

## **Supporting document 3**

Provision of information – Proposal P1028

Infant Formula

# **Executive Summary**

The purpose of labelling on infant formula is to provide information to help caregivers of formula-fed infants make informed choices as well as information about the appropriate preparation and safe use of infant formula products. This Supporting Document discusses the labelling elements that provide non-safety related information (safety related information is discussed in Supporting Document 2), and other labelling-related issues that require further consideration.

Stakeholder views are being sought for issues relating to ingredient claims, nutrition declaration requirements, the inter-relationship between declarations in the nutrition information statement and the ingredient list, and the format of the nutrition information statement. In some cases, FSANZ is seeking evidence to characterise the issues in order to assess whether a change may be warranted. FSANZ is also interested in exploring how product reformulation changes can be communicated to caregivers without referring to prohibited representations, such as voluntary nutrition content claims.

The current prohibition for nutrition content claims and health claims is discussed in the context of the current Standard 2.9.1 – Infant Formula Products, the relevant Ministerial policy guidelines and Standard 1.2.7 – Nutrition, Health and Related Claims, the latter which took full effect in January 2016. FSANZ is not proposing to change the prohibition requirement and has outlined the rationale for this position in this document.

Although most labelling requirements set out in Standard 2.9.1 are applicable to infant formula, follow-on formula and infant formula products for special dietary use, Proposal P1028 is only considering the infant formula (0–<12 months) category. As a result, several issues raised in the 2012 Consultation paper are not in scope of this project. These include the issue of line marketing, proxy advertising and online marketing.

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## 1 Introduction

The purpose of labelling on infant formula is to provide information to help caregivers of formula-fed infants make informed choices, as well as information about the appropriate preparation and safe use of infant formula products.

The intent of Standard 2.9.1 is to regulate the compositional and labelling requirements for infant formula products. These specific requirements reflect the special purpose nature of these foods and the vulnerable population group who consume them. In addition, certain general labelling provisions in Chapter 1 – General Food Standards in the *Australia New Zealand Food Standards Code* (the Code), in particular Part 1.2 – Labelling and other Information Requirements, also apply to infant formula products.

Most of these labelling requirements have remained unchanged since the gazettal of Standard 2.9.1 in 2002, which resulted from the assessment of Proposal P93 – Infant Formula (ANZFA 2002).

This Supporting Document considers those labelling requirements for infant formula that are not safety-related, but relate to the provision of information in Standard 2.9.1. Labelling elements relating to safety (for example for required warnings, directions and statements) are considered in Supporting Document 2.

## 1.1 Scope of consideration

For P1028, labelling elements relevant to the infant formula category (0 –<12 months) will be considered. While some issues and requirements considered may also be relevant for follow-on formula (6 – <12 months) and infant formula products for special dietary use, these two categories are **not** in the scope of P1028.

General labelling requirements set out in Chapter 1 – General Food Standards in the Code (in the revised Code, Chapter 1 – Introduction and standards that apply to all foods) apply to infant formula unless there are specific requirements in Standard 2.9.1 that prevail. General labelling requirements will not be reviewed under P1028; the focus of the review will be on the specific labelling requirements set out in Standard 2.9.1. FSANZ has only referred to general labelling requirements where they are relevant for the discussion.

#### 1.1.1 The revised Code

FSANZ has developed and approved a revised version of the Code which takes effect and replaces the current version of the Code on 1 March 2016.

For Standard 2.9.1, some information, including the *Guidelines for Infant Formula Products* (Guidelines) attached to the Standard now appear in a separate Schedule in the revised Code, Schedule 29 – Special purpose foods.

The relevant sections in the revised Code are signposted in this Consultation paper.

#### 1.1.2 Issues not in scope

FSANZ referred to the following labelling issues in the 2012 Consultation paper, and received a number of submitter comments on these issues:

- trade marks
- line marketing

- proxy advertising and
- online marketing.

These matters are considered out of scope of consideration Proposal under P1028. See Attachment A3.1 for further details on the reasons why these issues are not in scope.

## 1.2 Background

#### 1.2.1 Ministerial policy guidelines

The following specific policy principles relate to the labelling and advertising of infant formula products:

- (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.
- (I) 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 claims, including 'infant foods'. In having regard to this policy guidance, a prohibition on nutrition and health claims (unless expressly permitted) was incorporated in Standard 1.2.7, as part of Proposal P293 – Nutrition, Health and Related Claims (FSANZ 2013). This Standard came into full effect in January 2016.

#### 1.2.2 The current environment

Since Standard 2.9.1 was gazetted in 2002, the regulatory environment for labelling and representation of infant formula products has changed. The controls on marketing practices 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, by the Australian and New Zealand governments have remained. However, change has occurred with the development of the Ministerial Policy Guideline on Nutrition, Health and Related Claims (ANZFRMC, 2003) and on infant formula products (ANZFRMC 2011) and the gazettal of Standard 1.2.7 – Nutrition, Health and Related Claims in 2013. In addition, both the Australian and New Zealand infant feeding guidance have been revised and relevant international and overseas regulations updated during this time.

#### 1.2.3 Controls on marketing practices

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 infant formula products into voluntary codes of practice.

In Australia, the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (MAIF Agreement) (Department of Health and Aging 2003) is a voluntary code of practice for manufacturers, marketers and distributors of infant formula products. This agreement is implemented and overseen by a MAIF Complaints Tribunal that was established in 2014 by the Infant Nutrition Council in collaboration with the Australian Government Department of Health and key stakeholders. The new tribunal is independent of industry and is managed by the St James Ethics Centre. The Infant Nutrition Council (INC) is currently seeking re-authorisation of the MAIF Agreement through the Australian Competition and Consumer Commission (ACCC)<sup>1</sup>.

