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

4 April 2022
196-22

Supporting document 3

Provision of information

Proposal P1028 Infant Formula

Executive Summary

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

Infant formula is currently specifically 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).

This Supporting Document (SD) considers labelling requirements for infant formula products (IFP) that provides information to enable caregivers of formula-fed infants to make informed choices and to assist health professionals when providing infant feeding advice. Labelling information about the preparation and safe use of IFP and for Special Medical Purpose Products for infants (SMPPi) are considered in SD1 and SD4, respectively.

In considering labelling requirements for provision of information (ingredient and nutrition labelling, specific labelling of modified products, overall representation), FSANZ has had regard to the assessment criteria prescribed by the FSANZ Act, the current policy and regulatory environment, current requirements in the Code, international and overseas regulations, consumer evidence (Attachment 1 to this SD) and stakeholder comments received in response to earlier consultations in 2012 and 2016.

FSANZ is proposing to maintain existing requirements except for proposed changes to the following labelling elements:

Labelling of ingredients

- permit the optional grouping of added vitamins and minerals in the statement of ingredients under the subheadings ‘vitamins’ and ‘minerals’ and within these groups the vitamins and minerals need not be listed in descending order of ingoing weight.

Nutrition information

- to prescribe the format of the nutrition information statement (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.
- to only permit the base unit of expression (per 100 mL as reconstituted) in the NIS.

- for average energy:
  - to require nutrition information (excepting energy) to be expressed as the 'average quantity' in the NIS
  - to clarify that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to IFP.
- clarify nutrition information 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)) must not be located in the NIS.
- 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'.

Representations

- 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).

In addition, FSANZ is specifically seeking evidence and stakeholder comment to inform consideration of the following three labelling issues discussed in this SD:

- format of the nutrition information statement
- specific labelling of partially hydrolysed formula as a modified IFP.
- stage labelling and proxy advertising related only to IFP.

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Glossary

Abbreviation or Term	Meaning
ARA	Arachidonic acid
Breast milk	A general term for human milk provided from a mother's breast (described as mature milk to distinguish it from colostrum).
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
Codex	Refers to Codex Alimentarius
Codex Draft Standard for FuFOI	Refers to the Proposed Draft Revised Standard for Follow-up Formula, Section A: Follow-up Formula for Older Infants (see 22REP/NFSDU Appendix III)
DHA	Docosahexaenoic acid
EPA	Eicosapentaenoic acid
EU	European Union
EU 2016/127	European regulation on compositional and information requirements for infant formula and follow-on formula
Follow-on formula (FOF)	An infant formula product that is represented as either a breast milk substitute or replacement for infant formula and is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months, as defined in Standard 1.1.1 of the Code.
Follow-up formula (FUF)	Under CODEX STAN 156-1987, this is a food intended for use as a liquid part of the weaning diet for older infants (age 6-12 months) and for young children (age 12 -36 months).
IFPSDU	Infant formula products for special dietary use
Infant	A person under the age of 12 months, as defined in Standard 2.9.1
Infant formula (IF)	An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months, as defined in Standard 1.1.1 of the Code
Infant formula products (IFP)	Products based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants; as defined in Standard 1.1.1 of the Code
Infant formula products for special dietary use (IFPSDU)	An infant formula product listed in Division 4 of Standard 2.9.1
Infant formula products for special medical purpose (IFPSMP)	Category of IFSPDU under the regulatory framework proposed in FSANZ 2021 CP3
INC	Infant Nutrition Council
MAIF Agreement	The Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement

Abbreviation or Term	Meaning
NIS	Nutrition information statement
SD	Supporting document
SMPPi	Special medical purpose products for infants
The Code	Australia New Zealand Food Standards Code
WHO	World Health Organization
WHO Marketing Code	WHO International Code of Marketing of Breast-milk Substitutes

1 Introduction

Other than important information about the preparation and safe use of infant formula products (IFP) (as considered in Supporting Document 1), labelling on IFP also provides information to assist caregivers of formula-fed infants and the health professionals who provide infant feeding advice, to make informed choices. This Supporting Document considers labelling requirements for IFP (i.e. infant formula (IF) and follow-on formula (FOF)) that are not safety related, but provide information to enable informed choice.

This information primarily relates to ingredient and nutrition labelling. Issues regarding the specific labelling of modified products and the overall representation of IFP are also considered. Labelling specific to Special Medical Purpose Products for infants (SMPPi) is considered in SD4.

In considering labelling requirements for provision of information, FSANZ has had regard to the current policy and regulatory environment, current requirements in the Australia New Zealand Food Standards Code (the Code), international and overseas regulations and stakeholder comments received in response to earlier consultations in 2012 and 2016.

1.1 Background

1.1.1 Ministerial policy guidelines

The following specific policy principles in the Ministerial Policy Guideline on the Regulation of Infant Formula Products (ANZFRMC 2011) relate to the labelling and advertising of IFP:

(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization *International Code of Marketing of Breast Milk Substitutes* as implemented in Australia and New Zealand.

(l) The labelling and advertising of infant formula products should not represent those products as equivalent to, or better food than, breast milk.

(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.

(n) The Authority should ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Code are clear and effective for infant formula products; and consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.

In addition, the Ministerial Policy Guideline on Nutrition, Health and Related Claims adopted in 2003 (ANZFRMC 2003) refers to the exclusion of certain categories of foods from making nutrition content and health claims, including ‘infant foods’.

1.1.2 Controls on marketing practices

Marketing practices are controlled in Australia and New Zealand through the implementation of the World Health Organization’s (WHO *International Code of Marketing of Breast-milk Substitutes* (WHO 1981), commonly known as the WHO Marketing Code. Both Australia and New Zealand are signatories to the WHO Marketing Code. The WHO Marketing Code sets out various principles that aim to protect and promote breastfeeding by ensuring the proper use of breast milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

The WHO Marketing Code labelling principles are given effect as mandatory provisions in Standard 2.9.1. In addition, both the Australian and New Zealand governments have taken steps to incorporate relevant principles of the WHO Marketing Code relating to marketing practices for IFP into voluntary codes of practice.

In Australia, the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (MAIF Agreement) is a voluntary code of practice for manufacturers, marketers and distributors of IFP.

In New Zealand, the WHO Marketing Code is implemented through three voluntary codes of practice, relating to manufacturers, importers, and health workers:

1. *INC Code of Practice for the Marketing of Infant Formula in New Zealand* (INC 2018)
2. *Code of Practice for Health Workers* (Ministry of Health 2007)
3. *Code for Advertising of Food* (Advertising Standards Authority (2018)

The INC Code of Practice for the Marketing of Infant Formula (INC Marketing Code of Practice) applies to the manufacturers, marketers and distributors.

1.1.3 International and overseas regulations

In developing and reviewing food standards, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In the first instance, FSANZ has considered any Codex standards and guidelines relevant to labelling requirements in Standard 2.9.1. These include:

- Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex CXS 72-1981)
- Codex Guidelines for Use of Nutrition and Health Claims (CXG 23-1997)
- Codex Standard for Follow-up Formula (Codex CXS 156-1987).

FSANZ also notes the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is currently revising the Follow-up Formula Standard (CXS 156-1987). The Proposed Draft Revised Standard for Follow-up Formula: Section A: Follow-up Formula for Older Infants[1] (Codex Draft Standard for FuFOI), incorporating provisions for composition and labelling, is now held at Step 7, which is the final step prior to being submitted to the Codex Alimentarius Commission for adoption. The proposed Codex Draft Standard FuFOI mostly aligns with specifications for IF in CXS 72-1981.

Labelling requirements in current EU regulations for IF and FOF (EU 2016/127) have been also been considered because the majority of imported IFP are sourced from the European Union. Although, other overseas regulations have also been considered where relevant.

1.2 Previous consideration and consultation

FSANZ has consulted on the provision of information labelling elements in 2012 (FSANZ 2012 CP) and 2016 (FSANZ 2016 CP).

The purpose of FSANZ 2012 CP was to identify regulatory issues relating to labelling requirements. In relation to labelling for information, FSANZ sought stakeholder views on claims and representations, trademarks, guidelines for nutrition information, advertising of IFP (including use of line marketing, proxy advertising and online advertising). The FSANZ 2016 CP discussed ingredient claims, the declaration of permitted nutritive substances, nutrition declaration requirements (including the format of the nutrition information statement,

[1] 22REP/NFSDU Appendix III, Section A: Follow-up Formula for Older Infants

base units of expression and average amount), the inter-relationship between the nutrition information statement (NIS) and statement of ingredient declarations and product reformulation notifications. At this time, issues concerning line marketing/proxy advertising/trademarks and on-line advertising were excluded from the scope of the proposal.

More generally, the labelling of infant formula products for special dietary use (IFPSDU) was explored in 2017 (FSANZ 2017 CP) and 2021 (FSANZ 2021 CP3).

2 Labelling of ingredients

2.1 Statement of ingredients

2.1.1 Current regulation

Infant formula products are subject to generic requirements in Standard 1.2.4 Information requirements – statement of ingredients. This Standard requires all ingredients to be listed in a statement of ingredients (with few exceptions).

