

Supporting Document 2

Safety & Food Technology – Proposal P1028

Infant Formula

Executive summary

The protection of public health and safety is a primary objective for FSANZ. Infant formula must be safe for formula-fed infants to consume, and caregivers need to know how to safely prepare, use and store the product.

Infant formula is currently regulated under Standard 2.9.1 – Infant Formula Products in the *Australia New Zealand Food Standards Code*. Other standards also contain provisions related to safety and food technology for infant formula, such as Standards 1.3.1 – Food Additives, 1.4.1 – Contaminants and Natural Toxicants, 1.6.1 – Microbiological Limits for Food, and various labelling standards. FSANZ has developed and approved a revised version of the *Australia New Zealand Food Standards Code* (the Code) which takes effect and replaces the current version of the Code on 1 March 2016. However, in this SD all references are to the current Code and the relevant sections in the revised Code are noted (in brackets) following any reference to a specific provision of the current Code.

This Supporting Document discusses issues relating to the safety of infant formula – from manufacture of the product to preparation by caregivers. The Supporting Document is structured in eight sections with a number of issues addressed within each section:

1. Microbiological criteria
2. Preparation, use and storage directions to manage microbiological hazards
3. Other safe preparation and storage issues
4. Warning, advisory and other statements
5. Nutritive substances and novel foods in infant formula
6. Contaminants
7. Food additives
8. Processing aids

Four attachments to this SD provide further detail on some issues.

FSANZ is seeking stakeholder views on a number of issues in each of these sections. Many issues are assessed in full and we seek comment on our preliminary position. Whereas for other issues, we are seeking further information and evidence to characterise the issue and assess whether a regulatory change may be warranted. Questions are included throughout this Supporting Document and are also in Attachment A to the Consultation paper.

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1 Introduction

The protection of public health and safety is a primary objective for FSANZ. Infant formula must be safe for formula-fed infants to consume, and caregivers need to know how to safely prepare, use and store the product.

This Supporting Document (SD) considers issues relating the safety of infant formula – from manufacture of the product to preparation by caregivers. The SD is structured in eight sections with a number of issues addressed within each section:

1. Microbiological criteria
2. Preparation, use and storage directions to manage microbiological hazards
3. Other safe preparation and storage issues
4. Warning, advisory and other statements
5. Nutritive substances and novel foods in infant formula
6. Contaminants
7. Food additives
8. Processing aids

Four attachments provide further detail to support the assessment of some issues addressed in this SD:

- Attachment A1 – Microbiological safety of powdered infant formula
- Attachment A2 – Rapid evidence assessment on infant formula preparation, perceptions and label use
- Attachment A3 – Overseas regulatory approaches to the addition of substances to infant formula
- Attachment A4 – Risk profile of contaminants in infant formula.

FSANZ has developed and approved a revised version of the *Australia New Zealand Food Standards Code* (the Code) which takes effect and replaces the current version of the Code on 1 March 2016. In this SD, the relevant sections in the revised Code are noted (in brackets) following any reference to a specific provision of the current Code.

1.1 Scope of consideration

Safety and food technology issues related to infant formula (for infants aged 0-<12 months) are discussed in this SD. Although some issues may also be relevant for follow-on formula (for infants aged from 6-<12 months) and infant formula products for special dietary use (IFPSDU), these two categories are not in scope for this Proposal (P1028).

The issues considered in this SD have been identified from a range of sources, including a FSANZ review of existing infant formula requirements in the Code, stakeholder consultation (including submissions to the 2012 Consultation paper on the *Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code*), other FSANZ projects, and regulatory and policy activities at a national and international level. Generally, these issues relate to:

- safety concerns about certain substances in infant formula
- clarity and enforceability of the Code

- international trade barriers created by existing regulations
- the communication of public health messages
- concerns with caregiver practices when preparing and storing infant formula.

Other safety issues will be considered in future P1028 reports (section 10.1) and some issues raised in stakeholder consultation activities are noted as out of scope (section 10.2).

1.2 Background

1.2.1 International and overseas regulations

In developing or reviewing food standards, FSANZ must have regard to, among other things, the promotion of consistency between domestic and international food standards. The most relevant Codex standard for this Proposal is the *Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (Codex STAN 72-1981). Other Codex standards, guidelines and codes of practice are also relevant to issues discussed in this SD, namely:

- CODEX STAN 193-1995 – General Standard for Contaminants and Toxins in Food and Feed
- CAC/RCP 66-2008 – Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children
- CODEX STAN 192-1995 – General Standard for Food Additives
- CAC/GL 10-1979 – Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children
- CAC/GL 75-2010 – Guidelines on Substances used as Processing Aids
- CAC/GL 36-1989 – Class Names and the International Numbering System for Food Additives
- CAC/MISC 6-2015 – List of Codex Specifications for Food Additives.

