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

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Supporting document 3

Labelling for Infant Formula Products

Proposal P1028 – Infant Formula 2nd CFS

Executive Summary

Food Standards Australia New Zealand (FSANZ) is reviewing regulatory requirements of infant formula products under Proposal P1028.

Infant formula is 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).

Label information about an infant formula product is important for assisting caregivers to identify and purchase the correct product for their infant and for instructing how to safely prepare and use it. FSANZ's primary statutory objectives for the protection of public health and safety, provision of adequate information to enable informed choices, and prevention of misleading or deceptive conduct are each particularly relevant for infant formula products.

This Supporting Document (SD) considers labelling matter examined through the review and issues raised by submitters during previous consultations. It has been divided into three parts:

- Part A - Safety-related labelling for infant formula and follow-on formula
- Part B - Labelling for provision of information about infant formula and follow-on formula
- Part C - Labelling for special medical purpose products for infants (SMPPi).

Submitter comments to the 1st CFS on labelling issues for each part have been addressed in one of two ways. Where FSANZ has considered comments and not changed its preferred option between the 1st CFS and the 2nd CFS, the rationale is provided in the summary table of submitter comments along with FSANZ's responses. For those issues where FSANZ is proposing to change its preferred option from the 1st CFS, the main body of this report provides a detailed discussion and rationale for the change. The regulatory approach for each part has been incorporated into two draft variations at Attachment A to the 2nd CFS:

- a draft variation amending Standard 2.9.1 (the primary draft variation); and
- a draft variation amending Schedule 29 and other Standards in the Code, as a consequence to the proposed amendments set out in the primary draft variation (the consequential draft variation).

The draft variations were made with consideration to the objectives of the proposal, the requirements of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) and relevant risk management principles.

A summary of the regulatory approach for these safety-related labelling requirements, including a comparison compared with existing requirements (if any), is provided in Table 1.

Table 1. Comparison between existing and new safety-related labelling requirements for infant formula and follow-on formula

Existing labelling requirements	Draft variation in Attachment A to the 2nd CFS
Directions for preparation and use	
(a) each bottle should be prepared individually.	Direction varied by replacing the word 'should' with 'must'.
(b) if a bottle of made up formula is stored prior to use, it must be refrigerated and used within 24 hours.	Direction varied by replacing the word 'made up' with 'prepared'.
(c) potable, previously boiled water should be used.	Direction varied by adding the word 'cooled' and replacing the word 'should' with 'must'.
(d) if a package contains a measuring scoop—only the enclosed scoop should be used.	Direction varied by replacing the word 'should' with 'must'.
Warning statements to follow instructions exactly	New directions (e) for powdered or concentrated formula—do not change proportions of the powder or concentrate or add other food except on medical advice (f) for ready-to-drink formula—do not dilute or add other food except on medical advice.
(g) formula left in the bottle after a feed must be discarded.	Direction varied by adding the words 'within 2 hours'
	New provisions • directions (a), (b), and (c) do not apply to ready-to-drink formula • direction (d) does not apply to concentrated formula and ready-to-drink formula.
Other specific labelling requirements in Standard 2.9.1	
Representations about food as an infant formula product.	• Provision varied to refer to food as infant formula or a follow-on formula
Prescribed names 'infant formula' and 'follow-on formula'.	New provision • for the existing name of the food (the prescribed name) to be stated on the front of the package.
Requirement for measuring scoop for an infant formula product.	Provision varied to apply to infant formula or follow-on formula.
Storage instructions must cover the period after the package has opened.	Provision varied to apply to infant formula or follow-on formula.
Print size is specified for warning statements, based on net weight.	Provision varied to apply to infant formula or follow-on formula.
Warning statement about following instructions exactly, by product type (e.g., powdered, concentrated and ready-to-drink)	Single warning statement applicable for all product types.
Warning statement 'Breast milk is best for babies'.	Retained
Statement that infant formula may be used from birth.	• Statement varied by replacing the words 'infant formula product' with 'infant formula'

Existing labelling requirements	Draft variation in Attachment A to the 2nd CFS
	New provision • require the statement to appear on the front of the package.
Statement that follow-on formula should not be used for infants aged under 6 months.	• Statement varied by replacing the words 'infant formula product' with 'infant formula' New provision • requiring the statement to appear on the front of the package.
Statement about age to offer foods in addition to formula.	Statement varied by clarifying it applies to infant formula and follow-on formula only.
Protein source statement.	• Provision varied to require the specific animal or plant source(s) of protein and replace the word 'product' with 'food' • Retained requirement for protein source statement to be included in the statement of the name of the food New provision • requiring this information to be stated on the front of the package.
Statements relating to dental fluorosis.	Removed.
Application of certain general labelling requirements in Part 1.2 of the Code	
Date marking requirements in Standard 1.2.5	Retained.
General legibility requirements in Division 6 of Standard 1.2.1	Retained.

Table 2 summarises the regulatory approach for labelling requirements that provide information about infant formula and follow-on formula to enable caregivers to make informed choices and assist health professionals when providing infant feeding advice. These requirements have been compared against existing labelling requirements (if any).

Table 2. Comparison between existing and new provision of information labelling requirements for infant formula and follow-on formula

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
General requirements for statement of ingredients in Standard 1.2.4.	Retained. New provision • permitting an optional format for declaring added vitamins and minerals that are required nutritive substances in the statement of ingredients • if optional format used, the statement of ingredients need not list the added vitamin and mineral in descending order of ingoing weight, provided that the statement of ingredients lists all added vitamins together under the subheading 'Vitamins' and lists all added minerals together under the subheading 'Minerals'.
Allergen declaration requirements in Division 3 of Standard 1.2.3.	Retained.
Requirement for the statement 'genetically modified' in Standard 1.5.2.	Retained.
Declaration of nutrition information in the nutrition information statement (NIS)	
Requirement to declare energy, protein, fat, carbohydrate, vitamins, minerals, permitted nutritive substances, inulin-type fructans, galacto-	Retained. New provision • requiring choline, inositol, and L-carnitine to be declared in the NIS for infant formula.

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
oligosaccharides (or a combination of inulin-type fructans and galacto-oligosaccharides).	
	New provision • permitting declaration of specified fatty acids and whey and casein in the NIS • if declared, these sub-group nutrients must appear in the NIS in the prescribed format.
Nutrition information declared per 100 mL made up formula; guidance indicates per 100 mL concentrated or per 100 g powder also permitted.	Provision varied to require the unit quantity of food expressed in per 100 mL.
Nutrition information must be expressed in terms of the product as reconstituted according to directions on the package.	Provision varied to clarify it applies to powdered and concentrated formula.
Average energy content, average amount.	• Retained average energy content • Provision varied to require the average quantity for nutrients, substances, and nutritive substances New provision • for how average quantity must be calculated.
	New provision • requiring a prescribed format for the NIS • include subheadings 'Vitamins,' 'Minerals', 'Additional' in the NIS for infant formula and follow-on formula; and the subheading 'Other nutrients' in the NIS for infant formula • subheadings must be printed in a size of type that is the same or larger than the nutrient names in the NIS.
Weight of one scoop (for powdered formula), the proportion of powder or concentrate required to reconstitute formula according to directions (for powdered and concentrated formula).	Provision varied to prohibit this information from appearing in the NIS, and to apply to infant formula or follow-on formula.
Other information requirements	
Prohibition for nutrition content and health claims, and therapeutic claims	New Note • Explains that existing prohibitions for nutrition content and health claims, and therapeutic claims in Standard 1.2.7 apply to infant formula and follow-on formula.
Requirements for lactose free and low lactose formulas.	• Provision varied to apply to infant formula that is represented as lactose free or low lactose • Removed permission for follow-on formula to be represented as lactose free or low lactose • Retained requirement to declare lactose and galactose in the NIS. New provisions • requiring the words 'lactose free' or 'low lactose' to be included with the name of the food on the front of the package • an explicit prohibition for the words 'lactose free' and 'low lactose' elsewhere on the label.
Partially hydrolysed protein.	New provision • for infant formula that is represented as partially hydrolysed, requiring the words 'partially hydrolysed' immediately adjacent to the statement of protein source • permitting the words 'partially hydrolysed' or any word or words having the same or similar effect in the statement of ingredients

Existing labelling requirements	Draft variations in Attachment A to the 2nd CFS
	• The requirement applies to infant formula only. Representations about partially hydrolysed follow-on formula would not be permitted.
Stage labelling.	New provisions • permit the use of the number '1' on infant formula and the number '2' on follow-on formula to identify for consumers that the product is infant formula or follow-on formula, respectively • if used, the number must appear on the front of the package of the product and immediately adjacent to the relevant age statements for infant formula and follow-on formula.
Product differentiation.	New provision • requiring that a food represented as infant formula or follow-on formula must not be also represented as another food.
Prohibited representations (including proxy advertising).	Retained existing prohibited representations New provisions • Unless expressly permitted or required by the Code, prohibiting representations made in infant formula or follow-on formula about: – information relating to another product (a name, number, picture, image, word or words). – ingredients – animal or plant sources of protein – the words 'partially hydrolysed' (or any word or similar words in the statement of ingredients) – the words 'lactose free' or 'low lactose' – a number used to identify for consumers that the product is infant formula or follow-on formula. Included a Note to clarify existing prohibition for nutrition content and health claims, and therapeutic claims apply.

FSANZ has summarised the regulatory approach for labelling of SMPPi in Table 3 below. The table lists the Standard 2.9.5, Standard 2.9.1 and Chapter 1 labelling requirements that would or would not apply to SMPPi. Given significant labelling changes have been made for the new SMPPi category, a labelling comparison of these requirements with new SMPPi requirements has not been provided.

Table 3. New labelling requirements for SMPPi

Draft variation in Attachment A to the 2nd CFS
Standard 2.9.5 food for special medical purposes (FSMP) labelling requirements applied to SMPPi
Requirements that a food may only be represented as an SMPPi if it complies with Division 4 in Standard 2.9.1 Mandatory labelling information: • name of the food • lot identification • information on irradiated food • ingredient labelling • date marking • directions for use or storage • legibility requirements • Mandatory statements and declarations • Nutrition information about any other nutritive substance added to the product to achieve its intended medical purpose

Draft variation in Attachment A to the 2nd CFS
Inner package requirements Transportation outer requirements.
Standard 2.9.1 labelling requirements applied to SMPPi
Permission for information on the source or sources of protein Prohibited representations: • a picture of an infant • the word 'humanised' or 'maternalised' or any word or words having the same or similar effect • the words 'human milk oligosaccharide,' 'human milk identical oligosaccharide' or any word or words having the same or similar effect • the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect • information relating to another food.
Other Chapter 1 labelling requirements applied to SMPPi
Existing prohibition for nutrition content and health claims, and therapeutic claims (a Note included in Division 4 of the primary draft variation) Information relating to foods produced using gene technology.
Labelling requirements <u>not</u> applied to SMPPi (Chapter 1, Standard 2.9.1 and Standard 2.9.5 FSMP)
Name and address of supplier Labelling requirements relating to infant formula and follow-on formula in new Division 3 would not apply to SMPPi. For example: • Directions for preparation and use for infant formula and follow-on formula • Warning statements for infant formula and follow-on formula – 'Follow instructions exactly' – 'Breast milk is best' • Age-related statements for infant formula and follow-on formula Requirements for lactose and gluten claims for FSMP A prescribed name for SMPPi.

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Introduction

Labelling requirements for infant formula products have remained essentially unchanged since Standard 2.9.1 – Infant formula products was finalised in 2002. While the intent of most of the labelling requirements is clear, certain provisions are viewed as ambiguous and stakeholders have either sought clarification or requested a change in intent.

FSANZ has undertaken four non-statutory consultations to seek stakeholder views on the review of the infant formula product standard including labelling measures:

- The 2012 Consultation paper comprised of a preliminary review of the regulation of infant formula products to ascertain which issues (including labelling issues) stakeholders thought needed to be considered further (FSANZ 2012 CP)

- The 2016 Consultation paper which discussed labelling requirements for safety and the provision of information relating to infant formula (FSANZ 2016 CP)

- The 2017 Consultation paper which considered labelling requirements for infant formula for special dietary use (IFPSDU) (FSANZ 2017 CP), and

- The 2021 Consultation paper which included further assessment of safety-related labelling for infant formula (FSANZ 2021 CP1).

In April 2022, FSANZ published the first statutory Call for Submission (1st CFS) which covered safety-related labelling issues in Supporting Document 1 (SD1), labelling for provision of information in SD3, and labelling for special medical purpose products for infants (SMPPi) in SD4. All consultation documents for Proposal P1028 are available from the FSANZ website[1].

In this SD, labelling matters for each of the infant formula product categories have been brought together. This SD has been divided into three parts as follows:

- Part A - Safety-related labelling for infant formula and follow-on formula
- Part B - Labelling for provision of information about infant formula and follow-on formula
- Part C - Labelling for special medical purpose products for infants.

In Part B, FSANZ has considered three issues for which there was no preferred option at 1st CFS. These issues are:

- the format of the nutrition information statement
- partially hydrolysed formula
- stage labelling, product differentiation and proxy advertising.

FSANZ has also undertaken further assessment to support the labelling risk management decisions for these issues. This assessment has comprised of:

1. A rapid systematic evidence summary of consumer literature that builds on the infant formula product labelling literature review in the 1st CFS (Attachment 1). This assessment is supplementary to the consumer evidence presented in Attachment 1 to SD3 for the 1st CFS.
2. A market survey of 82 infant formula and follow-on formula labels to support analysis of current stage labelling and proxy advertising practices of products in Australia and New

[1] https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx.

Zealand (Attachment 2). The products were available for sale in the domestic market between February 2021 and June 2022..

Over the course of Proposal P1028, FSANZ's assessment of the various labelling requirements for infant formula products has included the following matters:

- a review of existing labelling requirements as to whether or not they remain fit for purpose
- submitter comments provided during statutory and non-statutory consultations, including targeted consultation
- current industry labelling practices
- an updated microbiological safety risk assessment to support appropriate directions for preparation and use
- Australian and New Zealand infant feeding guidance
- consumer evidence to assess caregiver awareness, understanding and behaviour associated with existing labelling requirements and whether or not changes are warranted
- relevant Ministerial policy guidance
- international and overseas regulations (specifically Codex and the European Union regulations)
- voluntary Australian and New Zealand codes of practice designed to control marketing.

Part A Safety-related labelling for infant formula and follow-on formula

This part considers the labelling requirements for infant formula and follow-on formula relating to directions for use and storage, date marking, storage instructions, warning statements and their legibility, age statements, prescribed name, statement on protein source and its co-location with the name of the food. Table 4 below provides a summary of submitter comments to the 1st CFS and FSANZ's response.

Table 4: Safety & technology labelling issues: summary of submitter comments & FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
A.1 Directions for use and storage *FSANZ's preferred option at 1st CFS was to:* • *maintain without change the mandatory requirement for directions about preparing each bottle individually, storing made up formula prior to use and using only the enclosed scoop* • *revise the directions: to include the word 'cooled' in the direction to use potable, previously boiled water, and to include the text 'within 2 hours' in the direction to discard unfinished formula* • *to not apply the following directions to ready-to-drink formula: prepare each bottle individually, storing made up formula prior to use and using potable, previously boiled and cooled water* • *to not apply the direction to only use the enclosed scoop to concentrated and ready-to-drink formula.*			
Yes, the preferred option is supported.	These submitters supported the preferred option. INC and VIC also explicitly supported not applying selected directions to ready-to-drink formula due to their limited relevance.	DAN, DA, FCG, INC, NES, NZMoH, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option, with minor amendments. These amendments include: • replacing the word 'should' with the word 'must' in paragraphs 2.9.1—22(5)(a), (c) and (d) in the primary draft variation. • changing the words 'made up formula' to 'prepared formula' in paragraph 2.9.1—22(5)(b) in the primary draft variation. See section 1 in this report for discussion about these wording changes.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support the preferred option relating the discard direction. They commented that instructions must align with NHMRC Infant Feeding Guidelines to discard formula after 1 hour rather than 2 hours, because: • NSW Health facilities provide advice to caregivers based on the NHMRC Infant Feeding guidelines • the Ministerial Policy Guideline recommends 'regulation of infant formula products should not be inconsistent with the national nutrition policies of Australia relevant to infant feeding.' • overfeeding is common and can lead to overweight and obesity (Appleton J et al 2018).	DA, NSWFA	Comments regarding the discard direction are noted. However, paragraph 18(2)(a) of the FSANZ Act requires FSANZ, in developing or reviewing food standards and variations of standards, to have regard to the need for standards to be based on risk analysis using the best available scientific evidence (among other things). The proposed direction to discard unfinished formula within 2 hours is supported by FSANZ's risk assessment using the best available scientific evidence (see section 8.2 of SD1 to the 1st CFS). FSANZ also notes that the proposed direction is consistent with the recently updated New Zealand Infant Feeding guidance (Ministry of Health, 2021). Consumer evidence indicates caregivers want to know how long they can keep unfinished formula before they have to dispose of it (see SD4 to the FSANZ 2021 CP1). Providing a time limit of 2 hours would give assurance to caregivers that prepared formula remains safe for a longer feeding period. Further, manufacturers may choose to refer to one hour as wording of the direction is not prescribed, and a shorter duration does not represent a risk to infants. In regard to the issue of overfeeding, the study cited within Appleton J et al (2018) was not directly relevant because it associated weight gain with the practice of putting a baby to sleep with a bottle. FSANZ also notes that two other studies cited in the same article found no similar association and that many of the studies included in the reference were based on self-reported data of unknown validity (Appleton et al, 2018). FSANZ considers the issue of overfeeding should be addressed through infant feeding guidance.

Issue	Comment	Submitter(s)	FSANZ Response
The submitter(s) provide a new proposed option.	Two submitters did not indicate if they supported the approach for directions for use and storage, but instead provided comments on the addition of 'cooled' to *paragraph 2.9.1—19(3)(c):* • QLDH commented that the addition of 'cooled' and a time to discard unused formula will help address some, but not all of the issues with the directions for use and storage. Instead, prescribing information could address inappropriate information such as the instruction that qualified cooling to lukewarm as being 40°C. • CMA stated that including the word 'cooled' without further qualification may result in consumer confusion and inadvertently lead to unsafe formula preparation. Wording for a recommended optimal temperature may assist caregivers.	CMA, QLDH	At the 1st CFS, FSANZ provided details on a temperature risk assessment for prepared infant formula products, which determined that a precise cooling temperature was not required for safe use. FSANZ considers the inclusion of the word 'cooled' therefore remains appropriate for the direction (see paragraph 2.9.1—22(5)(c) in the draft variation). Further, FSANZ notes some manufacturers voluntarily specify the water temperature for cooling on their product labels. See section 8.2.4 in SD1 to the 1st CFS for previous discussion on these issues.
Other.	To provide greater clarity, and for alignment with other directions, recommend replacing the word "must" with "should' in paragraphs 2.9.1—19(3)(b) and (e). For example: b) that if a bottle of made up formula is to be stored prior to use, it ~~must~~ *should* be refrigerated and used within 24 hours e) that formula left in the bottle after a feed ~~must~~ *should* be discarded.	DAN, INC	FSANZ agrees that consistency in the wording is helpful for caregivers. As FSANZ considers the word 'must' conveys the importance for caregivers to follow the directions for use, and for consistency, the word 'should' in paragraphs 2.9.1—22(5)(a), (c) and (d) in the primary draft variation has been replaced with 'must'. Refer to section 1 to this report for further discussion about this wording change to the directions for preparation and use.

Issue	Comment	Submitter(s)	FSANZ Response
A.2 Standardised wording or pictures for directions for preparation and use *FSANZ's preferred option at 1st CFS was to maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use on infant formula products.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DAN, FCG, INC, NES, NZFS	FSANZ is proceeding with the preferred option, for the reasons provided in section 8.3 of SD1 of the 1st CFS.
No, the preferred option is not supported.	These submitters did not support the preferred option for the following reasons: • DA recommended aligning with images and language similar to the World Health Organization (WHO) guidelines for Safe Preparation, Storage and Handling of Powdered Infant Formula. • VICDoH commented that FSANZ's consumer research shows a significant proportion of test subjects misunderstood certain instructions. This provides clear evidence that instructions need a greater level of prescription.	DA, VICDoH	FSANZ reiterates that the suggestion to align with the WHO PIF guidelines (WHO 2007) would not be possible given there are inconsistencies with Australian and New Zealand infant feeding guidelines, and for the reasons set out in section 8.3 of SD1 to the 1st CFS. FSANZ notes the majority of submitters to the FSANZ 2021 CP1 supported an approach not to standardise wording or pictures for directions for preparation and use. FSANZ also notes recent consumer research which found that between 16 and 43% of Australian and New Zealand consumers responded incorrectly to questions about infant formula preparation after reading a set of instructions consistent with current regulations. The study identified that these results could be improved on some questions with different framing or additional information (Magill, Kalafatelis & Wallace 2020). While not requiring standardised directions, FSANZ's preferred option would address some more common areas of misunderstanding, such as appropriate temperature, disposal timeframes and not adding other food. (Continued next page)

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.		DA, VICDoH	While consumer evidence suggests that a lack of understanding of directions contributes to incorrect formula preparation, there was no evidence that the lack of standardisation was creating confusion for consumers. There is also evidence that caregivers deviate from preparation instructions for reasons other than not understanding them, such as for efficiency or convenience (Malek 2017). The chosen approach affords industry flexibility to word the required directions appropriately for their particular product and is consistent with Codex specifications. It also does not prevent more detailed instructions from being put on the label.
A.3 Date marking *FSANZ's preferred option at 1st CFS was to maintain existing date marking requirements for infant formula products.*			
Yes, the preferred option is supported.	These submitters expressed support for FSANZ's preferred option. VICDoH also commented that it is unclear what would trigger a use-by date in terms of nutrient deterioration, and FSANZ should provide written guidance on the expectation for use of the use-by date.	DAN, FCG, INC, NES, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option for the reasons provided in section 8.4 of SD1 to the 1st CFS. Generic date marking requirements in Standard 1.2.5 would continue to apply to infant formula and follow-on formula. FSANZ does not consider written guidance on the use of a use-by date is necessary. The Code does not specify the actual date mark to be used or the shelf life of most individual foods, including infant formula products. The onus is on the supplier of the food to determine the most appropriate date mark for their products.
A.4 Storage instructions *FSANZ's preferred option at 1st CFS was to maintain:* • *existing generic requirements for storage instructions* • *the specific requirement for infant formula products, to cover the period after the package is opened.*			

Issue	Comment	Submitter(s)	FSANZ Response
Yes, the preferred option is supported.	These submitters provided support for the preferred option without further commentary.	DAN, FCG, INC, NES, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option based on the assessment in section 8.5 of SD1 to the 1st CFS. Generic requirements for storage instructions in Standard 1.2.6 would continue to apply. See section 2.9.1—18 in the primary draft variation for specific storage instructions.
No, the preferred option is not supported.	DA recommended prescribing generic requirements for the storage instructions relating to the period after the package is opened e.g., 4 weeks.	DA	As noted in section 8.5 of SD1 to the 1st CFS, section 2.9.1—22 of the current Standard already requires the storage instructions on the package of infant formula products to cover the period after the package is opened. FSANZ is not proposing to prescribe a time period because it may differ between products. The onus is on the manufacturer to determine storage instructions that are appropriate for their product. The existing requirement has been retained in section 2.9.1—18 in the primary draft variation.
A.5 Legibility requirements for warning statements *FSANZ's preferred option at 1st CFS was to maintain existing legibility requirements for generic or specific warning statements on infant formula product labels.*			
Yes, the preferred option is supported.	These submitters provided support for the preferred option without further commentary.	DA, DAN, FCG, INC, NES, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option based on the assessment in section 8.6 of SD1 to the 1st CFS. Generic legibility requirements in Section 1.2.1—24 would continue to apply. See section 2.9.1—23 in the primary draft variation for print size requirements for specific warning statements on infant formula and follow-on formula.