Ingredients must be listed using their common name, a name that describes the true nature of the ingredient, or a generic name (if any) that is specified in Schedule 10 in accordance with any conditions specified in that Schedule (section 1.2.4—3). In Schedule 10, the generic name ‘milk solids’ may be used to describe any two or more of the following ingredients (whey, whey powder, whey proteins, lactose, caseinates, milk proteins, milk fat). ‘Fats’ or ‘oils’ may be used as generic terms on condition that the source (animal or vegetable) is declared. The specific source of animal fats or oils must be declared if the food is a dairy product.

Food additives (including a vitamin or mineral) must be listed in the statement of ingredients by specifying the applicable class name in Schedule 7 (if one applies, e.g. ‘acidity regulator’), followed in brackets by the name or code number of the substance as indicated in Schedule 8 (e.g. ‘330’ or ‘Citric acid’) . If the food additive can be classified into more than one class, the most appropriate class name must be used. In the absence of a class name, the name of the substance as indicated in Schedule 8 applies (section 1.2.4—7).

Vitamins and minerals may be declared using the class name ‘vitamin’ or ‘mineral’ (section 1.2.4—8).

Ingredients must be declared in descending order of ingoing weight (section 1.2.4—5). Requirements for listing of compound ingredients (subsections 1.2.4—5(5) and (6)) also apply to IFP. Compound ingredient means “an ingredient of a food is a compound ingredient if it is itself made from two or more ingredients” (section 1.1.2—2(3)).

2.1.2 International and overseas regulations

Specifications in Codex CXS 72-1981 are similar to Code requirements, except where vitamins and minerals may be grouped separately in the ingredient list, and within these groups the vitamins and minerals need not be listed in descending order of proportion. FSANZ notes the Codex Draft Standard FuFOI has been proposed to align with specifications in CXS 72-1981.

EU regulations (EU 1169/2011) are also similar to Code requirements. However, the regulations include requirements to list the specific origin of vegetable and animal fats and

refined oils when generic terms ‘vegetable [oil(s)/fats(s)]’ or ‘animal [oil(s)/fat(s) are used as generic names. Food additives may be labelled with E numbers.

2.1.3 Previous consideration

FSANZ has not consulted stakeholders on the issue of ingredient labelling for IFP.

2.1.4 Consumer evidence

The available evidence in Attachment 1 to this SD indicates that when caregivers use the statement of ingredients they do so to identify the presence or absence of specific nutrients and substances and when making product comparisons. The main reason caregivers give for looking at the ingredient list is if they believe their infant has specific nutritional requirements or health concerns (e.g. allergies or intolerances). However, many caregivers report not looking at the ingredient list on account of not understanding what the ingredients are.

An online survey of Australian and New Zealand caregivers found that when presented with a statement of ingredients and asked if they found it helpful when deciding which formula product to buy, less than half of respondents reported it was helpful. When asked about their perceptions of ease of understanding, only a small proportion (approximately 5%) indicated the statement of ingredients is easy to understand on all products.

Earlier qualitative studies of both Australian and New Zealand caregivers suggest those caregivers who found the ingredient information less useful may have done so for several reasons, including not knowing what many ingredients are and being unsure of what ingredients are meant to be in formulas.

Caregivers believe a standardised statement of ingredients and grouping nutrients and substances by their type (e.g. vitamins and minerals) would be helpful. Standardising the location of the statement of ingredients was also supported.

2.1.5 Discussion

Ingredient names

Ingredient naming requirements in the Code are similar to Codex and European provisions. These generic requirements also apply across the domestic food supply. They provide consistency and potentially familiarity to caregivers of infants, and some flexibility for manufacturers. FSANZ acknowledges IFP contain a long list of ingredients (including vitamins and minerals) with many having technical names. The consumer evidence indicates many caregivers find this information less helpful, mainly due to their poor understanding of what the ingredients are. While specific technical names for some ingredients are required for enforcement purposes, there are other labelling measures to assist caregiver understanding (for example, the generic name ‘milk solids’ and shorter micronutrient names in the nutrition information).

Unlike Codex CXS 72-1981, the Code relies on generic name conditions for fats and oils, and where relevant, generic ingredient name requirements to identify if ingredients are from an animal or plant origin. When used together, these requirements ensure ingredients can be appropriately identified by caregivers. FSANZ notes the protein source statement provides additional information about the animal or plant origin of protein.

The Code and European Regulations differ in how food additive code numbers (if used) are labelled, however these differences apply to all food products.

There are different declaration requirements for permitted forms of vitamins and minerals that may be added to IFP as nutritive substances (section S29—7), and vitamins and minerals permitted for use as food additives (Schedule 8). In some cases the permitted form of the vitamin and mineral is also listed as a food additive (e.g. calcium carbonate). In other cases the permitted form(s) of the vitamin or mineral has no equivalent food additive code name or only one food additive code name.

These differences are not unique to IFP; they also apply to permitted forms of vitamins and minerals added to other special purpose foods. Additionally, these requirements align with Codex and the European Regulations, which do not specify permitted forms must be declared in ingredient lists.

Based on this assessment, FSANZ considers current generic declaration requirements for ingredient names should be maintained for IFP.

Format and location of the statement of ingredients

As noted in section 2.1.4, available evidence suggests caregivers believe that standardising the format and location of the statement of ingredients, and grouping nutrients by type, would be beneficial.

FSANZ considers any further standardisation of the statement of ingredients beyond the current requirements would reduce labelling flexibility and be a barrier to trade, noting international and overseas regulations contain no such provisions.

However, there is merit in considering grouping added vitamins and minerals within the statement of ingredients, under their respective subheadings ‘vitamins’ and ‘minerals’ as a means to assist caregivers’ understanding of these ingredients.

FSANZ has observed the majority of IFP already group added vitamins and minerals under subheadings and sometimes the micronutrients are listed within brackets. An explicit permission in the Code would provide regulatory certainty and would harmonise with provisions in Codex CXS 72-1981.

Based on the above, FSANZ considers that further standardising the format and location for the statement of ingredients is not practical, however the optional grouping of added vitamins and minerals will be permitted.

2.1.6 Preferred option

In relation to labelling of the statement of ingredients, FSANZ’s preferred option is:

- that generic labelling requirements should continue to apply to IFP
- 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.

2.2 Allergen declarations

2.2.1 Current regulation

New requirements for how certain foods must be declared when present in food were introduced in the Code on 25 February 2021. These generic requirements are contained in Division 3 Mandatory declarations of Standard 1.2.3 and apply to food for sale, including IFP.

These declarations relate to foods which may be present as ingredients or ingredients of a compound ingredient, and as food additives or processing aids or as ingredients or components of these. Foods listed in Column 1 of the table to section S9—3 (or derivatives of such a food) must be declared in the statement of ingredients using the required name of the food listed in Column 3 of that table (e.g. ‘milk’; ‘soy’, ‘soya’ or ‘soybean’).

For each ingredient that is or contains the relevant food, the required name must be listed in the statement of ingredients:

- separately for each ingredient
- as a separate word or words if the required name is contained in the name of the ingredient, and
- separately from but next to the name of the ingredient.

A summary statement is required in the same field of view and directly next to the statement of ingredients, but must be distinctly separated from it. The summary statement must commence with the words ‘Contains’ and the list the required name of each food to be declared and contain no other words. The required names that apply to the summary statement are listed in Column 4 of the table to section S9—3 (e.g. ‘milk’, ‘soy’).

Division 3 also includes specific requirements for typeface, size of type and use of bold font.

Food manufacturers have until 25 February 2024 to change over to these new requirements. If a food was packaged and labelled before 25 February 2024 and it complied with the previous allergen labelling requirements, then that food can remain on sale for another two years as long as it complies with the rest of the Code.

2.2.2 International and overseas regulations

General provisions in Codex CXS 1-1985 for the declaration of foods and ingredients known to cause hypersensitivity apply to IF. The list of foods and ingredients differs slightly to the required allergen declarations in the Code, and Codex CXS 1-1985 does not specify how declarations should be made on food labels.

General requirements in EU 1169/2011 for allergen declarations apply to IF and FOF. Other than the use of a typeset to distinguish allergen declarations from other ingredients, formatting is not prescribed.

2.2.3 Previous consideration

FSANZ has not consulted stakeholders on the issue of allergen labelling for IFP.

2.2.4 Discussion

After extensive consideration through Proposal P1044, the Code was updated in February 2021 to include new requirements for the presentation of allergen information and the use of plain English allergen labelling applicable to most foods including for IFP. These requirements were put in place to provide clearer, more consistent information for food allergic individuals and their caregivers in Australia and New Zealand and is underpinned by consumer evidence.

2.2.5 Preferred option

FSANZ’s preferred option is for the generic allergen declaration requirements in Division 3 of Standard 1.2.3 to continue to apply to IFP.

2.3 Labelling as ‘genetically modified’

2.3.1 Current regulation

Generic labelling requirements for food derived from genetically modified (GM) food, including GM ingredients, food additives and processing aids, apply to IFP.