The Codex approach has been considered in assessing many issues discussed in this SD such as contaminants and food additives. Where relevant, the approach taken in major overseas jurisdictions is also considered, for example, the regulation of addition of new substances to infant formula.

1.2.2 Ministerial policy guidelines

The specific policy principles that address compositional safety, specifically:

- d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.
- i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that: i) does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii) has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.
- j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and

development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.

- k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand.
- m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.

The Policy Guideline also refers to the regulation of infant formula products “being consistent to the greatest extent possible” with relevant World Health Organization (WHO) and World Trade Organization (WTO) agreements, and Codex standards.

1.3 Approach

The safety and food technology issues covered in this SD are wide ranging, thus this document is organised into sections which focus on groups of issues.

Several approaches have been used to consider the issues depending on the topic. The approach used to assess an issue is described at the beginning of each section. In summary, the approach to the assessment for contaminants and food additives compared the current Code permissions with those of the Codex Alimentarius. For safety-related labelling issues, all current labelling requirements were reviewed and are discussed to varying detail. The section on nutritive substances and novel foods provides background to the issue and seeks to identify stakeholders' positions for the future regulation of substances in infant formula. Lastly, issues relating to microbiological criteria are discussed although they are addressed more fully through another proposal.

For most issues FSANZ provides its preliminary view on whether amendments to the Code may or may not be required, and seeks comments from stakeholders to further assist its consideration of the issue. It is not a decision on whether amendments to the Code will be made, which will be made once an assessment and decision is taken under section 59 of the FSANZ Act.

Overarching question to submitters:

Q2.1 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.

2 Microbiological criteria

The development of microbiological criteria to verify the safe production of infant formula is currently being considered under [Proposal P1039 – Microbiological Criteria for Infant Formula¹](#). The risk management approach taken under P1039 is to establish microbiological criteria as either:

- food safety criteria (included in the Code and applied to determine the safety of a food lot)
- process hygiene criteria (provided in guidance and applied to verify hygiene measures or control of process).

This approach recognises that the microbiological safety of powdered infant formula is ensured through good hygienic practices during both manufacture and use. The microbiological criteria proposed under P1039 will support through chain risk management and is consistent with Codex.

2.1 Codex Alimentarius

To reduce the risk to infants from microbiological hazards in powdered infant formula, Codex developed the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008). The Codex CAC/RCP 66-2008 refers to the 2007 WHO Guidelines on the *Safe Preparation, Storage and Handling of Powdered Infant Formula* (the WHO PIF Guidelines) and identifies relevant control measures that can be employed at various steps of the food chain to reduce risks to infants associated with consumption of powdered infant formula. These include:

- implementation of good manufacturing and hygienic practices and food safety control systems by ingredient manufacturers
- implementation of good manufacturing and hygienic practices and food safety control systems by infant formula manufacturers
- education and guidance on the safe preparation, storage and use of powdered infant formula.

Internationally agreed microbiological criteria were also established for powdered infant formula and included in CAC/RCP 66-2008. These include food safety criteria for *Salmonella* and *Cronobacter spp.* and process hygiene criteria for Enterobacteriaceae and Mesophilic Aerobic Bacteria (MAB).

2.2 Proposal P1039

P1039 is considering replacing the existing microbiological limits for powdered infant formula and follow-on formula with microbiological food safety criteria for *Salmonella* and *Cronobacter spp.*, based on the principles within Codex CAC/RCP 66-2008. These food safety criteria apply to the finished product (powder form) after packaging and at any stage from that point to the point when the primary package is opened. In addition, process hygiene criteria will be incorporated into a guidance document that will be available on the FSANZ website. Process hygiene criteria are used to verify that the hygiene measures in a manufacturing facility are working as intended. In line with Codex CAC/RCP 66-2008, criteria for Mesophilic Aerobic Bacteria and Enterobacteriaceae in powdered infant formula will be incorporated in this guidance.

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1039MicroReviewInfantFormula.aspx>

The approach taken for powdered infant formula in P1039 is supported by stakeholders who submitted to the 2012 Consultation paper and to the 2015 Consultation paper on *Completing the Review of Microbiological Criteria*. Stakeholders supported a review of current criteria in line with Codex, and development of criteria for either safety or hygiene (process control) purposes.

As microbiological criteria for infant formula is being considered in P1039, this issue will not be considered as part of this Proposal. It is expected that P1039 will be completed in the first half of 2016, further information is available on the [FSANZ website](#).

3 Preparation, use and storage directions to manage microbiological hazards

There are various risks associated with incorrect preparation of infant formula, including microbiological hazards. The current provisions in the Code provide a group of risk management measures relevant to the manufacture, storage and use of infant formula to help ensure the microbiological safety of the product.

