23 February 2016
[05–16]

Consultation Paper – Proposal P1028 (amended 4 May 2016)

Infant Formula

Following preliminary consideration of issues related to infant formula including category definitions, composition, labelling and representation of products in the *Australia New Zealand Food Standards Code,* FSANZ calls for submissions to assist the full assessment of the Proposal and the preparation of a draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. 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 quote the correct project number and name. 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.

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) 31 May 2016

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.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

SD1 Definitions and nutrient composition
SD2 Safety and food technology
SD3 Provision of information

Executive summary

Although breastfeeding is the recommended way to feed a baby, a safe and nutritious substitute for breast milk is needed for babies who are not breastfed.

The objective of Proposal P1028 is to revise and clarify standards relating to infant formula in the *Australia New Zealand Food Standards Code* (the Code). Although the standards for infant formula in the Code are, on the whole, functioning adequately, there is scope to improve the clarity of some standards, and to consider the application of Ministerial policy guidance and alignment with international regulations.

This Proposal focuses on the regulations relating to infant formula (suitable from birth to <12 months).

Other infant formula products will be considered in a later Proposal.

The scope of this Proposal is limited to the product category of infant formula. This includes all types of infant formula whether in powder, liquid concentrate or 'ready to drink' form. Infant formula is safe and suitable for consumption by an infant under the age of 12 months, and when consumed as a sole source of nutrition by an infant aged up to four to six months. Although some issues may also be relevant for follow-on formula (for infants aged from 6–<12 months) and/or infant formula products for special dietary use, these two categories are out of scope of P1028.

This Consultation paper provides FSANZ's preliminary assessment of a broad range of issues related to infant formula. These issues were identified from a range of sources including previous stakeholder consultations, other FSANZ projects, and other regulatory and policy activities at a national and international level. The issues covered relate to:

- category definitions
- essential composition
- microbiological criteria
- safe preparation, use and storage
- warning, advisory and other statements
- nutritive substances and novel foods
- contaminants
- food additives and processing aids
- provision of information to inform consumers/caregivers
- representation of products.

The three supporting documents (SDs) contain the detailed assessments for issues.

The paper is structured as a main document with three supporting documents (SDs) which contain the detailed assessments of issues. These SDs cover issues relating to definitions and nutrient composition (SD1), safety and food technology (SD2), and provision of information (SD3). Questions to submitters are asked throughout the SDs, and we are seeking your feedback and related evidence to help inform the future assessment for these issues.

Next steps

Submissions will help inform the assessment process and preparation of a consultation regulation impact statement. There will be further opportunity to comment and provide feedback when the next document is published, which is expected to occur in late 2016.

Questions to submitters are asked throughout the SDs, and we are seeking your feedback to inform the next steps

Abbreviations and glossary

2012 Consultation paper	Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code: Consultation paper, 26 September 2012
AA	Arachidonic acid C20:4, n-6
ABS	Australian Bureau of Statistics
ADI	Acceptable Daily Intake
AI	The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
AIHW	Australian Institute of Health and Welfare
ALARA	As Low As Reasonably Achievable
Amino acids	In this paper, refers to L-amino acids which are the only forms that are biologically active/available
ANZ	Australia and New Zealand
ANZFA	Australia New Zealand Food Authority; the former name for FSANZ
ANZFRMC	The Australia and New Zealand Food Regulation Ministerial Council; the former name for the Australia and New Zealand Ministerial Forum on Food Regulation
ATDS	Australian Total Diet Study
α-TE	Alpha-tocopherol equivalent
Breast milk	A general term for human milk provided from a mother's breast and is described as mature milk (to distinguish it from colostrum).
CAC	Codex Alimentarius Commission
CCFA	Codex Committee on Food Additives
CCFH	Codex Committee on Food Hygiene
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
Codex	Refers to Codex Alimentarius
Complementary feeding	Complementary feeding is the gradual introduction of solid food and fluids along with the usual milk feed (breast milk or infant formula) to an infant's diet (Ministry of Health, 2008).
Crude protein	Crude protein in this paper is based on all N-containing substances in breast milk and is calculated from the total N content multiplied by a conversion factor. Crude protein thus captures amino acid protein and other N-containing substances that do not contribute to protein.
DHA	Docosahexaenoic acid C22:6, n-3
Health	Australian Department of Health
DPA	Docosapentaenoic acid C22:5, n-3

DFE	Dietary folate equivalents
EAR	Estimated Average Requirement
EC SCF	European Commission Scientific Committee on Food
EPA	Eicosapentaenoic acid C20:5, n-3
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FNB:IOM	Food and Nutrition Board, US Institute of Medicine
GL	Guideline Level
GMP	Good Manufacturing Practice
GUL	Guideline Upper Level
HBGV	Health-based Guidance Value
IFPSDU	Infant formula products for special dietary use
Infant	A person under the age of 12 months; as defined in Standard 2.9.1
Infant formula	An infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months; as defined in Standard 2.9.1
Infant formula product	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; as defined in Standard 2.9.1
INS	International Numbering System (for food additives)
IOM	US Institute of Medicine
IFPSDU	An infant formula product for special dietary use, as defined in Standard 2.9.1
JECFA	FAO/WHO Joint Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
LOR	Limit of Reporting
LSRO	Life Sciences Research Organization
Mature breast milk	Breast milk from four weeks post-partum
ML	Maximum Level
MPL	Maximum Permitted Level
MBIE	Ministry of Business, Innovation and Enterprise (New Zealand)
MoH	Ministry of Health (New Zealand)

MPC	Maximum Permitted Concentration
NHMRC	National Health and Medical Research Council (Australia)
NFA	National Food Authority; the predecessor of ANZFA
NMI	National Measurement Institute (Australia)
NPN	Non-protein nitrogen which consists mainly of free amino acids, peptides, and urea. Breast milk contains 20–25% total nitrogen as NPN
NRV	Nutrient Reference Value established by NHMRC & MoH (2006)
Policy Guideline	The Policy Guideline on the *Regulation of Infant Formula Products* notified to FSANZ by the Australia and New Zealand Food Regulation Ministerial Council
PTWI	Provisional Tolerance Weekly Intake
RDI	Recommended Dietary Intake
Requirement	Refers to nutritional requirements that are established by NHMRC/MoH, EFSA, IOM or other expert body for the nutrient amount that denotes a concentration or intake level that supports normal growth and development
Soy-based formula	An infant formula product in which soy protein isolate is the sole source of protein; as defined in Standard 2.9.1
SPS	Sanitary and Phytosanitary Measures Agreement, WHO
TBT	Technical Barriers to Trade Agreement, WHO
TDS	Total Diet Survey/Study
The Code	*Australia New Zealand Food Standards Code*; which ceases to have effect on 1 March 2016
The revised Code	*Australia New Zealand Food Standards Code;* which takes effect on 1 March 2016. A list of standards and relevant schedules is available at: http://www.foodstandards.gov.au/code/Pages/Revised-code-list-of-standards-and-schedules.aspx
True protein	Is based on all N-containing substances minus NPN multiplied by an appropriate conversion factor (e.g. 6.38 for milk proteins). However, the calculation excludes nitrogen that may be metabolically available, e.g. amino acids, small peptides, urea, amino sugars, nucleotides, carnitine and choline
US	United States of America
US FDA	US Food and Drug Administration
WHO	World Health Organization
WHO Code	WHO International code of marketing of breast-milk substitutes (1981)
WHO Guidelines	WHO Safe preparation, storage and handling of powdered infant formula guidelines (2007)
WTO	World Trade Organization

1 Introduction

1.1 The Proposal

Although breastfeeding is the recommended way to feed a baby, a safe and nutritious substitute for breast milk is needed for infants who are not breastfed.

The purpose of Proposal P1028 is to revise and clarify standards relating to infant formula in the *Australia New Zealand Food Standards Code* (the Code). The following objectives are considered in the assessment of issues in the three supporting documents:

- the health and safety of infants are protected
- there is consistency with advances in scientific knowledge
- industry innovation or trade is not hindered.

A broad range of issues relating only to infant formula are addressed, including those relating to category definitions, composition, microbiological safety, labelling and representation of products. The intent of this Consultation paper is to build on FSANZ's current understanding of the issues and seek further information to progress to the assessment of the Proposal.

1.2 The revised Code

All references to the Code in this Consultation paper and supporting documents (SDs) are to the current Code. On 1 March 2016, a revised Code will replace the current Code. For this reason, the corresponding reference to the revised Code is provided in brackets after a reference to the current Code.

The revised Code does not change the effect of current Code provisions. The changes include restructuring the contents of standards, and some information has been moved into separate schedules. For Standard 2.9.1 – Infant Formula Products, some information, including the Guidelines attached to the Standard, now appears in Schedule 29 – Special purpose foods.

1.3 The current standards for the regulation of infant formula

Infant formula is defined in subclause 1(2) of Standard 2.9.1 (2.9.1—3 in the revised Code) as: *an infant formula product represented as a breast milk substitute for infants which satisfies the nutritional requirements of infants aged up to four to six months.* The intent of the current definition and thus of Standard 2.9.1 is that infant formula is safe and suitable for **consumption by an infant under the age of 12 months.** This includes when consumed as a sole source of nutrition by an infant aged up to 4 to 6 months and as part of a progressively diversified diet, from 6 to less than 12 months of age.

