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

**6 September 2022**

# Stakeholder Feedback Summary:
# 1st Call for Submissions
Proposal P1028 – Infant Formula

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# Executive summary

Food Standards Australia New Zealand (FSANZ) commenced Proposal P1028 *Infant formula* in July 2013. The purpose of the proposal is to revise and clarify standards relating to infant formula in the Australia New Zealand Food Standards Code (the Code). The main standards under review are Standard 2.9.1 *Infant formula products* and Schedule 29 *Special purpose foods* but amendments to other relevant standards are being considered. Revision and clarification of the standards ensures that infant formula products (IFP) remain safe and suitable, account for market developments, and reflect changes in the international regulatory context.

The first call for submissions (1st CFS) was released for public consultation between April and June 2022. The 1st CFS summarised FSANZ's assessment across all topics within the scope of P1028. Broadly these covered all types of IFP (infant formula, follow on formula and infant formula for special dietary uses) regulated under Standard 2.9.1 and issues related to the regulatory framework, nutrient composition, and labelling. The 1st CFS included FSANZ's preferred options for amendments to relevant standards but did not include proposed drafting.

A total of 32 submissions were received from industry, government, consumer groups and public health stakeholders. The submissions reflected diverse comments and suggestions, some of which had been considered by FSANZ in previous consultations for P1028[1]. FSANZ has carefully analysed all submissions and summarised the key topics in this report in order to inform stakeholders on the submissions received. The summary does not represent FSANZ's views on or response to submissions and should not be interpreted as such. Nor is FSANZ seeking further comments at this stage. A second CFS will seek written submissions on final proposed changes to standards and drafting of revisions to the Code.

[1] A full list of consultations is provided in the 1st CFS. Submissions to previous consultations as well as the 1st CFS are located on the FSANZ website: P1028 – Infant Formula (foodstandards.gov.au)

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# About this report

This report provides a summary of responses to the first call for submissions (1st CFS) released for Proposal P1028 Infant formula. This summary does not represent FSANZ's views on or response to submissions and should not be interpreted as such.

Selected quotes from select submissions are included to reflect the range of views expressed. All submissions are available on our website:

P1028 – Infant Formula (foodstandards.gov.au)

# Acknowledgements

FSANZ wishes to acknowledge the time and effort that submitters put into preparing their submissions.

# 1 Background

## 1.1 The Proposal

Breastfeeding is the recommended way to feed a baby. Infant formula products (IFP) are the only safe and nutritious substitute for breast milk for infants who are not breastfed. IFP are specifically regulated through Standard 2.9.1 and Schedule 29 of the Australia New Zealand Food Standards Code (the Code).

Food Standards Australia New Zealand (FSANZ) commenced Proposal P1028 in July 2013. The purpose of the proposal is to revise, clarify and update the standards relating to infant formula in the Code. The proposal aims to ensure that IFP remain safe and suitable, account for market developments, reflect changes in the international regulatory context and appropriately consider Ministerial Policy Guidance[2].

Proposal P1028 is complex and a number of important considerations should be acknowledged. Standards for infant formula contain the most prescriptive requirements of any food category in the Code. Changes to one Code requirement, whether related to composition, labelling or the overall regulatory framework, can impact on other requirements. As a food for a vulnerable population, a greater level of assessment is needed. As IFPs are the sole source of nutrition for some infants, assurance of continued supply is critical.

## 1.2 Previous consultation

Given the size and complexity of this proposal, several previous consultations[3] were conducted as part of the assessment phase of the proposal. This enabled FSANZ to gather information and reach a preferred view on some issues. FSANZ responses to previous consultations were presented in the first call for submissions (1st CFS).

## 1.3 The 1st call for submissions

FSANZ assessed the proposal to revise and clarify standards for the composition, labelling, category definitions and representation of infant formula products. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ called for submissions to assist further consideration of the proposal. The 1st CFS presented the summary of FSANZ's assessment for the proposal and the preferred options to amending Standard 2.9.1, Schedule 29 and related standards.

The 1st CFS was released for public comment between 4 April and 17 June 2022. During the consultation period, FSANZ also held a series of workshops with stakeholders to provide information and discuss key issues on regulatory options proposed in the CFS.

FSANZ received 32 submissions from a range of stakeholders (Appendix 1). FSANZ has carefully analysed the comments and summarised the key results in this report. Nine submitters provided confidential information to support their submissions. This information has not been included in this report.

[2] The Policy Guideline on Infant Formula Products. Food Regulation - Policy guideline on infant formula products
[3] Previous consultation papers and stakeholder submissions are available on the FSANZ website: P1028 – Infant Formula (foodstandards.gov.au)

# 2 Key results

There was significant interest in the 1st CFS from submitters who appreciated the opportunity to provide feedback on Proposal P1028. Many diverse views, perspectives and suggestions were received, some of which had been considered in our previous public consultations for P1028.