Section 1.5.4—4 of Standard 1.5.2 requires GM ingredients to be labelled as ‘genetically modified’ if novel DNA or novel protein (GM material) is present in the final food, or if the GM food which the ingredient is derived from is listed in the Code (specifically subsections S26–3(2) and (3) of Schedule 26, where the listed foods have an altered characteristic). There are some exemptions to the labelling requirement (e.g. the unintentional presence of approved GM food that is present in an amount of no more than 10 g (1%) in a kilogram of each ingredient).

For packaged food, the ‘genetically modified’ statement must be used in conjunction with the name of the GM food. If the GM food is an ingredient, the statement may be included in the statement of ingredients.

2.3.2 International and overseas regulations

Codex CXS 72-1981 applies general specifications in Codex CXS 1-1985 for the name to indicate the true nature of the food and for labelling to not be false, misleading or deceptive applies to IF. The same text has been proposed for the Codex Draft Standard for FuFOI.

European Union regulation EC 1830/2003 requires the labelling all food containing, consisting of or produced from an authorised genetically modified organism. All food and food ingredients must be labelled. Specific labelling requirements for the list of ingredients apply to:

- foods consisting of more than one ingredient: the words “genetically modified” in parentheses immediately following the ingredient concerned or “produced from genetically modified (name of the ingredient)”
- ingredients designated by the name of a category (e.g. vegetable oil): the words “contains genetically modified (name of organism) or “contains (name of ingredient) produced from genetically modified (name of organism)”.

The presence of authorised GM material in conventional food does not have to be labelled if it is below 0.9% and if it can be shown to be adventitious and technically unavoidable.

2.3.3 Previous consideration

FSANZ has not consulted stakeholders on the issue of labelling IFP as ‘genetically modified’.

2.3.4 Discussion

Labelling requirements for GM food were developed by Food Ministers when Standard 1.5.2 was under development in 2000. Noting that labelling is not required for safety reasons (all GM food must be assessed as safe before being approved for sale), Food Ministers decided to adopt a policy of labelling for informed consumer choice. This policy position remains unchanged and it applies to GM food and ingredients in all food for sale in Australia and New Zealand.

FSANZ also notes the increasing use of gene technology to manufacture novel ingredients, including specific ingredients for IFP. For example, FSANZ recently approved the addition of two oligosaccharides (2′-O-fucosyllactose and Lacto-N-neotetraose) to IFP[2].

FSANZ considers the existing requirement for the statement 'genetically modified' to apply to IFP should remain. Should an IFP contain a GM ingredient, the labelling statement will provide information to inform the purchase decisions of caregivers with infants being fed IFP.

2.3.5 Preferred option

FSANZ's preferred option is to continue to apply existing labelling requirements in subsection 1.5.2—4 for GM foods to IFP.

3 Declaration of nutrition information

3.1 Current regulation

Section 2.9.1—21 requires the label on an IFP to include a statement declaring certain nutrition information (referred to as a nutrition information statement (NIS) in this report). The specific nutrition information for 'ready to drink' and for powdered or concentrated IFP includes:

- the average energy content expressed in kJ/100 mL
- the average amount of the protein, fat and carbohydrate expressed in g/100 mL
- the average amount of each vitamin or mineral and any other permitted nutritive substance expressed in weight/100 mL (including any naturally occurring amount), and
- if added, the average amount of inulin-type fructans, galacto-oligosaccharides or a combination of these, expressed in weight/100 mL.

Paragraph 2.9.1—21(1)(b) requires, for a powdered or concentrated form of IFP, an additional declaration of the proportion of powder or concentrate required to reconstitute the formula according to directions is required. The provision also states powdered IFP labels must include a declaration of the weight of one scoop.

Subsection 2.9.1—21(3) indicates the information required in a NIS may be expressed in the form of a table. An example of how the nutrition information may be presented is provided in the guidelines in section S29–10. These guidelines recommend a tabular format in which the order of energy, nutrients and other substances is listed under the heading 'Nutrition information'. Additional base units of expression for per 100 g powder (or per 100 g liquid concentrate) are indicated as optional declarations. The guidelines are voluntary and not legally enforceable.

3.2 International and overseas regulations

Codex CXS 72-1981 applies provisions in the Guidelines on Nutrition Labelling (CXG 2-1985) to IF. Recommendations for presenting nutrition information are similar to the Code, although CXG 2-1985 also refers to other presentation features (e.g. font and contrast) and recommends nutrients are declared in a specific order and should be consistent across food products. There is no specification to include the weight of one scoop (for powdered IFP) or the proportion of powder or concentrate required to reconstitute the formula according to directions.

[2] Application A1155 2'-FL and LNnT in infant formula and other products

Codex CXS 72-1981 specifies the declaration of macronutrients, listed vitamins and minerals, and when added, any optional ingredients that should be declared. While this aligns with the regulatory approach in the Code, Codex CXS 72-1981 differs by specifying additional base units of expression for food as sold (per 100 g or per 100 mL) and for food ready for use (per 100 g). Base units of expression as energy values (per 100 kCal or per 100 kJ) are also permitted for voluntary use in addition to the other specified base units.

The proposed Codex Draft Standard for FuFOI aligns with CXS 72-1981, however unlike the Code, neither standard specifies the use of the term 'average quantity' or similar words.

In the European Union, generic (EU 1169/2011) and specific (EU 2016/127) provisions for nutrition declaration apply to for IF and FOF. Generic presentation requirements in Regulation (EU) No 1169/2011 for nutrition information and base units of expression generally align with Code requirements, except the order of nutrients is specified and nutrition information may in addition refer to per 100 g of the food as sold. Similar to Codex, there is requirement to declare the weight of one scoop, the proportion of powder or concentrate or to use of the term 'average quantity' or similar words.

EU 2016/127 regulates the content of the mandatory nutrition declaration similarly to the Code. It differs by permitting voluntary declarations for the amounts of components of protein, carbohydrate or fat, the whey protein/casein ratio, and the amount of any substances whose suitability has been established by generally accepted scientific data as described.

3.3.1 Previous consideration

In the FSANZ 2016 CP, FSANZ was interested in submitter views and sought further information on several issues relating to the declaration of nutrition information. These included whether there is a need to clarify the declaration of permitted nutritive substances and if existing nutrition declaration requirements were appropriate, specifically the format of the NIS, and the value of macronutrient sub-group nutrient declarations and certain base units of expression in the NIS. FSANZ also suggested use of 'average quantity' to align with nutrition information panel (NIP) requirements for general foods.

Requirements in paragraph 2.9.1—21(1)(b) for the declaration of powder or concentrate required for reconstitution and the weight of one scoop (powdered IFP) were noted in section 5.4.3 of FSANZ 2021 CP1.

3.3 Format of the nutrition information statement

3.3.2 Stakeholder views

There were seventeen submitters (8 industry, 6 government, 1 health professional, 1 consumer group and 1 individual) who responded, although not all submitters commented on this issue.

Government, health professional and consumer submitters supported clarifying provisions for declaring nutritive substances, whereas industry submitters made no comment on this issue.

Views were split in response to whether a consistent NIS format would be useful to caregivers or not. Submitters representing government, health professionals, a consumer group and an individual supported a consistent approach, while industry submitters were opposed.

In regard to base units of expression, there was general support for the existing requirement per 100 mL for reconstituted formula to remain. For other base units relating to food as sold

(per 100 g powder or per 100 mL liquid concentrate) and energy values (per 100 kJ and per 100 kCal), there were diverging views about their use as either mandatory or voluntary declarations.

The majority of submitters who commented on the use of the term 'average quantity' instead of 'average amount' were supportive of this change.

FSANZ received no comments about requirements to declare the proportion of powder or concentrate and the weight of one scoop from submitters to the FSANZ 2021 CP1.

3.3.3 Consumer evidence

FSANZ's assessment of available consumer evidence in Attachment 1 to this SD indicates caregivers use the NIS to identify particular nutrients and substances and their levels, as well as to make product comparisons (e.g. between standard and premium formulas). In a survey of Australian and New Zealand caregivers, more than two-thirds found the NIS to be helpful when making purchase decisions. However, around half of respondents reported the NIS was difficult to use when comparing products. Listing nutrients in the same order within the NIS made product comparisons easier, although caregiver knowledge of the nutrients was poor.

NIS formats that grouped micronutrients under subheadings 'vitamins', 'minerals' and a subheading for optional nutrients improved caregivers' understanding of the nutrition information. These NIS formats also enable faster product comparisons compared to NIS formats with no subheadings and with nutrients listed in different orders on different products. The evidence indicates that uniformed NIS labelling across IFP labels assist caregivers to make quicker comparisons between products, and that uniformed NIS labelling is preferred by caregivers who use IF.

Caregivers considered the subheadings 'additional' and 'non-essential' were understood to mean those nutrients and substances that are added voluntarily by the manufacturer. Terms such as 'others' and 'optionals' were least understood.

3.3.4 Discussion

In a survey of 18 IF (stage 1) labels available in 2021, FSANZ observed that all products used a tabular format that included 'Nutrition Information' as the title. However, within that format there were a number of inconsistencies in how nutrition information was presented. Eight product labels had nutrients listed in the same order as recommended in the guideline, however another ten labels listed nutrients in a different order or were only partly aligned. Thirteen product labels referred to nutrient names as recommended in the guideline. Another five product labels included additional names for certain nutrients (e.g. declaring 'Vitamin B_3' instead of Niacin, or declaring these names together in the NIS). One product declared 'beta-carotene' as the permitted form of Vitamin A in addition to a 'Vitamin A' declarations. FSANZ noted retinol equivalents for Vitamin A and alpha-tocopherol equivalents when expressing Vitamins A and E content as per 100 mL were used instead of micrograms as recommended.

