# Ministry of Health submission on Proposal – P1028 Infant Formula (1st Call for Submissions)

The key points in the Ministry of Health's (the Ministry) submission include:

a) the Ministry recommends there is consistency between the definitions and representation of infant formula products in the Code and the Ministry's policy advice on infant feeding

b) information on the label of infant formula products should be limited to necessary information about the appropriate use of the products. When considering permitting additional information on the label, the potential to mislead caregivers must be considered

c) the Ministry considers line marketing and proxy advertising should be addressed in the labelling provisions for infant formula products within the Code.

This submission provides feedback on aspects of the revised standard for infant formula products that are within the scope of the Ministry of Health's work. The submission is structured using the supporting document (SD) headings. Responses to issues covered in the Call for Submissions paper are covered under the heading 'Regulatory framework and definitions for infant formula products'.

## Regulatory framework and definitions for infant formula products (Call for Submissions)

Changes to the regulatory framework and definitions for infant formula products are discussed in the *Call for Submissions* document. The Ministry has the following feedback on the preferred options.

Food Standards Australia New Zealand's preferred option:
*Infant formula products* are proposed to include the following:

1. nutritionally complete infant formula products with a standard nutrient formulation which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for infants

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

*Ministry of Health response:*

The Ministry supports part 1.

With regards to part 2, the Ministry supports the proposed approach to include a subcategory for modified infant formula products to capture low risk products that are for the dietary management of a transient condition (refer to section 2.4.2 - CFS). However, the Ministry can only support the inclusion of partially hydrolysed formula products if there is a clear role for these products based on appropriate scientific evidence. We note that partially hydrolysed formulas are no longer recommended for the primary prevention of allergic disease in high-risk infants, nor are they recommended for the dietary management of cow's milk allergy (ASCIA 2020). The Ministry's view is that products with "partially hydrolysed protein" should only be included in part 2 if there is a scientific basis to support their use for the dietary management of a specific condition or conditions in infants.

Food Standards Australia New Zealand's preferred option:
*Special medical purpose products for infants* are proposed to be:

1. nutritionally complete with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used under medical supervision in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the infants for whom it is intended

2. nutritionally incomplete with a nutrient-adapted formulation specific for a disease, disorder or medical condition that is supplementary and is not suitable to be used as the sole source of nourishment.

*Ministry of Health response:*

The Ministry supports the proposed approach to include a new category for *Special Medical Purpose Products for infants* and the preferred option (above).

**Definitions for infant formula products**

Food Standards Australia New Zealand's preferred options for the definitions of infant formula product, infant formula and follow-on formula are:

**Infant formula product** means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.

**Infant formula** means an infant formula product that:

a. is represented as a breast milk substitute for infants; and

b. satisfies by itself the nutritional requirements of infants under the age of six months.

**Infant** means a person under the age of 12 months.

**Follow-on formula** means an infant formula product that:

a. is represented as either a breast milk substitute or replacement for infant formula; and
b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months.

*Ministry of Health response:*

Although the proposal is not specifically seeking feedback on the existing definition for **infant formula**, the Ministry considers the definition to be incomplete as it does not describe the complete role of the product.

The role of infant formula from 6 to 12 months is missing from this definition. New Zealand's infant feeding guidelines (Ministry of Health 2021) recommend for non-breastfed infants, that infant formula (suitable from birth) can be used until 12 months of age, alongside complementary foods from around six months of age. The Ministry notes that the proposed mandatory composition for infant formula is the same as for follow-on formula, apart from the maximum level for calcium. Given the almost identical nutritional profile of the two products, it is appropriate to state, both in the definition and on the product label, that infant formula is safe and suitable for continued use up to 12 months of age alongside complementary feeding.

The Ministry proposes an addition to FSANZ's preferred option for the definition of infant formula. The Ministry recommends adding part (b) of the definition for follow-on formula to the definition for infant formula, so that the definition will read:

**Infant formula** means an infant formula product that:

a. is represented as a breast milk substitute for infants; and
b. satisfies by itself the nutritional requirements of infants under the age of six months; and
c. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of six months.

**Definition for Special Medical Purpose Products for Infants (SMPPi)**

Food Standards Australia New Zealand's preferred option is a new definition for SMPPi, as follows:

A **Special Medical Purpose Product for infants** means a food that is

a. specially formulated for the dietary management of infants
   (i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
   (ii) whose dietary management cannot be completely achieved without the use of the food; and
b. intended to be used under medical supervision; and
c. represented as being
   (i) a food for special medical purposes intended for infants; or
   (ii) for the dietary management of a disease, disorder or medical condition in infants.

*Ministry of Health response:*

The Ministry supports the preferred option.

**Definition for protein substitute and other definitions**

*Ministry of Health response:*

No comment.

**Novel foods and nutritive substances**

*Ministry of Health response:*

No comment.

## Safety and food technology (SD1)

*Ministry of Health response:*

No comment on the proposed changes for food additives, processing aids, contaminants and lactic acid producing microorganisms.

