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

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Supporting document 4

Costs and benefits

Proposal P1028 – Infant Formula 2nd CFS

Executive summary

This Supporting Document (SD) contains impact analysis for P1028. The SD:

- discusses the problems associated with Standard 2.9.1
- establishes why government action is required to address the problems identified
- provides a high level summary of all the proposed changes to Standard 2.9.1 as well as consequential amendments to other parts of the Australia New Zealand Food Standards Code (the Code)
- analyses the costs and benefits of the proposed changes
- provides a conclusion on whether there is a net benefit to the proposed changes
- includes questions to stakeholders that are designed to improve the cost benefit analysis
- discusses consultation undertaken to date
- responds to stakeholder feedback on the 1st CFS relating to costs and benefits.

The impact analysis finds that although the standards for infant formula products are, overall, functioning adequately, there is scope to make improvements.

FSANZ expects that the proposed changes to the Code (as described in section 4.2) 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).

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1. Introduction

1.1. Infant formula products Standard

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).

Standard 2.9.1 covers infant formula products including:

- infant formula, for use from new born 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).

These products may be in powder, liquid concentrate or 'ready to drink' form. Toddler milks (designed for children 1 to 3 years), which are regulated under Standard 2.9.3, are not included in this proposal.

The 2nd CFS notes that the definitions for infant formula, follow-on formula and infant formula products have been slightly modified to ensure products represent themselves correctly. The proposed draft variation revokes the term IFPSDU and instead defines specialised infant formula products as a new category called Special Medical Purpose Products for infants (SMPPi).

This SD will use SMPPi when referring to specialised infant formula products unless referring to current regulatory requirements.

1.2. Purpose of the infant formula products Standard

The protection of public health and safety is a primary objective for the Code, including the infant formula products Standard. Infant formula products must be safe for formula-fed infants to consume, and the nutrient composition must support normal growth and development when infant formula is used as the sole or principal source of nutrition up to 12 months of age.

1.3. Purpose of this document

Food Standards Australia New Zealand (FSANZ) has reviewed the Standard under Proposal P1028 – Infant formula.

A proposed set of new regulations has been developed, which are discussed in detail in the 2nd Call for Submissions (CFS).

This Supporting Document (SD) has been developed to accompany the 2nd CFS and focuses on issues related to the costs and benefits of the Proposal.

1.4. Exemption from CRIS requirements

The Office of Impact Analysis (OIA) has exempted FSANZ from the need to prepare a Consultation Regulation Impact Statement (CRIS) in relation to the regulatory change proposed. [1]

A CRIS is not required because the function of the CRIS has been achieved by an appropriate alternative mechanism. This includes the statutory consultation under the FSANZ

[1] The Office of Impact Analysis (OIA) was formerly known as the Office of Best Practice Regulation (OBPR). To review the exemption, refer to the OIA website under reference number 25089

Act for the 1st CFS and this 2nd CFS. FSANZ also undertook ongoing consultation prior to the development of the 1st CFS.

While a formal CRIS has not been prepared, SD4 has been drafted in the same format as a CRIS with each of the seven RIS questions answered.

1.5. Assessment of costs and benefits under the FSANZ Act

In assessing this Proposal and in making its decision to prepare the proposed amendments to the Code, FSANZ was required by the FSANZ Act to have regard to, among other things, whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure. In doing so, it had to have regard to submissions received in response to the first Call for Submissions.

As explained, FSANZ has decided to prepare a set of proposed amendments to the Code in relation to infant formula products.

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 SD sets out the reasons for that assessment.

The assessment was and is based on the best available information at the time the decision was made to prepare the proposed amendments. That information included information provided in submissions received in response to the first Call for Submissions.

FSANZ is now seeking submissions in relation to the proposed amendments, including its conclusion that the costs arising from those amendments will not outweigh their direct or indirect benefits.

Submissions received will inform FSANZ's decision whether to approve, amend or reject the proposed amendments. While FSANZ's decisions and assessments to date have been based on the best available evidence, FSANZ is aware that data gaps remain.

1.6. Development of a Decision RIS

Feedback will also inform the Decision Regulation Impact Statement (DRIS) that will be prepared and presented to Ministers ahead of the FSANZ Board's consideration on the changes presented in this 2nd CFS.

The DRIS will be based on the analyses presented in SD4, updated based on stakeholder feedback.

Challenges exist around qualification of a number of costs and benefits and the analysis by necessity relies on several assumptions. These gaps, challenges in relation to quantification and assumptions are identified for further stakeholder feedback prior to a decision on whether to approve, amend or reject the proposed amendments.

Feedback, including answers to the specific questions asked, will help inform the decision. [2]

2. What is the problem?

The overarching purpose of this Proposal is to address a series of regulatory problems with current standards for infant formula products, and to provide clarity where there is uncertainty about the intent of the relevant standards.

[2] Refer to Appendix A for the full list of questions

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 in the Code are regarded as:

- out-of-date with current scientific knowledge for some issues
- not harmonised with international and overseas regulations
- difficult to interpret in some respects.

2.1. Current standards out of date with current scientific knowledge

Standard 2.9.1 was gazetted in 2002. In the years following, a series of consequential amendments have been made, however, a complete review of the mandatory composition requirements has not been undertaken.

Minor changes have also been made through successful applications to FSANZ, permitting additional optional substances such as lutein, inulin-type fructans and galacto-oligosaccharides and review of other substance requirements such as Medium Chain Triglycerides and minimum protein in follow-on formula.

Scientific knowledge of infant formula products and the needs of infants has continued to improve. Part of this proposal therefore involves more comprehensively updating the Standard so that it is consistent with latest scientific knowledge, potentially leading to better outcomes for formula fed infants.

2.2. Improving harmonisation with international and overseas regulations

Infant formula is a globally traded product, therefore differences in regulation between jurisdictions increase the cost to trade goods between jurisdictions. These costs impact both consumers (in terms of product availability and cost of infant formula products) and industry.

In developing standards relating to infant formula products, FSANZ must have regard to: [3]

- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry.

Two major international sets of standards are the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex CXS 72-1981) and the European regulation on compositional and information requirements for infant formula and follow-on formula (EU 2016/127).

The Codex CXS 72-1981 is intended to guide and promote the establishment and elaboration of definitions and requirements for foods in national food law, to assist international harmonisation and facilitate international trade.

Codex Alimentarius and the European Union have been updated more recently based on the latest scientific data presented above. Therefore, the difference between the standards is increasing.

The proposed updates to the Standard bring it closer to international standards. However, some differences will remain to reflect the unique circumstances in Australian and New Zealand.

[3] Ministerial policy guideline on infant formula products (2011)

2.3. Parts of the current Standard are difficult to interpret

Stakeholder feedback has indicated that parts of the Standard are difficult to interpret. This includes government authorities who have reported difficulties in enforcing parts of the standard due to ambiguities in how it applies. The proposed updates to the Standard are designed to address these challenges.

To explore the problems with the Standard in more detail, refer to Supporting Documents 1 to 3 where each problem is explained in more detail.

In addition to the above identified problems, FSANZ committed to reviewing infant formula product regulations after receiving policy guidance from the then Australia New Zealand Food Regulation Ministerial Council in May 2011.3 P1028, including the changes proposed in this Supporting Document, is the result of this commitment.

3. Why is government action needed?

3.1. Infant formula products are highly regulated worldwide

Worldwide, infant formula products are subject to a higher level of regulation than other food. The regulation of breast milk substitutes, such as infant formula, has potential implications for health outcomes for all infants who may potentially consume infant formula.

Infant formula is, for many infants, their sole source of nutrition in a key development period from birth to 12 months old.

Exclusive breastfeeding is recommended for infants as evidence suggests it results in better health, nutritional and developmental outcomes (as well as health benefits for the breastfeeding mother). Exclusive breastfeeding means the infant receives only breast milk, not infant formula.

Although breastfeeding is the recommended way to feed a baby, a safe and nutritious substitute for breast milk is needed for babies who are not breastfed. Infant formula products are the only safe and suitable alternative to breast milk.

Policy advice and infant feeding guidelines (NHMRC 2012; MoH 2008) are in place to encourage breastfeeding as much as possible to improve long term health outcomes for infants.

The Code, and Standard 2.9.1 more specifically, are set to maintain FSANZ's role in regulating infant formula products and ensuring that the product is safe and suitable and the regulation continues to be fit-for-purpose and up to date with the latest science.

3.2. Infants are a vulnerable population group, development dependent nutrition

Infants are a vulnerable population group because they have immature immune systems and organs and are dependent on adults for feeding. For some infants, infant formula products may be the sole or principal source of nutrition. For this reason there is a greater level of risk to be managed compared to other population groups.

The regulatory framework for infant formula products aims to ensure that the composition of infant formula is:

- safe
- suitable for the intended use
- achieves as closely as possible the normal growth and development of exclusively breastfed infants.

The regulatory framework for infant formula products also includes labelling requirements that are commensurate with the level of risk associated with this vulnerable population group.

Labelling is intended to achieve two objectives, which are to:

- enable caregivers to safely prepare and use formula
- provide information that assists caregivers to make appropriate and informed choices, and is not misleading.

FSANZ ensures these key compositional and labelling objectives are met through the setting and maintenance of Standard 2.9.1.

3.3. Population health benefits from promoting breast milk, rather than substitutes

In 1981 the World Health Organisation released the *International Code of Marketing of Breast-milk Substitutes,* commonly known as the WHO Code, and subsequent World Health Assembly (WHA) resolutions.

The WHO Code recommends various requirements and restrictions for the marketing and distribution of breast milk substitutes for industry and health care workers. This includes restrictions on infant formula being advertised or otherwise promoted to the public, and that health care providers should not be given free or subsidised supplies of these products and must not promote these products.

Marketing is restricted in order to encourage breastfeeding as much as possible.

A significant number of jurisdictions have implemented the WHO Code. Standard 2.9.1 gives effect to relevant elements of the WHO Code in Australia and New Zealand through the Standard's composition and labelling requirements.

4. What options are being considered?

FSANZ is considering two options to address the identified problems:

1. Maintaining the status quo
2. A series of amendments to Standard 2.9.1[4]

These options are discussed in more detail below.