Standard 2.9.1 (2.9.1 and Schedule 29 of the revised Code) specifically regulates the compositional and labelling requirements for infant formula (and other infant formula products). The Standard applies to all infant formula 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 current Standard 2.9.1 includes the following key aspects:

- mandatory composition
- restrictions on the addition of substances (vitamins, minerals, food additives and other substances) unless expressly permitted
- labelling and advertising conditions.

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

- Standard 1.3.1 – Food Additives (1.3.1 and Schedule 15 of the revised Code) which regulates the use of food additives in the production and processing of food.
- Standard 1.4.1 – Contaminants and Natural Toxicants (1.4.1 and Schedule19 of the revised Code) sets out the maximum levels of specified metal and non-metal contaminants and natural toxicants in nominated foods.
- Standard 1.6.1 – Microbiological Limits for Food (1.6.1 and Schedule 27 of the revised Code) 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 Standards 1.2.7 – Nutrition, Health and Related Claims (1.2.7 and S4—6 of the revised Code) and 2.9.5 – Food for Special Medical Purposes (2.9.5 of the revised Code).

1.4 Reasons for preparing the Proposal

The overarching purpose of this Proposal is to address regulatory problems with current standards for infant formula, and to provide clarity where there is uncertainty about the intent of the relevant standards. Although the standards for infant formula are, on the whole, functioning adequately, there is scope to improve the clarity of some standards and to consider the application of Ministerial policy guidance and alignment with international regulations.

FSANZ committed to reviewing the standards for infant formula (products) in the Code after receiving policy guidance from the then Australia and New Zealand Food Regulation Ministerial Council[1] in May 2011. Also, the international benchmark for infant formula standards was updated with Codex Alimentarius' revised *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981) in 2007.

P1028 builds on the work of the preliminary review project: Reviewing Standard 2.9.1 – Infant Formula Products. The purpose of the review project was to develop a detailed record and understanding of regulatory issues to inform the development of this Proposal. A key part of the work was the 2012 Consultation paper on the *Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code*, and the corresponding input from stakeholders that we received in submissions. Several issues were raised by stakeholders about the lack of clarity for aspects of Standard 2.9.1 and other relevant standards. The 2012 Consultation paper and related submissions are available on the FSANZ website at Reviewing Standard 2.9.1 – Infant Formula Products[2].

1.5 Procedure for assessment

P1028 is being assessed under the Major Procedure. The Proposal is a large and complex project prepared under section 113(6) of the FSANZ Act. Although the Proposal is suited to a major procedure, it may require more than the minimum two calls for submissions to ensure the large number of issues can be fully assessed. This Consultation paper provides FSANZ's preliminary assessment of a broad range of issues related to infant formula, rather than providing a summary of a formal assessment of the Proposal under section 59 of the FSANZ Act. As such, it does not include a formal summary of our assessment or a consultation regulation impact statement (RIS). These components will form part of future reports.

[1] now the Australia and New Zealand Ministerial Forum on Food Regulation
[2] http://www.foodstandards.gov.au/code/infant/Pages/default.aspx

All issues relating to infant formula will be assessed in this one proposal. If any intractable issues arise, these could be transferred to another proposal to avoid any delays in progressing the other matters.

Issues relating to follow-on formula and IFPSDU will be considered in a separate proposal(s). Gazettal of any changes to the standards for infant formula will not disrupt the regulation of follow-on formula and IFPSDU, which are currently based on the regulation of infant formula.

2 Scope

P1028 relates to infant formula (for infants aged 0-<12 months) only, and to all types of product whether in powder, liquid concentrate or 'ready to drink' form. Although some of these issues may also be relevant to: follow-on formula (for infants aged 6–<12 months) and/or IFPSDU, these two categories out of scope of P1028.

For clarity, the infant formula products included and excluded from the scope of P1028 are:

Infant formula product		**Included ✓ or excluded ✖**
Infant formula	Infant formula based on mammalian sources of milk (e.g. cows' milk, goats' milk)	✓
	Infant formula based on edible constituents of plant origin (e.g. soy)	✓
	Lactose free formula and low lactose infant formula	✓
Follow-on formula	Infant formula based on mammalian sources of milk (e.g. cows' milk, goats' milk)	✖
	Infant formula based on edible constituents of plant origin (e.g. soy)	✖
IFPSDU	Lactose free formula and low lactose infant formula	✖
	For premature or low birth weight infants	✖
	For metabolic, immunological, renal, hepatic and malabsorptive conditions	✖
	For specific dietary use based upon protein substitutes	✖
	Hydrolysed (partially or extensively) infant formula	✖

3 Issues considered

A broad range of issues will be considered under this Proposal. These issues have been identified from a range of sources including previous stakeholder consultations, other FSANZ projects, and other regulatory and policy activities at a national and international level.

The issues for infant formula covered in this paper relate to:

- category definitions
- nutrient composition
- microbiological criteria
- safe preparation, use and storage
- warning, advisory and other statements

- nutritive substances and novel foods
- contaminants
- food additives and processing aids
- provision of information to inform consumers/caregivers
- representation of products.

The summary of assessment in section 5 of this document outlines the issues addressed in each of the supporting documents, and the preliminary view for each issue. All of these preliminary views are subject to consideration of stakeholder comments.

Also provided are the references to the corresponding section in the SDs, where readers can find further analysis and discussion about specific issues.

Questions to submitters are included in the SDs alongside the assessment of issues, and are also collated in Attachment 1 – Summary of questions to submitters.

4 Background

This section provides an overview of the current food regulatory environment relevant to this Proposal. Further background information specific to issues is provided in the relevant SD.

4.1 History of the Code requirements for infant formula

Standard 2.9.1 was finalised in 2002 after 10 years of development under Proposal P93 – Infant Formula (ANZFA, 2002). Related reports are available on the FSANZ website: Proposal P93 - Review of Infant Formula[3].

Since Standard 2.9.1 was finalised, a series of consequential amendments have been made, however, a complete review of the mandatory composition requirements has not been undertaken in this time. A few additional optional substances have been permitted in recent years through applications to FSANZ, such as lutein, inulin-type fructans and galacto-oligosaccharides.

4.2 Regulatory approach to developing or varying food standards

Section 18 of the *Food Standards Australia New Zealand Act 1991* (the 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;

3 http://www.foodstandards.gov.au/code/proposals/Pages/proposalp93reviewofinfantformula/Default.aspx

(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 and New Zealand Food Regulation Ministerial Council[4].

These objectives and principles are all relevant for the revision and clarification of standards. The three primary objectives are paramount given the vulnerability of formula-fed infants, particularly those for which infant formula provides the sole source 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.

As indicated above, 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)[5] was notified to FSANZ in May 2011. The Policy Guideline contains several Specific Policy Principles that address product composition, labelling and advertising. The relevant Specific Policy Principles are discussed in each Supporting Document. Overall the Policy Guideline guides a more rigorous standard of assessment of product composition but in other respects upholds FSANZ's current approaches to labelling. The Policy Guideline also refers to the regulation of infant formula "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 this Proposal and any future applications and proposals on the regulation of infant formula products.

As part of this Proposal, FSANZ will prepare a RIS, which will include a cost benefit analysis. The overall net benefit to the community will need to be considered in any decision to vary the current regulations for infant formula.

4.3 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, and subsequent World Health Assembly (WHA) resolutions. 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 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 promote these products.

Various national authorities have implemented the WHO Code within their respective jurisdictions. Both the Australian and New Zealand governments have each taken several 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 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 through voluntary agreements.

[4] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[5] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Documents/Infant%20Formula%20May%202011.pdf

In Australia, this is through the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (the MAIF Agreement), which is overseen by a MAIF Complaints Tribunal[6]. The Tribunal was established by the Infant Nutrition Council and is managed by St James Ethics Centre, operating in collaboration with the Department of Health (Health) and key stakeholders. Health receives all complaints and refers in-scope complaints to the MAIF Tribunal. The tribunal is independent of industry. Additionally, the marketing of infant formula remains subject to the Australian Consumer Law prohibitions of misleading and deceptive conduct and false representations.

In New Zealand, it is implemented through the *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, which includes the *Infant Nutrition Council Code of Practice for the Marketing of Infant Formula* (CoPMIF), and is overseen by the Ministry of Health (MoH). The MoH receives complaints about potential breaches of the code of practice, and if resolution cannot be reached, MoH then submits them to a Compliance Panel for a decision.

Although 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 12 months of age.

4.4 International and overseas regulations

Requirements for infant formula in overseas markets vary; however, most standards are developed with reference to the international Codex standards.

The international standards of Codex and overseas regulations from the Europe Union, the United States of America and Asian countries 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 WTO. Support for this principle is provided in both the FSANZ Act and the Ministerial Policy Guideline.

The relevant Codex standards for infant formula 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.
- CAC/RCP 66-2008 – Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (Codex code of hygienic practice for infant formula), published in 2008.
- CODEX STAN 193-1995 – General Standard for Contaminants and Toxins in Food and Feed; revised 2015.
- CODEX STAN 192-1995 – General Standard for Food Additives; revised 2015.
- 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.