**Labelling - Safety and food technology**

*Ministry of Health response:*

The Ministry supports the proposed changes to the directions for preparation and use (refer to section 8.2.5 – SD1).

The Ministry supports the proposed changes to the warning statements about following instructions exactly (refer to section 8.7.5 – SD1).

The Ministry supports FSANZ's preferred option to maintain, as it is currently worded, the statement indicating that infants from the age of six months should be offered food in addition to the infant formula product (refer to section 8.12.5 – SD1). The current wording 'from six months' is preferable to 'around six months' as 'around six months' could be interpreted to mean different things to different people. From a public health perspective, we are concerned about infant's being introduced to foods much earlier than recommended as research has shown nearly half of New Zealand babies are introduced to solids before four months of age (Ferreira et al 2022).

The Ministry supports FSANZ's preferred options for the protein source statement (refer to sections 8.13.5 and 8.14.5 – SD1). The Ministry agrees that the origin of the protein (eg, 'cow's' milk, 'goats' milk) will provide clearer information to caregivers. The Ministry supports maintaining the requirement for the co-location of the protein source statement with the name of the food and for it to appear in a prominent position once on the label.

## Nutrient Composition (SD2)

*Ministry of Health response:*

The Ministry notes that the proposed composition for follow-on formula is identical to the composition for infant formula apart from the maximum level for calcium. This point of difference is not significant as an infant aged between 6 and 12 months will obtain calcium from food sources in addition to what is provided in infant formula. This raises the important question, what differentiates these two products? The Ministry is concerned that consumers are currently being misled as to the necessity of follow-on formula and are unnecessarily switching from an infant formula product to follow-on formula. This is a representation issue and conflicts with the core objective 'Misleading and deceptive conduct statement' of the *Food Standards Australia New Zealand Act 1991*.

## Provision of information (SD3)

*Ministry of Health response – Overarching comment:*

It is apparent from the consumer research on infant formula labelling that caregivers perceive different brands of infant formula products as being significantly different from one another. Elements such as price, trademarks, premium products, pack design and

cross-promotion all strengthen this perception, even though the difference between products is minimal.

Caregivers may use the nutrition information statement (NIS) and the statement of ingredients to compare products. However, consumer evidence shows that most caregivers have limited knowledge and understanding of the contents of the NIS and ingredients list, thereby limiting its use.

A concerning finding from the consumer research is that some caregivers are not confident that all infant formula products are nutritionally complete. This is a key concern that needs to be addressed under the provision of information. The label should provide this reassurance with words to the effect "all infant formula products must comply with standards for composition, so they meet the nutritional needs of a growing infant".

Food Standards Australia New Zealand is proposing changes to the NIS and labelling of ingredients to enable caregivers of formula-fed infants to make informed choices. The Ministry is not convinced that adding more content to an already long list of technical terms will be that useful for caregivers.

By permitting the grouping of nutritive substances that have been added voluntarily by the manufacturer, consumers are likely to interpret that a product with more "added" ingredients is superior to a product with less or none. Careful consideration is needed when naming this group so that consumers are not mislead about the extent of possible health benefits that these additional substances may provide.

**Labelling of ingredients**

*Ministry of Health response:*

- Statement of ingredients

The Ministry supports FSANZ's preferred option to permit the optional grouping of added vitamins and minerals to assist caregivers understanding of these ingredients and since these subheadings are already commonly being used on labels (refer to section 2.1.6 – SD3).

- Allergen declarations

The Ministry supports FSANZ's preferred option for the generic allergen declaration requirements in Division 3 of Standard 1.2.3 to continue to apply to infant formula products as this has recently been introduced following extensive consultation (refer to section 2.2.5 – SD3).

- Labelling as 'genetically modified'

No comment.

**Declaration of Nutrition Information**

*Ministry of Health response:*

- Format of the nutrition information statement

The Ministry of Health supports FSANZ's preferred option to prescribe the format of the nutrition information statement as the consumer research suggests that this approach is preferred by caregivers who use infant formula.

The Ministry considers there is potential for caregivers to be misled by grouping optional substances in the NIS. The Ministry does not support the proposed term 'Additional' to group optional substances. If the decision is made to permit this grouping, the Ministry proposes that the subheading 'Non-essential' be used, which was also found to be understood by caregivers. 'Non-essential' more accurately describes this grouping of substances, for which the evidence is not sufficient to mandate their inclusion in the core compositional requirements for all infant formula products. The term 'Non-essential' will help convey the important message to caregivers that all infant formula products, including 'standard infant formula', are nutritionally complete and contain everything an infant requires for normal growth and development. The proposed subheading 'Additional' has a positive connotation, suggesting that the product provides 'extra' benefits, 'in addition to' other infant formula products. This interpretation is misleading as there is insufficient evidence to support a beneficial health effect to the infant.

The Ministry has no comment to make on base units of expression, average amount or proportion of powder or concentrate and weight of one scoop of powder (refer to section 3.3.5 – SD3).