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

- 1. INC Code of Practice for the Marketing of Infant Formula in New Zealand (INC 2012)
- 2. Code of Practice for Health Workers (Ministry of Health 2007)
- 3. Code for Advertising of Food (Advertising Standards Authority (2014)

In early 2015, INC was authorised by the New Zealand Commerce Commission to enforce its voluntary Code of Practice. The Ministry of Health oversees the monitoring of compliance with the voluntary Code of Practice for Health Workers through a compliance panel and independent adjudicator.

#### 1.2.4 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 considers any Codex standards that are relevant.

In the case of P1028, any labelling specified in the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (referred to as Codex STAN 72-1981) has been compared against current requirements in Standard 2.9.1.

On 18 December 2014, the New Zealand Government issued a notice under the *Animal Products Act 1999* (Ministry for Primary Industries 2014) to regulate the labelling of all infant formula products and formulated supplementary foods for young children intended for export. The provisions take full effect on 18 June 2016 and clarify the information that must be on labels of infant formula intended for export, and the information or representations that are restricted or prohibited on these products. For example, infant formula labels must contain a list of ingredients and lot identification, but must not contain pictures that idealise the use of infant formula or a health claim, unless the latter is expressly permitted by the importing country or market in its laws or executive directives. The Animal Products Notice does not apply to infant formula intended for sale in New Zealand or Australia.

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<sup>&</sup>lt;sup>1</sup> http://registers.accc.gov.au/content/index.phtml/itemId/1188093/fromItemId/278039

## 1.3 Approach

FSANZ has reviewed the existing Code requirements for labelling of infant formula and has identified issues that require further consideration. Issues with existing requirements have also been identified from other information sources including from stakeholders through previous consultations, other FSANZ projects, including the 2012 Consultation paper – Regulation of Infant Formula Products, and regulatory and policy activities at an international and national level. FSANZ has also been made aware of some enforcement issues relating to clarity.

This document considers issues relating to declarations about nutrients and nutritive substances, ingredient claims, nutrition content claims and health claims and the nutrition information statement. FSANZ has taken a preliminary view on the identified labelling issues that they either: require further consideration, including where FSANZ is seeking evidence to characterise the issue, or are proposed to remain unchanged. For the latter, FSANZ does not intend to consider these further in Proposal P1028 unless stakeholders identify specific issues and provide sufficient evidence to support a change.

FSANZ collected a range of infant formula product labels available in the marketplace in September 2013. These labels were used to obtain a snapshot of the labelling information present at that time and for FSANZ to understand how the different labelling elements were being used.

## 2 Issues under consideration

## 2.1 Claims about ingredients

The specific requirements set out in clause 20 of Standard 2.9.1 (section 2.9.1—24 in the revised Code) limit references to the presence of any nutrient or nutritive substance to the statement of ingredients or the nutrition information statement. References to lactose (in accordance with clause 30 (subsection 2.9.1—14(6) in the revised Code), and representations that the food is suitable for a particular condition, disease or disorder (in accordance with Division 3 (subsection 2.9.1—14(2) in the revised Code) are permitted.

The term 'nutrient' is not defined in the Code, but 'nutritive substance' is defined in clause 2 of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Provisions (section 1.1.2—12 in the revised Code).

Subclause 6(1) of Standard 2.9.1 (subsection 2.9.1—5(1) in the revised Code) prohibits the addition of nutritive substances to infant formula unless expressly permitted, or if it is naturally present in an ingredient of the infant formula. Only those nutritive substances listed in the Table to clause 7 (section S29—5 in the revised Code) are permitted to be added.

The Standard does not, however, specifically exclude the voluntary declaration of an ingredient elsewhere on the label. The term 'ingredient' is defined in Standard 1.2.4 – Labelling of Ingredients for the purposes of that Standard, but is not defined in the revised Code (Standard renamed as 'Information requirements – statement of ingredients').

Generic requirements for claims are set out in Standard 1.2.7. Clause 3 of Standard 1.2.7 (subsection 1.2.7—4(1) in the revised Code) explicitly prohibit the making of nutrition content claims and health claims about infant formula products.

#### 2.1.1 Discussion

FSANZ has looked at a range of current labels of packaged infant formula and has found that some product labels appear to contain nutrition content claims about specific ingredients (for example, 'fish oil' or 'unique prebiotics') or health claims (for example, 'fish oil to help support brain and eye development' and 'with Bifidus BL, a beneficial (probiotic) bacteria for healthy infants from birth').

Other products carry claims that do not refer to specific ingredients, but appear to describe the health effect expected from consuming the product (for example, 'unique ingredients to help promote comfortable digestion').

FSANZ notes that, despite the explicit prohibition in clause 3 of Standard 1.2.7 (subsection 1.2.7—4(1) in the revised Code) for infant formula to carry nutrition content claims and health claims, there may be confusion about whether the claim definitions and provisions contained in that Standard would also apply to claims about ingredients made on packaged infant formula.

Clause 2 of Standard 1.2.7 (section 1.2.7—2 in the revised Code) defines 'health claim' to mean a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect. The term 'property of food' is defined in the same clause to mean a component, ingredient, constituent or other feature of food. It could be argued that 'fish oil' is a property of food and that therefore the claim 'fish oil to help support brain and eye development' is a health claim.

Additionally, the term 'nutrition content claim' means in part a claim about the presence or absence of... a biologically active substance. Clause 1 of Standard 1.2.8 – Nutrition Information Requirements (section 1.2.8—4 in the revised Code) defines 'biologically active substance to mean a substance, other than a nutrient, with which health effects are associated. A voluntary declaration made on packaged infant formula that the food contains 'probiotics' could be viewed as a nutrition content claim.

FSANZ is seeking stakeholder views on whether there is a need for greater clarity in the Code about ingredient claims on packaged infant formula, and if requirements should be specified in the Code for such claims when used in relation to infant formula.

#### **Question to submitters:**

- Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?
- If no, then why not?
- If yes, then how should they be regulated?

