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## Consultation Paper

# Regulation of Infant Formula Products in the *Australia New Zealand Food Standards Code*

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Food Standards Australia New Zealand (FSANZ) is investigating issues relating to current regulations for infant formula products in the *Australia New Zealand Food Standards Code* (the Code). This consultation paper has been prepared to inform stakeholders about this work; outline the regulatory issues identified and call for stakeholder views on the scope and issues to be addressed. Responses from stakeholders will help FSANZ prepare a proposal to review and revise the regulations for infant formula products in the Code. Work on this proposal will begin in 2013.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

Under the Information Publication Scheme, all submissions will be published on our website. We will not publish any material provided in-confidence. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and 'Consultation Paper – Regulation of Infant Formula Products'. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 7 November 2012**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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### Supporting documents

The following documents which informed the development of this Paper are available on the FSANZ website:

SD1 Composition comparisons to Codex standards

<http://www.foodstandards.gov.au/foodstandards/reviewingstandard2915640.cfm>

Standard 2.9.1 <http://www.foodstandards.gov.au/foodstandards/foodstandardscode.cfm>

Ministerial Council Policy Guideline

<http://www.foodstandards.gov.au/foodstandards/legislativeandgovernanceforumonfoodregulation/policyguidelines.cfm>

## Executive summary

While breastfeeding is the recommended way to feed a baby; a safe and nutritious substitute for breast milk is needed for babies that are not breastfed.

Infant formula products are currently regulated under Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code*. These products include: infant formula (for infants aged 0–12 months); follow-on formula (for infants aged from 6–12 months); and infant formula products for special dietary use.

FSANZ is preparing to review the regulations for infant formula products.

Other standards also contain provisions for infant formula products, such as standards 1.3.1 – Food Additives; 1.4.1 – Contaminants and Natural Toxicants; 1.6.1 – Microbiological Limits for Food, and various labelling standards.

FSANZ has committed to reviewing infant formula product regulations and will prepare a proposal to undertake this work in 2013. To help us with this work, we have prepared this consultation paper, in order to obtain the views of a broad range of stakeholders.

Issues covered in this paper include:

FSANZ is seeking comments on issues with the current regulations for infant formula products.

- the operation and structure of Standard 2.9.1 – product definitions, the role of guidelines
- composition – essential vitamins, minerals and electrolytes, nutritive substances, optional substances, permitted forms, and food additives
- safety – microbiological limits, renal solute load and contaminants
- labelling and advertising – directions for use, warning statements, nutrition information, claims and representations, and advertising
- formula for special dietary use – composition and labelling.

Questions are included at the end of each section and also in Attachment A. Stakeholders are also able to raise any additional concerns about current regulations along with any evidence to support changing those regulations.

Toddler milks (designed for children 1-3 years) will not be reviewed as part of this work.

FSANZ will not be reviewing products marketed as toddler milks (designed for children aged one to three years). These products are regulated as ‘formulated supplementary foods for young children’ under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods. Permissions for new optional ingredients will also not be considered in this work.

### Next steps

Information gathered from submissions to this paper will help inform the preparation of a formal proposal to review and potentially revise the regulations for infant formula products. There will be further opportunity to comment and provide feedback when a proposal is developed in 2013.

This paper does not include an exhaustive list of issues – submitters are welcome to raise other issues relevant to the Standard in submissions.

# 1. Introduction

Infant formula products are regulated under Standard 2.9.1 – Infant Formula Products. Standard 2.9.1 defines ‘infant formula product’ as *a product 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*. An infant is a person under the age of 12 months.

Infant formula products include:

- infant formula – for infants aged 0–12 months;
- follow-on formula – for infants aged from 6–12 months; and
- infant formula products for special dietary use (IFPSDU) – e.g. formulas for premature infants or those with metabolic or immunological conditions, which are specifically formulated for the intended use.

Standard 2.9.1 was gazetted in 2002. Other standards in the Code also contain provisions for infant formula products, such as those relating to food additives, contaminants, labelling and microbiological limits.

## Why are we undertaking this work?

FSANZ committed to reviewing infant formula regulations after receiving policy guidance from the Australia New Zealand Food Regulation Ministerial Council<sup>1</sup> in May 2011.

The international benchmark for infant formula regulations was also updated after Codex Alimentarius revised the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* in 2007. In addition, in recent years a number of issues have been raised by stakeholders about the lack of clarity for aspects of Standard 2.9.1.

A review of the current regulations will enable consideration of consistency with the policy guidance and the updated international regulations. The overarching goal will be to address regulatory problems with current regulations and provide clarity where there is uncertainty about the intent of the relevant standards.

## The consultation paper

This consultation paper will help FSANZ identify and clarify issues with the regulations for infant formula products. Information received through this process will inform a proposal to review and revise relevant standards in the Code.

Some of the issues in this paper have been drawn to FSANZ's attention through stakeholder enquiries or through targeted consultation with key government, industry, public health, and consumer stakeholders in April/May 2012.

Others were identified through FSANZ work, such as the legislative audit of the Code; relevant overseas and international regulations; and other related external projects, such as the present review of the *Australian Infant Feeding Guidelines for Health Workers*.

While we have identified a range of issues; stakeholders are welcome to raise additional issues, providing supporting rationale for any issues that have not been discussed in the paper.

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<sup>1</sup>now the COAG Legislative and Governance Forum on Food Regulation

## Related projects

A number of activities and projects may impact on a review of the regulations for infant formula products. These include:

- FSANZ's work on the Proposed Future Regulation of Nutritive Substances and Novel Foods in the Code
- FSANZ's work on the draft Standard 1.2.7 – Nutrition, Health and Related Claims
- the National Health and Medical Research Council's (NHMRC) current review of the *Australian Infant Feeding Guidelines for Health Workers*
- Codex Alimentarius's potential revision of the *Codex Standard for Follow-up Formula*.

## Next steps and proposed way forward

Information gathered from submissions on this paper will be used to inform the preparation of a proposal to review and revise the regulations for infant formula products in the Code. This proposal is expected to be a comprehensive review of the regulations to address the range of issues identified. FSANZ will consult widely with stakeholders during the consideration of the proposal.

# 2. Background

## 2.1 Current regulatory environment

### 2.1.1 Australia New Zealand Food Standards Code

Standard 2.9.1 specifically regulates the compositional and labelling requirements for infant formula products. The Standard applies to all infant formula products whether in powder, liquid concentrate or 'ready-to-drink' forms. Standard 2.9.1 is the most prescriptive of all standards in the Code that regulate a food category. The intent of the current Standard 2.9.1 includes the following key aspects:

- mandatory composition for infant formula and follow-on formula
- restrictions on the additional of substances (vitamins, minerals, food additives and other substances) unless expressly permitted
- labelling and advertising conditions; specifically prohibits some types of representations on product labels.

Standard 2.9.1 was finalised in 2002 after 10 years of development (ANZFA, 2002). Since then, a series of consequential amendments have been made, however substantive changes to the mandatory composition requirements have not been made. A few additional optional substances have been permitted in recent years, such as lutein, inulin-derived substances and galacto-oligosaccharides, through applications to FSANZ. Currently, FSANZ is considering two applications that relate to infant formula products, namely Application A1055 – Short chain fructo-oligosaccharides in infant formula products, foods for infants and formulated supplementary foods for young children, and Application A1074 – Minimum L-histidine in Infant Formula Products.

Other standards in the Code also contain specific provisions for infant formula products:

- Standard 1.3.1 – Food Additives which regulates the use of food additives in the production and processing of food

- Standard 1.4.1 – Contaminants and Natural Toxicants sets out the maximum levels (MLs) of specified metal and non-metal contaminants and natural toxicants in nominated foods and
- Standard 1.6.1 – Microbiological Limits for Food which lists the maximum permissible levels of foodborne microorganisms that pose a risk to human health in nominated foods, or classes of foods

In addition, some standards explicitly state that they do not apply to infant formula products, such as Standard 2.9.5 – Food for Special Medical Purposes and draft Standard 1.2.7 – Nutrition, Health and Related Claims.