Preparing and storing reconstituted infant formula correctly can reduce potential risks. The product label on infant formula is one source of information for caregivers on the correct handling of infant formula. Several current labelling requirements in the Code relate to directions for the safe preparation, use and storage of infant formula, with the purpose to inform caregivers of how to handle the product safely to minimise the risks from pathogens. The individual elements of these directions are considered in detail here in section 3. FSANZ has considered international advice including the risk assessments that underpin this advice (Attachment 1), current national guidelines, evidence on caregiver practices (Attachment 2), and relevant issues raised by stakeholders to determine whether any of these requirements should be revised to reflect best available scientific evidence and current international and national guidelines.

As there is no single risk reduction measure that, by itself, will ensure the microbiological safety of infant formula, a group of measures is needed.

Other information requirements relating to preparation, use and storage of infant formula that do not have a microbiological safety component are discussed in section 4.

3.1 Background

3.1.1 Current regulation

Standard 1.2.6 – Directions for Use and Storage (Standard 1.2.6 – Information requirements – directions for use and storage in the revised Code) outlines generic requirements for all foods (including infant formula). Foods must provide directions for use and storage if the food is of such a nature as to require the directions for health or safety reasons. In the case of infant formula, there are additional specific requirements that reside in Standard 2.9.1 to ensure the safe preparation, use and storage of these products. Subclause 14(2) of Standard 2.9.1 (subsection 2.9.1—19(3) in the revised Code) requires the label on a package of infant formula to include directions, as both words and pictures, for the preparation and use of the infant formula. Words and pictures are both used to provide clear and unambiguous directions for preparing and using these products; however the exact wording is not specified. The subclause requires that the label on a package of infant formula must include directions for its preparation and use, which include words and pictures instructing:

- a) that each bottle should be prepared individually
- b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours
- c) that potable, previously boiled water should be used
- d) where a package contains a measuring scoop, that only the enclosed scoop should be used
- e) that formula left in the bottle after a feed must be discarded.

The current Code requirements for directions for preparation and use align with the Codex approach. Section 9.5 of Codex STAN 72-1981 specifies that adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, appear on the label and in any accompanying leaflet. It also specifies clear graphic instructions illustrating the method of preparation of the product, and notes that powdered products should be reconstituted with water that is safe or has been rendered safe by previous boiling.

The Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (Codex RCP 66-2008) (CoHP) provides practical guidance and recommendations to governments, industry, health care professionals/caregivers of infants and young children, as appropriate, on the hygienic manufacture of powdered formula and on the subsequent hygienic preparation, handling and use of reconstituted formulae. The CoHP has an emphasis on the control of microbiological hazards, in particular *Salmonella* and *Cronobacter* species.

3.1.2 Other guidelines

Australia and New Zealand have each developed their own national infant feeding guidelines. For Australia, the National Health and Medical Research Council (NHMRC) released a revised version of the *Infant Feeding Guidelines – Information for Health Workers* in 2012. These guidelines include a section on infant formula which discusses preparation of infant formula and the risks associated with incorrect preparation. The New Zealand guidance on the preparation, handling and storage of infant formula is part of the *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2)*; published by the Ministry of Health in 2008 and updated in December 2012. A comparison of the relevant advice from both guidelines is summarised in Attachment 1.

Internationally, the WHO released guidelines titled *Safe Preparation, Storage and Handling of Powdered Infant Formula* (the WHO PIF guidelines) in 2007. These were based on a 2006 microbiological risk assessment by the 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. Further information on the WHO Guidelines and the FAO/WHO risk assessment can be found at Attachment 1.

3.2 Direction to prepare bottles individually

The directions for preparing and using infant formula includes the instruction that each bottle should be prepared individually (paragraph 14(2)(a) of Standard 2.9.1 in the current Code (paragraph 2.9.1—19(3)(a) in the revised Code)). During the development of Standard 2.9.1, it was considered that this instruction provided a measure to address two safety issues: microbiological safety of the product and the use of incorrect proportions of formula to water during reconstitution as diluted or concentrated formula can seriously impact infant health (ANZFA, 1999a).

The instruction to prepare each bottle individually aligns with WHO Guidelines, and both the Australian and the New Zealand guidance on infant feeding (refer to Attachment 1 for a summary of the advice provided). No stakeholders have raised any issues regarding this requirement.

FSANZ's preliminary view is that it is appropriate to retain this labelling requirement, and stakeholders' views are sought.

3.3 Directions for the storage of made up formula

Paragraph 14(2)(b) of Standard 2.9.1 (paragraph 2.9.1—19(3)(b) in the revised Code) requires a direction instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours. During the development of Standard 2.9.1, ANZFA's assessment determined it was microbiologically safe to make up several bottles of formula at one time provided they were stored refrigerated ($\leq 5^{\circ}\text{C}$) for not more than 24 hours before use.