The summary presented in this report does not represent FSANZ's response to submissions and should not be interpreted as such. A comprehensive list of issues raised in submissions and FSANZ responses will be provided in the second call for submissions (2nd CFS).

## 2.1 General comments

Most submissions upheld the importance of breastmilk and breastfeeding for optimal infant health. Some submitters recognised the significant challenges involved in the P1028 review.

*"NSW recognises the challenge in undertaking this review to balance: i) infant health and safety, ii) innovation, iii) international market access and iv) certainty for medical professionals and care-givers." – NSW Food Authority*

*"We appreciate the huge effort of the team involved and want to make it clear that the areas of concern we identify below should not detract from our appreciation of the analysis and thought that has gone into this stage of the work." – New Zealand Food and Grocery Council*

*"We appreciate the significant work FSANZ has undertaken to date on this Proposal to cumulate in this substantial CFS. We also thank FSANZ staff for the opportunity to participate in workshops during the consultation period to clarify proposed approaches and discuss key issues for New Zealand." – New Zealand Food Safety*

**Comments about the objectives of the proposal and the FSANZ Act**

Objectives of the proposal were stated in the 1st CFS. Submitters provided their support for many of these objectives and those of the FSANZ Act. Of primary importance is the protection of infant health and safety. However, perspectives on other priorities were divergent and highlighted the tension that exists between objectives and setting appropriate standards. This was apparent in views on compositional issues, provision of adequate information to caregivers, and on aligning with international regulations and standards. Despite divergent views on specific issues, stakeholders agreed the best possible nutrition should be available for all infants.

*"The AFGC supports the provision of the best possible nutrition for non-breastfed infants. To achieve this, policy and regulatory measures need to balance restrictions on use and formulation to protect public health, while at the same time permit flexibility and incentive for innovation by the food industry. In this way, improvement of infant formulas shall continue in line with scientific developments." – Australian Food & Grocery Council*

*"…whilst alignment of Australian and New Zealand standards with international regulations is important, the health and safety of infants must be the priority. Therefore, whilst industry innovation should be facilitated by regulations, this must advance the health incomes of formula fed infants closer to breast fed infant health outcomes. Broad innovation by industry which does not positively influence a reduction of adverse health effects in formula fed infants, may lead to the promotion of unnecessary consumption of infant formula products (IFP) with resultant negative impacts on breastfeeding rates." – Queensland Health*

**Comments related to the level of scientific evidence of data**

Throughout the 1st CFS, FSANZ indicated that compositional requirements, in particular for specialised infant formulas, should be supported by generally accepted scientific data. Some submitters agreed with this approach and acknowledged its alignment with international standards and regulations. Others considered that high quality or strong scientific evidence was required given the vulnerable population in question.

*"SMPPi must be safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data." – Infant Nutrition Council*

*"EU 2016/127 outlines requirements similar to the Food Standards Code. However, it also allows for the voluntary declaration of components of protein, carbohydrate or fat, the whey/casein ratio, and the amount of substances whose suitability has been established by generally accepted scientific data." – Fonterra Co-operative Group Limited*

*"Generally accepted scientific data' does not provide an adequate level of certainty for jurisdictions to enforce. Jurisdictions require a level of evidence for SMP that is clear, un-ambiguous and unequivocal." – NSW Food Authority*

*"The term 'generally accepted scientific data' is used throughout the P1028 CFS, to support the use of a novel ingredient or additive. However, this is inadequate. The term should be defined to require high quality scientific evidence." – Australian Breastfeeding Association and World Breastfeeding Trends Initiative Australia.*

**Approach to align with international regulations and standards**

Submitters stated that FSANZ gave minimal consideration for the optimal levels of nutrients for infants and instead prioritised alignment with Codex levels, which in their view fundamentally places trade ahead of infant health. Submitters also noted that another significant limitation of FSANZ's assessment was a lack of specific research on the risks or harm of setting a certain minimum or maximum nutrient level. Submitters assert that this leads to a false conclusion that the lack of evidence means there is a low risk of harm.

Submitters also stated that alignment with Codex does not result in universal alignment or necessarily meet the import requirements for major export markets, and noted other regulations such as EU, US and China should be further considered.

Industry submitters agreed with the approach to align with international regulations and standards where public health and safety objectives have been met.