### **2.1.2 Regulatory approach to developing or varying food standards**

Section 18 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) sets out the three primary objectives FSANZ is required to meet in developing or varying a food standard. These are:

- a. the protection of public health and safety;
- b. the provision of adequate information relating to food to enable consumers to make informed choices; and
- c. the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- a. the need for standards to be based on risk analysis using the best available scientific evidence;
- b. the promotion of consistency between domestic and international food standards;
- c. the desirability of an efficient and internationally competitive food industry;
- d. the promotion of fair trading in food; and
- e. any written policy guidelines formulated by the Australia New Zealand Food Regulation Ministerial Council.

These objectives and principles are all relevant to a review of the regulations for infant formula products. The three primary objectives are paramount given that formula-fed infants are vulnerable because these products provide the sole source of nutrition during the first months of life. It is also important that parents/carers have accurate and adequate information about products to make an informed choice.

FSANZ must also have regard to ministerial policy guidance in developing and varying standards in the Code. The relevant Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline) was notified to FSANZ in May 2011. The Policy Guideline contains Specific Policy Principles that address product composition, labelling and advertising, and products for special dietary use. It foresees a more rigorous standard of assessment of product composition but in other respects upholds FSANZ's current approaches to labelling and regulation of special infant formulas. The Policy Guideline also refers to the regulation of infant formula products "being consistent to the greatest extent possible" with relevant World Health Organization (WHO) and World Trade Organization (WTO) agreements, and Codex standards. The Policy Guideline is prospective and FSANZ will have regard to the policy principles during work on any future applications and proposals on the regulation of infant formula products.

As part of a proposal, FSANZ is required to prepare a regulation impact statement, which will include a cost benefit analysis. The overall net benefit to society will need to be considered in any decision to vary the current regulations for infant formula products.

### 2.1.3 WHO Code and relevant national agreements

An international influence in the infant formula environment is the *International Code of Marketing of Breast-milk Substitutes* (WHO 1981), commonly known as the WHO Code. The WHO Code was adopted in 1981 and recommends various requirements and restrictions for the marketing and distribution of breast milk substitutes for industry and health care workers. This includes restrictions on infant formula products being advertised or otherwise promoted to the public, and that health care providers should not be given free or subsidised supplies of these products and must not these promote products.

Various national authorities have implemented the WHO Code within their respective jurisdictions. Both the Australian and New Zealand governments have each taken a number of different steps in support of their international commitments to the WHO Code, by incorporating the relevant articles into food standards and voluntary Codes of Practice. Standard 2.9.1 of the Code gives effect to some elements of the WHO Code through composition, labelling and advertising requirements. Both governments have also implemented the WHO Code requirements that relate to manufacturers, marketers and distributors of infant formula products through voluntary agreements. In Australia, this is through the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (the MAIF Agreement), which is overseen by the Australian Government Department of Health and Ageing (DoHA). In New Zealand, it is implemented through the *Infant Nutrition Council Code of Practice for the Marketing of Infant Formula* (CoPMIF), and is overseen by the Ministry of Health.

While the Australian and New Zealand agreements share the common principles of the WHO Code, a key difference is that the New Zealand agreement applies only to products suitable for infants up to the age of six months, whereas the Australian agreement covers products for use up to twelve months of age. The DoHA is currently conducting a review of the Australian MAIF Agreement. Given the potential overlap between the principles outlined in the MAIF Agreement and requirements in the Code, FSANZ anticipates working closely with DoHA to ensure the alignment of the Code and the MAIF Agreement.

### 2.1.4 International and overseas regulations

International and overseas regulations from Europe, the United States of America and Asian countries as well as the standards of the Codex Alimentarius are particularly relevant for the trade of products to and from Australia and New Zealand. To assist trade, it is preferable for product regulations to be consistent as much as possible between countries and consistent with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization. Support for this principle is provided in both the FSANZ Act and the Policy Guideline.

The relevant Codex<sup>2</sup> standards and European regulations for infant formula products are:

- CODEX STAN 72-1981 – Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants (Codex infant formula standard); revised 2007 and amended 2011.
- CODEX STAN 156-1987 – Codex Standard for Follow-up Formula (Codex follow-up formula standard); amended 1989, 2011.

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<sup>2</sup> The following Codex standards: CODEX STAN 72-1981, CODEX STAN 156-1987, CAC/GL 10-1979 can be found at <http://www.codexalimentarius.org/committees-task-forces/?provide=committeeDetail&idList=11> accessed 20 August 2012.

- CAC/GL 10-1979 – Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (Codex advisory list of nutrients); revised in 2008.
- CAC/RCP 66-2008 – Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (Codex code of hygienic practice for infant formula), published in 2008.
- European Commission Directive 2006/141/EC – Infant Formula and Follow-on Formulae and amending Directive 1999/21/EC; published in 2006.
- Annex VI of the European Union Council Directive 95/2/EC Food Additives other than Colours and Sweeteners (updated in 2006).

Inconsistencies between the Code and international and overseas regulations primarily relate to definitions, compositional requirements and labelling of products.

## **2.2 Current market**

### **2.2.1 Traded products**

Infant formula products are traded globally, with products on the Australian and New Zealand markets either made locally or imported. Similarly, a number of products manufactured in Australia and New Zealand are for export only, particularly to Asian markets.

Companies that manufacture, import and/or market infant formula products in Australia and New Zealand include Bayer, Bellamy's Organic, Carrickmore Nutrition, Dairy Goat Co-operative (NZ) Ltd, Fonterra, Heinz Watties, Infant Formula Australia, Nestlé, Nutricia, Pfizer Nutrition, Snow Brand and Tatura.

On the domestic market, most brands have both a 'standard' and 'premium' range of infant formula products. The typical point of difference is that 'premium' products contain added optional ingredients, such as lutein and omega-3 fatty acids, which in turn commands a higher price for the product.

FSANZ understands from industry stakeholders that most IFPSDU are imported into Australia and New Zealand, predominantly from the European Union (EU), as there is only a small domestic market for these products.

Market data on the volume and value of infant formula products manufactured in and imported into Australia and New Zealand will be used by FSANZ to inform its cost benefit analysis of potential changes to the regulations.

The market analysis undertaken to prepare the [Regulatory Impact Statement: Policy Guideline for the Regulation of Infant Formula Products](#) (2011) provides an insight into the domestic and export market for infant formula products in Australia and New Zealand. It valued the domestic consumption of infant formula products in 2009 in Australia and New Zealand as approximately A\$133 million and NZ\$40 million respectively. The value of imports into New Zealand in 2008 was approximately NZ\$4.3 million (value for duty) and of exports approximately NZ\$192 million. Similar data were not available for Australia, but it was reported that the majority of infant formula products are imported to Australia from the EU or from New Zealand.

### **2.2.2 Export only products manufactured in Australia and New Zealand**

Some infant formula products manufactured in Australia and New Zealand are produced exclusively for overseas markets. In both countries, these export-only products are required by legislation to comply with the Code, as well as the regulations of the importing country.

Inconsistencies between the regulations can create trade barriers and limit innovation.

In New Zealand, infant formula products that are manufactured for export can be issued with an exemption from the compositional requirements of the Code by the Ministry for Primary Industries under the *Animal Products Act 1999*. These exemptions are product and country specific, and are commonly known as 60B exemptions. In addition, there is a blanket exemption for labelling of infant formula products for export from the requirements in the Code. Instead, these products must meet the labelling requirements for the importing country.

However, a similar process for provision of exemptions does not exist in Australia. As infant formula products are considered high risk from a food safety perspective, the Department of Agriculture, Fisheries and Forestry does not give an exemption under the Export Control (Milk and Milk Product) Orders 2005. Thus, infant formula products produced in Australia for export must comply with the Code and any additional importing country requirements.

#### Questions to submitters

1. What is the total volume of each of infant formula, follow-on formula and IFPSDU manufactured in Australia New Zealand for domestic consumption and export? What proportion of the total volume is for export only?
2. What is the total volume of each of infant formula, follow-on formula and IFPSDU imported into Australia New Zealand? Where are these products imported from?
3. What is the value for each component listed in Q1 and Q2?

### 3. Issues relating to the structure of Standard 2.9.1

Standard 2.9.1 provides provisions and requirements for the composition and labelling of infant formula products. The Standard is organised into three divisions:

1. General provisions; including definitions, calculations, general compositional requirements and general labelling and packaging requirements.
2. Specific compositional provisions for infant formula and follow-on formula; where the composition of follow-on formula typically adopts that for infant formula with some adjustments for different energy and protein requirements of older infants.
3. Compositional and labelling provisions for infant formula products for special dietary uses (IFPSDU).