Issue	Comment	Submitter(s)	FSANZ Response
A.6 Warning statements about following instructions exactly *FSANZ's preferred option at 1st CFS was to require a new direction for the preparation and use of infant formula products:* • *for powdered and concentrated formula - not to change proportions of [powder/concentrate] or add other food except on medical advice* • *for ready-to-drink formula - not to dilute or add anything except on medical advice.* *FSANZ also proposed to consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types that states:* *Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.*			
Yes, the preferred option is supported.	These submitters supported the preferred option.	DA, DAN, FCG, INC, NES, NZFS, NZMoH, SAH, VICDoH	FSANZ is proceeding with the preferred option based on the assessment in section 8.7 of SD1 to the 1st CFS. See paragraph 2.9.1—22(1)(a) in the primary draft variation for the revised warning statement to follow instructions exactly, and paragraphs 2.9.1—22(5)(e) and (f) for the new directions.
No, the preferred option is not supported.	NSWFA supports the original proposal for a warning statement *'Do not add anything or change proportions of powder except on medical advice'*. This sentence is very clear to caregivers that nothing should be added (or taken away) from the preparation of infant formula products. Moving such information to preparation instructions (unless bolded and underlined) will not carry equivalent weight to a warning statement.	NSWFA	FSANZ notes these concerns, however the consumer evidence indicates locating the information to not 'add other food' in a direction would have greater utility for caregivers (see section 8.7.4 of SD1 to the 1st CFS).
Other.	NES and NZFS also suggested that for consistency with powdered and concentrated infant formula products, the following part of the statement for ready-to-drink infant formula products should be amended: "not to dilute or add ~~*anything*~~ *other food* except on medical advice".	NES, NZFS	FSANZ agrees with the suggestion to change the word 'anything' to 'other food'. Refer to section 2 to this report for further discussion about the wording change to the directions for preparation and use and paragraph 2.9.1—22(5)(f) in the primary draft variation.

Issue	Comment	Submitter(s)	FSANZ Response
A.7 'Breast milk is best for babies' warning statement *FSANZ's preferred option at 1st CFS was to retain the existing 'breast milk is best for babies' warning statement as currently required by paragraph 2.9.1—19(1)(d).*			
Yes, the preferred option is supported.	These submitters supported the preferred option. VICDoH also commented that no research has been provided on the relative merits of gain-framed versus loss/risk-framed statements and the impacts on intention to breastfeed or use formula.	DAN, DA, FCG, INC, NES, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option based on the assessment in section 8.8 of SD1 to the 1st CFS. See paragraph 2.9.1—22(1)(b) in the primary draft variation.
A.8 Statement that infant formula product may be used from birth *FSANZ's preferred option at 1st CFS was to maintain the requirement for the statement indicating that the infant formula product may be used from birth as currently required by paragraph 2.9.1—19(4)(a).*			
Yes, the preferred option is supported.	These submitters supported the preferred option. INC also commented that this requirement is for "infant formula" only and not "infant formula product". DAN commented the age indication statement should be permitted to vary, for example "0 to 6 months," "from birth," or other equivalent terms.	DA, FCG, INC, NES, NZFS, SAH, VICDoH, DAN	FSANZ is proceeding with the preferred option, with one amendment to vary the provision to refer to 'infant formula'. For discussion on this issue, refer to section 3 to this report and paragraph 2.9.1—22(2)(a) in the primary draft variation.
The submitter provided an alternative option.	DAN commented that it understands carers find this information useful and important, and that it already voluntarily provides age indications on the front of the label for its products. They proposed mandating this age statement in a prominent position on the label for these reasons and noted the approach would be consistent with clause 9.6.5 of Codex CXS 72-1981, which specifies "products shall be labelled in such a way as to avoid the risk of confusion between infant formula, follow-on formula…".	DAN	FSANZ agrees age information must be readily accessible to caregivers when purchasing infant formula and follow-on formula. Subsection 2.9.1—22(3) in the primary draft variation requires the age statements for infant formula (e.g., may be used from birth) and follow-on formula (e.g., follow-on formula should not be used for infants under the age of 6 months) to appear on the front of the package of the product. See section 3 in this report for further discussion on this issue.

Issue	Comment	Submitter(s)	FSANZ Response
A.9 Statement that follow-on formula should not be used for infants aged under 6 months *FSANZ's preferred option is to maintain the requirement for a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months as currently required by paragraph 2.9.1—19(4)(b).*			
Yes, the preferred option is supported.	These submitters supported the preferred option. INC and DAN commented that the statement should clearly indicate the product is only suitable from 6 months.	DA, INC, NES, NZFS, SAH, VICDoH	FSANZ is proceeding with the preferred option, with one amendment to vary the provision to refer to 'follow-on formula'. For discussion on this issue, refer to section 3 to this report and paragraph 2.9.1—22(2)(b) in the primary draft variation.
The submitters provided an alternative option.	DAN supported the preferred option and proposed mandating an age statement in a prominent position on the label. INC commented that age indication information should be included on the front of label.	INC, DAN	Similar to the statement for infant formula in item A8, subsection 2.9.1—22(3) in the primary draft variation requires the age statement for follow-on formula to appear on the front of the package of the product. Refer to section 3 to this report for further discussion about the location of this statement on the label.
A.10 Statement about age to offer foods in addition to formula *FSANZ's preferred option is to maintain, as it is currently worded, the statement indicating that infants from the age of 6 months should be offered foods in addition to the infant formula product in paragraph 2.9.1—19(4)(c).*			
Yes, the preferred option is supported.	These submitters expressed support for the statement with the wording proposed by FSANZ.	NES, NZFS, NZMoH	FSANZ has clarified that the statement applies to infant formula and follow-on formula. Refer to section 3 to this report and paragraph 2.9.1—22(2)(c) in the primary draft variation.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	AAA, DA, DAN, FCG, INC and NAS expressed support for the statement, subject to a change to align the statement with Australian and New Zealand infant feeding guidelines, as well as the ASCIA Infant Feeding and Allergy Prevention Guidelines. The change proposed was to include the word 'around' as follows: *…statement indicating that infants from **around** the age of 6 months should be offered foods…* Some of these submitters argued that the current wording advises caregivers to delay the introduction of solids beyond the date prior to which introduction of solids may assist in preventing the development of allergies. It is also important there is consistency between product labels and national guidelines, so that parents do not receive any confusing and contradictory feeding information.	AAA, DA, DAN, FCG, INC, NAS	FSANZ notes the proposal to include the word 'around' and submissions advocating for consistency between labelling and national guidelines. However, FSANZ disagrees with the proposed wording for the following reasons: First, food standards are legislative instruments, not guidance materials. As legislative instruments, food standards must be drafted clearly, so that requirements in the standards can be clearly understood by those who must comply with, and those who enforce, those requirements. Drafting a requirement where compliance is based on judgment, e.g. "*from around* the age of .." could likely result in uncertainty and, consequently, be open to interpretation. Second, Australian and New Zealand infant feeding guidelines and ASCIA Guidelines for Infant Feeding and Allergy Prevention (ASCIA 2020) serve a different purpose i.e. to provide advice, and are offered in conjunction with further infant feeding guidance, context and practical advice such as references to readiness. The infant formula labels, as required by the Code, are not able to provide such further information alongside the requisite statement and therefore, would not present clear and complete information to caregivers.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	In contrast, NES, NZFS, NZMoH did not support the inclusion of the word 'around' for the following reasons: • the wording of the statement is not prescribed. 'From the age of 6 months' is clear, whereas 'around 6 months' could be open to interpretation and result in other months stated on the product label (e.g., 4, 5, 6 or 7 months). • NZMoH was concerned about the introduction of foods much earlier than recommended (before four months of age). • NZFS noted the terminology 'around' in the New Zealand infant feeding guidance is used in conjunction with reference to the signs of readiness.	NES, NZFS, NZMoH	FSANZ considers the timing of introduction to foods is subject to growth and developmental need, as advised by health professionals, and in any case should generally occur from six months.
A.11 Prescribed name *FSANZ's preferred option at 1st CFS was to maintain the requirement for 'Infant formula' and Follow-on formula' as prescribed names for these products.*			
Yes, the preferred option is supported.	These submitters provided support for the preferred option without further commentary.	DA, DAN, FCG, INC, NZFS, NSWFA, SAH	FSANZ is proceeding with the preferred option. The requirement for these prescribed names is located in section 2.9.1—16 in the primary draft variation. Section 2.9.1—19 in the primary draft variation requires the name of the food to be stated on the front of a package of infant formula or follow-on formula. The name of the food (prescribed name) assists caregivers to choose appropriate products for their infants. See section 4 to this report for further discussion on the location requirement for the name of the food and the protein source statement.

Issue	Comment	Submitter(s)	FSANZ Response
Other.	VICDoH supported the prescribed name 'infant formula' but commented that follow-on formula is not a recommended or necessary product in the national infant feeding guidelines and so does not see any value in a prescribed name for follow-on formula.	VICDoH	Follow-on formula is recognised as a breast milk substitute in the Code and in the Ministerial Policy Guideline. FSANZ is retaining its position, based on the reasons provided in section 8.9 of SD1 in the 1st CFS. These reasons include that prescribed names provide important information to assist caregivers in distinguishing between infant formula and follow-on formula. Additionally, use of a prescribed name for follow-on formula ('Follow-up formula, 'Follow-up formula for older infants', Follow-on formula') is consistent with Codex and EU Regulations (Codex 1981; EU 2016a).
A.12 Statement on protein source *FSANZ's preferred option at 1st CFS was to clarify that the 'source' of protein in section 2.9.1—23 refers to the origin of the protein (e.g., cow's milk) and not the protein fractions (e.g., whey protein or casein).*			
Yes, the preferred option is supported.	These submitters supported clarification that the 'protein source' in refers to the origin of the protein, for the following reasons: • references to protein fractions in the protein source statement are not useful for caregivers and are used primarily for marketing purposes. • the clarification ensures the information is simple and more easily identified by caregivers. • clarifies the intent of the Code requirements for the statement for enforcement purposes.	DA, NZFS, NZMoH, SA, VICDoH	FSANZ is proceeding with the preferred option. See section 2.9.1—20(1) in the primary draft variation for the requirement for a statement of protein source to include the specific animal or plant source or sources of protein.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters commented that information about relevant protein fractions and processing methods should be maintained within the protein source statement for the following reasons: • the proposed option limits the information and clarity that can be provided to consumers and healthcare professionals, specifically on partially hydrolysed and A2 beta casein. • there is no evidence of consumer confusion or issues with the status quo. • the proposed option does not align with Codex, which does not prohibit what can be included in the protein source statement. • using the statement as allergen information is inappropriate and suggesting this to caregivers poses a food safety risk. • manufacturers could not provide a true, complete, and accurate product description without information on protein fractions or partially hydrolysed whey protein being permitted on labels.	DAN, FCG, INC	FSANZ considers the protein source (origin) provides information for caregivers to enable informed choice. Consumer evidence indicates caregivers lack understanding of protein fractions and look for the protein origin (see section 5.6.4 of FSANZ 2021 CP1). Furthermore, FSANZ considers that, in accordance with the intent of the Policy Guideline (ANZFRMC 2011), other protein fractions or isolates must undergo a pre-market assessment as a nutritive substance before they are permitted for addition and declaration (section 4.1 in the 2nd CFS). FSANZ is permitting a voluntary declaration for whey and casein in the nutrition information statement (NIS) (see section 3.4 of SD3 to the 1st CFS for the consumer evidence and discussion on this issue). If declared, information requirements in paragraphs 2.9.1—25(2)(d) and (e) and formatting requirements in subsection 2.9.1—26(2) in the primary draft variation would apply. FSANZ also notes the Codex Infant Formula Standard provides that the sources of protein to be clearly shown on the label and refers to cow's milk in association with the name of the food (Codex 1981). Section 8.1.3 of the Codex Draft Standard for Follow-up Formula for Older Infants (FuFOI) is more explicit as it specifies the name of animal and/or name of plant in association with the name of the product. These provisions do not specify or indicate protein fractions are appropriate (see 22REP/NFSDU Appendix III, Section A: Follow-up Formula for Older Infants) (Codex 2023).

Issue	Comment	Submitter(s)	FSANZ Response
Other.	VICDoH also recommended an additional prohibition against labelling protein fractions in the protein source statement and requests a list of protein sources be prescribed for use in this statement.	VICDoH	FSANZ considers a specific prohibition for labelling protein fractions (for example, 'whey', 'casein') in the protein source statement is unnecessary. Subsection 2.9.1—20(1) of the primary draft variation would require the specific animal or plant source or sources of protein as the statement of protein source. The Examples to that subsection indicate the intent. FSANZ has listed the permitted sources of protein in subsection 2.9.1—6(1) in the primary draft variation. Other protein fractions or isolates would not be permitted in the protein source statement.
A.13 Co-location of protein source statement with the name of the food *FSANZ's preferred option at 1st CFS was to:* • *maintain the requirement for the co-location of the protein source statement with the name of the food* • *clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's proposed option for the following reasons: • enables caregivers to immediately identify infant formulas which are problematic with respect to listed allergens. • it aligns with section 8.1.4 of the Codex General Standard for the Labelling of Prepackaged Foods (GSLPF), which requires the name of the food to appear a 'prominent position' on the label (Codex 1985).	AAA, DA, NZFS, NZMoH, SAH, VICDoH	FSANZ is proceeding with the preferred option, with a requirement for the co-located protein source statement and statement of the name of the food to appear on the front of the package of infant formula or follow-on formula (see section 2.9.1—19 and subsection 2.9.1—20(1) in the primary draft variation). See section 4 to this report for further discussion on this issue.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters supported the co-location of the protein source statement with the name of the food, and it only needs to appear once on the label. However, they did not support a requirement for it to be "prominent" for the following reasons: • there are no issues with the status quo; the inclusion of this information more prominently will not be of value for carers or healthcare professionals. • requiring prominence for the reason of allergen management is inappropriate, as this statement is not a full and complete allergen statement. • general legibility requirements already contain a requirement for wording to be: "*prominent so as to contrast distinctly with the background of the label*". • INC considers it was inconsistent with Codex CXS 72-1981, which states 'the sources of protein in the product shall be clearly shown on the label'.	DAN, FCG, INC, NES	FSANZ considers there is a need for this information to be visible to caregivers to enable informed choice. FSANZ has addressed submitter comments in section 4 to this report.

The following sections discuss the regulatory approach for labelling matters not addressed in Table 4 and where FSANZ has changed its preferred option from the 1st CFS.

1 Directions for use and storage

1.1 Background

Subsection 2.9.1—19(3) of the current Standard requires the label on a package of an infant formula product to include directions (in words and pictures) for the preparation and use, which instruct that:

(a) each bottle should be prepared individually; and
(b) if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
(c) potable, previously boiled water should be used; and
(d) if a package contains a measuring scoop—only the enclosed scoop should be used; and
(e) formula left in the bottle after a feed must be discarded.

FSANZ's preferred option at 1st CFS was to maintain without change paragraphs 2.9.1—19(3)(a), (b) and (d). However, FSANZ proposed to revise:

- paragraph 2.9.1—19(3)(c) to include the word 'cooled'
- paragraph 2.9.1—19(3)(e) to include the text 'within 2 hours'.

FSANZ also proposed to create two new directions using text excised from warning statements in paragraphs 2.9.1—19(1)(a) – (c) of the current Standard. Matters relating to these new directions are discussed in section 2 below.

1.2 Stakeholder comments

Most submitters supported FSANZ's preferred option to the directions for use and storage. However, some submitters requested minor alterations to subsection 2.9.1—19(3) of the current Standard:

- paragraphs (b) and (e) use the word 'must' whereas paragraphs (c) and (d) use the word 'should'. There were requests for consistency to use 'should' within subsection 2.9.1—19(3)
- replace the words 'made up' with the word 'prepared' in paragraph 2.9.1—19(3)(b), as this direction should align with the wording used for the direction required by section 2.9.1—19(3)(a).

1.3 Discussion

FSANZ has considered the comments regarding the wording of these provisions and recognises the merit of some arguments put forward by submitters. In regard to 'must' versus 'should', FSANZ considers the word 'must' conveys the importance for caregivers to follow the directions for use. However, the wording of the directions for use is not prescribed, and manufacturers would retain flexibility in how to apply the directions for use on their product labels.

In respect to the comments regarding 'made up', FSANZ agrees that, for the purposes of regulatory certainty and consistency for caregivers, the wording of directions for use and storage should be consistent in their language with other label information where possible. FSANZ is replacing the words 'made up' with the word 'prepared' instead of the words 'made up' as suggested by one submitter, noting this is consistent with the terminology in the statement instructing that each bottle must be prepared individually, in the warning statement

to follow instructions exactly (see section 2 below) and in the average quantity heading of the nutrition information statement (NIS).

1.4 Conclusion

Based on previous risk assessment, consumer evidence and stakeholder comments, FSANZ concludes subsection 2.9.1—22(5) in the primary draft variation will include the following directions for preparation and use required for infant formula and follow-on formula:

- each bottle must be prepared individually; and
- if a bottle of prepared formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
- previously boiled and cooled potable water must be used; and
- if a package contains a measuring scoop—only the enclosed scoop must be used; and
- formula left in the bottle after a feed must be discarded within 2 hours.

2 Warning statements about following instructions exactly

2.1 Background

Paragraph 2.9.1—19(1)(a) of the current Standard requires the label on a package of powdered infant formula product to include the warning statement: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill.* The current warning statement in paragraph 2.9.1—19(1)(b) for concentrated infant formula product is the same (except the word 'concentrate' is used in place of the word 'powder').

Paragraph 2.9.1—19(1)(c) requires the label on a package of 'ready to drink' infant formula product to include the warning statement: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill.*

At 1st CFS, FSANZ proposed the following text would be new directions for preparation of infant formula and follow-on formula, and would apply to each product type as follows:

- for powdered and concentrated infant formula products - not to change proportions of [powder/concentrate] or add other food except on medical advice
- for ready-to-drink infant formula products - not to dilute or add anything except on medical advice.

FSANZ also proposed to consolidate other aspects of paragraphs 2.9.1—19(1)(a) to (c) into a single prescribed warning statement for all product types as follows:

> *'Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill'.*

2.2 Stakeholder comments

Most submitters supported FSANZ's preferred option. However, two industry submitters suggested replacing the word 'anything' with the words 'other food' in the new direction for ready-to-drink formula, for consistency with the new direction for powdered and concentrated infant formula products. For example, "—not to dilute or add *other food* except on medical advice".

2.3 Discussion

The words ‘not to add anything’ were included in the ready-to-drink warning statement when Standard 2.9.1 was developed through Proposal P93 (finalised in 2001). At that time there were anecdotal reports of caregivers adding powdered infant formula or concentrated infant formula to ready-to-drink infant formula products to increase the concentration.

FSANZ understands the suggested wording change would not have a significant impact because ready-to-drink infant formulas and follow-on formulas are not commercially available in the domestic market. If these products become available for sale in the future, FSANZ considers that greater alignment in the wording of the new directions would provide clarity for industry and potentially for caregivers (noting, however, that the wording and pictures of directions for use are not prescribed). The primary draft variation reflects this amendment.

2.4 Conclusion

Based on the assessment in the 1st CFS and submitter comments, FSANZ concludes a single warning statement about following instructions exactly would apply to powdered, concentrated and ready-to-drink infant formula and follow-on formula. Paragraph 2.9.1—22(1)(a) in the primary draft variation includes the following single warning statement:

> *‘Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill’.*

Two new instructions have been included in the primary draft variation for directions for use and storage requirements. These are:

- for powdered or concentrated formula—do not change proportions of powder or concentrate or add other food except on medical advice (paragraph 2.9.1—22(5)(e)).
- for ready-to-drink formula—do not dilute or add other food except on medical advice (paragraph 2.9.1—22(5)(f)).

3 Age-related statements

3.1 Background

Paragraph 2.9.1—19(4)(a) of the current Standard requires a statement on infant formula labels indicating the infant formula product may be used from birth. Paragraph 2.9.1—19(4)(b) requires a statement on follow-on formula labels indicating that the infant formula product should not be used for infants aged under the age of 6 months. Paragraph 2.9.1—19(4)(c) requires a statement on infant formula product labels (except pre-term formula) indicating it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula product.

FSANZ’s preferred option at 1st CFS was to maintain the requirement for the age statements for infant formula and follow-on formula as they are currently required in subsection 2.9.1—19(4).

3.2 Stakeholder comments

The majority of submitters supported FSANZ’s preferred option. Two industry submitters recommended mandating these age-related statements in a prominent position on the label, with one submitter commenting they should appear on the front of the label. One industry submitter commented that the statement indicating that the infant formula product may be used from birth is intended to apply to ‘infant formula’ and not ‘infant formula product’.

3.3 Market survey

All of the 82 infant formula and follow-on formula products observed included age information on the front of pack. The prominence and size of age statements in comparison to stage labelling varied between product labels (see Attachment 2 to this report).

3.4 Discussion

3.4.1 Location

Age statements provide important information to caregivers about the suitability of a product for their infant. FSANZ previously reported that caregivers find age information (e.g., '0-6 months') to be the most useful label element for differentiating between products and assists with the interpretation of stage labels (Attachment 1 to SD3 of the 1st CFS).