Industry submitters to FSANZ 2016 CP opposed a consistent approach for the NIS for several reasons, in particular that there was no evidence to support a change. As discussed above, recent consumer research indicates a uniform NIS format may assist caregivers to make quicker product comparisons and aid their understanding of the nutrition information that it contains. Consistency between products may also inform caregivers that all IFP adhere to base nutritional requirements and are nutritionally complete.

As indicated in section 2.7 of FSANZ 2016 CP, the presentation of nutrition information on a NIP for general foods is more prescriptive than for a NIS on IFP labels. Subsection 1.2.8—6(2) requires that a NIP must be set out in the format in section S12—2, unless the Code provides otherwise. Section S12—2 specifies the following format requirements for the NIP:

- a tabular format, with font and contrast that align with general legibility requirements in section 1.2.1—24
- the title 'Nutrition Information'
- a prescribed order of mandatory nutrition information
- the prescribed name of the nutrients to be declared, and
- the units of measurement.

FSANZ considers a similar approach should be adopted for the NIS, noting it would be generally consistent with international and overseas regulations, and is supported by the consumer evidence. FSANZ is therefore proposing to apply the format requirements as listed above to the guideline recommended format in section S29—10(3) for IFP. In the case of permitted optional nutrients and substances, the naming of these will not be prescribed.

Based on the available evidence indicating that it can assist caregivers to make quicker product choices, FSANZ is also proposing additional formatting requirements to the NIS including the use of subheadings to group micronutrients and optional substances. FSANZ found these subheadings are already commonly being used on labels (13 of the 18 product labels observed). The subheadings would need to be distinct from other text for clarity and ease of use (e.g. through the use of lines or bolding).

A single separate heading would be required to group the optional nutrients, which include permitted nutritive substances, galacto-oligosaccharides and inulin-type fructans that, when added voluntarily, must be declared. Ten of the 18 product labels FSANZ observed included one or more headings to indicate the listed substances that had been added voluntarily. The most common heading used was 'Other' or 'Others', although some product labels included the headings 'Other nutrients', 'Additional nutrients', 'Prebiotics', 'Probiotics' or 'Nucleotides'. FSANZ notes caregivers had a higher level of understanding of the terms 'additional' or 'non-essential' and is proposing the term 'Additional' for this subheading. References to other headings such as 'probiotics' and 'prebiotics' would not be allowed by virtue of the prescribed format and wording.

Industry submitters stated that a consistent approach for the NIS would be challenging to implement, would stifle innovation and be a barrier to trade. FSANZ considers that changes to the NIS could be made as part of the suite of proposed label changes during an appropriate transition period. Although the proposed prescribed format is not consistent with international and overseas labels, FSANZ notes this is also true for prescribed NIPs on general foods. FSANZ considers providing more consistent nutrition information through a prescribed NIS format is likely to assist caregiver use and understanding and would provide regulatory certainty to industry and enforcement agencies.

Base units of expression

FSANZ notes submitters supported the continued use of per 100 mL and considers this base unit of expression should be retained. Although, FSANZ doesn't have evidence to indicate caregivers are confused by the addition of different base units, Australian and New Zealand caregivers would likely not be familiar with multiple base units because most product labels typically only use per 100 mL as reconstituted.

Noting there was little submitter interest in mandating additional base units, FSANZ has considered whether their voluntary use is warranted. Industry submitter support for per 100 g powder as sold was centred on enabling trade and health professionals found per 100 kJ and

per 100 kCal energy values to be useful. However, the majority of submitters also agreed these base units cannot be used by caregivers for comparative purposes and health professionals can obtain this nutrition information directly from companies. FSANZ also notes nutrition information for these base units can be calculated from other required nutrition information.

In a 2021 product survey, FSANZ observed only 3 of 43 products available referred to additional nutrition information per 100 g (powder), and only 2 of 43 products expressed nutrition information on a per 100 kJ basis. Industry has advised no liquid concentrate products are being marketed. If liquid concentrate IFP were commercially available, FSANZ believes caregivers would likely to find the presence of two volumetric base units to be confusing (i.e. per 100 mL as reconstituted and per 100 mL liquid concentrate as sold).

Based on this assessment and submitter comments, FSANZ's preferred option is to maintain the requirement for per 100 mL as reconstituted, and prohibit the voluntary use of other base units of expression.

Average amount

For consistency with the NIP for general foods, and formulated supplementary foods for young children which are offered in the same type of packaging as IFP, FSANZ considers the term 'average quantity' should be used on IFP. FSANZ also notes there is general support for its use from submitters and that some manufacturers are already using it on IFP labels. Further, this term as defined in the Code will provide greater certainty for industry and enforcement agencies noting the calculation methods rely upon this definition.

A government submitter noted the calculation method for average quantity in paragraph 1.1.1—6(3)(c) is not appropriate for IFP. FSANZ agrees it should not apply to IFP because of restrictions on the amounts of energy, nutrients, nutritive substances and other substances that can be present. The other calculation methods in paragraphs 1.1.1—6(3)(a) and (b) will still apply.

Proportion of powder or concentrate and weight of one scoop of powder

In line with FSANZ's preferred approach to retain the requirement for the proportion of powder or concentrate required to reconstitute formula, and, if a powdered product, the weight of one scoop (see section 4.3 of SD2), FSANZ considers the requirement to declare this information should be maintained.

FSANZ notes the requirement in paragraph 2.9.1—21(1)(b) indicates this nutrition information should appear as part of the NIS, although recommended NIS format in the Guidelines to the Standard does not include it. FSANZ notes it is common for IFP manufacturers to locate this nutrition information in close proximity to the feeding guide. FSANZ considers that requiring information about proportion of powder or concentrate and scoop weight in the NIS is unnecessary and is proposing to clarify these nutrition information requirements must not be located in the NIS.

Prescribed NIS format

By way of example, the proposed prescribed NIS format is illustrated in Figure 1. As noted above in section 3.3.4, the recommended NIS format from the Guidelines in Schedule 29 is shown with proposed modifications for average quantity, use of the single base unit of expression per 100 mL, and subheadings 'Vitamins', 'Minerals' and 'Additional'. As noted above FSANZ is considering options to separate these subheadings from other text and in

this example the subheadings have been separated using lines. However we welcome views on other approaches such as bolding, etc.

Figure 1. Example of the proposed prescribed format of the NIS

NUTRITION INFORMATION	
	Average quantity per 100 mL made up formula
Energy	kJ
Protein	g
Fat	g
Carbohydrate	g
Vitamins	
Vitamin A	µg
Vitamin B_6	µg
Vitamin B_{12}	µg
Vitamin C	mg
Vitamin D	µg
Vitamin E	µg
Vitamin K	µg
Biotin	µg
Niacin	mg
Folate	µg
Pantothenic acid	µg
Riboflavin	µg
Thiamin	µg
Minerals	
Calcium	mg
Copper	µg
Iodine	µg
Iron	mg
Magnesium	mg
Manganese	µg
Phosphorus	mg
Selenium	µg
Zinc	mg
Chloride	mg
Potassium	mg
Sodium	mg
Additional	
(insert any other substance used as a nutritive substance or inulin-type fructans and galacto-oligosaccharides to be declared)	g, mg, µg

FSANZ is interested in stakeholder views regarding the proposed prescribed format of the NIS, including options to separate subheadings from other text.

Questions to submitters:

Q1 Do you agree with FSANZ's preferred option to prescribe the format of the NIS as shown in Figure 1? Please provide the reasons for your views

Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)?

3.3.5 Preferred option

FSANZ's preferred option is:

- to prescribe the format of the nutrition information statement (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.

- only permit the base unit of expression (per 100 mL as reconstituted) in the NIS

- for average energy:
  - 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 IFP.

- 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.

3.4 Macronutrient sub-group nutrients in the nutrition information statement

3.4.3 Consumer evidence

As discussed in the literature review (Attachment 1 to this SD), from a focus group study undertaken in Australia and New Zealand in 2018, some caregivers indicated they found listing nutrients under their relevant macronutrient heading (e.g. docosahexaenoic acid (DHA) under 'omega 3' which is under 'fat') useful as it helped them to make sense of what type of nutrients they are. However other caregivers said they didn't find the additional nutrient information useful as they still did not understand the role or benefit of the specific nutrients. Some caregivers also found the label with the additional headings and nutrients (e.g. omega 3 and nutrients such as DHA) to be "messy", "too detailed" and "cluttered".

While some caregivers felt the additional nutrient information was unnecessary, others acknowledged the usefulness of the information would depend on caregiver understanding of nutrient names and also personal relevance in terms of whether their infant had any requirements related to the nutrients listed. Indeed, some caregivers with infants who had specific nutritional requirements said they would find the additional information useful, providing the label format made it more noticeable.