The Standard also includes an attached set of guidelines: *Guidelines for Infant Formula Products* (the Guidelines), though these are not part of the legally binding standard.

#### 3.1 Definitions for product categories

Division 1 of Standard 2.9.1 provides definitions for infant formula products, including infant formula, follow-on formula, lactose free formula and pre-term formula.

The Code definitions for infant formula and follow-on formula relate to the role of the product type in an infant's diet and a specified age range. These definitions differ slightly from those stated by Codex and in European regulations, as shown in Table 1. Differences relate to the product type and specified age range for use. For example, the Codex follow-up formula definition captures products for use from 6–36 months of age, whereas the equivalent definition in the Code for follow-on formula relates to products for use from 6–12 months of age, which is similar to the European definition.

In addition, Codex uses the term ‘follow-up formula’, whereas the Code and European regulations use ‘follow-on formula’. Another point of difference, as shown in Table 1, is that the Code provides definitions for lactose free formula and low lactose formula, pre-term formula and soy-based formula. These terms are not defined in international and overseas regulations.

**Table 1: Comparison of definitions for product types between the Code and Codex and European regulations**

Product	Regulation	Definition
Infant formula	<b>Standard 2.9.1, the Code</b>	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
	<b>Codex infant formula standard</b>	A breast milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.
	<b>European Commission Directive 2006/141/EC</b>	Foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding.
Follow-on formula	<b>Standard 2.9.1, the Code</b>	An infant formula product represented as either a breast milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.
	<b>Codex follow-up formula standard</b>	A food intended for use as a liquid part of the weaning diet for the infant from the 6 <sup>th</sup> month on and for young children. Known as ‘follow-up formula’.
	<b>European Commission Directive 2006/141/EC</b>	Foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants.
Other product types	<b>Standard 2.9.1, the Code</b>	<p><i>Lactose free formula</i> and <i>low lactose formula</i> means infant formula products which satisfy the needs of lactose intolerant infants.</p> <p><i>Pre-term formula</i> means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.</p> <p><i>Soy-based formula</i> means an infant formula product in which soy protein isolate is the sole source of protein.</p>

### 3.2 Infant formula products for special dietary use

The provisions for IFPSDU are provided in Division 3 of Standard 2.9.1, separate to those provisions for infant formula and follow-on formula. This approach is consistent with that used in the recently revised Codex infant formula standard (2011a), in which Section B is specific to formula for special medical purposes intended for infants.

The Code allows IFPSDU to be specially formulated for a particular use, such as for pre-term infants or those with metabolic or immunological conditions. This means their composition may vary from the mandatory compositional requirements for infant formula and follow-on formula. However, there appears to be some ambiguity in Division 3 about other requirements of the Standard, with which IFPSDU must comply.

Previously, it was questioned whether it would be more appropriate for IFPSDU to be regulated under Standard 2.9.5, given the similarities between these products. This option was considered as part of Proposal P242 – Foods for Special Medical Purposes, which led to the development of Standard 2.9.5. At the time it was noted that infants are a unique population group and that regulating IFPSDU under Standard 2.9.5 could result in inconsistency, potential confusion and difficulty for enforcement purposes. Therefore, for clarity and consistency, it was decided to specifically exclude infant formula products from Standard 2.9.5, so that they would continue to be regulated by the one standard, namely Standard 2.9.1.

### 3.3 Guidelines

The Guidelines attached to Standard 2.9.1 provide guidance on three key elements:

1. Guideline upper levels (GULs) for vitamins and minerals, which are recommended to be observed as maximums for those nutrients that do not have a maximum prescribed in the Standard.
2. Additional labelling advice to the effect that consumption of vitamin or mineral preparations are not necessary.
3. The format for nutrition information tables on product labels.

The Guidelines are not part of the legally binding Standard, and are therefore voluntary and cannot be enforced. It has been noted that any regulatory requirement that is substantive should be in a clause, and that as a rule it should be able to be understood without reference to guidance material. Therefore, the *status quo* cannot be maintained and the proposal will need to consider whether some or all of the content of the Guidelines should be incorporated into Standard 2.9.1.

#### Questions to submitters:

4. Is the current structure of Standard 2.9.1 (i.e. organised from general to specific requirements by division) logical and easy to use? What changes would you suggest are made to the structure of Standard 2.9.1 and why?
5. Are the current definitions in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see made?
6. What additional terms, if any, do you consider should be defined in Standard 2.9.1? Why? How would you suggest we define these terms?

## 4. Compositional issues

Standard 2.9.1 prescribes the compositional requirements for infant formula products. The purpose of these requirements is to ensure that infant formula products provide all the essential nutrients, and in the right amounts, to support the normal growth and development of formula-fed infants.

When Standard 2.9.1 was developed in the late 1990s and early 2000s, the compositional requirements were based on best available scientific evidence, as well as alignment with the Codex infant formula standard and European regulations of the time. Since then, the Codex infant formula standard has been revised (revised 2007 and amended 2011) to reflect the current scientific understanding of nutritional needs of infants and methods of infant formula production. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) sought advice from international scientific experts in the area of infant nutrition.

The experts, coordinated by the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN), published a report with recommendations for the composition of infant formula based on current scientific evidence (Koletzko *et al.* 2005). The ESPGHAN recommendations led to several amendments to the relevant Codex and European standards.

No substantive revision of the Codex follow-up formula standard (amended 1989 and 2011) has been undertaken since it was adopted in 1987. CCNFSDU is currently considering a proposal to commence a revision of the standard. If a revision does proceed, it is anticipated that changes to the compositional requirements for follow-up formula will be made. As noted previously, the definition used by Codex for follow-up formula relates to a wider age group (6–36 months) compared to the Code (6–12 months).

Tables 3.1-3.3 of SD1 shows the compositional requirements for infant formula and follow-on formula as prescribed in the Code and the relevant Codex standards. In general, the requirements of the Code and Codex are comparable; however, there are some inconsistencies as outlined in the following sections.

## **4.1 Energy**

The energy content of an infant formula product is based on the energy contributed by the fat, protein and carbohydrate ingredients in the product, and can be calculated using energy factors. A range for total energy content for both infant formula and follow-on formula is provided in clause 21 of Standard 2.9.1; the minimum content is the same but the maximum is higher for follow-on formula than infant formula.

Minimum and maximum requirements for total energy, as well as for fat and protein, are prescribed in Standard 2.9.1 to ensure that these products provide sufficient energy to promote normal growth and development of the formula-fed infant, but not in excess to requirements.

The total energy requirements in the Code are comparable to those set by Codex, except that the Codex maximum energy content for infant formula is lower at 2950 kJ/L compared to 3150 kJ/L in the Code.

## **4.2 Macronutrients**

The requirements for macronutrient composition for infant formula and follow-on formula are set out in clauses 21-23 of Standard 2.9.1. Minimum and maximum requirements for total fat and protein per 100 kJ of product are prescribed for both product types, with higher maximum levels for protein in follow-on formula. These requirements, along with the values for total energy, indirectly control the energy contributed by carbohydrate, which is not explicitly prescribed.

Specific requirements relating to minimum levels of essential amino acids and the fatty acid composition of products are also detailed in the Standard, as well as a maximum potential renal solute load for follow-on formula.

Codex uses a similar approach to the Code, specifying minima and maxima for total energy, protein and fat, and in addition a requirement for carbohydrate content in infant formula. Both regulations specify different requirements for infant formula compared to follow-on formula. As shown in Table 3.1 of SD1, the macronutrient requirements prescribed in the Code are comparable to those set by Codex, however, there are some differences in the minimum protein and fat requirements for follow-on formula.

## 4.2.1 Calculation of protein content

Standard 2.9.1 prescribes a mathematical equation for calculating the protein content of infant formula products, which involves use of a nitrogen conversion factor. This mathematical equation differs from that used in the Codex infant formula standard (2011a), by virtue of the differing nitrogen conversion factors.

Currently, Standard 2.9.1 applies nitrogen conversion factors specific to the protein type, as follows:

- For milk proteins and their partial protein hydrolysates:  
protein content = nitrogen content x 6.38
- For any other proteins (such as soy):  
protein content = nitrogen content x 6.25

Based on the ESPGHAN recommendations (Koletzko *et al.* 2005), the revised Codex infant formula standard uses a single nitrogen conversion factor of 6.25 (unless there is scientific justification to use a different factor for a particular product). The Codex mathematical equation to calculate protein content is:  
protein content = nitrogen content x 6.25.