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

[6] http://www.infantnutritioncouncil.com/code-compliance/australia/

4.5 International infant feeding guidance

WHO and UNICEF jointly developed the Global Strategy for Infant and Young Child Feeding[7] whose aim is to improve—through optimal feeding—the nutritional status, growth and development, health, and thus the survival of infants and young children. The objectives of the strategy are to:

- raise awareness of the main problems affecting infant and young child feeding, identify approaches to their solution, and provide a framework of essential interventions
- increase the commitment of governments, international organisations and other concerned parties for optimal feeding practices for infants and young children
- create an environment that will enable mothers, families and other caregivers in all circumstances to make - and implement - informed choices about optimal feeding practices for infants and young children.

The WHO released guidelines titled *Safe Preparation, Storage and Handling of Powdered Infant Formula* (WHO PIF guidelines) in 2007. These were based on a 2006 microbiological risk assessment by FAO and WHO, which was undertaken primarily to investigate growing concerns about the risk to formula-fed infants from exposure to the pathogen *Cronobacter* species from infant formula products.

4.6 National infant feeding guidance

Australia and New Zealand each have national guidance on infant feeding. In Australia, the National Health and Medical Research Council (NHMRC) released the *Infant Feeding Guidelines – Information for Health Workers* in 2012. The New Zealand guidelines are part of the *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2)*, which were published by the MoH in 2008 and updated in December 2012 (MoH, 2013). Both sets of infant feeding guidance contain information relevant to some of the issues considered in this Proposal, particularly those related to reducing microbiological hazards associated with the preparation, use and storage of infant formula.

4.7 The current marketplace

Infant formula is traded globally. Products sold in Australia and New Zealand are either manufactured locally (in Australia or New Zealand) or imported. Although some infant formula manufactured locally is sold in Australia and New Zealand, others are for export only, particularly to Asian markets.

4.7.1 Manufacture for domestic use

Australia and New Zealand are considered as a single market with locally manufactured products produced in Australia or New Zealand. Most brands available on the domestic market have both a ‘standard’ and ‘premium’ range of infant formula. ‘Premium’ products usually contain added optional ingredients, such as lutein and omega-3 fatty acids.

There are a number of small and large companies that manufacture, export, import and/or market infant formula in Australia and New Zealand. Comprehensive data on the size of the market of infant formula manufactured in and imported into Australia and New Zealand are difficult to obtain. Information, which comes from a variety of sources, may not be comparable. For example, grocery volume sales data may not specify whether products

[7] http://www.who.int/nutrition/publications/infantfeeding/9241562218/en/

include toddler milks as well as infant and follow-on formulas. In addition, import data on milk powders may not distinguish between infant formula and other milk-based products.

4.7.2 Manufacture for export

Some infant formula manufactured in Australia and New Zealand is 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 Australia, export of a food that is known as a 'prescribed good' is subject to the *Export Control Act 1982* and its subordinate legislation, primarily the *Export Control (Prescribed Goods – General) Order 2005* and the *Export Control (Milk and Milk Products) Orders 2005*. Dairy (i.e. milk and milk products) are prescribed goods. As such, milk products including infant formula products, manufactured for export as food, and their ingredients, must comply with requirements in the orders on production, processing, transport, identification and traceability. In addition, the *Export Control (Milk and Milk Products) Orders 2005* set out specific requirements to ensure exported milk and milk products are fit for human consumption or further manufacturing, that they meet importing country requirements, and can be identified and traced if a recall is required. Schedule 6 of this Order specifies that milk and milk products for export as food and their ingredients must comply with the Food Standards Code in relation to composition, processing aids, microbiological limits, contaminants, natural toxicants and residues, unless they comply with an alternative requirement from the importing country.

Certain products in Australia are not subject to export legislation. The *Export Control Act 1982* does not apply to dairy products including infant formula and their ingredients exported to New Zealand. Similarly, small consignments of milk and milk products, and some dairy products exported from Australia are not regarded as prescribed goods (e.g. ice cream and bovine colostrum) and are therefore not subject to the *Export Control Act*, unless an importing country requires health certification for that type of product.

Requirements for foods exported from New Zealand are regulated through several pieces of legislation, those relevant to infant formula include:

- the *Animal Products Act (APA) 1999*, the *Animal Products (Dairy) Regulations 2005*, and associated tertiary Notices. This Act applies to all animal products including dairy products.
- the *Australia New Zealand Foods Standards Code*, issued as a food standard under Part 2 of the *Food Act 2014*.

In New Zealand, infant formula that is 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.

4.7.3 Importing for sale in Australia and New Zealand

All foods produced or imported for sale in Australia and New Zealand are required by law to comply with the composition and labelling requirements of Code, state and territory food legislation, and other legislative requirements.

Australian imported food legislation includes:

- *Imported Food Control Act 1992*
- Imported Food Control Regulations 1993
- Imported Food Control Order 2001.

For imported foods, the relevant standards in the Code are enforced under the *Imported Food Control Act 1992* and are implemented through the Australian Government's Imported Food Inspection Scheme (IFIS). The Australian Department of Agriculture and Water Resources (Agriculture) has operational responsibility for inspecting and sampling of food when it reaches the border. Inspections are risk and intelligence-based, targeting food products that may pose a risk to public health or may not comply with legal requirements. In addition to the role of Agriculture at the border, state and territory enforcement agencies are responsible for enforcing the Code for all food available for sale within their jurisdictions, including imported food.

In addition to the Code, infant formula products imported into New Zealand must also comply with:

- the *Food Act 2014* and any other legislation made under the Food Act, such as all general food standards, and the following import standards:
    - Food (Importer Listing) Standard 2008
    - Food (Importer General Requirements) Standard 2008
    - Food (Imported Milk and Milk Products) Standard 2009.

5 Summary of the preliminary assessment

The following three tables, one for each of the SDs: (1) definitions and nutrient composition, (2) safety and food technology, and (3) provision of information, provide a summary of the assessment of the main issues addressed in this paper. The summary provides the preliminary view for each issue, which may be a proposed approach or a request for further information. The preliminary view is subject to consideration of stakeholder comments. Readers are strongly encouraged to refer to the relevant section of the SD for the more detailed assessment and discussion of an issue. A reference to the corresponding section in the SD is provided in the tables.

Table 5.1: Definitions and Nutrient Composition (Supporting Document 1)

Topic and specific issues		Preliminary view	Section (in SD1)
Definitions and terminology	Definition of infant formula product	Standard 2.9.1 includes this as an overarching definition to capture all products regulated by the Standard. There is no similar overarching definition in Codex STAN 72-1981. Small modifications have been suggested by stakeholders, and the definition was recently modified through P1025 – Code Revision. We consider that the definition developed in Proposal P1025 is appropriate and propose to retain this.	2.1
	Definition of infant formula	The definition of infant formula relates to product representation and purpose in the diet of infants up to certain age. There is some confusion around the age range of the infant formula (in relation to the follow-on formula product categories). Stakeholders proposed alternative definitions for consideration which could provide clarity by eliminating the confusion around age range. We are seeking further views from stakeholders to inform a proposed approach.	2.2
Protein	Content	Protein amounts are aligned already, however there is growing interest in lowering the requirements to potentially lower risk of obesity in childhood. FSANZ considers that more evidence is required to demonstrate the advantages of lower protein intakes for infants. Thus we propose retaining the current total protein content and range in Standard 2.9.1 consistent with Codex STAN 72-1981.	3.1

Topic and specific issues		Preliminary view	Section (in SD1)
	Calculation of protein: nitrogen conversion factors	Currently Standard 2.9.1 specifies two conversion factors: 6.38 for milk proteins and 6.25 for all other protein sources. This is effectively aligned with Codex STAN 72-1981. However soy proteins have a different molecular weight and therefore different total nitrogen content. At this stage, we propose that only two factors should be specified, thus the conversion factor of 6.25 should apply to mammalian milk and the conversion factor for soy protein sources should be 5.71.	3.2
	Protein source	Standard 2.9.1 does not specify the source of protein that can be used; the definition of an infant formula product requires that the product must be based on milk or other edible food constituents of animal or plant origin. Codex STAN 72-1981 defines infant formula as a product based "on milk of cows or other animals or mixture thereof and other ingredients proven to be suitable for infant feeding." Both standards set minimum requirements for protein content and essential amino acid amounts to align with the reference protein i.e. breast milk, regardless of protein source. Codex STAN 72-1981 has some specific differences in protein requirements which relate to protein source e.g. different minimum amounts for protein are listed for cows' milk protein and soy protein, noting other minimums may apply to non-cows' milk protein. Our preliminary view is that the current sources of protein are appropriate.	3.3
	Protein quality	Stakeholders suggested that FSANZ should consider the recent FAO/WHO report recommending the Digestible Indispensable Amino Acid Score (DIAAS) as a protein quality calculation methodology. FSANZ considers that the amino acid composition of breast milk should still be the reference for determining an infant's amino acid requirements. This approach aligns with Codex i.e. the minimum recommendations under Codex STAN 72-1981 are based on the average amount of amino acids present in breast milk, rather than a protein scoring system. It is FSANZ's preliminary view that the amino acid composition of breast milk should remain the reference. Therefore, it appears appropriate not to adopt the PDCAAS or DIAAS methods.	3.4