*"It appears that alignment with Codex is the predominant influence on this decision rather than a consideration of potential risk" – NSW Food Authority*

*"The departments are concerned that FSANZ has had little consideration for the optimal levels of nutrients for infants (based on infant requirements and breastmilk levels) and instead has made the priority to align with Codex levels, purely based on evidence of harm to infants. This fundamentally prioritises trade over infant health (noting Codex levels take into account issues such as developing countries' infrastructure and supply chains that may not be relevant to Australia and New Zealand)" - Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.*

*"IFF supports the primary objective of FSANZ's P1028 review to protect public health and safety. We also agree with the premise that infant formula must be safe for formula-fed infants to*

*consume, and caregivers need to know how to safely prepare, use and store the product. It is also our general position that the FSANZ Standard 2.9.1 Infant Formula products should, where FSANZ's primary objectives are satisfied, align with the relevant Regulations and Standards in the EU and CODEX, respectively." – Danisco Australia and Danisco New Zealand*[4]

## 2.2 Regulatory framework and definitions

This topic was discussed in pages 11-29 of the 1st CFS.

FSANZ proposed a change to the regulatory framework for Standard 2.9.1 so that products would fall into two categories: IFP and Special Medical Purpose Products for Infants (SMPPi).

IFP would include all infant formula and follow-on formula products for healthy infants and would meet compositional and labelling requirements for the defined category IFP. The category would also include those products for transient gastrointestinal conditions that are based on a modified protein source with specified modifications defined to be (1) partially hydrolysed protein or (2) low lactose/lactose free protein.

SMPPi would be those products for unhealthy infants with a serious disease, disorder or medical condition. These would be allowed to vary from the Standard 2.9.1 compositional requirements and be labelled appropriately to indicate their intended purpose. It was proposed that relevant requirements under Standard 2.9.5 *Food for special medical purposes* would be mirrored in Standard 2.9.1 for SMPPi. Due to the need for SMPPi to be used under medical supervision, SMPPi were also proposed to be restricted from sale in grocery stores, and only available through pharmacy, hospitals or health clinics, or by prescription.

Many submitters commented on the categorisation of products with many divergent views and issues raised.

**SMPPi**

Submitters who supported this category (or supported it in principle) considered that it appropriately separated products for infants with a specific disease, disorder or medical condition from low-risk products that could be consumed by healthy infants.

Opposing submitters had concerns about the enforcement of the SMPPi category and considered that it would be manipulated to enable products that varied compositionally to be placed on the market without pre-market assessment. Because of the more flexible labelling approach proposed for SMPPi, it was also thought that the prohibition on claims that applies to all IFP could be circumvented. There was also the view that all infant formula (including special purpose products) should be retained under the umbrella term Infant Formula Products.

On the other hand, industry was opposed to the SMPPi category because they did not agree that products should be restricted from grocery store sales, and that the category creates confusion between products suitable for healthy infants and those for special conditions to be used under medical supervision. There were also concerns that SMPPi includes other supplementary food products which currently fall under Standard 2.9.5.

There were various comments on the definition for SMPPi with several proposed alternatives that strengthened the terminology and requirements for use under medical supervision.

[4] Danisco is a subsidiary of International Flavors and Fragrances Inc (IFF).

*"The creation of a new category, Special Medical Purpose Products for infants (SMPPi) within Standard 2.9.1 is consistent with our support for the retention of such products within 2.9.1 whilst providing a clear distinction from other products for special dietary use" – Allergy & Anaphylaxis Australia*

*"NSW notes that both IFP product categories are under the same umbrella of 'infant formula' in Standard 2.9.1, to ensure that general requirements of Standard 2.9.1 (e.g. prescribed name, prohibited representations) apply to all 'infant formula' labelling products. Creation of a Special Medical Purpose Products for Infants (SMPPi) breaks this link and proposes Standard 2.9.1 contain two product categories with different rules applying to each category. This is considered inconsistent with the policy principles of the MPGI[5]." – New South Wales Food Authority*

*"The inclusion of products currently regulated under Standard 2.9.5 presents as a new area and requires thorough consideration. Danone is concerned that other products have been inadvertently brought into the scope of 2.9.1 and the changes to the regulation of these products may not have been thoroughly assessed by FSANZ for risks." – Danone Nutricia*

*"The AFGC has concern regarding the general restriction on sale of SMPPi that are specifically developed for a disease, disorder or condition. Caregivers may be left with less accessibility and availability of products to feed their babies and may in lieu use unsuitable and potentially harmful alternatives." – Australian Food & Grocery Council*

**Modified IFP**

In the 1st CFS, FSANZ's preferred option was to include within the category of *Infant Formula Products*:

Nutritionally complete infant formula products with a modified formulation relating only to partially hydrolysed protein and/or low lactose/lactose free which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants.