3.4.1 Previous consideration

In the FSANZ 2016 CP FSANZ noted it was common industry practice to declare specific macronutrient sub-group nutrients (referred to hereafter as sub-group nutrients) in the NIS that are not explicitly permitted by Standard 2.9.1. At that time, these voluntary declarations were predominantly the whey to casein ratio and alpha-lactalbumin (as subgroups of protein), and total or individual omega-3 fatty acids (as subgroups of fat).

FSANZ asked submitters if this information was of value, if it could mislead caregivers about the nutritional value of IF, and if the Standard should include an explicit permission for this information to appear in the NIS.

3.4.2 Stakeholder views

There were 20 submitters (10 industry, 6 government, 2 health professionals, 2 individuals) who commented on these matters in response to the FSANZ CP 2016.

Industry submitters supported explicit permissions for voluntary listing of sub-group nutrients to enable informed choice, provide information for health professionals, allow product differentiation and provide regulatory clarity. These submitters were interested in declaring the whey: casein ratio and fatty acids.

Health professional submitters and an individual submitter commented that sub-group nutrients should be mandatory in the NIS. Health professionals were particularly interested in fatty acids being declared.

Government submitters and another individual submitter were opposed to this information being declared in the NIS, noting there is no justification for its inclusion, may cause consumer confusion and that macronutrients are sufficient for informing choice. Other views expressed were that caregivers are unlikely to understand the information and that some may use it to make erroneous purchase decisions, it may encourage new products that are unsupported by scientific evidence, and that compositional changes should only be varied where a nutritional or health effect has been substantiated (in accordance with the Policy Guideline). However, two government submitters indicated conditional support for sub-group nutrients if the NIS was prescribed and some government submitters acknowledged both fat and protein subgroups could be useful for health professionals.

3.4.4 Discussion

FSANZ has considered the consumer evidence, submitter comments and overseas regulations and is proposing to permit the voluntary listing of the following sub-group nutrients:

- whey and casein
- docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and arachidonic acid (ARA).

The fatty acids above are those permitted by Standard 2.9.1 and in the table to section S29—8. The wording of the sub-group nutrients for whey and casein would be prescribed as well as the specific name of the long chain polyunsaturated fatty acid (see Figure 2 below).

The permission will be limited to these specific sub-group nutrients for several reasons. FSANZ notes some caregivers may find the additional information useful for making an informed choice. However, equally providing too much information by not limiting the specific subgroups could hinder caregivers' ability to effectively use the NIS to make product comparisons.

In relation to the whey: casein ratio, FSANZ notes health professionals use this information (usually obtaining it directly from manufacturers). FSANZ has observed some manufacturers refer to whey: casein information as part of the protein source statement (e.g. 'whey dominant'). However, FSANZ is proposing to clarify the protein source refers to the protein origin e.g. cow's milk (see section 7.1.3 of SD1). A permission for a voluntary listing in the NIS would enable whey: casein information to be provided and would align more closely with EU regulations. However, FSANZ considers listing the L-amino acids in section S29—6 in the NIS is unnecessary because the compositional requirements are that these amino acids must be present in IF and FOF. FSANZ is proposing whey and casein is indented under 'Protein'.

In regard to fatty acids, health professional submitters commented this information is clinically useful. FSANZ considers that the permitted long chain polyunsaturated fatty acids DHA, EPA and ARA could be included in the NIS, although the format of this declaration would be prescribed. However, FSANZ believes listing linoleic acid and alpha-linolenic acid is unnecessary given the compositional requirement for all IFP to contain these essential fatty acids. Further, total *trans* fatty acids and Erucic acid will not be permitted in the NIS.

Limiting the permission to only those approved long chain polyunsaturated fatty acids would mean Code provisions would partially align with EU regulations.

Under the proposed approach, long chain polyunsaturated fatty acids that are listed voluntarily must be indented under the required sub-group nutrient heading 'Long chain polyunsaturated fatty acids', which is itself indented under 'Fat'. This approach is similar to the required format for 'polyunsaturated' in the NIP for general foods (in section S12—3).

FSANZ received no comments relating to carbohydrate sub-group nutrients and is not proposing any permissions for voluntary listing in the NIS.

An example of the proposed NIS format including voluntary listing for protein and for long chain polyunsaturated fatty acids is provided in Figure 2.

Figure 2. Example of the prescribed format of the NIS including permitted voluntary listings for protein and long chain polyunsaturated fatty acids

NUTRITION INFORMATION	
	Average quantity per 100 mL made up formula
Energy	kJ
Protein	g
— Whey	g
— Casein	g
Fat	g
— Long chain polyunsaturated fatty acids	
— Docosahexaenoic acid	mg
— Eicosapentaenoic acid	mg
— Arachidonic acid	mg
Carbohydrate	g
Vitamins*	

* The remainder of the NIS is the same as in Figure 1.

3.4.5 Preferred option

FSANZ's preferred option is 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'.

4 Inter-relationship between declarations in the nutrition information statement and the statement of ingredients

4.1 Ingredient and nutrient names

4.1.1 Current regulation

Clause 16 of Standard 2.9.1 requires certain nutrition information to be declared but does not mandate the wording to be used. The Guidelines for IFP in Schedule S9—10 recommend the use of common names in the nutrition information statement (NIS), however this is not legally binding.

Under Standard 1.2.4 a statement of ingredients is required on IFP which identifies each ingredient using either a name by which the ingredient is commonly known, a name that describes the true nature of the ingredient, or a generic name for the ingredient that is specified in Schedule 10.

The Code does not specifically require the names used in the provision of nutrition information to be the same as the names used in the statement of the ingredients.

4.1.2 Previous consideration

In the 2016 consultation paper, FSANZ noted the variability between declarations in the NIS versus the statement of ingredients on IF. An example identified was that whey protein was declared in the statement of ingredients but alpha-lactalbumin was declared in the NIS statement, indented under protein.

While this issue is applicable to most packaged foods, FSANZ sought stakeholder views in the context of IF formula about whether there was evidence to suggest caregivers and health professionals find the differences between ingredient and nutrition information labelling confusing and if the names of ingredients should align with nutrient declarations in the NIS.

4.1.3 Stakeholder views

Sixteen submitters (11 industry, 3 government, 1 health professional and 1 individual) responded to questions about the inter-relationship between declarations in the nutrition information statement and the statement of ingredients.

No submitters provided evidence that caregivers are confused by labelling differences between these two elements. Industry and government submitters opposed the alignment of ingredient names and NIS declarations for several reasons. In particular, they commented that information provided by each labelling measure serves different purposes, it is not practically possible to align (e.g. there may be multiple sources of a vitamin in the statement of ingredients that is declared as a total in the NIS), prescribed ingredient declarations could create significant trade barriers and alignment would also reduce transparency.

The health professional submitter and individual submitter stated the current approach was potentially confusing and supported alignment for consistency and ease of understanding.

4.1.4 Consumer evidence

The available evidence indicates caregivers use the statement of ingredients and the NIS to compare products, for example ‘standard’ versus ‘premium’ products or to identify the presence or absence of specific ingredients or nutrients of interest. While caregivers report a lack of understanding of what many of the ingredients or nutrients are in both the NIS and the ingredients list, the studies did not specifically investigate whether caregivers find differences between the terms used for ingredient labelling and nutrition information labelling to be confusing (see Attachment 1 to this SD).

4.1.5 Discussion

FSANZ is not aware of any evidence to indicate caregivers or health professionals find the differences between ingredient and nutrition information terminology confusing.

Of those submitters that commented, the majority did not support alignment of the names of ingredients with nutrient declarations in the NIS due to practical and trade issues.

After considering the consumer evidence and submitter comments, FSANZ is of the view that alignment of the terminology in the statement of ingredients and NIS is impractical and the status quo is the only option moving forward.

4.1.6 Preferred option

FSANZ’s preferred option is to maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.

5 Modified infant formula products

5.1 Lactose free and low lactose formula

5.1.1 Current regulation

Paragraph 2.9.1—14(6)(a) states that if a label contains a claim that the IFP is lactose free, low lactose or words of similar import, the name of the food must include the words 'lactose free' for formula represented as lactose free and 'low lactose' for formula is represented as 'low lactose'. In addition, paragraph 2.9.1—14(6)(b) requires statements about the amount of lactose and galactose expressed in g/100 mL.

5.1.2 International and overseas regulations

There are no Codex specifications for 'lactose-free' or 'low-lactose'.

EU 2016/127 permits the use of a 'lactose free' statement (but not a 'low lactose' statement) if specific compositional criteria are met. When the statement 'lactose free' is used for IF and FOF manufactured from protein sources other than soya protein isolates, it must be accompanied by the statement 'not suitable for infants with galactosaemia'. The latter statement must have the same font size and prominence as the 'lactose free' statement and be in close proximity to it.

5.1.3 Previous consideration

In FSANZ 2021 CP3, FSANZ proposed a new regulatory framework for IFPSDU in which the lactose free and low lactose IFP would not be captured by the proposed IFPSMP category for high risk IFP.

Based on this proposed regulatory framework, FSANZ's preliminary view was to maintain the existing labelling requirements for lactose free and low lactose IFP and clarify that labelling requirements proposed for IFPSMP would not apply to lactose-free and low lactose IFP.

