor changes have been made to the standards.	Generally these changes are to: <ul style="list-style-type: none"> • aid interpretation of the standards by removing current areas of ambiguity • make consequential amendments to other parts of the Code, to reflect changes to the standards. 	Refer to the entire draft variation that is attached to the approval report.

6 Consideration of costs and benefits

This section contains the final consideration of the costs and benefits for the proposed changes to the standards.

In assessing this proposal and in deciding to prepare the amendments to the standards, FSANZ was required by the FSANZ Act to have regard to whether the costs that would arise from the proposed measure outweigh its direct or indirect benefits. In doing so, it had regard to submissions received in response to the 1st and 2nd CFS processes.

6.1 Summary of cost and benefit analysis findings

Updating the standards will impact three main groups:

- infants fed infant formula products and their caregivers
- the infant formula industry
- governments.

The following table summarises the impacts, by group.

Table 6-1 Major potential impacts by stakeholder group

Stakeholder group	Benefit or cost	Impact and description
Infants fed infant formula products and their caregivers	Benefits	Health improvements due to higher quality products that better meets infants' development needs Overall net improvement in the ability to compare and choose products, removal of misleading claims Better advice at point of sale for specialised products which could result in both improved health outcomes and avoidance of unnecessary costs if specialised formula is not desirable or needed Clearer instructions on product labels leading to reduced risk of unsafe preparation
Infant formula industry		
Base powder manufacturers	Benefit	Improved international harmonisation increasing cost efficiencies of manufacturing base powder ³⁹
	Cost	Reformulation costs ⁴⁰
Finished product manufacturers	Benefits	Improved international harmonisation increasing cost efficiencies of manufacturing finished products ³⁹ Improved regulatory certainty
	Costs	Reformulation and relabelling costs ⁴⁰ Potential reduction in demand for some SMPPi Transition costs (for example, increased calls to hotlines) ⁴⁰
General retailers (supermarkets)	Costs	Loss of sales (SMPPi) Transition costs (for example, increased calls to hotlines)
Specialised retailers (pharmacists)	Benefit	Increase in sales (SMPPi)
Government	Benefits	Improved ability to enforce standards Savings in health care expenses
	Cost	Some small costs of adapting to new standards

³⁹ These cost savings may flow through the supply chain, potentially reducing costs for retailers and/or consumers. They may be passed on in part or in full.

⁴⁰ These cost increases may flow through the supply chain, potentially increasing costs for retailers and/or consumers. They may be passed on in part or in full.

The impacts identified in the above table are expanded on in more detail in the sections that follow.

Not all of the impacts can be quantified, either due to a lack of data, or the nature of the impact making it extremely difficult to quantify (e.g. the relationship between multiple improvements to infant formula product composition and the lifelong health outcomes of an infant).

The only impacts that were able to be quantified in this DRIS were reformulation costs and relabelling costs.

Note that a number of impacts identified for specific groups above are expected to net to zero at an economy-wide level, including:

- the impact on specific ingredient manufacturers⁴¹
- lost sales of SMPPi at supermarkets that are either gained by pharmacies or retained by supermarkets as sales of general infant formula products.

6.2 Overview of impacts on infants and caregivers

6.2.1 Summary

Infants that are fed infant formula products will likely benefit from potential lifelong improved health outcomes, particularly those that rely on the products as a sole source of nutrition. This is due to improvements in the composition of infant formula products.

This benefit is extremely difficult to quantify, however the magnitude is expected to be large at a population level given:

- over ten years more than 2 million infants will consume infant formula (and a proportion of these will also consume follow-on formula)
- improvements in early nutrition will have lifelong impacts for the above cohort

Labelling changes will make it easier to compare infant formula products and reduce food safety risk by providing clearer preparation instructions.

Some products will no longer be sold in supermarkets as a result of restricting the sale of SMPPi to pharmacies and other responsible institutions.⁴² FSANZ expects the impact of restricting the sale of SMPPi to result in a net benefit for infants and their caregivers. The pharmacy network provides good access to the community, with most pharmacies offering formula at similar prices to supermarkets.

Better health outcomes may arise as a result of restricting SMPPi sales to pharmacies and other responsible institutions where caregivers receive medical advice that will assist in the management of medical conditions. Caregivers may also benefit as they may be appropriately advised not to purchase a product that is more costly and not necessary for their infant.

⁴¹ Changes to the permissions for additives, macronutrients and micronutrients and nutritive substances will result in infant formula manufacturers changing their infant formula product recipes. FSANZ has assumed that some ingredients will be used more, some will be used less, netting out to zero impact.

⁴² Specifically, these are products marketed for reflux, anti-regurgitation, colic, constipation, sensitivity, intolerance, allergies.

In summary, the impacts on infants and their carers are:

- Likely improved health outcomes for formula fed infants, due to:
 - improved composition
 - potential for more health advice at the point of sale for specialty products
 - further reducing contaminants
 - reduced risk of negative health impacts, due to clearer preparation instructions
- Improved information about infant formula products through clearer labels, including:
 - improved ability to compare products through a standardised NIS
 - removing misleading information.

These impacts are expanded on in the following subsections.

6.2.2 Extent of infant formula use

Every year, approximately 190,000 Australian and 50,000 New Zealand infants are fed infant formula by age six months. It is not known how many infants above this age consume infant follow-on formula.⁴³

Over ten years, it is expected that the total number of infants under six months fed infant formula (either exclusively, or in combination with breast milk) is expected to be:

- 1.9 million in Australia
- 0.5 million in New Zealand.

By proportion 62.5% of Australian infants under 6 months are fed an infant formula product at least once.⁴⁴ A 2008 report shows that 75% of New Zealand infants were fed an infant formula product at least once at 6 months of age.⁴⁵

Caregivers, per year, purchase approximately:

- 14 million infant formula products in Australia
- 3 million infant formula products in New Zealand.⁴⁶

Most infant formula products are purchased in supermarkets, with the remainder purchased through community pharmacies. The following chart summaries the data.

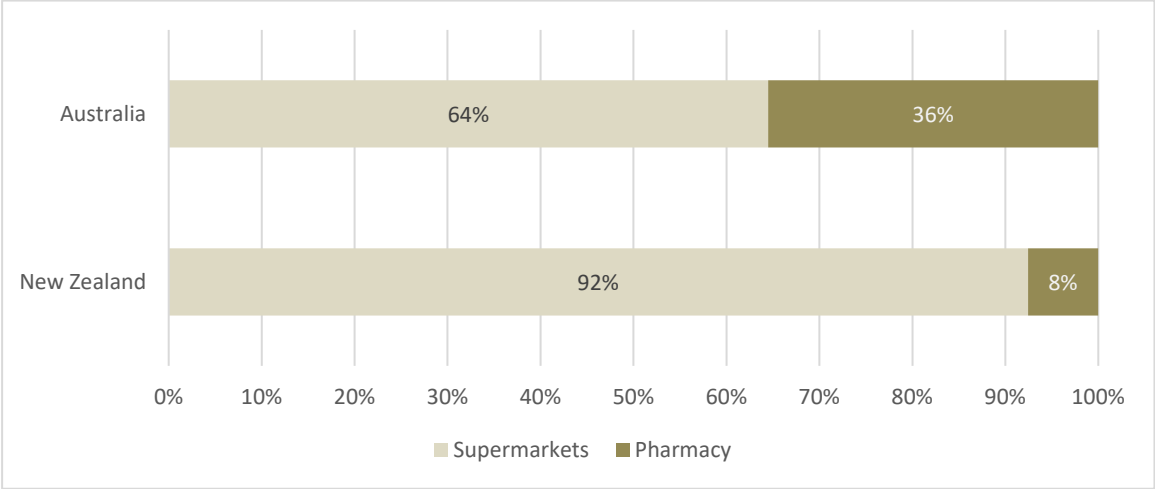
⁴³ To see how this figure was calculated refer to Appendix A.

⁴⁴ ABS: Breastfeeding (2023)

⁴⁵ Ministry of Health: Protecting, Promoting and Supporting Breastfeeding in New Zealand - Background report (2008). Data from Table 1.

⁴⁶ Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS. Data provided on a moving annual total basis, for the year ending 27 May 2023.

Figure 6-1 Proportion of infant formula product sales made at supermarkets and pharmacies, by country (2023 MAT)



*Note: Moving annual total (MAT) to 27 May 2023. Data was provided for sales in the 'grocery channel'—for simplicity FSANZ has assumed all grocery channel sales are in supermarkets.
Source: Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.*

FSANZ has assumed that approximately 95% of infant formula products are purchased in-store. This is based on stakeholder feedback and Australian Bureau of Statistics (ABS) data. ABS data indicates that online sales of food in Australia are approximately 5% of total food sales. Based on this, FSANZ has assumed that online sales of infant formula products is also approximately 5% of total infant formula product sales (in both Australia and New Zealand).⁴⁷

6.3 Benefits for infants and caregivers

6.3.1 Health benefits from improved composition based on more current science

Formula fed infants will directly benefit from the improved nutrient composition of infant formula products, particularly where these products provide their sole source of nutrition.

For some infants, infant formula will be their sole source of nutrition in a significant phase of their development. Nutrition at this phase of an infant’s development will have lifelong impacts.

Therefore, any enhancements (including minor enhancements) to infant formula that lead to improved health of infants is likely to have significant public health benefits when considered in aggregate.

Improvements to the composition of follow-on formula will also lead to health benefits for infants, noting that not all infants fed infant formula progress to follow-on formula.

⁴⁷ For more information on online sales statistics, refer to ABS [Online sales, June 2021 - Supplementary COVID-19 analysis](#).

The updates follow FSANZ's assessment of the existing standard, which took into account:

- recommendations of key expert bodies
- comparison with human milk concentrations
- estimation of intakes and comparison with Australia and New Zealand Nutrient Reference Values (NRVs) for adequate and excess intakes
- physiological, biochemical and functional outcomes
- identification of new or emerging scientific evidence.

The standards have not been significantly updated in over 20 years. Within this period science, research and intentional regulations have progressed.

Infants may benefit through:

- reduced risk of negative health outcomes, for example:
 - protein sources will be prescribed, reducing the risk of infants receiving unsafe formula
 - limiting carbohydrate source, limiting potential adverse effects for infants with hereditary fructose intolerance
- improved composition based on the latest scientific evidence, through:
 - mandating previously optional substances
 - updating minimum and/or maximum quantities for some substances.

For each proposed change to the compositional requirements FSANZ performed a review of the scientific literature and has only proposed changes where appropriate. Section 2.2 of the approval report provides information on the assessments undertaken.

Some examples of the compositional changes and how they benefit infant health, are provided in a table at Appendix A.

This regulatory change is of benefit to infants and their carers as it increases the quality of all infant formula products available and means that base-level infant formula products will include these essential ingredients. This is of benefit to infants and their carers who currently purchase base-level infant formula instead of products marketed as 'premium' with higher price points.

Quantifying this benefit in monetary terms is not possible given the complex relationship between nutrition and health outcomes.

Approximately 2 million Australian and New Zealand infants are expected to benefit (to some extent) from the improvements made to infant formula over the next ten years.

A subset of these infants will also benefit from the improvements made to follow-on formula.

6.3.2 Improved labelling increasing safety

The proposed standards improve the labelling of infant formula and follow-on formula by clarifying safety aspects of certain directions for preparation and use, based on updated research on human behaviour.

Consumer research suggests that caregivers do not always prepare or use infant formula products properly. For example, they may add other foods to infant formula products, or may use infant formula prepared several days ago instead of discarding what is not used within 24 hours.

Research suggests that these behaviours are sometimes driven by a misunderstanding of or uncertainty around labelled instructions, among other reasons (e.g. a desire to reduce wasted formula, not reading instructions etc.).

This could lead to a number of associated risks for infants (FSANZ 2021). These risks include:

- under and over nutrition
- bacterial infections
- choking
- diarrhoea
- constipation
- too little or too much weight gain.

The likelihood and impact of these risks increase the longer these behaviours continue.

Improved product labelling may therefore lead to improved health outcomes by reducing the risk of improper preparation and use, such as requiring a stated time after which to discard prepared any unfinished infant formula.

This benefit is difficult to quantify. FSANZ is not aware of any domestic incidents of serious health issues related to improper infant formula preparation, however the risk still remains. Most benefits will be at the low level, i.e. reduced incidences of minor impacts like infant discomfort or hospital visits due to improper preparation.

6.3.3 Improved labelling increasing comparability of infant formula products

The proposed changes will require infant formula products to display a standardised NIS. This change means caregivers benefit from more readily understood information, to enable them to make informed choices.

Standardising the NIS will assist caregiver understanding of the nature of nutrients and substances that have technical names (for example, pantothenic acid (B₅) grouped under the subheading 'Vitamin').

It will also help caregivers to make quicker product choices by making comparisons between products easier.

Caregivers will also be able to more readily identify product differences relating to beneficial additional nutritive substances and other substances that have been voluntarily added.

Industry stakeholders noted that some aspects of the proposed changes will decrease comparability:

- Some caregivers will not understand the standardised terminology used in the NIS.
- Caregivers will no longer be able to compare general infant formula products to SMPPi in a supermarket setting.

While these impacts are noted, FSANZ expects that overall the changes to labelling will benefit caregivers. FSANZ also notes that SMPPi are intended to be used under medical supervision and should not be compared with infant formula and follow-on formula which are formulated for healthy infants.

6.3.4 Removing proxy advertising and misleading claims from labels

The proposed changes also improve product labelling through:

- establishing requirements for stage labelling
- a prohibition of proxy advertising
- requiring infant formula products to be distinctly labelled and differentiated from non-infant formula products
- requiring specific labelling for infant formula products represented as containing partially hydrolysed protein.

The labelling measures listed above are intended to reduce the risk of caregivers purchasing a similarly packaged product that may be unsuitable for their infant.

Requirements for stage labelling (if used) and the prohibition of proxy advertising (e.g. information about another product provided on an infant formula product label) will assist caregivers to distinguish between an infant formula and follow-on formula and identify the correct product for their infant.⁴⁸

These requirements will also reduce the influence of marketing that may suggest to caregivers that their infant must progress from stage 1 and 2 to stage 3 and beyond, when infant formula is no longer necessary.

The proposed standards will require the label on a package of infant formula or follow-on formula to differentiate that infant formula or follow-on formula from other foods by the use of text, pictures and/or colour. The intent of this requirement is to ensure these products are distinctly labelled to reduce potential caregiver confusion when making product choices.