The directions in the Australian infant feeding guidelines (NHMRC 2012) and the WHO Guidelines (2007), align in relation to the storage time for prepared infant formula however, it differs from the New Zealand infant feeding guidance (MoH 2008). The New Zealand guidance states that the prepared formula may be stored at up to 4°C in the lower half of the fridge, at the back, but should be kept for only a maximum of four hours. Codex STAN 72-1981 does not specify storage duration for made up formula. The WHO PIF guidelines state if feeds need to be prepared in advance, they should be prepared in individual bottles, cooled quickly and placed in the refrigerator (no higher than 5°C) for use within 24 hours. The Codex CoHP states that guidance to the caregiver should be provided on the need to refrigerate product, if formula is not used immediately.

3.3.1 Stakeholder views

Most industry submissions on the 2012 Consultation paper supported the current requirement, but many also sought regulatory clarity on whether a time of less than 24 hours could be provided on the label (for example, between 0–24 hours, or specify that storage is up to a 'maximum' of 24 hours). In their view, a shorter storage period is safe if the 24 hour storage period is already assessed as safe. One industry submitter believed it was unsafe to store reconstituted formula after it is made, due to the risks of one or more of the directions for preparation and use not being met. That submitter recommended a statement to the effect that the reconstituted formula should be used immediately after it is made and not be stored. Another industry submitter noted the current requirement does not take into consideration the storage of 'ready-to-drink' formula after it has been opened. They advised that their 'ready-to-drink' product was packed aseptically and did not require refrigeration prior to use.

One submission from a health professional did not support a 24 hour maximum storage time; instead supporting a maximum of 4 hours as a precautionary measure. Other submissions from health professionals noted that the directions for storage time varied between infant formulas and several pointed to an inconsistency with New Zealand infant feeding guidance. It was also suggested that storage times should be considered in the context of the temperature of water used to reconstitute formula; a maximum of 24 hours was considered unsafe if cooled water was used.

One government submission noted that the requirement was consistent with the Australian Infant Feeding Guidelines (NHMRC 2012). Another government submission commented that the storage time should only be changed to a maximum of 4 hours if there is evidence to demonstrate that the current 24-hour period is unsafe.

3.3.2 'Ready-to-drink' formula

The Australian Infant Feeding Guidelines note that 'ready-to-drink' products may be poured into a sterilised bottle and can be warmed in the bottle, just before feeding. Once opened 'ready-to-drink' product should be poured into sterilised containers and refrigerated below 5°C for no more than 24 hours.

The requirement in paragraph 14(2)(b) of Standard 2.9.1 (paragraph 2.9.1—19(3)(b) in the revised Code) is intended to apply to powdered and concentrated formula that has been reconstituted and set aside for later use, as well as 'ready-to-drink' formula that has been opened but set aside for later use.

3.3.3 Risk assessment findings

To investigate the impact of different preparation and storage conditions on the relative risk of *Cronobacter* species infection in infants, FSANZ ran a number of scenarios using the FAO/WHO risk assessment model. Three different storage scenarios (2, 4 and 24 hours) were modelled using three different reconstitution temperatures (10, 30 and 45°C)². Prepared formula left unrefrigerated (2 hour ambient) was also modelled for the different reconstitution temperatures. The baseline for comparison was a scenario of reconstitution at 45°C with no storage time (i.e. immediately consumed). For all refrigeration scenarios modelled, there was minimal difference in the relative risk reduction from the baseline scenario.

3.3.4 Current industry practice

FSANZ reviewed the labels of both powdered and ready-to-drink products available on the Australian and New Zealand market and identified some variation in the directions for storage of prepared formula:

- Some manufacturers do not list a maximum storage time for prepared formula at all, as they direct the caregiver to use it immediately after preparation. Some specifically state that made up formula should not be stored.
- A number of products included the statement that it was "safer to use immediately after preparation", but also carried an additional statement to the effect that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within a defined maximum period of time (which varied between 12 and 24 hours).
- Some of these statements referred to storing the reconstituted formula at the back of the refrigerator, and some referred to the recommended refrigerator temperature as either a fixed temperature (e.g. at 4°C) or within the temperature range of 2–4°C.

3.3.5 Caregiver practices

Findings from overseas studies indicate that caregivers understand the importance of storing prepared infant formula in the refrigerator. In one US survey, 94.6% of participants reported storing prepared infant formula in the refrigerator as soon as it is made. Another US survey found that 85% of participants believed it was very important to follow the label directions to refrigerate prepared formula. A US observational study examined how long caregivers thought prepared formula could be stored this way; more than 80% believed prepared formula could be kept for 24 hours or less in the refrigerator.

² The temperature of water used to reconstitute the powdered infant formula

More recent studies have been conducted in the United Kingdom (UK). One qualitative study reported caregivers storing made up formula for up to 24 hours (Redmond and Griffith 2013a), although the typical storage times were between nine and 12 hours. The results of another study in which storage practices were logged found refrigeration storage times ranged from over two hours to under 20 hours (Redmond and Griffith 2013b). None of the studies examining refrigeration of prepared infant formula were conducted in Australia or New Zealand (refer to Attachment 2).