4.1. 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 Standard unchanged. As a result, the problems identified above will continue.

FSANZ has completed an extensive review of the Standard as part of Proposal P1028 and found that most parts of the Standard are working as intended. Therefore, in regards to these aspects of the Standard, FSANZ has decided to maintain the status quo. Detailed discussion on these aspects of the Standard (including why no change is recommended) can be found in Supporting Documents 1 to 3.

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

4.2. Option 2 – A series of amendments to the Code

As discussed in section 2, the aim of P1028 is to resolve a multitude of small problems within the Code.

Therefore, a series of amendments have been developed, and are presented as a single set of proposed changes to the regulation of infant formula products extending throughout the Code.

The most significant of these amendments would:

- Amend the categorisation of medical infant formula products (creating the SMPPi category)
- Restrict the sale of SMPPi to healthcare settings (including pharmacies)
- Update food additive permissions
- Exclude automatic food additive carry-over permissions
- Update the permitted maximum level of contaminants
- Update macronutrient permissions
- Update micronutrient permissions
- Update permissions for nutritive substances
- Standardise the nutrition information statement
- Include new requirements for stage labelling (where used)
- Prohibit the use of proxy advertising
- Update a warning statement and the directions for preparation and use of formula
- Clarify Novel Food permissions to exclude infant formula products, where there is regulatory ambiguity
- Clarify other parts of the Code.

At a high level, the proposed changes are explored in more detail below.

4.2.1. Amend the categorisation of medical infant formula products

4.2.1.1. Re-define the IFPSDU category to SMPPi

The proposal will amend the IFPSDU category within Standard 2.9.1 to include regulatory parameters prescribed for other Food for Special Medical Purposes (FSMP) prescribed in Standard 2.9.5.

The Division will be renamed *Special Medical Purpose Products for infants* (SMPPi) and will remove the specific subsections that noted differing compositional parameters for varying medical conditions, such as premature and low birthweight infants, metabolic, immunological, renal, hepatic and malabsorptive conditions and products for specific dietary use based on a protein substitute.

SMPPi will capture infant formula products that are represented as:

- being specially formulated for the dietary management of infants who have medically determined nutrient requirements (such as limited or impaired capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food)
- being as suitable to constitute either the sole or principal liquid source of nourishment where dietary management cannot medically be achieved without use of the product
- being for the dietary management of a medically diagnosed disease, disorder or condition of an infant
- intended to be used under medical supervision; and
- is not suitable for general use.

This proposed approach more clearly aligns with international regulations, the intended purpose of specialised products for infants and how other FSMP are regulated within the Code. It also retains the regulation of these products within Standard 2.9.1.

The Division introduces mandatory labelling requirements for SMPPi. This includes:

- a name or description that indicates the true nature of the food and a statement indicating the medical purpose of the food
- a statement describing the properties or characteristics which make the food appropriate for the medical purpose
- a statement to the effect that the food must be used under medical supervision.

These labelling requirements are consistent with international and overseas regulations and will ensure the continued supply of SMPPi, which are predominantly imported.

For more information on:

- the regulatory framework for SMPPi – refer to the Call for Submissions document
- nutrient composition requirements – refer to Supporting Document 2
- labelling requirements for SMPPi – refer to Supporting Document 3

4.2.1.2. Changes for partially hydrolysed formula

The proposed amendments repeal subsection 2.9.1—15 *Products for specific dietary use based on a protein substitute,* removes the definition for protein substitute and introduces new composition, labelling and sales requirements.

Products based on hydrolysed protein will have the ability to be classified as infant formula, or SMPPi depending on their intended purpose and product representation.

Partially hydrolysed formula is sometimes marketed as easier to digest and is commonly a part of the modified composition for formulas developed for babies with transient gastrointestinal conditions. At present, partially hydrolysed products are prominently marketed (typically under the name of the product on the front of the pack) as being for ‘colic’ or ‘anti-reflux’, which are prohibited health claims under the current and proposed standard.

The updated regulation proposes that infant formula may be represented as ‘partially hydrolysed’ through the protein source statement noting ‘partially hydrolysed protein’. Products that continue to be represented as formulas for colic, reflux or other conditions would need to comply with SMPPi requirements under the new regulatory framework and Division 4.

SMPPi will be subject to different compositional and labelling requirements and their sale will be restricted. The sale of SMPPi within the grocery channels will not continue.

For detailed discussion of this change refer to:

- definition of protein substitute – section 3.3 of the 2nd CFS
- labelling partially hydrolysed formula – section 8 of Supporting Document 3.

4.2.2. Restrict the sale of SMPPi to healthcare settings

FSANZ is proposing to restrict the sale of SMPPi to the following:

- a medical practitioner or dietitian
- a medical practice, pharmacy or responsible institution
- a majority seller of that food for special medical purposes.

The newly defined category of SMPPi products are not suitable for general use, and should be used under medical supervision. General retail channels, like supermarkets, do not

provide carers with advice on the appropriate use of these products and position medical products directly next to infant formula products for healthy babies.

The former category of IFPSDU included products such as:

- premature and low-birthweight formulas
- products for metabolic, immunological, renal, hepatic and malabsorptive conditions
- products for specific dietary use based on a protein substitute.

The sale of IFPSDU is currently spilt between supermarkets and pharmacies, with the majority of products mentioned above being sold in the pharmacy channel and require a prescription.

Products for specific dietary use based on a protein substitute typically address transient gastrointestinal conditions such as such as reflux, colic, and constipation. These formulas are currently sold in both supermarkets and pharmacies and will be largely effected by the imposed sale restriction depending on how the products are positioned and represented.

Physical categorisation of SMPPi from infant formula and follow-on formula clearly communicates the differences of the products to consumers when shopping. The sale restriction applied to SMPPi aligns with the sale restriction already prescribed in Standard 2.9.5 – Food For Special Medical Purposes.

No other medical products are permitted to be sold in the grocery channel by the Code, and as infant formula products are prescribed for the most vulnerable population the sale restriction of these products is justified.

Therefore, to improve public health outcomes, the sale of SMPPi will be restricted.

For more information on this change, refer to section 2.3.4 of the 2nd Call for Submissions.

4.2.3. Update food additive permissions for infant formula

FSANZ is proposing to update the food additive permissions for infant formula and follow-on formula. These permissions specify what can be added, and in what quantity.

Food additives perform a range of functions, including for improving taste, appearance, quality, stability and extending shelf life.

Changes to these permissions;

- ensure the safety and technological justification of use of the food additives
- align as best as possible with relevant international regulations, especially Codex standards and EU Regulations.

The protection of public health and safety is a primary objective for FSANZ in reviewing the Standard. All infant formula products must be safe for consumption by vulnerable infants so any food additives added to such products must also be safe for their proposed use.

FSANZ has also assessed the technological justification for using food additives in infant formula products to ensure their technological purpose is justified.

Reviewing existing permissions for food additives is to improve harmonisation with Codex standards and European regulations to facilitate the importation of infant formula products, especially SMPPi, which generally are not manufactured in Australia and New Zealand. It is therefore critical to ensure a continued supply of essential products for vulnerable infants as they are often the infant's sole source of nutrition.

For detailed discussion of food additives, refer to Section 3 of Supporting Document 1.

4.2.4. Removal of automatic carry-over provisions for food additives

FSANZ is proposing that the carry-over of food additives should not be permitted unless a specific permission exists for that food additive in the final food (i.e. Infant Formula Products (IFP)).

The 'carry-over principle' refers to the presence of food additives in a final food, as a result of them having been added (as permitted) to ingredients used in the production of that food. Whilst they provide a technological function in the raw materials or ingredients used to produce the final food, they do not provide a technological function in that final food.

This aligns with relevant international regulations and is consistent with the principle that food additive use should be minimised in products for infants who are a vulnerable population.

For more information see the discussion in section 3.2 of Supporting Document 1.

4.2.5. Update the permitted maximum level of contaminants

FSANZ is proposing to reduce the maximum level of toxicants aluminium and lead in IFP.

Chemical contaminants can be naturally occurring components of foods, found naturally in the environment, produced by microorganisms, or produced through industrial activities. It is not always possible to completely eliminate the presence of very low levels of contamination in foods, however risk management measures can help minimise human exposure.

Changes to these maximum levels ensure that public health is protected by keeping exposure levels as low as possible.

FSANZ is proposing to reduce the maximum limit (ML) for lead in IFP from 0.02 mg/kg by half to 0.01 mg/kg.

It is also proposing to require a single ML for aluminium in IFP of 0.5 mg/kg which includes for soy based IFP which is currently listed at twice this number.

Both these changes are for food safety reasons.

For detailed discussion on contaminants, refer to section 4 of Supporting Document 1.

4.2.6. Update macronutrient permissions

FSANZ is proposing to update macronutrient permissions for infant formula and follow-on formula. These permissions set an allowable range for macronutrients that are scientifically proven to be appropriate for infants.

The most significant changes include:

- Restricting the addition of sucrose and fructose
- Prescribing an explicit list of protein sources, specifically
  - cow milk protein
  - goat milk protein
  - sheep milk protein
  - soy protein isolate
  - partially hydrolysed protein of one or more of these specified proteins
- Updating the permitted range for protein

- Updating the permitted ranges and percentage of total fatty acids for long chain poly unsaturated fatty acids (LCPUFA).

Changes to these permissions (when taken together):
- Update permissions based on the latest scientific data
- Improve public health outcomes
- Achieve greater international alignment.

For detailed discussion of macronutrient permissions, refer to section 4 of Supporting Document 2.

4.2.7. Update micronutrient permissions

FSANZ is proposing to update the micronutrient permissions for infant formula and follow-on formula. These permissions specify the level of micronutrients that must be present in formula (for example Vitamin A, Iron, Folic acid, etc).

Changes to these permissions (when taken together):
- Update permissions based on the latest scientific data
- Improve public health outcomes
- Achieve greater international alignment.

For detailed discussion of micronutrient permissions, refer to section 5 of Supporting Document 2.

4.2.8. Update permissions for nutritive substances

FSANZ is proposing to update the requirements for nutritive substances in infant formula and follow-on formula. The changes in requirements include:
- Updated minimums, maximums and Guidelines Upper Levels (GUL)
- Updated permissions for choline, myo-inositol and L-carnitine to be mandatory additions to infant formula.