5.1.5 Stakeholder views

Eight submitters (3 industry, 3 health professionals, 2 government) commented on this issue. These submitters were generally opposed to FSANZ's preliminary view, with government and health professionals stating these products should be considered IFPSMPs and therefore subject to IFPSMP labelling requirements. Health professional submitters also suggested an additional, prominent statement that lactose free products are not suitable for infants with milk allergy.

Industry submitters considered the requirements for the name of the food to include the words 'lactose-free' or 'low lactose', and the condition for 'free' meaning no detectable presence, to be restrictive. Some of these submitters proposed flexibility in labelling to allow for alignment with international regulations, such as EU 2016/127.

5.1.6 Discussion

Under the proposed regulatory framework the preferred option is that lactose free and low lactose IFP are not SMPPi (see section 2.4 of the CFS). Therefore FSANZ is not proposing to change the requirement to have the name of the food include the words 'lactose free' and 'low lactose'. This will ensure the nature of the modified IFP is clearly identified to caregivers. Also FSANZ notes the name of the food is either 'Infant Formula' or 'Follow-on Formula', in accordance with section 2.9.1—17 and paragraph 1.2.2—2(1)(a) and because 'lactose free'

and ‘low lactose’ are required to be included in the name of the food they are not nutrition content claims.

The requirement to declare the amount of lactose and galactose in the NIS remains appropriate because it provides information to caregivers to determine how much of the food, if any, is suitable for infants with galactosaemia. This approach also aligns with other requirements for the mandatory declaration of nutrition information in the NIS.

FSANZ is not proposing a change to the ‘no detectable lactose’ criterion for ‘free’. The rationale for this is in section 5.5.2 of the 2021 CP3. Further, FSANZ considers a separate statement about the unsuitability of lactose-free IFP for infants with milk allergy is not warranted. As is the case for general foods, these products are required to declare milk in bold text in the statement of ingredients and in a separate bolded summary statement which provides information to caregivers about the presence of milk for infants with a milk allergy.

5.1.7 Preferred option

FSANZ’s preferred option is to maintain existing specific labelling requirements for ‘lactose free’ and ‘low lactose’ IFP.

5.2 Partially hydrolysed formula

5.2.1 Current regulation

Section 2.9.1—15 includes compositional requirements for products for specific dietary use based on a protein substitute, but there are no specific labelling requirements for these IFP.

5.2.2 Discussion

As noted in section 2.4 of the CFS and section 4.4 of SD2, the preferred option is that partially hydrolysed formula is not SMPPi. These products will be subject to the same labelling requirements as for IFP, including the prohibition on the use of claims. The definition of ‘health claim’[3] as defined relies on the definition of ‘health effect’[4] which references conditions. The intent therefore is that references to conditions such as ‘anti-reflux’ or ‘Colic’ will be not be permitted.

FSANZ notes the words ‘partially hydrolysed’ are used in the protein source statements of some IFP labels, however is proposing to clarify the source of protein refers to the origin of the protein (e.g. cow’s milk) (see section 7.13 in SD1). FSANZ recognises that it would be helpful for caregivers to be informed about the nature of the modification and to distinguish partially hydrolysed products from unmodified IFP. Therefore FSANZ’s preliminary view is to require the words ‘partially hydrolysed’ to inform caregivers of the nature of the modification. FSANZ is interested in stakeholder views on this preliminary view or alternative approaches.

Question to submitters:

[3] **Health claim** means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.

[4] **Health effect** means an effect on the human body, including an effect on one or more of the following:
(a) a biochemical process or outcome;
(b) a physiological process or outcome;
(c) a functional process or outcome;
(d) growth or development;
(e) physical performance;
(f) mental performance;
(g) a disease, disorder or condition.

Q3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other IFP?

6 Representations

6.1 Prohibited representations

6.1.1 Current regulation

Paragraphs 2.9.1—24(1)(a) to (e) state the label on a package of IFP must not contain:

(a) a picture of an infant, or
(b) a picture that idealises the use of IFP, 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) abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect, or
(d) words claiming that the formula is suitable for infants, or
(e) information relating to the nutritional content of human milk.

6.1.2 Discussion

Prohibited representations in paragraphs 2.9.1—24(1)(a) to (c) and (d) to (e) were adopted in 2002 at the time Standard 2.9.1 was gazetted for consistency with recommendations in the WHO Marketing Code. Their inclusion in the Code ensured these prohibitions were enforceable by law. The provisions implement specific policy principles k and l of the Ministerial Policy Guideline, which was published later in 2011 (see section 1.1.1).

Paragraphs 2.9.1—24(ca) and (cb) were gazetted in March 2021 through Application A1155 - 2'-FL and LNnT in infant formula and other products[5]. FSANZ considered the prohibition clearly communicates that such terminology is inconsistent with specific policy principle (l) of the Policy Guideline. FSANZ also noted the restrictions are consistent with the WHO Marketing Code and ensured products containing 2'-FL and LNnT cannot be represented as equivalent to, or better than, breast milk, and reinforce the prohibition on claims for IFP.

As these provisions support the Australian and New Zealand governments' international commitments to the WHO Marketing Code and are consistent with ministerial policy guidance, FSANZ is not proposing changes to these provisions.

6.2 Nutrition content and health claim prohibition

6.2.1 Current regulation

Section 1.2.1—23 of Standard 1.2.1 states that if the Code prohibits a label on or relating to food from including a statement, information, a design or a representation, an advertisement for that food must not include that statement, information, design or representation.
This applies to Division 3 of Standard 1.2.7 (subsection 1.2.7—4(1)) which states that a nutrition content or health claim must not be made about an IFP.

[5] https://www.foodstandards.gov.au/code/applications/Pages/A1155.aspx

Paragraph 24(1)(f) of Standard 2.9.1 prohibits a reference to the presence of a nutrient or nutritive substance except where it relates to the name of a 'low lactose' or 'lactose free' IFPSDU, or is in the ingredient list or the NIS.

Subsection 2.9.1—24(2) prohibits a reference to inulin type fructans (ITF) or galacto-oligosaccharides (GOS) except for a reference in the statement of ingredients or the NIS.

Mandatory nutrition information requirements, such as the declaration of nutrition information (section 2.9.1—21), and the statement of ingredients (paragraph 1.2.1—8(1)(e) and section 1.2.4—2)) do not constitute nutrition content claims.

6.2.2 Previous consideration

The Code provisions for the existing prohibition on nutrition content and health claims were outlined in Section 3.1 of SD3 to the FSANZ 2016 CP. FSANZ also noted consistency with the Policy Guideline on Nutrition, Health and Related Claims and the Policy Guideline on the Regulation of Infant Formula Products, the previous consideration of claims on IFP through Proposal P293 Nutrition, Health and Related claims and stated that the issue of claims on IFP was a policy matter. Therefore any changes to the prohibition on claims in Standard 2.9.1 and the explicit prohibition as included in Standard 1.2.7 through Proposal P293 were proposed to remain unchanged.

6.2.3 International and overseas regulations

Codex CXS 72-1981 states the Codex Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) applies to IF. The Guidelines specify a prohibition on the use of nutrition and health claims for foods for infants except where specifically provided for in relevant Codex Standards or national legislation. Codex CXS 72-1981 also provides that recommendations made in the WHO Marketing Code (1981) and the Global Strategy for Infant and Young Child feeding and World Health Assembly resolution WHA 54.2 (2001) should be taken into account.

EU 2016/127 came into force in February 2020 and prohibits nutrition and health claims on IF. Statements related to 'lactose only'[6], 'lactose free' and statements related to the presence of DHA are permitted, although the latter only applies to products placed on the market before February 2025.

6.2.4 Discussion

Despite outlining the Ministerial policy guidance in the 2016 Consultation paper, FSANZ received comments from industry, government, public health and consumer submitters. Industry submitters supported allowing nutrition content and health claims while government, public health and consumer submitters opposed any change to the existing prohibition on nutrition content and health claims. The issues raised repeated many of the views expressed by these submitters to the 2012 Consultation paper (and reported in the 2016 Consultation paper). For example, industry submitters noted that claims would enable caregivers to make informed choices and promote product innovation; whereas submitters representing government, public health and consumers referred to the potential for caregivers to assume equivalency of formula with breastmilk, and the risk of impacting breast feeding.

In more recent discussions, government agencies, have re-affirmed the intent of the relevant Policy Guidelines is to prohibit all nutrition content and health claims on IFP.

[6] The statement 'lactose only' may be used for infant formula and follow-on formula provided that lactose is the only carbohydrate present in the product (Article 9(1) of EU 2016/127).

As noted in the literature review, the evidence shows that when nutrient content claims were permitted on IF, caregivers often did not understand them and therefore did not find them helpful when assessing IF. Some caregivers found health claims (as opposed to nutrient claims) to be useful as they were easier to understand and outlined the purpose of the nutrient/substance. This could be useful when comparing products. However, some caregivers were sceptical about claims made on IF and considered them to be marketing tactics unsupported by evidence.

Based on the current domestic policy settings, FSANZ maintains its previous approach to not consider further the existing prohibition on nutrition content and health claims. FSANZ notes this approach is consistent with regulatory developments internationally to restrict claims on IFP.