3.3.6 Information sources Various risk reduction strategies have been identified to reduce microbiological hazards associated with the preparation, use and storage of infant formula. The strategies for safe storage need to be communicated to caregivers of formula-fed infants to help ensure that infant formula is handled safely to protect the health of the infant. The rapid evidence assessment (Attachment 2) found that the preparation instructions are an important source of information for caregivers learning how to safely prepare infant formula, and some caregivers will refer to them, although only the first few times they prepare formula. The rapid evidence assessment found that some caregivers felt they did not receive enough information about preparation from health care professionals.

However, product labelling is only one of the sources to provide information on the safe use of infant formula. A number of infant formula company websites, as well as health organisations, include information on how to correctly prepare and use infant formula.

The NHMRC infant feeding guidelines (2012) note that when required health workers have a responsibility to educate and support parents about correct methods for safe formula feeding. The guidelines also state it is essential that health workers should monitor methods regularly, particularly for parents without literacy skills or from a non-English speaking background who may need extra help. Similarly, the New Zealand guidance states health practitioners must give formula feeding parents “objective, consistent and accurate advice on the proper use of formula. Such information should include.... how to prepare the formula and the equipment.....”. An explanation on how formula should be handled and stored carefully, and made up as close as possible to feeding time is specifically mentioned in this guidance.

Internationally, the Codex CAC/RCP 66 - 2008 also states that consumer education programs and training of health professionals are important strategies to ensure that adequate information is provided to caregivers on the safe preparation and use of infant formula.

3.3.7 Summary

Storage time and storage conditions of made up infant formula are some of the risk reduction strategies to reduce potential microbiological risks of powdered infant 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’s preliminary view is that the current requirement to include this information in the preparation and use instructions on the label remains appropriate. There is little evidence that caregivers do not understand the instructions for storage once formula is made up. FSANZ is seeking stakeholders’ views on this issue.

3.4 Directions on water used to reconstitute powdered infant formula

Paragraph 14(2)(c) of Standard 2.9.1 (paragraph 2.9.1—19(3)(c) in the revised Code) requires the directions for the preparation and use of the infant formula to include instructions that potable, previously boiled water should be used. The intent of this labelling requirement is to communicate to the caregiver the importance of using water that is microbiologically safe for reconstituting infant formula. No specific directions are made on the temperature of water used to reconstitute powdered infant formula.

3.4.1 Stakeholder views

A number of submissions from health professionals and individuals supported aligning this direction with the WHO Guideline recommendation to reconstitute powdered formula with water at or above 70°C to address any contamination of the infant formula powder with pathogens such as *Cronobacter* species.

Industry submissions argued against aligning Standard 2.9.1 with the WHO 70°C water recommendation because of possible adverse effects on nutrients and the risk of severe scalding and burns.

3.4.2 Alignment with national guidelines

The instruction to use potable, previously boiled water to reconstitute powdered infant formula aligns with the Australian and the New Zealand infant feeding guidance. The Australian infant feeding guidelines state that cooled, previously boiled water can be used to safely reconstitute formula with negligible risk of infection from *Cronobacter* species, when other correct preparation techniques are used (NHMRC, 2012). This practice is recommended to prevent serious burns (Turck 2012) and the depletion of vitamins and nutrients (ESPGHAN Committee on Nutrition 2004; AFSSA 2005) from using water at 70°C. New Zealand infant feeding guidance recommends that caregivers only need to use previously boiled water when preparing powdered infant formula for infants aged up to three months, as this is the most vulnerable age group identified in the international risk assessment work on the *Cronobacter* species.

3.4.3 Caregiver practices

As discussed in Attachment 2, findings from overseas studies published between 1997 and 2008 (no Australian or New Zealand studies were identified) indicate that some caregivers do not use boiled water to prepare infant formula. More recent research in the UK found that the proportion of caregivers following UK recommendations to boil water and use within 30 minutes increased 12% over a five-year period to 71% (Bolling et al. 2007; McAndrew et al. 2012). In a UK-based observational study, 100% of parents boiled water before using it to prepare formula (Redmond and Griffith 2013c).

Based on the published international literature found, FSANZ considers it is likely that some Australian and New Zealand caregivers are not boiling water before using it to prepare infant formula.

3.4.4 International guidance and assessment

Section IX of the CoHP notes that the use of good hygienic practices during reconstitution, handling and feeding, including storage is important in minimising the risk of foodborne illness. Various combinations of hygienic measures can achieve significant risk reduction. The CoHP notes that various risk reduction strategies are provided in the WHO PIF

guidelines, also that the FAO/WHO expert report (2006) and the web based tool provide a means to consider different risk management options which may be appropriate in certain situations. For example, where there is a high confidence in the microbiological quality of the infant formula and adherence with good hygienic practices in the preparation, handling and use of the formula, then alternative risk reduction strategies which do not involve the use of water at 70°C for reconstitution are available.