## 4.2.2 Protein quality

Standard 2.9.1 applies controls on protein quality for infant formula and follow-on formula by specifying minimum levels for nine amino acids (in L-amino acid form). The Codex infant formula standard (2011a) uses the same approach, with the minimum levels based on the average content in breast milk. The older Codex follow-up formula standard (2011b) prescribes different protein quality criteria and method of determination, requiring a minimum proportion (85%) of the quality of casein and specifies use of the protein efficiency ratio (PER) method. The Codex follow-up formula standard (2011b) also permits addition of essential L-amino acids only to improve its nutritional value.

## 4.3 Vitamins, minerals and electrolytes

### 4.3.1 Essential requirements and level of addition

The requirements for vitamins, minerals and electrolytes in infant formula products are provided in clause 24 of Standard 2.9.1, and are the same for infant formula and follow-on formula. Infant formula products are required to contain a total of 25 vitamins, minerals and electrolytes. As well as minimum amounts, maximum amounts are also prescribed for those vitamins, minerals and electrolytes for which high intakes in this population group are associated with safety concerns. In addition, specific requirements relating to the amount of vitamin E per gram of polyunsaturated fatty acids, the ratio of calcium to phosphorus and the ratio of zinc to copper are also specified in Standard 2.9.1.

The approach adopted in the Code and in the Codex infant formula and follow-up formula standards is similar, with both requiring minimum amounts of the same nutrients and, if required, prescribing maximum amounts on the grounds of safety. However, there are differences in the minimum and maximum levels for some of these essential nutrients between the Code and Codex.

Table 3.2 in SD1 provides a comparison between the Code and Codex requirements for essential vitamins, minerals and electrolytes for infant formula.

As part of the proposal, FSANZ will consider alignment of the vitamin, mineral and electrolyte requirements in the Code with those set by Codex and appropriate Australian and New Zealand nutrient reference values for infants.

#### **4.3.2 Guideline upper levels**

As discussed in section 3.3, the Guideline Upper Levels (GULs) recommended in the Guidelines attached to Standard 2.9.1 are not legally binding. FSANZ took this 'advisory' approach during the development of the original standard to provide guidance on appropriate maximum levels of vitamins and minerals in formulas. The intent of the approach was to minimise the potential risk of adverse health effects from consumption of vitamins, minerals and electrolytes above requirements, and also to minimise any adverse interactions with other vitamins, minerals and electrolytes.

The Codex infant formula standard also adopts the GUL approach to provide more latitude for the vitamins and minerals that do not pose a safety concern.

#### **4.3.3 Permitted forms**

The permitted forms of vitamins, minerals and electrolytes in infant formula products are provided in Schedule 1 of Standard 2.9.1. The Codex advisory list of nutrients (Codex 2008) includes the permitted forms of vitamins, minerals and electrolytes for use in foods for special dietary uses intended for infants and young children, including infant formula, follow-up formula and formula for special dietary use.

There are some differences in the forms permitted in Schedule 1 and those specified by Codex. Table 3.4 in SD1 lists the differences in permitted forms between the Codex advisory list of nutrients and Schedule 1 of Standard 2.9.1.

#### **4.3.4 Fluoride**

Standard 2.9.1 does not prescribe a maximum level for fluoride in infant formula products. However, it requires a statement on dental fluorosis to be made on packaging of infant formula products when the powdered or concentrated product contains more than 17 µg of fluoride per 100 kJ prior to reconstitution or more than 0.15 mg of fluoride per 100 mL in 'ready-to-drink' formula.

Codex and Europe have both set maximum levels of fluoride in infant formula of 100 µg of fluoride per 100 kcal (24 µg/100 kJ) 'ready to feed'. There is no requirement for a dental fluorosis statement in either the Codex infant formula standard or the European regulation.

### **4.4 Other substances**

#### **4.4.1 Nutritive substances**

Standard 1.1.1 includes a definition of nutritive substance and includes a prohibition on the addition of nutritive substances to food unless expressly permitted in the Code. Standard 2.9.1, and the Code in general, require the pre-market approval of all nutritive substances, novel foods, food additives, and processing aids proposed to be used in infant formula products. In order to be used in infant formula products, such substances must be listed in the Code for that specific use.

FSANZ recognises there is a regulatory problem resulting from the current regulation of nutritive substances in the Code. The definition includes terms that are themselves not clearly defined.

The lack of clear meaning of these terms creates uncertainty and ambiguity in the overarching definition of nutritive substance. In addition, some substances that require pre-market assessment are not necessarily characterised by having a nutritive function and thus are not adequately captured by the current prohibitions in the Code for nutritive substances.

In recent years, FSANZ has become aware of some confusion in relation to the permissions for additional of optional ingredients to infant formula products. Some stakeholders have raised concerns about the ambiguity of paragraph 6(1)(b) of Standard 2.9.1. In particular, there appears to be uncertainty around the potential to add nutritive substances that are derived from an ingredient of infant formula or are naturally present in an ingredient of the infant formula, such as milk.

This uncertainty and ambiguity makes it difficult to be certain which substances and foods should be considered nutritive substances and therefore, whether particular substances require specific permission in the Code before they can be added to, or sold as, foods.

These issues are being considered by FSANZ in a separate project focused on the future regulation of nutritive substances and novel foods in the Code. FSANZ recognises that the outcomes of the nutritive substances and novel foods project will have an impact on Standard 2.9.1; these will be considered and addressed as work in both these areas progresses.

#### **4.4.2 Optional nutritive substances**

Table 3.3 of SD1 lists the nutritive substances (other than vitamins and minerals) and other substances that are permitted to be added to infant formula products. In Standard 2.9.1, choline, inositol and L-carnitine are permitted as optional nutritive substances for addition to infant formula products. At the time of the development of the Standard, these substances were identified as being present in breast milk and while not essential to health, it was considered that they may provide a physiological benefit. On this basis, they were permitted for voluntary addition to infant formula. Maximum levels for these substances were set to protect infants from excessive intakes. The rationale for setting minimum levels was to ensure that these substances, if added, would be present at levels sufficient to achieve their intended purpose. In the case of L-carnitine, the levels were intended to provide for the addition of carnitine to soy-based or amino acid-based formula which had no innate carnitine levels. Since the development of Standard 2.9.1, the NHMRC and New Zealand Ministry of Health have listed choline as an essential nutrient and set an Adequate Intake for infants (2006).

The Codex infant formula standard (2011a) lists choline, inositol and L-carnitine as essential, based on the approach recommended by ESPHGAN (Koletzko et al. 2005).

Standard 2.9.1 also permits the optional addition of five specific nucleotides to infant formula products, setting minima and maxima for each of the permitted nucleotides. It also prescribes a combined total nucleotide content, which includes naturally occurring nucleotides. FSANZ is aware that there has been some confusion for stakeholders between the total maximum for individual nucleotides and the combined total limit of nucleotides. The Codex infant formula standard permits the addition of nucleotides at the discretion of national authorities.

#### **4.4.3 Other optional substances**

Standard 2.9.1 permits the voluntary addition of lactic acid producing cultures in infant formula products. There are no specified minimum or maximum levels for these substances. Infant formula products are also permitted to contain added inulin-derived substances and galacto-oligosaccharides.

As for added nucleotides, the maximum permitted amounts for inulin-derived substances and galacto-oligosaccharides apply to the total of added and naturally occurring substance.

## **4.5 Food additives**

A food additive is any substance added to a food to achieve a technological function, such as an emulsifier, thickener or acidity regulator. Food additives can only be added to food in order to achieve their identified technological function and when permission for their addition exists in the Code.

The food additive permissions for infant formula products are provided in food category 13.1 (infant formula products) in Schedule 1 of Standard 1.3.1 – Food Additives. The current permissions were set when Standard 2.9.1 was originally developed. The Code presents the food additive permissions using a hierarchical system, such that the permissions for the general category (i.e. infant formula products) also apply to the subsequent subcategories (e.g. soy-based infant formula and IFPSDU based on protein substitutes), along with any additional permissions specific to these subcategories.