Topic and specific issues		Preliminary view	Section (in SD1)
	Amino acid content	The minimum requirements for amino acids in infant formula are mainly based on 'typical' amino acid profiles of breast milk. Some differences exist between the minimum amount of some of the 11 required amino acids in Standard 2.9.1 and Codex STAN 72-1981. We propose aligning the minimum levels of isoleucine, leucine, lysine, threonine, tryptophan and valine with those in Codex STAN 72-1981. However, FSANZ's preliminary view is to maintain the current expression for two sulphur amino acids and aromatic amino acids in specifying the minimum for Cys and Phe and the summed values of SAA and AAA because the expression is clear and not subject to possible misinterpretation. In addition, our view is to retain the current minimums for the SAA and AAA in Standard 2.9.1. However, feedback from submitters will assist in further assessment.	3.5
Fat	Fat content	Standard 2.9.1 and Codex STAN 72-1981 prescribe the same minimum for total fat; the maximum fat is higher in Standard 2.9.1. We propose to retain the minimum and lower the maximum to align with Codex STAN 72-1981.	4.1
	Essential fatty acid composition	There are requirements for the essential omega 6 and omega 3 fatty acids, Linoleic acid (LA 18:2,n-6) and α- linolenic acid (ALA, 18:3,n-3) in both standards, although there are some differences. Overall, we consider that alignment with Codex STAN 72-1981 is appropriate and unlikely to pose a risk to infants for the following essential fatty acids provisions: • maximum (GUL) for LA • minimum amount for ALA • no prescribed maximum for ALA • LA: ALA ratio range. However, alignment with the minimum amount of LA needs further consideration and submitter input would be helpful. The evidence supports maintaining the Standard 2.9.1 minimum amount for LA rather than aligning with Codex. The amount of LA and ALA in Standard 2.9.1 is expressed as a proportion of total fatty acids. Codex STAN 72-1981 expresses the essential fatty acid requirements as an amount per energy unit. We propose to continue to require the amount of essential fatty acids be expressed as a proportion of total fatty acids.	4.3

Topic and specific issues		Preliminary view	Section (in SD1)
	Long chain polyunsaturated fatty acids (LC-PUFAs)	FSANZ considers that a mandatory minimum amount of DHA is not supported and retaining the voluntary permission is appropriate and is unlikely to pose a risk to infant health. Maintaining this voluntary permission would not impact on the manufacture of infant formula. However, maintaining the permissions as they are stated in Standard 2.9.1 may provide added clarity by explicitly permitting arachidonic acid and setting a maximum (rather than adopting the Codex approach). We consider that the intention of the approaches will remain aligned with Codex STAN 72-1981. Therefore, FSANZ proposes to retain the current EPA: DHA ratio requirement in Standard 2.9.1 to reduce the risk of a potential metabolic imbalance between n-3 and n-6 LC-PUFAs.	4.4
	Source of fat	Standard 2.9.1 does not specify or prohibit any particular sources of fat. Instead, criteria for the fat composition in infant formula are outlined. Fatty acids which are considered harmful are restricted or limited to protect infants from adverse health consequences. A similar approach is taken in Codex STAN 72-1981. We are seeking feedback from stakeholders on whether this approach remains appropriate.	4.5

Topic and specific issues		Preliminary view	Section (in SD1)
	Restrictions on certain fats: • Medium-chain triglycerides (MCT) • Trans-fatty acids • Myristic acid (C14:0) and lauric acids • Phospholipids • Erucic acid	FSANZ considers the current limitations on the presence of MCT in Standard 2.9.1 remain appropriate. However this would not be consistent with Codex. Stakeholder feedback would be helpful to determine the final approach. We propose to lower the maximum amount of trans fatty acids to 3% total fatty acids. However, we are seeking feedback as infant formula companies may need to adjust their formulations to comply with the lower maximum amount permitted under Codex. We consider it is appropriate to maintain no restriction on the levels of myristic and lauric acids in Standard 2.9.1 in line with the recent expert opinion. This approach is inconsistent with Codex but may be less restrictive for infant formula companies. Standard 2.9.1 does not contain provisions that relate to phospholipids in infant formula however, Codex STAN 72-1981 specifies a maximum permitted amount of phospholipids. FSANZ's preliminary view is that total phospholipids should be restricted but that more information is needed before a maximum could be established. The evidence does not support alignment with the higher Codex maximum. Any final maximum amount needs to take account of the level of lecithin in infant formula. We are seeking further input from stakeholders As Standard 2.9.1 is currently aligned with Codex, FSANZ considers an appropriate risk management measure is to retain the limit on erucic acid.	4.6
Carbohydrate	Definitions and calculations relevant to carbohydrate	Several definitions relevant Standard 2.9.1 were previously located across different standards in the Code. All of these definitions now apply throughout the revised Code, and section S11—3 sets out how to calculate available carbohydrate and available carbohydrate by difference. This clarifies previous confusion about whether definitions located in other standards did apply to Standard 2.9.1. FSANZ's preliminary view is that definitions and the method of calculation relevant to carbohydrate identity in the revised Code are appropriate for infant formula.	5.1

Topic and specific issues		Preliminary view	Section (in SD1)
	Introduction of maximum and minimum level	Standard 2.9.1 does not directly specify a minimum or maximum level of carbohydrate for infant formula as it is indirectly controlled by the regulations on protein, fat and energy content. Codex STAN 72-1981 lists a carbohydrate range of 2.2–3.3 g/100 kJ. We consider it appropriate to retain the current approach by not specifying a minimum and maximum amount for carbohydrate, noting this is in effect aligned with the Codex range.	5.2
	Carbohydrate source	Standard 2.9.1 does not include any provisions relating to the source of carbohydrate in infant formula. Codex STAN 72-1981 includes guidance on the type of digestible carbohydrate to be used (e.g. 'preferred' sources of carbohydrate and that sucrose and fructose" should be avoided"), but this is not mandatory. As evidence is not strong for mandatory restrictions on the source of carbohydrate in infant formula, FSANZ's preliminary view is to maintain the current provisions in Standard 2.9.1. We recognise this will not align with Codex STAN 72-1981. Submitter views are sought.	5.3
Energy	Energy content	The Code's minimum energy amount is aligned with Codex STAN 72-1981, however its maximum amount for energy is higher. We propose to reduce the maximum amount to align with that in Codex STAN 72-1981.	6.1
	Calculation of energy density	Standard 2.9.1 specifies that the energy density of infant formula must be calculated using only the energy contributions from fat, protein and carbohydrate ingredients, using the equation and energy factors specified for nutrition labelling in Standard 1.2.8. There is some confusion as the Code also states that the nutrition labelling requirements do not apply to infant formula. FSANZ expects that the relevant modifications in the revised Code have resolved that confusion. Our preliminary view is to maintain application of energy factors for calculating the energy density of infant formula. Furthermore, that the Code's energy factors should continue to apply to infant formula including both energy factors for available and unavailable carbohydrate.	6.2

Topic and specific issues		Preliminary view	Section (in SD1)
Vitamins, minerals and electrolytes	Approach to setting guidelines or maximum amounts	In Standard 2.9.1 all nutrients have either a maximum amount or a recommended guideline maximum amount (referred to as GULs). Codex uses a similar approach, though there are some differences as in the Codex standard GULs are assigned to 20 micronutrients compared to 14 in the Code. The GULs in the Code are not binding and serve as guidance for industry in designing formulations. The 2009 audit of the legal efficacy of the Code queried whether the use of GULs in the guideline is appropriate. Thus we are considering whether the GULS should be formally incorporated into Standard 2.9.1. Stakeholders support the advisory maximums being retained in the Code. The nutrition assessment identified no evidence to indicate that a voluntary maximum would pose a risk to infant health for most nutrients. Thus, FSANZ's preliminary view that it is appropriate for some nutrients to retain a GUL in Standard 2.9.1, and for others to be amended from a prescribed maximum to a GUL to align with Codex (as summarised in Table 7.2 of SD1). Folate, phosphorus and selenium require further information.	7.1