Under the current standards, it is common practice for both infant formula and follow-on formula to be sold in packaging that is similar to the packaging of toddler milks and growing-up milks. Typically the only difference is the text on the products, with all other design elements (like package size and shape, label colours, position of statements, icons) remaining the relatively similar. The products are typically placed next to or near infant formula and follow-on formula at retailers.

Under the proposed standards, partially hydrolysed formulas that are currently represented as suitable for transient gastrointestinal conditions (for example 'anti-reflux') will not be permitted to refer to these conditions, unless they are represented as SMPPi.

These representations can mislead caregivers. For example, consumer research has shown that the marketing of formulas for colic and reflux can suggest to some caregivers that what the infant is eating must be causing the problems and can imply that changing (either from another infant formula product or from breastfeeding) to a specialised formula for the condition will solve the problem.

The presence of these representations can therefore influence consumer choice when purchasing infant formula products and these products are typically sold at a higher price point despite not being that different compositionally.

The intent is for caregivers to seek medical advice if their infant is experiencing a medical issue. This is further explored in section 6.3.6.

⁴⁸ Stage labelling is the use of the numbers '1' and '2' to identify a product is infant formula or a follow-on formula, respectively.

6.3.5 Further reducing the presence of chemical contaminants in some products

Chemical contaminants can be:

- found naturally in the environment, therefore are naturally occurring components of foods
- produced by microorganisms
- produced through industrial activities.

It is not always possible to completely eliminate the presence of very low levels of contaminants in foods, however risk management measures can help minimise human exposure.

The current standards already set a high safety benchmark for the permitted level of contaminants.

The proposed standards reduce the permitted level of aluminium and lead. This will reduce the exposure of these contaminants for infants currently consuming infant formula products with concentrations above the proposed limits. This will lead to an overall positive health impact for the population as a whole, but the extent of the health benefits is unknown.

Feedback from industry has confirmed that most infant formula products already comply with the proposed permitted levels.

6.3.6 Health benefits from restricting sale of special purpose products to healthcare settings

Products within the new SMPPi category will only be sold in pharmacies or other responsible institutions. Caregivers who believe their infant has a potential medical condition, who would have purchased these products in a supermarket under the status quo, are expected to purchase these products at a community pharmacy.

Caregivers and infants may benefit from this through:

- reduced the risk of caregivers buying any formula product that is not suitable and/or necessary
- increased clarity around the purpose of the products
- potential recommendations to seek advice from specialists (where required) resulting in reduced risk of harm from delaying appropriate investigations or treatments for underlying medical problems
- potential for caregiver-pharmacist relationship, leading to more support and advice
- reduced risk of harm for infants with allergies.

The following sections expand on this conclusion.

6.3.6.1 *Products that address medical conditions will only be sold in medical settings*

Products within the new SMPPi category will only be sold in pharmacies or other responsible institutions. This includes products that are marketed as addressing conditions such as colic, regurgitation and constipation that were previously available at supermarkets.⁴⁹ Caregivers are likely to be purchasing these products when they believe their infant has symptoms of a medical condition.

6.3.6.2 *Caregivers often seek medical advice after purchasing a speciality product*

Infant behaviours such as crying, sleep-waking, possetting and gassiness are normal. However, a FSANZ systematic literature review found caregivers may interpret these behaviours as concerns that could be addressed through a speciality formula (FSANZ 2023).

Studies suggest that almost half of caregivers do not seek medical advice for potential medical conditions until after purchasing speciality infant formula products. A study by Appleton et al. (2022) found 53% of Australian parents surveyed who use 'premium or specialised' formulas sought advice from a health professional about infant formula product feeding. However only 48% of premium or specialised infant formula product users sought any advice (medical or other sources) prior to starting on the formula product.⁵⁰

6.3.6.3 *Pharmacists will provide advice to concerned caregivers, improving outcomes for infants*

Caregivers who believe their infant has a potential medical condition, who would have purchased these products in a supermarket under the status quo, are expected to purchase these products at a community pharmacy.

Caregivers accessing SMPPi through pharmacies may receive improved medical advice about potential medical conditions. Pharmacies are required to have a pharmacist on site at all times, who will be available to provide health advice to caregivers. Supermarkets typically do not have qualified staff who can provide health advice.

This arrangement will:

- reduce the risk of caregivers buying any formula product that is not suitable or necessary for their infant
- increase clarity around the purpose of the products and the differences between SMPPi and infant formula and follow-on formula.

The intent of the Code is that where an infant has a specific medical condition a medical professional will provide advice and may recommend that specialised formula is used. This applies to all other food for special medical purposes under the Code. Selling specialised formula in a grocery setting can break the link between caregivers and the health advice needed to manage conditions.

⁴⁹ There will be no change for infants who rely on highly specialised SMPPi. These products are currently not sold in general retailers like supermarkets and are usually purchased in pharmacies (with a prescription and/or government support from the PBS or Pharmac) or provided directly in healthcare settings. This is a commercial decision made by general retailers—under the status quo there are no restrictions on where any infant formula product (including specialised products) can be sold.

⁵⁰ 'Premium or specialised' was defined in the relevant study (Appleton et al. 2022, p911) as "organic, extensively or partially hydrolysed protein, milk other than standard cow milk and those marketed as premium or for specific infant medical issues, such as reflux".

6.3.6.4 Recommendation to seek advice from other medical professionals if symptoms require further investigation

As noted above, while behaviours such as crying, sleep-waking, possetting and gassiness are normal, the frequency and severity can indicate signs of an undiagnosed medical condition.

If these behaviours are actually symptoms of a medical condition such as gastro-oesophageal reflux, cow's milk protein allergy, or poor weight gain, use of these products without medical advice may cause harm by delaying appropriate investigations or treatments for underlying medical problems (Munblit et al, 2020).

In this situation, a pharmacist can recommend a caregiver seek advice from an appropriate specialist for further investigation, diagnosis and proper treatment.

6.3.6.5 Benefit of the caregiver-pharmacist relationship, including assistance in the case of supply shortages

The proposed changes may result in some caregivers developing a relationship with a pharmacist that they wouldn't have had otherwise, resulting in more support and advice.

Pharmacists also have the ability to manage provision of vital medical products during supply disruptions (not that this is suggested as a likely outcomes of these changes).

6.3.6.6 Reduced risk for infants with allergies

Infant formula products marketed for lactose intolerance will be regulated as SMPPi and therefore, sold at pharmacies and other responsible institutions. Stakeholders have reported that some caregivers (including parents, early childhood educators, healthcare professionals) can mistake these infant formula products as being suitable for infants with a cow's milk protein allergy.

Infant formula products designed for lactose intolerance (like most dairy products designed for lactose intolerance) are milk-based, therefore will cause anaphylaxis if consumed by an infant with a cow's milk protein allergy. Moving the sales of these products to pharmacy and other responsible institutions will lower the risk of these events occurring, where caregivers receive advice on what products are suitable for infants with a cow's milk protein allergy.

No incidence data is available for the occurrence of this issue. However the consequences for infants with allergies are severe.

6.3.6.7 No negative health impacts for caregivers

Industry stakeholders provided feedback that periods of infant discomfort can lead to stress for caregivers. This is supported by studies identified in the FSANZ literature review (FSANZ, 2022). Dykes (et al., 2012) identified that healthcare professionals believed that caregivers struggled with infants going through normal unsettled or difficult periods. They noted that some parents would seek out interventions, which health professionals considered unnecessary, to address these problems and therefore reduce stress.

However, proper management of medical conditions by specialists will ultimately lead to reduced stress for caregivers.

6.3.6.8 *Situations where caregivers may not receive medical advice*

Non-prescription SMPPi will be stocked on pharmacy shelves, rather than behind the counter.⁵¹

Therefore, it is still possible that some caregivers may not receive advice from a pharmacist when purchasing a product. This may limit the benefits of the proposal, in the circumstances described below.

In a larger pharmacy the caregiver may not approach the pharmacist to ask a question. However, this same concern exists for a significant number of other products that are available in a pharmacy but not in supermarkets. It is up to caregivers to interact with pharmacy staff if they have any questions.

Caregivers will be able to purchase SMPPi in an online setting, where information is provided as text rather than explained by a person. Some caregivers may not understand or read the information provided. However, there is a likelihood that online sales will only be for subsequent purchases after the caregiver has sought advice on the appropriateness of a product for their child in-store.

6.4 Costs for infants and caregivers

In the short-run, some product manufacturers may pass on some (or all) of the increased costs of meeting new standards to caregivers through higher prices of infant formula products.

However, any potential price increase per item would be very small. The calculation of the potential costs to be passed on is shown in the industry costs section below.

In the longer-run, greater alignment with international regulations may reduce production costs and caregivers may then benefit from price reductions.

FSANZ expects the impact of restricting the sale of SMPPi to be minor for caregivers. Under the status quo, a significant majority of these products are sold in large supermarkets; under the proposed changes they are expected to be purchased at pharmacies. The price of products will be very similar at large pharmacies and caregivers are unlikely to have to travel further to access a pharmacy given how they are distributed geographically.

Some caregivers may purchase the products at a smaller pharmacies, which may result in a small increase in prices relative to the status quo due to smaller economies of scale.

However these price increases will be limited. During consultation with the pharmacy sector FSANZ was advised that pharmacies follow the pricing strategy set (using a recommended retail price or RRP) by infant formula manufacturers, however there is strong price competition from big pharmacies in metropolitan areas that results in prices being lower than the RRP.

The sector also advised that many pharmacies have discount arrangements with wholesalers or distributors of infant formula products.⁵²

The potential impacts on caregivers are discussed in more detail in the sections that follow.

⁵¹ This information was received in targeted consultations with the pharmacy sector.

⁵² This information was received in targeted consultations with the pharmacy sector.

6.4.1 Change in location of sale for subcategories of special purpose infant formula

Under the variation, SMPPi can only be sold or distributed through medical practitioners and dietitians, responsible institutions, or permitted sellers. Permitted sellers will include pharmacies and other responsible institutions.

Products for the following issues are currently sold at supermarkets, but will be subject to the restriction of sale:

- reflux and anti-regurgitation
- colic and constipation
- sensitivity and/or intolerance
- allergy.

Caregivers who would have purchased these products in a supermarket under the status quo are expected to purchase these products at a community pharmacy or purchase a more appropriate product to their needs (in some cases substituting to a product that can be sold in supermarkets).⁵³

FSANZ expects the impact of restricting the sale of SMPPi to be minor for caregivers. Under the status quo, a significant majority of these products are sold in large supermarkets, under the proposed changes they are expected to be purchased at pharmacies many of which charge similar prices.

As a result, the price of products will be similar and caregivers are unlikely to have to travel further to access a pharmacy given their geographic distribution. Some caregivers may purchase the products at a smaller pharmacy, increasing costs for those caregivers.

This conclusion is discussed in more detail below.

6.4.1.1 Quantifying the extent of the impact – number of SMPPi sold in supermarkets

The following tables show the approximate number of SMPPi sold in supermarkets per year. Under the proposed changes, these products would not be able to be sold in supermarkets.

The data was provided by industry. Note that the term ‘milk allergy’ was used in their data. FSANZ did not seek clarification (for the purposes of this cost and benefit analysis) on whether this category of data captures only formulas suitable for cow’s milk protein allergy, or a broader range of products. The following tables (and some subsequent tables) use the term ‘milk allergy’ to refer to the category of products, as defined within the report provided.

⁵³ Note that references in this analysis to ‘pharmacies’ means community pharmacies, not hospital pharmacies.

Table 6-2 Approximate SMPPi sales in Australian supermarkets, by type (2023 MAT)

Product type	Number of units sold	Proportion of all infant formula products sold
Reflux and anti-regurgitation	220,000	1.5%
Colic and constipation	175,000	1.2%
Sensitivity and/or intolerance	175,000	1.2%
Milk allergy	130,000	0.9%
Total	700,000	4.8%

Note: Moving annual total (MAT) to 27 May 2023. Numbers are approximate; they may differ from some numbers in the source report due to rounding. Data was provided for sales in the 'grocery channel'—for simplicity FSANZ has assumed all grocery channel sales are in supermarkets.

Source: Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.

Table 6-3 Approximate SMPPi sales in New Zealand supermarkets, by type (2023 MAT)

Product type	Number of units sold	Proportion of all infant formula products sold
Reflux and anti-regurgitation	40,000	1.3%
Sensitivity and/or intolerance	25,000	0.9%
Colic and constipation	15,000	0.4%
Milk allergy	-	0%
Total	80,000	2.6%

Note: Moving annual total (MAT) to 27 May 2023. Numbers are approximate; they may differ from some numbers in the source report due to rounding. Data was provided for sales in the 'grocery channel'—for simplicity FSANZ has assumed all grocery channel sales are in supermarkets.

Source: Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.

6.4.1.2 SMPPi sales data – concentration of sales in large format supermarkets and pharmacies

The sale of SMPPi (under the status quo) is highly concentrated to large supermarkets and large pharmacy chains.

Sales data indicate that:

- in Australia – 807 pharmacies (13%) sell 80% of SMPPi
- in New Zealand – 80 pharmacies (7%) sell 80% of SMPPi⁵⁴.

⁵⁴ IQVIA report. Note that this data counts only pharmacies that sell at least one SMPPi tin.

Data provided by Woolworths indicates that of total supermarket SMPPi sales, a significant proportion (likely over 80%) is sold at large supermarkets rather than at smaller supermarkets.⁵⁵

This concentration of sales demonstrates that caregivers typically do not buy SMPPi from smaller supermarkets or smaller pharmacies. This is likely because both satisfy a broad range of consumer demands with limited space and therefore stock of SMPPi will be limited due to competition for shelf space.

6.4.1.3 Minimal time, travel or other cost impacts for caregivers

FSANZ does not expect the change in location of sale will have a significant impact on caregivers in terms of time, travel, or other costs (outside of the price of the products, which is explored separately).

A number of caregivers will substitute general infant formula products for SMPPi and therefore continue purchasing from supermarkets. This is an intended outcome of the amendments to the standards, where a SMPPi is not necessary. The proportion of caregivers in this category is unknown.

Based on the sales concentration data above, the caregivers who continue to buy the products will (in the majority of cases) be switching from purchasing SMPPi at large supermarkets to large pharmacies.

⁵⁵ Woolworths submitted that in FY 2022 it sold approximately 450,000 SMPPi. The IQVIA report shows that in the year to May 2022, supermarkets sold approximately 700,000 SMPPi. This represents approximately 60% of SMPPi supermarket sales. Woolworths' share of total grocery sales in Australia is around one third of total sales. While these two data points are from different data sources and should not be directly compared, they indicate that large supermarkets (such as Woolworths) sell a significant majority of SMPPi.