Codex permissions for food additives are provided in the respective infant formula and follow-up formula standards, and in the Codex advisory list of nutrients. Some food additives permitted by Codex for use in follow-up formula are not permitted for use in infant formula. A number of the current Codex permissions did not exist when Standard 2.9.1 and the respective food additive permissions for infant formula products were first developed.

Annex VI of the European Union Council Directive 95/2/EC *Food Additives other than Colours and Sweeteners* (updated in 2006) contains permissions for food additives for foods for infants and young children, including infant formula and follow-on formula for infants in good health. There are a number of very specific conditions attached to the various food additive permissions for the different classes of infant formula products.

Stakeholders have requested that the permissions for food additives be reviewed, noting inconsistencies between the Code and international and overseas regulations. The differences in permissions for food additives in the Code compared to the Codex permissions for infant formula are shown in Table A3.4 (the limits have been converted and provided in the same units as those in the Code, for ease of comparison). In addition, FSANZ is aware that the European regulations permit some additional food additives that are currently not permitted by either the Code or Codex.

## **4.6 Processing aids**

Processing aids differ from food additives in that the substance is added to perform their technological function during the manufacture or processing of the food, but do not perform a technological function in the final food. Processing aids are regulated in the Code by Standard 1.3.3 – Processing Aids, and a general prohibition on the use of processing aids applies unless expressly permitted in this Standard. There is not a specific list of processing aids that can only be used in the production of infant formula. There are a variety of different types of processing aids that can be used for different types of foods, or all foods, with or without qualifications. Codex does not have a specific list of processing aids that can be used to manufacture infant formula products.

FSANZ is not aware of any issues relating to the permissions for processing aids in the manufacture of infant formula products.

**Questions to submitters:**

7. What provisions in the Code for the composition of infant formula and follow-on formula are unclear and ambiguous? What are the specific issues and how would you suggest the intent of the specific provision be clarified?
8. Is alignment of the compositional requirements for infant formula products in the Code with the relevant Codex standards appropriate? What is the rationale for your view to align/not align with Codex?
9. Should there be different compositional requirements for infant formula and follow-on formula? If yes, for which nutrients? Please provide evidence to support your view.
10. Should the two nitrogen conversion factors (6.25 and 6.38; for different protein sources) continue to be prescribed in Standard 2.9.1 for the calculation of protein content of products? If only one nitrogen conversion factor was to be prescribed, which factor (i.e. 6.25, 6.38 or other) would you recommend and why?
11. Is alignment of the minima and maxima for vitamins, minerals and electrolytes in the Code with those specified in the Codex infant formula standard appropriate? What is the rationale for your view to align/not align with Codex?
12. Is alignment with Codex for the permitted forms of nutrients appropriate? What is the rationale for your view to align/not align with Codex?
13. Do manufacturers follow the guideline upper levels (GULs) for certain vitamins and minerals specified in the Guidelines attached to Standard 2.9.1?
14. Would it be appropriate to include the GULs for vitamins and minerals in the legally binding Standard?
15. What additional forms of vitamins, minerals and electrolytes would you like permitted in Standard 2.9.1? Why?
16. Are the current food additive permissions in Standard 1.3.1 fit for purpose? If not, why not and what changes would you like to see made?
17. What additional food additives do you consider should be permitted in the Code? What is your rationale for these?
18. Are the current permissions for processing aids for use in the manufacture of infant formula products fit for purpose? If not, why not and what changes would you like to see made?

## 5. Safety issues

### 5.1 Microbiological limits

Standard 1.6.1 – Microbiological Limits for Food specifies microbiological limits for powdered infant formula products, with and without added lactic acid producing cultures. These microbiological limits were established under Proposal P178 – Microbiological Standards (FSANZ, 1999) and gazetted in 2000. Criteria are specified for:

- *Bacillus cereus*
- Coagulase-positive staphylococci
- Coliforms
- Salmonella
- Standard plate count (SPC)

Since Standard 1.6.1 was gazetted, the Codex Committee on Food Hygiene has developed additional microbiological criteria for powdered infant formula, formula for special medical purposes and human milk fortifiers.

The Codex code of hygienic practice for infant formula (2008) includes recent risk assessment work, such as the FAO/WHO microbiological risk assessment for *Enterobacter sakazakii* and other microorganisms in powdered infant formula (FAO/WHO 2004). The Codex code of hygienic practice for infant formula includes criteria for the following additional pathogens:

- *Cronobacter sakazakii*
- Salmonella

In addition, the Codex code of hygienic practice for infant formula also includes criteria for process hygiene for:

- Mesophilic Aerobic Bacteria
- Enterobacteriaceae.

Standard 1.6.1 currently specifies some limits for indicator organisms in foods, including Standard Plate Count (SPC) and *E. coli*, often in combination with pathogen limits. Where pathogens can be detected directly and reliably, it is preferable to set limits for the pathogen rather than testing for indicator/index organisms. Indicator and index tests can provide a cost effective, simple and rapid means of assessing the microbiological status of food, particularly for monitoring and verifying production processes and hygiene controls. However, microbiological limits based on indicator/index organisms do not indicate a direct health hazard.

## 5.2 Maximum potential renal solute load

Standard 2.9.1 includes a maximum potential renal solute load (RSL) for follow-on formula but not infant formula. The renal solute load is the amount of metabolic waste products that must be excreted by the kidney. Urea from protein, sodium, potassium, phosphorus and chloride are the main dietary contributors to RSL. The safety of formula for infants is influenced by the potential RSL of the formula. The potential RSL is regulated to minimise the risk of dehydration illness from formulas with high protein and electrolyte contents. It can be calculated from the formula composition, and a mathematical formula for doing so is prescribed in the Standard.

The Codex infant formula standard and follow-up formula standard do not set a restriction for potential RSL. However, there are some differences between the Code and Codex in respect to the maximum protein in follow-on formula and maximum amounts of sodium, potassium, phosphorus and chloride for infant formula (see Tables 3.1 and 3.2, SD1) which may influence the requirement for controls on the renal solute load.

## 5.3 Contaminants

Maximum levels controlling contaminants in infant formula products are located in both Standard 1.4.1 – Contaminants and Natural Toxicants and Standard 2.9.1. Stakeholders have suggested that all contaminant maximum levels for infant formula products should be located in one standard within the Code.

The Codex *General Standard for Contaminants and Toxins in Food and Feed* (Codex STAN 193-1995) lists the maximum levels for contaminants in food. The Codex infant formula standard also specifies a maximum level for lead in ready-to-use products. Standard 1.4.1 of the Code contains a maximum level of for lead in infant formula products which is consistent with the Codex maximum level. Standard 2.9.1 sets a maximum level for aluminium in infant formula and follow-on formula, with other levels set for soy-based formula and for pre-term formula. Codex does not specify a maximum level for aluminium in infant formula products.

**Questions to submitters:**

19. Is alignment of the microbiological limits in the Code with international approaches as developed by Codex under the *Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* appropriate?
20. Is it appropriate to include criteria that verify good hygiene practice (e.g. indicators) as regulatory standards in the Code or should these be established as reference or guidance criteria?
21. Can you provide evidence to suggest that the maximum potential renal solute load has not been effective in minimising the risk of dehydration illness from formulas with high protein and electrolyte contents?
22. Is full alignment of the Code with the Codex contaminant standard appropriate? Or is there a rationale for only partial alignment of maximum contaminant levels with those set by Codex?

## 6. Labelling issues

Food labels on infant formula products carry a wide range of information for the consumer. Mandatory label elements include a name or description of the food, a nutrition information statement to provide compositional information, a statement of ingredients, allergen declarations, date marking, directions for use and storage and food recall information. Certain warning and advisory statements specific to infant formula products are also mandated. Often, the labelling requirements for infant formula products differ substantially from those for general purpose foods, due to the specialised information requirements associated with these foods.

The Code stipulates mandatory information that must appear on infant formula product labels. Infant formula products are also subject to voluntary codes of practice that extend beyond the Code's labelling requirements into the management of marketing and advertising practices for these products. As Australia and New Zealand are signatories to the WHO Code, its requirements have been adopted through the voluntary agreements. Labelling requirements in the WHO Code were given effect as mandatory provisions in Standard 2.9.1, through Proposal P93.