Some submitters have requested the mandating of age information in paragraphs 2.9.1—19(4)(a) and (b) of the current Standard in a 'prominent' position on the product label. FSANZ notes current industry practice is to locate this information on the front of the package.

Based on consumer evidence, submitter comments and industry practice, FSANZ is requiring these age statements to appear on the front of the package of infant formula and follow-on formula, respectively. FSANZ considers this location requirement would provide regulatory certainty for manufacturers while having a minimal impact. The mandatory requirement would ensure these age statements continue to be accessible to caregivers to enable appropriate product choices. Such references would be useful to assist caregivers to identify the correct formula for their infant. Further, the primary draft variation includes a provision clarifying that age statements are not prevented from appearing more than once on the label.

Mandating the location of these provisions on the front of the package would ensure age information is prominent. FSANZ does not consider it necessary to apply additional size and formatting requirements or further restrictions on exactly where to place age information. Consumer evidence indicates that some Australian and New Zealand caregivers choose an appropriate formula for their infants, although the sampling was skewed to highly educated, high-income consumers (see Attachment 1). General legibility requirements in section 1.2.1—24 would continue to apply.

Currently, there is no definition for 'front of the package' in the Code. FSANZ notes in the Codex Guidelines on Front-of-Pack Nutrition Labelling the definition of 'front-of-pack nutrition labelling' includes the footnote 'front-of-pack' means the total area of the surface (or surfaces) that is displayed or visible to the consumer under customary conditions of sale'[2]. Canada recently adopted a similar meaning for the terms 'principal display panel' and 'principal display surface' in relation to mandating a nutrition symbol on the front of pack[3].

FSANZ is of the view that it is unnecessary to define the term 'front of the package' and is proposing the ordinary meaning would apply. Note FSANZ is also requiring other label information to appear on the front of the package (i.e., see section 4 Co-locating protein source statement with name of the food; section 7 'Lactose free' and Low lactose formulas'; section 8 Partially hydrolysed formula; and section 9.5 Stage labelling).

[2] Section 3.1 of Annex 2 to Guidelines on Nutrition Labelling CXS 2-1985

[3] 'Principal display panel' and 'principal display surface' are defined in Part 1 Interpretation of the Safe Food for Canadians Regulations SOR/2018-108 https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/page-1.html#h-843679

3.4.2 Statement wording

FSANZ notes the words 'for infant formula – ' in the existing provision reflects the intent. However, FSANZ agrees with the industry submitter's comment that the words 'infant formula product' in the statement indicating it may be used from birth should be amended to the words 'infant formula' for the purposes of regulatory certainty and for ensuring the information is appropriate and clear for caregivers. FSANZ considers the wording change would further clarify the statement is intended to apply to infant formula and not follow-on formula.

FSANZ considers the same approach should be applied to the statement for follow-on formula, where follow-on formula (and not 'infant formula product) should not be used for infants under the age of 6 months.

The statement about the age to offer foods in addition to formula has been clarified to apply to both infant formula (suitable for infants aged from birth up to 12 months) and follow-on formula. The words 'infant formula product' have been replaced with the words 'infant formula or follow-on formula'.

In accordance with existing requirements, the wording of the age statements would not be prescribed, and manufacturers would retain flexibility (for example, "0 to 6 months," "from birth…"). FSANZ has no evidence of caregiver confusion resulting from current industry practice and considers this approach is appropriate. Responses to other comments about age statements can be found in Table 1 above (see issues A.8, A.9 and A.10).

3.5 Conclusion

Based on submitter comments, FSANZ concludes subsection 2.9.1—22(2) in the primary draft variation will require the following age-related statements:

- for infant formula—the infant formula may be used from birth
- for follow-on formula—the follow-on formula should not be used for infants aged under the age of 6 months.
- for infant formula and follow-on formula—it is recommended that infants from the age of 6 months should be offered foods in addition to the infant formula or follow-on formula.

Further, subsection 2.9.1—22(3) requires the statements required by paragraphs (2)(a) and (b) to appear on the front of the package of the product.

Subsection 2.9.1—22(4) does not prevent the age-related statements from appearing more than once on the label.

4 Co-locating protein source statement with name of the food

4.1 Background

Paragraph 2.9.1—17 of the current Standard states that 'Infant formula' and 'Follow-on formula' are prescribed names, however the location for the prescribed names to appear on the label is not mandated.

FSANZ's preferred option at 1st CFS was to clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.

4.2 Stakeholder comments

Government, public health, and consumer group submitters supported FSANZ's preferred option for the co-located protein source statement and name of the food to appear in a prominent position just once on the label, noting it would be consistent with the Codex GSLPF (Codex 1985) and would enable caregivers of infants with allergies and intolerances to identify appropriate products.

Industry submitters opposed the preferred option for reasons, stating that prominence would not add value to caregivers or health professionals, mandating a prominent position is inappropriate because the protein source statement is not a full and complete allergen statement, that the preferred option is inconsistent with Codex Infant Formula Standard specifications (Codex 1981), and the Code already regulates prominence in the context of general legibility requirements.

4.3 Discussion

The primary purpose of the protein source statement is to inform caregivers about the true nature of the product. The prominence of this statement is important because the protein source is one of the primary differences between various infant formula products that are available on the market. The increase in infant formulas and follow-on formulas with different and new protein sources (e.g., sheep milk) highlights the growing importance of this aspect of product formulation to caregivers.

FSANZ agrees with submitter comments that the protein source statement is not a full and complete allergen statement. However, as supported by consumer evidence, a prominent protein source statement can provide additional assistance to those caregivers of infants with allergies and intolerances by making the protein source more visible (see SD4 to FSANZ 2021 CP1). The statement is not intended to replace mandatory allergen information in the statement of ingredients and in a 'contains' summary statement. These parts of the label remain the primary method for identifying allergens in infant formula and follow-on formula products.

FSANZ also does not view the preferred option for a 'prominent' co-located name of food and protein source statement to be inconsistent with the Codex Infant Formula Standard (Codex 1981). Section 9.1.3 of that standard specifies the sources of protein shall be clearly shown on the label, and section 9.1.2 specifies 'the name of the product shall be either 'Infant Formula' or any appropriate designation indicating the true nature of the product, in accordance with national usage.'

FSANZ agrees with submitter comments that it would be inappropriate to refer to 'prominent' in the context of location in the primary draft variation, given the Code refers to prominence in the context of contrasting distinctly with the background of the label (subsection 1.2.1—24(1) General legibility requirements). The primary draft variation is more explicit by requiring the name of food and protein source statement to be co-located on the front of the package.

The primary draft variation also clarifies that protein source information is permitted in the statement of ingredients for consistency with generic ingredient name requirements. Other references to protein source are prohibited elsewhere on the label, to prevent nutrition content claims being made. The name of the food (i.e., the prescribed names 'Infant formula' or 'Follow-on formula') can appear without the protein source statement elsewhere on the label since this information is important for caregivers to distinguish between product categories.

4.4 Conclusion

Based on submitter comments and international standards, FSANZ concludes the co-located protein source statement and statement of the name of the food would be required to appear on the front of the package of infant formula or follow-on formula (see section 2.9.1—19 and subsection 2.9.1—20(1) in the primary draft variation). The animal or plant source(s) of protein in the infant formula or follow-on formula would be prohibited on the label, except in the protein source statement and the statement of ingredients (paragraph 2.9.1—29(1)(k) in the primary draft variation).

Part B Labelling for provision of information about infant formula and follow-on formula

Part B discusses issues relevant to the provision of information to enable informed choice. Table 5 includes submitter comments and FSANZ's response for the following issues: statement of ingredients, allergen declarations, labelling as 'genetically modified', declaration of nutrition information (format, base units of expression, average energy/average quantity, weight of one scoop, separation of headings, macronutrient sub-group nutrients, ingredient and nutrient names, lactose free and low lactose formula, partially hydrolysed formula, prohibited representations, nutrition content and health claim prohibition, claims about ingredients, line marketing and proxy advertising, notification of product reformulation, trademarks and on-line advertising and two additional issues raised by submitters.

Table 5: Provision of information labelling issues: summary of submitter comments & FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
B.1 Statement of ingredients *FSANZ's preferred option at 1st CFS was:* • *that generic ingredient labelling requirements should continue to apply to infant formula products* • *to permit the optional grouping of added vitamins and minerals under the subheadings 'Vitamins' and 'Minerals' and within these groups the vitamins and minerals need not be listed in descending order of ingoing weight.*			
Yes, the preferred option is supported.	These submitters provided support for the preferred option without further commentary. They noted flexibility allows for inclusion of common terms or acronyms/abbreviations which is more consumer friendly.	DAN, FCG, INC, NZFS, NZMoH, SAH, AFGC	FSANZ is proceeding with the preferred option. An optional format for declaring added vitamins and minerals would be permitted in the statement of ingredients. Vitamins and minerals that are added to infant formula and follow-on formula in accordance with section 2.9.1—8 (required nutritive substances) would not be required to be listed in descending order of ingoing weight, provided that the statement of ingredient lists all added vitamins together under the subheading 'Vitamins' and list all added minerals together under the subheading 'Minerals'. See section 2.9.1—24 in the primary draft variation.

No, the preferred option is not supported.	Supports the application of generic ingredient labelling requirements, and in principle the grouping of vitamins and minerals in the ingredient list. However, does not support the optional grouping and not mandating grouped vitamins and minerals to be listed in descending order because it will: • create inconsistencies between products in ingredient listing • make product comparisons more difficult for caregivers and health professionals • have minimal impact on label flexibility as only additional information would be the subheadings 'vitamins' and 'minerals'.	VICDoH	FSANZ notes these concerns, however it is retaining its position for the reasons previously stated, including that grouping of vitamins and minerals in the ingredient list is a common industry practice and it assists caregiver understanding (see section 2.1 in SD3 of the 1st CFS). Given vitamins and minerals are subject to compositional limits, the order in which they are declared is of less value to caregivers. FSANZ also notes the approach is consistent with Codex specifications.
B.2 Allergen declarations *FSANZ's preferred option at 1st CFS was for the generic allergen declaration requirements in Division 3 of Standard 1.2.3 to continue to apply to infant formula products.*			
Yes, the preferred option is supported.	These submitters supported the preferred option. DAN and INC also commented that their support is separate from comments on the protein source statement.	AAA, DAN, FCG, INC, NZFS, NZMoH	FSANZ is proceeding with the preferred option. Requirements in Division 3 of Standard 1.2.3 would continue to apply to infant formula and follow-on formula.
B.3 Labelling as 'genetically modified' *FSANZ's preferred option at 1st CFS was to continue to apply existing labelling requirements in subsection 1.5.2—4 for GM foods to infant formula products.*			
Yes, the preferred option is supported.	These submitters provided support for the preferred option without further commentary.	DAN, FCG, INC, NZFS	FSANZ is proceeding with the preferred option. Requirements in subsection 1.5.2—4 of Standard 1.5.2 to label food and ingredients as 'genetically modified' would continue apply to infant formula and follow-on formula.

B.4 Declaration of nutrition information – format • *FSANZ's preferred option is to prescribe the format of the NIS in accordance with the recommended format in the existing guideline in Schedule 29 of the Code with additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances.* • *Question 1 from SD3: Do you agree with FSANZ's preferred option to prescribe the format of the NIS as shown in Figure 1?*			
Yes, the preferred option is supported. (Prescribed format)	Support the proposed format for the NIS as it was presented in SD3 at 1st CFS. DA and NSWFA further commented that a mandatory NIS format would assist consumers to make product comparisons.	DA, NSWFA, QLDH, SAH, VICDoH, NZFS, NZMoH	FSANZ is proceeding with the preferred option. Subsection 2.9.1—26(2) in the primary draft variation states the NIS must be in the same format as specified in the table to section S29—10 (the table is located in the consequential draft variation), and specifies the title, subheadings, the requirement to state nutrients and sub-group nutrients using the names and units of measurement specified in the table and to not include a unit quantity other than per 100 mL.
No, the preferred option is not supported. (Prescribed format)	DAN, FCG, and INC did not support the proposed NIS format, stating that the format: • is too restrictive on the use of subheadings, consumer-friendly common terms, acronyms and abbreviations. • does not allow provision of adequate information. • lacks any scientific evidence that there is an issue with the current NIS and the effectiveness of the proposed NIS in Figure 1. • does not allow for an efficient and competitive food industry or for fair trading as differences in formulations will stifle innovation and create a barrier to trade. • is inconsistent with international food standards, which do not prescribe a format for the NIS.	DAN, FCG, INC, AFGC, NZFGC	FSANZ maintains the intent of the preferred option is to standardise the content and format of the NIS, to assist caregivers in making quicker product comparisons and aid their understanding of the nutrition information it contains (section 3.3 of SD3 to the 1st CFS). As outlined in FSANZ's literature review in SD3 of the 1st CFS, consumer evidence suggests that caregivers currently have difficulty using the NIS. Caregivers are often unsure what they should be looking for in the NIS (Malek et al. 2019), and approximately 50% of Australian and New Zealanders reported finding it difficult to use the NIS to compare products (Malek 2017, Malek 2018a). Research suggests that the proposed changes to the NIS would assist caregivers. More than 70% of Australian and New Zealand consumers in one survey reported that grouping types of nutrients and optional substances consistently would help to make product comparisons easier (Malek 2017). Focus group research also identified that grouping vitamins, minerals and optional substances under subheadings in the NIS was preferred by participants compared to other NIS presentations, as it helped them to identify what the nutrients were and to compare products

	AFGC and NZFGC provided support for a more regularised NIS (i.e. some level of prescription), but not the extent proposed.		across categories (Malek 2018b). The proposed NIS format also helped consumers to make faster product comparisons, relative to the status quo (Malek 2018a). There is also limited evidence that consumers have a better understanding of acronyms and abbreviations of nutrients. Malek et al. (2019) found that Australian and New Zealand consumers generally did not understand nutrition content claims on infant formula products, when stated as either a full name or as an acronym (Malek 2019). Further, there are examples where the prescribed format in the preferred option is consistent with overseas regulations. EU regulations prescribe the order in which nutrients must appear (EU 2016a). United States regulations prescribe the format and content of the nutrient information statement, including the subheadings for 'vitamins' and 'minerals' (U.S. Code of Federal Regulations 2023). FSANZ understands industry concerns relating to a prescribed NIS content and format as barriers to innovation are related to the tension between: • pre-market assessment requirements for nutritive substances (including what constitutes a substance used as a nutritive substance), and • the current ambiguity in Standard 2.9.1 regarding current nutrition declaration requirements (e.g., a lack of clarity regarding the declaration of sub-group nutrients). FSANZ has advised of its intent to address the issue of nutritive substances and novel foods under Proposal P1024 and is stating the expectation for all substances as defined in the Code that are added to infant formula and follow-on formula to undergo premarket assessment (see section 4.1 in the 2nd CFS). FSANZ also previously noted the NIP for general foods already has a prescribed format and FSANZ considers consistency in the formatting and terminology will assist caregiver understanding and provide regulatory clarity (section 3.3 of SD3 to the 1st CFS).

Yes, the preferred option is supported. (Subheading)	Independent of comments on other aspects of the NIS, INC, QLDH and VICDoH supported the use of subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances. NZFS and NZMoH supported the subheadings 'Vitamins' and 'Minerals'. QLDH commented this change will enable caregivers to compare products with ease and reduce confusion, and notes FSANZ stakeholder surveys indicate most consumers use the NIS for comparison across products.	INC, NZFS, NZMoH, QLDH, VICDoH	FSANZ is proceeding with the preferred option, with one change (discussed below). The subheadings 'Vitamins', 'Minerals' and 'Additional' would apply to infant formula and follow-on formula. See subsection 2.9.1—26(2) in the primary draft variation.
These submitters provided an alternative option. (For a subheading)	NZFS sought clarification on whether mandated nutritive substances that are not macronutrients or micronutrients (e.g., choline, L-carnitine, inositol mandated for infant formula) must be declared in the NIS. If so, they suggested an additional sub-heading such as 'other essential' or 'other essential substances' would be required. NZMoH noted it was concerned the use of the term 'Additional' could infer additional benefits, which is straying towards a claim. Suggested that the term 'non-essential' is used instead to identify substances voluntarily added by manufacturers.	NZFS, NZMoH	FSANZ acknowledges that choline, inositol and L-carnitine are mandated for addition to infant formula and these substances would not be included under the subheading 'Additional'. FSANZ is requiring the subheading 'Other nutrients' for infant formula only, under which these substances would be indented. See section 5 to this report for discussion on this issue and subparagraph 2.9.1—26(2)(d)(ii) in the primary draft variation. In response to concerns about the use of the term 'Additional', consumer evidence indicates caregivers have a high level of understanding of the term when used in the context of voluntary additions to infant formula and follow-on formula. FSANZ considers the subheading 'Additional' more clearly articulates the substances listed underneath it are not part of the base composition, compared to the subheading 'Non-essential'.
These submitters provided an alternative option. (for the order and units of	DAN and INC recommended aligning the order and units of vitamins and minerals with the NHMRC Nutrient Reference Values (NRVs). They considered this format would make it easier for healthcare professionals to use the NIS. • B vitamins be presented together. • change units of Vitamin A to µg-RE • change units of Vitamin E to mg α-TE	DAN, INC	FSANZ considers it is unnecessary to align the order and units of vitamins and minerals with as suggested. The primary purpose of declarations in the NIS is to provide nutrition information to caregivers to enable product comparisons and inform choice. This approach is consistent with the approach for the NIP on the labels of general foods. Caregivers are more likely to be familiar with the term 'folate' than folic acid.

vitamins and minerals)	• change units of Pantothenic acid to mg • change folate to folic acid, to reflect accurately what the value includes and not mislead that the value includes all folate.		In addition to nutrition information on the product label, health professionals can access specific information about the composition of an infant formula or follow-on formula directly from the manufacturer or use the label information to calculate the amounts of certain nutrients into different units.
B.5 Declaration of nutrition information – base units of expression *FSANZ's preferred option at 1st CFS was to only permit the base unit of expression (per 100 mL as reconstituted) in the NIS.*			
Yes, the preferred option is supported.	These submitters supported the option to permit '100mL as reconstituted', as well as the prohibition of other base units of expression (e.g., per 100g powder).	DA, NSWFA, QLDH, VICDoH	FSANZ is proceeding with the preferred option. Paragraph 2.9.1—25(1)(a) in the primary draft variation requires the unit quantity of the food to be expressed in per 100 mL. The term 'unit quantity' is used for consistency with Standard 1.2.8 requirements for general foods and is defined in subsection 1.1.2—2(3) of Standard 1.1.2 Definitions used throughout the Code. Paragraph 2.9.1—26(2)(f) specifies that the NIS must not include a unit quantity other than per 100 mL.
No, the preferred option is not supported.	INC and NES supported the per 100 mL as reconstituted' base unit but argued that manufacturers should have the option of voluntarily adding information in per 100g, as this unit is permitted under Codex and European infant formula regulations, and many imported products would be disadvantaged if per 100g is not allowed. NZFS commented that prescribing expression per 100 mL as reconstituted does not enable caregivers to directly compare products' nutrient composition as the energy density per 100 mL differs. The easiest option to compare nutrient content would be per 100 kJ. Internationally, there is no precedent for prohibiting other units of expression. DAN and INC requested that manufacturers should be permitted to voluntarily include kcal, as it is useful for healthcare professionals.	INC, NES, NZFS, DAN	FSANZ acknowledges submitter views that other unit quantities (also referred to in reports as 'base units of expression') should be permitted. However, FSANZ is retaining its position to only permit the unit quantity of the food expressed in per 100 mL (prepared formula) in the NIS for the following reasons: *Per 100 mL* FSANZ considers nutrition information based on per 100 mL (as reconstituted) as currently required provides meaningful information to caregivers. FSANZ disagrees that per 100 mL does not enable caregivers to directly compare the nutrient composition of a product due to differences for energy density. Energy density and nutrient content are strictly controlled to ensure all infant formula and follow-on formula are suitable as breast milk substitutes. Further, the voluntary inclusion of extra columns for other unit quantities would lead to more inconsistency between product

			labels and may affect caregiver's ability to make product comparisons. The use of the per 100 mL unit quantity is also consistent with how nutrition information is presented in the NIP for general foods. FSANZ notes the majority of infant formulas and follow-on formulas are declaring nutrition information using only the per 100 mL base unit. *Other base units* As noted in SD3 to the 1st CFS, FSANZ considers the primary purpose of the NIS is to provide nutrition information to caregivers. Health professionals can source nutrition information presented using other base units (such as per kcal) directly from manufacturers or calculate using other required nutrition information on the label. FSANZ notes other overseas regulators have not adopted Codex specifications for permitting different base units: For example: • EU regulations require per 100 mL and permit per 100 g, but do not permit base units relating to energy values (per 100 kCal, per 100 kJ) (EU 2016a). US regulations require per 100 kCal and permit per 100 mL or per L, but do not permit per 100 g (U.S. Code of Federal Regulations 2023).
Other.	NZFS also noted that a column heading in Figure 1 reads 'average quantity per 100ml made up formula'. Its preference is for this statement to refer to 'prepared formula' to be consistent with the preparation instructions.	NZFS	FSANZ agrees with the suggestion to change the wording 'made up formula' to 'prepared formula'. See the table to section S29—10 in the consequential draft variation. This change would be consistent with the wording change in item A.1 of this table.
B.6 Declaration of nutrition information – average energy/average quantity *FSANZ's preferred option at 1st CFS was to:* • *require nutrition information (excepting energy) to be expressed as the 'average quantity' in the NIS* • *clarify that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to infant formula products.*			

Yes, the preferred option is supported.	These submitters expressed support for nutrition information (except energy) to be expressed as the 'average quantity' in the NIS, and to clarify that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to infant formula and follow-on formula.	INC, NES, NZFS, VICDoH	FSANZ is proceeding with the preferred option. See subsection 2.9.1—25(1) and section 2.9.1—27 in the primary draft variation.
B.7 Declaration of nutrition information - weight of one scoop *FSANZ's preferred option at 1st CFS was to maintain the requirements for the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula) (paragraph 2.9.1—21(1)(b)) and clarify this nutrition information must not be located in the NIS.*			
Yes, the preferred option is supported.	These submitters supported the requirement to declare the weight of one scoop, the proportion of powder or concentrate required to reconstitute the formula, and for this information to not be included in the NIS.	NZFS, VICDoH	FSANZ is proceeding with the preferred option. Subsection 2.9.1—25(4) specifies that the NIS must not contain any other information unless specified. Section 2.9.1-25 of the draft variation specifies the information that must be included in the NIS. Information about the weight of one scoop and the proportion of powder or concentrate are not listed in this provision. Instead, such information would have to be declared on a label of infant formula or follow-on formula under subsection 2.9.1—22(8) of the primary draft variation.
No, the preferred option is not supported.	These submitters did not support prohibiting the inclusion of the weight of one scoop and reconstitution information in the NIS. DA, DAN and NES commented that the NIS is a logical position for reconstitution information, as it provides the link between the product and the nutrition information expressed per 100mL in the NIS.	DA, DAN, NES, NSWFA.	FSANZ notes this information is currently required and that it is common industry practice to locate this required information in close proximity to the feeding guide. Therefore FSANZ does not consider it necessary to require this information in the NIS but rather provide industry some flexibility in providing this information.
B.8 Declaration of nutrition information – separation of headings *Question 2 from SD3: How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g., using lines, bolding)?*			

Lines and bolding.	Lines/indentation and bolding for the subheadings were suggested to enable clear separation. NZFS considered indentation would be consistent with sub-groups of macronutrients in the NIP for general purpose foods.	QLDH, NZFS	FSANZ is proposing all subheadings must be printed in a size of type that is the same or larger than the nutrient names in the statement (subsection 2.9.1—26(2)(d) in the primary draft variation). Refer to section 6 in this report for discussion on this issue.
Contrasting background colour.	It is common practice among current market products to use a contrasting background colour behind the text of subheadings, and this approach appears to be effective in clearly separating the nutrient sections.	VICDoH	FSANZ is proposing all subheadings must be printed in a size of type that is the same or larger than the nutrient names in the statement (subsection 2.9.1—26(2)(d) in the primary draft variation). Refer to section 6 in this report for discussion on this issue.
No prescribed format for the separation of subheadings.	There were a number of submitters that did not support any requirements being applied to the format of subheadings 'vitamins', 'minerals' and 'additional'. However, the reasons for this position varied: • DAN, FCG and INC did not support this level of prescription because it does not align with international food regulations, and companies are already required to meet legibility provisions under Standard 1.2.1 Division 6. • NES stated that the inclusion of subheadings will already group the nutrients, so prescribing the format of the subheadings will not bring additional benefit but would add cost and complexity for manufacturers • LS and DA did not support shading in the NIS to highlight nutrients, as this may be perceived as a claim. LS further stated that highlighting the use of additional ingredients e.g., docosahexaenoic acid (DHA) supports 'premiumisation' as a marketing strategy, which is inequitable and misleading for consumers.	ABA and WBTi, DA, DAN, FCG, INC, NES	FSANZ is proposing all subheadings must be printed in a size of type that is the same or larger than the nutrient names in the statement (subsection 2.9.1—26(2)(d) in the primary draft variation). Refer to section 6 in this report for discussion on this issue.