Topic and specific issues		Preliminary view	Section (in SD1)
Vitamins, minerals and electrolytes	Vitamin dietary equivalents and conversion factors • Vitamin A • Folate • Vitamin E • Niacin	Standard 2.9.1 and Codex STAN 72-1981 differ in the way in which vitamin equivalents are managed and expressed. • Vitamin A: FSANZ's preliminary view is to exclude β-carotene from the total amount of vitamin A in infant formula in light of uncertainty around its bioavailability, and also to support expressing of vitamin A requirements in units of µg alone (rather than RE), as this clarifies that β-carotene should not contribute to the vitamin A content. The Code would then align with Codex and other international regulations in relation to β-carotene contribution to vitamin A content but will differ in relation to the vitamin A units. • Folate: As neither Codex STAN 72-1981 nor Standard 2.9.1 currently use dietary folate equivalents (DFE) to express the folate content of infant formula, our preliminary view is to retain units of µg folate although this differs from Codex STAN 72-1981. It is unclear whether allowing for natural folate but not adopting the DFE units would make any difference. We are seeking further information from stakeholders to inform future assessment. • Vitamin E: Standard 2.9.1 lists the vitamin E units as mg vitamin E referring to α-tocopherol (α-TE). Codex STAN 72-1981 lists units of vitamin E as α-TE although a note specifies that 1 mg α-TE = 1 mg d-α-tocopherol. It is FSANZ's preliminary view that mg α-TE should be adopted as the units for vitamin E to indicate the relative activities of natural and synthetic forms of alpha-tocopherol. The revised Code specifies conversion factors in section S1—5 for some of the synthetic forms of vitamin E permitted in infant formula and this list could be completed as part of this Proposal if relevant to infant metabolism. Both Standard 2.9.1 and Codex STAN 72-1981 specify a minimum amount of vitamin E per g of PUFA. Standard 2.9.1 sets a minimum amount of 0.5 mg vitamin E per g of PUFA. Codex STAN 72-1981 also lists 'factors of equivalence' from 0.5 mg/g for LA and increasing in increments of 0.25 mg/g to 1.5 mg/g for DHA according to the number of fatty acid double bonds in individual PUFAs in an infant formula. These factors are applied to determine the minimum amount of vitamin E for a particular PUFA mixture in infant formula. Following assessment, FSANZ's preliminary view is that the current approach to vitamin E requirements relating to the PUFA content of infant formula retained. • Niacin: We consider it is appropriate to retain the requirement for niacin amount in infant formula to be limited to the form pre-formed niacin.	7.2

Topic and specific issues		Preliminary view	Section (in SD1)
Vitamins, minerals and electrolytes	Permitted range for micronutrients: minimum and maximum amounts • Aligned with Codex • Could be aligned with Codex • Uncertainty whether alignment is appropriate	A permitted range is established for each of the 25 vitamins, minerals and electrolytes required in infant formula. The approach adopted in Standard 2.9.1 and the Codex standard is similar, with both setting minimum amounts and either a maximum amounts or a GUL for the same range of micronutrients although the actual minimum and maximum amounts may vary. • Aligned with Codex: We propose to retain the current minimum and maximum amounts for both vitamin A and vitamin D, which are already aligned with Codex STAN 72-1981. • Could be aligned with Codex: Our preliminary view is to align the minimum and maximum amounts for vitamin B_6, vitamin B_{12}, pantothenic acid, riboflavin, thiamine, folate, niacin (preformed), vitamin E, vitamin K, biotin, calcium, manganese, magnesium, copper, potassium, chloride and sodium. However, whether to align the amounts for phosphorus requires further consideration. • Uncertainty whether alignment is appropriate: Further information is sought from stakeholders to inform further assessment for vitamin C, chromium, molybdenum, iodine, zinc, iron and selenium. For phosphorus, it is FSANZ's preliminary view is that it is appropriate to change the current maximum (25 mg/100 kJ) in Standard 2.9.1 to a GUL of 24 mg/100 kJ in alignment with Codex. We also propose to adjust Standard 2.9.1 to align with the minimum Ca:P ratio of 1:1.	7.3

Topic and specific issues		Preliminary view	Section (in SD1)
	Permitted forms	A comparison of the permitted forms of vitamins, minerals and electrolytes in Standard 2.9.1 with the list in Codex CAC/GL 10-1979 shows there are some differences. FSANZ's preliminary views on the nutrient forms for the following individual vitamins, minerals and electrolytes are: • Vitamin A: Retain the permitted forms of vitamin A, providing alignment between the Code and Codex. However, we seek further information on the justification to retain β-carotene as a provitamin A form in Standard 2.9.1. • Vitamin D: Retain the two permitted forms (i.e. both vitamin D_3 (cholecalciferol) and vitamin D_2 (ergocalciferol)). • Pantothenic acid: Not appropriate to permit DL-panthenol acid for use in infant formula. We are seeking further information and technological justification for calcium D-pantothenate and sodium D-pantothenate as forms suitable for use in infant formula. • Niacin: Not to permit nicotinic acid for use in infant formula • Copper: Seeking further information on the technological justification for the use of cupric carbonate in infant formula to inform further assessment. • Magnesium: Seeking further information on the technological justification for the use of magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid in infant formula to inform further assessment. • Potassium: Seeking further information on the technological justification for the use of potassium L-lactate in infant formula to inform further assessment. • Zinc: Seeking further information on the technological justification for the use of zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate) in infant formula to inform further assessment. • Iron: Seeking further information on the technological justification for the use of ferric citrate, ferrous bisglycinate and ferrous sulphate in infant formula to inform further assessment.	8

Topic and specific issues		Preliminary view	Section (in SD1)
Other optional substances	Choline	Standard 2.9.1 permits choline as an optional substance in infant formula, whereas Codex STAN 72-1981 prescribes the mandatory addition of choline. Both standards specify the same minimum amount, but different maximum amounts. Also Codex STAN 72-1981 lists the maximum as a GUL. Choline is now classed as an essential nutrient in the Australia and New Zealand Nutrient Reference Values; however there is no upper level. Our preliminary view is that choline should be listed as a mandatory substance in infant formula with a mandatory range of 1.7-12 mg/100 kJ. We are seeking information on the technological justification for the use of choline, choline citrate and choline hydrogen tartrate as permitted forms of choline in infant formula to inform further assessment.	9.1
	L-carnitine	Standard 2.9.1 permits L-carnitine as an optional substance, whereas Codex STAN 72-1981 prescribes the mandatory addition of L-carnitine. Our preliminary view is that L-carnitine should be listed as a mandatory substance in infant formula with a mandatory range of 0.3–0.8 mg/100 kJ. We are seeking information on the technological justification for the additional forms of L-carnitine (L-carnitine hydrochloride and L-carnitine tartrate) and evidence to demonstrate safety of these forms in infant formula to inform future assessment.	9.2
	Inositol	Standard 2.9.1 and Codex STAN 72-1981 permit the same range 1.0–9.5 mg/100 kJ, although Codex lists inositol as a mandatory inclusion with a GUL. Our preliminary view is that it is appropriate to prescribe the mandatory inclusion of inositol in infant formula at the current minimum amount (which already aligns with Codex STAN 72-1981) and list a GUL of 9.5 mg/100 kJ. We also consider listing the permitted form of inositol as myo-inositol will provide clarity.	9.3

Topic and specific issues		Preliminary view	Section (in SD1)
	Nucleotides	Standard 2.9.1 permits the optional addition of five specific nucleotides to infant formula, and outlines a minimum and maximum for each of the permitted nucleotides. It also states that “infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5’ monophosphates”. Codex STAN 72-1981 permits the addition of nucleotides at the discretion of national authorities. Comparison of the permitted forms of nucleotides in each standard shows they are already aligned. FSANZ is aware that there has been confusion amongst submitters between the prescribed maximum amount for individual nucleotides, and the combined total limit of nucleotides. The revised Code clarifies this issue. FSANZ’s preliminary view is to retain the current permission and maximum combined total limit of nucleotides. We are seeking feedback on the clarity of the drafting in the revised Code.	

Table 5.2: Safety and Food Technology (Supporting Document 2)

Topic and specific issues		Preliminary view	Section (in SD2)
Microbiological criteria	Microbiological Criteria for Infant Formula	This issue is being considered in Proposal P1039 – Microbiological Criteria for Infant Formula, and therefore will not be considered as part of Proposal P1028. Proposal P1039 proposes that the existing microbiological limits for powdered infant formula (and follow-on formula) be replaced with microbiological food safety criteria for *Salmonella* and *Cronobacter spp.*, based on the principles within Codex CAC/RCP 66-2008.	2

Topic and specific issues		Preliminary view	Section (in SD2)
Preparation, use and storage directions to manage microbiological hazards	Directions to prepare bottles individually	FSANZ considers it is appropriate to retain the current labelling requirement for an instruction that each bottle should be prepared individually.	3.2
	Directions for the storage of made up formula	The evidence demonstrates that it is safe to store prepared formula for up to 24 hours in the refrigerator, if the refrigerator temperature is operating at 4°C or less. FSANZ considers that the current labelling requirement for an instruction (that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours) remains appropriate.	3.3
	Directions on water used to reconstitute powdered infant formula	FSANZ is of the view that the current requirement to use cooled previously boiled water does not need to be modified, as there are no public health and safety concerns with caregivers following labelling directions regarding the use of potable, previously boiled water when the other instructions are followed. The requirement also reflects both the Australian and New Zealand infant feeding guidance. FSANZ is therefore proposing to maintain this labelling requirement as one of a group of risk reduction strategies.	3.4
	Discarding leftover formula	The Code requires the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded. FSANZ is proposing to retain the existing requirement based on findings from studies examining this practice and as it is consistent with Australian and New Zealand infant feeding guidance, and the WHO powdered infant formula guidelines.	3.5
	Standardised directions for preparation and use	The words and pictures for the directions for preparation and use of infant formula are not prescribed. FSANZ has received little evidence to indicate that caregivers are confused by the presentation and information differences in directions between products. FSANZ proposes to maintain the existing overarching requirement, which does not prescribe the words and pictures for the instructions.	3.6