### 6.1 Directions for use and storage

Powdered infant formula products are not sterile and may occasionally contain pathogens, though these must be within the microbiological limits prescribed in the Code. Standard 2.9.1 includes a labelling requirement for guidance on the safe preparation and storage of powdered formula, as infants are physiologically vulnerable and infant formula is a sole source of nutrition for formula-fed infants in the first months of life. During the development of the current Standard, FSANZ determined that it was microbiologically safe to make up several bottles of formula at one time provided they are stored in the fridge for not more than 24 hours. Based on this analysis, paragraph 14(2)(b) of Standard 2.9.1 requires a statement or pictures instructing that if a bottle of formula is made up and stored prior to use, it must be refrigerated and used within 24 hours. Similarly, paragraph 14(2)(e) requires a statement or pictures instructing that formula left in the bottle after a feed must be discarded.

These statements, aligned with the instructions in the then NHMRC *Infant Feeding Guidelines for Health Workers* (1996), and align with the present draft *Australian Infant Feeding Guidelines for Health Workers* (2011). The statement about appropriate storage also aligns with the *Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (Codex 2009).

However, some stakeholders have noted that this statement is in conflict with advice given in New Zealand Ministry of Health guidance documents on infant feeding<sup>3</sup>. The New Zealand guidance recommends made-up formula is stored in the back of the fridge (0–4°C) for no more than four hours.

Stakeholders have previously requested clarity on whether the current wording of paragraph 14 is prescribed. An Implementation Sub-Committee (ISC)<sup>4</sup> Working Group has recommended that further clarification or guidance be provided for paragraphs 14(2)(b) and 14(2)(e). The basis for this recommendation was the variation in wording used on labels, with some infant formula products labels found to omit directions for made-up formula that is to be stored prior to use.

Manufacturers have suggested that the wording should not be prescribed. This would allow flexibility and permit manufacturers to advise on an appropriate storage time between 0-24 hours, ranging from 'do not store, use immediately' through to the current recommended no more than 24 hours as a maximum permitted time. There is no specific direction or prescribed wording for direction and storage outlined in the Codex infant formula standard.

## **6.2 Measuring scoop**

Powdered infant formula products available in Australia and New Zealand are required to contain a scoop to enable the correct use of the product. Paragraph 14(2)(d) of Standard 2.9.1 requires that the label on a package of infant formula product, where the package contains a measuring scoop, must include words and pictures instructing that only the enclosed scoop should be used. The size of the measuring scoop is not standardised. Therefore, different size scoops are found in different brands of products, where one scoop can be equal to 30, 50 or 60 mL of powdered formula depending on the product.

Stakeholders have noted that because the wording used in paragraph 14(2)(d) is not prescribed, different instructions appear on products. For example, product labels may include the words 'fill the enclosed scoop', but not specify that 'only the enclosed scoop should be used'. Stakeholders have expressed concern that this represents a potential risk as formula may be prepared incorrectly if parents switch between products and use the incorrect scoop, as make-up ratios vary between products.

Codex standards do not refer specifically to the use of a measuring scoop; however most countries include provisions for feeding quantities on the label of infant formula and follow-on formula.

## **6.3 Claims and representations**

Standard 2.9.1 sets out specific mandatory requirements to provide nutrition information on infant formula products to assist consumer choice. Other nutrition information, such as the use of voluntary nutrition claims or health claims, is potentially another means of providing additional information for consumers. However, in relation to infant formula it is unknown how this information influences parent/carer purchase behaviour. An objective of the FSANZ Act is 'the provision of adequate information to enable consumers to make informed choices about the food they purchase'.

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<sup>3</sup> <https://www.health.govt.nz/resource/feeding-your-baby-infant-formula> New Zealand Ministry of Health, accessed 23 July 2012.

<sup>4</sup> ISC is a sub-committee of the Food Regulation Standing Committee. Its role is to develop and oversee a consistent approach across jurisdictions to implementation and enforcement of food regulations and standards.

Infant formula manufacturers would like the ability to provide more information on labels about the presence of optional ingredients in infant formula products, which would currently constitute either a nutrition claim or health claim. Their request is based on the view that provision of this information would support consumers to make an informed choice. Conversely, other stakeholders support the prohibition on nutrition and health claims for infant formula products, to support the public health approach to promote breastfeeding first and foremost. Their concern is that label claims may imply 'health benefits' beyond that provided by breast milk, which may influence the decision to feed an infant with formula rather than breast milk.

Currently, the intent of the Code is to prohibit nutrition and health claims on infant formula products. Paragraph 20(2)(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 infant formula product, or is in the ingredient list or the nutrition information statement. Paragraph 3(f) of Standard 1.1A.2 – Transitional Standard – Health Claims prohibits foods standardised in Standard 2.9.1 from carrying a health claim, including IFPSDU. Since its gazettal, Standard 2.9.1 has been amended several times to clarify this intent and support the regulatory approach for a prohibition on nutrition and health claims.

The Ministerial Policy Guideline contains a specific policy principle for labelling and advertising of infant formula products, which states that FSANZ *should ensure that the prohibitions and restrictions on nutrient content, health, therapeutic and prophylactic claims in the Food Standards Code are clear and effective*. FSANZ continues to progress its work on draft Standard 1.2.7 – Nutrition, Health and Related Claims which is currently due to be considered by Ministers by the end of 2012. Under the draft Standard, it is proposed that infant formula products will be ineligible to carry nutrition and health claims, which reflects the intended status quo. The draft Standard also includes a prohibition for infant formula products to carry therapeutic claims. Internationally, most regulatory bodies also apply restrictive approaches to nutrition and health claims on infant formula products.

## 6.4 Trademarks

Some stakeholders are concerned that trademarks used on labels of some infant formula products may be construed as an implied health claim, and also that trademarks appeared to offer an opportunity to make health claims. They noted apparent differences in understanding of interactions between Commonwealth trademark legislation and state and territory legislation.

Trademarks are regulated through the Australian *Trade Marks Act 1995* and the New Zealand *Trade Marks Act 2002*. There are obvious overlaps with the proposed health claim regulations and the use of trademarks that appear to be health claims or endorsements. IP Australia consults with FSANZ when new trade marks (that include potential health claims) are being registered.

The Review of Food Labelling Law and Policy (Blewett et al., 2011) recommended 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 (Recommendation 21).

In its consideration of this recommendation, the COAG Legislative and Governance Forum on Food Regulation (the Forum) commented (2011) that *under the uniform food laws in each jurisdiction, the use of trade names or trademarks, including devices and brand identifiers, cannot be used as a means to make claims about food that would otherwise not be allowed under the Food Standards Code. This position is irrespective of the position on Recommendation 20 relating to health claims.*

Recommendation 20 supported the finalisation of the draft health claims Standard.

The Forum also commented that *the current law already seeks to achieve the object of this recommendation as it currently provides that an application for the registration of a trademark must be rejected if the use of the trademark in relation to particular goods or services would be either contrary to law or likely to deceive or cause confusion.*

In its response, the Forum have requested that the Food Regulation Standing Committee (FRSC) investigates and reports on the scope of trade mark law and provisions of the Code, with a view to suggesting improvements in the manner in which food and trade mark regulators work together to ensure problematic trademarks as they relate to food are identified prior to their being registered. FRSC has signalled that this work will be completed in 2013.

## **6.5 Prescribed names and declaration of protein source**

'Infant Formula' and 'Follow-on Formula' are prescribed names, as required by clause 12 of Standard 2.9.1, and must appear on labels of relevant infant formula products. In addition, clause 18 requires a mandatory statement of the specific source(s) of protein in the infant formula product to appear immediately adjacent to the name of the product. Protein sources may, for example, refer to cow's milk, soy protein isolate or protein substitutes.

There are some inconsistencies between the Code requirements for prescribed names for infant formula products and Codex and European regulatory approaches for naming these foods. In addition, Codex and European regulations do not require a separate declaration of protein source; rather they require an alternative prescribed name when the infant formula product is made solely from cow's milk.

In relation to infant formula, all regulations refer to, or mandate, 'infant formula' as the name of the food. However, there are inconsistencies in the naming convention for follow-on formula. For example Codex prescribes the terms 'Follow-up Formula' and 'Follow-up Formula based on milk' if products are prepared predominantly from whole or skimmed milk.