## 2.2 Declaration of permitted nutritive substances

Subclause 7(2) of Standard 2.9.1 states that:

the label on a package of infant formula product must not include any words indicating, or any other indication, that the product contains a nutritive substance specified in column 1 or in column 2 of the Table to this clause unless the total amount of the added and any naturally occurring nutritive substance in the food is no less than the amount specified in column 3 of the Table.

The equivalent drafting in subsection 2.9.1–5(2) of the revised Code is similar i.e. the intent is unchanged. Permitted nutritive substances are listed in section S29–5 in the revised Code.

In relation to subclause 7(2), one government stakeholder has suggested that it could be interpreted as permission to refer to nutritive substances outside the statement of ingredients and nutrition information statement. Such references would constitute nutrition content claims, which are prohibited on packaged infant formula. It has been suggested that the link between subclause 7(2) and paragraph 20(1)(f) (paragraph 2.9.1–24(1)(f) in the revised Code) (the latter which restricts references to nutritive substances in the statement of ingredients or the nutrition information statement) should be made clearer. The intent of subclause 7(2) is to prohibit the declaration of nutritive substances unless certain conditions are met. It is not intended as permission for nutritive substances to be declared elsewhere on the label. Subclause 7(2) operates in conjunction with paragraph 20(1)(f), with the latter provision limiting where a permitted nutritive substance can be declared.

FSANZ recognises there is potential for ambiguity in the current Standard. FSANZ seeks stakeholders' views on whether or not there is a need to clarify the intent of the current Standard.

## 2.3 Nutrition declaration requirements

Nutrition declaration requirements for packaged infant formula reside in clause 16 of Standard 2.9.1 (section 2.9.1—21 in the revised Code). These include which nutrients must appear in the nutrition information statement and how this nutrition information must be expressed for either ready-to-drink formula or powdered/concentrated infant formula.

Examples of problems arising from the interaction between the requirements in Standard 2.9.1 and the prohibition on nutrition content claims in Standard 1.2.7 have been brought to FSANZ's attention.

In addition to the mandatory nutrition information prescribed for the macronutrients protein, fat and carbohydrate, many infant formula companies are declaring macronutrient subgroups (for example, 'omega-3' indented under fat; 'whey' and/or 'casein' indented under protein) and specific nutrients (for example, lactose indented under carbohydrate; 'alpha-lactalbumin' indented under protein) in the nutrition information statement.

Where this information is added voluntarily, it constitutes a claim. The term 'claim' is defined in clause 2 of Standard 1.1.1 (subsection 1.1.2—2(3) in the revised Code) to mean an express or implied statement, representation, design or information in relation to a food or property of food which is not mandatory in this Code.

#### 2.3.1 Stakeholder views

FSANZ did not seek comments from stakeholders on this issue through the 2012 Consultation paper. However, one industry submitter requested that clause 16 of Standard 2.9.1 of the existing Code (section 2.9.1—21 in the revised Code) be amended to allow macronutrients to be declared in the nutrition information statement in units of weight other than 'grams per 100 mL' (e.g. in milligrams or micrograms per 100 mL). The rationale provided for this request is to allow more appropriate units to be used for the expression of subgroups of total protein, fat and carbohydrate (e.g. alpha-lactalbumin, alpha linolenic and lactose) in the nutrition information statement.

Government stakeholders have expressed the view that the voluntary declarations of nutrition information in the nutrition information statement (for those nutrients that are not already mandated or permitted e.g. inulin-type fructans) are nutrition content claims.

#### 2.3.2 Current industry practice

FSANZ has looked at the labels of packaged infant formula currently available in Australia and New Zealand. Many of these products were found to voluntarily declare the content of specific macronutrient subgroups, in addition to the total for each macronutrient, in the nutrition information statement. The predominant macronutrient subgroups were for protein (for example the whey to casein ratio and alpha-lactalbumin) and fat (total or individual omega-3 fatty acids). It was much less common for carbohydrate subgroups to be listed in the nutrition information statement. For some products, the macronutrient subgroups declared in the nutrition information statement also appeared on the front of the label, and details of the purported health benefits of these nutrients were provided in company website information.

#### 2.3.3 Codex

The Codex STAN 72-1981 specifies that nutrition information for protein, fat and carbohydrate should be declared on labels, but does not mention the macronutrient subgroups.

#### 2.3.4 Summary

FSANZ notes that clause 16 of Standard 2.9.1 (section 2.9.1—21 in the revised Code) does not state that the label may only contain the information listed, or that the label is prohibited from referring to subgroup macronutrients. Therefore it will be important to clarify the requirements. The Code would need to make clear that such a declaration is not a nutrition content claim.

The purpose of declaring nutrition information is to provide caregivers with adequate information to be able to make informed choices. The nutrition information statement and statement of ingredients are the primary elements on infant formula labels that provide nutrition information to caregivers.

The issue of whether macronutrient subgroups should be permitted to be declared in the nutrition information statement for packaged infant formula therefore raises a number of issues. FSANZ is seeking stakeholder views and evidence in relation to the requirements for mandatory nutrition information declarations.

FSANZ notes that the issue of regulatory clarity regarding the units for declaration of macronutrient subgroups will need to be considered subsequent to consideration of macronutrient subgroups permissions in the nutrition information statement.

#### **Questions to submitters**

- Q3.2 Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?
- Q3.3 Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?
- Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alphalactalbumin etc.), or specific proteins (only whey and casein).

- Q3.5 If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).
- Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?
- Q3.7 What would be the cost and trade implications of mandating macronutrient subgroups or concersely expressly prohibiting them?

# 2.4 Inter-relationship between declarations in the nutrition information statement and the ingredient list

Standard 2.9.1 does not require the name of ingredients declared in the ingredients list to be the same as the mandatory declarations in the nutrition information statement.

As part of its consideration of what must and can be declared in the nutrition information statement versus the ingredient list, FSANZ has become aware of the variability between these declarations on packaged infant formula in the market place.