Topic and specific issues		Preliminary view	Section (in SD2)
Other safe preparation and storage issues	Date marking of food	FSANZ is unaware of any specific issues concerning date marking for infant formula. It is proposing to maintain the existing requirement that the label must carry a date mark.	4.1
	Storage instructions for opened infant formula	The Code requires the infant formula label to contain storage instructions covering the period after the package is opened. No issues have been raised by stakeholders and the current approach aligns with Codex STAN 72-1981 specifications. Therefore, FSANZ is proposing to maintain the existing requirement.	4.2
	Measuring scoop	There is concern from stakeholders that some caregivers unintentionally use the wrong measuring scoop (for the particular product) to prepare powdered infant formula. Unintentional over-concentration or dilution of infant formula can have acute and chronic negative health effects for the infant. Although there is some evidence that caregivers may misuse the scoop in some way during preparation of infant formula, there is little evidence that this is a result of confusion or lack of understanding of the current labelling instructions. Without stronger evidence of a problem there is limited rationale to consider further the suggestion to standardise the scoop size. Also, standardisation of the scoop size would require all products to have the same powder density, and would present a number of technical challenges and require widespread reformulation of products. There is likely to be significant cost associated with reformulating products to achieve a standardised powder to water ratio for all products. Similarly, consideration of mandating the statement “that only the enclosed scoop should be used” may not be justified given the lack of evidence of a problem. FSANZ notes that some industry stakeholders said they would not oppose this change, if there was evidence to justify the change. All products surveyed on the Australian and New Zealand retail market currently include the statement about using the enclosed scoop on the label, and the majority use the exact wording *only the enclosed scoop should be used.*	4.3

Topic and specific issues		Preliminary view	Section (in SD2)
Other safe preparation and storage issues	Inaccurate volume indicators on infant feeding bottles	There is concern that volume indicators on some infant feeding bottles available in Australia and New Zealand are not accurate. Use of these indicators to measure the volume of water to prepare formula may lead to errors in the ratio of water to powder used, and result in the infant formula being either over-concentrated or excessively diluted. Unintentional over-concentration or dilution of infant formula can have acute and chronic negative health effects for the infant. FSANZ acknowledges the issue of inaccurate volume measure indicators on some infant feeding bottles sold in Australia and New Zealand. As infant feeding bottles are regulated as general consumer goods they are not covered by the Code, and as they are not solely for the purpose of feeding infant formula to infants, this issue is outside the scope of this Proposal and will not be considered further by FSANZ.	4.4
Warning, advisory and other statements	Legibility requirements for warning statements	FSANZ has not identified any evidence to indicate that the current legibility requirements for infant formula requirements are inadequate, and proposes to maintain the existing requirements set out in Standard 2.9.1.	5.1
	Adding other foods to formula	It is recommended that powdered infant formula is prepared according to the instructions on the product label, and that it should not be concentrated, diluted or have any other foods added to it unless on the advice of a health practitioner. Some stakeholders cited anecdotal evidence of caregivers adding other foods, particularly baby cereal products, to bottles of infant formula. This practice is often on the assumption that it will delay hunger and prolong sleep for the infant. Comments also suggested another reason these foods are added is to reduce the cost of feeds. FSANZ search of the literature suggests that this may be common practice, though it is not possible to estimate the prevalence of this behaviour. Options to communicate to caregivers that other foods should not be added to infant formula may need to be considered. FSANZ is seeking stakeholder comments on three questions to inform further analysis on this issue.	5.2

Topic and specific issues		Preliminary view	Section (in SD2)
	Statement on protein source	The Code requires the infant formula label to contain a statement of the specific source, or sources, of protein in the product. FSANZ does not consider that there is a need to mandate a list of permitted protein sources for declaration on the label, as protein quality and quantity are regulated in the Code for health and safety reasons. We are proposing to maintain the current requirement to label the protein source as it ensures correct identification of products suitable for infants with particular dietary requirements.	5.3
	Co-location of protein source statement with the name of the food	The Code requires the mandatory statement about protein source to be located immediately adjacent to the name of the infant formula (i.e. the prescribed name 'Infant Formula'). The Code does not prescribe where the prescribed name (and by association, the protein source statement) should be located on the label. Preliminary analysis suggests there is a lack of regulatory clarity on this issue. We are proposing to maintain the existing requirement, and will consider how to make it clearer in the Code that the name of the food is the prescribed name. Also, we are seeking further information from stakeholders to assess whether the position of this information on the label should be prescribed.	5.4
	Warning statement about following instructions exactly	The Code requires that the labels of infant formula display warnings about following the instructions exactly to ensure the correct preparation of the powdered, concentrated, or 'ready-to-drink' formula. The wording of these warning statements is prescribed. A few stakeholders suggested to either amend the existing statement on following instructions exactly, or to require an additional warning statement that discouraged this practice. There is anecdotal evidence that while some caregivers do not follow instructions exactly when preparing formula, this is often a deliberate practice to address infant hunger and prolong sleep (not related to a misunderstanding of label statements). Several submissions noted there is evidence that suggests a high level of compliance with the information on the preparation of infant formula in general. There is no evidence to show that the current statement influences whether the instructions are followed by caregivers. At this stage, we are not proposing any changes to this requirement.	5.5

Topic and specific issues		Preliminary view	Section (in SD2)
	Warning statement that 'breast is best'	The Code requires an infant formula label to contain the prescribed warning statement: *Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice*. Some stakeholders support amending the statement to a risk-based statement about the risks to infant health of not breastfeeding. Others are opposed to a risk-based statement approach. FSANZ recognises the body of evidence supporting the importance of breastfeeding for infants. However, we consider there is sufficient rationale to retain the existing 'breast is best' statement.	5.6
	Statement that infant formula product may be used from birth	The Code requires a statement indicating that the infant formula product may be used from birth, in the case of infant formula. We are of the view that the statement remains relevant and is proposing to maintain the requirement.	5.7
	Statement about age to offer foods in addition to formula	The Code requires a statement on infant formula labels indicating that infants over the age of 6 months should be offered foods in addition to the infant formula product. This statement is consistent with current Australian and New Zealand infant feeding guidance, and with Codex. We consider this labelling statement is appropriate and propose to maintain this requirement.	5.8
	Guidance statement about additional vitamin and mineral supplementation	The Guidelines attached to Standard 2.9.1 (S29—10 in the revised Code) include a guideline statement regarding additional vitamin and mineral supplementation; to the effect that consumption of vitamin or mineral preparations are not necessary. As this is guidance only, companies can choose whether to provide this information on their product labels. Background information is provided on the issue and gaps in the evidence base are identified. We are seeking further information to consider the relevance of the advice in the context of public health and safety, and the regulatory and non-regulatory options available to address this issue.	5.9

Topic and specific issues		Preliminary view	Section (in SD2)
	Prescribed name	'Infant Formula' is a prescribed name, and the Code requires the label on a package of food to include the prescribed name of the food if one is prescribed. The requirement to use the prescribed name 'Infant Formula' was put in place to alert consumers to the appropriate formula choice for infant age and stage. We consider the prescribed name 'Infant Formula' is appropriate and propose to maintain this labelling requirement.	5.10
Nutritive substances and novel foods in infant formula		FSANZ is currently undertaking work on the regulation of nutritive substances and novels foods under Proposal P1024 – Nutritive Substances and Novel Foods. Proposal P1028 will consider the regulation of nutritive substances and novel foods in infant formula, as infant formula products are excluded from the scope of P1024. FSANZ will consider the basis for requiring pre-market assessment of new substances for use in infant formula, and subsequently the procedure and information required to determine the safety and the nutritive or health benefit of these substances. Background information is provided on the intent of the Code, problems with the current definitions of nutritive substance and novel food, the differing interpretations of the provision for nutritive substances naturally present in an ingredient, stakeholder views, ministerial policy guidance, and international and overseas approaches. The review of the regulatory approach for the addition of new substances to infant formula will progressively develop over the course of P1028. At this stage, we are seeking input on the principles for the overarching regulatory approach.	6
Contaminants	Acrylonitrile	The ML for acrylonitrile of 0.02 mg/kg applies to all foods, including infant formula, and is listed in the general contaminants standard (Standard 1.4.1). The intent is that the MLs in Standard 1.4.1 apply to infant formula as a default if a specific contaminant is not specifically listed in Standard 2.9.1.	7.2
	Aluminium	FSANZ considers it is appropriate to retain a ML for aluminium. We propose to set an ML of 0.05 mg/100 mL to apply to all infant formula. However we are seeking information from stakeholders on the feasibility of this for soy-based infant formula.	7.3