Changes to these permissions (when taken together):
- Update permissions based on the latest scientific data
- Improve public health outcomes
- Achieve greater international alignment.

For detailed discussion of nutritive substances permissions, refer to section 7 of Supporting Document 2

4.2.9. Standardise the nutrition information statement

FSANZ is proposing to prescribe the content and format of the nutrition information statement (NIS) for infant formula and follow-on formula to require:
- A tabular format with the title ‘Nutrition Information’
- Additional subheadings ‘Vitamins’, ‘Minerals’ and ‘Additional’ for both formula categories and the additional subheading ‘Other nutrients’ for infant formula only
- A prescribed order of mandatory nutrition information, including grouping nutrients and substances under subheadings
- If declared voluntarily, a prescribed order for certain sub-group nutrients
- Use of the prescribed name of nutrients and substances (except for nutritive substances and other substances which must be grouped under the subheading ‘Additional’)
- The base unit of expression “per 100 mL as reconstituted” only in the NIS

- Nutrition information to be expressed as the 'average quantity' in the NIS except for energy which is to be expressed as an average energy content.

The requirements (when taken together):

- Will assist consumer understanding of nutrition information and enable easier comparisons when making product choices
- Provide greater alignment with the regulatory approach for nutrition information panels on general foods
- Provide regulatory certainty for industry in relation to what can be declared and the prescribed format, in accordance with pre-market assessment requirements
- Provide clearer regulations for enforcement agencies.

For detailed discussion of what changes are being made to the NIS, refer to section 5 and 6 of Supporting Document 3.

4.2.10. Requirements for stage labelling

FSANZ is proposing a specific permission for the number '1' for infant formula and the number '2' for follow-on formula to be voluntarily added to the label.

Referred to as 'stage labelling', these numbers are currently used voluntarily on the majority of infant formula and follow-on formula labels.

FSANZ is setting requirements that, if used, the stage numbers must appear on the front of the package immediately adjacent to the relevant age statement for that product. This requirement will ensure stage labelling is visible to consumers when they are making purchasing decisions.

Stage labelling is used by consumers to distinguish between an infant formula and a follow-on formula and identify the correct product for their infant.

For a detailed discussion on stage labelling, refer to section 3 of Supporting Document 3.

4.2.11. Prohibit the use of proxy advertising

FSANZ is proposing to prohibit information about other products within a product range on the labels of infant formula and follow-on formula.

The intent is to ensure that infant formula and follow-on formula are distinctly labelled so consumers are not influenced by the presence of information (including a name, a number, a picture, an image, a word or words) about other products and are able to choose the appropriate product for their infants. Information about other products may suggest to consumers a progression through different age/stage products is necessary.

This prohibition is also intended to prevent permitted claims made about toddler milks appearing on infant formula and follow-on formula labels as a means of influencing purchase decisions.

FSANZ is also proposing that a food represented as infant formula or follow-on formula must not also be represented as another food.

The intent is for industry to consider other measures to differentiate products within their product range (for example, use of colour, images, words). Consumers must be able to distinguish between formula products with a product range so they can choose a product that is suitable for their infant. Products that have a similar appearance may cause confusion and

lead a consumer to purchase an incorrect product. This may pose a safety issue if the nutrient composition is unsuitable for their infant.

For a detailed discussion on proxy advertising, refer to section 9.7 of Supporting Document 3.

4.2.12. Updating a warning statement and directions for preparation and use of formula

To ensure the safety of infants fed formula, the updated standard contains a number of small changes in relation to safety labelling information that are included on the packaging of infant formula and follow-on formula.

This includes:

- A simplified warning statement that will apply to all product types (powdered, ready-to-drink and concentrated infant formula), with the prescribed wording: 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill'
- A new directions for preparation to clarify:
  - for powdered and concentrated formula—do not change proportions of [powder/concentrate] or add other food except on medical advice
  - For ready-to-drink formula—do not dilute or add other food except on medical advice
- Additional information to clarify two mandatory directions, relating to water temperature to be used when preparing powdered or concentrated formula and when to discard unfinished formula.

For a detailed discussion on directions for use and warning statements, refer to sections 1 and 2 of Supporting Document 3.

4.2.13. Other labelling related clarifications to the Code

The proposed changes also include a number of labelling related clarifications to the Code, including amendments to ensure the relevant provisions more accurately reflect the regulatory intent.

These clarifications include:

- That certain directions for preparation and use do not apply to ready-to-drink and/or concentrated formula
- For the protein source statement, the source of protein refers to the origin of protein (e.g. cow's milk) and not the protein fractions (e.g. casein and whey)
- The co-located protein source statement and the name of the food (prescribed name) must be stated on the front of a package of infant formula or follow-on formula
- Which calculation methods for average quantity in the NIS will apply to infant formula and follow-on formula
- That other than for lactose and partially hydrolysed formula, information about ingredients is only permitted in the statement of ingredients and (where relevant), in the NIS.

These clarifications are discussed throughout the Call For Submissions documents and Supporting Documents 1 to 3.

5. Consideration of costs and benefits, and likely net benefit

In assessing this Proposal and in making its decision to prepare the proposed amendments

to the Code, FSANZ was required by the FSANZ Act to have regard to, among other things, whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure. In doing so, it had to have regard to submissions received in response to the first Call for Submissions.

5.1. Summary of impact analysis findings

The purpose of section 5 is to consider the costs and benefits of the proposal (Option 2, as described in section 4), and determine whether the proposal results in a net benefit.

Updating the Standard will impact three main groups:

- consumers (both infants and their parents/caregivers)
- the infant formula industry
- governments.

Table 5-1 shows the main groups likely to be affected by the proposed regulation and the main potential impacts on these groups.

Table 5-1 Major potential impacts by social group

Social group	Potential Impact	Notes on potential impact
Infant formula consumers	Benefits	Health improvements due to higher quality formula that better meets infants development needs
		Long term potentially lower cost formula
		Improved ability to compare and choose products
		Better advice at point of sale for specialised products which could result in both improved health outcomes and unnecessary costs being avoided if advised specialised formula is not desirable or needed
		Clearer instructions on product labels leading to reduced risk
	Costs	Restricted sales of specialised formula may cause some inconvenience
		Short term price increases are possible
Infant formula industry		
Base powder manufacturers	Benefits	Improved harmonisation increasing cost efficiencies of manufacturing
	Costs	Reformulation costs
		Potential additional manufacturing cost to reduce contaminants
Finished product manufacturers	Benefits	Improved cost efficiencies due to greater international harmonisation, improved regulatory certainty
	Costs	Reformulation costs, relabelling costs
General retailers (supermarkets)	Benefits	Potential lower cost of goods
	Costs	Loss of sales for specialised formula
Other retail (pharmacists, etc)	Benefits	Increased sales (specialised formula), lower cost of goods
Government	Benefits	Improved ability to enforce Standard, savings in health care expenses
	Costs	Adapting to new Standard

The impacts identified in Table 5-1 are expanded on in more detail in the sections that follow.

Question 1: Have all major impacts of the proposed changes to the Standard been identified? Please provide evidence (data, studies or other information) to support the inclusion and magnitude of other impacts.

Note: additional impacts were raised in the 1st CFS. Where they have not been included in the above list, FSANZ has provided an explanation on why they were not included at Appendix C.

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

Table 5-2 lists the major costs and benefits that are quantified in this report as well as some of the unquantified factors.

Table 5-2 Quantified and unquantified potential impacts

General cost or benefit	Social group	Specific cost or benefit
Quantified costs	Infant formula industry	Reformulation costs
		Relabelling costs
Unquantified benefits	Consumers	Health improvements due to higher quality formula that better meets infants development needs
		Long term potentially lower cost formula
		Improved ability to compare and choose products
		Better advice at point of sale for specialised products which could result in both improved health outcomes and unnecessary costs being avoided if advised specialised formula is not desirable or needed
		Clearer instructions on can leading to reduced risk
	Infant formula industry	Improved cost efficiencies due to greater international harmonisation
		Improved regulatory certainty
	Government	Improved ability to enforce Standard
		Savings in health care expenses
Unquantified cost	Consumers	Restricted sales of specialised formula
		Short term price increases
	Infant formula industry	Reducing contaminants
	Government	Adapting to new Standard

Note that a number of impacts identified for specific groups above are expected to net to zero, including:

- the impact on specific ingredient manufacturers[5]
- lost sales of specialised formula at supermarkets either shifting to pharmacies or to sales of general formula.

Benefits that result in reduced cost are shown as flowing in part or full through to the consumer. As discussed in the consumer impacts section, whether this occurs is not certain.

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

5.2. Consumer impacts

5.2.1. Summary of impacts on consumers

Consumers will likely benefit from potential life-long improved health outcomes from infants that are fed infant formula products, particularly those that rely on the products as a sole source of nutrition. This benefit is extremely difficult to quantify, however the magnitude is expected to be large.

There are some negative impacts of this proposal for consumers. Some consumers may be negatively impacted where access to infant formula products are restricted to pharmacies and other healthcare settings, where previously certain products were available at supermarkets. While the products will still be available, friction will be added to the market which may impact on price and availability.

However, this restricted access will result in parents and caregivers receiving medical advice that will help them manage potential medical conditions resulting in better health outcomes. Consumers may also benefit as they may be appropriately advised not to purchase a product that is more costly and not necessary for their child.

The impacts on consumers are:

- Likely improved health outcomes for formula fed infants, due to:
  - Improved composition
  - Improved labelling
  - Further reducing contaminants
- Changing the way that information is presented on labels
- Increased variety of highly specialised infant formula
- Reduced access to subcategories of special purpose infant formula.

These impacts are expanded on in the following subsections.

5.2.2. Infant formula consumption

Every year, around 168,000 Australian and 25,000 New Zealand infants are likely fed infant formula by age six months.

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

- 1.7 million in Australia
- 0.3 million in New Zealand

[5] Changes to the permissions for additives, macro and micro nutrients, 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

To see how this figure was calculated – refer to Appendix B.

For some infants, 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 life-long 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.