B.9 Macronutrient sub-group nutrients in the nutrition information statement *FSANZ's preferred option at 1st CFS was to permit, with prescribe wording and format, the voluntary listing in the NIS of:* • *'Whey' and 'Casein', indented under the macronutrient 'Protein'* • *'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid', indented under the sub-group nutrient heading 'Long chain polyunsaturated fatty acids', which is indented under the macronutrient 'Fat'.*			
Yes, the preferred option is supported.	QLDH supports the proposed approach, as the inclusion of these nutrients would enable parents/carers/ health professionals to easily compare the nutrient profile of various infant formulas and follow-on formulas. Limiting the permission to the stated sub-group nutrients also avoids over-crowding of the NIS.	QLDH	FSANZ is proceeding with the preferred option. Subsection 2.9.1—25(2) in the primary draft variation permits the voluntary declaration of these nutrients in the NIS. If listed, the format for how they must be declared is specified in the table to section S29—10 in the consequential draft variation.
No, the preferred option is not supported. (Explicit list, prescription, format)	These submitters support permissions for the voluntary declaration of macronutrient sub-group nutrients in the NIS, but do not support an explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-group nutrients. The reasons cited were: • Information about macronutrient sub-group nutrients supports informed choice. • Flexibility to use common terms and acronyms/abbreviations would allow companies to provide information using language that health professionals use, and consumers will understand. E.g., use of DHA rather than a prescribing use of 'docosahexaenoic acid'. • The NIS is the only section of the label which allows consumers to directly compare one product to another, and so is the only place on the label that industry can communicate differences to consumers. • There is a lack of scientific evidence that there is an issue with the current voluntary listing of macronutrient sub-groups.	DAN, FCG, INC, NES, AFGC	The explicit list is necessary for setting mandatory formatting requirements in the prescribed NIS because it: • ensures consistency between infant formula and follow-on formula product labels for caregivers to make easier product comparisons, and • provides regulatory clarity for manufacturers and enforcement agencies. FSANZ considers that listing the permitted fatty acids under the sub-group heading 'Long chain polyunsaturated fatty acids', indented under 'Fat' would inform caregivers about the substance type. Refer to FSANZ's response to item B.4 above regarding consumer evidence of caregiver understanding of the NIS, including nutrient names and acronyms. Refer to FSANZ's response to item B.4 above regarding the issue of inconsistency with international food standards.

	• Is inconsistent with international food standards. EU regulations allow the voluntary declaration of protein, carbohydrate or fat components, whey/casein ratio, and the number of substances whose suitability has been established by generally accepted scientific data. The Codex Infant Formula Standard (Codex 2018) does not prescribe macronutrient sub-groups and is silent on voluntary declaration.		
No, the preferred option is not supported. (Voluntary listing of macronutrient sub-group information)	These submitters do not support permitting the voluntary listing of the sub-group nutrients whey and casein and permitted long chain polyunsaturated fatty acids. The reasons stated were: • there is no justification for including the additional nutrient information, and it sets a precedent for the continued addition of sub-groups to an already very comprehensive NIS • the majority of caregivers are unlikely to have the skills to interpret this information • provision of complex information may result in confusion or decisions made on an incorrect and uninformed basis • casein and whey protein, and long chain polyunsaturated fatty acid sub-group labelling may lead to undesirable product innovation that deviates from the intended breast milk reference. NSWFA also requested further information is sought on the caregiver benefit from declaring whey: casein ratios and alpha-lactalbumin on infant formula and follow-on formula labels, noting health professionals are already using it to advise caregivers on specific products.	NSWFA, NZMoH, VICDoH	FSANZ's preferred option was based on the view that this nutrition information would be useful for health professionals, assist with informing caregivers' choices, align in part with international and overseas regulations and provide some flexibility for industry. See section 3.4 of SD3 to the 1st CFS for the full discussion. FSANZ considers that other sub-group nutrients are likely to be isolates of a macronutrient (e.g., alpha-lactalbumin) and permission for their voluntary addition would need to be as a nutritive substance via the pre-market assessment process (and if permitted and added, they would be declared under the 'Additional' subheading). FSANZ is also unclear how the permission to voluntarily declare these sub-group nutrients would result in undesirable product innovation. For example, the Code includes compositional limits on the amount of long-chain polyunsaturated fatty acids (see the table to S29—4 in the consequential draft variation). There is also limited evidence that some caregivers look for information about whey-based formula (SD4 to the 2021 CP1).

B.10 Ingredient and nutrient names *FSANZ's preferred option at 1st CFS was to maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's proposed option. The reasons cited were: • complex ingredient names are often present in the ingredients list, together with the common term (e.g., sodium ascorbate (vitamin C)). Within the nutrition information statement common terms are used. • ingredients and nutrients are not the same • there is no evidence of confusion between the differences in ingredient declarations and nutrition information declarations.	DAN, FCG, INC, NES, NZFS, VICDoH.	FSANZ is proceeding with the preferred option. FSANZ considers the preferred option is appropriate because the purpose for declaring ingredient names and nutrition information differs (see section 4 of SD3 to the 1st CFS for previous discussion on this issue).
Other.	CareA2 expressed concern about the inability to identify ingredients not required by regulation or the absence of ingredients or allergens outside of the NIS.	CareA2	As noted in section 4.1 in the 2nd CFS, novel foods and nutritive substances that are added to infant formula or follow-on formula without premarket assessment would be an enforcement issue. FSANZ is clarifying the NIS content and format to better reflect this regulatory approach (the status quo). New labelling requirements for allergen declarations came into effect on 25 February 2021 and require allergen declarations to be made in the statement of ingredients and in a separate summary statement (among other things). These requirements would apply to general foods for sale as well as infant formula and follow-on formula. Consistency in formatting, terminology and location requirements between these foods would assist caregiver understanding of allergen information.

B.11 Lactose free and low lactose formula *FSANZ's preferred option at 1st CFS was to maintain existing specific labelling requirements for 'lactose free' and 'low lactose' infant formula products.*			
Yes, the preferred option is supported.	These submitters provided support for the preferred option. DA also mentioned that the preferred option was supported because 'lactose free' and 'low lactose' are commonly used for marketing purposes.	DA, FCG, NZFS	FSANZ is proceeding with the preferred option, with additional clarification and a requirement for these voluntary representations to be included in the statement of the name of the food on the front of the package of infant formula (from birth up to 12 months). For further discussion, see section 7 in this report and section 2.9.1—21 in the primary draft variation.
Does not support the preferred option.	The AAA and NES considered that lactose-free and low-lactose formulas should display a warning statement indicating they are unsuitable for infants with cow's milk (dairy) allergy. The reason cited was that even lactose-free infant formula for infants may contain milk products other than lactose, and that allergen labelling would require appropriate declaration. DAN, INC and NES did not support the preferred option because under Australian and New Zealand consumer laws a 'free' claim requires a nil detectable limit. INC also stated that 'low lactose' and 'lactose free' should not be required as part of the name for these products.	AAA, NAS, DAN, INC, NES	FSANZ notes that, similar to general foods carrying a 'lactose free' claim, caregivers of infants with cow's milk allergy are advised to always read the statement of ingredients for allergen information. Infant formula must also carry a warning statement instructing caregivers to consult their doctor or health workers for advice before deciding to use the product. Further, FSANZ notes that neither Codex nor the European Union require such a statement. FSANZ is not proposing to change the condition for a 'lactose free' claim on an infant formula product to contain no detectable lactose for the reasons given in section 5 of SD3 to the 1st CFS. Further, the condition is the same as for a 'lactose free' claim about a general food for sale. It would be a matter for businesses to decide whether or not to represent a food as 'lactose free'.
These submitters provided alternative options	DAN requested that dairy-based lactose modified products be considered as SMPPi, and therefore the label would be able to refer to the condition "lactose intolerance." NES said that infant formula products containing cows' milk protein for the dietary management of lactose malabsorptive conditions will continue to be managed and labelled as other IFPSDU, with the additional requirement to label the amounts of lactose and galactose expressed in g/100 mL and/or	DAN, NES, NSWFA	To refer to a condition on the label, a lactose modified product would need to meet the definition of SMPPi (see section 2.9.1—3 in the primary draft variation) and comply with Division 4 of the proposed amended Standard 2.9.1, including specific labelling requirements and the restriction on sale for products in that category. Infant formula that is represented as being suitable for 'lactose intolerance' but is not SMPPi would be non-compliant under the new labelling requirements. As noted above SMPPi would need to comply with Division 4 of the proposed amendment which

	an equivalent statement “not suitable for infants with galactosaemia”. NSWFA suggested that low lactose and lactose free formulas should have an advisory statement to inform caregivers that such products should only be purchased following medical diagnosis of a lactose susceptibility or intolerance.		includes specific mandatory statements and declarations (see section 2.9.1—38 in the primary draft variation). As noted in Table 1 of this SD, FSANZ’s preferred option is to retain the existing warning statement *Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.* This requirement applies to infant formula represented as either ‘lactose free’ or ‘low lactose’ and thereby directs carers to seek medical advice about the suitability of an infant formula.
B.12 Partially hydrolysed formula • *FSANZ’s preliminary view was to require the words ‘partially hydrolysed’ to inform caregivers of the nature of the modification.* • *Question 3 from SD3: Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other infant formula products?*			
Yes, the preliminary view is supported.	NES and NZMoH commented specifically that they supported the wording ‘partially hydrolysed’.	NES, NZMoH,	FSANZ is proceeding with the preferred option. For infant formula (from birth up to 12 months) that is represented as partially hydrolysed, FSANZ is requiring the words ‘partially hydrolysed’ to be used immediately adjacent to the statement of protein source. Section 4 of this report sets out the requirement for the protein source statement and statement of the name of the food to appear on the front of the package. See section 8 of this report for discussion on this issue, and section 2.9.1—20 in the primary draft variation.
Does not support the preliminary view.	INC and DAN stated they do not support the categorisation of partially hydrolysed formula as an infant formula or follow-on formula. INC noted FSANZ’s assessment has referred to evidence that partially hydrolysed proteins are safe and appropriate for use in starter formulas. DAN commented that: • partially hydrolysed products are designed for a special medical condition. Labelling that refers to conditions is useful for caregivers	INC, DAN	See to section 8 of this report for discussion on this issue.

	and healthcare professionals to correctly identify products. • caregivers would be confused by information about ingredient modification.		
Other. (Terminology)	DAN considered the term 'partially hydrolysed' should be permitted, although it did not support the prohibition for infant formula product labels to refer to conditions. A2M, FCG, INC, supported including partially hydrolysed protein information on the label but did not comment on the wording. NZFS recommended adding the word 'protein' to clarify what component has been partially hydrolysed. ABA and WBTi, DA, NSWFA, QLDH and VICDoH did not explicitly state they supported the wording 'partially hydrolysed', however they agreed references to conditions such as 'anti-reflux' or 'colic' should be prohibited. A2M also agreed that conditions should not be permitted on the label.	DAN, NZFS, QLDH, VICDoH, A2M FCG, INC, ABA and WBTi, DA, NSWFA	See to section 8 of this report for discussion on this issue.
Other. (Location)	QLDH, VICDoH, A2M, FCG, INC, NES and NZMoH supported including partially hydrolysed protein information in the statement of ingredients. QLDH and VICDoH considered the information should only appear in the statement of ingredients for the following reasons: • partially hydrolysed formulas are a variation of a normal infant formula, and a healthy infant would have no requirement for such a product. • the words would imply there is an associated physiological or health effect, such as one relating to digestion, and that this would be a	QLDH, VICDoH, A2M, FCG, INC, NES, NZMoH, DAN, NZFS	FSANZ agrees the words 'partially hydrolysed' should be included in the protein source statement for infant formula represented as 'partially hydrolysed' and may be used in the statement of ingredients. The words 'partially hydrolysed' or any words or words having the same or similar effect would be prohibited on the label except in the statement of ingredients or where required with the statement of protein source. FSANZ considers information in the NIS on the content of partially hydrolysed protein is not appropriate. See section 8.3.2 of this report for discussion on this issue, and paragraph 2.9.1—21(1)(l) in the primary draft variation.

	prohibited claim if it appeared elsewhere on the label. • such formulas are not recommended by health professionals • generally accepted science does not support their use in infants. A2M considered that the ingredient declaration should include the percentage of the partially hydrolysed protein in the formula. DAN, FCG, INC, NES, NZMoH and NZFS also suggested including partially hydrolysed protein information in the protein source statement. NZMoH and NZFS noted it was appropriate for partially hydrolysed formula to be subject to same labelling approach as for lactose free and low lactose formulas. NES suggested the NIS contains information on the content of partially hydrolysed protein.		
B.13 Prohibited representations *FSANZ proposed at 1st CFS that there would be no changes to the prohibited representations in paragraphs 2.9.1—24(1)(a) to (e).*			
Yes, the preferred option is supported.	These submitters supported retaining the labelling provisions for prohibited representations in paragraphs 2.9.1—24(1)(a) to (e).	A2M, ABA and WBTi, DA, NSWFA	FSANZ is retaining the prohibited representations in paragraphs 2.9.1—24(1)(a) to (e) of the current standard. Other prohibited representations have been added for regulatory clarity to reflect the intent that nutrition content and health claims are prohibited. See section 2.9.1—29 in the primary draft variation.

No, the preferred option is not supported.	These submitters opposed the provisions in Standard 2.9.1—24(1)(a) to (e) of the Code. DAN commented that these prohibitions constituted an over-restriction on representations, which is a disincentive for innovation. The prohibition also does not consider matters of value and benefit to the consumer.	DAN, INC	FSANZ acknowledges these comments but is not considering a change in the approach. FSANZ previously noted these (long standing) provisions support the Australian and New Zealand governments' international commitments to the WHO International Code of Marketing of Breast-milk Substitutes and are consistent with ministerial policy guidance (see section 6.1 of SD3 in the 1st CFS).
Other.	In addition to supporting the existing prohibitions, these submitters also proposed the following additions: • DA recommended that Standard 2.9.1 explicitly addresses and prohibits claims like 'helps with sleep'. Noted that these types of claims that may sit outside the definition of a health claim. • NSWFA suggested the terms 'anti-reflux' and 'colic' could be explicitly added to section 2.9.1—24 Prohibited representations to ensure exclusion from the market. NSWFA asked if FSANZ has approached IP Australia, so it is proactively aware of certain marketing practices of some infant formula products (e.g., names using terms 'colic' or 'anti-reflux).	DA, NSWFA	FSANZ considers that words such as 'helps with sleep' would be a matter for enforcement agencies to determine if it constitutes a health claim. Paragraph 1.2.7—4(b) of Standard 1.2.7 states that a health claim must not be made about an infant formula product. Infant formula represented as 'partially hydrolysed' would be subject to the same nutrition content and health claim prohibitions as for other infant formula with no such representation. FSANZ considers the existing drafting in the Code is adequate because the words 'partially hydrolysed' would be a requirement (and would therefore not constitute a voluntary health claim). FSANZ also considers there is no need to prohibit terms such as 'anti-reflux' and 'colic' on infant formula labels because the current paragraph 1.2.7—4(b) provides that a health claim must not be made about an infant formula product. FSANZ expects to liaise with IP Australia and the Intellectual Property Office of New Zealand (IPONZ) about the proposed changes to Standard 2.9.1—24 to ensure they are aware of the intent of the changes.
B.14 Nutrition content and health claim prohibition *FSANZ's position at 1st CFS was to maintain its approach to not consider further the existing prohibition on nutrition content and health claims.*			
Supports FSANZ's approach.	These submitters supported retention of the existing prohibition on nutrition, health and related claims on infant formula.	NAS, NSWFA, NZFS, QLDH, VICDoH	The existing prohibition would remain as discussed in section 6.2 of SD3 to the 1st CFS. See the Note to paragraph 2.9.1—29(1) in the primary draft variation, which refers to the prohibition for making nutrition content and health claims in Standard 1.2.7. FSANZ considers the words 'partially hydrolysed' associated with

	NAS, QLDH and VICDoH also stated that a nutrition content or health claim, or reference to partially hydrolysed formula should not be permitted on infant formula products. QLDH also recommended infant formula and follow-on formula content published on company websites that contains health claims should be subject to the prohibition on these claims.		the protein source statement and ingredients list is important to assist caregivers to differentiate products and make appropriate choices. Use of these words outside of these statements would constitute a claim. Paragraph 1.2.7—4(b) prohibits the use of nutrition content and health claims on the label of a package of infant formula or follow-on formula. Section 1.2.1—23 states that 'if this Code prohibits a label on or relating to food from including a statement, information, design or a representation, an advertisement for that food must not include that statement, information, design or representation'. The presence of nutrition content or health claims on company websites is an enforcement matter.
Does not support FSANZ's approach.	Does not support the prohibition on nutrition content and health claims for the following reasons: • does not allow provision of adequate information. • does not allow for product comparison and recommends that FSANZ consider labelling requirements which facilitate further comparisons between different infant formula products. • there is a need to provide caregivers with contextual information in order for them to truly understand the nutrients in a formulation. • creates disincentives for innovation and the substantial clinical research that goes into improving infant formula products.	DAN, INC	For the reasons noted in section 6.2 of SD3 to 1st CFS, FSANZ is not considering changes to the existing prohibition on nutrition content and health claims
Other.	Understands any claim or implication that a partially hydrolysed product is effective in the prevention or mitigation of allergy would be a prohibited health claim. Although such formulas are not marketed for the management or prevention of allergy, that absence of intent may not prevent practitioners from recommending such products for that purpose. The	AAA	Partially hydrolysed formula is categorised as an infant formula and would be subject to the same labelling requirements for infant formula, including the prohibition on the use of nutrition content and health claims.

	advisory statement “Not recommended for the mitigation or prevention of allergies” or similar wording would make this clearer.		FSANZ considers the prohibition is sufficient and notes that no evidence has been provided to indicate an additional advisory statement is necessary.
B.15 Claims about ingredients *FSANZ’s preferred option at 1st CFS was to only permit information about ingredients in the statement of ingredients (except for ingredients (e.g., nutritive substances) that are required to be declared in the NIS).*			
Yes, the preferred option is supported.	These submitters supported the proposal to limit ingredient claims by only permitting information about ingredients in the statement of ingredients. NZMoH commented that ingredient claims, like nutrition and health claims, are promotional tools, and so is opposed to claims made about ingredients. NZFS stated that the drafting of this provision should not be limited to only those ingredients “required” to be declared in the NIS but is also applicable to those that are expressly permitted.	ABA and WBTi, NZFS, NZMoH, VICDoH	FSANZ is proceeding with the preferred option for the reasons in section 6.3 of SD3 to the 1st CFS. Section 2.9.1—25 includes the nutrients, nutritive substances and other substances that are either mandated or expressly permitted to be declared in the NIS.
No, the preferred option is not supported.	These submitters were strongly opposed to limiting ingredient claims to the statement of ingredients for the following reasons: • prevents the provision of adequate information to caregivers. • general information about ingredients outside of the ingredients list is common, because it allows food to be correctly described. • general information about ingredients is not the same as the nutrition content and health claims as defined by FSANZ. • the restriction is not supported by evidence of any issues or associated risks • the restriction is not consistent with international food standards • it is a disincentive for innovation.	DAN, FCG, INC, AFGC	FSANZ notes these comments however, for the reasons previously stated (see section 6.3.5 of SD3 to the 1st CFS), FSANZ’s preferred option is only permit information about ingredients in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are required to be declared in the NIS)

	• does not allow for an efficient and competitive food industry or fair trading • the ministerial policy guideline on infant formula does not include ingredient claims.		
Other.	These submitters mentioned there is no definition of an ingredient in the Code, and so there is confusion regarding what is an ingredient claim. NES stated there is some confusion between nutrient, health and related claims, which are not permitted on infant formula products, and reference to specific ingredients. Suggests that clarification is needed of what is a nutrient, health and related claim rather than new prohibitions on ingredient information.	DAN, FCG, INC, AFGC, NES	Paragraph 2.9.1—29(1)(j) in the primary draft variation prohibits information relating to ingredients to be on the labels on packages of infant formula or follow-on formula, except for a reference in the statement of ingredients or a declaration or statement expressly permitted or required by the Code. FSANZ notes the ordinary meaning of 'ingredient' would apply and considers it is unnecessary to define 'ingredient' for this purpose.
B.16 Line marketing and proxy advertising *At 1st CFS, FSANZ sought evidence and invited stakeholder comment about stage labelling and proxy advertising specific to the labelling of infant formula and follow-on formula, noting the labelling of toddler formula is out scope.*			
Supported the use of stage information.	These submitters commented that stage information provides the following benefits: • provides a factual, age-appropriate guide to caregivers for clearly distinguishing between infant formula and follow-on formula (in addition to information about other products in the product range). • numbers are simple and easily recalled by caregivers. • is useful for caregivers with English as a second language, and for caregivers who normally don't purchase formula. • the removal of stage numbers from labels could cause confusion for caregivers of formula-fed infants and increase the risks of choosing an inappropriate product for the age of the infant.	DAN, FCG, INC, NES	See section 9.5 of this report for discussion on these issues.