Topic and specific issues		Preliminary view	Section (in SD2)
	Arsenic	There is no current ML for arsenic (inorganic) or 'arsenic, total' in the Code for infant formula. Due to the limited detections of arsenic in infant formula, there is no evidence of a risk to public health and safety from residues of arsenic in infant formula. Therefore, we see no specific need to establish an ML for arsenic (inorganic) for infant formula in the Code. This approach is consistent with Codex.	7.4
	Lead	The Code includes an ML for lead of 0.02 mg/kg in infant formula. We are proposing to lower the ML for lead to 0.01 mg/kg in infant formula in view of the withdrawal of the PTWI by JECFA and the recent adoption of the lower level by Codex.	7.5
	Melamine	No MLs have been established for melamine in the Code. However, Codex has an ML for melamine in powdered information formula of 1 mg/kg and liquid infant formula (as consumed) of 0.15 mg/kg. Based on the absence of any associated risk, and that the Codex ML was specifically set to control illegal adulteration of infant formula, there is no rationale for the incorporation of the Codex ML for melamine into the Code.	7.6
	Tin and inorganic tin compounds	The Code includes an ML of 250 mg/kg for tin in all canned foods. Codex takes a similar approach, with a ML of 250 mg/kg for 'canned foods (other than beverages)'. We consider there is no case for the exception of infant formula *per se* from the scope of the tin ML in the Code. Also, the general contaminant definition for tin as a metal in Standard 1.4.1 should be applied to infant formula.	7.7
	Vinyl chloride	The Code includes a ML of 0.01 mg/kg for vinyl chloride in all foods except packaged water. Codex has established a GL for vinyl chloride that is identical to the ML in the Code. We consider the current ML for vinyl chloride remains relevant, and no amendment to the level in the Code is considered necessary.	7.8
	Location of MLs in the Code	FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, including those set for infant formula.	7.9

Topic and specific issues		Preliminary view	Section (in SD2)
	Concentration units for infant formula MLs	The default unit for all contaminant MLs in Standard 1.4.1 is mg/kg unless specified otherwise. The ML for lead for infant formula in Standard 1.4.1 is in mg/kg, however, the ML for aluminium currently included in Standard 2.9.1 is expressed in terms of mg/100 mL. While FSANZ proposes to consolidate all MLs for contaminants in Standard 1.4.1, the consistency of expression of these MLs is yet to be determined. Also, it is proposed that MLs for infant formula apply to a reconstituted ready-to-feed form, rather than to a product *prior to drying, dehydration or concentration*.	7.10
	Contaminant definition	The current MLs in the Code do not usually specify a *contaminant definition*. As this may lead to confusion as to the nature of the analyte for which testing is applicable, it may be useful to include contaminant definitions for some of the metals relevant to infant formula for clarity. We are not proposing to change the definition of analytes which are common to both infant formula and other foods, but will address this issue as part of a proposed future review of Standard 1.4.1.	7.11

Topic and specific issues		Preliminary view	Section (in SD2)
Food additives	Aligning food additive permissions in the Code with Codex: • acidity regulators • Citric and fatty acid esters of glycerol • Starch sodium octenyl succinate • Updates to nomenclature and INS numbers • Changes to maximum permitted levels:	We are considering whether to align the food additive provisions in the Code with those of Codex for ease of trade. If the Code were to align with Codex, then a range of amendments to the Code would be needed, such as additional permissions, changes to maximum permitted levels (MPLs), and revision of some nomenclature and INS numbers. *Additional and extension of food additive permissions:* Codex lists 14 food additives that are not currently permitted as food additives for use in infant formula in the Code. These are 12 acidity regulators, as well as citric and fatty acid esters of glycerol, and starch sodium octenyl succinate. • 12 acidity regulators: As well as use as food additives, the 12 acidity regulators could also be used as processing aids or as permitted forms of minerals in the manufacture of food. Therefore, FSANZ is seeking information on how these substances are used in the manufacture of infant formula. • Citric and fatty acid esters of glycerol: FSANZ could consider an extension of use for these food additives as part of future work within this Proposal if there was justification for the use, and information provided in submissions to enable an assessment. • Starch sodium octenyl succinate: An extension of use is out of scope for P1028, as the Codex permission relates to hydrolysed protein-based infant formula products. *Updates to nomenclature and INS numbers:* There are some inconsistencies in nomenclature and INS numbers used in the Code and Codex. To align the Code with Codex would have flow on consequences for other food categories, and therefore will not be considered further under this Proposal. We may prepare a proposal at a later date to address this issue. *Changes to maximum permitted levels:* To align with Codex the MPL for hydroxylpropyl starch for use in soy-based infant formula would need to be lowered from 25000 to 5000 mg/L, singly or in combination.	8.2
	Carry-over principle for food additives and infant formula	There has been confusion about how the carry-over principle in the Code operates for infant formula. For clarity, and to be consistent with the Codex approach, we consider that the carry-over principle should not apply to infant formula.	8.3

Topic and specific issues		Preliminary view	Section (in SD2)
	Clarifications to the Code • Carrageenan permission for liquid soy-based infant formula • Permitted starches, removal of qualification statements	*Carrageenan:* The hierarchy of the food categories in the Code lists liquid infant formula as a separate subcategory to soy infant formula. The permission for carrageenan is listed only for liquid infant formula and there is no permission for carrageenan in soy-based infant formula. FSANZ is aware that there is some confusion about whether the subcategories of infant formula are mutually exclusive. We are seeking information from interested parties in relation to their interpretation of the current permissions, the current use of carrageenan and whether changes are required to ensure permissions reflect the expectation. *Permitted starches:* Remove the qualification statement that subclause 6(1) of Standard 1.3.1 applies, as it automatically applies for all four of the starches.	8.4
Processing aids	Comparison between Code and Code permissions	We are not aware of any issues relating to the permissions for processing aids in the Code for the manufacture of infant formula. Accordingly, we are not considering any changes to Standard 1.3.3 or processing aids in the manufacture of infant formula under P1028.	9.2
Other issues raised by stakeholders	Issues to be addressed during further consideration of P1028	The statements on dental fluorosis will be considered in a future report for P1028. The issue of fluoride will be considered from a risk assessment perspective, and the related statements will be considered based on the outcome of this assessment.	10.1
	Issues that will not be considered further in P1028	Issues that will not be considered further in P1028 include certain suggested advisory statements (e.g. that formula is not sterile, statement for aluminium content), and declaration of forms of vitamins and minerals.	10.2

Table 5.3: Provision of information (Supporting Document 3)

Topic and specific issues		Preliminary view	Section (in SD3)
Provision of information	Claims about ingredients	There appears to be a lack of regulatory clarity in the Code about ingredient claims on packaged infant formula. We are seeking stakeholder views on whether there is a regulatory gap and if requirements should be specified in the Code for such claims when used in relation to infant formula.	2.1
	Declaration of permitted nutritive substances	The intent of labelling requirements in Standard 2.9.1 is to prohibit the declaration of nutritive substances unless certain conditions are met (e.g. minimum and maximum amount), and to limit where a permitted nutritive substance can be declared on a label (i.e. the statement of ingredients or the nutrition information statement). We recognise there is potential for ambiguity in the current Standard and will seek to make the intent clear in the drafting of the revised Standard.	2.2
	Nutrition declaration requirements	Standard 2.9.1 sets out the nutrients that must appear in the nutrition information statement and how this information is to be expressed. In addition to the mandatory nutrition information for the macronutrients protein, fat and carbohydrate, many infant formula companies also voluntarily declare subgroups of macronutrients (e.g. omega-3, whey and/or casein) in the nutrition information statement. Where information is provided voluntarily, it is considered to constitute a claim, which is prohibited for infant formula. We are considering whether macronutrient subgroups should be permitted to be declared in the nutrition information statement for packaged infant formula, and are seeking stakeholder views and evidence to support the assessment of this issue.	2.3

Topic and specific issues		Preliminary view	Section (in SD3)
	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. Consequently, there can be a difference in terminology used. For example, whey protein declared in the ingredient list and alpha-lactalbumin in the nutrition information statement, 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, and FSANZ is not aware of evidence to suggest confusion among caregivers and health professionals about this label information. However, we are seeking any evidence to demonstrate confusion, and stakeholder views on whether the names of ingredients should align with nutrient declarations in the nutrition information statement on packaged infant formula.	2.4
	Base units of expression	Nutrition information is required 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 recommended format for nutrition information (in the Guidelines attached to Standard 2.9.1) suggests that in addition to the per 100 mL requirement, nutrition information per 100 g for powdered formula and per 100 mL for liquid concentrate as sold be expressed. The pros and cons of expressing the nutrition information as sold, in addition to the current requirement, are discussed. We are seeking further information from stakeholders on the merits of additional base units of expression that differ from the current requirement, and whether the declaration of these base units should be mandatory or voluntary.	2.5
	Average amount	The ‘average amount’ of macronutrients and micronutrients is required to be declared in the nutrition information statement for an infant formula. However, the term ‘average amount’ is not defined in the Code, but a term with the same intent is (i.e. ‘average quantity’). We are seeking comment on the impacts of changing the declaration from ‘average amount’ to ‘average quantity’ in the Code.	2.6

Topic and specific issues		Preliminary view	Section (in SD3)
	Format of the nutrition information statement	An infant formula label must include a statement declaring certain nutrition information expressed per 100 mL for the product as consumed. Standard 2.9.1 and the attached Guidelines recommend that this information is presented in a tabular format. FSANZ is considering whether to mandate, remove or retain the format for the nutrition information statement. Stakeholder views, current industry practice, information for caregivers, and the impact on trade and supply is considered. FSANZ is seeking further information to be able to make a full assessment of this issue.	2.7
	Notification of product reformulation	The Code does not explicitly permit or prohibit a labelling statement to alert caregivers to changes in product formulation. 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. A number of stakeholders suggested that product labels should include information about compositional changes to alert caregivers and health professionals, as some infants may experience side-effects when transitioning to an infant formula with a new formulation. We are interested in whether there are alternative approaches to alert caregivers that an infant formula has been reformulated.	2.8
	Nutrition content claim and health claim prohibition	The Code is clear that a nutrition content claim or health claim must not be made about an infant formula (product). We believe that the issue of whether to permit claims on infant formula labels should, at first, be considered within the policy arena, particularly given the recent consideration of voluntary nutrition content claims through Proposal P293 and the relevant ministerial policy guidance.	2.9
Other issues raised by stakeholders	Issues out of scope for P1028	Issues relating to trademarks, line marketing, proxy advertising and online marketing are considered out of scope for P1028.	Attachment A

6 Risk communication

6.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ has prepared a communication strategy for this Proposal, which includes targeted consultation with key stakeholders.