Industry stakeholders report that most infant formula is purchased in supermarkets, with the remainder purchased through pharmacies. A significant portion of these sales are online. Online sales account for half of purchased consumer goods by Australian households, of which FSANZ assumes infant formula products are included.

5.2.3. Benefits to consumers

5.2.3.1. Improved composition of formula, based on the more current science

Formula fed infants will directly benefit from the improved nutrient composition of infant formula products. The updates are reflective of progressed science which better establishes:

- infant nutritional requirements
- population deficiencies
- potential health effects.

Standard 2.9.1 and Schedule 29 have not been updated in over 20 years. Within this period science, research and intentional regulations have progressed.

The compositional changes established in Proposal P1028 will likely lead to improved health outcomes for formula-fed infants, particularly as these products provide their sole source of nutrition.

Some of the most significant improvements include updating the composition in line with:

- the best available scientific evidence
- updated breast milk level, specific to the Australia and New Zealand populations (where available)
- updated intake assessed and compared with Australia and New Zealand Nutrient Reference Values (NRVs)
- intentional standards and regulations
- recommendations from key expert bodies.

P1028 has also assessed mandating the addition of essential substances, such as choline, L-carnitine and myo-inositol, in infant formula. These substances are currently included as optional additions in infant formula. However internationally they are prescribed as mandatory additions.

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

Quantifying this benefit is not possible given the complex relationship between nutrition and health outcomes. However, ensuring the nutrient composition of infant formula is appropriately prescriptive to provide sufficient energy and nutrients which promote normal growth and development is of indisputable benefit.

5.2.3.2. Improved labelling increasing safety

The proposed standard improves 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.

Improper preparation of infant formula can lead to serious health problems such as choking, bacterial infection, constipation, diarrhoea, over- or under-feeding.

Consumer research suggests that caregivers do not always prepare or use infant formula properly. For example, they may add other foods to formula, or may not discard unfinished formula for several days.

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 increase efficiency, not reading instructions etc.).

This could lead to a number of associated risks for infants including under and over nutrition, bacterial infections, choking, diarrhoea, constipation and too little or too much weight gain (FSANZ 2021).

These risks to infants 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 time within which to discard unfinished formula.

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

5.2.3.3. Improved labelling increasing comparability of infant formula products

This proposal will require a standardised NIS.

Standardising the NIS will assist consumer understanding of the nature of nutrients and substances that have technical names (for example, Pantothenic acid grouped under the subheading ‘Vitamin’).

It will also help consumers to make quicker product choices by making comparisons between products easier. Consumers will also be able to more readily identify product differences relating to additional nutritive substances and other substances that have been voluntarily added.

5.2.3.4. Removing proxy advertising and misleading claims from labels

This proposal also improves product labelling through:

- establishing requirements for stage labelling
- removing proxy advertising
- requiring products to be distinctly labelled
- requiring specific labelling for infant formula represented as lactose free, low lactose or partially hydrolysed.

Requirements for stage labelling (if used) and the removal of proxy advertising will assist consumers to distinguish between an infant formula and follow-on formula and identify the correct product for their infant. [6]

The requirement is intended to reduce the risk of consumers purchasing a similarly packaged product that may not be suitable for their infant.

It also reduces the influence of marketing that may suggest to consumers that their infant must progress from stage 1 and 2 to stage 3 and beyond, when formula is no longer necessary.

There will be a new requirement that food represented as infant formula or follow-on formula must not also be represented as another food. The intent of the requirement is to ensure these products are distinctly labelled to reduce potential consumer confusion when choosing products for their infant.

In addition to voluntary stage labelling and mandatory age statements, products may be differentiated using colour, images or text, however industry will retain flexibility on how they wish to differentiate products within a product range.

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

These representations can mislead consumers. For example, consumer research has shown that the marketing of formulas for problems such as 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 formula 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 formula and these products are typically sold at a higher price point despite not being that different compositionally.

The intent is for consumers to seek medical advice if their infant is experiencing a medical issue. Formula that is represented as partially hydrolysed will be required to include the words 'partially hydrolysed' immediately adjacent to the statement of protein source and will be located on the front of the package label to assist consumers to make informed choices.

5.2.3.5. 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.

[6] Stage labelling indicates whether the product is for infants under 6 months (typically labelled with a "1"), 6 to 12 months (typically labelled with a "2"), or older (stages "3" and above)

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

The proposed standard reduces the permitted level of aluminium and lead. This will reduce the exposure of these contaminants for infants consuming formula where exposure levels are 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 this will only impact some infant formula products (particularly soy), as most already meet the new standard.

5.2.3.6. Greater access to medical advice

Products within the new SMPPi category will only be sold in pharmacies and other medical settings. For most consumers of SMPPi products this does not represent a change, as highly specialised products are currently not available for sale in general retailers like supermarkets.

Consumer research suggests that approximately 38% of Australian caregivers who introduced formula in the first three months of life may not have sought advice from a health care professional (FSANZ 2022).

Consumers that will now be required to access SMPPi through pharmacies or medical settings may receive improved medical advice on the right formula to feed to their infants.

This may lead to improved health outcomes through better management of their infant's condition and a reduced likelihood of inappropriate product use. For example, consumer research from the UK identified that some caregivers may look for unnecessary interventions to help with infants who are going through normal unsettled or difficult periods, including seeking out a specialised formula (FSANZ 2022). Improved access to medical advice at the point of sale for specialised products may help to reduce this behaviour, should this also be occurring in Australia and New Zealand.

Selling medical purpose products, such as SMPPi, within pharmacies gives clear distinction from general infant formula products and will:

- reduce the risk of caregivers buying formula 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.

Question 2: Do you have any information that can be used to quantify the value of any of the health benefits identified in this impact analysis?

5.2.4. Costs to consumers

In the short-run, some product manufacturers may pass on some (or all) of the increased costs of meeting new standards to parents and caregivers through higher prices of infant formula products. The costs that are expected to be passed on are shown in the industry costs section below.

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

5.2.4.1. Reduced access to subcategories of special purpose infant formula

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

As a result, parents and caregivers will no longer be able to access some products from supermarkets. In particular, these are infant formula products that are marketed to address conditions such as colic, regurgitation, and constipation.

Research (Vandenplas, Y, et al 2015) indicates that the likely prevalence of these conditions (in infants aged under 12 months) were:

- 20% for colic
- 30% for regurgitation, and
- 15% for constipation

It is common for around 50% of infants to experience functional gastrointestinal symptoms such as those listed above, but in only 1-5% of cases is dietary or medical intervention indicated.

Manufacturers of the impacted products will have the choice to:

- continue to offer the products, however position as SMPPi,
  - for sale in healthcare settings (including pharmacies)
  - label is required to address the true nature of the product and the condition it is formulated for such as colic, reflux and others.

- re-position the product as infant formula or follow-on formula,
  - general retail sale (including supermarkets, and pharmacies)
  - label cannot reference ability of the product to address conditions such as colic, reflux and others
  - must comply with the nutrient composition requirements for infant formula and follow-on formula
  - can label for prescribed compositional modifications including partially-hydrolysed protein (labelled through the protein source statement) and low-lactose or lactose free.

Industry stakeholders provided feedback that these conditions can lead to stress for parents and caregivers. They also noted that these products should be used under the guidance of a medical professional.

Industry stakeholders provided data on the proportion of sales for products for reflux and colic at supermarkets. The confidential data evidenced manufacturers sell these products through different channels, with no common trend across the industry. Some manufacturers sell these specialised formulas predominantly through the supermarket channel, whereas others spilt the products equally between supermarkets and pharmacies.

Based on the data provided, FSANZ considers these specialised formulas, such as those of transient gastrointestinal conditions, already have established sale in pharmacies.

This restriction of sale will not have impact on health outcomes, and may improve health outcomes (as outlined in section 5.2.3.6). The intent of the Code is that where an infant has a specific medical issue, 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 carers and the health advice needed to manage conditions.

There may be increased difficulty in accessing infant formula for some parents and caregivers, because:

- some will have to travel to a pharmacy, where before they didn't have to
- rural and remote areas may have a lack of providers.

Industry stakeholders have argued that removing these products from supermarkets will increase costs for consumers, as the grocery distribution channel has the highest efficiency of all retail distribution channels, which results in lower costs to consumers. [7]

Industry reports that supply levels at supermarkets are more efficient and reliable, because:

- Supermarkets source their products directly from manufacturers, where other retailers obtain products from wholesalers, introducing an extra step to stock replenishment and longer lead times
- Pharmacies have less storage space, meaning less stock is held on premise
- Smaller pharmacies, especially in rural settings, will have less ability to stock a wide range of infant formula types, due to financial constraints.

Industry stated that some specialised products may be withdrawn, where reduced access reduces sales volumes, and reformulation makes the product commercially non-viable. It is not known how many product lines will be withdrawn, but it is expected to be a small number if any.

The proposal will not impact on the access to highly specialised infant formula, as these typically require a prescription and are already sold in healthcare settings.

Question 3: Do you have any evidence that could be used to quantify the impact of restricting sales of SMPPi products?

5.2.4.2. Impact on consumers of changing elements of IFP labels

The proposal introduces a standardised 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 example permitted nutritive substances/other substances will appear in one location under the subheading 'Additional'.

Some consumers may be required to adjust to different terminologies, where acronyms or other language is currently used. However, evidence suggests that consumers generally do not understand nutrition content claims, when either the full name or acronyms are used (FSANZ 2022). Prescribed terminology will allow consumers to easily compare across products, and reliably look up information where required.

The above impacts will largely be limited to parents and caregivers who cared for infants before the new standard came into effect, and after the new standard took effect.

Caregivers will be able to compare the composition of different products more readily as a result of consistent format and terminology. 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. 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 example permitted nutritive substances/other substances will appear in one location under the subheading 'Additional'. Some consumers may be required to adjust to different terminologies, where acronyms or other language is currently used. However, evidence suggests that consumers generally do

[7] Comments in industry submission and verbal comments from industry during consultation.

not understand nutrition content claims, when either the full name or acronyms are used (FSANZ 2022). Prescribed terminology will allow consumers to easily compare across products, and reliably look up information where required.