This subset of caregivers are not expected to experience a significant change, because:

- pharmacies are ‘health destinations’, many caregivers would be visiting pharmacy anyway
 - data indicates that the average Australian visits a pharmacy 18 times a year⁵⁶
 - similar data is not available for New Zealand, however 1.3 million people visited a pharmacy per month in 2016⁵⁷
- the sale of SMPPi (as well as general infant formula products) in large pharmacies is well established under the status quo (refer to data below)
- pharmacy location rules create a legal obligation for pharmacies to be conveniently located (in Australia)⁵⁸
 - in Australian capital cities, 97% of people have access to at least one pharmacy within a 2.5 km radius⁵⁹
 - large supermarkets are typically located within shopping centres or precincts that contain large pharmacies⁶⁰, minimising potential additional travel distance
- SMPPi can be purchased online.

The sale of SMPPi in pharmacies is well established and in many pharmacies the products are stocked under the status quo.

The following charts demonstrate the proportion of SMPPi sold in pharmacies, by product type.

⁵⁶ NAB [Pharmacy Survey 2021](#). Data is not available for caregivers specifically, however 25–34 year-olds visit 15.3 times per year on average and 35–44 year-olds 20.2 times per year. It has been assumed that people in New Zealand visit at a similar rate to Australians.

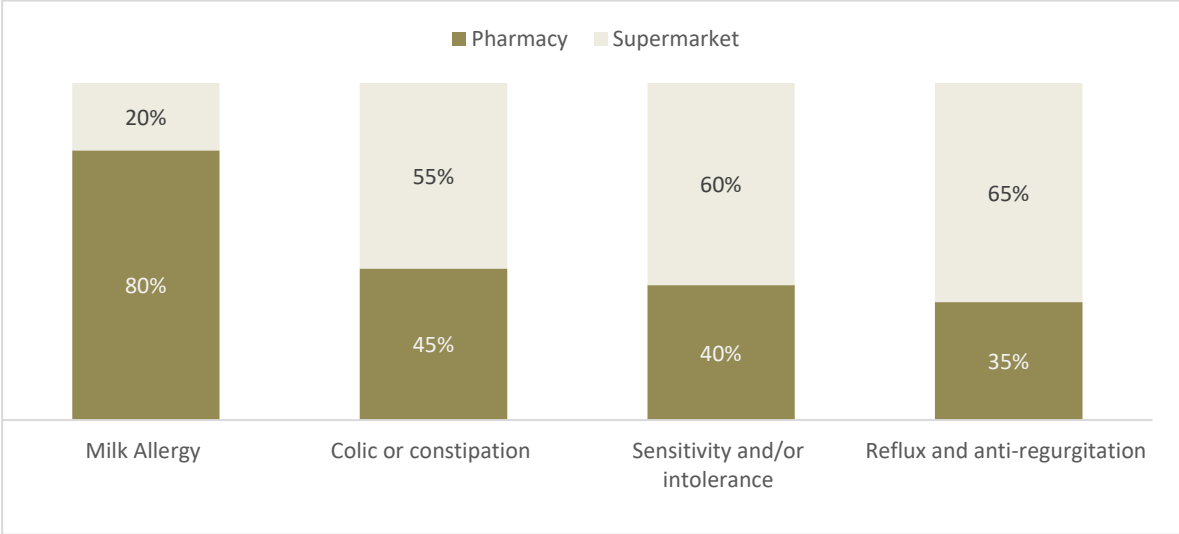
⁵⁷ Ministry of Health Pharmacy Action Plan 2016 to 2020 (2016).

⁵⁸ This legal obligation is created by the *National Health Act 1953* (Aus.), with the location rules set by the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (Aus.).

⁵⁹ Information provided to FSANZ by the Pharmacy Guild of Australia.

⁶⁰ In Australia, pharmacy location rules encourage pharmacies to locate within a shopping centre with a supermarket by modifying the rules that would otherwise apply. Refer to Pharmacy Location Rules Applicant's Handbook (Department of Health, 2022).

Figure 6-2 Approximate proportion of SMPPi sold at pharmacies in Australia, by type (2023 MAT)



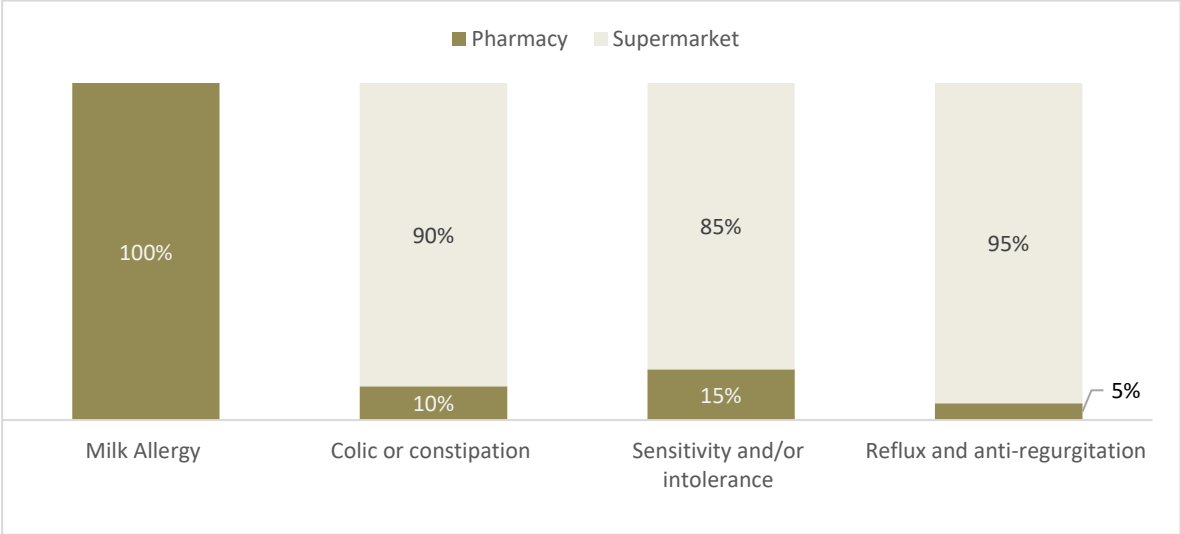
Note: Moving annual total (MAT) to 27 May 2023. Numbers are approximate due to rounding. Data was provided for sales in the ‘grocery channel’—for simplicity FSANZ has assumed all grocery channel sales are in supermarkets.

Source: Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.

This shows that a significant proportion of pharmacies in Australia are able to meet the additional demand from a restriction on sale.

Sales of these products are less established in New Zealand (except for ‘milk allergy’ products).

Figure 6-3 Approximate proportion of SMPPi sold at pharmacies in New Zealand, by type (2023 MAT)



Note: Moving annual total (MAT) to 27 May 2023. Numbers are approximate due to rounding. Data was provided for sales in the ‘grocery channel’—for simplicity FSANZ has assumed all grocery channel sales are in supermarkets.

Source: Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.

However, it should be noted that SMPPi sales as a proportion of total infant formula product sales are lower in New Zealand (4%) compared to Australia (11%), which reduces the potential impact.⁶¹

Some caregivers will purchase impacted products at small pharmacies, that currently stock a limited range of the impacted products. These pharmacies will be able to respond to demand and increase supply.

Feedback from pharmacy groups indicates that pharmacists are also able to order in any product in response to caregiver requests.

Pharmacy wholesalers will be able to supply any infant formula product from the most common products to small-demand prescription products.

6.4.1.4 Impact of potential difference in trading hours between pharmacies and supermarkets

There is not expected to be a significant impact as a result of any difference in trading hours between supermarket and pharmacy.

FSANZ has been provided data that indirectly demonstrates the extent of after-hours purchasing. Woolworths SMPPi sales data shows that:

- 35% (155,700 of 450,000 total) were purchased outside 9 am to 5 pm (any day of the week)
- the most common day to purchase SMPPi was Sunday.⁶²

⁶¹ Impact Analysis on Restriction of SMPPi Sale (IQVIA), provided to FSANZ by the INC in response to the 2nd CFS.

⁶² Woolworths sales data for Woolworths branded Australian retail outlets, provided to FSANZ in response to the 2nd CFS.

The extent of the impact will be limited because:

- many caregivers will substitute to infant formula, resulting in no change
- caregivers may already be visiting a pharmacy to meet other needs and will be able to purchase SMPPi at that time
- pharmacies are typically open weekends, after hours and public holidays in metropolitan areas⁶³
- caregivers will be able to buy impacted products online.

6.4.1.5 *Impact on caregivers in rural and remote areas*

Caregivers in rural and remote areas are not expected to be significantly impacted.

This is because stock of specialised formula is already limited in these areas. Rural and remote supermarkets have limited stock and shelf space due to smaller populations and lower demand (similar to small metropolitan supermarkets).

Government policies mean that rural and remote caregivers will be able to access a pharmacy for infant formula products where needed. Legal requirements applying to pharmacies in Australia and New Zealand include Section 90 of the *National Health Act 1953* and the *Medicines Act 1981*, respectively. The legislative requirements cover ownership, location and compliance with professional requirements.

Australia also the pharmacy location rules. These rules are designed to achieve the objective of the National Medicines Policy which is to improve the health outcomes of all Australians through access to and quality use of medicines.

In Australia, outside of capital cities, 66% of people live within 2.5 km of a pharmacy.

As noted above, pharmacies are able to order in any product in response to caregiver requests. Pharmacies can procure any infant formula product from the most common products to small-demand prescription products in response to infant needs.

Rural and remote caregivers also have an option to purchase products online.

6.4.1.6 *Minimal (or no) price increase for SMPPi sold at pharmacies*

FSANZ does not expect the price paid for SMPPi to change as a result of the proposed changes. A small number of caregivers who switch from purchasing SMPPi at large supermarkets to a small pharmacy may pay more.

Data collected by FSANZ indicates that, under the status quo, large pharmacies are more likely to have lower prices for SMPPi than large supermarkets.⁶⁴ On this basis, FSANZ has assumed that for most caregivers there will be no net price change.

Prices at small pharmacies may be higher relative to large supermarkets, due to lower demand and reduced economy of scale. However as explained above the number of caregivers expected to purchase impacted products at smaller pharmacies is assumed to be small. Data has not been collected on the price of SMPPi at smaller pharmacies.

⁶³ This was confirmed by pharmacy peak bodies in targeted consultation sessions.

⁶⁴ Based on the list of products collected by FSANZ (see section 2 of Appendix A), FSANZ conducted a desktop search of the price of all SMPPi available for sale in Australia at Woolworths and Coles. The price was compared to the price at Chemist Warehouse and Priceline. 7 of the 10 products were cheaper at the pharmacist chains than the supermarket chains on the day of the survey. The analysis included any discounts provided.

As noted above, some caregivers will switch to general infant formula from SMPPi. These caregivers are likely to spend less per unit purchased, resulting in a saving to those caregivers.⁶⁵

6.4.1.7 Response of manufacturers to restrictions – some products may be withdrawn

There is the potential for some products within the categories above to be withdrawn, reducing consumer choice if insufficient people purchase them having received health advice. However, products will be available to manage medical issues for those infants that need them. The proposed changes will not impact access to highly specialised infant formula designed to address specific medical conditions.

Manufacturers of the impacted products will have the choice to:

- continue to offer the products, positioned as SMPPi and therefore:
 - only for sale in pharmacies and other responsible institutions
 - labelled to state the true nature of the products and the condition/s they are formulated for
- reposition the products as infant formula or follow-on formula and therefore:
 - available for general retail sale (including in supermarkets and pharmacies)
 - unable to reference on the label the ability of the product to address conditions such as colic, reflux, allergy and others⁶⁶
- withdraw the products from sale.

6.4.1.8 No impact on health of infants as a result of the changed location of sale

This restriction of sale will not negatively impact the health of infants. As outlined in section 6.3.6, there may be an improvement in health outcomes due to improved access to health advice.

The proposed changes will not impact on access to highly specialised formula designed to address specific medical conditions. Specialised products are already only sold in pharmacies and other responsible institutions because their specialised nature makes them commercially un-viable to sell at supermarkets, or because they are available on prescription only and funded by governments when purchased at a pharmacy (under certain circumstances).⁶⁷

6.4.2 Impact on caregivers of changing elements of infant formula product labels

The proposed changes introduce a standardised nutrition information statement (NIS). The major differences between the current and proposed requirements for the NIS include the requirement to use specific nutrient names, subheadings and a prescribed format, for

⁶⁵ This is based on data collected by FSANZ (see section 2 of Appendix A). Standard infant formula products (excluding 'premium' products like organic or A2 milk) typically cost less than SMPPi versions of the same branded product.

⁶⁶ The protein source statement will be able to reference that the product is partially hydrolysed. These products must also comply with the nutrient composition requirements for infant formula and follow-on formula.

⁶⁷ Under the status quo, the standards do not restrict where specialised products can be sold. Some products are not sold in a retail setting, for example they can only be provided by a hospital treating an infant.

example permitted nutritive substances/other substances will appear in one location under the subheading 'Additional'.

This labelling approach would also bring the NIS format for infant formula and follow-on formula into greater alignment with the format of nutrition information panel (NIP) for general foods.

Caregivers will be able to compare the composition of different products more readily as a result of consistent format and terminology.

Almost all nutrients must be declared using the names as specified. Some caregivers may be required to adjust to different terminologies, where other terms are currently used. This impact will largely be limited to caregivers who cared for infants while the existing standards are in place and continue to do so after the new standards take effect.

6.5 Overview of infant formula industry impacts

This section discusses impacts on the infant formula industry, some of which FSANZ has been able to quantify.

The impacts have been analysed based on a five year transition period that begins when standards are gazetted. The reason for this transition period is discussed in section 9.5.

The impacts are:

- quantifiable:
 - reformulation - A\$44m one off cost
 - relabelling - A\$2–4m one off cost
- unquantifiable:
 - benefit of greater alignment with international standards
 - benefit of increased regulatory certainty
 - impact of restriction of sale of certain products to pharmacies and other responsible institutions⁶⁸.

6.5.1 Background on infant formula industry

The infant formula industry is complex. Some companies participate in the entire chain (from base powder to finished product on a shelf) while others only participate in part of the supply chain. Therefore, the impacts will not simply be a function of how many stock keeping units (SKU) are manufactured, there will also be impacts on companies that manufacture the ingredient inputs.

⁶⁸ Supermarkets and other general retailers will experience a reduction in sales of certain infant formula products, while pharmacies will gain sales of these products; refer to section 6.7.3.

For this analysis, industry impacts have been analysed from the following industry perspectives:

- base powder manufacturers
- ingredient manufacturers
- finished product manufacturers and sellers
- retailers
 - general retailers, including supermarkets
 - pharmacies and other responsible institutions.