6.3 Claims about ingredients

6.3.1 Current regulation

Beyond the generic requirement to provide a statement of ingredients that applies to IFP (see section 2.1.1 above), Standard 2.9.1 does not specifically prohibit voluntary information being provided about an ingredient outside the statement of ingredient (i.e. an ingredient claim[7]). The term 'ingredient' is not defined in the Code and so the ordinary meaning applies. References to a nutrient or nutritive substance (and to inulin-type fructans and galacto-oligosaccharides) may only be made in the statement of ingredients or in the NIS (subparagraphs 2.9.1—24(1)(f)(ii) and (iii) and subsection 2.9.1—24(2)).

As noted above, Division 3 of Standard 1.2.7 (subsection 1.2.7—4(1)) states that a nutrition content or health claim must not be made about an IFP.

6.3.2 Previous consideration

In the FSANZ 2016 CP, FSANZ noted it had observed claims about specific ingredients (for example, 'fish oil', 'unique prebiotics', 'fish oil to help support brain and eye development'), or specific health effects (for example, 'unique ingredients to help promote comfortable digestion') on IFP labels.

FSANZ suggested there may be confusion about how nutrition content and health claim definitions and provisions contained in Standard 1.2.7 apply to claims about ingredients made on IFP labels. The 2016 Consultation paper discussed how the relevant clauses in Standard 1.2.7 and Standard 1.2.8 Nutrition information requirements might be interpreted in the context of IFP (see section 2.1 of SD3 to the 2016 Consultation paper). FSANZ sought stakeholder views on whether there is a regulatory gap and if requirements should be specified in the Code for ingredient claims when used in relation to IFP.

6.3.3 Stakeholder views

Twenty-one submitters (10 from industry, 7 from government, 3 from public health and one individual) to FSANZ 2016 CP commented on this issue.

Submitter views were similar to those discussed in section 6.2 above, that is industry supported claims about ingredients, while government, health professional and individual submitters were opposed. Government, health professional and individual submitters stated that if the evidence is sufficient to mandate the addition of an ingredient there is no need for

[7] **Claim** means an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code (subsection 1.1.2—2).

a claim. These submitters considered current Code requirements reflect the Policy Guideline and clearly prohibit ingredient claims. One government submitter noted that claims made about ingredients added for a nutritional reason or a health effect are effectively nutrition content or health claims. Government submitters also suggested ingredients should only be declared in the statement of ingredients.

6.3.4 Consumer evidence

As noted at Attachment 1 to SD3, the available evidence suggests there are mixed views from consumers when presented with either nutrition content or ingredient claims. Some consumers regard them as helpful, while others report disregarding them as they do not understand the specific nutrient/ingredient being claimed, or they considered claims in general to be for marketing purposes.

Qualitative research suggests the presence of ingredient claims can influence caregivers' perceptions of IFP. The claims can give caregivers a more favourable view of IFP, thereby making IF seem a close substitute for breastmilk. The presence of claims may influence caregivers' choice of IF. Claims may also reduce the level of guilt some caregivers experience when introducing IF.

6.3.5 Discussion

As discussed above, government and health professional submitters strongly opposed claims about ingredients. Government submitters noted that specific policy principles for labelling and advertising in the Policy Guideline on Infant Formula Products capture ingredients in addition to nutrients and nutritive substances. FSANZ notes the definition of 'claim' refers in part to express or implied statements about a property of food which is not mandatory in the Code. A property of food[8] may be an ingredient.

Consumer evidence suggests that while some caregivers may find ingredient claims helpful, others may be misled and have a more favourable view of IF in response to such claims. In accordance with specific policy principle (n), we consider this potential for caregivers to be misled from ingredient claims needs to be addressed in the Code.

FSANZ therefore considers that information about ingredients should only appear in the statement of ingredients (except for ingredients (e.g. nutritive substances) that are also required to be declared in the NIS).

6.3.6 Preferred option

FSANZ's preferred option is 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).

6.4 Line marketing and proxy advertising

6.4.1 Current regulatory situation

The Code does not contain specific requirements or definitions relating to line marketing or proxy advertising.

'Advertisement' is defined in relevant Australian state and territory and New Zealand food legislation. Subsection 2(1) of Annex A of the Model Food Act defines 'advertisement' to

[8] **Property of food** means a component, ingredient, constituent or other feature of food.

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.

The (Australian) MAIF Agreement and the (New Zealand) Infant Nutrition Council (INC) Marketing Code of Practice are voluntary industry codes of practice for manufacturers, marketers and distributors of IFP that restricts the advertising and promotion of IFP. The scope of these do not cover toddler milks (formulated supplementary foods for young children). Manufacturers and marketers who are INC members are signatories to the voluntary MAIF Agreement or INC Marketing Code of Practice.

In 2015, the New Zealand Commerce Commission (NZCC) authorised the INC Marketing Code of Practice under section 58 of the New Zealand Commerce Act to apply to infant formula (0-6 months). On 8 November 2018, an extension on the marketing restrictions in the INC Marketing Code of Practice to include follow-on formula (6-12 months) was authorised[9].

On 27 July 2021, the Australian Competition and Consumer Commission (ACCC) issued a final determination granting re-authorisation to the arrangements of the MAIF Agreement until 31 August 2024. In its final determination[10], the ACCC noted its concern that the effectiveness of the MAIF Agreement is being substantially undermined by a number of factors including the ability for signatories to advertise toddler milk products, which often have almost identical packaging to IF and can have the effect of promoting IF. The ACCC also referred to the importance of an upcoming comprehensive review of the MAIF agreement by Commonwealth Department of Health and stated it understands the review will consider strengthening the regulatory requirements for the marketing of breastmilk substitutes, the scope of the MAIF Agreements (including the age range of products captured), how products are defined, and whether a voluntary agreement remains an appropriate mechanism.

6.4.2 Previous consideration

While the issues of line marketing and proxy advertising were discussed in the 2012 Consultation paper in response to some stakeholder concerns, they were considered to be out of scope in the 2016 Consultation paper due to the decision at that time to confine the proposal to IF. FSANZ noted the interlinked issues of ‘proxy advertising’ and ‘line marketing’ extended beyond IF.

The 2016 Consultation paper described ‘line marketing’ as “the labelling of infant formula as stage 1, follow-on formula as stage 2 and toddler milk as stage 3.” FSANZ described ‘proxy advertising’ to be “where the presence of legitimate 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’.” Some IFP labels include these claims to promote the benefits of toddler milks (line marketing). Proxy advertising may also be known as ‘cross promotion’.

6.4.3 International and overseas regulations

No international or overseas regulations currently include requirements for line marketing and proxy advertising. However, the WHO has made calls for the practice of cross-promotion of breast-milk substitutes to be curbed[11].

[9] https://www.health.govt.nz/our-work/who-code-nz/commerce-commission-authorisation-extend-marketing-restrictions
[10] https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/infant-nutrition-council-limited
[11] WHO/UNICEF information note: cross-promotion of infant formula and toddler milks

In considering revision of labelling provisions in the Codex Draft Standard for FuFOI, CCNFSDU acknowledged at its November 2019 meeting that the intent was to avoid consumer confusion through the clear differentiation in labelling between the different products and to prevent references about toddler milks and IF on the labelling of follow-up formula for older infants[12]. CCNFSDU has proposed draft text in Section A (Follow-up Formula for Older Infants) and Section B (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) of the draft revised Follow up Standard to reflect this intent[13].

6.4.4 Stakeholder views

Government, health professionals and individual submitters to the 2012 Consultation paper expressed concern about proxy advertising as it could encourage caregivers to transfer what they know about toddler milks to IFP, undermine the public health message that 'breast milk is best' and undermine the intent of the WHO Code. They stated research has identified proxy advertising causes confusion between products. Submitters also suggested IFP take on an implied claim when the same brand of toddler milk carries a claim, regardless of the lack of explicit claims on IFPs.

Similarly, government, health professionals, consumer groups and individual submitters expressed concern about line marketing across product categories. They considered line marketing gets around Code restrictions for IFP, undermines the WHO Code, doesn't align with Australian and New Zealand infant feeding guidelines and leads consumers to perceive there are nutritional benefits in moving from Stage 1 to Stage 2. They also strongly opposed the current practice of toddler milks carrying brand features such as logos, graphics, package type, colour, shape and product name that are almost identical to IFPs.

Government, health professionals, consumer groups and individual submitters supported the introduction of provisions that would restrict or prohibit line marketing. They also suggested consideration could be given to developing additional guidance including a statement that follow-on formulas and toddler formulas are not essential and/or including a statement in Standard 2.9.1 to prevent the use of words indicative of a sequential or progressive feeding regime which use a stage, step or numbered approach.

In response to the 2016 Consultation paper, government submitters reiterated their views that line marketing of products, particularly beyond 12 months of age as being essential for normal growth and development, is unnecessary and potentially misleading to caregivers. They noted IF is adequate for infants 0-12 months in conjunction with complementary foods at around 6 months of age. Government submitters consider IF needs to be clearly distinguished from FOF and toddler milks to reduce the safety risks associated with the wrong formula being given to an infant.