FSANZ will seek submissions from interested stakeholders on a number of documents prepared as part of P1028. All consultation papers and calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are notified about the availability of reports for public comment. We recognise that this Consultation Paper involves several large and complex documents with many issues for consideration. Thus we have planned an extended consultation period of 12 weeks to ensure all interested parties have time to provide input.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties, including on the draft variation to the Code (if appropriate). FSANZ places all related Proposal documents and submissions on the FSANZ website. All public comments received are reviewed and considered by the FSANZ Board in making its final decision.

7 Next steps

FSANZ will consult widely with stakeholders on this paper. Submissions will be used to complete a more detailed assessment of issues, and to inform any decisions to vary the current standards for infant formula in the Code. The information will also assist the preparation of the consultation RIS, which will include a cost benefit analysis.

For most issues, a preliminary assessment has been undertaken in this paper. However, there are some issues that have been noted for consideration in future P1028 papers, such as: statements on dental fluorosis, further consideration of food additives and permitted forms of nutrients.

It is expected that the next P1028 documents released for public comment will be following the formal completion of the assessment of issues (under section 59 of the FSANZ Act) for further stakeholder comment to inform our decision as to whether or not to prepare a draft food regulatory measure (under section 60 of the FSANZ Act) .

8 References

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WHO (2007) Safe Preparation, Storage and Handling of Powdered Infant Formula. World Health Organization: Geneva. http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf

Attachments

A1. Summary of questions to submitters

Attachment 1 – Summary of questions to submitters

Questions to submitters are included in the Supporting Documents alongside the assessment of issues. Stakeholders are also able to raise any additional concerns about current regulations along with any evidence to support changing those regulations.

Supporting Document 1: Definitions and Nutrient Composition

No.	Section of the SD	Question
Q1.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.
Q1.2	2.2	Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula? (1) "satisfies by itself the nutritional requirements of infants less than 6 months of age" (2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding " (3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age (4) no change
Q1.3	3.1	Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?
Q1.4	4.3	Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.
Q1.5	4.5	What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale
Q1.6	4.6.5	What amount of lecithin is used in infant formula for technological purposes?
Q1.7	5.1	Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?
Q1.8	5.3	What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.
Q1.9	7.2.1	Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.
Q1.10	7.2.1	If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.
Q1.11	7.3.2	Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio? Please provide a rationale in support of your view.
Q1.12	7.3.3.1	Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.
Q1.13	7.3.3.2	Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.
Q1.14	7.3.3.3	Do you support raising the minimum and maximum amount of selenium

No.	Section of the SD	Question
		required in infant formula? Please provide your rationale.
Q1.15	7.3.3.3	Do you support moving the maximum amount to a GUL? Please provide your rationale
Q1.16	7.3.3.4	Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL? Please provide your rationale.
Q1.17	7.3.3.5	Can you provide data on the chromium levels in commercially available infant formula in Australia and New Zealand? This information can be provided as 'Commercial in confidence' if required.
Q1.18	7.3.3.6	Can you provide any data on the molybdenum levels in commercially available infant formula in Australia and New Zealand? This information may be provided as confidential commercial information.
Q1.19	7.3.3.8	What information can you provide on the phytic acid content of soy-based infant formula?
Q1.20	7.3.3.8	Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?
Q1.21	7.3.3.8	Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?
Q1.22	8.1.1	What is the justification to retain β-carotene as a provitamin A form?
Q1.23	8.3	What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?
Q1.24	9.1	Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.
Q1.25	9.1	What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
Q1.26	9.1	If you have provided a technological justification for these forms of choline can you provide: (a) reference to a specification for choline citrate and/or choline hydrogen tartrate in an internationally accepted monograph of specifications (including those referenced in Standard 1.3.4)? (b) evidence to demonstrate safety can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
Q1.28	9.2	What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
Q1.29	9.2	If you have provided a technological justification for these forms what evidence to demonstrate safety can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
Q1.30	9.3	Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.
Q1.31	9.3	Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?
Q1.32	9.4	Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?

Supporting Document 2: Safety and Food Technology

No.	Section of the SD	Question

No.	Section of the SD	Question
Q2.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.
Q2.2	4	For all views presented in section 4, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons and evidence as appropriate. If not, indicate this in your submission and provide your reasons including further relevant evidence, current practice, impact on manufacture, or other relevant information.
Q2.3	5.2	What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?
Q2.4	5.2	What evidence can you provide on whether this practice is more common with powdered infant formula products compared to liquid concentrate or 'ready to drink' products?
Q2.5	5.2.	What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?
Q2.6	5.4	What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?
Q2.7	5.4	What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?
Q2.8	5.4	If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?
Q2.9	5.4	What are the cost and trade implications of prescribing the position of the statement of protein source ion the label?
Q2.10	5.9	What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?
Q2.11	5.9	Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?
Q2.12	5.9	What data are available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements (in addition to their normal diets)?
Q2.13	5.9	What advice is given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for formula-fed (or breastfed) infants?
Q2.14	5.9	What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?
Q2.15	6	Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?
Q2.16	6	What would be the cost and trade implications of your preferred position?
Q2.17	6	If only certain substances for use in infant formula should require pre-

No.	Section of the SD	Question
		market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?
Q2.18	6	If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?
Q2.19	7.3	What evidence can you provide as to whether this proposed ML would/would not be achievable in soy-based formula? Reference should be made to relevant concentration data in soy-based formula products where possible.
Q2.20	7.3	What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?
Q2.21	7.5	What are the cost and trade implications of reducing the ML for lead in infant formula?
Q2.22	7.6	What if any, issues are associated with not including the Codex ML in the Code for melamine?
Q2.23	7.10	Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.
Q2.24	7.11	Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?
Q2.25	7.11	Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?
Q2.26	8.2.2	What is the technological purpose for using the following 12 substances in the production of infant formula – INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525? i.e. are they best described as food additives, processing aids or permitted forms of minerals? Please explain and provide examples of how they are used in the manufacture of infant formula.
Q2.27	8.2.2	What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?
Q2.28	8.2.2	What, if any, information can you provide to support an assessment of an extension of use of a food additive in infant formula?
Q2.29	8.2.2	To what extent is 472c used in IFPSDU? Is it widely used, and are the levels used close to the maximum permitted level in the Code?
Q2.30	8.2.3	What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?
Q2.31	8.2.4	Will lowering the MPL of hydroxypropyl starch to 5000 mg/L create any difficulties for infant formula companies?
Q2.32	8.3	Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.
Q2.33	8.4	Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?
Q2.34	8.4	Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?
Q2.35	8.4	Will the correction of the hydroxypropyl starch MPL to the lower level of 5000 mg/L cause any issues? Are you aware of any infant formula marketed in Australia and New Zealand that uses hydroxypropyl starch as a food additive at levels above?

Supporting Document 3: Provision of Information

No.	Section of the SD	Question
Q3.1	2.1	Should claims about specific ingredients be permitted on packaged infant formula? If no, then why not? If yes, then how should they be regulated?
Q3.2	2.3	Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?
Q3.3	2.3	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	2.3	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, alpha-lactalbumin etc.), or specific proteins (only whey and casein).
Q3.5	2.3	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	2.3	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	2.3	What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?
Q3.8	2.4	Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?
Q3.9	2.4	Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?
Q3.10	2.5	Which base units of expression do stakeholders find to be of greatest value?
Q3.11	2.5	Is there any evidence that caregivers are confused by the use of different base units of expression?
Q3.12	2.5	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	2.5	What would the cost and trade implications be of mandating these base units?
Q3.14	2.5	Should the voluntary use of the base unit of per 100 kJ be permitted?
Q3.15	2.6	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’?
Q3.16	2.7	Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?
Q3.17	2.7	Would a consistent approach to format across product labels assist consumer understanding of this information?
Q3.18	2.7	If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

No.	Section of the SD	Question
Q3.19	2.8	How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?
Q3.20	2.8	What information about the change in composition would caregivers and health professionals find useful?
Q3.21	2.8	What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?