The primary issue is that generic requirements apply for declaring ingredients, whilst the Code is somewhat more restrictive about what must appear in the nutrition information statement. Clause 4 of Standard 1.2.4 – Labelling of Ingredients (section 1.2.4—4 in the revised Code) states that ingredients must be declared using their common, descriptive or generic name, whereas clause 16 of Standard 2.9.1 requires certain nutrition information to be declared but does not mandate the wording (the Guidelines display a nutrition information statement, however this example is not legally binding). An example of the difference between the ingredient list and the nutrition information statement is where whey protein is declared in the former and alpha-lactalbumin is declared in the latter, indented under protein (notwithstanding the issue of whether macronutrient subgroups are permitted to be declared in the nutrition information statement).

The purpose of these two labelling elements differs: the statement of ingredients lists all of the ingredients used to make the infant formula as sold; the nutrition information statement describes the nutritional profile of the infant formula.

FSANZ is unaware of evidence to suggest caregivers and health professionals find the differences between ingredient and nutrition information labelling confusing. While this issue applies to most packaged foods, as part of this Consultation paper FSANZ is interested in stakeholder views about these labelling differences in the context of packaged infant formula.

#### **Questions to submitters**

- Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?
- Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

## 2.5 Base units of expression

Clause 16 of Standard 2.9.1 (subsection 2.9.1—21(1) in the revised Code) requires nutrition information to be expressed per 100 mL for ready-to-drink products, as well as for powdered and concentrated products (where they have been reconstituted according to the directions).

However, the Guidelines that are attached to Standard 2.9.1 include a recommended format for the declaration of nutrition information. This recommended format suggests that, in addition to the per 100 mL requirement, nutrition information for per 100 g for powdered formula and per 100 mL for liquid concentrate can be expressed i.e. as sold. The Guidelines now reside in section S29—10 in the revised Code.

This inconsistency was noted in the 2012 Consultation paper.

#### 2.5.1 Stakeholder views

Some submitters to the 2012 Consultation paper, predominantly those from industry, commented that nutrition information per 100 mL as consumed is most appropriate and more useful for caregivers than per 100 g as sold. Some also noted that to require information per 100 g would be inconsistent with key international and overseas standards. Two industry submitters commented that an additional column for per 100 g information would further restrict available space on the label and risk legibility issues if other text needed to be reduced in size.

Only one government submitter supported consideration of the provision of per 100 g information, citing the importance of this information for paediatric dietitians to allow them to calculate a more concentrated formula for infants who fail to thrive.

#### 2.5.2 Codex

Codex STAN 72-1981 specifies the base units of expression as g per 100 g or 100 mL as sold as well as per 100 mL of the food ready for use. Declaration of nutrients per 100 kcal or per 100 kJ is also permitted in addition to the base units specified.

#### 2.5.3 Nutrient comparisons between products

As all infant formula are consumed in liquid form, a volumetric declaration for nutrition information as consumed is more appropriate than a weight-based declaration for the product as sold. The current volumetric declaration of the average amount of each nutrient per 100 mL as consumed allows nutrition information to be accurately compared between products. This same comparison cannot be made with weight-based (i.e. per 100 g) information as sold, as every product has a different density. For example, the amount of powder required to make 100 mL of formula typically ranges from 10–20 g between different products. Therefore, per 100 g information is unlikely to provide additional benefit to caregivers to inform their choice of packaged infant formula. Also, per 100g information on labels may lead to confusion if caregivers do not understand that it cannot be used for comparative purposes, unlike for most other foods that are consumed in the form they are sold.

#### 2.5.4 Benefit of per 100 g information for health professionals

One government submitter commented that energy/nutrient information expressed per 100 g assists paediatric dietitians and other health professionals that need to adjust formula concentrations for the management of certain medical conditions in infants (e.g. failure to thrive). This issue was also raised as part of Proposal P93 when the current requirements for

units of expression were set. FSANZ notes that this issue is outside the scope of Proposal P1028 because it pertains to the special dietary use category of infant formula products.

Nutrient content per 100 g product as sold can be calculated from other information on the product label. As well as the nutrient declaration per 100 mL, Standard 2.9.1 also requires the declaration of the weight of product per scoop (if a powdered product) and the percentage solution on a weight/volume basis for the product. From this information, health professionals can calculate nutrients per 100 g product as sold from the information provided on an 'as consumed' basis. Product information per 100 g can also be sourced elsewhere, including direct from companies.

#### 2.5.5 Current industry practice and potential cost implications of a change

FSANZ has found that the base units used to express nutrition information vary on labels of powdered infant formula currently in the marketplace. Some products were found to display the average quantity per 100 mL as mandated. Other products included the average quantity per 100 g and/or per 100 kJ, but did not display nutrition information as mandated. Still others included all three options in the nutrition information statement. All examples related to powdered product.

While not permitted by clause 16 (subsection 2.9.1—21(1) in the revised Code), some products have been found to declare nutrients on a per 100 kJ in the nutrition information statement. This reflects the way the compositional requirements in Division 2 of Standard 2.9.1 are presented.

As only some product labels currently provide per 100 g information, there would be a potential cost for industry to make label changes if per 100 g information was mandated in addition to the existing per 100 mL requirement.

It is unclear what potential trade implications might result if nutrition information per 100 g (or per 100 mL for liquid concentrate) were mandated, in addition to per 100 mL as consumed, for packaged infant formula. A 'per 100 g' declaration would align with the Codex STAN 72-1981.

#### **2.5.6 Summary**

Mandating nutrition information on a per 100 g basis for the powder (or per 100 mL for liquid concentrate) as sold (as suggested in the Guidelines) could potentially lead to consumer confusion. In particular, for those consumers who might use the information to compare products, as they might for general purpose foods, but who are unaware that the nutrient density and powder/concentrate to water ratio differ between products could be confused.