	NES referred to the Australia Feeding Infants and Toddlers Study which indicated Australian infants were consuming infant formula products appropriate for their age. NES considered these findings supported current labelling of infant formula products.		
Opposed stage information.	DA, QLDH, NZMoH and NSWFA did not support stage information for the following reasons: • the use of numbers or words may mislead caregivers that follow-on formulas (and formulas for toddlers) are necessary as part of a progressive feeding regimen or create an impression that there are nutritional benefits in moving through the stages. • the stage number is a promotional tool and is usually the largest and most prominent element on the label. Additionally, infant formula products are commonly displayed alongside other products within a brand's product range. • stages can undermine the importance of breast milk, with evidence indicating caregivers were not aware that breast milk also changed as their baby developed and that this lack of awareness can make a 'stage' more appealing. • stage information can make caregivers feel as if their child/infant is behind if they have not moved onto a new 'stage' of formula. VICDoH commented there is evidence in the literature that stage labelling is used to circumvent restrictions on the marketing of infant formula. LS provided references in response to FSANZ's request for evidence of caregiver understanding of stage labelling, which referred to caregiver confusion.	DA, QLDH, NSWFA, VICDoH, NZMoH, ABA and WBTi	See to section 9.5 of this report for discussion on these issues.

	QLDH noted anecdotal clinical practice suggests caregivers have a moderate to good understanding of the difference between formulas with regards to stage labelling. However, there is confusion that Stage 1 can be continued to be used up to 12 months, with some caregivers expressing concern that they have not swapped over to the next stage. DA recommended age labelling instead of stage numbers to differentiate products and indicate suitability of use, and that age information should be prominently positioned on the front of the package.		
Other.	NZFS did not specify a position on line marketing but commented it was open to further consideration of regulatory provisions to restrict or prohibit it.	NZFS	See to section 9.5 of this report for discussion on these issues.
Supported information on infant formula product labels about other products. (Proxy advertising)	Industry submitters supported the continuation of labelling information (including stage numbers) about other product categories on infant formula and follow-on formula, for the following reasons: • INC and NES commented there was limited research on caregiver understanding and behaviours associated with proxy advertising. In their view the studies referenced in FSANZ's literature review in SD3 of the 1st CFS were insufficient (i.e., older studies, small sample sizes and study quality) to support a decision on proxy advertising behaviours. • the INC also noted FSANZ did not undertake further research to consider this issue. • NES referred to evidence that women do not refer to toddler milk advertising as the reason they stop breastfeeding (Newby & Davies, 2016). • INC and DAN commented that the MAIF Agreement and the New Zealand Marketing	INC, NES, DAN, FCG	See to section 9.7 of this report for discussion on these issues.

	Code of Practice for Health Workers (INC 2018) do not permit advertising of infant formula products, so it is not possible to research caregivers' understanding and behaviours in this category because they are not advertised. • information about the next stage provides factual age-appropriate guide to caregivers and should not be seen as 'add on' products or 'advertising'.		
Opposed proxy advertising on infant formula product labels.	These submitters commented that proxy advertising should not be permitted on infant formula and follow-on formula, for the following reasons. • evidence indicates proxy advertising impacts on product recognition and consumer choice, and enables industry to circumvent restrictions on marketing of infant formula • FSANZ's literature review referred to evidence that, for toddler milk advertisements, caregivers were unable to distinguish between advertising for infant formula and that for toddler milk. • other marketing practices on labels have been shown to add to consumer confusion, influence choice and undermine breastfeeding. • Follow-on formula advertising on infant formula product labels is common, and this meets the definition of an advertisement and is a breach of the WHO marketing Code. QLDH provided no evidence but commented that caregivers are influenced by follow-on formula advertising as a means of increasing brand association and familiarity. They also commented that advertising should be prohibited because follow-	DA, QLDH, VICDoH, NZMoH, ABA and WBTi	See to section 9.7 of this report for discussion on these issues. Studies provided by submitters on this topic are noted and have been included in the Rapid Systematic Evidence Summary on Infant Formula Line Marketing and Proxy Advertising where relevant (see Attachment 1).

	on formula and toddler milks are not necessary for health. VICDoH strongly supported the removal of follow-on formula (stage 2) formula because it is not recommended by national feeding guidelines. They commented that this approach would address the issue of line marketing and ensure infant formula sufficiently differentiated from other products. VICDOH also suggested FSANZ undertakes further work to determine appropriate controls to ensure infant formula is sufficiently differentiated from other products sold in a similar format. NZMoH, VICDoH and LS commented that infant formula regulations must ensure there is a clear distinction between products. NZMoH expressed concern that infant formula, follow-on formula and toddler milks have the same or similar labelling across a product line, including colour scheme, design, logos and graphics.		See to section 9.7 of this report for discussion on these issues.
Other.	NZFS did not specify a position on proxy advertising but commented it was open to further consideration of regulatory provisions to restrict or prohibit it. LS recommended FSANZ also consider cross promotion of infant formula and follow-on formula on toddler milk labels.	NZFS, ABA and WBTi	Noted. Proxy advertising in relation to toddler milk labels is not in scope for Proposal P1028. FSANZ is proposing to prohibit information relating to another product on infant formula or follow-on formula labels. See section 9.7 of this report and paragraph 2.9.1—29(1)(c) in the primary draft variation.
B.17 Notification of product reformulation *FSANZ's preferred option for the notification of changes in product formulations is to maintain the current non-regulatory approach. That is, manufacturers would continue to decide how best to inform caregivers and health care professionals about formulation changes as appropriate.*			
Yes, the preferred	These submitters support FSANZ's approach that manufacturers continue to decide how to inform	DAN, FCG, NZMoH	FSANZ is proceeding with the preferred option.

option is supported.	caregivers and healthcare professionals about the change of the formulation.		
No, the preferred option is not supported.	DA supported a regulatory approach where notifications are only permitted for a set period of time, e.g., 6 months.	DA	FSANZ notes the guidance to clause 5(a) of the MAIF Agreement was updated in February 2022[4], and indicates a 'reasonable period' e.g., 6 weeks post formulation change for off label announcements. The guidance does not explicitly refer to the product label notifications, however FSANZ considers its preferred option of a non-regulatory approach for product notifications remains appropriate for the reasons provided in section 6.5 of SD3 to the 1st CFS.
The submitter provided an alternative option.	NZFS is not opposed to further consideration of the current non-regulatory approach. However, the provision of information about a change in formulation by manufacturers and distributors must not be used as a mechanism to make nutrition content and health claims. NZFS proposes an alternative approach of only allowing a sticker stating "New formulation" to appear on packaging.	NZFS	FSANZ considers that regulating the words on packaging is unnecessary. Section 1.2.7—4 of the Code states a nutrition content claim or a health claim must not be made about an infant formula product. As noted in section 6.5 of SD3 to the 1st CFS, FSANZ considers that manufacturers should continue to decide how best to inform caregivers and health care professionals about formulation changes.
B.18 Trademarks and online advertising *FSANZ's position at 1st CFS was that the application to online sale of food is an enforcement matter, and the issues of trademarks or online advertising will not be considered further as part of Proposal P1028.*			
Yes, the preferred option is supported.	These submitters expressed support for FSANZ's position without further qualification.	DAN, INC, NZFS	FSANZ is proceeding with the preferred option.

[4] https://www.health.gov.au/resources/publications/guidance-document-for-interpretation-of-the-maif-agreement-general-public-and-parents-and-or-carers-clause-5a

No, the preferred option is not supported.	Stated that the display of health claims through the use of trademarks on infant formula needs to be considered in Proposal P1028, as it is not in the public interest to allow the use of healthy trademarks on infant formula. FSANZ should seek legal opinion whether a health claim trademark on infant formula is grounds for rejection under the Trade Mark Regulations 42(b).	SAH	For the reasons described in section 6.6 of SD3 to the 1st CFS, FSANZ is not considering further the issue of trademarks. However, as note above (see B.13) FSANZ expects to liaise with IP Australia and the Intellectual Property Office of New Zealand (IPONZ) about the proposed changes to Standard 2.9.1—24 (prohibited representations) to ensure they are aware of the intent of the changes.
B.19 Other issues			
Plain packaging.	DA recommended FSANZ mandates plain packaging for ready-to-drink formulas. As the hospital system is a major distribution channel for ready-to-drink formulas, DA is of the view that parents and caregivers may see this as endorsement of products. LS supported plain packaging of all infant formula products.	DA, ABA and WBTi	It is unclear what is meant by 'plain packaging', given all infant formula products, including those available in a ready-to-drink format, must comply with current labelling requirements, including prohibited representations, in Standard 2.9.1. Further, ready-to-drink infant formula products that are made available in a hospital setting are generally SMPPi, and therefore used under medical supervision.
Bottle while sleeping statement.	Suggests an additional warning statement for infant formula product labels: *"Putting your baby to bed with a bottle unsupervised can cause tooth decay and risk ear infections".* NSWFA provided a discussion on the evidence base in support of the above statement.	NSWFA	Standards within the Code are legislative instruments and are not health guidance documents. Standards are also required to be prescriptive, clear and applicable to the product they regulate. FSANZ therefore does not consider a statement on putting an infant to sleep with a bottle is needed for infant formula and follow-on formula product labels and is better suited to Australian and New Zealand infant feeding guidelines.

Labelling issues not addressed in Table 5 are discussed in the following sections. These sections include the regulatory approach at 2nd CFS for those provision of information labelling issues where FSANZ has changed its position from the 1st CFS. The regulatory approach for three issues for which there was no preferred option at 1st CFS has also been included. These issues are:

- the format of the nutrition information statement
- partially hydrolysed formula
- stage labelling, product differentiation and proxy advertising.

5 Declaration of nutrition information — subheadings used in the NIS

5.1 Background

At 1st CFS, FSANZ's preferred option in SD3 was to prescribe the format of the NIS in accordance with the existing guideline in Schedule 29 of the Code, with additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances.

FSANZ also noted its preferred option was to require choline, L-carnitine and inositol to be added to infant formula (section 2.5.1 of SD2) and continue to permit these substances as optional ingredients in follow-on formula (section 3.5.2 of SD2).

5.2 Stakeholder comments

One government submitter sought clarification on how to declare choline, L-carnitine and inositol in the NIS for infant formula, given these substances are not 'Vitamins' or 'Minerals' and they are mandated for infant formula. This submitter suggested an additional subheading of 'other essential' or 'other essential substances.'

5.3 Discussion

As noted, FSANZ is requiring the mandatory addition of choline, L-carnitine and inositol to infant formula (see section 2.9.1—8(1) of the primary draft variation).

Similar to specified vitamins and minerals, the location of the mandatory declaration of choline, L-carnitine and inositol must indicate it is part of the base composition for infant formula. Therefore, the declarations cannot be made under the subheading 'Additional', as they would be if these nutritive substances are optionally added to follow-on formula.

FSANZ agrees that it would be inappropriate to declare choline, L-carnitine and inositol under the subheadings 'Vitamins' or 'Minerals' and that an additional subheading is needed to group these substances in the NIS. However, FSANZ considers a subheading that refers to 'essential' (as suggested by a submitter) could cause caregiver confusion over the essential or optional status of nutrients and substances. FSANZ considers the term 'Other nutrients' is appropriate for this additional subheading. The term would inform caregivers that choline, L-carnitine and inositol are not vitamins, minerals or macronutrient sub-group nutrients.

FSANZ is requiring the average quantity of choline, L-carnitine and inositol (including any naturally-occurring amount) to be declared in the NIS under the subheading 'Other nutrients' for infant formula. Prescribing the location would provide consistency for caregivers, regulatory certainty for manufacturers and enforcement agencies. The declaration must be made in the same format specified in the table to section S29—10.

5.4 Conclusion

FSANZ concludes that infant formula labels must include the subheading 'Other nutrients' in the NIS, and the substances choline, L-carnitine and inositol must be included in the NIS under this subheading, in the specified format (see subparagraph 2.9.1—26(2)(d)(ii) and paragraphs 2.9.1—26(4)(a) and (c) in the primary draft variation).

6 Declaration of nutrition information — format of subheadings

6.1 Background

FSANZ's preferred option at 1st CFS was to prescribe the format of the NIS in accordance with the recommended format in the existing guideline in Schedule 29 of the Code with additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances.

FSANZ reported on the findings of commissioned consumer studies (Malek 2018a, Malek 2018b, in Attachment 1 Consumer research on infant formula labelling, in SD3 to the 1st CFS), in which participants viewed mock labels that included subheadings in the NIS. The mock labels for each study included a contrasting background colour to subheading text, however participants were not asked specifically about this formatting element.

The 1st CFS included illustrative examples of a NIS that included lines to separate subheadings from specific nutrient information (Figures 1 and 2 in section 3.3 of SD3). FSANZ sought stakeholder views on this approach and any other approaches that would separate subheadings from other text, such as bolding.

6.2 Stakeholder comments

Industry and government submitters that responded to this issue held divergent views. Industry submitters opposed an approach that explicitly prescribed how the subheadings should appear in the NIS for reasons of inconsistency with international and overseas regulations, cost, and complexity for manufacturers. These submitters viewed general legibility requirements and current, flexible use of subheading formats to be adequate for grouping nutrients.

Three government submitters suggested options for ensuring a clear separation between subheadings and surrounding text. Two government submitters suggested using lines or bolding, with one of these submitters noting indentation of subheadings would be consistent with sub-group nutrients in the nutrition information panel (NIP) for general foods. The remaining government submitter considered using a contrasting background colour behind the text of subheadings was effective.

6.3 Discussion

The Code contains a precedent for formatting of a subheading. In section S12—5 of Schedule 12, the specified NIP for a formulated caffeinated beverage includes the subheading 'COMPOSITION INFORMATION' in upper case type, under which specific nutrients are listed. Lines are used to separate this subheading from surrounding text.

The generic NIP for other general foods has no subheadings for sub-group nutrients. When declared, sub-group nutrients are indented under the relevant macronutrient. Additionally, there is scope for flexibility in how nutrition information is presented in the NIP. FSANZ reviewed the NIP format in 1999 through Proposal P167 (ANZFA 1999a). At that time, FSANZ recommended a prescribed format, but that manufacturers may, within the context of

these prescriptions, and those provided by the Proposal P142 (ANZFA 1999b), apply additional enhancement features, such as the use of colour contrast banding, lines, bolding or different type face (ANZFA 1999a).

FSANZ is applying a similar, flexible approach to formatting of the subheadings 'Vitamins,' 'Minerals', 'Other nutrients' and 'Additional' in the NIS for infant formula and follow-on formula (noting the subheading 'Other nutrients' is required for infant formula only; refer to section 5 above). These subheadings are required to be printed in a size of type that is the same or larger than the nutrient names. The subheadings would also be subject to general legibility requirements in accordance with section 1.2.1—24.

In section 3.3.4 of SD3 to the 1st CFS, FSANZ stated that the subheadings would need to be distinct from other text for clarity and ease of use (e.g., using lines or bolding). However, given current industry practice is to emphasise voluntary subheadings from surrounding text using lines, bolding, or shading, FSANZ considers further regulation is unnecessary. FSANZ considers the combined regulatory measures and voluntary formatting would assist caregivers' understanding and their ability to make product comparisons.

There was little comment from submitters supporting some type of formatting, and for those that did comment, there was no consensus on an approach. FSANZ acknowledges industry submitter comments that specific formatting requirements for subheadings would be more prescriptive than the declaration of sub-group nutrients in the NIS for general foods and more prescriptive than international and overseas regulations. FSANZ does not consider indentation for subheadings to be appropriate as, unlike the NIP where sub-group nutrients are indented under a macronutrient, the sub-group headings in the NIS represent a category of substances. However, if certain permitted macronutrient sub-group nutrients are listed voluntarily (e.g., 'Whey', 'Casein', 'Docosahexaenoic acid'), FSANZ is requiring them to be indented under the relevant macronutrient or macronutrient sub-group heading.

6.4 Conclusion

Based on consumer evidence, international and overseas regulations, submitter comments and existing requirements for a NIP, FSANZ concludes all subheadings must be printed in a size of type that is the same or larger than the nutrient names in the statement (subsection 2.9.1—26(2)(d) in the primary draft variation).

7 'Lactose free' and 'low lactose' formulas

7.1 Background

Paragraph 2.9.1—14(6)(a) states that when a formula (infant formula product) is represented as lactose free or as low lactose, the name of the food must include the words 'lactose free' or 'low lactose', respectively. FSANZ's preferred option for 'lactose free' and 'low lactose' at 1st CFS was to maintain the existing requirement for these words to be included in the name of the food where relevant. As noted in section 4 above, Standard 2.9.1 does not prescribe the location for the name of the food.

Paragraph 2.9.1—14(6)(b) currently requires statements for the amount of lactose and the amount of galactose expressed in g/100 mL. At 1st CFS, FSANZ's preferred option was to prescribe the format of the NIS, including the order of nutrients and sub-group nutrients. However, FSANZ did not specify where lactose and galactose declarations would be made in the NIS for lactose-free and low lactose formulas.

7.2 Stakeholder comments

Three submitters (one each representing government, health professionals and industry) supported FSANZ's preferred approach to maintain the existing requirements for 'lactose free' and 'low lactose' products but did not specifically refer to the location of the words 'lactose free' and 'low lactose' in conjunction with the name of the food. Another industry submitter specifically opposed the requirement for the words 'lactose free' and 'low lactose' to be part of the name of the food.

No submitters commented on the location of lactose and galactose in the NIS.

7.3 Discussion

7.3.1 Location of 'lactose free' and 'low lactose' words

The industry submitters' opposition to the existing requirement for 'lactose free' and 'low lactose' words as part of the name of the food was consistent with previous industry comments in FSANZ 2021 CP3. In response to that consultation, industry submitters considered the requirement to be restrictive and some submitters proposed flexibility to allow for harmonisation with overseas regulations such as those from Europe. European Union regulations permit the use of the statement 'lactose free,' but do not set requirements for where it must appear on the label (EU 2016a).

In Australia and New Zealand, FSANZ notes lactose modified products are currently marketed as being suitable for lactose intolerance, rather than as 'lactose free' or 'low lactose'. However, under the primary draft variation, a reference to 'lactose intolerance' would be prohibited because it would constitute a health claim. Current industry practice is to provide information about lactose modification on the front of pack, in association with the name of the food (the prescribed name). Claims about lactose also appear elsewhere on the label (as currently permitted by subsection 2.9.1—14(6).

As noted in the 1st CFS, FSANZ considers the words 'lactose free' and 'low lactose' as part of the name of the food would ensure the nature of the modification is clearly identified to caregivers. Mandating these words for formulas represented as lactose free or low lactose means they are not nutrition content claims. The primary draft variation requires the words 'lactose free' and 'low lactose' to be included in the statement of the name of the food. The effect of linking these requirements is that the combined statement must appear only once on the front of pack. This co-location requirement is consistent with the requirement for the protein source statement and, where relevant, the use of the words 'partially hydrolysed'. The front of pack location ensures caregivers can distinguish a 'lactose free' or 'low lactose' product from other products when making their purchase decisions.

The words 'lactose free' and 'low lactose' would be prohibited elsewhere on the label, including in the statement of ingredients. However, the word 'lactose' may be used to declare lactose as an ingredient in the statement of ingredients.

7.3.2 Declaration in the NIS

As noted in the 1st CFS, the words 'lactose' and 'galactose' must be declared in the NIS. Given FSANZ is prescribing the format of the NIS, it is necessary to specify where the declarations for lactose and galactose must be made. FSANZ considers that for infant formula that is represented as lactose free or low lactose, the mandatory statements for lactose and galactose expressed in g/100 mL must be declared in the NIS indented under the macronutrient carbohydrate. FSANZ considers this location for the declaration is

appropriate given these are sub-group nutrients of carbohydrate, they are mandated for such products, and it reflects current industry practice.

7.3.3 Requirements apply to infant formula

Labelling requirements for food represented as lactose free and low lactose formulas are set out in section 2.9.1—21 in the primary draft variation. FSANZ notes that lactose intolerance typically occurs earlier in an infant's life and resolves by the age of one. As such, formula represented as low lactose or lactose free are positioned as infant formulas suitable for infants aged 0 – 12 months (see section 2.3.4 of the 2nd CFS). Given current industry practice is to market lactose modified formulas as suitable for infants aged from birth up to 12 months, FSANZ has specified the labelling requirements would apply to infant formula and not follow-on formula. It is assumed that manufacturers would continue with this approach. This means that 'lactose free' or 'low lactose' representations made about a follow-on formula would be prohibited. FSANZ is interested in stakeholder views regarding the application of labelling requirements in section 2.9.1—21 in the primary draft variation to infant formula only.

7.4 Conclusion

Based on the categorisation of lactose modified formulas in the proposed regulatory framework, submitter comments and current industry practice, FSANZ concludes the words 'lactose free' or 'low lactose' must be included in the statement of the name of the food on the front of the package if the label represents that an infant formula is lactose free or low lactose (paragraphs 2.9.1—21(1)(a) and (b) in the primary draft variation).

Infant formula represented as lactose free and low lactose must declare the average quantity of lactose and galactose expressed in grams in the NIS indented under 'Carbohydrate', in the same format as specified in the table to S29—10 for those substances (paragraph 2.9.1—21(1)(c)) in the primary draft variation.