Submitters had mixed views on this proposed option. Some agreed with this approach on the basis that it appropriately separates IFP that contain low lactose/lactose free and/or hydrolysed protein which are not products to treat diseases or other serious condition. It also retains these products under the restrictions imposed on IFP. Other submitters opposed this approach as it creates confusion between products suitable for healthy infants and products for serious conditions. Opposing submitters also argued that because these modified products would be available through grocery stores, this approach would create a way for them to be marketed to infants who do not need them. Several submitters considered that the standard would need better definitions to separate partially hydrolysed and extensively hydrolysed products.

**Suggested additional or alternative elements**

Submitters also suggested the following additional or alternative elements to the proposed regulatory framework:

- setting a prescribed name for SMPPi
- two tiers of special infant formulas

[5] The Policy Guideline on Infant Formula Products. Food Regulation - Policy guideline on infant formula products (abbreviated as 'MPGI' by this submitter)

- pre-market assessment for all special medical purpose formulas by a process separate to the normal standards management process for amending the Code.

## 2.3 Supplementary products

This topic was covered on pages 21-22 in the 1st CFS.

Under the proposed regulatory framework in the 1st CFS, modular products such as human milk fortifiers and pre-term supplementary products would be included in the SMPPi category. This would enable permissions and restrictions to be applied to all SMPPi products without need for duplication in Standard 2.9.5.

Submitters who supported the preferred option noted that it provides regulatory clarity by having highly specialised products as well as IFPs (whether as the sole or principal source of nourishment or not) in the same standard. As well, it ensures greater control of this product category to protect the health and safety of the vulnerable infants that consume these products, and enables provisions that protect infants to be applied, where relevant, to these products (such as ensuring food additives have been assessed as safe for infants).

A number of submitters opposed the preferred option. These submitters cited problems with application of the SMPPi principles to partial products that are not complete or principle sources of nutrition for infants. Mainly this related to products that are not human milk fortifiers, but a range of nutritionally incomplete special medical purpose products (e.g. feed thickeners and specialty cereals).

*"INC believes that only special medical infant formula products that form the sole or principal liquid source of nourishment should be considered under Standard 2.9.1 at this time. The extension and impact to other infant products has not previously been fully considered and it could have unintended health and safety and trade restrictive consequences. INC recommends that all other special infant products that do not meet the definition of an infant formula product should otherwise remain under Standard 2.9.5." – Infant Nutrition Council*

*"NZFS supports the proposed approach to regulate all SMPP in Standard 2.9.1 of the Code. This approach provides regulatory clarity by having all highly specialised products that may be consumed by infants from birth (whether as the sole or principal source of nourishment or not) in the same standard as IFPs that may also be consumed from birth. It will also help ensure greater control of this product category (now and into the future) to protect the health and safety of the vulnerable infants that consume these products" – New Zealand Food Safety*

*"The AFGC suggests, at a later time, FSANZ to consider raising a separate proposal for consultation of these latter products in Standard 2.9.5." – Australian Food & Grocery Council*

## 2.4 Novel foods and nutritive substances

**Framework for pre-market assessment**

This topic was covered on pages 32-37 in the 1st CFS.

The preferred option in the 1st CFS was to consider the requirements for novel foods and nutritive substances in IFP as part of the broader review of these substances for all food categories under the proposal P1024. The general prohibition on the addition of novel foods or nutritive substances to IFP unless these are expressly permitted through an application or proposal would be retained. The 1st CFS also noted that there is no exemption for food additives and processing aids used for IFP.

Jurisdictions maintained their opposition to FSANZ's preferred option on the basis that it did not ensure the regulatory certainty needed for all substances added to IFP. They also cited regulatory gaps in the Code that they considered enables novel foods used in IFP to be managed under Standard 1.5.1 and Schedule 25.

Other submitters supported FSANZ's preferred option in the 1st CFS.

*"This objection is made more pertinent with the proposal that substances added to SMPPi for 'medical purpose' do not require pre-market safety assessment, whereas 'nutritive substances' would. This is akin to a self-substantiation pathway for IFP and is wildly out of step with the MPGI[5] and its advice 'there is a greater level of risk to be managed compared to other population groups'."* – *New South Wales Food Authority*

*"We continue to support the proposed approach. Novel foods to be used within infant formula products should be reviewed under P1024. We support exclusion of pre-market assessment requirements in P1028 to ensure a consistent and comprehensive review under P1024."* – *Fonterra Co-operative Group Limited*

## 2.5 L(+) lactic acid producing microorganisms

This topic was covered on pages 57-60 in Supporting Document 1 (SD1) and summarised on page 41 of the 1st CFS.