FSANZ notes that information per 100 g as sold cannot be used for comparative purposes and that therefore it offers no additional benefit to caregivers to inform product choice. If this information is required for clinical purposes, health professionals are currently able to calculate nutrients per 100 g as sold from other information that is required to be present on the label, or source this information direct from the company.

FSANZ, however, is seeking further information from stakeholders about the merits of additional base units of expression that differ from the current requirement, and whether the declaration of these units should be mandatory or voluntary.

#### **Questions to submitters:**

- Q3.10 Which base units of expression do stakeholders find to be of greatest value?
- Q3.11 Is there any evidence that caregivers are confused by the use of different base units of expression?
- Q3.12 In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?
- Q3.13 What would the cost and trade implications be of mandating these base units?
- Q3.14 Should the voluntary use of the base unit of per 100 kJ be permitted?

## 2.6 Average amount

Clause 16 (subsection 2.9.1–21(1) in the revised Code) requires the average amount of macronutrients and micronutrients (and when added, inulin-type fructans and galacto-oligosaccharides) to be declared in a nutrition information statement for infant formula that are ready-to-drink or reconstituted according to directions. The term 'average amount' is not defined in the Code.

The term was adopted at the time Standard 2.9.1 was developed. At that time, the declaration of average amounts of nutrients was preferred over the use of minimum levels, because the nutrient levels could vary due to degradation over the shelf life of the food or when there are variations in the manufacture of products.

The term 'average amount' on the labels of packaged infant formula differs from the term 'average quantity', which is defined in the Code in clause 2 of Standard 1.1.1 (subsection 1.1.2–2(3) in the revised Code) and is a labelling requirement for general purpose foods and other special purpose foods that require a nutrition information panel (NIP) (for example, food for infants).

Under the revised Code, the term 'average quantity' is now defined in subsection 1.1.2–2(3), with a new section 1.1.1—6 describing how average quantity is to be calculated. The latter section expands on the calculation methods that were included in the definition in the existing Code.

Current Code	Revised Code
Standard 1.1.1:	Section 1.1.2–2(3)
Average quantity in relation to a substance in a food is the quantity determined from one or more of the following –	Average quantity, of a substance in a food, means the average, for such foods from that producer or manufacturer, of:
<ul> <li>(a) the manufacturer's analysis of the food; or</li> <li>(b) calculation from the actual or average quantity of nutrients in the ingredients used; or</li> <li>(c) calculation from generally accepted data;</li> </ul>	<ul> <li>(a) where a serving or reference amount is specified—the amount of the substance that such a serving or reference amount contains; or</li> <li>(b) otherwise—the proportion of that substance in the food, expressed as a percentage.</li> </ul>

Current Code	Revised Code
which best represents the quantity of the substance that the food contains, allowing for seasonal variability and other known factors that could cause actual values to vary.	Note See also section 1.1.1–6  Section 1.1.1–6 How average quantity is to be calculated
vai y.	(1) This section applies where this Code requires an <i>average quantity</i> of a substance to be declared in the labelling of a food for sale, whether as a percentage or as the amount of the substance in a serving or other amount of the food.
	Note The term average quantity is defined in section 1.1.2—2.  Example The Code requires the 'average quantity' of a variety of substances to be listed in the nutrition information about a food for sale, for example protein, carbohydrate and sugars.
	(2) The average quantity is to be calculated by the manufacturer or producer using whichever of the methods in subsection (3) the manufacturer or producer considers to best represent the average quantity, taking into account any factors that would cause the actual amount of the substance in the food to vary from lot to lot, including seasonal variability.
	(3) The methods are:  (a) the amount that the manufacturer or producer of the food determines, based on an analysis, to be the average amount of the substance in a serving or other amount of the food; or  (b) the calculation of the actual amount of
	the substance, or the calculation of the average amount of the substance, in the ingredients used for the food; or  (c) the calculation from generally accepted data relevant to that food.

#### **Discussion**

FSANZ notes that the intent underpinning the terms 'average amount' and 'average quantity' is the same and that this is an inconsistency in the Code. If the term 'average quantity' was adopted, nutrition information (excepting energy) would need to be expressed on infant formula labels as the average quantity per 100 g (or 100 mL). These amounts would also need to be declared similarly to other special purpose foods and general purpose foods e.g. 'quantity per 100 g of powder', 'quantity for 100 mL made up formula'.

The Codex STAN 72-1981 specifies that the actual amount of macronutrients and micronutrients should be expressed.

FSANZ is interested in stakeholder views about the impacts of changing the declaration from 'average amount' to 'average quantity' in clause 16 (subsection 2.9.1—21(1) in the revised Code) of Standard 2.9.1.

#### **Question to submitters**

Q3.15 What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?

#### 2.7 Format of the nutrition information statement

Clause 16 of Standard 2.9.1 (section 2.9.1—21 in the revised Code) requires the label on an infant formula product to include a statement declaring certain nutrition information expressed per 100 mL for the product as consumed. The clause also states that the statement may be in the form of a table. The Guidelines attached to the Standard (section S29–10 in the revised Code) also recommend that this information, including the order of nutrients, to be presented in a tabular format. These Guidelines are not part of the legally binding Standard, and are therefore voluntary and not enforceable.

The format for providing nutrition information on infant formula product labels differs to that required for most packaged foods. Mandatory provisions for most packaged foods are set out in Standard 1.2.8. Subclause 5(1) of Standard 1.2.8 (subsection 1.2.8—6(1) in the revised Code) prescribes the mandatory nutrients and the format in which they must be declared in the NIP. The NIP format is tabular, requires declared nutrients to be listed in a prescribed order (energy, macronutrients, sodium, other), and quantities of nutrients must be declared per serving and per 100 g (or 100 mL). Subclause 1A of Standard 1.2.8 (section 1.2.8—3 in the revised Code) specifically states these requirements do not apply to infant formula.