Infant formula is traded globally. Products sold in Australia and New Zealand are either manufactured locally (in Australia or New Zealand) or imported.

6.5.1.1 Base powder manufacturers

Base powder manufacturers take raw milk (typically from surrounding farms) and process it into a powder suitable for infant formula products. This powder is either kept by the manufacturer to make into infant formula products, or sold for another company for that purpose. Some base powder is exported (outside of Australia and New Zealand) to make infant formula products in other markets. Some base powder is also imported. In New Zealand 30 to 40% of infant formula product inputs (base powder and ingredients) are imported.⁶⁹

The Code does not directly apply to base powders. However, standards for finished products need to be kept in mind when developing base powders, as they make up approximately 95% of the finished product.

Differences between regulations applying to finished products in base powder export markets and Australian and New Zealand standards result in inefficiencies for manufacturers. The fewer unique sets of requirements that need to be met, the lower the cost to manufacture.

6.5.1.2 Ingredient manufacturers

Ingredient manufacturers provide ingredients that are mixed in to base powders to make the finished products, for example vitamins and minerals. The ingredients are added to assist in meeting the standards, as well as for commercial purposes. These ingredients are either imported or produced locally.

Ingredients produced in Australia and New Zealand are also exported for use by manufacturers in other markets. Industry has noted that these products do not need to meet the standards, but buyers place value on their compliance with the standards. Therefore, it can be expected that exported product is likely to still be manufactured to meet the proposed standards to meet demand.

6.5.1.3 Finished product manufacture for domestic sale or export

Finished product are products ready to be sold to caregivers—a combination of a base powder and ingredients.

⁶⁹ New Zealand Food and Grocery Council submission to the 2nd CFS.

Most finished product produced in Australia and New Zealand is exported. Infant formula product exports are valued at:

- Approximately NZ\$2bn per year from New Zealand ⁷⁰
- A\$462m in 2022 from Australia.⁷¹

China is the largest importer of Australian and New Zealand infant formula products. Australian data shows that, prior to the pandemic, 83% of Australian exported infant formula products by volume went to China. In 2023, the top volume export markets for Australian products were China (50%), Vietnam (17%), Bangladesh (10%) and Thailand (5%).⁷²

Exports to China can be made via:

- the Cross Border eCommerce (CBEC) regime
- Daigou.

CBEC is a regulatory environment where products are imported to China to a bonded warehouse and then directly sold to China-based caregivers online. Products participating in this system are required to comply with the standards applying in the exporting country.

Products sold via Daigou are typically purchased in retail environments (off the shelf in supermarkets and pharmacies in Australia and New Zealand) and therefore comply with the standards in the relevant jurisdiction.

6.5.1.4 *Finished products manufactured exclusively for export*

Some infant formula products manufactured in Australia and New Zealand are produced exclusively for overseas markets.

In New Zealand, infant formula products that are manufactured for export (excluding to Australia) must comply with New Zealand standards (i.e. the standards analysed in this DRIS) and also meet requirements set by the *Animal Products Act 1999*.

Stakeholders have noted that complying with these requirements is time-consuming and costly and limits these products from being sold into the domestic market where necessary.⁷³

The Act sets additional requirements for exported products (to maintain the reputation of the industry in export markets and enable access to certain markets) and requirements for how the products must be labelled where products are not labelled in accordance with the standards.

In Australia, businesses must get approval to export infant formula products and comply with the export control rules for milk products (unless exported to New Zealand).⁷⁴ The export control rules only require compliance with a small number of specific elements in the Code (for example, contaminant levels). Other general requirements also apply, such as a requirement that the food is safe to consume and labelling requirements (including a description of the product, country of origin and ingredients).

⁷⁰ New Zealand Food and Grocery Council submission to the 2nd CFS; includes exports to Australia.

⁷¹ Excludes exports to New Zealand. Department of Agriculture, Fisheries and Forestry – [Australian agriculture trade – reference tables](#) (January, 2024).

⁷² This data excludes exports to New Zealand. Data for the year-to-November 2023, on a volume basis. Source: Department of Agriculture, Fisheries and Forestry – [Australian agriculture trade – reference tables](#) (January, 2024).

⁷³ Labelling requirements are set by the Animal Products Act Notice for Infant Formula Labelling.

⁷⁴ Export Control (Milk and Milk Products) Rules 2021.

Products that do not meet these requirements cannot be exported. They must also meet the requirements of the importing jurisdiction.

6.5.1.5 Infant formula product retailers

Products sold at retail are either produced in Australia and New Zealand (as described above), or imported.

Infant formula products are typically purchased at supermarkets, but also have significant sales in pharmacies. Sales can also be made through other channels, such as directly from the manufacturer's website.

Most infant formula products are sold at supermarkets. In the year to May 2023, supermarkets sold:

- Over 9 million infant formula products in Australia (approximately 65% of all sales)
- Just under 3 million infant formula products in New Zealand (approximately 90% of all sales)⁷⁵.

They are also sold in pharmacies (either with or without a prescription) and can also be provided in other healthcare settings. In the year to May 2023, pharmacies sold:

- over 5 million infant formula products in Australia (approximately 35% of all sales)
- approximately 200,000 infant formula products in New Zealand (approximately 10% of all sales)⁷⁶

6.6 Infant formula industry benefits

6.6.1 Greater alignment with international standards, lowering costs

Industry is expected to benefit from greater alignment with international infant formula product regulations.

The proposed amendments for infant formula product standards achieves much greater alignment with Codex Alimentarius standards than the current standards. As discussed in section 2.2, Codex Alimentarius develops international food standards which support cross-jurisdictional trade (while also protecting the health of caregivers).

The following tables show the extent of alignment to Codex under the current standards and the proposed standards. The table uses the term 'permissions' to refer to a broad collection of regulatory permissions relating to infant formula composition, including energy (kJ) ranges and values for macronutrients and micronutrients (which can be minimums, maximums or ranges depending on the micronutrient).⁷⁷

⁷⁵ IQVIA report; this data does not include highly specialised infant formula products.

⁷⁶ IQVIA report; this data does not include highly specialised infant formula products.

⁷⁷ The Approval Report contains a complete table outlining the current and proposed permissions.

Table 6-4 Greater alignment to Codex – infant formula

	Current standards	Proposed standards
Number of permissions changed to match Codex		+25
Total number of permissions aligned to Codex	30	55
Total number of permissions	68	67
Proportion of permissions aligned to Codex	44%	82%

Note: The total number of permissions is lower in the proposed standards, due to removal of out of date nutrient ratios.

Table 6-5 Greater alignment to Codex – follow-on formula

	Current standards	Proposed standards
Number of permissions changed to match Codex		+24
Total number of permissions aligned to Codex	31	55
Total number of permissions	68	67
Proportion of permissions aligned to Codex	46%	82%

Note: The total number of permissions is lower in the proposed standards, due to removal of out of date nutrient ratios.

FSANZ considers that the composition of infant formula and follow-on formula should only vary where there is adequate scientific evidence that demonstrates a different nutrient requirement between the age groups in Australian and New Zealand populations. Where the permissions for follow-on formula do not align with the Codex Draft Standard for Follow-on-Formula, they are aligned with the permissions for infant formula within the proposed standards.

The benefit of full international alignment is attributed to industry’s ability to produce one base powder for multiple markets. Production of base powders through recipe development and testing is one of the most costly activities for manufacturers when producing infant formula products. In the future this efficiency will save manufacturers time and costs.

Greater alignment will reduce costs involved in product development as there will be fewer differences between infant formula product compositions for the Australia and New Zealand market and overseas markets. However, as there are still some differences, the benefit of full alignment is not realised.

6.6.2 Increased regulatory certainty

It is also expected that businesses would benefit from the increased regulatory certainty under the new standards, including greater certainty about:

- permitted additives and contaminants
- clarifications about conditions for permitted novel foods in Schedule 25
- definitions of SMPPi vs other infant formula products
- the content and format of nutrition and ingredient information declared on the label and
- other aspects of the proposed changes that improve regulatory certainty.

Increased regulatory certainty is likely to result in more investment into the infant formula industry. In general terms, regulatory uncertainty is an investment risk and as risk increases the investment required to cover the risk increases. This can make some investments commercially unviable, resulting in an opportunity cost.

Regulatory certainty is important in the infant formula industry. There can be long time periods between investment decisions and project completion (the time where returns on investment start). These long time periods are due to:

- parts of the supply chain being capital intensive⁷⁸
- a complex global supply chain, where a number of complex and interconnected factors increases decision making complexity and time.

Greater investment may result in:

- businesses entering the industry and making a return on investment
- existing businesses investing in new projects (for example, to produce new product lines, expand capacity, increase efficiency) and making a return on investment.

These investments into the industry will benefit caregivers, for example through more product choice or lower-priced products.

The benefit of this to industry has not been quantified. Quantifying the benefit would require detailed modelling—FSANZ is not aware of any such models.

⁷⁸ As an example – the capital investment required to produce infant formula products from raw milk includes chillers, mixers, ingredient storage systems, evaporators, spray dryers and other pieces of equipment. Other businesses within the industry also have capital costs, like ingredient manufacturers and dairy farmers.

6.7 Infant formula industry costs

This section discusses the impacts on the infant formula industry.

In summary, the expected cost impacts on industry are:

- quantifiable:
 - reformulation - A\$44m one off cost
 - relabelling - A\$2–4m one off cost
- unquantifiable:
 - cost of restriction of sale of SMPPi to pharmacies and other responsible institutions (potential lost sales for supermarkets and potential withdrawal of some products).

These costs are explored in detail in the following sections.

6.7.1 Reformulation costs

Industry will incur costs to reformulate impacted infant formula products to meet the new standards. The total cost to reformulate is estimated to be A\$44m. This is a one off cost. For more information on how this is calculated, refer to Appendix A.

The cost estimate is based on information provided by industry, both in response to FSANZ consultation processes and meetings with industry.

FSANZ has taken a conservative approach to estimating the reformulation costs creating an estimate that is unlikely to be an underestimate.

6.7.1.1 Transition time may reduce reformulation costs

Because FSANZ has allowed for a long transition time, industry may be able to reformulate infant formula products to comply with the amended standards at the same time they are reformulating for other commercial purposes. Where this occurs, the cost of compliance is shared with the commercial investment in reformulation, which reduces the compliance cost.

Industry reported in consultation that some products are not frequently reformulated, particularly lower-cost products or certain brands that are designed to maintain a consistent recipe over time.

6.7.1.2 All infant formula products will need reformulating

All infant formula and follow-on formula SKU lines will need to be reformulated, which industry confirmed in consultation.

Less-specialised SMPPi (those marketed to treat conditions such as regurgitation, etc) will have to be reformulated to meet the new compositional requirements.

Highly specialised-SMPPi are assumed to not be impacted by the changes.

6.7.1.3 What drives the cost of reformulation

Reformulating infant formula products generally involves the following steps:

1. Raw material qualification
2. Specification set-up
3. Production trials
4. Quality testing

5. Shelf-life testing programs
6. Setting scoop sizes
7. Preparing implementation documentation.

The above changes will need to be done for:

- base powders
- pre-mixes
- final products.

Base powders and pre-mixes can be used across multiple products therefore they cannot be changed in isolation. Therefore, when reformulating, the impact on the entire product range needs to be considered.

Multinational producers and domestic producers are expected to be impacted by similar reformulation costs. While multinational producers may experience economies of scale that would result in lower reformulation costs (relative to domestic producers), multinational companies face other costs in adapting final products and product inputs (base powders, etc) to different regulatory regimes.

6.7.1.4 Impact on other products that may share manufacturing processes

For manufacturing efficiency purposes, some manufacturers may combine aspects of the manufacturing process for infant formula products and other products like formulated supplementary foods for young children (FSFYC, often referred to as toddler milks). This may involve shared processes, ingredients or base powders.

Manufacturers will incur a direct increase in costs where the change to the infant formula standards also forces a change in the manufacturing of products not subject to the standards.

This impact has not been quantified due to a lack of information and data, however the extent of the impact is expected to be small relative to the direct impact from changes to infant formula products.

6.7.2 Relabelling costs

Industry will incur costs to update product labels.

The total relabelling cost is estimated to cost industry between A\$2–4m. This is a one-off cost. For more information on how this is calculated, refer to Appendix A.

Relabelling costs include the following activities:

- update values in the NIS as a result of reformulation
- update the format of the NIS to comply with the new standards
- update the wording of a warning statement and preparation instructions to comply with the new standards
- comply with new requirements on declaring the protein source
- remove references to other products in a product range
- remove references to 'anti-reflux' and all other conditions.

6.7.2.1 Relabelling costs for SMPPi

Highly specialised SMPPi (including PBS/Pharmac subsidised prescription products) are not likely to have to be relabelled. The proposed changes are consistent with EU regulations and the majority of SMPPi are imported to Australia and New Zealand from the EU. The labelling requirements are also sufficiently flexible so that the supply of SMPPi imported from other places such as the United States will be unaffected.

Other SMPPi will need to be relabelled. This includes products designed for:

- reflux and regurgitation
- colic and constipation
- sensitivity and/or intolerance
- low lactose and lactose free and some other allergy products.

These products are required to be relabelled because:

- SMPPi requirements now apply, including labelling rules that previously did not apply
- the composition of SMPPi is required to be as close to updated composition requirements for general infant formula products as possible, this will result in changes to the NIP and ingredient list.

6.7.3 Impact of restricting sale of special purpose infant formula

Under the proposed standards SMPPi can only be sold or distributed through medical practitioners, responsible institutions including pharmacies, or other permitted sellers.

Supermarkets will no longer be able to sell some products they are able to sell under the current standards (products described as for conditions such as 'reflux' and others).

The impact on retailers will be mixed and the net impact is difficult to determine.

Data provided by industry shows the number of SMPPi (as defined in the proposed standards) sold in supermarkets in the year to May 2023 was:

- 700,000 units (A\$20m in value) in Australia
- 77,000 units (NZ\$2m in value) in New Zealand⁷⁹.

The net impact for supermarkets will depend on:

- whether customers substitute products supermarkets can sell (general infant formula products)
- the relative profit margins of specialty products compared to general infant formula products.

Any sales lost by supermarkets (where caregivers do not substitute to general infant formula products) will be gained by pharmacies. Pharmacies currently sell 47% of SMPPi in Australia and 9% of SMPPi in New Zealand.⁸⁰

The net impact on the industry overall will depend on the relative profit margins of specialty products compared to general infant formula products.