In the 1st CFS, FSANZ's preferred option was to retain the existing permission for addition of L(+) lactic acid producing microorganisms in Standard 2.9.1 but to clarify that L(+) lactic acid producing microorganisms may only be added *for acidification purposes*. This conclusion was based on FSANZ's consideration that clarifying the current permission to indicate the purpose of use (for acidification) would align with the original intent of the permission and would provide regulatory certainty around the addition of microorganisms. FSANZ also proposed to clarify the permission that only non-pathogenic or non-toxigenic microorganisms may be used.

Many submitters commented on this issue with divergent views. Industry opposed the proposed clarification of the existing permission. This was based on the significant impact a restricted permission will likely have on current products on the market, along with the fact that the existing permission has been in place for >20 years with no evidence of harm and can be considered safe and traditional for infants. They commented that FSANZ's proposed restriction runs counter to international regulations, scientific literature and FSANZ's risk assessment.

Several submitters support an approach that provides regulatory certainty for both industry and enforcement agencies, and better aligns with the approach under Codex CXS 72-1981 and the Codex Draft Standard for Follow up Formula for Older Infants (Codex Draft Standard for FuFOI).

A number of submitters suggested the permission should be revised to include specific strains of L(+) lactic acid producing microorganisms. In this regard it was suggested that strains currently in use in IFP - as named in FSANZ's risk assessment (FSANZ 2021) or based on data provided in confidence by individual manufacturers - could be 'grandfathered' into the Code. Other submitters indicated that specific strains are novel foods and as such must undergo pre-market assessment in line the Ministerial Policy Guideline. If this is the case, submitters commented that many new applications are likely be submitted to FSANZ for assessment.

Two submissions (VICDoH and QLDH) opposed FSANZ's preferred option and raised a new issue not considered in P1028. This issue relates to fermented infant formulas and production of bioactive metabolites from the fermentation process ('postbiotics').

*"INC strongly opposes turning the clock back two decades in relation to L(+) lactic acid producing microorganisms and requiring all except those for acidification to have pre-market approval. This would take products off the shelf in Australia and New Zealand, could impact IF supply (potentially creating shortages similar to the current US situation) and impact New Zealand and Australian export markets since our customers offshore look to our domestic product/market for comfort on what they are putting on their shelves." – Infant Nutrition Council*

*"Even if FSANZ were to specify that only non-pathogenic and non-toxigenic bacteria could be added for acidification purposes and no live bacteria could be present, these restrictions may not prevent novel practices such as the use of lactic acid bacteria to supplement infant formula with fermentation-produced metabolites (known as postbiotics), which can include human milk oligosaccharides." – Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.*

## 2.6 Food additives

These topics were covered in SD1, pages 11-40, and summarised on pages 38-39 of the 1st CFS.

**Removal of carry-over principle for food additives in IFP**

In the 1st CFS (and earlier consultation documents), carry-over of food additives was proposed to be not permitted unless a specific permission exists for that food additive in the final food.

Submitters that supported the proposed option noted that this approach would be consistent with international standards and regulations, would provide clearer restrictions on use of food additives for IFP, and would be aligned with the Ministerial Policy Guideline that provides for a pre-market safety assessment of all food additives in IFP.

Submitters that opposed the proposed option noted that they had opposed this change in previous consultations and preferred the status quo as it is a major change and will require substantial work with suppliers. They also noted that if the carry-over principle is removed, then new permissions that align with international regulations were requested be included in the 2nd CFS to enable a smooth transition.

In removing the carry over principle for IFP, the 1st CFS also proposed to harmonise food additive permissions with Codex or EU regulations in line with risk management principles, FSANZ's safety assessment conclusions and the stated technological justification for individual food additives.

Some submitters generally agreed with the preferred option for the removal of the carry-over principle for IFP as long as the permissions in the Code are aligned with international regulations and standards. However there was opposition to some provisions because appropriate technological justification according to the Ministerial Policy Guideline had not been considered, especially for SMPPi.

*"MPGI[5] support the proposed approach and the need to ensure consistency with relevant international regulations and standards, in particular those of the EU and Codex. This will serve to both support New Zealand's infant formula exports and to maintain importation of infant formula*

*products, especially special medical purpose formulas which generally are not manufactured in Australia and New Zealand." – New Zealand Food Safety*

*"In specific regards to carry-over, Fonterra would prefer to maintain the status quo but can accept the removal of the carry-over principle for infant formula products in alignment with the Codex position on this." – Fonterra Co-operative Group Limited*

*"For new permissions for food additives in infant formula it is not demonstrated in Proposal P1028 that an assessment of the technological justification for the additives has been completed. An existing permission for a food additive in other food categories should not be extended to infant formula without demonstration of technological justification for its use specifically in infant formula." – South Australia Health*

## 2.7 Nutrient composition

Nutrient composition permissions for infant formula and follow-on formula were covered in Supporting Document 2 (SD2) and summarised on pages 41-43 of the 1st CFS.