The words 'lactose free' or 'low lactose would be prohibited elsewhere on the label (paragraph 2.9.1—29(1)(m) in the primary draft variation.

8 Partially hydrolysed formula

8.1 Background

FSANZ's preferred option at 1st CFS was to categorise partially hydrolysed formula as a subset of infant formula and follow-on formula, rather than as SMPPi. Under this regulatory approach, partially hydrolysed formula would be subject to the same labelling requirements as for infant formula and follow-on formula, including the existing prohibition on the use of nutrition content and health claims. Terms such as 'anti-reflux' or 'colic' would be prohibited on the label because a reference to a condition would constitute a health claim.

FSANZ put forward a preliminary view to require the words 'partially hydrolysed' to inform caregivers of the nature of the modification and to distinguish partially hydrolysed products from unmodified infant formula or follow-on formula. No location was proposed for these words, however FSANZ sought stakeholder views on this preliminary view or alternative approaches to indicate the nature of the modification without referencing specific conditions. The discussion also noted some manufacturers currently refer to 'partially hydrolysed' in the protein source statement.

8.2 Stakeholder comments

8.2.1 Terminology

Two submitters (representing industry and government) expressed support for the proposed wording 'partially hydrolysed,' while five submitters (3 industry, 2 government) supported including information about partially hydrolysed protein but did not elaborate on the terminology. Another government submitter recommended extending the wording to 'partially hydrolysed protein,' to indicate what nutrient was partially hydrolysed.

Two industry submitters opposed the prohibition for conditions (e.g., 'Colic') on the basis that partially hydrolysed products should be categorised as a subset of SMPPi, with one noting partially hydrolysed products are designed for a special medical condition, and references to conditions were useful for caregivers and health professionals to correctly identify products. This submitter also stated caregivers would be confused by information about ingredient modification if there was no reference to the condition.

In contrast, six submitters (3 government, 2 health professionals, 1 industry) supported prohibiting references to conditions such as 'anti-reflux' or 'colic' on infant formula and follow-on formula labels, due to their support for the health claim prohibition.

8.2.1 Location

There was general stakeholder support for information about partially hydrolysed protein to appear on the label. Most submitters (4 industry, 3 government) supported declaring partially hydrolysed information in the statement of ingredients. Of these, two government submitters recommended restricting partially hydrolysed information to the statement of ingredients because the presence of these words elsewhere on the label would constitute a claim, and they viewed such products as unnecessary and not supported by generally accepted science.

Some submitters (4 industry, 2 government) supported this information forming part of the protein source statement, with two of these submitters citing consistency with the labelling approach for 'lactose free' and 'low lactose' products. Two industry submitters considered the amount of partially hydrolysed protein should be declared, either as a percentage in the statement of ingredients or in the NIS.

8.3 Discussion

8.3.1 Terminology

FSANZ's position regarding the regulatory framework has remained unchanged (see section 2 of the 2nd CFS). FSANZ's assessment concluded that partially hydrolysed proteins are safe and appropriate for use in starter formulas (section 4.4 of SD2 to the 1st CFS). As such, FSANZ still considers these products to be a subset of infant formula and follow-on formula, instead of addressing a specific medical condition. References to a condition (e.g., 'Anti-reflux', 'Colic') would be prohibited because they would constitute a health claim (see section 5.2.2 in SD3 to the 1st CFS). This approach was supported by government and health professional submitters, and one industry submitter. However, FSANZ notes industry submitters (including in comments to previous consultations) opposed this preferred approach because they considered references to conditions was important for caregivers to make appropriate choices for their infants.

FSANZ understands this would necessitate a labelling change for products marketed for a specific transient gastrointestinal condition. FSANZ will work with industry on appropriate measures to inform caregivers and health professionals about this labelling change.

As noted in section 4.3 above, the word 'protein' would be prohibited on the label except in the NIS as a declaration for protein, and when used as part of an ingredient name (e.g., 'demineralised whey protein', 'whey protein concentrate'). FSANZ considers the word 'protein' is unnecessary in the protein source statement. Use of the words 'partially hydrolysed' in association with the protein source (origin) would be sufficient to inform caregivers of the ingredient the words relate to. Examples for declaring the 'partially hydrolysed' words for a partially hydrolysed formula include:

- 'Infant Formula from partially hydrolysed cow's milk and goat's milk'
- 'Partially hydrolysed cow's milk Infant Formula'.

The requirement would apply to infant formula that is represented as partially hydrolysed. A requirement to declare the words 'partially hydrolysed' for these products means they do not constitute a claim.

8.3.2 Location

After considering submitter comments, FSANZ is proposing to require the words 'partially hydrolysed' for infant formula that is represented as partially hydrolysed, and for these words to be used immediately adjacent to the statement of protein source. As noted in section 4 above, the protein source information (i.e. the specific animal or plant source or sources of protein) would be co-located with the name of the food (the prescribed name) on the front of the package of infant formula. The presence of this information would assist caregivers to distinguish between products that are represented as partially hydrolysed and unmodified formula and would assist caregivers to make an informed choice.

This approach is also consistent with labelling requirements for products that are represented as 'lactose-free' or 'low-lactose' (see section 7 above).

FSANZ considers the use of the words 'partially hydrolysed' (or words to that effect) in the statement of ingredients would be useful to inform caregivers of the true nature of the relevant ingredient(s). In FSANZ's view, it is unnecessary to mandate or prescribe the words 'partially hydrolysed' for use in this context given the Code does not prescribe ingredient names unless there is a public health and safety reason to do so. As noted in the 1st CFS, evidence indicates partially hydrolysed proteins are safe and appropriate for use in starter formulas for infants that cannot be exclusively breastfed and show no difference in growth or development when compared to infant who consume cow's milk protein formula. FSANZ considers the words 'partially hydrolysed' or any word or words having the same or similar effect should be permitted in accordance with generic ingredient naming requirements in section 1.2.4—4.

FSANZ does not consider the degree of protein hydrolysis needs to be declared in the statement of ingredients or in the NIS, as suggested by two submitters. In FSANZ's view, this information is unlikely to be meaningful for caregivers. Further, FSANZ is permitting information about 'whey' and 'casein' in the NIS and considers additional information about the degree of protein hydrolysis would create greater inconsistency between product labels and may be confusing for caregivers. FSANZ is also controlling the degree of protein hydrolysis by compositional means to distinguish between a partially hydrolysed IFP and an extensively hydrolysed SMPPi (see section 2.3.3 in 2nd CFS), and is establishing other controls for SMPPi (e.g., specific labelling for SMPPi, restricted access).

8.3.3 Requirements apply to infant formula

FSANZ has applied the same approach to partially hydrolysed formula as the approach for lactose modified products, where labelling requirements apply to infant formula (suitable for infants aged from birth up to 12 months) and not follow-on formula (refer to section 7 above). This would mean follow-on formula could not be represented as 'partially hydrolysed'. FSANZ notes this approach is consistent with current industry practice for products currently marketed as suitable for 'Colic', 'Anti-reflux' or 'Constipation'. However, FSANZ is interested in stakeholder views regarding the application of labelling requirements in section 2.9.1—20(2) to infant formula only.

8.4 Conclusion

Based on FSANZ's assessment, including submitter comments, consumer evidence and existing nutrition content and health claim prohibition, FSANZ concludes that if the label represents that an infant formula is partially hydrolysed, the words 'partially hydrolysed' must be used immediately adjacent to the statement of protein source (subsection 2.9.1—20(2) in the primary draft variation).

The label on a package of infant formula must not contain the words 'partially hydrolysed' or any word or words having the same or similar effect, except in a statement of ingredients, or when used adjacent to the statement of protein source (see paragraph 2.9.1—29(1)(l) and subsection 2.9.1—20(2) in the primary draft variation).

The word 'protein' would be prohibited on the label except for a reference in a statement of ingredients or as required in the NIS (paragraph 2.9.1—29(1)(i) in the primary draft variation).

9 Stage labelling, product differentiation and proxy advertising

9.1 Background

The labelling issues of line marketing and proxy advertising were first raised by submitters to the 2012 Consultation paper but were not considered further until in the 1st CFS (2022) when the scope of Proposal P1028 was extended to include follow-on formula.

'Line marketing' has been described previously by FSANZ as the 'labelling of infant formula as stage 1 and follow-on formula as stage 2.' This description is now used to refer to 'stage labelling' to this report (e.g., the number 1 for infant formula) as a means of assisting caregivers to make appropriate product choices for their infant.

In addition to stage labelling and age information, manufacturers use colour, images and text to ensure products within a product line are labelled distinctly. FSANZ refers to this practice as 'product differentiation'. Some submitters commented on product differentiation in previous consultations, however FSANZ has not discussed this particular issue previously.

In past consultation papers, FSANZ has referred to 'proxy advertising' as 'where the presence of permitted nutrition content and health claims on formulated supplementary foods for young children (toddler milks) may influence caregivers' feeding decisions, for example choosing toddler milks over infant formula because the former were 'better'. FSANZ noted some infant formula and follow-on formula labels include these claims to promote the benefits of toddler milks.

FSANZ also noted that proxy advertising is also known as 'cross promotion'. This latter term reflects a broader meaning to the extent that any reference (including names, numbers,

images and nutrition content and health claims) made about another product on the label of an infant formula or follow-on formula would constitute proxy advertising. FSANZ has now adopted this broader meaning for the purposes of this report and for consistency with the Codex Draft Standard for FuFOI (Codex 2023).

Section 6.4 of SD3 to the 1st CFS outlined the current domestic regulatory situation, explaining:

- the Code does not contain specific requirements or definitions relating to proxy advertising and line marketing.
- that marketing practices relating to infant formula and follow-on formula are controlled by voluntary industry codes of practice (the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement)(Department of Health and Ageing 2022) and the INC Code of Practice for the Marketing of Infant Formula in New Zealand (INC 2018)).
- the MAIF Agreement would be subject to a comprehensive review by the Commonwealth Department of Health, and the findings of this review would inform how the breast milk substitutes can be marketed.

FSANZ reported the findings from a literature review on consumer awareness, understanding and behaviour in relation to line marketing and proxy advertising, and sought further evidence and stakeholder comment on:

- caregivers' understanding of stage labelling on infant formula and follow-on formula, and
- caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula and follow-on formula.

This information was requested to inform possible regulatory approaches.

9.2 International and overseas regulations

9.2.1 Codex

Codex standards address the issues of product differentiation and proxy advertising as shown below in Table 6. The Codex Draft Standard for FuFOI refers to stage numbers in the context of proxy advertising (Codex 2023), however no Codex standard includes specific provisions for use of stage labelling.

Table 6: Existing and draft Codex labelling provisions for infant formula and follow-up formula relating to product differentiation and proxy advertising.

Issue	Infant formula	Follow-on formula
Product differentiation	Section 9.6.5 (Section A Standard for Infant Formula) in the Codex IF Standard: *'The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula and formula for special medical purposes.'*	The current Codex Standard for Follow-up Formula (CXS 156-1987) has no labelling provisions relating to differentiating follow-up formula from other products. Section 8.6.4 of the Codex Draft Standard for FuFOI: *'Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, and Formula for special medical*

Issue	Infant formula	Follow-on formula
		purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.'
Proxy advertising Proxy advertising	There is no provision regarding references to other products on an infant formula label.	The current Codex Standard for Follow-up Formula (CXS 156-1987) has no labelling provisions relating to information about other products on follow-up formula labels. Section 8.6.5 of the Codex Draft Standard for FuFOI: *'The labelling of follow-up formula for older infants shall not refer to Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.'*

The draft text is in Section A (Follow-up Formula for Older Infants) and is at Step 5 and Step 5/8 (Codex 2023).

9.2.2 European Union

The European Union Regulations include requirements for product differentiation of infant formula and follow-on formula (EU 2016a). Article 6(6) states:

> *'The labelling, presentation and advertising of infant formula and follow-on formula shall be designed in such a way that it avoids any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used'.*

These regulations do not include specific provisions for proxy advertising or stage labelling.

9.3 Voluntary marketing codes in Australia and New Zealand

9.3.1 Australian MAIF Agreement

FSANZ noted in the 1st CFS that the Australian Competition and Consumer Commission (ACCC) re-authorised the MAIF Agreement until 31 August 2024.

Clause 5(a) of the current MAIF Agreement specifies that 'Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public (WHO Code Article 5.1)'. However, the MAIF Agreement does not explicitly refer to the marketing of other products on an infant formula or follow-on formula product label.

In December 2020, the MAIF Complaints Committee issued further guidance about information relating to the appropriate age range on infant formula labels, to assist in the interpretation of Clauses 5(a) and 9(b) of the current MAIF Agreement. Clause 6(c) of the guidance states "the use of symbols and/or infographic showing all numbers and/or stages of the product range, including highlighting where the product being purchased is in the range, and the use of arrows, triangles or flow-chart symbols, is not appropriate". It also states that, in relation to the front of pack/label, "the use of text, numbers on the label (additional to that required in Standard 2.9.1) to further assist consumers in the identification of age appropriateness of the infant formula product, such as Stage 1 or Stage 2 or the number 1 or 2, is acceptable".

Item 8 of the guidance states that, in relation to the back of pack/label, 'information about the range of infant formula products suitable for infants of different ages is acceptable, noting the following: (a) images and/or pack shots of other infant formula products in the brand range are not appropriate'.

The Commonwealth Department of Health and Aged Care has engaged a consultant to undertake an independent a review of the MAIF Agreement. The Department's website provides a link to the review terms of reference and states there will be opportunities for public consultation in the first half of 2023[5]. FSANZ notes the scope of the review includes issues concerning cross-promotion of products.

9.3.2 INC Code of Practice for the Marketing of Infant Formula in New Zealand

Article 9.2 of the INC Code of Practice states that labelling of infant formula should be designed to provide the necessary information about the appropriate use of the product and to conform to the provisions of Article 4.4. The relevant text in Article 4.4 states that explicit instructions must be given to guide mothers and carers of infants on the appropriate and correct use of infant formula. The terms 'necessary information' and 'explicit instructions' are not defined further.

9.4 Scope of food regulatory measures in the Code

Section 16 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) lists the matters that may be included in standards and variation of standards. Paragraph 16(1)(d) specifies that standards and variations of standards, developed by FSANZ may relate to any information about food including labelling, promotion and advertising.

The FSANZ Act and the Code do not define 'advertisement'. This term is defined in subsection 2(1) of the Model Food Act to mean 'any words, whether written or spoken; or any pictorial representation or design; or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale of food.'

Model Food Provisions form the basis of the food acts in the Australian states and territories. The New Zealand Food Act does not define 'advertisement,' because it does not rely on Model Food Provisions. Instead, the provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *New Zealand Food Act 2014*.

Further, the prevention of misleading or deceptive conduct is a priority objective for FSANZ.

9.5 Stage labelling

9.5.1 Stakeholder views

Industry submitters supported the continued use of stage labelling on infant formula and follow-on formula for reasons that it assists caregivers to differentiate products based on age, numbers are easily recalled and understood, it is useful for caregivers with English as a second language and useful for those caregivers who normally don't purchase formula. These submitters expressed concern that removal of stage numbers could lead to caregiver confusion and an increased risk of them choosing the wrong formula. One industry submitter referred to evidence indicating Australian caregivers were choosing age-appropriate products for their infants.

[5] https://www.health.gov.au/topics/pregnancy-birth-and-baby/breastfeeding-infant-nutrition/marketing-infant-formula

Five submitters (4 government, 1 health professional, 1 consumer group) opposed stage information appearing on infant formula and follow-on formula. These submitters viewed follow-on formula and toddler milks as unnecessary and considered stage labelling promotes the continued use of formula products as part of a progressive feeding regime or creates the impression that there are nutritional benefits in moving through the stages. One government submitter referred to evidence that products targeted for older infants may appeal to caregivers who are unaware that breast milk changes as their baby develops. This submitter considered stages can undermine the importance of breast milk.

One government submitter commented that anecdotal clinical practice suggests caregivers have a moderate to good understanding of the difference between formulas with regards to stage labelling. However, there is confusion that Stage 1 can be continued to be used up to 12 months, with some caregivers expressing concern that they have not swapped over to the next stage.

Five submitters provided FSANZ with evidence relating to caregiver understanding of stage labelling, which was reviewed and included (if relevant) in the Rapid Systematic Evidence Summary on Infant Formula Line Marketing and Proxy Advertising (Attachment 1).

9.5.2 Consumer evidence

FSANZ's literature review of consumer research on infant formula product labelling (Attachment 1 to SD3 of the 1st CFS) investigated caregiver understanding of stage labelling. Additional evidence was also identified through a supplementary rapid systematic evidence summary and stakeholder submissions to the 1st CFS. This evidence is collated and presented in Attachment 1.

The identified evidence suggests that stage labelling on IFPs may be used by some caregivers to differentiate between formula products. However, age labelling was viewed as the most important label element for product differentiation, with the information often used together with stage labels when making initial purchase decisions. An online survey of 501 Australian mothers found that 11% of mothers reported looking at stage labelling when asked an open-ended question about the information they had looked for on the label to help them make purchasing decisions, while 81% reported finding stage labelling useful when presented with a list of options. Australian and New Zealand research also suggests that caregivers generally understand that each stage has a specific nutrient composition designed to meet the needs of children at a certain age.

International research suggests that the meaning of stage labelling may not always be well understood, with some common misinterpretations potentially leading to confusion about the appropriate product for a child's age (e.g., stage label '2' interpreted as 'for two-month olds'), or appropriate formula preparation and servings (e.g., 'two cups'). However, it is not clear if this study presented age information alongside the stage label. Furthermore, in some countries, stage labelling may encourage caregivers to continue formula feeding beyond infancy and early childhood, sometimes as an alternative to breast milk. However, this effect may be reduced with messaging from health professionals that later stage products are not required. The results from international studies may not be generalisable to Australia and New Zealand, due to potential differences in infant nutrition literacy and exposure to infant formula product advertising, as well as differences in cultural or regulatory environments.

9.5.3 Market survey

The market survey of 82 infant formula and follow-on formula labels enabled FSANZ to examine current industry practice relating to the use of stage numbers. Every product label included stage labelling. Most products (74, or 90.2%) only referred to the stage specific to

the product itself. The remaining products referenced other stages within the product range (including ‘stage 4’ products).

All products labels included stage labelling on the front of the package. Most product labels (51, or 62.2%) displayed stage labelling solely on the front of the package, while the remainder (31, or 37.8%) included stage labelling on both the front and the back of the package. In nearly all cases (74, or 95.1%), stage labelling was larger than age information, however the prominence of these elements in relation to each other and with other label elements varied across the products observed (see Attachment 2).

9.5.4 Discussion

The consumer evidence indicates that Australian and New Zealand caregivers consider stage numbers to be useful when differentiating between formula products in a product line, particularly when used together with age statements. FSANZ notes age statements (e.g., ‘from birth’, ‘from 6 months’) are required by Standard 2.9.1 and provide context to the relevant stage number regarding the suitability of the product. Consumer evidence appears to support this, with Australian and New Zealand caregivers understanding each stage has a specific nutrient composition suitable for infants from a certain age. Industry submitters and one government submitter understood this to be the case.

Current industry practice is to include stage labelling on infant formula products. All products observed had stage numbers on the front of the package that were specific to the product only. This is likely due in part to the MAIF Agreement guidance supporting its voluntary use as means of distinguishing between products (see section 9.3.1 above).

Given there is evidence of its value to caregivers, FSANZ considers that stage labelling specific to the product itself is helpful for caregivers to be able to distinguish between infant formula and follow-on formula. The Codex Draft Standard for FuFOI specifies that numbers relating to other products should not appear on the labels of follow-on formula. However, it is silent on whether a number specific to the product only could be used for product differentiation (see section 9.2.1).

FSANZ notes government, health professional and consumer group submitters’ concerns that stage labelling promotes a progressive feeding regime when follow-formula and toddler milks are unnecessary. To this end, FSANZ is prohibiting the use of numbers relating to other products (proxy advertising) on the labels of infant formula and follow-on formula (see section 9.7 below). Further, follow-on formula and toddler milks are well established in the market and are generally sold in packaging of a similar size and shape which may make it difficult for caregivers to identify the correct product. The presence of a stage number specific to the product only is helpful for product differentiation.

FSANZ is permitting the use of stage numbers on infant formula and follow-on formula labels only. Their use would be voluntary, which is consistent with guidance to the current MAIF Agreement. FSANZ is setting terminology and location requirements for their use as described below.

9.5.4.2 Terminology

If the product is infant formula, FSANZ is requiring the number ‘1’ to be used. If the product is follow-on formula, the number ‘2’ must be used. FSANZ notes this is more restrictive than indicated in guidance to the MAIF Agreement (which refers to the words ‘Stage 1’ or ‘Stage 2’ in addition to the number 1 or number 2. The majority of product labels observed in the market survey referred to numbers only.

9.5.4.2 Location

It is common industry practice to place stage labelling on the front of the package of infant formula and follow-on formula, which aligns with MAIF Agreement guidance. The guidance is less clear regarding its inclusion on the back of the package, however FSANZ notes this location was only used in combination with the front of pack.

If infant formula manufacturers choose to include stage labelling on their formula products, FSANZ is requiring the number used to identify for consumers that the product is infant formula or follow-on formula to appear once on the front of the package of the relevant product. The number is to be placed immediately adjacent to the mandatory age statement for that product.

As noted in section 3 above, FSANZ is requiring age statements to be co-located with the relevant stage number (if used). This would ensure important information relating to product differentiation is provided in the same field of vision for caregivers. Consumer evidence also indicates caregivers use stage labelling together with age information to identify appropriate products. FSANZ considers that the co-location requirement would also mitigate caregiver concerns regarding whether Stage 1 formulas can continue to be used up to 12 months.

FSANZ is also prohibiting stage numbers appearing elsewhere on the label of infant formula and follow-on formula. FSANZ considers that, unlike age statements, it is unnecessary to repeat stage numbers on labels of infant formula and follow-on formula as this practice may be seen to promote a progressive feeding regime. However, the intent is that the numbers '1' or '2' would be permitted elsewhere on the label if they are used in another context (for example, as part of the nutrition information in the NIS or an ingredient name in the statement of ingredients).

9.5.4.3 Formatting

The findings of the market survey indicate stage numbers are commonly larger and more prominent than age statements. FSANZ considers that co-locating these label elements on the front of the package is sufficient to ensure that caregivers can differentiate between formula products. Requirements for the format and size of the number are not prescribed to provide flexibility to industry. This regulatory approach is consistent with current MAIF Agreement guidance.