- Macronutrient sub-group nutrients in the nutrition information statement

The Ministry does not support permitting the voluntary listing of sub-group nutrients - whey and casein, and permitted long chain polyunsaturated fatty acids. There is no justification for including the additional nutrient information, and it sets a precedent for the continued addition of subgroups to an already very comprehensive NIS. Further, if it is decided that optional substances can be grouped in the NIS, then long chain fatty acids will appear twice. Regarding the need to provide health professionals with this information, health professionals do not rely solely on information on the label. Health professionals receive product information from infant formula companies and can access information from company websites.

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

*Ministry of Health response:*

No comment.

**Modified infant formula products**

*Ministry of Health response:*

- Lactose free and low lactose formula

No comment.

- Partially hydrolysed formula

The Ministry agrees that modified products for specific dietary use should be subject to the same labelling requirements as for infant formula products, including the prohibition on the use of claims. The Ministry also agrees that caregivers need to be informed about the nature of the modification so that they can distinguish partially hydrolysed products from unmodified infant formula products.

Food Standards Australia New Zealand's question (Q3) for respondents:
Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other infant formula products?

*Ministry of Health response:*

The Ministry suggests taking the same approach as FSANZ has proposed for lactose free and low lactose formula, which is to have the name of the food include words that describe the nature of the modification. For example, the word "thickened" could be used in the name of an anti-reflux product and "partially hydrolysed" used in the name for a partially hydrolysed formula.

Products that come under this subcategory of infant formula products are intended to only be used following advice from a health professional. Therefore, it is appropriate that manufacturers provide communication on the indications for use of these products to health professionals rather than directly to consumers (ie, on the label).

**Representations**

*Ministry of Health response:*

- Claims about ingredients

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

option to only permit information about ingredients in the statement of ingredients (except for ingredients that are also required to be declared in the NIS).

- Line marketing and proxy advertising

The Ministry is pleased that FSANZ has raised the important issues of line marketing and proxy advertising, which are recognised by the World Health Organization and UNICEF as marketing practices that undermine the intention of the WHO Marketing Code (WHO 2019). The Ministry considers these issues should be addressed in the labelling provisions for infant formula products within the Code.

Food Standards Australia New Zealand's question (Q4) for respondents:
What evidence can you provide of caregivers' understanding of stage labelling on infant formula products?

*Ministry of Health response:*

The Ministry does not have any evidence of caregivers' understanding of stage labelling but has the following comments to make.

The Ministry has made the following observations that highlight the use of stage labelling (also known as line marketing) by manufacturers to promote their entire product range.

1. The Ministry has observed on supermarket shelves, that infant formula products are commonly displayed alongside other products within a brand's product range (ie, stage 1, 2, 3 and 4).
2. The stage number is the largest and most prominent element on the label. In comparison, the name of the product (eg, infant formula) and the age information are typically much smaller. This indicates that stage numbering is an important labelling feature and has an important function.
3. Stage labelling indicates a progression, creating the impression that there are nutritional benefits in moving from Stage 1 to Stage 2 and beyond. This practice does not align with Australian and New Zealand infant feeding guidelines that state that follow-on formula (Stage 2) and toddler milks (Stages 3 and 4) are not necessary for most infants and young children.
4. Displaying the product range together encourages caregivers to affiliate the nutrient and health claims on toddler milks with infant formula products of the same brand. This indirect advertising is often seen in advertisements for toddler milks. The advertisement shows three separate products but the labels for the Stage 1 and Stage 2 products are obscured by the toddler milk product in front.

Food Standards Australia New Zealand's question (Q5) for respondents:

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?

*Ministry of Health response:*

The Ministry does not have any evidence of caregivers' understanding of proxy advertising (also known as cross-promotion) appearing on the labels of infant formula or follow-on formula but has the following comment to make.

Follow-on formula advertising on infant formula product packaging is common. This practice meets the definition of an advertisement and therefore is a breach of the WHO Marketing Code. This should be prohibited under the Code as it is inconsistent with the *INC Code of Practice for the Marketing of Infant Formula* and the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement*.

The Ministry is concerned about different products (eg, infant formula, follow-on formula, toddler milk) having the same or similar labelling across a product line, including colour scheme, design, logos and graphics. This is a safety risk as it could result in the wrong formula being given to an infant. International regulations have addressed this issue in their regulation by requiring that a clear distinction can be made between infant formula and follow-on formula. The Ministry recommends FSANZ take a similar approach.

Codex Alimentarius
Proposed Draft Revised Standard for Follow-up Formula, includes the following labelling requirements:

> "Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, and Formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.
>
> The labelling of follow-up formula for older infants shall not refer to Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products."

European Union
Regulation (EU) 2016/127. regulates cross-promotion by having the specific requirement:

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

- Notification of product reformulation

The Ministry agrees with FSANZ's rationale for maintaining the current approach for providing information about product reformulations, which is no standard requirement. The Ministry is not aware of any issues arising from the way in which formula companies are providing this information.

## Special Medical Purpose Formula for infants (SD4)

*Ministry of Health response:*

No comment.

## Costs and benefits (SD5)

*Ministry of Health response:*

No comment.

## References

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