Unanimous support was received from submitters on 58 nutrient composition permissions. However, opposing views and disagreement with FSANZ preferred option was evident for 47 nutrient composition permissions. Key issues raised within the 1st CFS included the justification for follow-on formula, trade being prioritised over public health, optional ingredients, and protein source.

**Follow-on Formula**

In the 1st CFS, follow-on formula was re-introduced into the scope of P1028 with the nutrient composition being considered within SD2.

Submitters that supported follow-on formula as an IFP also supported the approach taken by FSANZ, noting that follow-on formula should only deviate from infant formula where there is substantiated science to support the differences in needs between the age groups, and that both products should be regulated within Standard 2.9.1.

Submitters that opposed follow-on formula as an IFP noted that follow-on formula is not a necessary product and that there is no significant point of difference between infant formula or follow-on formula and their associated proposed nutrient compositions. Submitters also noted that consumers are currently being misled regarding the necessity of follow-on formula and are unnecessarily switching from an infant formula to a follow-on formula. A submitter stated that where nutrient needs are higher for older infants, these requirements can be obtained from complimentary feeding.

*"...Follow-on formula is not a necessary product and that infants who are not able to have breastmilk should be fed infant formula from birth to 12 months of age ... regulations would better protect infant health and recognise the importance of breastfeeding if follow-on formula was phased out of use" – Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions*

**Optional ingredients**

Permissions for optional ingredients including minimum levels, maximum levels and their status as voluntary in infant formula and follow-on formula generated opposing views from submitters. Optional ingredients discussed within the 1st CFS included erucic acid, docosahexaenoic acid (DHA), arachidonic acid, trans fatty acid, phospholipids (PL), 2′-O-

fucosyllactose, taurine, lutein, nucleotides in infant formula, and choline, myo-inositol, L-carnitine in follow-on formula only.

Industry submitters generally supported FSANZ's preferred option to retain the voluntary permissions for the above ingredients noting that it was based on the rationale provided by FSANZ within SD2, international alignment with Codex CXS 72-1981 (as set out in the Ministerial Policy Guideline), and a demonstrated history of safe use.

Submitters that did not support FSANZ preferred approach to retain the voluntary permissions instead recommended that the ingredients be assessed and considered as mandatory additions to IFP. The functional purpose and justification for the addition of these optional ingredients against the MPGI[5] was also requested, as this policy guideline was specifically developed for P1028 to guide regulatory decisions.

Significant opposing commentary was evident for DHA and PL in infant formula products and choline, L-carnitine, myo-inositol and nucleotides in follow-on formula.

*"Public health stakeholders have informed us they are strongly opposed to optional ingredients in infant formula on the basis that it creates inequity of access to these infant formula products (which are an essential replacement where breastmilk is not available), creates confusion for carers, misleads carers about the benefits of these ingredients marketed in formulas and leads mothers to consider these premium products as a benign or superior choice over breastfeeding, reducing breastfeeding rates" – Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions*

**Protein source**

In the 1st CFS FSANZ's proposed to prescribe protein sources as 'cow's milk protein, goat's milk protein, protein hydrolysates of one or more proteins normally used in infant formula and soy protein isolate'.

Submitters that supported FSANZ preferred approach noted that non-listed sources would require pre-market safety assessment before they could be included in the Code, ensuring safety and suitability for infant growth and development.

Some of these submitters also supported the need for pre-market assessment of new sources of plant-based protein to ensure that issues related to protein digestibility and bioavailability of micronutrients is assessed, in addition to potential issues of allergenicity.

Submitters that did not support FSANZ preferred approach recommended wording similar to Codex 'milk of cows or other animals or a mixture thereof...' to include mammalian milks such as buffalo, goat and specially sheep.

Many submitters did not support the exclusion of sheep's milk from the protein source statement. Submitters noted that sheep's milk had been on the market for a number of years and is considered to have a history of safe use. Submitters also noted that the New Zealand Ministry of Health recommend infants are fed a standard dairy based infant formula (made from cow's, goat's or sheep's milk protein) in their Health Eating Guidelines for New Zealand Babies and Toddlers (0-2 years old). Multiple submitters provided nutrient composition of sheep's milk in comparison to human milk and cow's milk which evidenced similarities in amino acid sequences and protein digestible indispensable amino acid scores.