The proposal will also allow the voluntary declaration of certain macronutrient subgroup nutrients in the NIS (for example 'whey', 'casein', certain fatty acids). The format and terminology for these will be prescribed. The intent is to provide caregivers with a consistent format and terminology, enabling them to compare the composition of different products more readily.

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.

5.3. Infant formula industry impacts

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

The impacts are:

- Quantifiable:
  - Reformulation - $40m one off cost
  - Relabelling - $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[8]
  - Cost of reducing contaminant levels

5.3.1. Background on infant formula industry

The infant formula industry is complex.

There is a manufacturing supply chain, with some companies participating in the entire chain (from base powder to finished product on a shelf) while others only participating 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 those that manufacture the ingredient inputs.

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
  - Specialist retailers, including pharmacies

Infant formula is traded globally. Products sold in Australia and New Zealand are either manufactured locally (in Australia or New Zealand) or imported. Although most infant formula manufactured locally is sold in Australia and New Zealand, others are for export only, particularly to Asian markets.

[8] 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 5.4.3.3

5.3.1.1. Base powder manufacturers

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

Food Standards do 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/New Zealand standards results in inefficiencies for manufacturers. The less unique requirements that need to be met, the lower the cost to manufacture.

5.3.1.2. 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 Code, 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 Code, but buyers place value on their compliance with the Code. Therefore, it can be expected that exported product is likely to still be manufactured to meet the proposed code to meet demand.

5.3.1.3. Finished product manufacture and sale

Finished product is infant formula ready to be sold to consumers, a combination of a base powder and ingredients.

Finished product is either produced in Australia and New Zealand, or imported.

Most finished product produced in Australia and New Zealand is exported. The products are exported:

- To China, via the Cross Border eCommerce (CBEC) regime
- To China, via Daigou
- To other export markets, including south east Asia

Industry data shows that exports to China (via both channels) make up the largest proportion of exports.

CBEC is a regulatory environment where products are imported to China to a bonded warehouse, and then directly sold to China-based consumers 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 Code.

Some infant formula products manufactured in Australia and New Zealand is produced exclusively for overseas markets. In both countries, these export-only products are required

by legislation to comply with the Code, as well as the regulations of the importing country. Inconsistencies between the regulations can create trade barriers and limit innovation.

In New Zealand, infant formula that is manufactured for export can be issued with an exemption from the compositional requirements of the Code by the Ministry for Primary Industries under the Animal Products Act 1999. In addition, there is a blanket exemption for labelling of infant formula products for export from the requirements in the Code. Instead, these products must meet the labelling requirements for the importing country.

5.3.1.4. Infant formula retailers

As noted in the consumer impact section, industry stakeholders reported that most infant formula is sold at supermarkets. It is also sold in pharmacies (either with or without a prescription) and can also be provided in other healthcare settings.

5.3.2. Benefits to infant formula industry

5.3.2.1. Greater alignment with international standards

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

Codex Alimentarius develops international food standards which enable more cross jurisdictional trade (while also protecting the health of consumers), including for infant formula products. The proposed amendments for infant formula products achieves much greater alignment with Codex than the current standard.

Table 5-3 and show the extent of alignment to Codex under the current standard and the proposed standard.

Table 5-3 Greater alignment to Codex – infant formula

	Current Standard	Proposed Standard
Number of permissions changed to match Codex		+24
Total number of permissions aligned to Codex	30	54
Total number of permissions	68	67
Proportion of permissions aligned to Codex	44%	81%

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

Table 5-4 Greater alignment to Codex – follow on formula

	Current Standard	Proposed Standard
Number of permissions changed to match Codex		+21
Total number of permissions aligned to Codex	32	53
Total number of permissions	68	67
Proportion of permissions aligned to Codex	47%	79%

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

Of the permissions that did not align with Codex CXS 72-1981, none have a greater impact on reformulation. [9] In most cases the ranges are inclusive of the Codex permissions.

For follow-on formula, FSANZ considers that the composition between infant formula and follow-on formula should only vary where there is substantiated scientific evidence that demonstrates a different nutrient requirement between the age groups in the 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 proposed permission for infant formula within the Code.

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 manufactures time and costs.

Greater alignment will reduce duplication costs after requiring fewer differences in infant formula product compositions for the Australia and New Zealand market compared to overseas markets. However, as there are still some differences, the benefit of full alignment may not be realised.

As noted by some stakeholders in response to the 1st CFS, this proposal lowers costs relative to the status quo. Supply chain pressures mean that costs are increasing faster than the historical average rate. This change will reduce some of the cost increases.

Question 4: Do you have any information that can be used to quantify the benefits of increased alignment between the Standard and major international standards?

5.3.2.2. Increased regulatory certainty

It is also expected that businesses would benefit from the greater regulatory certainty, 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 proposal that improve regulatory certainty.

Increased regulatory certainty is likely to result in more investment into the infant formula industry. The benefit of this to industry is difficult to quantify. Greater investment into the industry also benefits consumers.

5.3.3. Costs to infant formula industry

The expected cost impacts on industry are:

- Quantifiable:
  - Reformulation - $40m one off cost
  - Relabelling - $4m one off cost
- Unquantifiable:
  - Cost of restriction of sale of certain products to pharmacies
  - Cost of reducing contaminant levels

[9] Carbohydrate range, trans fatty acids, fluoride, guanosine-5′-monophosphate, arachidonic acid and iron

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

5.3.3.1. Reformulation costs

Industry will incur costs to reformulate impacted products to meet the new standards. The total cost to reformulate is estimated to be $40m AUD. This is a one off cost. For more information on how this is calculated, refer to Appendix B.

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

FSANZ has taken a conservative approach to estimating the reformulation costs, therefore the above costs are on the high side. Because FSANZ has allowed for a long transition time, industry may be able to reformulate products to comply with the regulation at the same time they are reformulating for 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 do not frequently reformulate, particularly lower cost products or certain brands that are designed to maintain a consistent recipe over time.

All product lines will need to be reformulated, which industry confirmed in consultation. The only exception is products that are considered special purpose infant formulas under both the current standards and new standards.

Products that will become special purpose formulas (for example products designed for infants with allergy) under the proposed standard may need to reformulate. This is because they are expected to meet the new compositional requirements in order to be considered a sole source of nutrition (except where required to address the health condition the formula is designed to address).

Some products may not be reformulated, where:

- A product is unable to meet the need standard
- It is not commercially viable to invest in reformulating the product.

Reformulating infant formula 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. Implementation documentation

The above changes will need to be done for:

a. Base powders
b. Pre-mixes
c. Final products[10]

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 to that would lower reformulation costs (relative to domestic producers), multinational companies face unique costs in adapting final products and product inputs (base powders, etc) to different regulatory regimes.

[10] a blend of base powders and pre-mixes for sale to consumers

Question 5: Do you agree with the reformulation cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy? Refer to Appendix B for more information.

Question 6: FSANZ has estimated that 200 SKU will need reformulation. This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

5.3.3.2. Relabelling costs

Industry will incur costs to update and print new labels. The total relabelling cost is estimated to be $4m. This is a one off cost. For more information on how this is calculated, refer to Appendix B.

Relabelling costs include the following activities:

- Update values in the NIS as a result of re-formulation
- Update the format of the NIS to comply with the proposed standard.
- Update the wording of a warning statement and preparation instructions to comply with the new standard requirements
- 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.

The changes to SMPPi labelling requirements would most likely not lead to label changes. The proposed changes are consistent with EU requirements, and the majority of SMPPi products are imported from the EU. The labelling requirements are also sufficiently flexible so that the supply of SMPPi imported from other countries such as the United States will be unaffected.

Infant formula that is regulated as special purpose under the existing standard will not be required to change labels.

Question 7: Do you agree with the relabelling cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy (for example a cost per SKU to update product labels)?

Note: more detail on how the costs were estimated is presented at Appendix B.

Question 8: FSANZ has estimated that 217 SKU will need relabelling. This includes the impact on different packaging for the same product (example, tins and sachets). This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

5.3.3.3. Impact of restricting sale of special purpose infant formula

Under the proposed standard SMPPi can only be sold or distributed through medical practitioners, responsible institutions, or permitted sellers. Permitted sellers will include pharmacies and other health facilities. Therefore, this category of infant formula products will no longer be sold in general retailers like supermarkets.

This impacts products defined as SMPPi in the proposed standard.

Evidence from stakeholders in response to the 1st call for submissions indicates that the majority of infant formula product sales occur in supermarkets. This includes the sales of formula designed for babies with reflux and other conditions that will be impacted most.

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

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

The net impact for supermarkets will depend on:

- Whether customers substitute toward products supermarkets can sell
- The relative profit margins of specialty products compared to general infant formula products.

Any sales lost by supermarkets (where consumers do not substitute to general infant formula products) will be gained by pharmacies.

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

5.3.3.4. Cost of reducing contaminant levels

Industry may incur costs to reduce contaminant levels of lead and aluminium. FSANZ understands that most products are already under the proposed limit.

Where the limit is not being met, manufacturers will need to work with their suppliers to reduce the contaminant levels, or find a new supplier. Using a new supplier will result in initial costs to ensure that the new supplier can meet quality standards set by the manufacturer. The new ingredients may cost more than the original ingredients.

Submissions from industry indicate that there may be difficulty in meeting the aluminium contaminant level for soy milk. Aluminium is present in the earth, and absorbed by plants. Milk from animals such as cow and goat is filtered by the animal's liver, reducing the aluminium levels. Plant based milks do not have this natural filtration process, increasing the difficulty in meeting the proposed levels.

There is a risk of an increase in the cost or decrease in the availability of soy milk where industry is unable to source ingredients that meet the proposed standard.

5.3.3.5. Impacts of a standardised NIS

As discussed in section 4.2.9, the proposal introduces the requirement for a standardised NIS. The content and format of the NIS is prescribed by the standard, with a small allowance for deviation.[11] Industry must declare the presence of permitted nutritive substances or other permitted substances in the NIS if these are have voluntarily permissions.

Currently, infant formula 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 therefore declaration on the label.

FSANZ is clarifying the policy intent that new ingredients require pre-market assessment and an explicit permission before they can be added, to ensure FSANZ has oversight of the safety of infant formula, and whether the ingredient have a substantiated beneficial role in the normal growth and development of infants.