6.4.5 Consumer evidence

FSANZ's literature review (see Attachment 1 to SD3) indicates caregivers use age information (e.g. '0-6 months'), stage labelling (e.g. 'stage 1') and the product name (e.g. 'Infant formula') to differentiate between formula products. Research indicates age information is considered the most important as it gives context to caregivers as to the suitability of a product for their infant. No research was found where caregivers were tested on their understanding of stage labelling.

[12] REP20/NFSDU paragraph 25
[13] 22REP/NFSDU Appendix III Section A: Follow-up Formula for Older Infants, sections 8.6.4 and 8.6.5

Australian research by Berry and colleagues suggest that some caregivers who see advertisements for toddler milks believe they are seeing or have seen advertisements for IF. Research by Berry *et al*. (2010) found that first-time mothers understood toddler milk advertisements to be promoting a range of products that included IF and FOF, when products shared brand identities. This is more likely to occur where they glance at an advertisement and do not read it carefully. Research also suggests caregivers who can recall the claims they saw in a toddler milk advertisement may then associate these with IF. While this research was focussed on off-label advertising, it suggests there is potential for caregivers to associate information about toddler milks with IF.

As discussed in FSANZ's literature review, no research was found that examined caregiver perceptions of toddler milk advertisements on IFP packaging. For example, an IF (stage 1) product might carry advertising for a FOF (stage 2) product and a toddler milk (stage 3) product from the same brand. It is not known whether this proxy advertising could confuse or influence caregivers. For example, such advertising could cause caregivers to be confused about the product they are purchasing and/or influence them to purchase a stage 2 or stage 3 product and/or conflate the information about the toddler milk with an IF or FOF product.

6.4.6 Discussion

Line marketing (i.e. Stage 1, 2 etc.) is used by caregivers to identify appropriate products for their infants, but age information is considered the most important. From a 2021 product survey, FSANZ has observed IFP labels (stage 1 and stage 2) carrying advertising and claims about toddler milks (stage 3) as stage information. This practice is viewed by government, health professionals, consumer groups and individual submitters as potentially undermining breastfeeding and misleading consumers into believing their infants should progress through the stage, however, FSANZ found no evidence of this effect from proxy advertising in available research.

Given FOF is now in scope of P1028, FSANZ is seeking evidence and inviting stakeholder comment about stage labelling and proxy advertising specific to the labelling of IFP (0 - 12 months) noting the labelling of toddler formula is out scope.

Questions to submitters:

Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products?

Q5 What evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?

6.5 Notification of product reformulation

6.5.1 Current regulation

The Code does not explicitly permit or prohibit a labelling statement to alert caregivers to changes in product reformulation. However, references to nutrition information outside the NIS and the statement of ingredients may constitute a nutrition content claim, which is prohibited on IFP labels (subsection 1.2.7—4(b) of Standard 1.2.7 – Nutrition, health and related claims) and in advertising (section 1.2.1—23 of Standard 1.2.1 Requirements to have labels or otherwise provide information).

6.5.2 Previous consideration

Submitters to the 2012 Consultation paper suggested IFP labels should include information about any compositional changes. Submitters considered this information was important,

because some infants may experience side-effects (such as constipation, diarrhoea or discomfort) when transitioning to a IFP with a new formulation. Some IFP manufacturers have expressed an interest in being able to communicate recipe changes to caregivers and health care professionals.

In the 2016 Consultation Paper, FSANZ noted the adverse reactions identified by submitters are unrelated to the overall safety of IFP, as the composition of IFP is tightly regulated and that caregivers are often advised to alternate feeds to 'transition' their infants to the new brand or reformulated IFP.

6.5.3 Stakeholder views

Thirteen submitters (6 industry, 6 government, 1 health professional) responded to questions about the notification of a product reformulation.

Industry submitters to the 2016 Consultation paper indicated current practice for communicating reformulation changes include putting a sticker on the package lid, including information on the manufacturer's website, dietitians providing information for caregivers through company care lines and manufacturers providing information to health care professionals. An industry peak body did not support a standardised approach for providing reformulation information because flexibility with the communication method enables industry to choose the most appropriate method for the specific formulation change made, the cost of label changes, the lack of strong evidence for a mandatory requirement and that such an approach would be inconsistent with other jurisdictions and therefore be a potential trade barrier. It was also noted there can be timing issues when using stickers on an older product advising caregivers to alternate with a newer product.

Submitters suggested a number of additional approaches for communicating changes in formulations including the use of a QR code, brochures attached to products, 'new formulation' statement on the product or an over-sticker on the NIS.

While government submitters agreed caregivers should be informed of formulation changes, most suggested changes in formulation should continue to be provided to health professionals and made available via other methods as noted above. Government submitters were not in favour of including detailed information on labels that could constitute nutrition content claims.

6.5.4 Discussion

Submitters identified a range of approaches that could be used to provide information about reformulation changes to caregivers and health professionals. As reflected in submissions, FSANZ considers it is important that caregivers and health care professionals are informed about reformulation changes.

FSANZ proposes there be no standardised requirement for providing information about product reformulations in the Code, that is, the current approach is maintained for the following reasons:

- all IFP are safe and the composition is prescribed
- products could be reformulated for a variety of reasons, therefore it is best industry decide what communication method is most appropriate
- IFP have a long shelf life and so a statement on the package may be misleading after a certain period of time
- industry will have flexibility with alerting caregivers and health care professionals in a number of ways

- is consistent with the approach taken for allergens, whereby communication about reformulation of products resulting in a change in the presence of an allergen status is managed by industry.

6.5.5 Preferred option

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.

6.6 Trade marks and online advertising

The issues of trade marks and online advertising were discussed in FSANZ 2012 CP in response to some stakeholder concerns. Similar to line marketing and proxy advertising, they were considered not in scope of Proposal P1028 in FSANZ 2016 CP, however the reasons differed.

At the time, the reasons trade marks were out of scope of P1028 were because:

- trade marks are outside FSANZ's remit being regulated through the Australian Trade Marks Act 1995 and the New Zealand Trade Marks Act 2002.
- FSANZ had previously considered trade marks and their interaction with nutrition content and health claim provisions in the Code through Proposal P293 Nutrition, health and related claims[14].
- IP Australia can consider potential interactions with the Code for any new trade marks as brought to its attention.

Further, FSANZ reported in FSANZ 2016 CP that the Food Regulation Standing Committee (FRSC) had concluded its investigation into the scope of trade mark law and provisions in the Code (in response to Recommendation 21 of Labelling Logic: Review of Food Labelling Law and Policy[15]) and agreed the action was complete.

In relation to online advertising, FSANZ stated in FSANZ 2016 CP that this issue (then referred to as online marketing and in-store promotions) was considered not in scope because marketing and distribution of IFP are overseen by the voluntary industry agreements (the Australian MAIF Agreement and the New Zealand Code of Practice for the Marketing of Infant Formula in New Zealand (also referred to in section 1.1.2 of this report). FSANZ noted that neither agreement captures retailers as signatories and to do so would require consideration by the Australian Government Department of Health and the New Zealand Ministry of Health.

As noted in section 6.1.1 of this report, prohibited statements, information, designs or representations that apply to a label also apply to advertisements. For IFP, this means the prohibited representations in Standard 2.9.1 (see section 6.1 above) and the prohibition on nutrition content and health claims (as discussed in section 6.2.1 above) for IFP apply to advertisements. The application of these Code requirements to the online sale of food is an enforcement matter.

FSANZ does not intend to consider the issues of trade marks or online advertising further as part of Proposal P1028.

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[14] Proposal P293
https://www.foodstandards.gov.au/code/proposals/Pages/proposalp293nutritionhealthandrelatedclaims/index.aspx

[15] Progress report – Labelling Logic Recommendations
https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/review-food-labelling

7 Summary of preferred options

FSANZ's preferred options for the labelling elements for informed choice are provided below.

Labelling of ingredients:

- that generic labelling requirements should continue to apply to IFP
- 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.
- the generic allergen declaration requirements in Division 3 of Standard 1.2.3 to continue to apply to IFP
- to continue to apply existing labelling requirements in subsection 1.5.2—4 for GM foods to IFP.

Nutrition information:

- to prescribe the format of the nutrition information statement (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. to only permit the base unit of expression (per 100 mL as reconstituted) in the NIS.
- for average energy:
  - to require nutrition information (excepting energy) to be expressed as the 'average quantity' in the NIS
  - to clarify that the calculation method for average quantity in paragraph 1.1.1—6(3)(c) will not apply to IF and FOF.
- 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.
- 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'.

Inter-relationship between declarations in the nutrition information statement and the statement of ingredients

- maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.

Lactose free and low lactose formula:

- to maintain existing specific labelling requirements for 'lactose free' and 'low lactose' IFP.

Representations:

- 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).

- to maintain the current non-regulatory approach for the notification of changes in product formulations (i.e. manufacturers would continue to decide how best to inform caregivers and health care professionals about formulation changes as appropriate).

FSANZ is specifically seeking evidence and stakeholder comment to inform consideration of three labelling elements:

- format of the nutrition information statement
- labelling the nature of the modification of partially hydrolysed formula from other IFP.
- stage labelling and proxy advertising related only to IFP.

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