3.4.5 Summary

FSANZ's preliminary view is 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. Therefore, FSANZ's preliminary view is to maintain this labelling requirement as one of a group of risk reduction strategies, and seeks stakeholders' comments on this position.

3.5 Discarding leftover formula

Paragraph 14(2)(e) of Standard 2.9.1 (paragraph 2.9.1—19(3)(e) in the revised Code) requires the directions for the preparation and use on the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded. Discarding formula leftover from a feed is important because powdered infant formula is not a sterile product and, when reconstituted, it provides an ideal environment for the growth of harmful bacteria.

FSANZ's literature review (Attachment 2) found only four studies which examined this practice, one of which was a qualitative study conducted in New Zealand. These studies found caregivers generally discarded the formula or were aware of the recommendation, although the New Zealand study found that some parents did not throw it away, generally because they were concerned about wasting money. No Australian studies examined whether caregivers discarded leftover infant formula. It is difficult to conclude whether this instruction is or is not commonly followed.

Stakeholders have not raised concerns with this labelling provision. The requirement is consistent with Australian and New Zealand infant feeding guidance (refer to Attachment 1), and the WHO PIF guidelines. Therefore, FSANZ's preliminary view is to retain the existing requirement, and is seeking stakeholders' views on this position.

3.6 Standardised directions for preparation and use

Four of the five directions in subclause 14(2) of Standard 2.9.1 (subsection 2.9.1—19(3) in the revised Code) relate to microbiological risk reduction strategies. The words and pictures for the directions in subclause 14(2) and its revised Code counterpart are not prescribed. This gives infant formula companies flexibility in how they display this information for their products. Thus there is some variation in the wording and images used for directions on products marketed in Australia and New Zealand. However, some stakeholders consider that the directions should be standardised so that the same words and pictures are provided on all infant formula product labels.

3.6.1 Stakeholder views

In response to the 2012 Consultation paper, a consumer group noted its concern that directions for use and storage of powdered infant formula vary significantly between brands. This submission suggested the labels include standardised directions based on evidence-

based best practice and suggested the WHO PIF Guidelines could be used. One submission supported prescribed wording on labels to provide consistent advice, noting that socio-economic disadvantage and lack of health literacy are compounded by lack of standardised label instructions for preparation and storage of infant formula.

Most industry submitters believed the requirements were clear, appropriate and provided flexibility for companies. One industry submitter stated that it is not clear what benefits prescribing wording and/or pictures would deliver to consumers.

3.6.2 Background to the Code requirement

Proposal P161 – Specific Labelling Statements and Proposal P93 were undertaken at the same time during the development of the joint Code. Thus the approach taken in Standard 2.9.1 was based on the criteria developed in P161. Based on the assessment undertaken in P93 and the criteria of P161, it was determined that the label of infant formula must provide adequate directions for use to ensure the safety of the product. In addition to these directions for use and storage, the label of infant formula should contain a warning statement against the health hazards of inappropriate preparation. In addition the directions must include words and pictures. The exact wording or type of picture was not prescribed, as it is the manufacturer's responsibility to ensure that the product can be made up as intended by ordinary consumers (ANZFA 1999a). Manufacturers may then use their own words to convey the required intent. This approach aligns with Codex STAN 72-1981 and the WHO Guidelines.

3.6.3 Evidence of caregivers understanding of preparation instructions on infant formula labels

Consistency in the placement and content of consumer messages will generally assist consumers in their search for, and acquisition of, such messages. Standardisation can benefit consumers by reducing the search time for finding information, and through enhancing the ease of knowledge acquisition (Mercer et al 2014). The rapid evidence assessment (Attachment 2) found that the preparation instructions are an important source of information for caregivers learning how to safely prepare infant formula. Though caregivers will refer to them only the first few times they prepare formula. Some felt they did not receive enough information about preparation. Research which examines caregivers' preparation practices has noted that a small proportion of caregivers deliberately prepare infant formula incorrectly. Where caregivers do not follow recommended preparation practices, it is not clear to what extent this is due to lack of awareness or other reasons.

3.6.4 Summary

FSANZ has received little evidence to indicate that caregivers are confused by the presentation and information differences in directions between products. Most submitters to the 2012 Consultation paper reported anecdotal evidence that the majority of caregivers can follow the directions for preparation and use on the label. FSANZ's preliminary view is to maintain the existing overarching requirement in subclause 14(2) of Standard 2.9.1 (subsection 2.9.1—19(3) in the revised Code), which does not prescribe the words and pictures for the instructions. Stakeholders' views are sought on this preliminary position.