Substitution to general infant formula from SMPPi will reduce sales of SMPPi. This may make some SMPPi commercially unviable, resulting in their withdrawal from the market.

⁷⁹ IQVIA report.

⁸⁰ IQVIA report, excluding sales supported by PBS (Australia) and Pharmac (New Zealand).

6.7.4 Transition costs

Submissions from industry stakeholders stated there will be costs for industry to communicate the changes to caregivers. This includes increased calls to hotlines, as well as the development and implementation of manufacturer communications to health care professionals. FSANZ expects this cost to be small.

6.7.5 Impact of reducing contaminant levels

Industry may incur costs to reduce contaminant levels of aluminium (in non-soy formula) and lead.

FSANZ understands (based on industry feedback) that most products are already compliant with the proposed limits and therefore it is likely that there will be no additional cost incurred to meet the new levels.

6.7.6 Impacts of a standardised NIS

The proposed changes introduce the requirement for a standardised NIS. The content and format of the NIS is prescribed by the standards, with a few optional inclusions.⁸¹ Industry must declare the presence of permitted nutritive substances or other permitted substances in the NIS, if used.

Currently, infant formula product manufacturers use the NIS to highlight added ingredients which are marketed as beneficial to infants. These ingredients can be sub-group nutrients (for example, 'alpha-lactalbumin' is a sub-group of protein), or nutritive substances which have no explicit permission for addition and associated declaration on the label.

FSANZ is clarifying the policy intent that nutritive substances require pre-market assessment and an explicit permission for addition to infant formula and follow-on formula before they are declared in the NIS. The clarification is made to ensure FSANZ has oversight of the safety of infant formula and whether the nutritive substance has a substantiated beneficial role in the normal growth and development of infants.

The proposed changes will change what is presented in the NIS for some products.⁸² However, industry can still highlight the addition of permitted nutritive substances and other permitted substances in the NIS.

Therefore, the changes proposed to the regulation of infant formula products do not inhibit innovation.

Instead the changes guide innovation through the FSANZ pre-market assessment process. This ensures additions to infant formula product composition or labelling are safe and suitable. As infants are a vulnerable population group it is FSANZ's continued view that the establishment and assessment of these products should be rigorous and based on significant scientific evidence.

⁸¹ For example, certain fatty acids, whey and casein may be declared voluntarily, but if so, must comply with terminology, location and formatting requirements.

⁸² The cost impact of this has been discussed and calculated in section 5.4.3.2.

6.8 Impact on market access and competition

FSANZ does not expect that the proposed changes will negatively impact access to:

- the Australian and New Zealand infant formula products market for businesses not currently in the market
- export markets for infant formula products manufactured by Australian and New Zealand businesses.

This assessment is discussed in more detail below.

6.8.1 Impact on access and competition within the Australian and New Zealand market

FSANZ does not expect that the proposed changes would result in a change in access to the Australian and New Zealand market for infant formula products. The proposed changes do not create any additional barriers to new participants entering the market. At a high level, it clarifies and modifies existing regulation.

As the impact analysis above demonstrates, the proposed changes are not expected to significantly reduce market viability. As a result, competition between manufacturers would not be significantly affected.

FSANZ expects that few (if any) products would not be able to be adapted to the new standards.

6.8.2 Market access for and competitiveness of, locally manufactured infant formula products in other markets

FSANZ's assessment is that Australian and New Zealand manufacturers of infant formula products are likely to receive a small net improvement in access to (and competitiveness within) other markets.

6.8.2.1 Which export products will be impacted by changing the standards

As described in section 6.5.1, Australian and New Zealand manufactured infant formula products are exported for sale internationally.

Changes to the standards would impact on manufacturers' access to (and competitiveness within) these markets where these export products are expected to be compliant with the standards. This expectation may be set by:

- regulations applying in New Zealand, in cases where they do apply⁸³
- the importing country, most notably under the Chinese CBEC system
- caregivers, who see compliance with FSANZ standards as sign of quality⁸⁴.

⁸³ Refer to section 6.5.1 for more information on the requirements applying to New Zealand exports of infant formula products.

⁸⁴ This includes daigou sales, where a buyer's representative (in another country) purchases products from Australia or New Zealand (either from store shelves or directly from manufacturers) and sends them back to the buyer (typically in China). Stakeholders have noted this occurs predominantly in Australia due to restrictions on mailing infant formula products that apply in New Zealand.

Note that the analysis in this section only applies to finished products made in either Australia or New Zealand that are manufactured to Standard 2.9.1. Other export products will not be impacted, for example products manufactured to meet China's Guo Biao (GB) Standards.

6.8.2.2 Impacts on export products

The impacted products compete with products that comply with different standards. These standards may be more or less stringent across a number of domains (labelling, composition, etc.).

In response to the 2nd CFS, stakeholders commented that the labelling restrictions will have a particular impact on competitiveness.

However, this competitive disadvantage exists under the status quo. Current restrictions already prevent infant formula products from making claims that can be made on products made in other international jurisdictions.

For example, products produced to EU regulations are currently expressly permitted to include a statement on the front of the pack that the product contains DHA (docosahexaenoic acid). In the United States, products can go further and state that DHA helps with eye development.

By contrast, Standard 2.9.1 does not allow DHA to be advertised on the front of pack, under the proposed changes or under the status quo.

A competitive advantage for products produced in Australia and New Zealand have is trust in the quality of the products, which is created in part by the standards they are required to meet. P1028 is designed to maintain these high standards and therefore upholds this competitive advantage.

The proposed changes are also expected to reduce costs for industry over the longer term, by better aligning the standards with international standards. This will improve the competitiveness of Australian and New Zealand products relative to their competitors.

For these reasons, FSANZ's assessment is that Australian and New Zealand manufacturers of infant formula products are likely to see a small net improvement in access to (and competitiveness within) other markets.

6.9 Government impacts

The proposed changes will impact on governments in Australia (state and federal) and New Zealand.

Improved infant health outcomes (for formula fed infants) due to improved formulations will reduce burdens on healthcare by an unquantifiable amount.

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

Longer-term certainty of monitoring and enforcement is likely to improve, including (but not limited to) greater certainty regarding:

- prohibited labelling elements
- permitted food additives
- permitted protein sources
- contaminant levels
- what constitutes SMPPi
- other substances that are or are not permitted in infant formula products unless approved through pre-market assessment.

That will lead to longer-term effectiveness and efficiency of monitoring and enforcement.

7 Conclusion of cost and benefit analysis

7.1 Benefits outweigh costs

Based on the reasons outlined above, FSANZ's view remains that the costs that would arise from the amendments proposed by FSANZ would not outweigh the direct and indirect benefits that would arise from those proposed amendments.

This conclusion is further supported by the below break-even analysis, which was performed using the quantified costs.

7.2 Break-even analysis – benefit per infant required to offset total cost

Over ten years (the assumed lifespan of the proposed regulation), it is expected that the total number of infants fed infant formula (either exclusively, or in combination with breast milk) will be.⁸⁵

- 1.9 million in Australia
- 0.5 million in New Zealand.

The quantifiable cost to industry is:

- reformulation - A\$44m one off cost
- relabelling - A\$2–4m one off cost.

In order for society (Australia and New Zealand) to break-even on the quantified costs, for each infant fed infant formula (whether exclusively or in combination with breast milk), society will need to receive a benefit of approximately A\$26 to \$27 per infant.

FSANZ considers it likely that this benefit will be achieved, given the lifelong nature of the health benefits arising from the proposed changes.

This analysis does not include any benefits realised for infants fed follow-on formula, due to a lack of data for this cohort. It does include the cost for follow-on formula products. If this consumption data were available to use in the analysis then the break-even benefit per infant would be lower.

⁸⁵ Refer to Appendix A to see how this was calculated.

This break-even analysis is based on the domestic cost of the proposal (the impact on industry participants located in Australia and New Zealand) and the number of domestic infants who benefit.

The effect of this is, while the majority of infant formula products manufactured in Australia and New Zealand are exported, the break-even analysis applies the entire cost of the proposed changes to Australian and New Zealand infants. However, if industry pass on costs to domestic caregivers it is likely that industry will pass on costs to customers in export markets.

Changing the break-even methodology to take this into account would result in a global cost per infant of approximately A\$5.⁸⁶

8 Who was consulted and how was their feedback incorporated?

This proposal has been subject to extensive consultation. This section summarises this consultation, with more information provided at Appendix B.

In summary, FSANZ has over the life of the project released:

- six consultation papers (2012 to 2021)
- the 1st CFS (2022)
- the 2nd CFS (2023).

The proposal was developed iteratively—as each consultation paper was released the proposed changes to the standards were refined. The final version of the proposed changes were developed based on comments received in response to the 2nd CFS and subsequent targeted consultations.

The high level outcomes of the 2nd CFS consultation were that:

- the review was supported by all stakeholders
- most of the proposed changes to the Code were supported
- there were some significant areas of disagreement with the proposal
- stakeholder views were often polarised—elements supported by some groups were opposed by others
- most of the comments on the impact analysis were from industry, with a significant number of comments disagreeing on the assessment of impacts arising from restricting the sale of SMPPi products.

FSANZ considered all comments and either modified the final set of proposed changes or made no change (and provided reasons for all decisions).

Below are some aspects of the proposal that stakeholders disagreed with, that resulted in FSANZ reassessing and making a change for the final set of proposed changes:

- Categorising “lactose-free” or “low lactose” products as general infant formula.
- Prohibiting statements on labels relating to ‘milk’.
- Reducing the maximum permitted level (ML) of aluminium in soy products.

⁸⁶ This is calculated based on an assumption that 80% of infant formula products manufactured in Australia and New Zealand are exported.

- Not listing sheep milk as a permitted protein source in general infant formula products.
- Maintaining permission for lactic acid producing microorganisms (LAM), for acidification purposes only.

Below are some aspects of the proposed changes that stakeholders disagreed with, that resulted in FSANZ reassessing but ultimately maintaining the proposed changes:

- Limiting the sale of SMPPi to specialised settings, including pharmacies.
- Maintaining permission for lactic acid producing microorganisms (LAM), in accordance with industry practice.
- Specifically permitting stage ('1' or '2') labelling on infant formula products, with conditions.
- No specific requirement for novel foods or nutritive substances to undergo pre-market assessment when used in infant formula products.

It must be noted that stakeholder views were not unanimous on these topics. Stakeholder views are a key part of FSANZ's assessment but decisions are also informed by scientific evidence and ministerial policy guidance.

9 What is the best option and how will it be implemented?

FSANZ considers option 2 as the best option. This section explains why. It also discusses:

- the decision making process for the changes to be adopted
- how the standards will be implemented
- the transition period for the proposed changes.

This section concludes the impact analysis for the proposed changes to the infant formula product standards.

This consideration is broader than whether the proposed changes lead to a net benefit, it also considers if stakeholders have been appropriately consulted and whether the proposed changes achieve their objectives.

9.1 Why option 2 is the best option

The best option is to make the proposed changes to the standards (option 2) and not retain status quo (option 1).

Option 2 is best (from an impact analysis perspective), because it:

- is expected to lead to a net benefit (see section 7), noting that:
 - the net benefit was not quantified
 - the break-even analysis shows society will need to receive a benefit of approximately A\$24 per infant
- has been subject to comprehensive consultation with stakeholders (see section 8)
- achieves the objectives of the proposal (see below discussion).

9.2 How option 2 achieves the objectives of the proposal

The objectives of the proposal (as defined in section 4) are:

- the protection of infant health and safety
- the provision of information to enable informed choice and ensure caregivers are not misled
- consistency with advances in scientific knowledge
- industry innovation and/or trade is not hindered.

The proposed changes to the standards achieve these objectives.

9.2.1 *Infant health and safety will be protected*

This objective had already been fully achieved, as infant formula products are required to be safe and suitable by the Food Act. However, through the proposed changes to the standards FSANZ has updated specific compositional parameters for infant formula products that better support infant health.

In addition infant health is likely to be improved as a result of:

- potential for more health advice at the point of sale for specialty products
- further reducing contaminants
- reduced risk of negative health impacts, due to clearer preparation instructions

9.2.2 *The provision of information to caregivers will be improved.*

As noted in the impact analysis, caregivers will benefit from improved information about infant formula products through clearer labels, due to:

- the improved ability to compare products through a standardised NIS
- misleading information being removed from the market.

This objective will be fully met. In developing the proposed changes, FSANZ reviewed products on the market and stakeholder feedback to determine areas where informed choices may not be possible, based on the information provided. All issues identified have been addressed through the proposed changes.

9.2.3 *Consistency with advances in scientific knowledge will be fully achieved*

This objective is achieved as a result of developing standards that achieve the first two objectives. FSANZ considered and assessed all recent and relevant scientific information when developing the proposed changes to the standards.

9.2.4 *Industry innovation and trade is not unduly hindered*

Not hindering industry innovation and trade is subject to the constraints that apply to the development of infant formula standards, such as the WHO Code, ministerial guidance and the Food Standards Code.

The proposed standards will not unduly restrict innovation.

Future innovation will be supported through clear, enforceable regulations. The proposed standards will clarify where and when pre-market assessment is required for novel foods and nutritive substances providing food businesses with a clear and tangible pathway to bring product innovations to the market.

Innovation has also been supported in some specific cases. For example, by allowing sheep milk as a protein source the proposal supports innovation funded by the New Zealand

government's Sustainable Food and Fibre Futures fund.⁸⁷

The standards (and the broader food regulatory framework) continue existing restrictions on industry innovation. These restrictions are in place to protect public health, and therefore the continued existence of these restrictions do not unduly restrict innovation.

The changes to the standard do not unduly hinder trade. Where possible, the proposed changes remove hinderances to trade. Alignment with international standards has been improved to the greatest extent possible, as outlined in the impact analysis.

As discussed in section 6.8, the proposal does not add any additional barriers to external trade. Existing differences between the infant formula standards and international infant formula standards remain (which is a barrier to trade). However these differences are maintained to achieve the public health objectives of the proposal, and therefore the continued existence of the differences do not unduly hinder trade.

As discussed at section 2.2.1, FSANZ is unable to fully align with international standards, therefore some hinderances to trade will remain.

9.3 The decision making process for the proposed changes

The FSANZ Board will make a decision to approve, amend or reject each of the variations to the Code.

All FSANZ decisions on proposals are notified to ministers (from the Commonwealth, Australian States and Territories and New Zealand) responsible for food regulation who can decide to either:

- ask for a review, or
- agree that the standard should become law.

If ministers don't seek a review, the changes are:

- registered as legislative instruments in Australia on the Federal Register of Legislative Instruments and gazetted
- issued as a food standard in New Zealand by the New Zealand Minister for Food Safety.