*"It is of significant concern to MPI (as a wider organisation which includes NZFS) that sheep's milk protein is not one of the prescribed sources of protein proposed for use in IFPs–and we respectfully ask that this is reconsidered within P1028" – New Zealand Food Safety*

*"Sheep milk, like all mammalian milks, has a high nutritional content and quality protein even before modification in accordance with infant formula standards." – Australian Food & Grocery Council*

*"INC agrees that all proteins sources used in the manufacture of infant formula need to be safe, suitable, and support normal growth and development of infants, while also not interfering with absorption of other essential nutrients" – Infant Nutrition Council*

## 2.8 Labelling

**The issues noted here relate to infant formula and follow-on formula.**

### Safety and food technology

The 1st CFS provided preferred options on specific labelling requirements for directions for preparation and use, date marking, warning statements, prescribed names, certain age-related statements and protein source information that reside in Division 5 of Standard 2.9.1 (SD1, pages 60-80).

FSANZ previously consulted stakeholders on these labelling topics in 2016 and in 2021. As a result, there was general agreement amongst submitters on the preferred options for directions for preparation and use, application of these directions to ready-to-drink and concentrated formulas, date marking, storage instructions, and most age-related statements.

*Statement on protein sources*

The preferred option for the statement on protein source was to clarify that the 'source' of protein refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey protein or casein) (SD1, pages 77-78). Industry submitters opposed this approach because it limits the information provided to caregivers and health professionals and does not allow an accurate description of the product. These submitters noted there is no evidence of consumer confusion and the proposed option is inconsistent with Codex.

In contrast, other submitters supported the clarification because it simplifies protein source information for caregivers. This would aid product identification and be helpful for enforcement, whereas information about protein fractions is not useful for caregivers and is used primarily for marketing purposes.

*"…without information on protein fractions or partially hydrolysed whey protein being permitted on labels, manufacturers could not provide a true, complete and accurate product description. This information on protein is relevant and important for both consumers and healthcare professionals." – Fonterra Co-operative Group Limited*

*"A&AA strongly supports the retention of the requirement for the co-location of the protein source statement with the name of the food. This enables caregivers to immediately identify infant formulas which are problematic both with respect to listed allergens but also other protein sources including non-listed allergens which need to be avoided." – Allergy & Anaphylaxis Australia*

*"Dietitians Australia supports FSANZ's approach. We agree that references to protein fractions in the protein source statement are not useful for caregivers and that they are used primarily for marketing purposes. We support clarification of protein fractions for medical purposes as per NHMRC Infant Feeding Guidelines and ASCIA guidelines, (eg complete hydrolysed formula, amino acid formula) where needed." – Dieticians Australia*

**Labelling for provision of information**

Supporting Document 3 (SD3) of the 1st CFS covered preferred options for labelling of ingredients, the declaration of nutrition information, inter-relationships between declarations in the nutrition information statement (NIS) and the statement of ingredients, modified IFP and representations.

*Nutrition information statement*

The preferred option provided on pages 11-16 of SD3 was to prescribe the format of the nutrition information statement (NIS) in accordance with the recommended format in the existing Schedule 29 guideline. There was broad opposition from industry submitters to mandate the NIS format and content on the basis of reduced flexibility in language and terminology, inconsistency with international food standards, a lack of evidence that current NIS is problematic, imposition of a trade barrier, and questions about the effectiveness of proposed NIS. An industry submitter was supportive of a more regularised NIS, but not to the extent of prescription proposed by FSANZ.

Jurisdictions and a health professional group supported the prescribed NIS with the view that a mandatory NIS format would assist consumers to compare across products.

*"Danone want to support carers in choosing the best product for their infants through empowering them to compare and differentiate products easily. However, we are concerned that this proposal could severally limits the ability to do this." – Danone Nutricia*

*"The format for the NIP for all other pre-packaged foods is prescribed, so it is logical and consistent that the NIS for infant formula products is too….Also, a prescribed format should mean a consistent and easy-to-use format to aid caregivers' use and understanding of this nutrition information and is supported by consumer research as the preferred option for caregivers". – New Zealand Food Safety*

*"Companies only include information in the current NIS that they understand is important and useful for both caregivers and healthcare professionals to be able to make informed choices." – Australian Food & Grocery Council*

*Macronutrient sub-groups in the NIS*

The preferred option from the 1st CFS was to include permission for the voluntary declaration of subgroups in the NIS under the headings 'Protein', and 'Long chain polyunsaturated fatty acids'. Jurisdictions did not support the voluntary listing of macronutrient sub-groups (e.g. 'whey' and 'casein'), arguing that there is no justified need for information on macronutrient subgroup composition, and so do not support permission for its listing in the NIS. Industry supported the status quo or flexibility to allow terminology that will assist caregiver's ability to understand the label information.