4 Other safe preparation and storage issues

Several requirements in Standard 2.9.1 ensure that adequate information is provided to caregivers for safe and appropriate use of infant formula.

This section addresses other safe preparation and storage issues for infant formula, including instructions on storage, use of the enclosed measuring scoop, and date marking. Issues with the existing requirements have been identified from a range of information sources including from stakeholders through consultation, other FSANZ projects, and regulatory and policy activities at an international and national level. We have also been made aware of some enforcement issues relating to clarity. We have reviewed the existing requirements and have identified the following issues that require further consideration.

4.1 Date marking of food

Date marking is mandatory on most packaged food, including packaged infant formula, to provide consumers with adequate information about the shelf life of the unopened product.

Generic date marking requirements are set out in Standard 1.2.5 – Date Marking of Food (Standard 1.2.5 – Information requirements – date marking of food for sale in the revised Code). The generic requirements include the need for either a best-before date or a use-by date. It is the responsibility of the food business attaching the label to determine whether to place a best-before date or a use-by date on their food. Exemptions from date marking information are set out in subclause 2(1)(c) and (d) of Standard 1.2.5 (subsection 1.2.5—3(2) in the revised Code).

Specific date marking requirements for infant formula are set out in clause 17 of Standard 2.9.1 (subsection 2.9.1—22(1) in the revised Code). Subclause 17(1) states that the generic exemptions from date marking under paragraphs 2(1)(c) and (d) of Standard 1.2.5 do not apply to infant formula products. In the revised Code, subsection 2.9.1—22(1) states that an infant formula product that complies with Standard 2.9.1 does not need to be date marked in accordance with subsection 1.2.5—3(2).

The effect of these subclauses is that all infant formula products must carry a date mark, regardless of whether it is a use-by date or a best-before date. This approach was introduced when Standard 2.9.1 was developed, because although powdered infant formula could have a long shelf life, nutrient content would diminish over time in the unopened product. This approach is consistent with Codex STAN 72-1981.

Research finds that, in general, very high proportions of Australian and New Zealand consumers report looking for and using date mark information on foods. Despite these high levels of reported use, there is some confusion regarding the purpose and meaning of both use-by and best-before date marks among consumers (FSANZ 2007; Quigley & Watts 2014). While it is likely that the confusion about use-by and best-before date marks extends to infant formula, a change to the requirements for date marking for infant formula is unlikely to assist in resolving the general consumer confusion about date marking.

FSANZ's preliminary view is that it is important to maintain the existing requirement for date marking on infant formula. We are seeking input on whether there are any other issues associated with date marking requirements for infant formula.

4.2 Storage instructions for opened infant formula

Subclause 17(2) of Standard 2.9.1 (subsection 2.9.1—22(2) in the revised Code) requires the infant formula label to contain storage instructions covering the period after the package is opened. The intent of this provision is to provide caregivers with instructions for ensuring these products retain safety and quality characteristics through appropriate storage. This requirement was introduced during P93.

In the current Code, an editorial note to clause 17 notes that the full range of climatic conditions that exist in Australia and New Zealand may need to be considered when determining valid and appropriate storage instructions. This editorial note has been removed in the revised Code. This is because FSANZ has sought to reduce the number of editorial notes in the revised Code and has implemented a general policy of removing those which are not required for navigation within the revised Code, where possible. Similar to general purpose foods, infant formula companies are responsible for determining any appropriate storage instructions for their products.

None of the submissions to the 2012 Consultation paper commented on this clause. The approach taken by FSANZ aligns with Codex STAN 72-1981 specifications for directions for storage both before and after the powdered or concentrated product has been opened.

FSANZ's preliminary view is that the current requirement for storage instructions covering the period after the infant formula product has been opened to be appropriate and that the existing requirement should be maintained. FSANZ seeks stakeholders' views on this position.

4.3 Measuring scoop

Standard 2.9.1 requires that a package of infant formula in powdered form (excluding single serve sachets) must contain a scoop to enable the use of the product in accordance with the directions for preparation on the label. Paragraph 16(2)(d) (paragraph 2.9.1—21(1)(b) in the revised Code) requires the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be declared (if a powdered or concentrated form of infant formula). Also, the directions for the preparation and use of the infant formula must instruct the caregiver that where a package contains a measuring scoop, that only the enclosed scoop should be used (paragraph 14(2)(d) of Standard 2.9.1 (paragraph 2.9.1—19(3)(d) in the revised Code)). These directions are required to ensure caregivers have adequate clear and unambiguous information to safely prepare infant formula.