If a review is requested, FSANZ will review the proposal. The proposal will come back to the Board who will decide to either:

- reaffirm its decision (with or without changes to the proposal), or
- withdraw its approval (resulting in no change to the Code).

Reviewed decisions are returned to ministers for further consideration. Ministers can accept, amend or reject the draft standard.

9.4 How the proposed changes will be implemented

Successful implementation of the proposed changes to the standards is important to achieve its objectives.

This section outlines:

- FSANZ's expectation that there will be no significant challenges to implementation

⁸⁷ The specific project funded is titled – Scale up: building a regional and sustainable high-value New Zealand sheep milk industry

- implementation roles and responsibilities
- what FSANZ will do to support implementation.

9.4.1 No significant challenges to implementation expected

FSANZ does not expect there to be any significant challenges to successfully implementing the changes to the standards. This is because:

- changes to the Code are made frequently, therefore the food regulatory system is well equipped to manage changes
- stakeholders with a key role in implementation have been deeply involved in drafting the standards, therefore:
 - it is far less likely that there are issues with the standards that would prevent successful implementation
 - most stakeholders will be familiar with most aspects of the proposed changes
- there are a relatively small number of infant formula manufacturers, so risk of individual companies not being aware of the changes is minimal.

9.4.2 Implementation roles and responsibilities

FSANZ does not implement the Code. That role is undertaken by industry (in producing food and selling food in accordance with the Code) and enforcement agencies.

9.4.2.1 Infant formula industry to implement the standards

Infant formula manufacturers will lead the implementation of the standards. Once gazetted, it is expected that manufacturers will begin the process of analysing the final version of the standards and updating product recipes and labels.

Grocery retailers will also need to take action, by ceasing the sale of specialised infant formula products. Pharmacy staff may need to seek education on infant formula products.

9.4.2.2 Regulators to ensure industry are compliant with the standards

Ensuring that industry comply with the new standards is the responsibility of the food regulation agencies in New Zealand and Australian states and territories.

The responsible agencies vary in each jurisdiction. Across both countries, the bodies include:

- New Zealand government departments (imported, exported and domestically produced food)
- Australian state and territory government departments and authorities
- local government agencies responsible for monitoring and enforcement activities, including:
 - more than 530 local councils in Australia
 - 67 territorial authorities in New Zealand.

Government enforcement of the infant formula standards will be done through activities in the following areas:

- supporting compliance, including through guidance documents for industry
- monitoring and assessing compliance

- responding to non-compliance.

The extent and method of enforcement will vary between agencies. This is due to a number of factors including differences in food safety policy and legislation, the approach to food standards enforcement and resourcing.

Alternatively, these agencies could decide to act in a co-ordinated way through the joint food regulatory system. The Implementation Sub-Committee for Food Regulation (ISFR) could be used to facilitate a consistent implementation of standards by developing agreed implementation approaches and compliance materials.

9.4.3 Implementation supported by FSANZ communication

FSANZ will support implementation of the standards through various communication materials and channels. These activities support implementation by making stakeholders aware of the changes and helping them understand what they need to do or how the changes impact them.

FSANZ will communicate the changes with:

- an explanatory statement to accompany the standards, which explains the standards and their intent
- discussion in FSANZ consultation forums
- direct engagement with government agencies
- public communication materials, including:
 - a media release
 - social media posts
 - a dedicated public webpage
 - a Food Standards News article for subscribers (subscribers include industry, academics, consumer interest groups, interested members of the public)
 - specific communication materials aimed at caregivers
- support materials for healthcare professionals.

Communication materials for caregivers is particularly important for this proposal, as industry is prevented from communicating with caregivers about changes to infant formula products by the MAIF agreement.

9.5 Transition period for implementation

FSANZ is proposing a five-year transition period, which minimises the cost to industry adopting the standards, without excessively delaying resolving the problems identified.

The following factors were taken into account when deciding the transition period:

- 5 years will minimise the cost to industry
 - this is period has been informed by discussions with industry on the amount of time required
 - this minimises potential impacts on caregivers in terms of product cost and availability
- a shorter period will not lead to sufficient benefits to infants and their caregivers to justify the additional cost to industry

- infant formula products are already safe and suitable
- the benefits (over the status quo) are incremental
- stakeholder comments to the 2nd CFS.

These factors are discussed in more detail below.

More information on the consideration of the transition period is provided in section 7 of the approval report.

9.5.1 A five year transition period is proposed

FSANZ is proposing for the draft variation to take effect on the date of gazettal, with a five year transition period.

During the five year transition period, infant formula products can comply with either

- the standards as in force as if the variation had not taken effect, or
- the standards as amended by the variation.

After the transition period, all infant formula products available in the Australia and New Zealand market must comply with the new standards.

9.5.2 A five year transition period resolves problems as soon as is cost efficient

The transition period proposed is designed to minimise the cost of adjusting to the new standards, without excessively delaying resolving the problems identified.

Infant formula products produced under the current standards are safe and suitable, therefore there is no benefit to caregivers from reducing the transition time to be shorter than is cost-efficient.

For this reason, the transition period is based on FSANZ's understanding of the time industry will require to achieve compliance at minimum cost. This understanding was developed by FSANZ in one-on-one meetings with industry and tested at consultation.

A five year transition period allows for:

- three years for industry to update all products and achieve compliance with the new standards⁸⁸
- two additional years for old stock (not compliant with new standards) to be sold, based on a shelf-life of up to two years for some products.

The five year period reflects the scale of the transition task for industry:

- all infant formula and follow-on formula are impacted, as are some SMPPi (SMPPi products already on the PBS are not expected to be impacted)
 - five years allows industry to progressively change products to meet the standards
 - successfully reformulating products requires specialised capabilities
 - there is not likely to be enough specialists to reformulate every product at the same time

⁸⁸ Refer to the impact analysis section for activities that industry will need to undertake within the 36 months.

- reformulating infant formula products is complex
 - some ingredients perform multiple functions, modifying how much of these ingredients are used impacts on other parts of the recipe.

Manufacturers can take up to five years to achieve compliance with the standards. There is no stock-in-trade period, at the end of the five years products that do not comply with the new standard cannot be sold. Manufacturers who take more than three years will need to manage the risk of some products not being sold before the end of their shelf-life and the transition period.

Compliance will be assessed on an individual product basis. During the five year period products will be expected to fully comply with either the existing standard or the proposed standard. It will be possible for manufacturers to progressively update products within their range, producing some of their products to the existing standards and the remainder to the proposed standards.

For general retailers (like supermarkets) the restriction of sale applies to all products in the new SMPPi category. Therefore, the restriction of sale will apply gradually to general retailers, in accordance with manufacturers' reformulation schedules. Retailers can decide to end sales of specialised products at any time.

No retailer (including supermarkets or pharmacies) can sell any products manufactured to meet the old standard at the end of the transition period.

For caregivers, the five year transition period would minimise any potential cost increase passed on from industry and minimise the delay to receiving optimum nutrition and provision of information.

Caregivers may experience some confusion during the transition period if they are not aware of the changes. This is because the transition period allows products to be sold that comply with either the existing standards or the proposed standards. This could mean that two similar products (one complying with the old standard and the other complying with the new) could be sold at the same time.

9.5.3 Mixed stakeholder views on the five year transition period

Stakeholder views on the transition period were mixed. FSANZ proposed the five year transition period in the 2nd CFS.

The following is a summary of selected comments that demonstrate the different views on the proposed transition period. The views of other stakeholders not mentioned here can be found at appendix 3 of the approval report.

The majority industry respondents preferred a transition period of five years, plus an additional two years for stock-in-trade.

INC stated that their proposed transition arrangement "will reduce cost of change and smooth the impact for caregivers." However, the submission did not provide detail or evidence of how this time period would minimise costs, relative to the five years proposed.

Conversely, some government health agencies thought the five year period is too long.

Reasons for this view included that the transition period proposed will:

- create an unnecessarily extended period of regulatory cross-over and may cause confusion or uncertainty among caregivers, medical professionals and regulators
- there may be significant advancements in infant formula products over this time where the revised standard is no longer fit for purpose by the time it takes full effect.

Some alternative suggestions for a shorter period included:

- three years to achieve compliance, with a two year allowance to sell through existing stock (removing the flexibility resulting in more products complying sooner)
- a flexible transition period that is no more than three to four years.

Some stakeholders supported the five year period, this included one manufacturer and one government stakeholder.

FSANZ has considered the views of all stakeholders, however has decided to maintain a five year transition period (as initially proposed at the 2nd CFS).

FSANZ recognises the concerns about the length of the transition period proposed, however the negative impacts raised about a shorter period are not likely to outweigh the cost impact to industry (and caregivers if costs are passed through) of a shorter period. No evidence was provided to show that the cost of the transition period proposed is significantly different to longer period (as proposed by industry).

10 How will the changes to the standards be evaluated?

The primary responsibility for actively monitoring and evaluating food standards lies with the jurisdictional governments that have adopted the Code.

Jurisdictions develop the policy principles for food standards, including infant formula standards.⁸⁹ Therefore it is appropriate that they have responsibility for reviewing the outcomes of the standards against their policy principles.

Agencies with responsibility for food policy could act alone to evaluate or monitor the standards, or agencies could act jointly through the Food Regulation Standing Committee (FRSC).⁹⁰ FRSC provides advice to food ministers on food regulation issues, which can then result in FSANZ taking action.

An example of this where (in 2017) food ministers noted the number of foodborne illness outbreaks in Australia. A working group was formed, with members drawn from FRSC and Implementation Subcommittee for Food Regulation (ISFR). This working group evaluated the performance of the entire regulatory system (including the Code) in preventing foodborne illness. In response FSANZ created a proposal (P1053).

Non-food-policy entities within governments can also play a role in evaluation and monitoring food standards. These entities have the data required for evaluating the performance of the standards within their jurisdiction. They also have direct experience using the standards to take enforcement action. These entities include food inspection and enforcement agencies, hospitals, healthcare bodies, or poisons hotlines.

An example of this is the NSW Food Authority which conducted an allergen survey in 2018. This survey evaluated the performance of the Code in providing caregivers with clear and understandable information on the presence of allergens in food.⁹¹ The evaluation was used as evidence within a proposal for plain English allergen labelling (P1044).

⁸⁹ For example, the [Policy guideline on infant formula products](#).

⁹⁰ Refer to the [Food Regulation Policy Framework](#), which tasks FRSC with evaluating the effectiveness of policy.

⁹¹ Allergen Survey – Food Authority – January 2018.

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Appendix A – Examples of how infant health is improved due to compositional changes

Some examples of the compositional changes and the benefits to infants are listed in the table below.

Table A1 Examples of improved composition and resulting health benefits for infants

Proposed change	Health benefit
<p>Prescribed protein sources in infant formula products (cow milk protein, goat milk protein, sheep milk protein, soy protein isolate and partially hydrolysed protein as a protein source⁹²)</p>	<p>The Code has not previously prescribed the protein sources that may be used in infant formula products. There is a trend towards alternative proteins being used in food products, including infant formula products.</p> <p>This prescription mitigates potential health and safety risks by ensuring that the protein used in infant formula products is nutritionally adequate as well as being safe for vulnerable infants. Protein sources not prescribed, such as some plant proteins, have limited health evidence available and no demonstrated safe history of use.</p> <p>Some protein sources do not have an adequate amino acid profile to support infant health and growth and can pose an allergenic risk. Some may contain anti-nutrient factors that can interfere with nutrient absorption.</p> <p>Therefore, prescribing protein sources minimises health and safety risks to infants.</p>
<p>Limits on carbohydrate source (sucrose and fructose) in infant formula products</p>	<p>The carbohydrate source is not specified in the standard, however limits on the type of carbohydrate have been included to reflect that certain carbohydrates should not make up essential composition for infant formula products.</p> <p>The basis for the restriction is to limit potential adverse effects of sucrose and fructose for infants with hereditary fructose intolerance.</p>
<p>Move low-lactose and lactose-free from infant formula and follow on formula to SMPPi</p>	<p>Low lactose and lactose free products are often purchased with an assumption that the infant is lactose intolerant, however this condition is extremely rare in infants (Heyman 2006, TRCHM 2018, Mattar 2012).</p> <p>Elimination of lactose when not necessary is disadvantageous for the development of gut microbiome (Di Costanzo, 2019).</p> <p>Therefore, FSANZ has moved these products to the SMPPi category where they are subject to sale restrictions.</p> <p>This optimises population health by increasing the likelihood that the products are only used by those genuinely in need.</p>

⁹² Manufacturers will be able to use other protein sources where they submit an application to vary the standards to allow the other protein source and FSANZ approves the application after assessing the other protein source as safe and suitable.

Proposed change	Health benefit
Addition of choline to infant formula changed from optional to mandatory	<p>Choline is required for cell membrane biosynthesis and is essential for tissue growth and neurodevelopment.</p> <p>Since 2016 choline has been classed as an essential nutrient in the NHMRC's nutrient reference values (NRV).</p>
Addition of myo-inositol to infant formula changed from optional to mandatory	<p>Inositol has a role in transmembrane receptor signalling and lipid synthesis. Studies have concluded that there is a high myo-inositol (the form predominantly present in human tissue) content in breast milk and it plays a role in infant lung maturation and surfactant synthesis (Cavalli et al. 2006; Brown et al. 2008; Howlett et al. 2012).</p> <p>An EFSA 2014 review stated it was uncertain whether infants have the capacity to synthesise adequate endogenous inositol.</p> <p>Mandating myo-inositol ensures all formula-fed infants receive adequate amounts to aid in achieving the above developmental benefits.</p>
Addition of L-carnitine to infant formula changed from optional to mandatory	<p>Carnitine has a role in lipid metabolism and is considered as conditionally essential for infants, mainly because they may lack the developmental maturity for endogenous synthesis (Coombes, 2008).</p> <p>It supports the breakdown and storage of fat as energy and will improve the synthesis of other lipids that are used for structural functions such as cell membranes.</p>
Increased minimum and maximum requirements for iodine in infant formula products	<p>Iodine is vital for brain and nervous system development. It assists with the development of coordination, alertness and the five senses of sight, hearing, smell, taste and touch. A higher iodine minimum reduces the risk of iodine deficiency and underdevelopment.</p> <p>The revised minimum and maximum better align with Codex levels which were derived from the average breast milk iodine concentration and the amount of iodine needed to meet iodine reference intakes. Therefore, the new minimum and maximum levels will contribute to reducing the risk of iodine deficiency resulting in underdevelopment.</p>

Appendix B – Detailed discussion of consultation

This Appendix provides more detail on the consultation undertaken for this proposal.