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

This proposal will result in a change to what is presented in the NIS for some products.[12] 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 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.

Question 9: Do you have any evidence that can be used to quantify the unquantified costs to industry presented in this analysis?

5.3.3.6. Pre-market assessment for lactic acid producing microorganisms

In response to the 1st call for submissions, many industry stakeholders argued that the impact analysis should include cost of obtaining approval to include lactic acid producing microorganisms in infant formula.

FSANZ is not proceeding with this part of the proposal, and therefore there will be no impact as a result of having to obtain approval.

5.3.3.7. Sheep milk based formulas

In response to the 1st call for submissions, many industry stakeholders argued that the impact analysis should include cost of obtaining approval to use sheep milk as a protein source.

FSANZ has included sheep milk as a prescribed protein source and therefore there will be no impact.

5.3.3.8. Transition period – timeframe

FSANZ is proposing not to apply the Code's default standard transition arrangements provided by section 1.1.1—9 of the Code. This section provides for a 12 month stock-in-trade period for variations to the Code.

Instead, 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 Code as in force as if the variation had not taken effect
- the Code as amended by the variation.

After the transition period, all infant formula products available in the Australia and New Zealand market would need to comply with the variation.

These transitional arrangements take account of stock-in-trade and have been included within the draft variation because the proposed changes will be affecting products with a longer shelf life.

[12] The cost impact of this has been discussed and calculated in section 5.4.3.2

Developing a transition period is a balance

- a transition period that is too short increases costs for industry, with costs potentially passed on to consumers
- a transition period that is too long has the potential to increase costs for industry, particularly base powder manufacturers, and delays benefits for consumers and government.

A five year transition period would allow sufficient time for industry to adopt new labelling and composition requirements and minimise costs associated with labelling changes and reformulation. As demonstrated above, there are many activities that industry will need to undertake to achieve compliance with the new standards.

An adequate transition time will be required for industry to achieve compliance, and to avoid unnecessary costs. INC states that it will take approximately 36 months to reformulate and update product labels

The proposed transition period would not unduly impact consumers as the label information or updated composition has previously not been available, however a transition period greater than five years would delay optimum nutrition to infants and the provision of information to consumers.

For companies that produce base powder (inputs into finished infant formula products) longer transition times may increase cost. This is because their customers (manufacturers of final products) will likely transition to the new recipes according to different schedules. This means that the base powder manufacturer will need to switch between different recipes (old standard compliant and new standard compliant) more often, reducing manufacturing efficiency.

Further consideration of the transition period is included in section 11 of the 2nd CFS.

5.3.3.9. Transition period – food additive permissions

FSANZ is seeking to further minimise costs to industry for reformulation by permitting food additives in any product that meet the following criteria:

- are confirmed by a formal risk- assessment as being safe and suitable, and
- a permission is provided for such food additives to align with EU and Codex, especially for SMPPi.

5.3.3.10. Impact on market access and competition

The standards are not expected to result in a change to market access nor significantly reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected.

5.4. Impacts on government

This proposal 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 of 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) from greater certainty of:

- permitted food additives
- permitted protein sources
- contaminant levels
- what constitutes SMPPi, and
- 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.

Question 10: Have all the major impacts on government been identified? Question 11: Do you have any information that could be used to quantify any of the impacts on government?

5.5. Conclusion of analysis: 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 will 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.

5.5.1. Breakeven analysis

Over ten years (the assumed lifespan of the proposed regulation), it is expected that the total number of infants fed formula (either exclusively, or in combination with breast milk) is expected to be:[13]

- 1.7 million in Australia
- 0.5 million in New Zealand

The quantifiable cost to industry is:

- Reformulation - $40m one off cost
- Relabelling - $4m one off cost

In order for society to break-even on the quantified costs, for each infant fed infant formula products (whether exclusively or in combination with breast milk), society will need to receive a benefit of approximately $27 AUD per infant. FSANZ considers it likely that this benefit will be achieved, especially given the lifelong nature of the health benefits arising from this proposal.

FSANZ will take into account any feedback received during the 2nd CFS. This will be used to improve the analysis presented above, which will be incorporated into a Decision RIS.

6. Who was consulted, and how was their feedback incorporated?

Extensive targeted and public consultation has been undertaken prior to the release of this 2nd Call for Submissions. Please see Section 1.6 of the CFS for full details, or refer to the P1028 page on the FSANZ website.

[13] Refer to Appendix B to see how this was calculated

This includes consultation during the 1st CFS. Feedback on the 1st CFS has been listed in this 2nd CFS. To review the feedback provided, and the FSANZ response, refer to:

- The main body of the 2nd CFS
- Supporting Documents 1 to 4

To review feedback on the cost benefit analysis, as well as FSANZ's response, refer to Appendix C of the Supporting Document.

The proposal (and the cost benefit analysis) has been revised and presented again for stakeholder feedback in this 2nd CFS. In addition, the 2nd CFS presents the text of the proposed changes to the Standard (and related changes to other parts of the Code) for the first time as well as the accompanying explanatory statement. Submissions received will be considered when developing the final set of proposed updates to the Standard.

FSANZ will also finalise the cost and benefit analysis in light of the feedback received. The final cost benefit analysis will be presented in a Decision RIS (DRIS) document.

7. What is the best option from those considered?

As discussed in sections 4 and 5 , proceeding with the proposed changes is considered the best option, relative to the status quo.

The proposed changes:

- Have been considered in detail (refer to the Call for Submissions document and Supporting Documents 1 to 3)
- Address the problems raised in section 2
- Have been subject to comprehensive consultation with stakeholders
- Are expected to lead to a net benefit.

8. How will the chosen option be implemented and evaluated?

If the amendments to the Standard are agreed to, implementation and enforcement of the variation to the Code would be the responsibility of the food regulation agencies in New Zealand and Australian states and territories.

FSANZ will provide a transitional period from the date variations are gazetted and registered as a legislative instrument. This period gives industry and government authorities time to put measures in place to meet the requirements.

For this variation, a five year transitional period inclusive of stock-in-trade exemption is being proposed (see Section 11 of the CFS).

Australian states and territories and the New Zealand Government are responsible for any review of implementation and compliance. They are also typically responsible for initiating any substantive reviews of the Code through the Food Ministers' Meeting.

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List of appendices

Appendix A - List of questions for stakeholders on the cost benefit analysis

FSANZ is seeking additional information from stakeholders to test our assumptions and improve the analysis of the costs and benefits of the proposal for the Decision RIS (DRIS).

Answers to the following questions should be included with submissions.

Question 1: Have all major impacts of the proposed changes to the Standard been identified? Please provide evidence (data, studies or other information) to support the inclusion and magnitude of other impacts.

Question 2: Do you have any information that can be used to quantify the value of any of the health benefits identified in this impact analysis?

Question 3: Do you have any evidence that could be used to quantify the impact of restricting sales of SMPPi products?

Question 4: Do you have any information that can be used to quantify the benefits of increased alignment between the Standard and major international standards?

Question 5: Do you agree with the reformulation cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy? Refer to Appendix B for more information.

Question 6: FSANZ has estimated that 200 SKU will need reformulation. This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

Question 7: Do you agree with the relabelling cost estimates? Do you have any information that could be used to calculate this figure with greater accuracy (for example a cost per SKU to update product labels)?

Question 8: FSANZ has estimated that 217 SKU will need relabelling. This includes the impact on different packaging for the same product (example, tins and sachets). This is based on a search method detailed at section 2 of Appendix B. Do you agree with the estimate? Do you have evidence for a different estimate?

Question 9: Do you have any evidence that can be used to quantify the unquantified benefits to industry presented in this analysis?

Question 10: Have all the major impacts on government been identified?

Question 11: Do you have any information that could be used to quantify any of the impacts on government?

Appendix B – Detailed calculations of figures used in cost and benefit analysis

1. Estimated numbers of infants fed IFP and SMPPi

Data shows that in the ten years 2011-20 that there were:

- 305,000 live births per year in Australia[14]
- 60,000 live births per year in New Zealand[15]

The Australian National Infant Feeding Survey in 2010-2011 (the only edition so far) found that in the day before the survey, approximately;

- 40% of infants aged 1 month old received non-human milk or infant formula products
- 55% of infants aged 6 months old received non-human milk or infant formula products

A similar pattern was discernible from New Zealand statistics. A 2007 report from the New Zealand Ministry of Health National Breastfeeding Advisory Committee found:

- 41% 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 old[16]

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

- 168,000 in Australia
- 45,000 in New Zealand

Over ten years, it is expected that the total number of infants fed formula (either exclusively, or in combination with breast milk) is expected to be:[17]

- 1.7 million in Australia
- 0.5 million in New Zealand

2. 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 December 2022.

The search method to find the products was:

1. Write down 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 smaller 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

[14] Australian Bureau of Statistics data
[15] Stats NZ data
[16] Protecting, Promoting and Supporting Breastfeeding in New Zealand - Background report, table 1
[17] Projected using United Nations population projections

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.

3. Cost to reformulate impacted products

3.1. Number of impacted final product recipes

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

The below table shows the total number of products identified for general sale in December 2022. 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 code but not sold in Australia or New Zealand.

This is 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 proposal.

In the 1st CFS the number of impacted products was estimated to be 100. Industry stakeholders stated that this significantly underestimates the number of products. The new estimate responds to this feedback.

One stakeholder submitted that there is over 170 products for sale in Australia. This figure most likely includes products for sale via the pharmacy channel (including by prescription only), while the figure below is for general retail only.

	Products sold in Australia and/or New Zealand				
	Australia and NZ	**Australia only**	**NZ only**	**Total**	**Plus 50%**
Standard infant formula and follow on product lines	27	65	23	115	173
Impacted products for low-risk / temporary conditions (e.g. acid reflux, colic, sleepy baby)	5	12	1	18	27

3.2. Cost per product

The 1st call for submissions estimated the cost per product to be in a range of AU $80,000 to AU $200,000 per affected product line.

Some feedback from industry indicated that this was too low. However, confidential data provided by some within the industry indicates that the cost per SKU is within the band but at the higher range.

Therefore, a cost of $200,000 per product will be used.