*"…the departments do not believe there is a clear need to provide information on macronutrient subgroup composition and are concerned that this information may be more detrimental than beneficial." – Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions*

*"Companies already voluntarily provide relevant macronutrient sub-group information to inform carers and there is no evidence of issues with the status quo. Not all infant formula products are the same and prescribing a list may limit relevant information for carers to be informed and compare products." – Infant Nutrition Council*

*Claims about ingredients*

This topic was covered in SD3 pages 25-26. The preferred option was to only permit information about ingredients in the statement of ingredients (except for ingredients such as nutritive substances that are required to be declared in the NIS). Jurisdictions supported the preferred option but industry submitters were not supportive, stating (amongst other things) that the restriction is inconsistent with international food standards, ingredient information allows food to be correctly described, it is not the same as nutrition and health claims as defined by FSANZ, and there is no evidence of issues arising from it appearing elsewhere on the label.

*"Nestlé agrees that there is some confusion between nutrient, health and related claims, which are not permitted on infant formula products, and reference to specific ingredients. Nestlé suggests that clarification should be considered rather than new prohibition. Also, these must continue to allow for reference to the term 'ingredients' as a generic term to allow for descriptions which are required to provide the consumer with a truthful and accurate representation of some products (e.g. organic ingredients)." – Nestlé*

*"The Ministry agrees that clarification is needed regarding the use of ingredient claims on infant formula product labels. Ingredient claims, like nutrition and health claims, are promotional tools. The Ministry is opposed to their use and supports FSANZ's preferred option…" – Ministry of Health New Zealand*

## 2.9 Cost benefit assumptions

Views were mixed on the consideration of costs and benefits. Some submitters stated that FSANZ did not adequately consider potential improved public health outcomes of reduced infant formula use (arising from restricting the ability to market infant formula) where more infants are breastfed. Counter to this, it was also argued that improvements in the composition of infant formula over time will result in improved public health outcomes which should be included in the Cost Benefits Analysis.

The Infant Nutrition Council stated that benefits claimed by FSANZ resulting from reduced safety incidents will not materialise, because "*the safety record of products currently on the Australia and New Zealand market is exemplary*".

Some stated that the cost to consumers resulting from reduced innovation (resulting in less choice or higher prices) should be quantified.

Industry submitters provided information on cost impacts that will be considered when developing the Regulation Impact Statement for this proposal. Views were also shared on potential transition periods, to give industry time to (amongst other things) reformulate products, update labels, and sell-through existing stock.

# 3 Next steps

In preparation for the 2nd CFS, FSANZ is now in the process of responding to issues raised in submissions to the 1st CFS and regulatory changes. Based on the degree of divergent views, as summarised in this report, this may require additional targeted consultation with relevant stakeholders. The 2nd CFS will also address the requirements of the FSANZ Act which includes proposed drafting for the revised standards.

The 2nd CFS is anticipated to be released in January 2023.

# Appendix 1: Submitters to P1028 1st CFS

| | Submitter | Abbreviation |
|---|---|---|
| 1 | A2 Milk | A2M |
| 2 | Additive Solutions | AS |
| 3 | Allergy & Anaphylaxis Australia | AAA |
| 4 | Australian Breastfeeding Association, World Breastfeeding Trends Initiative Australia | ABA/WBTiA |
| 5 | Australian Food & Grocery Council | AFGC |
| 6 | Blue River Dairy | BRD |
| 7 | BODCO Dairy | BODCO |
| 8 | Care A2 Plus | CareA2 |
| 9 | Chr. Hansen | ChrH |
| 10 | Complementary Medicines Australia | CMA |
| 11 | Dairy Goat Cooperative | DGC |
| 12 | Danone Nutricia | DAN |
| 13 | Dansico/IFF | DIFF |
| 14 | Dieticians Australia | DA |
| 15 | Fonterra Co-operative Group Limited | FCG |
| 16 | Infant Nutrition Council | INC |
| 17 | Lonza | LON |
| 18 | Maui Milk | MM |
| 19 | Ministry of Health New Zealand | NZMoH |
| 20 | Morinaga Milk Industry | MMI |
| 21 | National Allergy Strategy | NAS |
| 22 | Nestle | NES |
| 23 | New Zealand Food & Grocery Council | NZFGC |
| 24 | New Zealand Food Safety | NZFS |
| 25 | NSW Food Authority | NSWFA |
| 26 | Produco | PRO |
| 27 | Queensland Health | QLDH |
| 28 | Sanulac | SAN |
| 29 | South Australia  Health | SAH |
| 30 | Spring Sheep Milk Company | SSM |
| 31 | Victoria Department of Health | VICDoH |
| 32 | WA Department of Health | WADoH |