## **6.6 Standard 2.9.1 guidelines for nutrition information**

As discussed in section 3.3, Standard 2.9.1 includes an attached set of guidelines. The Guidelines include a recommended format for presenting nutrition information on labels of infant formula products. As the Guidelines do not form part of the legally binding Standard, manufacturers and importers do not need to comply with this format. This is in contrast to nearly all other commodity standards in the Code (except for food for special medical purposes, and formulated caffeinated beverages), for which the presentation of nutrition information is prescribed.

In addition, the recommended format in the Guidelines shows nutrition information for powdered formula being expressed per 100 g in addition to per 100 mL. However, clause 16 of Standard 2.9.1 only requires that the values are expressed per 100 mL, for both ready-to-drink products as well as powdered products (in their reconstituted form). Therefore, inconsistencies exist between the recommended format in the Guidelines and what is required by the Standard.

## 6.7 'Breast is best' warning statement

Subclause 14(3) of Standard 2.9.1 requires the label on a package of infant formula product to contain the warning statement: 'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'. This statement is often referred to as the 'breast is best' statement. This requirement aligns with the recommendations in Article 4a of the WHO Code and Article 4.2 in both the New Zealand CoPMIF and the Australian MAIF agreement (see section 2.1.3). The WHO Code also recommends a statement advising consumers to seek advice from their healthcare professional prior to deciding to use an infant formula product.

Some stakeholders have suggested that the 'breast is best' warning statement be amended to a risk-based statement about the risks to infant health of not breastfeeding. These stakeholders state that such a statement would reflect a body of evidence showing that compared to formula feeding, breastfeeding is associated with lower incidence of infection and some chronic diseases, and evidence for improved cognitive development in the breastfed infant.

## 6.8 Legibility requirements

Clause 3 of Standard 1.2.9 – Legibility Requirements prescribes the print size (size of type or font) for warning statements. In addition, clause 15 of Standard 2.9.1 specifies the print size for specific warning statements, including the 'breast is best' statement. The legibility provisions in Standard 2.9.1 could potentially reside in the generic standard, Standard 1.2.9. However, the current legibility requirements in Standard 1.2.9 are linked generically to the size of the package, whereas in Standard 2.9.1 they relate to the volume of the package.

As discussed above, the Code only regulates the size of print for certain warning statements on infant formula products. It does not prescribe any specific formatting such as bolding or capitalisation of text, but does not prohibit it either. FSANZ has identified some countries that do require certain statements to be capitalised. Manufacturers and importers currently have some discretion as to how these statements are presented on the label of infant formula products to be sold in Australia and New Zealand (i.e. including the use of bolding and/or capitalisation of text).

### Questions to submitters:

23. What evidence can you provide to support an amendment to the current requirements for storage and/or disposal of made-up formula?
24. What evidence can you provide on how caregivers currently prepare formula? Do they follow the instructions on the packaging? If not, is there evidence to show that changes to the instructions on labels of products could potentially influence how caregivers prepare formula?
25. What evidence can you provide on whether caregivers use measuring scoops other than those supplied with the product, and whether they understand that scoop size (and therefore number of scoops per volume of water) differs between brands?
26. What evidence can you provide on (a) how consumers choose between infant formula products? (b) whether or not nutrition claims, by providing additional information, would 'enable consumers to make informed choices'? and/or (c) how their choice might be affected by the presence of nutrition claims?
27. What evidence can you provide on whether consumers perceive trademarks on food labels in a similar way to health claims?
28. Are the current prescribed names in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see?

29. Would it be appropriate to include the nutrition information format requirements in the Guidelines attached to Standard 2.9.1 in the legally binding Standard?
30. Do you consider that there is a rationale for revising the current requirements for size of type relating to mandatory warning statements on labels?
31. Should other presentation requirements (e.g. prescription of the use of bolding and capitalisation for certain statements) be considered as part of the proposal?

## **7. Advertising of infant formula products**

Clause 2 of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions defines ‘label’ to mean ‘any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package’.

Clause 13 of Standard 1.1.1 states that ‘advertisements for food must not contain any statement, information, designs or representations which are prohibited by this Code from being included in a label for that food’. The term ‘advertisement’ is not defined in the Code, however, it 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 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’.

As discussed in the background (section 2.1.3), non-regulatory measures through the Australian MAIF Agreement and the New Zealand CoPMIF recommend various requirements and restrictions for the marketing and distribution of breast milk substitutes for industry, including restrictions on products being advertised or otherwise promoted to the public. The New Zealand agreement applies to products suitable for infants up to the age of six months and the Australian agreement for products suitable up to the age of twelve months. Neither of these agreements restricts the marketing and advertising of ‘toddler milks’, which are designed for use by young children aged one to three years and regulated as FSFYC under Standard 2.9.3.

### **7.1 Use of ‘line marketing’**

Some stakeholders have expressed concern about the use of ‘line marketing’, such that infant formula is labelled as stage 1, follow-on formula as stage 2 and toddler milk as stage 3, implying that as an infant grows they should progress through these products. The almost identical presentation of these products and reference to stages for progression between products is considered to mislead consumers about the essentiality of toddler milk in a child’s diet. Also, the use of line marketing can link infant formula products and toddler milks in the minds of consumers, but the restrictions on marketing and advertising only relate to infant formula products. Research by Berry *et al.* (2010) found that first-time mothers understood toddler milk advertisements to be promoting a range of products that included infant formula and follow-on formula, when products shared brand identities. There is currently nothing in the Code that directly restricts or prohibits joint line marketing of infant formula products and toddler milks.

### **7.2 Proxy advertising**

Some stakeholders are concerned that the presence of nutrition claims on toddler milks act as proxy advertising for infant formula products. They consider that this could potentially pose a safety risk, in relation to use of products with inappropriate composition for age, if consumers believed toddler milks were better than infant formula products for their infant.

### 7.3 Online advertising

Some stakeholders have noted that infant formula products are often advertised on retailer websites and as part of in-store promotions. While some stakeholders believe that these activities are against the spirit of the Australian MAIF Agreement and the New Zealand CoPMIF, retailers are not signatories to either agreement and therefore are not subject to the same advertising restrictions as infant formula manufacturers and importers. FSANZ has not specifically considered this issue because monitoring and compliance activities relating to food for retail sale fall within the purview of enforcement agencies.

The Code does not expressly provide for circumstances where food products are offered for sale on the internet. Instead, the terms of the particular standard in the Code and the definition of the term 'advertisement' in the relevant food legislation will determine whether and how the Code applies to the online sale of food products.

However, retailers still have a regulatory obligation to comply with mandatory requirements in the Code. This is because the term 'label' is defined broadly to include (in part) statements, representations or descriptive matter that is attached or used in connection with or accompanying any food or package. Consequently, where promotional material refers to labelling elements regulated by the Code, it must comply with the relevant requirements.

## 8. Infant formula products for special dietary use

IFPSDU are regulated under Division 3 of Standard 2.9.1. The Division contains labelling and composition requirements for special purpose infant formulas, specifically those for:

- premature or low birthweight infants (subdivision 1)
- metabolic, immunological, renal, hepatic and malabsorptive conditions (subdivision 2)
- specific dietary use based on protein substitutes (subdivision 3).

In 2007, Codex Alimentarius updated its infant formula standard and incorporated a new standard for formula for special medical purposes intended for infants. Codex regulates these special medical purpose infant formulas under Part B of the Codex infant formula standard. Part B cross-references back to Part A (general purpose infant formulas) for most of its requirements. The provisions set out by Codex for these products draw considerably on both the provisions for foods for special medical purposes and those for infant formula. For example, the definition of special purpose infant formula is composite of the definition of FSMP<sup>5</sup> and the Codex definition of infant formula<sup>6</sup>.

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<sup>5</sup> Foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other specially medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses or by a combination of the two' Clause 2 Codex STAN 180-1991

<sup>6</sup> '.....which are manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding.' Clause 2.1.1 Section B Codex STAN 72-1981

## 8.1 Composition

Currently the composition requirements for IFPSDU formulated for premature or low birthweight infants (subdivision 1) are based on the general composition provisions for infant formula products. However, for products regulated by subdivisions 2 and 3, the compositional requirements do not use the same basis. Compositional requirements in subdivision 2 specify that the products can be specifically formulated to satisfy particular medical conditions. Subdivision 3 specifies minimum and maximum levels for protein and energy for formula for specific dietary use based on protein substitutes, and regulates the potential renal solute load.