This proposal has been subject to extensive consultation. It was incrementally developed over a number of consultation rounds.

The response to a number of issues was decided in early consultation rounds, particularly where there was unanimous stakeholder support.

In addition to the early consultation, there has also been statutory consultation. The proposal was assessed under FSANZ's major procedure (as described by the FSANZ Act), which requires two rounds of statutory public consultation.

This section provides information about the consultation rounds, including:

- details about the consultation rounds, which include:
 - six consultation papers (2012 to 2021)
 - the 1st CFS (2022)
 - the 2nd CFS (2023) – the final consultation round
- information about the 2nd CFS consultation outcomes, including
 - who responded
 - general summary of stakeholder views
 - the polarised nature of stakeholder views
 - elements of the proposed changes that were changed in response to stakeholder comments
 - elements of the proposed changes that were not amended, despite stakeholder comments.

This Appendix is just a summary of the consultation process for the DRIS. FSANZ has developed a webpage for P1028, which contains all consultation papers and all responses to them. The Approval Report contains a summary of all comments made on the 2nd CFS and FSANZ's responses.

Early consultation (from 2012 to 2021) identified issues

The proposed changes are a culmination of many years of consultation. Prior to the first statutory consultation, FSANZ released 6 consultation papers and analysed submissions to them.

This includes consultation on:

- A preliminary review of the standards (2012)
- A preliminary assessment of the standards applying to general infant formula (2016)
 - the issues assessed in this paper were partly guided by comments on the preliminary review in 2012
- A preliminary assessment of the standards relating specifically to infant formula products for special dietary use (IFPSDU)(2017)
 - FSANZ performed this consultation in response to stakeholder feedback on the 2016 consultation process

- A series of three consultation papers were released in 2021 to discuss potential regulatory options to manage risks assessed above. These papers discussed:
 - Safety and food technology (Paper 1)
 - Nutrient composition (Paper 2)
 - Regulatory framework and definitions (Paper 3).

1st CFS – preferred options released for stakeholder feedback

In 2022 FSANZ released the 1st CFS, which detailed FSANZ’s assessment of the standards (informed by the six prior consultation rounds) and presented stakeholders with FSANZ’s preferred options for potential amendments to the standards.

The 1st CFS included:

- the evidence and stakeholder feedback that supported the preferred options
- discussion on why some stakeholder views were not adopted in putting forward the preferred options
- why in some cases the preferred option was no change to the standards, with the evidence and stakeholder feedback that supported no change.

The 1st CFS received a total of 32 submissions from industry, government, consumer groups, academics and public health stakeholders. The submissions included diverse comments and suggestions, some of which had been considered in previous consultations for P1028.

2nd CFS – draft regulation released for stakeholder feedback

Based on stakeholder submissions to the 1st CFS, FSANZ made changes to the preferred options and developed the draft food regulatory measure.

This included a full draft of the standards proposed to replace the current standards. All comments on the 1st CFS were included in the 2nd CFS, along with a response from FSANZ for each comment.⁹³

Submissions closed for the 2nd CFS on 7 July 2023.

FSANZ received 34 responses to the 2nd CFS, plus two additional late submissions.

Post 2nd CFS – how stakeholder feedback was incorporated into the final proposed changes

The final set of proposed amendments to the standards analysed in this DRIS have been informed by submissions received to the 2nd CFS. All comments on the 2nd CFS were considered by FSANZ. This section provides a summary of the consultation on the 2nd CFS and some examples of disagreements with the proposed changes.

The high level outcomes of the consultation were that:

- the review was supported by all stakeholders
- most of the proposed changes to the Code were supported
- there were some significant areas of disagreement with the proposed changes

⁹³ Note that comments received with confidential commercial information (CCI) are all considered, but only published where possible to do so without revealing in-confidence information.

- stakeholder views were often polarised—elements supported by some groups were opposed by others
- where there was disagreement, FSANZ either modified or maintained the proposed changes to the standards based on other factors of its assessment.

A complete summary is provided in the approval report and all comments (to all consultation rounds) are published on the FSANZ website.

Stakeholders and general views

The table below lists the submitters who responded to the 2nd CFS and the broad interest group they represent.

Note that the table does not include three submissions made by individuals and two CCI submissions.⁹⁴

Table A2 List of submitters who made submissions to the 2nd CFS

Submitter group	Who made the submission
Industry	Abbott Australasia Pty Ltd Australian Food And Grocery Council Dairy Companies Association of New Zealand Danone Oceania DSM Nutritional Products Asia Pacific Fonterra Co-Operative Group Limited Global Organization for EPA & DHA Omega-3s IFF (Danisco) New Zealand Infant Nutrition Council Nestlé New Zealand Food and Grocery Council Sprout Organic Synlait Milk Limited The a2 Milk Company Limited Woolworths
Government	Department of Health Western Australia Ministry of Health NZ - Public Health Agency New Zealand Food Safety NSW Food Authority Public Health Services, Department of Health, Tasmania Queensland Health South Australia Health Victorian Department of Health and Department of Energy, Environment and Climate Action
Advocacy groups (for various interests)	Allergy & Anaphylaxis Australia Breastfeeding Advocacy Australia Gene Ethics National Allergy Council
Healthcare professional bodies	Advanced Dietitians Group Dietitians Australia ASCIA Dietitians

⁹⁴ Some of the listed stakeholders also provided additional CCI submissions.

The outcomes of the 2nd CFS consultation were (at a high level):

- all submitters that responded were supportive of FSANZ reviewing infant formula product standards and updating where appropriate
- most of the proposed amendments were supported⁹⁵
- some elements of the proposed changes were not supported by some submitters, this includes:
 - major disagreements, typically related to the purpose of the amendments (examples are provided below)
 - minor disagreements, typically related to how the drafting is expressed and practical difficulties that may arise
- stakeholder views were often polarised (see below discussion)
 - elements supported by some groups were opposed by others
 - on some elements submitters were diametrically opposed on whether the proposed changes went too far, or not far enough.

Elements of the proposed changes where stakeholder views were polarised

Generally, views within each stakeholder group were aligned at a high level. However, there was variation in details between submissions. Stakeholder views were polarised on a number of topics.

All submitters agreed that breastfeeding is the preferred way to feed an infant and that infant formula products are needed to support infants who are not able to be breastfed.

Disagreements arise from achieving an appropriate balance between two aims:

- protecting breastfeeding rates
- for infants that are formula fed, creating incentives for industry to innovate to improve infant formula products and providing them at lowest cost.⁹⁶

Generally, industry stakeholders suggested the changes to the standards should be less restrictive to promote health of formula-fed infants through innovation.

The tension between the two aims arises across a number of domains. An example is comments relating to restriction on what can be represented on labels. The industry view is that labelling elements (like statements about ingredients) are required to inform caregivers⁹⁷. Other groups view some labelling elements as marketing (undermining breastfeeding rates). One stakeholder recommended infant formula products be sold in plain packaging⁹⁸.

FSANZ's position is based on an assessment of the evidence, in accordance with requirements set by the FSANZ Act and ministerial guidance. Therefore, polarised views were not an issue for the purposes of developing the final set of proposed changes. FSANZ took all comments into account and made a decision based on the guiding principles set by the requirements.

⁹⁵ Note that, due to the significant scale of the proposal, most stakeholders did not comment on the entirety of the proposal. These stakeholders commented only on areas where they had a view. In addition, a number of stakeholders referred to (and reiterated) comments they had made at previous consultation rounds.

⁹⁶ For example, refer to Danone's submission to the 2nd CFS (page 33).

⁹⁷ INC submission to 2nd CFS.

⁹⁸ Breastfeeding Advocacy Australia submission to 2nd CFS.

Significant elements of the proposed changes that were amended based on stakeholder views

The following table highlights some of the more notable amendments made to the proposed changes in response to comments received.

These examples were chosen to be presented in this DRIS because they had the potential for a negative impact (from the point of view of the commenting stakeholder) if the issue identified remained unresolved.

As previously stated, all comments on the 2nd CFS (including the below) are presented in the Approval Report, with a response from FSANZ.

The views presented in the table are not unanimous and their presence in the table does not indicate submitters were in agreement on the issue. When submitters agreed on an issue, it often was for different reasons.

Table A3 Stakeholder comments that prompted a revision of the proposed changes

Element of the proposed changes	Stakeholder views	How the proposed changes were amended
Categorising “lactose-free” or “low lactose” products as general infant formula	<p>Government and public health stakeholders stated that these products should be classified as SMPPi, for various reasons. Health impacts were the primary concerns:</p> <ul style="list-style-type: none"> • primary lactose intolerance can be a sign of a more serious condition that must be investigated⁹⁹ • the products are not safe for infants with cows’ milk protein allergies • there is no evidence that removing lactose supports normal health and development.¹⁰⁰ 	<p>FSANZ has modified the proposed changes so that lactose-free products will be considered SMPPi—products will be able to be labelled as “lactose-free” if there is no detectible lactose.</p> <p>SMPPi restrictions mean that the product will have to state what condition it is for (like cow’s milk protein allergy).</p> <p>Lactose-free products will only be sold in specialised settings, where caregivers are likely to receive medical advice which may lead to an infant receiving further care (if required).</p>

⁹⁹ Queensland Health submission to the 2nd CFS.

¹⁰⁰ Refer to the Approval report for the full list of reasons why government stakeholders did not support lactose free being classified as general infant formula.

Element of the proposed changes	Stakeholder views	How the proposed changes were amended
Prohibiting statements on labels relating to specific ingredients Example: “Contains Ingredient X”	Some industry stakeholders stated that the prohibition would restrict statements on labels like “Made from New Zealand milk”. This removes a competitive advantage for domestic products sold in international markets. ¹⁰¹ INC stated that the restriction is ‘extremely detrimental’.	The standards will permit the word ‘milk’ to appear on the product label, meaning general statements can be made about the milk in the product. Industry will continue to be able to make the statement “Made from New Zealand milk”.
Reduction in the maximum level (ML) of aluminium permitted	Some industry submissions said some soy-based infant formula product manufacturers may not be able to consistently meet the ML proposed. Manufacturers are not able to guarantee compliance, potentially resulting in these products being withdrawn from sale.	This element of the proposed changes will not apply to soy-based products; therefore the ML will remain at the current level. The intention of this change was to set MLs at a level as low as possible. Comments indicate that this ML is not possible for soy formula (at this time). FSANZ has assessed this level as adequate for ensuring products are safe.
Specifically listing what can be used as a protein source in general products: cow and goat milk, soy protein isolate	Some stakeholders did not support the standards being specific. One reason given was that it prevents sheep milk as a protein source: <i>“Sheep milk-based infant formulas are made in New Zealand exported [...]. Sheep milk formula has been available for years on the market without any issues raised”</i> ¹⁰²	FSANZ added sheep milk to the list of protein sources that can be used. This followed assessment of the composition of sheep milk, its history of safe use, acceptance and inclusion within New Zealand feeding guidance and other factors.

¹⁰¹ Stakeholders were particularly concerned about the impact on the New Zealand industry, which exports significantly more infant formula products than the Australian industry. It should be noted that under New Zealand law products exported from New Zealand must fully comply with the standards. Exemptions can be granted which would allow exported products to state “Made from New Zealand milk” but industry stated that seeking exemptions is costly and time consuming.

¹⁰² Spring Sheep Milk Co submission to 1st CFS.

Element of the proposed changes	Stakeholder views	How the proposed changes were amended
Maintaining permission for lactic acid producing microorganisms (LAM), in accordance with industry practice	<p>There are two opposing views on this issue (refer to the next table for the opposing view).</p> <p>FSANZ had initially proposed to continue to allow LAM to be added, but only for acidification purposes.</p> <p>Industry stated that removing permissions for LAM for purposes other than acidification would significantly disrupt the supply of infant formula.</p> <p>If broader permissions for LAM were removed, products would need to be reformulated, or an application would need to be submitted. A significant number of imported products would not meet the standards.</p>	<p>Noting that the permission for LAM was intended for acidification purposes only, FSANZ amended the proposed changes (resulting in the standards being left unchanged). Industry practice will be allowed to continue.</p> <p>This decision reflects an assessment that any potential benefits of changing the standards would not outweigh the costs.</p> <p>See the following table for more details.</p>

Dissenting stakeholder views that were not adopted

While some dissenting views on the proposed changes led to amendments, there were a number of cases where FSANZ did not make an amendment in response to stakeholder views.

The following table highlights some significant examples and explains FSANZ's decisions.

As previously stated, all comments on the 2nd CFS (including those below) are presented in the Approval Report, with a response from FSANZ.

The views presented in the table are not unanimous and their presence in the table does not indicate submitters were in agreement on the issue.

Table A4 Dissenting stakeholder comments that were not adopted

Element of the proposed changes	Stakeholder views	Why FSANZ did not amend the proposed changes
<p>Limiting the sale of SMPPi to specialised settings, including pharmacies</p>	<p>Industry submitters did not support this element of the proposed changes. They recommended “low risk” products should not be restricted (products for reflux etc). Reasons cited included the inconvenience to caregivers because pharmacies have limited locations and opening hours, limited product range and higher prices than supermarkets. This inconvenience would lead to negative health outcomes (including stress for the caregiver) and inequitable access in rural communities. INC stated that the restriction could lead to products being withdrawn and/or production moving offshore, resulting in lost employment.</p>	<p>FSANZ reconsidered this element of the proposed changes in detail (refer to the Approval Report). In FSANZ’s view, the impacts of the changed location of sale are minor, including on rural communities (see caregiver and infant impacts section of this DRIS). This view was formed following discussions with pharmacy groups and a review of data provided by industry. It is not expected that the total demand for infant formula products will reduce—caregivers will still buy a form of infant formula. Therefore there will be no impact on local production. FSANZ also reviewed additional studies and comments provided by other submitters in support of the restrictions. FSANZ’s view remains that the benefits to infant health are greater than the negative outcomes.</p>
<p>Maintaining permission for lactic acid producing microorganisms (LAM), in accordance with industry practice</p>	<p>There are two opposing views on this issue (refer to earlier table for the industry view). FSANZ had initially proposed to continue to allow LAM to be added, but only for acidification purposes. Government stakeholders do not support a broad permission for LAM. The general view is that the safety of LAM for purposes other than acidification has not been assessed and therefore poses a safety risk.</p>	<p>FSANZ’s reasons for not restricting LAM include: no identified safety concerns, a long history of safe use, alignment with Codex, other elements of the standards restrict use of LAM that may impact on objectives like breastfeeding rates (like labelling provisions).</p>

Element of the proposed changes	Stakeholder views	Why FSANZ did not amend the proposed changes
Specifically permitting stage ('1' or '2') labelling on infant formula products, with conditions	<p>Some submitters' preference was for the use of stage numbers to be prohibited.</p> <p>Reasons included that the practice suggests that infants have to progress through each stage¹⁰³, it enables advertising of the benefits of infant formula products on toddler milks and statements such as "for ages 6 months and under" can cause confusion.</p>	<p>FSANZ considered new evidence provided at the 2nd CFS but retained this element of the proposed changes.</p> <p>FSANZ's decision is informed by evidence that some caregivers do use the numbers to identify the correct product.</p> <p>Additionally, in FSANZ's assessment, other elements of the proposed changes resolve issues identified. This includes the requirement that infant formula products look different to other formula products and that the age statement appears with the stage label on the front of the pack.</p>
No specific requirement for novel foods or nutritive substances to undergo pre-market assessment when used in infant formula products	<p>Some government submitters were concerned that the standards did not specifically require novel foods or nutritive substances to undergo pre-market assessment when used in infant formula products. This creates a potential lack of clarity.</p> <p>They consider that the general requirement that applies for all standards "<i>leaves potential gaps for substances which may not fall within the current distinct categories</i>".¹⁰⁴</p> <p>INC stated that it appears that what is a novel food or nutritive substance is open to interpretation.</p>	<p>FSANZ view is that the Code is clear in prohibiting any substance from being added to infant formula products unless expressly permitted.</p> <p>There is a proposal (P1024) which will review arrangements for nutritive and novel substances.</p>

Comments on impact analysis at the 2nd CFS

The 2nd CFS contained impact analysis on the proposed changes (as they were defined within the 2nd CFS).¹⁰⁵ This DRIS is an updated version of the impact analysis presented at the 2nd CFS.