In addition to the commentary above in relation to which nutrients should be declared (refer to Section 2.3 of this Supporting Document), and the base units used to express them (refer to Section 2.5), the issue of whether to mandate, remove or retain the format of the nutrition information statement in a guideline attached to the Standard is considered below.

#### 2.7.1 Stakeholder views

The 2012 Consultation paper asked stakeholders whether it would be appropriate to include the nutrition information format requirements in the Guidelines attached to Standard 2.9.1 in the legally binding Standard. Submitters expressed mixed views on this issue. Some government, health professional and consumer groups supported a change to mandate the format requirements, arguing that infant formula should be consistent with the broader food supply in this respect. One of these submitters also commented that a standardised format would allow consumers to make easier comparisons between products. Two government submitters commented that the Standard needs to be clear about nutrition information requirements, and if there is a need for a standardised and prescribed approach then this should form part of the Standard.

Conversely, of the industry submitters that commented on this issue, none supported mandating the format for the nutrition information statement. While many did not give an explanation for their position, some commented that the current Guidelines provide an appropriate level of guidance and that there is no evidence to support a change at this time.

#### 2.7.2 Codex

The Codex STAN 72-1981 states that the declaration of nutrition information shall contain the following information which should be in the following order: energy, macronutrients, vitamins, minerals, choline and then the optional nutrients. It does not mandate the layout of this information (e.g. tabular form),

#### 2.7.3 Current industry practice

All of the infant formula product labels that FSANZ looked at presented the required nutrition information in a tabular format, similar to that outlined in the Guideline (section S29–10 in the revised Code). While all products provided nutrition information for the average amount per 100 mL of made up formula, some also provided the average amount per 100 g of powder (or per 100 mL of liquid concentrate) as recommended in the Guidelines. The order of nutrients used is generally the same as the Guidelines for energy and macronutrients; however, the order for vitamins, minerals and other substances differed between some products.

### 2.7.4 Information for caregivers

It is important that caregivers of formula-fed infants have ready access to nutrition information to inform their choice of infant formula. The Code already requires certain nutrition information to be declared on labels, and caregivers who wish to know the nutrient content of a product or to compare products can use this information.

One advantage of a mandated format for caregivers is that it may allow easier comparison of nutrition information between products. Also, caregivers would likely be familiar with a tabular format for nutrition information as this is the format used for most general purpose foods.

FSANZ reviewed the available literature and found little available information on caregivers' use of nutrition information on infant formula packaging. Relatively little research examined whether caregivers use the nutrition information displayed on infant formula packaging, and no studies were found from Australia or New Zealand. More general research on NIPs suggests that consumers tend to find nutrition information easier to read when it is displayed in table format rather than in a paragraph (Ares et al. 2012).

Only two studies in the literature search were found in which the proportion of caregivers who read the nutrition information on infant formula was mentioned (Fein and Falci 1999; Define Research & Insight 2006). The two studies on this topic had differing findings.

Qualitative research conducted in the United Kingdom (Define Research & Insight 2006), found that few participants had read nutrition information on infant formula packaging. In contrast, in the United States Infant Feeding Practices Study (Fein and Falci 1999), 60 per cent of mothers of 2 month old formula-fed infants reported that they had read the nutrition panel on infant formula.

There are a number of possible reasons why the findings of the two studies diverged. They were conducted in different countries, and used different methodologies. The qualitative research conducted in the United Kingdom did not specifically prompt participants to talk about the nutrition information on infant formula packaging (Define Research & Insight 2006), whereas participants in the United States study were questioned specifically on their use of nutrition information (Fein and Falci 1999). This suggests that even for caregivers who have read nutrition information on infant formula packaging, it may not be a key part of the label compared to other parts, such as preparation instructions (Winstanley and Cressey 2008; Yockney and Comfort 2013).

No research was found which examined whether consumers understand the nutrition information presented on infant formula packaging.

However one study was found which compared consumers' ability to read nutrition information in a table and when presented in paragraph format on two products: pan bread and yoghurt (Ares et al. 2012). This study, conducted in Uruguay, found that respondents were more likely to correctly classify pan bread products as regular or low in sodium when

the nutrition information was presented in a table instead of paragraph format. Respondents' response times were also faster when the information was presented in a table, when interpreting both the pan bread and yoghurt labels. A brief search revealed no other studies which examined consumers' ability to read nutrition information in a table compared to in other formats (such as in a paragraph).

Insufficient research is available on caregivers' use of nutrition information on infant formula packaging to determine whether this is frequently referred to or useful for caregivers.

#### 2.7.5 Impact on trade and supply

If the Code was amended to mandate the format for the nutrition information statement, the potential for technical barriers to trade would need to be considered. These could be avoided if the requirements were consistent with these overseas regulations. In addition, the potential impact is reduced given that labels for general infant formula tend to be Australia and New Zealand specific and not shared with other countries.

Prescribing the format would, however, likely incur some costs for industry. Particularly given that there is considerable variation of formats for Australian and New Zealand infant formula currently on the market. The current approach affords industry some flexibility in how nutrition information is presented.

In contrast, those submitters that supported prescribing the format gave the following reasons; namely to:

- align with the prescribed format for general purposes foods
- assist caregivers in making product comparisons
- provide clarity regarding nutrition information requirements.

FSANZ is seeking further information to be able to make a full assessment of this issue, noting that the discussions pertaining to nutrient declarations (Section 2.3) and base units of expression (Section 2.5) already include questions about a level of prescription in the nutrition information statement.

#### **Questions to submitters**

- Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?
- Q3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?
- Q3.18 If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

## 2.8 Notification of product reformulation

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 nutrition information statement and the statement of ingredients may constitute a nutrition content claim, which is prohibited on infant formula labels.

#### 2.8.1 Stakeholder views

A number of submitters to the 2012 Consultation paper, representing industry, consumer groups, health professionals and individuals, suggested that infant formula product labels should include information about compositional changes. They sought explicit label information that lists the change in ingredients and an explanation for the change, to be included in a prominent location on the front of the label.