3.3. Industry wide costs

The total cost of reformulation is estimated to be $40m AUD. This is based on the above number of SKU, plus the cost per product.

4. Cost to relabel products

4.1. Number of impacted SKUs

The below table shows the total number of products identified for general sale in December 2022. 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 code but not sold in Australia or New Zealand.

This table is based on the list of products developed by FSANZ, using the methodology discussed at section 3.1.

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 proposal.

	Products sold in Australia and/or New Zealand				
	Australia and NZ	**Australia only**	**NZ only**	**Total**	**Plus 50%**
Standard infant formula and follow on product lines	26	65	30	121	182
Impacted products for low-risk / temporary conditions (e.g. acid reflux, colic, sleepy baby)	5	12	1	18	27

4.2. Cost per impacted product

The first CFS assumed a cost of $8,000 per product, "with general variations of +/- 20% per product line". This was based on a 2021 cost survey of changing labels for alcoholic beverage cans, as well as a PricewaterhouseCoopers cost schedule (refer to the 1st CFS for more information.

Industry feedback was that this cost was too low, and that alcoholic beverages are not an appropriate proxy for infant formula.

Some industry stakeholders provided what they thought the cost would be to update labels (based on their experience). As anticipated in the 1st CFS, there was a large variation amongst respondents.

Taking into account all the data received, the new estimated cost per product is $16,000. This represents a mid-point for the data received.

To continue to improve these estimates, FSANZ has contracted Marsden Jacob Associates to survey businesses on the cost of changing labels for various products, including IFPs.

This data will update and extend FSANZ's label change cost model. If this data is available when the Decision RIS is drafted, it will be used to inform the Decision RIS. These estimates may be higher or lower than the current estimate.

4.3. Total industry wide cost

The total cost to the infant formula industry to relabel products is $3,895,000.

The 1st CFS estimated a total cost of $800,000 +/- 20%. The increase is due to:

- an increase in the number of identified impacted products,
- an increase in cost per product, and
- a sharp increase in the cost of production over the last 12 months.

The cost is a one off cost for products already on the market to meet the new standard. These costs 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 is not done in steps
- an adequate transition period to change labels and to run-down stocks of packaging and labels
- there are no lost stocks of cans, boxes, other packaging or labels due to an adequate transition time and stock-in-trade provisions.

In addition to this, stakeholders mentioned that there may 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 exiting stock of labels that no longer reflect the contents of the can. This cost is un-quantifiable, as the cost is dependent on the success of the project manager within a company and their ability to minimise wastage through schedule management.

5. Impact of increasing rates of inflation

Some industry stakeholders raised 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 possible.

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 this proposal are subject to high inflation rates.

Appendix C – Submitter comments & FSANZ responses for costs and benefits

The following tables summarise comments made on the costs and benefits section of the 1st CFS. It does not include comments that were described as commercial-in-confidence.

Table 1 – Stakeholder comments on costs and benefits for consumers

Comment	FSANZ Response
Submitters supported the following aspects of the analysis: 1. INC agrees that increased costs will likely be passed on to consumers. 2. INC agrees that infants will benefit from updated composition and additives that align with more recent science. 3. Nestlé generally agrees that benefits will outweigh costs in the longer term 4. The Queensland Department of Health agrees benefits outweigh costs.	1. This has been mentioned in the SD4 discussion on consumer impacts. 2. Noted. 3. Noted. 4. Noted.
Submitters supported the following aspects of the analysis, for the reasons outlined below: 1. Australian Breastfeeding Association (ABA) and the World Breastfeeding Trends Initiative (WBTi) Australia submission stated that the analysis 'vastly' undervalues the financial benefits of restricting marketing of infant formula. It is argued that the benefits of preventing premature weaning should be included. A number of studies that demonstrate and estimate the cost of premature weaning were provided. Also highlighted are a number of studies documenting high environmental costs of not breastfeeding. Breastfeeding also increases resilience (i.e. during emergencies and natural disasters). 2. The Victorian Department of Health and the Victorian Department of Jobs, Precincts and Region (VIC) disagrees that benefits outweigh costs. This is because the proposal does not (for a number of reasons identified in the submission) appear to result in real benefits for infants or governments. 3. VIC states that the costs of not prioritising infant health (both formula fed and breastfeeding rates) in proposed regulatory positions and the opportunity cost of not providing a more balanced regulatory framework	1. While the proposal does further restrict marketing of infant formula (relative to the status quo), the choice to use formula (where breastfeeding is possible, i.e. what could be considered 'unnecessary consumption' as described in the submission) is driven by many factors, of which marketing is just one factor. It is therefore difficult to determine whether the further restriction will have any impact on infant formula use, and to what extent there may be an impact. The likely impact is low, and given the difficulty estimating the impact, it will not be included in the CBA. 2. FSANZ's assessment, based on the best available evidence, is that benefits will outweigh costs. Discussion on how the new standard will benefit infants and governments can be found through this CFS. 3. Infant health has been prioritised in FSANZ's assessment (refer to other supporting documents). FSANZ is not proposing to relax any restrictions, therefore the cost benefit analysis does not consider the opportunity cost of other potential frameworks.

Comment	FSANZ Response
for optional ingredients for the benefit of all formula-fed infants should be taken into account. 4. VIC states that aligning to Codex for trade purposes needs better justification. FSANZ should analyse the requirements of major export markets, and compare the benefits of aligning to these to the benefits of aligning with Codex. 5. VIC states that consideration of costs have been limited to costs born by industry. 6. INC states that current products are already safe and suitable (and therefore there will be no benefit from improved safety outcomes) 7. INC states that any label change will result in a negative impact on consumers. This includes high concern and uncertainty. 8. INC rejects the improved product labelling will help parents and caregivers to select appropriate products for their infants. Some ordering of the NIS will be a step in this direction but many of the proposed changes could have a negative impact on the ability to provide adequate information. 9. INC states that FSANZ is adding additional highly restrictive labelling requirements that are not aligned internationally and could be to the detriment of parents, carers, and their infants. A lack of differentiation between brands is a significant disincentive to innovation, which is not in the best interest of a formula-fed infant and ongoing public health outcomes. *10.* The NZFGC states that it "*is concerned that the lack of ability to communicate the differences between products could ultimately distort consumer choice, as there could be very little that indicates to a consumer why one product is different to another, what scientific rigour has gone into the development of one over the other, and/or the effort that goes into improving one product over the other. We are concerned this would result in the use of other cues to differentiation such as packaging. Price could also be used as a way to differentiate the quality of different formulas."* 11. NZFGC states that the inability differentiate will act as a disincentive for innovation, leading to poorer health outcomes.	4. This is out of scope for the cost and benefit analysis, which analyses the proposal as developed. 5. FSANZ has included the costs and benefits for all impacted parties, and quantified them where possible. 6. FSANZ agrees with this comment, improved safety is not listed as a benefit in the 2nd CFS. Infant formula is safe under the status quo (as shown by a lack of safety incidents) and will continue to be safe under the new standard. 7. This impact is noted. 8. For discussion on how the new standard improves labelling leading to appropriate product selection, refer to SD3. Note that the FSANZ statement referred to by INC is not included in the 2nd CFS. 9. The standard already contains highly restrictive labelling requirements. FSANZ believes there will be minimal impact on innovation, as there is still the ability to make certain voluntary declarations on the nutrition information panel (NIP). For further information on labelling requirements please see SD3. 10. Refer to (9) regarding innovation. Price and packaging is already used by consumers of any product to differentiate quality, therefore this is true under the status quo as well as under the proposed Standard. 11. See response to (9).

Table 2 – Stakeholder comments on costs and benefits for industry

Comment	FSANZ Response
Submitters supported the following aspects of the analysis 1. INC agrees that all products (SKUs) will need to be reformulated 2. Nestlé agrees that there is a benefit to international alignment, in that it lessens cost increases over time. INC adds that benefits will likely be out-stripped by other cost increases impacting production. Ingredient costs are rising, transport costs are rising, packaging materials costs are rising. It is not correct to state that costs for consumers will reduce. 3. In relation to the above (2), INC states the cost reductions above may not be achieved if there is not full international alignment. There may be some benefit of greater alignment however, not all composition requirements proposed are internationally aligned (e.g. iron minimum) and this means that formulations will likely still need to be specific to Australia and New Zealand. Danone listed areas where full alignment has not been achieved (for the proposal as described in the 1st CFS). 4. In relation to (2), Nestlé does not agree that all of FSANZ's preferred approaches will reduce costs.	1. The industry cost analysis has assumed this. 2. FSANZ has updated the benefits to industry section to state that this proposal lowers costs relative to the status quo. Supply chain pressures mean that costs are increasing at a faster than the historical average rate. The proposal is expected to reduce some of the cost increases. 3. The discussion on the benefits of international alignment have been updated to include this limitation. 4. FSANZ has noted where costs will increase for both industry and consumers in the 2nd CFS. FSANZ's assessment remains that that, overall, benefits will outweigh costs.
Submitters did not support the following aspects of the analysis, for the reasons identified 1. Danone stated "*it is overly simplistic to only consider potential direct costs without any accounting for increasing and persisting supply chain and logistic challenges, inflationary pressures, scarcity in raw materials, ingredients, packaging, etc, following on from multiple governmental COVID responses in an environment with continued demand for safe and healthy sources of infant formula that will reach consumers when needed. The recall of Abbott infant formula powders in the USA is a recent example of how these pressures can penalise the most vulnerable. This cost is not accounted for in Section 9 or SD5*" 2. Danone states: "*FSANZ should consult to obtain new and up-to-date information on costs and benefits. The previous extensive consultation was not performed under the Act and FSANZ is not obliged to take it into consideration. Furthermore, previous consultation information was obtained over a 10-year timeframe and very likely to now be out-of-date*." 3. Danone states;	1. These challenges (supply chain, logistic, inflation, scarcity, ingredients, packaging) apply to both the costs to industry, as well as the health benefits. The health industry is subject to the same issues, potentially to a greater extent due to COVID's direct impact on the health industry. Therefore, while this could be taken into account, it would add to the challenges of costing this proposal with no net benefit in terms of accuracy. 2. FSANZ's assessment relied on the best evidence. This included submissions received in response to the first call for submissions. That call for submissions requested up to date data on costs and benefits. The updated costings in the 2nd CFS reflect the data provided. Remaining data gaps have been clearly identified, and all stakeholders are invited to provide data to fill these gaps. 3. Response:

Comment	FSANZ Response
a. "*The costs to industry are further reaching than what is covered here, and we submit that these greater costs far outweigh the stated benefits covered.* b. *It is insufficient to only consider the costs of reformulation and relabelling as the most significant costs incurred by these potential changes.* c. *Potential additional, indirect and unintended costs including negative health outcomes are possible.* d. *We foresee no cost savings resulting from this proposal;* e. *on the contrary costs to industry and consumers are steadily increasing due to multiple factors including inflation and supply chain constraints".*	a. FSANZ has broadened the range of costs considered, both quantitatively and qualitatively (as a result of comments received in response to the 1st CFS). However, no evidence of any un-identified quantifiable costs were provided. b. No evidence has been provided that there are greater costs than these, if there is evidence then FSANZ will consider it for inclusion in the DIA. c. FSANZ does not agree that there will be negative health impacts from this proposal. d. Noted, however other stakeholders have a different view, as shown in this Attachment. e. As noted above, these factors apply to both the costs, as well as the benefits for this proposal.
4. Danone states that the following claims should be substantiated with evidence. The CFS states that the standards are not expected to *a. limit market access nor* b. *notably reduce market viability*	4. Response: a. Market access – No evidence has been provided to demonstrate why a new entrant to the market could not meet the new standards. b. Viability – no evidence has been provided to demonstrate that overall viability of the industry will reduce. The potential for products to be withdrawn has been mentioned in the 2nd CFS.
5. Danone states that the loss of innovation represents a cost, as a result of 'no incentivisation' for innovation. INC adds; *the current pre-market assessment process requires demonstrable efficacy whereas Codex requires safety and suitability. There will be reduced competition for innovative and beneficial products as these become expensive to research, produce evidence and any benefit or differentiator will be unable to be communicated on labels.*	5. The marginal impact of the restrictions on the incentive to innovate has been discussed in section 5.
6. Danone states that "*the potential loss of innovation could lead to further pressure on the public sector for research on infant formula if the private sector investment no longer exists*."	6. This is a second round impact that is not typically considered by cost benefit analysis.
7. Danone states that "*generations of formula fed infants may be at a disadvantage because they do not have the same access to other technological advances in this space as compared to their non-Australia and New Zealand peers."*	7. Restrictions on marketing (and any resulting impacts on innovation) have not been introduced by the proposed new standard, they are an existing feature of the existing standard. 8. This risk has been noted in the 2nd CFS.

Comment	FSANZ Response
8. Danone states that the viability of soy products is at risk due to the lowering of the aluminium contaminant levels	
9. Danone states that "*specific products will no longer be available under this proposal or will require additional, costly pre-market assessments of currently used ingredients*."	9. The proposal has changed since the 1st CFS, and as a result FSANZ does not expect that pre-market assessments will be required for any currently used ingredients that comply with the current version of the code.
10. Danone states "*if regulatory ambiguity is introduced for many products currently classed as FSMPs, it will result in increased industry and governmental costs to deal with the effects."*	10. Cost and benefit analysis assumes that there is no ambiguity in proposed standards, and that the policy intent is fully realised. If the drafting of the Standard is not aligned with the policy intent then FSANZ welcomes feedback on this so that the drafting can be improved.
11. Danone – "*If there are no changes affecting special products for high-risk health conditions, then there will be no change to these trade conditions. A trade barrier may be introduced for SMPPi where the food additive Maximum Permitted Level (MPL) varies from the EU. Expanding the scope of the 2.9.1 Standard to FSMP products could introduce unintended trade barriers*."	11. SMPPi for high-risk health conditions are typically prescription based formula already sold in pharmacies. Under the proposed draft variation these products will experience no changes in trade conditions. Food additive MPL's prescribed for SMPPi align with the EU and Codex regulations and carry condition statements. All condition statements and MPL's for high-risk health conditions align with the requirements of the EU. Please see SD1 for further information. Under the regulatory framework SMPPi are regulated as infant formula products under Standard 2.9.1. There is clear differentiation between SMPPi and FSMP. Based on this, FSANZ considers there to be minimal risk of unintended trade barriers being introduced.
12. INC stated that: a. it is not appropriate to use alcohol labelling as a model for infant formula, as infant formula labelling is more complex b. the PWC (2014) cost schedule is out of date c. the pandemic has increased the cost of packaging d. the label updates are not as simple as changing text, the updates will likely be a full redesign	12. FSANZ has changed the data used to estimate the re-labelling cost, it is now based on data provided by industry. The data sources identified are no longer used. Feedback is welcomed on the new estimates.
13. Nestlé stated that the cost of PBS re-registration should be included in the costing	13. FSANZ does not expect that reformulation of SMPPi will be required, therefore PBS re-registration will not be required.
14. Nestlé noted that the requirement for all currently permitted L(+) lactic acid producing organisms to undergo pre-market assessment will add considerable extra costs to manufacturers and government.	14. This is no longer part of the proposal.
	15. An allowance has been made for packaging write off in the cost and benefit analysis.

Comment	FSANZ Response
15. INC states that "*due to the extent of composition and labelling changes, most companies will not be able to do 'one-off' changes. As there are reformulation changes companies will need to do a "hard change" which will result in packaging write-off*." 16. INC stated that cost information was provided in the 2021 consultation, particularly relabelling cost information, it should be used 17. INC states that there will be products unable to adapt to the proposed new Standard that would have to be withdrawn. Clinical trials and FSANZ applications are a barrier to entry into the market. Yet many of these products are considered safe and suitable in countries around the world. 18. INC, Nestlé, and NZFGC argue that the estimate of the number of SKUs is not accurate. INC state that there is at least 200 SKUs. FSANZ should survey industry separately to determine with greater accuracy the number of SKUs. 19. INC – FSANZ has assumed that highly specialised formula products for highly specialised conditions (SMPPi) will not require any label changes under the Proposal. Industry is yet to confirm this analysis.	16. FSANZ has used cost information provided for the 1st CFS, as it is directly relevant to the current proposal. 17. This point has been added to the industry costs section. 18. FSANZ has done an online study on the number of products produced in Australia and New Zealand. As a result, the assumed number of SKU has increased. FSANZ is open to the list of products being checked by industry to identify any missing products. 19. In the absence of evidence to the contrary, FSANZ has maintained this assumption.

Table 3 – Stakeholder comments on transitional arrangements

Comment	FSANZ Response
1. INC is of the view that 5 years transition period plus 2 years for stock-in-trade (7 years)is required to give effect to the extensive changes proposed. Every infant formula product SKU will change as FSANZ has observed, given the extensive number of compositional and labelling changes required. INC gave several reasons why this time frame is needed. 2. Nestlé highlight that the changes will require a suitable transition period to allow for reformulation, stability testing, labelling changes, manufacture and distribution, with some infant formula products having a 3-year shelf-life. 3. INC - The changes proposed do not always result in positive outcomes for Food Security. If significant amount of products are required to be reformulated and labelling changed this can create uncertainty in the market as "old" product is withdrawn, replaced by new. An appropriate transition will go someway to address this. 4. NZFGC states "*transition will be a major factor in minimising cost as FSANZ has identified. NZFGC recommends a 5 year transition plus a 2 year stock-in-trade period. This is on the basis that companies with multiple SKUs will not be able to achieve parallel changes across the board and the sequence of change will need to be spread in order to minimise market disruption, both domestically and for export."* 5. INC states there are trade costs if products cannot be reformulated pending applications, then the need to run two or more production lines –one for export where exemptions from domestic labelling and composition might be available –at a cost and time (lost markets) and another to meet some of the most restrictive standards in the world for addition optional ingredients.	FSANZ has the following response to all comments on the transitional arrangements: FSANZ's assessment, after regard to all submissions received, was that a five year transition period was appropriate. See section 11 of the 2nd CFS, and section 8 above.

Table 4 – Other stakeholder comments on the costs and benefits

Comment	FSANZ Response
1. INC notes that the Office of Impact Analysis[18] (OIA) granted FSANZ an exemption from the requirement to develop a Consultation Regulation Impact Statement (CRIS) for this proposal on the basis that a separate CRIS process was not expected to yield new information on costs and benefits. The OIA noted the extensive consultation that had already taken place and the two legislated six-week consultations planned for 2022. What was presumably not alerted to the OIA was that a new approach to a significant part of the Standard was being proposed by FSANZ (SMPPi) that was introducing non-infant formula products to the Standard.	1. The OIA's exemption for developing a CRIS was granted based on the number of consultation activities at FSANZ will complete as part of P1028. This includes the 1st CFS, where the approach referred to by INC was consulted on.
2. Danone questioned the OIA's conclusion that a CIA would not yield new information about costs and benefits. There are costs that go beyond direct costs covered in the CFS or SD5.	2. This 2nd CFS contains the same cost benefit analysis that a CRIS would have contained, had FSANZ developed a CRIS. Stakeholders are encouraged to comment on the analysis, in order to improve the Decision RIS (DRIS). This 2nd CFS covers both direct and indirect costs.
3. Danone states that the OIA provides guidance on cost-benefit analysis that can also be used for qualitative analyses for those effects where FSANZ could not assign a dollar value.	3. The OIA will be providing guidance to FSANZ to complete the DRIS, based on the data provided by stakeholders in response to the cost and benefit analysis presented in this 2nd CFS.
4. INC states that FSANZ should quantify any proposed benefits (using OIA CBA procedures) as validation for the proposed changes, even when full quantification is not possible. Danone adds – a correct CBA will account for all the positive and negative effects of the proposed regulation and allow FSANZ to determine on balance whether the community, government and industry is likely to benefit. The OIA provides guidance on CBA that can also be used for qualitative analyses for those effects where FSANZ could not assign a dollar value.	4. FSANZ has quantified all impacts where data is available to do so. All major impacts that cannot be quantified have been discussed qualitatively. FSANZ encourages stakeholders to provide data that would enable un-quantified impacts to be quantified.

[18] Formally the Office of Best Practice Regulation (OBPR)