9.5.5 Conclusion

Based on the consumer evidence, stakeholder views, current industry practice, MAIF Agreement guidance, and the Codex Draft Standard for FuFOI, FSANZ concludes:

- the number '1' for infant formula and the number '2' for follow-on formula would be permitted for use to identify for consumers that the product is infant formula or follow-on formula, respectively (subsection 2.9.1—28(1) in the primary draft variation).

- If used, the number must appear on the front of the package of the product and be located immediately adjacent to the age statement for that product:
  - for infant formula, the statement required by paragraph 2.9.1—22(2)(a)
  - for follow-on formula, the statement required by paragraph 2.9.1—22(2)(b) (see subsection 2.9.1—28(2) in the primary draft variation)

- use of the number for the purposes of identifying a product is infant formula or follow-on formula would be prohibited elsewhere on the label (paragraph 2.9.1—29(1)(n) in the primary draft variation).

9.6 Product differentiation

9.6.1 Stakeholder views

Two government submitters and a consumer group submitter commented there should be controls to ensure there is a clear distinction between infant formula products sold across a product line. One government submitter expressed concern that infant formula products within product line are similar with respect to colour schemes, designs, logos and graphics.

9.6.2 Consumer evidence

In the rapid systematic evidence summary, FSANZ sought further evidence on whether and why caregivers may be choosing the wrong formula for their infant, despite age and stage labelling. This was in response to a 2015 Australian study which found that 35% of surveyed mothers who introduced formula within 6 months of birth started with follow-on formula.

The available evidence indicates that the practice of choosing inappropriate infant formula products for infants was more common in the United States than in Australia. In one United States online study, 22% of infants aged between 6 – 11 months consumed toddler milk in the last month, with 10-11% consuming it as their most common milk product and 7% consuming it daily. The study authors suggested caregivers may be confused about the distinction between infant formula and toddler milks, with six to nine percent of caregivers misidentifying the milk product they provided most often to their child. Participants of a United States focus group study stated they were confused by the difference between infant formulas and toddler milks and that similar packaging and product extensions contribute towards this confusion.

The recently published multi-country study commissioned by the WHO and the United Nations International Children's Emergency Fund (UNICEF) reported similar findings to explain why caregivers may be providing incorrect formulas. This study identified that similarities in product labels, branding across infant formula products and toddler milks, and inconsistencies in recommended age ranges can lead caregivers (in the United Kingdom, China, Bangladesh, South Africa, Nigeria, Morocco and Mexico) to purchase the wrong product. Mothers reported being confused by similar labels and noted it was sometimes unclear which age group the products were intended for.

In contrast to the previous findings at 1st CFS, two additional studies indicate that the majority of Australian caregivers choose the correct formula for their infants. This may be due to domestic labelling requirements for prescribed names and age statements to appear on infant formula and follow-on formula labels. However, the two new studies used non-representative samples. As such, incorrect formula provision may still be occurring in sub-groups of the population that were not well represented in those studies, including single parent households, those with lower education or income levels, and those born overseas.

There is no evidence of the prevalence of incorrect formula provision in New Zealand, or of the reasons behind it in either Australia or New Zealand. However, branding, packaging and line extensions may be relevant with respect to consumer confusion. In a study of Australian and New Zealand consumer understanding of different formula categories, some participants noted that packaging can look similar across a product range and that age information is important to minimise the risk of using an incorrect stage.

9.6.3 Market survey

For the 82 products observed, most manufacturers (60, or 73.2%) used colour to differentiate products within their product line. This practice included product differences in colours of various label elements, for example the lid, text, age information and stage labelling.

For infant formula and follow-on formula that included images on their labels (n = 38), 20 products (52.6%) changed the images across their product lines. An example of this practice was the use of images of teddy bears 'growing up' and getting bigger as the stages progressed.

Products that did not change colours and/or images were difficult to distinguish between, regardless of how prominent the stage and/or age information was. In some instances, when the only change in labelling was the stage and age information, infant formula and follow-on formula from the same product line were nearly indistinguishable from one another (see Attachment 2).

9.6.4 Discussion

FSANZ considers that the use of colour, images, and text (in addition to stage labelling and age information) are helpful to assist caregivers in distinguishing between infant formula and follow-on formula.

FSANZ notes the 2022 WHO and UNICEF commissioned research, referred to in section 9.7.2 above, found caregivers in other countries are confused by similarities in product labels and branding for infant formula products and toddler milks. While there is no evidence for Australian and New Zealand caregivers, FSANZ notes that caregivers may find it difficult to distinguish between products that do not change colours or images, regardless of how prominent the stage and/or age information was.

The findings of the market survey indicated most manufacturers are already using either colour or images to differentiate their formula products. However, products within a product line that had no colour change and/or images were essentially the same in appearance. FSANZ considers that a lack of distinguishing features such as colour, images and text may cause confusion for caregivers and could lead them to purchase an inappropriate product for their infant.

As noted in section 9.2 above, the Codex Infant Formula Standard, the Codex Draft Standard for FuFOI and European Union Regulations require infant formula and follow-on formula to be distinctly labelled in such a way as to avoid the risk of confusion between products. The Codex Draft Standard for FuFOI and the European Union Regulations refer to the use of colour, text and images as means of differentiating products.

FSANZ agrees with the intent of these provisions. The primary draft variation therefore requires that a food represented as infant formula or follow-on formula must not also be represented as another food (see subsection 2.9.1—15(2)). FSANZ considers the intent of this subsection is consistent with that for Codex and European Union Regulations provisions, including allowing for flexibility in how this is achieved (for example, using colours, text, and images). When used, the stage number 1 on an infant formula label and the stage number 2 on a follow-on formula label would complement these labelling strategies to ensure caregivers can easily differentiate between products within a product line.

9.6.4 Conclusion

Based on consumer evidence, the Codex Draft Standard for FuFOI, current industry practice and submitter views, FSANZ concludes that to minimise the risk of consumers being confused and purchasing an inappropriate product, a food represented as infant formula or follow-on formula must not also be represented as another food (subsection 2.9.1—15(2) in the primary draft variation).

9.7 Proxy advertising

9.7.1 Stakeholder views

Submitter views on the issue of proxy advertising were split. Government, health professional and consumer group submitters recommended proxy advertising be prohibited on infant formula and follow-on formula. Reasons cited included the existing evidence in FSANZ's literature review that caregivers had difficulty distinguishing between advertising for infant formula and that for toddler milks, that follow-on formula advertising on infant formula and toddler milks is common, and it meets the definition of an advertisement and is a breach of the WHO Code. These submitters provided additional evidence that proxy advertising impacts on product recognition and consumer choice and enables industry to circumvent marketing restrictions on marketing for several reasons.

One government submitter considered that follow-on formula proxy advertising is used to increase brand association and familiarity, and this practice should be prohibited because follow-on formula is not necessary. Another government submitter commented that the removal of follow-on formula as a specific category of infant formula products would address the issue of line marketing and ensure infant formula is sufficiently differentiated from other products.

Industry submitters supported the continuation of labelling information about other product categories on the labels of infant formula and follow-on formula. These submitters commented that information about other products in the product line is a factual and age-appropriate guide to caregivers and did not consider this information to be advertising. Two of these submitters noted there was limited consumer evidence regarding the impact of this information on caregiver understanding and behaviours, and that it was not possible to research this issue given the Australian and New Zealand voluntary marketing codes of practice do not permit advertising of infant formula and follow-on formula. They also noted the studies referenced in FSANZ's literature review were insufficient to support a decision on proxy advertising behaviours. One industry submitter noted FSANZ did not undertake further research on this issue, while another provided evidence that women do not refer to toddler milk advertising as the reason they stop breastfeeding.

9.7.2 Consumer evidence

FSANZ's literature review of consumer research on infant formula product labelling (Attachment 1 to SD3 of the 1st CFS) investigated the impact of proxy advertising of later stage formulas (12 months +) on infant and follow-on formula labels, and off pack. Additional evidence was also identified through a supplementary rapid systematic evidence summary and through stakeholder submissions to the 1st CFS. This evidence is brought together and presented in Attachment 1.

The identified evidence indicates that some Australian caregivers who see advertisements for toddler milks believe they are seeing or have seen off-label advertisements for infant formula. Caregivers who can recall the claims they saw in a toddler milk advertisement may then associate them with infant formula. No research was found that examined caregiver

perceptions of toddler milk advertisements on infant formula product packaging, or whether they found this proxy advertising to be confusing or influential in their purchase decisions.

Evidence from Australia and New Zealand suggests that caregivers perceive that children's nutritional needs vary by age, and that different stages of formula are designed to meet these different needs. Providing the correct nutrient composition for their child's age is a key reason why caregivers move onto the next stage. Caregivers tend to use the same brand to ensure consistency for their baby and will aim to purchase that brand throughout the stages. However, it is unclear whether caregivers perceive nutritional benefit in progressing through the stages, relative to non-formula sources of nutrition.

International research has identified that in some countries, stage labels and the marketing surrounding them may be encouraging parents to view later stage products as necessary for their child's development and nutrition. For example, in countries such as China and Vietnam, caregivers and health professionals often believe that the quality of breast milk declines after the age of six months, and that later stage formulas can improve growth and development relative to breast or cow's milk. However, it is not clear from this research if individual products included stage numbers and marketing about other products, or the extent to which such perceptions exist in Australia and New Zealand.

9.7.3 Market survey

More than half of products observed (52.4%, or 39 out of 82 products) included proxy advertising and it commonly appeared on the back of pack (BOP) only.

For those products with BOP proxy advertising (n = 39), more than a third (14, or 35.9%) included only names and references to other products (including stage numbers) in the product range, while nearly two thirds (25, or 64.1%) provided additional text relating to those other products that was separate to the name and reference to the other products. Additional text was used to promote other products through vague phrases, and in some cases, specific nutrition content and health claims (made about toddler milks).

Most products with BOP proxy advertising (29, or 74.4%) referred to the product next in line and did not mention the preceding infant formula product, while the remainder (10, or 25.6%) included an advertisement of the entire product range.

Strategies to cross-promote product lines included the size of the advertisement, use of colour, text, and images, with each strategy having varying degrees of effectiveness. The most common strategy was to reference colours of other products in the product line (16, or 41%), followed by references to images present on other products (8, or 20.5%). Advertisements that referenced colours of other products were the most prominent.

9.7.4 Discussion

FSANZ considers the practice of including numbers, text, statements, and images relating to other products on infant formula or follow-on formula labels is proxy advertising, which goes beyond factual information about other products as noted by industry submitters. The direct impact of proxy advertising on Australian and New Zealand caregiver purchasing behaviour is unknown, and the domestic regulatory environment includes more labelling measures to assist caregivers in making product choices than in other countries (e.g., requirements for the name of the food and an age statement). However, the available evidence indicates caregivers perceive that product progression is necessary to meet the nutritional needs of their infant. The market survey indicates proxy advertising (in particular, names and references) is commonly used to promote other products within a product line.

The market survey also identified evidence of claims about toddler milks appearing on infant formula and follow-on formula labels. FSANZ notes that nutrition content and health claims made about toddler milks are permitted, however the Code is ambiguous about the presence of claims advertising a nutritional or health benefit of a toddler milk on infant formula or follow-on formula labels. The findings of the market survey indicate this practice is less prevalent than the use of numbers, images and general statements or text. FSANZ considers such information could mislead caregivers to choose an inappropriate product for their infant.

As noted in section 6.4.3 of SD3 to the 1st CFS, when considering the revision of labelling provisions in the Codex Draft Standard for FuFOI, the Codex Committee on Nutrition and Foods for Special Dietary Use (CCNFSDU) acknowledged its intent was to prevent references to toddler milks and infant formula on follow-up formula for older infants.

FSANZ is proposing to prohibit a reference to another product, by means of a name, a number, a picture, an image, a word or words, on an infant formula and follow-on formula. This regulatory approach is consistent with the intent of section 8.6.5 of the Codex Draft Standard for FuFOI (see Table 6 in section 9.2.1 of this report) and is also supported by government, health professional and consumer group submitters.

A prohibition on the use of images of other products would align with recent guidance issued by the MAIF Complaints Committee, but may be more restrictive in relation to the use of other information 'about the range of infant formula products suitable for infants of different ages' (which may include text and statements, although the guidance is not clear on what 'other information' may include). However, FSANZ notes the guidance indicates the "The use of symbols and/or infographic showing all numbers and/or stages of the product range, including highlighting where the product being purchased is in the range, and the use of arrows, triangles or flow-chart symbols, is not appropriate."

Industry submitter comments suggested that such labelling information was not advertising contrasts in part with the MAIF Agreement's prohibition on the use of images of other products. FSANZ notes industry comments that consumer research, particularly in relation Australian and New Zealand caregiver understanding and behaviours, is limited. FSANZ disagrees, noting there is evidence that Australian and New Zealand caregivers purchase different stage formula to satisfy the nutritional needs of their growing infant. There is also recent international evidence to support the influence of proxy advertising on progression of formula use through the various stages.

Given recent Codex developments, the foreshadowed review of the MAIF Agreement, the available consumer evidence and other submitter comments, FSANZ considers the prohibition of proxy advertising is appropriate. The impact to industry would be the removal of references to other products on infant formula and follow-on formula labels. This would include pictures representing other products, names, stage numbers, images, or words.

As noted in section 9.7.1 above, two industry submitters commented on the quality of the consumer evidence presented previously. FSANZ conducted consistent quality assessments on all studies included in the 2022 systematic literature review, for which the methodology is outlined on page 32 of the literature review report (see Attachment 1). Smaller sample sizes can be appropriate for qualitative research, and thus such studies may be able to obtain a high-quality rating. However, FSANZ has taken limitations in sampling and other methodologies into account when considering the generalisability of results, which has informed the weight given to each piece of evidence in informing FSANZ's decision.

FSANZ notes the reference provided by stakeholders to suggest that women do not refer to toddler milk advertising as a reason they stop breastfeeding (Newby & Davies 2016). However, this study asked women to rate the importance of a list of potential reasons, on

which infant formula or toddler milk labelling was not included. Thus, this study does not provide evidence on the influence of infant formula or toddler milk labelling on women's decisions to stop breastfeeding.

9.7.5 Conclusion

Based on current industry practice, consumer evidence, submitter views and the Codex Draft Standard for FuFOI, FSANZ concludes that information relating to another product would be prohibited on infant formula or follow-on formula labels (paragraph 2.9.1—29(1)(c) in the primary draft variation).

For the purposes of this prohibition, 'information' includes a reference by means of a name, a number, a picture, an image, a word or words (subsection 2.9.1—29(2) in the primary draft variation).

Part C Labelling for special medical purpose products for infants

Submitter comments and FSANZ's response for SMPPi labelling issues are discussed in Table 7. These issues include the application of labelling requirements from Standard 2.9.1 and Standard 2.9.5, prohibition on therapeutic claims, inner packages, information relating to ingredients and date marking information, directions for preparation and use, mandatory statements and declarations, nutrition information, nutrition content and health claims, name and business address, prescribed name, warning statements, age-related statements, protein source statement, prohibited representations and two additional issues raised by submitters.

Table 7 – Special medical purpose products for infants: summary of submitter comments & FSANZ response

Issue	Comment	Submitter(s)	FSANZ Response
C.1 FSANZ's preferred option at 1st CFS on what labelling requirements from Standard 2.9.1 and Standard 2.9.5 to apply to SMPPi • *A list of the existing labelling provisions in the Code that were/were not applied to SMPPi was provided at 1st CFS. Comments were made specifically on most of these labelling provisions, and so are presented as separate issues in the table below. In addition to those labelling provisions, FSANZ proposed the following at 1st CFS:* *To apply the following labelling provisions:* • *the requirement to label food as 'genetically modified' in section 1.5.2—4* • *transportation outers (in subsection 2.9.5—8(4)* • *mandatory labelling information in section 2.9.5—9* • *a general requirement to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose.* *To not apply the following labelling provisions:* • *characterising ingredients and components in Standard 1.2.10* • *requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 2.9.5—15 and the existing conditions for 'lactose free' and 'low lactose' for infant formula products.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option. DAN and INC clarified that the preferred option should apply only to SMPPi that have a restriction on sale.	AAA, DA, DAN, INC, NES, NZFS, VICDoH, NSWFA	FSANZ is proceeding with the preferred option. See Division 4 in the primary draft variation. The requirements would apply to all SMPPi products, which would be subject to a restriction on sale.

Issue	Comment	Submitter(s)	FSANZ Response
C.2 Prohibition on therapeutic claims *FSANZ did not include a preferred option at 1st CFS in relation to section 2.9.5—4.*			
Other.	NSWFA considered the prohibition on therapeutic claims in section 2.9.5—4 for FSMP should also apply to SMPPi.	NSWFA	FSANZ agrees that a prohibition on therapeutic claims should apply to SMPPi. However, existing section 1.2.7—8 of the Code prohibits the making of therapeutic claims in nearly identical terms as section 2.9.5—4 (FSMPs). As section 1.2.7—8 would also apply to SMPPi if the draft variation is approved, FSANZ does not consider it necessary to include a separate provision for SMPPi in the draft variation. Refer to section 10 below for further discussion of this issue.
C.3 Inner packages *FSANZ's preferred option at 1st CFS was to apply the labelling requirements for inner packages in subsection 2.9.5—8(3).*			
Other.	These submitters strongly recommend inner packages for SMPPi have an ingredient listing. AAA notes some infants are allergic to foods other than the major allergens, so it is essential that they have access to the full list of ingredients in the product. As an example, for Australian children with a condition called FPIES, the most common triggers are rice and oats (not major allergens).	AAA, NAS	FSANZ disagrees with this recommendation and considers an ingredient list on inner packages is unnecessary given SMPPi are for use under medical supervision. Further, this approach is consistent with the European Union approach, which does not apply ingredient labelling to inner packages of FSMPs, and the domestic approach for FSMPs. SMPPi would be required to declare information that is required by section 1.2.3—4 on the label of an inner package. See paragraph 2.9.1—42(1)(c) of the primary draft variation.
C.4 Information relating to ingredients; date marking information *FSANZ's preferred option at 1st CFS was to apply the mandatory labelling information in section 2.9.5—9.*			
Other.	DAN, INC and NAS requested that ingredient labelling and date marking provisions in sections 2.9.5-11 and 2.9.5-12 apply to SMPPi.	DAN, INC, NAS	As noted in section 3.2.4 of SD4 to the 1st CFS, these provisions are proposed to apply. See sections 2.9.1—39 and 2.9.1—40 in the primary draft variation.

Issue	Comment	Submitter(s)	FSANZ Response
C.5 Directions for preparation and use *FSANZ's preferred option for directions for preparation and use at 1st CFS was that the requirement in paragraph 2.9.5—9(1)(g) will prevail over requirements for infant formula products in existing subsection 2.9.1—19(3).*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred approach for the following reasons: • aligning with Standard 2.9.5—9(1)(g) allows for less prescriptive wording and enables imported products to meet international requirements. • the set of directions for preparation and use prescribed in Standard 2.9.1 cannot be applied to all SMPPi, because the broad range of SMPPi products means some will not be presented in a traditional formula-type format.	DAN, INC, NES, NZFS	FSANZ is proceeding with the preferred option. See paragraph 2.9.1—37(1)(g) in the primary draft variation.
C.6 Mandatory statements and declarations *FSANZ's preferred option at 1st CFS was to apply the mandatory statements and declarations in section 2.9.5—10 to SMPPi.*			
Yes, the preferred option is supported. (With a caveat)	These submitters support the mandatory statements and declarations proposed for application to SMPPi, but with the caveat that statement indicating the medical purpose of the food should not be misused to make a health claim. VICDoH also proposed that this statement should be worded 'not for general use, suitable only for X condition under medical supervision' to prevent health claims.	NZFS, VICDoH	Paragraph 1.2.7—4(b) of the Code would prohibit nutrition content and health claims being made about SMPPi, which is consistent with European Union regulations for FSMP (see section 3.2.3 of SD4 to the 1st CFS, and the Note to section 2.9.1—35 in the primary draft variation). The majority of SMPPi products (as FSMP for infants) are imported from the European Union and FSANZ notes the European regulations do not prescribe the wording of mandatory statements that are equivalent to those in section 2.9.5—10 of the Code. FSANZ considers it would pose a trade barrier to specify wording of these mandatory statements for SMPPi sold in the domestic market.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported. [subpara 2.9.5—10(1)(g)(ii)]	These submitters did not support subparagraph 2.9.5—10(1)(g)(ii) applying to SMPPi, which is the requirement when the composition of the formula varies from the prescribed compositional baseline, a statement must be displayed indicating the nutrient or nutrients which have been modified. It was argued that this does not align with international SMPPi requirements. DAN and INC proposed that if such information is important for SMPPi, then an alternative approach would be to provide the information directly to healthcare professionals upon request.	DAN, INC, NES	Subparagraph 2.9.5—10(1)(g)(ii) was included in Standard 2.9.5 so that FSMP can be modified for various medical conditions, while providing health professionals with sufficient information about the content of FSMPs that vary from the compositional requirements of that standard. Supervising health professionals cannot provide advice on FSMPs without knowing the product's nutritional attributes. FSANZ considered whether information on nutrient modifications could be provided through means other than the product label when developing Standard 2.9.5. At that time FSANZ determined information about the modified nutrients on the physical label was critical for the safe use of the product by supervising health professionals. FSANZ considers the requirement for a statement on nutrient modifications (paragraph 2.9.1—38(1)(d) in the primary draft variation) would be applicable to SMPPi given the importance of medical supervision for these products.
C.7 Nutrition information *FSANZ's preferred option at 1st CFS was to apply nutrition information requirements in subparagraphs 2.9.5—13(1)(b)(i) and (ii), and not apply the requirements in subparagraphs 2.9.5—13(1)(b)(iii) or (iv).*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred approach, including the approach of not requiring a prescribed format for nutrition information for SMPPi, and to require declaration of any other nutritive substances that has been added to SMPPi for its intended medical purpose.	NES, NZFS	FSANZ is proceeding with the preferred option. See subsection 2.9.1—41(1) in the primary draft variation.