Part B of the Codex infant formula standard bases composition requirements for IFPSDU on the composition of infant formula.

## 8.2 Labelling

Division 3 of Standard 2.9.1 outlines some additional labelling requirements for pre-term formula and infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions.

Similarly in the Codex infant formula standard, most of the labelling requirements are specified in Part A (general purpose infant formulas), however, there are some additional labelling requirements in Part B. Most of these requirements are an adoption of labelling requirements in the Codex Standard for *Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991).

### 8.2.1 Prescribed name

In addition to the requirements in clause 12, paragraph 26(2) of Standard 2.9.1 requires that the words 'pre-term' must appear as part of the name of a food standardised as an infant formula product formulated for premature or low birthweight infants. Therefore, these foods must be labelled 'Pre-term Infant Formula'.

There is no specific prescribed name other than the general requirement to label 'Infant Formula' for infant formula products manufactured for:

- metabolic, immunological, renal, hepatic and malabsorptive conditions (subdivision 2 IFPSDU products), or
- specific dietary use based upon protein substitutes (subdivision 3 IFPSDU products).

For infant formulas for special medical purposes, Codex prescribes the term 'Formulas for Special Medical Purposes Intended for Infants', unless the products are made from cow's milk in which case they must be labelled 'Formula for Special Medical Purposes Intended for Infants Based on Cow's Milk'.

### 8.2.2 Mandatory statements

Division 3 of Standard 2.9.1 mandates a number of statements for products regulated under subdivision's 1 and 2 that are in addition to those for other infant formula products:

- Subdivision 1: The label on a package of pre-term formula must include 'Suitable only for pre-term infants under specialist medical supervision'.

- Subdivision 2: Where a label contains a claim that the infant formula product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, then the label on the package of infant formula product must include a statement indicating:
  - that the product is not suitable for general use and should be used under medical supervision; and
  - the condition, disease or disorder for which the food has been specially formulated; and
  - the nutritional modifications, if any, which have been made to the infant formula product.

Subdivision 2 also provides criteria for low-lactose and lactose free claims. Subdivision 3 (protein substitute formulas) contains no additional labelling requirements.

### 8.2.3 Exemptions for general requirements

Division 3, standard 2.91 mandates an exemption from displaying the statement:

*Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice*

on the labels of IFPSDU. This exemption recognises that IFPSDU are used under the supervision of a health professional. The 'breast is best' statement must be placed on the labels of all other infant formula products.

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

32. Is the current location of the provisions for IFPSDU in Standard 2.9.1 appropriate? If not, why?
33. Do you consider that any of the labelling provisions of Standard 2.9.5 should apply to IFPSDU products? If yes, which requirements and what is your rationale?
34. Are there any additional labelling requirements (e.g. advisory statements) that should be displayed on the labels of IFPSDU that are not already required by either Division 3 of Standard 2.9.1, or by Standard 2.9.5? If yes, why?

## 9. Next steps

Information gathered from submissions on this paper will be used to inform the preparation of a proposal to review and revise the regulations for infant formula products in the Code. It is anticipated that the proposal will be prepared in 2013 and that a comprehensive review of the regulations will be required to address the range of issues identified. The overarching goal of the proposal will be to address regulatory problems with the current regulations for infant formula products, as well as provide clarity in areas of regulatory uncertainty as to the intent of the relevant standards.

FSANZ will consult widely with stakeholders during the consideration of the proposal. There are a large number of stakeholders who are interested in this work and who wish to participate. We will publically consult on written reports and may follow up with further group and targeted consultation or with individual submitters to obtain further information or to clarify comments.

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## **Attachment**

- A. Summary of questions to submitters

## Attachment A – Summary of Questions to Submitters

1. What is the total volume of each of infant formula, follow-on formula and IFPSDU manufactured in Australia New Zealand for domestic consumption and export? What proportion of the total volume is for export only?
2. What is the total volume of each of infant formula, follow-on formula and IFPSDU imported into Australia New Zealand? Where are these products imported from?
3. What is the value for each component listed in Q1 and Q2?
4. Is the current structure of Standard 2.9.1 (i.e. organised from general to specific requirements by division) logical and easy to use? What changes would you suggest are made to the structure of Standard 2.9.1 and why?
5. Are the current definitions in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see made?
6. What additional terms, if any, do you consider should be defined in Standard 2.9.1? Why? How would you suggest we define these terms?
7. What provisions in the Code for the composition of infant formula and follow-on formula are unclear and ambiguous? What are the specific issues and how would you suggest the intent of the specific provision be clarified?
8. Is alignment of the compositional requirements for infant formula products in the Code with the relevant Codex standards appropriate? What is the rationale for your view to align/not align with Codex?
9. Should there be different compositional requirements for infant formula and follow-on formula? If yes, for which nutrients? Please provide evidence to support your view.
10. Should the two nitrogen conversion factors (6.25 and 6.38; for different protein sources) continue to be prescribed in Standard 2.9.1 for the calculation of protein content of products? If only one nitrogen conversion factor was to be prescribed, which factor (i.e. 6.25, 6.38 or other) would you recommend and why?
11. Is alignment of the minima and maxima for vitamins, minerals and electrolytes in the Code with those specified in the Codex infant formula standard appropriate? What is the rationale for your view to align/not align with Codex?
12. Is alignment with Codex for the permitted forms of nutrients appropriate? What is the rationale for your view to align/not align with Codex?
13. Do manufacturers follow the guideline upper levels (GULs) for certain vitamins and minerals specified in the Guidelines attached to Standard 2.9.1?
14. Would it be appropriate to include the GULs for vitamins and minerals in the legally binding Standard?
15. What additional forms of vitamins, minerals and electrolytes would you like permitted in Standard 2.9.1? Why?
16. Are the current food additive permissions in Standard 1.3.1 fit for purpose? If no, why not and what changes would you like to see made?

17. What additional food additives do you consider should be permitted in the Code? What is your rationale for these?
18. Are the current permissions for processing aids for use in the manufacture of infant formula products fit for purpose? If not, why not and what changes would you like to see made?
19. Is alignment of the microbiological limits in the Code with international approaches as developed by Codex under the *Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* appropriate?
20. Is it appropriate to include criteria that verify good hygiene practice (e.g. indicators) as regulatory standards in the Code or should these be established as reference or guidance criteria?
21. Can you provide evidence to suggest that the maximum potential renal solute load has not been effective in minimising the risk of dehydration illness from formulas with high protein and electrolyte contents?
22. Is full alignment of the Code with the Codex contaminant standard appropriate? Or is there a rationale for only partial alignment of maximum contaminant levels with those set by Codex?
23. What evidence can you provide to support an amendment to the current requirements for storage and/or disposal of made-up formula?
24. What evidence can you provide on how caregivers currently prepare formula? Do they follow the instructions on the packaging? If not, is there evidence to show that changes to the instructions on labels of products could potentially influence how caregivers prepare formula?
25. What evidence can you provide on whether caregivers use measuring scoops other than those supplied with the product, and whether they understand that scoop size (and therefore number of scoops per volume of water) differs between brands?
26. What evidence can you provide on:
  - (a) how consumers choose between infant formula products?
  - (b) whether or not nutrition claims, by providing additional information, would 'enable consumers to make informed choices' (or choices that are more informed than they currently are) and/or
  - (c) how their choice might be affected by the presence of nutrition claims?
27. What evidence can you provide on whether consumers perceive trademarks on food labels in a similar way to health claims?
28. Are the current prescribed names in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see made?
29. Would it be appropriate to include the nutrition information format requirements in the Guidelines attached to Standard 2.9.1 in the legally binding Standard?
30. Do you consider that there is a rationale for revising the current requirements for size of type relating to mandatory warning statements on labels?
31. Should other presentation requirements (e.g. prescription of the use of bolding and capitalisation for certain statements) be considered as part of the proposal?
32. Is the current location of the provisions for IFPSDU in Standard 2.9.1 appropriate? If not, why?
33. Do you consider that any of the labelling provisions of Standard 2.9.5 should apply to IFPSDU products? If yes, which requirements and what is your rationale?
34. Are there any additional labelling requirements (e.g. advisory statements) that should be displayed on the labels of IFPSDU that are not already required by either Division 3 of Standard 2.9.1, or by Standard 2.9.5? If yes, why?