There were less comments on the impact analysis, relative to other 2nd CFS documents. The majority of comments were from industry.

¹⁰³ From stage 1 (the only stage for infants not exclusively breastfed to consume infant formula), to stage 2 and beyond to toddler formula (stage 3) and "growing up milk" (stage 4).

¹⁰⁴ Joint submission from the Victorian Department of Health and Department of Energy, Environment and Climate Action to the 2nd CFS.

¹⁰⁵ 2nd CFS – Supporting Document 4 – Costs and benefits

The following is a high level discussion of outcomes of the consultation on the impact analysis.

Stakeholders expressed agreement with the following aspects of the impact analysis:

- the proposed standards achieve greater harmonisation with international standards, which will benefit manufacturers
- the estimates for the quantifiable costs to industry (reformulation and relabelling costs).

There was partial support for the conclusion that benefits will outweigh costs:

- the AFGC supported the conclusion
- the NZFGC supported the conclusion, if:
 - the proposal is modified to allow statements relating to the provenance of ingredients (note: the proposed changes were modified to allow this)
- the INC (and other submissions that supported the INC¹⁰⁶) supported the conclusion, if:
 - the restricted sale provisions are removed and
 - statements relating to the provenance of ingredients are allowed (note: the proposed changes were modified to allow this).

Some comments stated that the impact of some issues had not been sufficiently considered, for example the impact of lowering the allowable level of aluminium in soy products. These concerns lead to FSANZ modifying the proposed changes, see

The most significant issue raised was the analysis of the impacts restricting the sale of SMPPi products. Most comments received were connected to this issue in some way.

The INC stated that the impacts of restricting the sale of SMPPi products had been severely understated/minimised by FSANZ.

Specifically, industry were concerned about restricting the sale of products designed for:

- reflux and anti-regurgitation
- colic and constipation
- sensitivity and/or intolerance
- allergy.

At a high level, stakeholders said that the restrictions will have the following outcomes:

- negative health effects for infants
- negative health impacts for caregivers with flow on impacts for caregivers (through panic, confusion, mental anxiety)
- a cost to industry, due to some products exiting the market.

¹⁰⁶ The following submitters supported the INC submission; Synlait Milk Limited, Danone Oceania, Dairy Companies Association of New Zealand, The a2 Milk Company Limited, Australian Food And Grocery Council, Fonterra Co-Operative Group Limited

Stakeholders stated that these outcomes would arise because:

- relative to supermarkets, pharmacies have:
 - reduced accessibility for caregivers in terms of opening hours and locations
 - have less shelf space and therefore smaller ranges
 - less warehouse space
 - less efficient logistics
- products will cost more, due to:
 - the factors listed above
 - higher prices of products under the status quo (when current pharmacy SMPPi prices are compared to supermarkets).

The INC provided a report to FSANZ, which quantified the higher selling price of SMPPi products at pharmacies under the status quo and the potential additional distance travelled by caregivers. The report also concluded that, because most SMPPi sales are concentrated in a small number of pharmacy chains, there will be significant challenges to expanding distribution of SMPPi products.

FSANZ considered these comments, however ultimately concluded that the impact of restricting sale will be minimal. This conclusion is discussed in more detail at section 6.3.6.

This consideration was partially informed by information provided by pharmacy peak bodies, a group that did not make a submission to the 2nd CFS.

Other consultation undertaken

World Trade Organization (WTO) consultation

The WTO must be notified of changes to infant formula standards, under the WTO Agreement on Technical Barriers to Trade.

The Australian and New Zealand governments both released a WTO notification in April 2023 outlining the proposed changes to the standards.

One submission was received from the United States Government.

A second notification will be made to the WTO once the amendments have been finalised, prior to the decision to adopt them in the Code.

One-on-one consultation held to discuss the final drafting of proposed standards

Prior to the final standards being submitted to the Board for decision, FSANZ held targeted consultations with stakeholders from government and industry.

The purpose of these consultations was to identify:

- instances where the content of the standards doesn't align with the regulatory intent
- instances where stakeholders may find it difficult to interpret what the standards are requiring
- any mistakes made in the drafting process, like typographical errors.

This additional consultation reduces the risk the proposal creates new problems related to a lack of clarity within the standards.

Appendix C – Detailed discussion of methodologies

Estimated numbers of infants fed infant formula

Data shows that in the ten years between 2011 and 2020 there were an average of:

- 305,000 live births per year in Australia¹⁰⁷
- 60,000 live births per year in New Zealand¹⁰⁸.

ABS Breastfeeding data (from 2022) shows that 37.5% of infants were exclusively breastfed up to 6 months of age. This means that 62.5% of infants under 6 months are fed an infant formula product at least once.

Data for New Zealand is less current. A 2008 report from the New Zealand Ministry of Health National Breastfeeding Advisory Committee found:

- 40% of infants were exclusively fed infant formula products at six months old
- 35% of infants were fed a combination of breast milk and infant formula at six months old¹⁰⁹.

Therefore, it is likely that the population of infants fed infant formula (exclusively or with breast milk) by six months of age are:

- 190,000 in Australia
- 50,000 in New Zealand.

Over ten years, it is expected that the total number of infants under 6 months fed infant formula (either exclusively, or in combination with breast milk) is expected to be:¹¹⁰

- 2.0 million in Australia
- 0.5 million in New Zealand.

Note that this estimate is specifically for infant formula, not follow-on formula, due to a lack of data.

Break-even analysis model

The break-even analysis was calculated using a model with the following parameters:

- 10 year time period, based on OIA standard assumptions that regulations have a 10 year life
- all costs occur in year 1
- benefits occur over 10 years, based on the number of infants born in that year
- a discount rate of 7%, based on OIA standard cost-benefit analysis assumptions
- the number of infants born per year is based on United Nations projections
- the proportion of infants fed infant formula is based on the percentages above, with no adjustment over the 10 years.

¹⁰⁷ Australian Bureau of Statistics data.

¹⁰⁸ Stats NZ data.

¹⁰⁹ Protecting, Promoting and Supporting Breastfeeding in New Zealand - Background report, Table 1.

¹¹⁰ Total number of projected births in Australia and New Zealand calculated using data from the UN 2022 Revision of World Population Prospects, accessed via the [UN population data portal](#).

With the above parameters, a 'goal seek' analysis was used to find the benefit per infant required for the total benefits to equal costs, factoring in the growth in number of infants born over the ten years and the discount rate.

Search method for creating a database of all infant formula products for sale in Australia and New Zealand

To determine the number of impacted products, FSANZ developed a spreadsheet to catalogue all infant formula products available for sale in Australia and New Zealand.

The data was collected in October 2023.

The search method to find the products was:

1. Record all products available for sale at a major Australian online pharmacy
2. Supplement the list with products from:
 - a. The websites of the major Australian supermarkets
 - b. The websites of other Australian pharmacy chains and independent supermarkets
3. Supplement the list with products from:
 - a. The websites of the major New Zealand supermarkets
 - b. The websites of four New Zealand pharmacy chains
4. Supplement the list with products found listed for sale on infant formula product manufacturers' websites.

At consultation for the 1st CFS, some manufacturers provided a complete list of their products. Their lists were compared to the spreadsheet and there were no missing products.

The list was also checked against a label survey performed by FSANZ staff.

Cost to reformulate impacted products

Number of impacted final product recipes

As discussed above, FSANZ has conducted an online search of infant formula products sold in Australia and New Zealand.

The below table shows the total number of products identified for general sale in October 2023 that would need to be reformulated to comply with the new standards. It excludes different packaging for the same product, i.e. sachets.

The total number has been increased by 50%, to account for any products for sale that weren't identified in our online search and products made to comply with the standards but not sold in Australia or New Zealand.

This represents the number of final product recipes that will need changing.

It has been assumed that special formula products for higher-risk conditions will not require any reformulation under the proposed changes.

Table A5 Number of products requiring reformulation

	Number of product recipes impacted				
	Aus and NZ market	Australian market only	New Zealand market only	Total (both markets)	Plus 50%
Infant formula and follow-on formula	31	80	18	129	194
Impacted SMPPi products	5	13	1	19	29
Total impacted	36	93	19	148	222

In the 2nd CFS the number of products requiring reformulation was estimated to be 200. The 2nd CFS asked submitters if they agreed with the number of SKU estimated. No direct feedback was received on the number of SKU, however industry supported the total estimated cost (which was calculated using the total SKU number).

The estimated number of impacted products is greater for this DRIS due to a net increase in products on the market.

Cost per product

The 2nd CFS assumed a reformulation cost of A\$200,000 per product. A number of submitters supported these estimations. A further submitter noted that their cost to reformulate would be higher but supported this cost as a general indication.

On this basis, the DRIS uses a cost per product of A\$200,000.

Total industry-wide reformulation costs

The total cost of reformulation is estimated to be A\$44m. This is based on the above number of SKU multiplied by the cost per product.

Cost to relabel products

Number of impacted SKUs

The below table shows the total number of products identified for general sale in October 2023 that would need to be relabelled to comply with the new standards. It includes different packaging for the same product, i.e. sachets.

The total number has been increased by 50%, to account for any products for sale that weren't identified in our online search and products made to comply with the standards but not sold in Australia or New Zealand.

This table is based on the list of products developed by FSANZ, using the methodology discussed earlier in this Appendix.

This represents the number of final product packets that will need to change. It has been assumed that special formula products for higher-risk conditions will not require any label changes under the proposed changes.

Table A6 Number of products requiring relabelling

	Number of SKU				
	Aus and NZ market	Australian market only	New Zealand market only	Total (both markets)	Plus 50%
Infant formula and follow-on formula	34	86	20	140	210
Impacted SMPPi products	5	13	1	19	29
Total impacted SKU	39	99	21	159	239

In the 2nd CFS the number of products requiring relabelling was estimated to be 209. The 2nd CFS asked submitters if they agreed with the number of SKU estimated. No direct feedback was received on the number of SKU, however industry supported the total cost (which was calculated using the total SKU number).

The number of impacted products is greater for this DRIS due to a net increase in products on the market.

Cost per impacted product

Cost used in the 2nd CFS

The 2nd CFS assumed a relabelling cost per product of A\$16,000. This represented a mid-point for the data received in response to the 1st CFS.

Marsden Jacob Associates relabel cost model

Separate to work on P1028, FSANZ had contracted Marsden Jacob Associates to survey businesses on the cost of changing labels for various products, including infant formula products. FSANZ received the final survey results after the 2nd CFS had been released for comment.

The survey shows that the cost of relabelling infant formula products depends on the packaging type. Listed below are infant formula packaging types and the cost to update their labels:

- Box of sachets - A\$9,700
- Tins - A\$9,200
- Pouch – A\$8,400
- Box - A\$4,100

These estimates are indicative averages only. Label change costs of an individual SKU may be notably less or more than the average for their pack type, depending on printing technologies used, size of available label space and other factors.

Total industry-wide relabelling cost

The total cost to the infant formula industry to relabel products has been estimated at A\$2–4m. This represents a range between the cost used at the 2nd CFS and the costs as estimated by the Marsden Jacob Associates model.

Using a range reflects the diverse views of industry stakeholders on the potential costs, including respondents to the Marsden Jacob Associates survey.

The cost is a one-off cost for products already on the market to meet the new standards.

This cost includes (but is not limited to):

- administration activities, including internal company discussions and approvals
- label redesign
- market testing.

It has been assumed that:

- all necessary label changes only need to be done once for each product line, i.e. reformulation and labelling are not done repeatedly
- the transition period is adequate to change labels and to run down stocks of packaging and labels.

In addition to this, stakeholders raised the potential for be write-off costs for existing stock of labelling. This will occur when a business switches to the reformulated product and is unable to continue using existing labels that no longer reflect the contents of the can. As discussed in the implementation section, manufacturers are likely to phase updating products to meet the new standards. This means that some labels may be printed for products complying with the old standards after the new standards commence.

This cost is un-quantifiable, as the cost is dependent on the ability of the project manager within a company to minimise wastage through schedule management.

It is unlikely that this element of relabelling costs will be significant, because:

- industry is aware that infant formula standards will change (subject to a final decision) and FSANZ has kept industry up to date on the approximate timeframe for the standards being approved, therefore industry has been able to factor this in to their decision making
- there is a five year transition period.

Impact of increasing rates of inflation

Some industry submitters raised (in responding to the 1st CFS) that any cost impacts should take into account inflation and increasing industry costs due to supply chain constraints.

FSANZ has used the latest data available and adjusted for inflation where appropriate to ensure costs and benefits are being calculated in the same years' dollars.

It should be noted that inflation impacts on the whole economy. Therefore, while industry costs are increasing due to high inflation rates, so are other sectors of the economy like healthcare. Which means that both the costs and benefits (predominantly improved health outcomes leading to reduced healthcare costs) of the proposed changes are both subject to high inflation rates so it is appropriate to calculate cost and benefits in current years' dollars.