Submitters considered that this information was important, because some infants may experience side-effects (such as constipation, diarrhoea or discomfort) when transitioning to an infant formula with a new formulation. One consumer group submitter believed additional information about the potential side-effects should also be included on the label.

FSANZ notes that some infant formula manufacturers have expressed an interest in being able to communicate recipe changes to caregivers and health care professionals. In particular, these submitters suggested that nutrition and health claims on infant formula labels would assist consumers in making an informed and safe choice in regard to specific nutrients and differences between infant formulas.

#### 2.8.2 Summary

It is commonly reported that infants can experience adverse reactions as a result of switching infant formula brands or changing to a formula that has been reformulated. These adverse reactions are, however, unrelated to the overall safety of the products. Adverse reactions, such as constipation, diarrhoea, vomiting and discomfort are more likely to occur in infants aged from birth to six months, where the formula is a sole source of nutrition. Caregivers are often advised to alternate feeds to 'transition' their infants to the new brand or reformulated infant formula.

Some stakeholders may believe that infant formula manufacturers are withholding information regarding compositional changes, thus preventing caregivers from being able to make informed choices about the products they purchase. In fact, Standard 2.9.1 prevents manufacturers from providing this nutrition information on the label, unless it is information which is either mandated or permitted and is declared in the nutrition information statement or the ingredient list. An infant formula manufacturer may be in breach of Code requirements if compositional changes were listed on the front of the label.

FSANZ is interested in whether there are alternative approaches to alert caregivers that an infant formula has been reformulated. These alternative approaches may be in the form a labelling statement that does not constitute a prohibited representation, or may involve communicating the information using methods other than on the product label.

#### **Questions to submitters**

- Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?
- Q3.20 What information about the change in composition would caregivers and health professionals find useful?
- Q3.21 What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?

## 3 Requirements proposed to remain unchanged

## 3.1 Nutrition content claim and health claim prohibition

The Code is clear that the voluntary declaration of nutrition information on a food product constitutes a claim, and therefore any claim provisions relevant to the food product must be met. For example, for a general purpose food, a voluntary declaration about omega-3 fatty acids in the NIP would need to meet the conditions for omega-3 fatty acids set out in Schedule 1 of Standard 1.2.7 (section S4—3 in the revised Code).

In the case of infant formula, clause 3 of Standard 1.2.7 (subsection 1.2.7—4(1) in the revised Code) states that a nutrition content claim or health claim must not be made about an infant formula product.

Standard 2.9.1 also sets out this prohibition in paragraph 20(1)(f) (paragraph 2.9.1—24(1)(f) in the revised Code), which 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' infant formula intended for special dietary use, or is in the ingredient list or the nutrition information statement. Subclause 20(2) (subsection 2.9.1—24(2) in the revised Code) prohibits a reference to inulin-type fructans or galacto-oligosaccharides unless these substances are referred to in the ingredient list or the nutrition information statement.

Additionally, clause 1A of Standard 1.2.8 – Nutrition Information Requirements (section 1.2.8—3 in the revised Code) clearly states that Standard 1.2.8 does not apply to infant formula (with the exception of definitions in clauses 1 and 2 of Standard 1.2.8, given effect through subclause 1(1) of Standard 2.9.1 (subsection 1.1.2—3(3) in the revised Code). This includes the general nutrition declaration requirements relating to nutrition information panels, because Standard 2.9.1 prescribes specific nutrition information requirements for infant formula.

Mandatory nutrition information requirements, such as the declaration of nutrition information (clause 16 of Standard 2.9.1; section 2.9.1—21 in the revised Code); the declaration of protein source (clause 18 of Standard 2.9.1; paragraph 2.9.1—23(1)(a) in the revised Code); and the statement of ingredients (clause 2 of Standard 1.2.4; paragraph 1.2.1–8(1)(e) and section 1.2.4—2 in the revised Code) do not, however, constitute nutrition content claims. The purpose of requiring this information on the label of infant formula is to provide caregivers with nutrition information to inform choice.

Clause 13 of Standard 1.1.1 – Preliminary Provisions – Application Interpretation and General Prohibitions (section 1.2.1—23 in the revised Code) states that *advertisements* for food must not contain any statement, information, designs or representations which are prohibited by the Code from being included in a label for that food.

#### 3.1.1 Previous consideration

The issue of voluntary nutrition content claims was extensively considered and consulted on as part of P293 – Nutrition, Health and Related Claims. The decision was made in that proposal to retain the prohibition for infant formula to carry nutrition content claims and health claims and to explicitly express this prohibition in Standard 1.2.7. As a result, only those claims expressly permitted by Standard 2.9.1 may be used in relation to an infant formula product (for example, claims relating to 'lactose free' and 'low lactose' formulas intended for special dietary use).

This approach is consistent with the Policy Guideline on Nutrition, Health and Related Claims and the Policy Guideline on the Regulation of Infant Formula Products.

#### 3.1.2 Stakeholder views

FSANZ acknowledges that stakeholder views on whether infant formula should be allowed to carry nutrition content claims vary considerably. In general, industry submitters to the 2012 Consultation paper expressed interest in making nutrition content claims on the labels of infant formula. Their rationale is to allow manufacturers to provide information to enable caregivers to make informed choices. Some industry submitters also noted that the inability to state the nutritional content of infant formula would discourage innovation and subsequently restrict the potential for improved health outcomes for those infants that rely on infant formula. One individual submitter considered that information about potentially beneficial ingredients should be made clear to consumers.

In contrast, some submitters representing government, health professionals, consumer groups and individual submitters supported the current prohibition for nutrition content claims and health claims on infant formula labels. One submitter believed there is a significant risk that infant formula would be seen as equivalent to breast milk if it carried claims. They noted there was the potential that this could lead to a reduction in breastfeeding rates in Australia and New Zealand. Other submitters believed that the presence of a claim on one product would imply that it was superior to another product that did not carry the claim and may or may not contain the claimed ingredient. There was also concern that claims about certain nutrients or ingredients could be made in the absence of research to support their clinical efficacy.