Issue	Comment	Submitter(s)	FSANZ Response
C.8 Nutrition content and health claims *FSANZ's preferred option at 1st CFS was not to apply requirements for claims in relation to lactose and gluten content in sections 2.9.5—14 and 2.9.5—15 and the existing conditions for 'lactose free' and 'low lactose' for infant formula products. Nutrition content and health claims will also not be permitted on SMPPi.*			
Yes, the preferred option is supported. (Claims in relation to lactose and gluten content)	These submitters supported FSANZ's preferred option of not applying lactose and gluten claim requirements in sections 2.9.5—14 and 2.9.5—15 to SMPPi. NZFS stated SMPPi products with lactose or gluten content as a feature of the formulation should declare the average quantity of lactose and galactose and/or gluten in the NIS DAN and INC also stated that SMPPi should be able to provide information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition, and rationale on what makes the product useful for its specific intended purpose. Such information should not be considered as claim under Standard 1.2.7.	DAN, INC, NES, NSWFA, NZFS	FSANZ is proceeding with the preferred option. Provisions for claims related to lactose and gluten content in SMPPi are not included in the primary draft variation. Mandatory information requirements in subsection 2.9.1—38(1) in the primary draft variation do not constitute a 'claim' as defined in the Code. This subsection requires certain statements and declarations to be on the label of an SMPPi, including (but not limited to) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated, and a statement describing the properties or characteristics which make the food appropriate for the medical purpose. These mandatory statements and declarations for SMPPi do not constitute nutrition content or health claims, which are voluntarily made. If the food is represented as being suitable for use as a sole source of nutrition, other statements are required, including a statement to indicate the nutrient(s) which have been modified and whether these have been increased, decreased or eliminated from the food, as appropriate.
Yes, the preferred option is supported. (Prohibition of nutrition content and health claims)	NES agrees with the prohibition on nutrition and health claims for SMPPi that serve either as a sole source of nutrition or as the principal liquid source of nourishment for infants. VICDoH commented that if SMPPi are a separate category in Standard 2.9.1 then amendments will be needed to Standard 1.2.7 to ensure SMPPi are recognised as infant formula products and the prohibition on nutrition and health claims continues to apply.	NES, VICDoH	FSANZ is proceeding with the preferred option that nutrition content and health claims would continue to be prohibited on SMPPi. See FSANZ's response to item C6 and the Note to section 2.9.1—35 in the primary draft variation. Note that the proposed definition of SMPPi is that it is a particular type of infant formula product and para 1.2.7-4(b) refers to infant formula product.

Issue	Comment	Submitter(s)	FSANZ Response
C.9 Name and business address *FSANZ's preferred option at 1st CFS was not to apply the requirements for a name and business address in section 1.2.2—4.*			
No, the preferred option is not supported.	NSWFA commented this information is important for product traceability in the case of food recalls. Considering high vulnerability of the infants who need these formulas, NSWFA did not see any rationale to exempt SMPPi from this requirement.	NSWFA	To provide flexibility and not prevent supply of imported SMPPi, FSANZ is proceeding with the preferred option to not apply generic requirements for name and business address. However, FSANZ is applying FSMP requirements for transportation outers in subsection 2.9.5—8(4) of Standard 2.9.5 to SMPPi (as noted in section 3.2.4 of SD4 to the 1st CFS). This subsection gives effect to paragraph 2.9.5—17(2)(c), which requires the name and address of the supplier in a label on the transportation outer or in a label on a package of the food for sale if it is clearly discernible through a transportation outer or provided in accompanying documentation. See the equivalent provision in subsection 2.9.1—36(4) and paragraph 2.9.1—43(2)(c) in the primary draft variation.
C.10 Prescribed name *FSANZ's preferred option at 1st CFS was to not apply a prescribed name for SMPPi*			
Yes, the preferred option is supported.	These submitters supported the preferred option to not prescribe a name for SMPPi for the following reasons: • generic provisions in Standard 1.2.2—2(1)(b) will would apply to SMPPi and are sufficient for product identification. • prescribing a name would result in international misalignment with labelling and a trade barrier.	DAN, INC, NES	FSANZ is proceeding with the preferred option to not apply a prescribed name for SMPPi, for the reasons given in section 3.3.1 of SD4 to the 1st CFS.
No, the preferred	These submitters were of the view that prescribed names should apply to SMPPi for the following reasons:	NZFS, VICDoH, WADoH, NSWFA	FSANZ does not agree with these comments for the following reasons.

Issue	Comment	Submitter(s)	FSANZ Response
option is not supported.	• the lack of a prescribed name may provide challenges for health professionals in identifying a specific product. • discount pharmacies can stock a range of general formula and medical purpose products, and carers may be confused between general and medical purpose formula. • use of a prescribed name can provide regulatory clarity and allows easy identification of products for enforcement purposes. NZFS and VICDoH indicated they would be amenable to some flexibility in the prescribed name, such as compliance with overseas prescribed naming requirements (e.g., EU requirements for 'food for special medical purposes').		FSANZ notes that although prescribing a name on SMPPi would be consistent with European requirements, it would still obstruct the importation of products from other countries that do not prescribe a name for SMPPi (e.g., the United States of America). FSANZ also notes that section 9.1.2 (Part B) of the Codex Infant Formula Standard specifies 'the name of the product shall be "Formula for Special Medical Purposes Intended for Infants" or any appropriate designation indicating the true nature of the product, in accordance with national usage'. (Codex 2018). The provision therefore allows for deviation of the name. Other labelling requirements would assist in the identification of a product as SMPPi, such as the requirement for the statement 'use under medical supervision', a statement on the properties that make the product suitable for the medical condition, and (if relevant) a statement to the effect that the food is intended for persons within the specified age group. Further, SMPPi products must include a statement describing the medical purpose of the food, which would indicate to health professionals and caregivers that the product is not a general formula.
C.11 Warning statements *FSANZ's preferred option at 1st CFS was to exempt SMPPi from warning statements for IFP in existing subsection 2.9.1—19(1). Also noted that a previous preferred option (above) was to apply the statement to the effect that the food must be used under medical supervision in subsection 2.9.5—10(1)(a) to SMPPi.*			
Yes, the preferred option is supported.	These submitters support the exemption from subsection 2.9.1—19(1). DAN and INC also support the application of subsection 2.9.5—10(1)(a) to SMPPi. Aligning with subsection 2.9.5—10(1)(a) allows for less prescriptive wording ('use under medical	DAN, INC, NAS, NES, NZFS	FSANZ is proceeding with the preferred option for the reasons provided in section 3.3.2 of SD4 to the 1st CFS. Warning statements that apply to infant formula and follow-on formula would not apply to SMPPi. A statement to the effect that the food must be used under medical supervision is required by paragraph 2.9.1—38(1)(a) in the primary draft variation.

Issue	Comment	Submitter(s)	FSANZ Response
	supervision') and therefore enables flexibility and ease of access to imported products.		
No, the preferred option is not supported.	LS mentioned that they preferred the application of subsection 2.9.1—19(1) ('breast milk is best statement') to SMPPi, except those for inborn errors of metabolism or lactose free formulas. The reasons provided were: • breast milk, and breastfeeding wherever possible, are the standard of clinical care for feeding preterm infants. • health professionals are not immune to marketing. • health professionals may not have the knowledge and skills in lactation to support mothers to provide breast milk, despite this being policy. LS proposed a modified statement that could apply to preterm formula products: 'Breast milk is best for babies, unless contraindicated'.	ABA and WBTi	FSANZ noted previously in section 3.3.2 of SD4 to the 1st CFS that it considers it is inappropriate to apply this warning statement to SMPPi. The reason an infant is fed an SMPPi is because a medical condition necessitates a partial or whole replacement of breast milk with a product specially formulated for their condition. Also, the majority of SMPPi are imported from the EU, where the 'breast milk is best' labelling statement is not required. Mandating this statement for SMPPi in the domestic market would pose a trade barrier and potentially interrupt supply. Further, these products are intended for use under medical supervision and their sale would be restricted and FSANZ considers health professionals to be best placed to advise when to breastfeed infant with medical conditions, rather than relying on SMPPi labels for this information.
C.12 Age-related statements *FSANZ's preferred option at 1st CFS was to exempt SMPPi from age-related statements for infant formula products in subsection 2.9.1—19(4)*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option to not apply subsection 2.9.1—19(4) for the following reasons: • applying the statement under Standard 2.9.5—10(e) is sufficient to cover requirements for an age-related statement on SMPPi. • given the specialised nature of SMPPi, information on when to introduce foods should be the responsibility of health professionals.	DAN, INC, NES, NZFS	FSANZ is proceeding with the preferred option to not apply the age-related statements for infant formula and follow-on formula to SMPPi for the reasons outlined in section 3.3.4 of SD4 to the 1st CFS.

Issue	Comment	Submitter(s)	FSANZ Response
C.13 Protein source statement *FSANZ's preferred option at 1st CFS was to not apply the requirement for a protein source statement in accordance with paragraph 2.9.1—23(1)(a) to SMPPi.*			
Yes, the preferred option is supported.	These submitters agreed that a statement regarding the specific source should not apply to SMPPi. NZFS also stated that SMPPi should not be prevented from voluntarily making such a statement on the label. Requests FSANZ consider a specific permission for SMPPi to allow a voluntary protein source statement.	DAN, INC, NES, NZFS	FSANZ is proceeding with the preferred option to not apply the the requirement for a protein source statement in accordance with paragraph 2.9.1—23(1)(a) to SMPPi. Although, FSANZ agrees it is appropriate to permit voluntary information relating to the source or sources of protein in the product on SMPPi labels. Refer to section 11 for further discussion and subsection 2.9.1—41(2) in the primary draft variation.
C.14 Prohibited representations *FSANZ's preferred option at 1st CFS was to not apply the provision in section 2.9.1—24 for prohibited representations to SMPPi.*			
Yes, the preferred option is supported.	These submitters supported FSANZ's preferred option. DAN noted that most of these products are highly specialized and intended for use under the supervision of a healthcare professional. DAN and INC also argued that a restriction on sale should not apply to SMPPi, and so these prohibited representations should be permitted for SMPPi sold through supermarkets.	DAN, INC, NES, NZFS	For the reasons outlined in section 12 below, FSANZ has re-considered the preferred option and is now proposing to prohibit the following representations on the labels of SMPPi (section 2.9.1—35 in the primary draft variation): • a picture of an infant • the word 'humanised' or 'maternalised' or any word or words having the same or similar effect • the words 'human milk oligosaccharide,' 'human milk identical oligosaccharide' or any word or words having the same or similar effect • the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect. • information relating to another food.

Issue	Comment	Submitter(s)	FSANZ Response
No, the preferred option is not supported.	These submitters did not support the exclusion of SMPPI from the prohibited representations in section 2.9.1—24. The following reasons were given: • an exclusion would create a loophole for human milk oligosaccharide formulas to shift into the SMPPi category and 'HMO' labelling on the front of pack. This would contradict the decision of the Food Ministers Forum on Application A1155. • FSANZ has not explained why SMPPi should need to make the representations prohibited by section 2.9.1—24. The restriction of access is also unlikely to prevent the marketing of, and access to, HMO products.	NSWFA, VICDoH	As noted above, FSANZ has re-considered the prohibited representations for SMPPi as discussed in section 12.
C.15 Other issues			
Potential Renal Solute Load (PRSL) on SMPPi labels.	VICDoH supports provisions that state the PRSL should be included on labels where possible. Clinical paediatric dietitians have informed VICDoH that infants with medical conditions have different fluid tolerances and information about the potential renal solute load (PRSL) of SMPPi is essential.	VICDoH	FSANZ is maintaining its preferred approach to remove requirements relating to the maximum PRSL from Standard 2.9.1 and Schedule 29. The reasons for this decision are discussed in Table 8 to Part C in SD2 Nutrient Composition.
Application of horizontal labelling requirements for SMPPi.	Products regulated by Standard 2.9.5 are generally exempt from the labelling requirements under Part 1.2 of Chapter 1 (see section 2.9.5—3) except when specifically required. See section 2.9.5—10 (2) and (3). This approach seems unduly cumbersome. A&AA would expect Standard 1.2.3 as a whole, and the relevant parts of standard 1.2.1 plus the relevant schedules to apply to such products under 2.9.5.	AAA	The exemption from Part 1.2 labelling requirements for SMPPi is consistent with a similar approach for the labelling of FSMPs. Labelling requirements for FSMPs have been applied to SMPPi where possible, noting there are some differences for SMPPi (e.g., certain claims are prohibited).

10 Therapeutic claims

10.1 Background

At 1st CFS, FSANZ considered how to apply the labelling requirements in Standard 2.9.5 – Food for Special Medical Purposes to SMPPi but did not include section 2.9.5—4 in this consideration. Section 2.9.5—4 states that a claim in relation to food for special medical purposes must not:

a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or

b) compare the food with a good that is:
   i) represented in any way to be for therapeutic use; or
   ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

10.2 Stakeholder comments

One government submitter requested that the prohibition on therapeutic claims in section 2.9.5—4 for FSMP should also apply to SMPPi.

10.3 Discussion

SMPPi are intended as a dietary intervention in a comparable manner to how FSMPs are used; that is both types of food are defined as being for the dietary management of a medically diagnosed disease, disorder, or condition. These products are not intended to be used for therapeutic purposes, such as the prevention or alleviation of a medical condition. FSANZ therefore considers that the prohibition against therapeutic claims on FSMPs is also applicable to SMPPi products.

FSANZ notes that a prohibition for therapeutic claims on SMPPi is consistent with similar requirements in article 9.5 of European Regulation EU 609/2013 (EU 2013).

FSANZ also notes that paragraph 1.2.7—4(b) of Standard 1.2.7 states a nutrition content claim or health claim must not be made about an infant formula product, and that section 1.2.7—8 provides that a claim must not be therapeutic in nature. These existing provisions would also apply to SMPPi given that SMPPi is an infant formula product. On that basis, FSANZ does not consider a specific provision to prohibit therapeutic claims in the primary draft variation that is consistent with section 2.9.5—4 for FSMP is necessary.

10.4 Conclusion

Based on a submitter comment and overseas regulations, FSANZ concludes that, in addition to the existing nutrition content and health claim prohibition for infant formula products, the existing prohibition for a therapeutic claim in section 1.2.7—8 would apply to SMPPI (see the Note to section 2.9.1—35 in the primary draft variation for explanation).

11 Protein information

11.1 Background

Paragraph 2.9.1—23(1)(a) of the current Standard requires a statement of the specific source, or sources, of protein in the product immediately adjacent to the name of the product.

The intent of the current provision is that it applies to infant formula products, including IFPSDU.

At 1st CFS, FSANZ noted the Codex Infant Formula standard states that if cow's milk protein is the only source of protein, the product may be labelled 'Formula for Special Medical Purposes Intended for Infants Based on Cow's Milk". However, FSANZ noted the European Union FSMP Regulation has no similar provision for SMPPi. FSANZ considered there was a need to maintain flexibility on the protein composition and to avoid creating a trade barrier, and noted its preferred option was to not apply the requirement for a protein source statement to SMPPi (see section 3.3.5 in SD4 to the 1st CFS).

11.2 Stakeholder comments

Four submitters (3 industry, 1 government) commented on this issue and agreed that the requirement for protein source statement should not apply to SMPPi. However, the government submitter stated that SMPPi should not be prevented from voluntarily making such a statement on the label, particularly if this information is relevant for the medical purpose for which the product has been formulated or if other proposed SMPPi labelling requirements would allow for such a statement to be made. This submitter suggested an explicit permission should be provided.

11.3 Discussion

FSANZ is permitting voluntary protein source information on SMPPi labels for the following reasons. An explicit permission is considered necessary because of the potential contradiction between:

- the existing prohibition for nutrition content and health claims (see the Note to section 2.9.1—35 in the primary draft variation), and
- the mandatory statement describing the properties or characteristics which make the food appropriate for the medical purpose (paragraph 2.9.1—38(1)(d) in the primary draft variation), and (if relevant) the mandatory statements relating to food that has been modified to vary from compositional requirements in section 2.9.5—32 (subparagraph 2.9.1—38(1)(g)(ii) in the primary draft variation).

The presence of protein source information would not constitute a nutrition content claim if an explicit permission is provided.

FSANZ also notes that Article 6(1)(d) of the European Regulation requires information on the source and nature of the protein and/or protein hydrolysates contained in the product (EU 2016b). Given the majority of SMPPi are imported from the European Union, it is necessary to ensure there is no trade barrier imposed for these products.

With the exception of it being made mandatory, the primary draft variation for protein source information about SMPPi is consistent with the European Regulation, and is considered to be separate from:

- draft compositional requirements for infant formula and follow-on formula about protein requirements, which do not apply to SMPPi (section 2.9.1—6 in the primary draft variation)

- requirements for a statement of protein source, which require the protein source to be included in the statement of the name of the food (subsection 2.9.1—20(1) in the primary draft variation).

11.4 Conclusion

Based on a submitter comment, overseas regulations and other requirements in the primary draft variation, FSANZ concludes that information on the source or sources of protein in the product should be permitted on SMPPi labels (subsection 2.9.1—41(2) in the primary draft variation).

12 Prohibited representations

12.1 Background

The prohibited representations listed in section 2.9.1—24 of the current standard apply to infant formula products, including IFPSDU. The prohibited representations listed are:

(1) The label on a package of infant formula product must not contain:

(a) a picture of an infant; or

(b) a picture that idealises the use of infant formula product; or

(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or

(ca) the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or

(cb) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect; or

(d) words claiming that the formula is suitable for all infants; or

(e) information relating to the nutritional content of human milk; or

(f) subject to subsection 2.9.1—14(2), a reference to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in:

(i) a statement relating to lactose under subsection 2.9.1—14(6); or

(ii) a statement of ingredients; or

(iii) a declaration of nutrition information under section 2.9.1—21; or

(g) subject to Division 4, a representation that the food is suitable for a particular condition, disease or disorder.

(2) Subject to subsection 2.9.1—14(2), the label on a package of infant formula product must not contain a reference to *inulin-type fructans or *galacto-oligosaccharides except for a reference in:

(a) a statement of ingredients; or

(b) a declaration of nutrition information under section 2.9.1—21.

FSANZ's preferred option at the 1st CFS was to not apply the prohibited representations to SMPPi, because these are highly specialised products for use under medical supervision, their sale would be restricted, and because provisions in paragraphs 2.9.1—24(1)(a) to (e) do not align with European regulations or Codex provisions for SMPPi.

12.2 Stakeholder comments

Several industry submitters expressed support for FSANZ's preferred option. However, two government submitters did not support this proposal because:

- an exclusion would create a loophole for infant formula and follow-on formula containing human milk oligosaccharides to shift into the SMPPi category and label on the front of pack with 'HMO' labelling. These submitters considered this would contradict the decision of the Food Ministers Forum on Application A1155.
- they stated FSANZ did not explain why the representations prohibited by section 2.9.1—24 should not apply to SMPPi.

These submitters also commented that the restriction on access is also unlikely to prevent the marketing of, and access to, SMPPi products with 'HMO' labelling.

12.3 Discussion

SMPPi are not marketed directly to infant caregivers but are instead labelled to indicate whether the product is suitable for an infant's medical condition. As a result, the SMPPi products currently on the Australian and New Zealand market do not contain many of the representations listed within section 2.9.1—24 of the current standard, specifically those in paragraphs (a) to (e).

FSANZ notes the main supply region for SMPPi, the European Union, has regulations for infant formula that are consistent with prohibitions in paragraphs 2.9.1—24(1)(a), (b) and (c) above, and have similar requirements to prohibitions (d) and (e) in the current standard (EU 2016b).

The following existing prohibited representations are not applicable to SMPPi:

- words claiming that the formula is suitable for all infants (paragraph 2.9.1—24(1)(d))
- information relating to the nutritional content of human milk (paragraph 2.9.1—24(1)(e))
- a reference to any nutrient or nutritive substances as indicated (paragraph 2.9.1—24(1)(f))
- a representation that the food is suitable for a particular condition, disease, or disorder (paragraph 2.9.1—24(1)(g))
- subject to subsection 2.9.1—14(2), a reference to *inulin-type fructans or *galacto-oligosaccharides except for a reference in a statement of ingredients or a declaration of nutrition information (subsection 2.9.1—24(2)).

The specialised nature of SMPPi means they are not intended to replicate breast milk, and they would often need to describe nutrient modifications that make the product suitable for a particular medical condition. The prohibition for a representation that the food is suitable for a particular condition, disease or disorder is unnecessary given FSANZ is requiring a statement for SMPPi indicating the medical purpose of the food. The prohibition for a reference to inulin-type fructans or galacto-oligosaccharides unless expressly permitted currently does not apply to infant formula products for special dietary use and FSANZ considers this approach is remains appropriate for SMPPi.

FSANZ has reconsidered the application of the remaining prohibited representations, and is applying a prohibition on the following representations for SMPPi (section 2.9.1—35 in the primary draft variation):

- a picture of an infant
- the word 'humanised' or 'maternalised' or any word or words having the same or similar effect

- the words ‘human milk oligosaccharide,’ ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect
- the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect.
- information relating to another food

Because none of the currently available SMPPi displays any of these prohibited representations, their application will not adversely affect the supply of SMPPi products to Australian and New Zealand infants. Prohibitions for the picture of an infant, and the word ‘humanised’ or ‘maternalised’ or similar are also consistent with European prohibited representations for SMPPi.

Prohibited representations about human milk oligosaccharide (HMO) terminology and abbreviations currently apply to infant formula products for special dietary use. In November 2020, the then Australia and New Zealand Ministerial Forum on Food Regulation (now the Food Ministers’ Meeting) reviewed the approval report for A1155 - 2’FL and LNnT in infant formula and other products. Food Ministers agreed to permit the voluntary addition of these (HMO) substances to infant formula products (including infant formula products for special dietary use) in Australia and New Zealand[6] subject to the prohibition of HMO labelling terminology.

FSANZ’s preferred option at 1st CFS was not to apply the prohibited representations listed in existing section 2.9.1—24 for the reasons noted in section 12.1 above. However, FSANZ notes government submitter comments in section 12.2 above and has concluded these labelling prohibitions should continue to apply to SMPPi. The specific prohibitions for HMO words or abbreviations would also complement the existing prohibition for nutrition content and health claims (for further information, see the Note to section 2.9.1—35 in the primary draft variation).

Further, FSANZ is also prohibiting information relating to another food from being on the label on SMPPi, which is consistent with the new, similar provision for infant formula and follow-on formula.

12.4 Conclusion

Based on submitter comments, trade matters and existing prohibitions in the Code, FSANZ concludes the following representations on SMPPi labels should be prohibited (section 2.9.1—35 in the primary draft variation):

- a picture of an infant; or
- the word ‘humanised’ or ‘maternalised’ or any word or words having the same or similar effect; or
- the words ‘human milk oligosaccharide’, ‘human milk identical oligosaccharide’ or any word or words having the same or similar effect; or
- the abbreviations ‘HMO’ or HiMO’ or any abbreviation having the same or similar effect; or
- information relating to another food.

[6] Australia and New Zealand Ministerial Forum on Food Regulation meeting 27 November 2020: Communiqué of outcomes https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2020-November27

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