One individual submitter expressed concern that 'medical' claims (e.g. for medical conditions such as reflux or constipation) may have a two-fold effect; it may reduce a mother's confidence in breast milk, and it may lead caregivers to give formula to infants for potentially serious medical conditions rather than seek medical advice.

#### 3.1.3 Summary

Noting the diverging views of stakeholders, and given the recent consideration of voluntary nutrition content claims through P293 and the specific policy principles in the *Policy Guideline on the Regulation of Infant Formula Products* (which prohibits claims on infant formula labels), FSANZ believes the issue of whether to permit claims on infant formula labels should be considered within the policy arena. The Australia and New Zealand Ministerial Forum on Food Regulation develops policy guidelines and statements and notifies them to FSANZ. In developing or reviewing food regulatory measures and variations of food regulatory measures, FSANZ must have regard to these policy guidelines and statements.

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## Attachment A3.1 – Issues not in scope

Issue	Details	FSANZ Response
Trade marks	In the 2012 Consultation Paper, FSANZ asked stakeholders for evidence on whether consumers perceive trade marks on food labels in a similar way to health claims  The majority of submitters representing government, industry and some consumer groups responded that there was no evidence. Some government and consumer group submitters supported further consideration by FSANZ of this issue.  One government submitter referenced a study which found trade marks on toddler milks can be perceived in a similar way to health claims. Another government submitter referred to anecdotal evidence from dietitians. One consumer group submitter noted that their own survey of parents' perceptions found no link between caregiver perceptions of trademarks and health claims.	The issue of trade marks that convey nutrition content claims and health claims was considered in Proposal P293 – Nutrition, Health and Related Claims (FSANZ 2013).  More recently, the Food Regulation Standing Committee (FRSC) (at the request of the Australia New Zealand Ministerial Forum on Food Regulation) has investigated the scope of trade mark law and provisions of the Food Standards Code in response to Recommendation 21 of the independent review of food labelling law and policy <sup>2</sup> . Recommendation 21 stated that applications for trade names and trademarks be scrutinised by the relevant agencies to identify and reject words and devices that have the effect of inferring health implications that are otherwise prohibited under the Code.  FRSC has subsequently reported that 'consultation with IP Australia in November 2013 confirms that there is no statutory basis for it to scrutinise applications as proposed, except in particularly obvious cases of deceptive or misleading trade mark elements There are opportunities for review, and revocation of registration under particular circumstances, however practical limitations such as the volume of trade mark applications received (including misspelt words or words that are not real) prevent proactive scrutiny (e.g. via electronic searches). The Forum has agreed that action on Recommendation 21 is now complete <sup>3</sup> .  FSANZ also notes that some products carry non-registered marks (including words and symbols) on their labels. Non-registered marks could be captured as express or implied nutrition and health claims, which are prohibited on infant formula products.  Given that there are already prohibitions for the display of nutrition content claims and health claims on infant formula products, FSANZ does not consider that additional regulatory measures are needed to address this issue. Instead, the use of non-compliant, non-registered marks is more appropriately dealt with as an enforcement matter.

<sup>&</sup>lt;sup>2</sup> Legislative and Governance Forum on Food Regulation (2011). Response to the Recommendations of Labelling Logic: Review of Food Labelling Law and Policy, <a href="http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/home">http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/home</a> accessed 31 October 2014

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Issue	Details	FSANZ Response
Line marketing and proxy advertising	FSANZ referred to the specific issues of 'line marketing' and proxy advertising in the 2012 Consultation Paper.  'Line marketing' was described as the labelling of infant formula as stage 1, follow-on formula as stage 2 and toddler milk as stage 3.  Proxy advertising is where the presence of legitimate claims on toddler milks may influence caregivers' feeding decisions, for example choosing toddler milks over infant formula because the former were 'better'.  No specific questions about these issues were asked in the 2012 Consultation Paper; however 20 submitters representing health professionals, industry, consumer groups, government and individuals provided a range of comments.	The issues of 'line marketing' and proxy advertising will not be considered further within Proposal P1028, because they involve two or more product categories. Proposal P1028 is considering labelling requirements for the infant formula category only (0 –<12 months), but not follow-on formula (for infants aged 6 – <12 months) or infant formula products for special dietary use.

Issue	Details	FSANZ Response
Online marketing and instore promotions	Online marketing is where infant formula products are advertised on retailer websites and as part of instore promotions.  FSANZ acknowledged this issue in the 2012 Consultation paper (see FSANZ response). One public health submitter noted that online advertising is a concern, but acknowledged that the issue was an enforcement matter.	FSANZ noted in the 2012 Consultation paper that requirements for the marketing and distribution of breast milk substitutes for industry are overseen by two voluntary agreements;  1. the Australian Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (the MAIF Agreement), and  2. the New Zealand Infant Nutrition Council Code of Practice for the Marketing of Infant Formula (CoPMIF).  Neither agreement captures retailers as signatories. To change this agreement would be a matter for the Australian Government Department of Health and the New Zealand Ministry of Health to consider.  FSANZ also noted in the 2012 Consultation paper that retailers undertaking such activities are still required to comply with Code requirements relating to advertising. In particular, clause 13 of Standard 1.1.1 (section 1.2.1–23 of the revised Code) is applicable, whereby the prohibition for statements, information, designs or representations on labels applies to any advertisements for food. In the context of infant formula products, only those statements and information required by Standard 2.9.1 are permitted to be included in advertisements. FSANZ considers the current Code requirements for advertising are adequate.  Finally, similar to line marketing and proxy advertising, the issue of online marketing is out of scope because it overlaps with other product categories e.g. follow-on formula, which are not the subject of this Proposal.