The size of the measuring scoop included in cans of powdered infant formula varies between products. There is concern from stakeholders that some caregivers unintentionally use the wrong measuring scoop (for the particular product) to prepare powdered infant formula. Using a measuring scoop that is either smaller or larger than the scoop provided with the product may result in either over-concentration or dilution of the infant formula 'as prepared'. Unintentional over-concentration or dilution of infant formula can have acute and chronic negative health effects for the infant. In the short term, the infant may not tolerate the formula, and problems such as vomiting, unsettled tummy and diarrhoea and/or constipation can occur. This could lead to dehydration if left untreated. In the longer term, an infant consuming over-concentrated formula may consume excess energy and nutrients compared to nutrient requirements, and be at risk of excess renal solute load (Fomon 2000). Conversely diluted formula may result in insufficient energy and nutrient intake for normal growth and development.

4.3.1 Stakeholder views

The 2012 Consultation paper sought information on this issue by asking for evidence on:

- caregivers' use of measuring scoops other than those supplied with the product
- whether caregivers understand that scoop size (and therefore number of scoops per volume of water) differs between products.

Two literature reviews were cited in submissions as evidence of misuse of scoops: Renfrew et al. 2003 and Lakshman et al. 2009. A study by Winstanley and Cressey (2008) was also cited as evidence of high level compliance with preparation instructions. The relevance of these reviews and other published studies addressing the use of scoops are discussed in section 4.3.2.

Many submissions from health professional and consumer groups referred to anecdotal evidence that caregivers did not realise that scoop sizes differ between products and make errors in reconstituting product. In contrast, one consumer group provided responses from an unpublished online survey of their members; the results suggested their members had a general understanding about the importance of using the scoop supplied with each product. Industry stakeholders reported that feedback through their company 'Carelines' indicates that caregivers have a good awareness and understand the importance of using the correct scoop. It was noted that, generally, any change to packaging, including the scoop, elicits a spike in calls and emails to the company.

Submissions also commented on standardisation of scoop sizes and prescribing the wording of the related labelling statement. Several submissions from jurisdictions, individuals and public health stakeholders suggested that the size of the scoop for powdered infant formula should be standardised across all products to minimise the risk of caregivers wrongly using scoops that are smaller or larger than the one provided with the product. Industry submissions commented that scoop size cannot be standardised because there are differences in the bulk density and energy density of each powdered infant formula. They noted that any change to scoop size and/or powder to water ratio would require extensive reformulation of products across the industry. It was also noted that scoop size is not mandated anywhere in the world. A few submissions noted that infant formula in the UK has a standard preparation ratio of one scoop of formula for 30 mL of water. An industry body commented that although infant formula companies in the UK are generally aligned with this scoop to water ratio, this appears to be a historical industry norm, rather than the result of regulation.

Several government and industry submissions acknowledged there was potential for safety issues if the wrong scoop was used to prepare powdered infant formula. Some industry submitters noted they "would not oppose" mandating the wording of the statement required by paragraph 14(2)(d) of Standard 2.9.1 (paragraph 2.9.1—19(3)(d) in the revised Code) that 'only the enclosed scoop should be used', if there was evidence that it is appropriate. They noted that the majority of infant formula companies already use this exact statement where relevant on powdered products. One submission suggested the current labelling statement be extended to include further warnings on the dangers of not following these instructions, or a statement describing accurate filling of a scoop with a diagram showing correct levelling off of the scoop.

4.3.2 Evidence on measuring scoop use

Limited evidence was identified which specifically explored consumer understanding of the instructions relating to the measuring scoop. Only two studies examined whether caregivers used the enclosed product scoop to measure infant formula powder before reconstitution (Herbold and Scott 2008; Watson 2012). Both these studies found a high rate of compliance with using the enclosed scoop.

FSANZ also considered the literature reviews cited by submitters to the 2012 Consultation paper – Renfrew et al. (2003) and Lakshman et al. (2009). Renfrew et al. (2003) reviewed qualitative research undertaken in developed countries with the aim to assess what caregivers knew about the risks associated with errors in reconstituting infant formula. In relation to scoop use, both reviews focussed on whether caregivers used the correct number of scoops to prepare the formula, rather than use of the incorrect scoop. Renfrew et al. reviewed five descriptive studies, four of which were published prior to 1990. There was wide variation in aims, study design and outcome measures across these studies. Lakshman et al. (2009) reviewed both qualitative and quantitative studies carried out in developed countries. Their aim was to investigate parents' experiences of bottle-feeding, and the objective was to understand how formula-feeding decisions are made. The authors identified 23 studies, six qualitative and 17 quantitative, that met their criteria. There was large variation in the study design, context, focus and quality of the studies included in both reviews. Both reviews reported that errors in the preparation of formula were common across the studies reviewed, with a tendency to over-concentrate feeds (although dilution also occurred). However, the reviews also reported that caregivers usually supplied a rationale for the reconstitution amendment.

Winstanley and Cressey (2008), commissioned by the then New Zealand Food Safety Authority, undertook a New Zealand-based study to examine aspects of the preparation of powdered infant formula. The study involved a series of focus groups of caregivers currently engaged in the preparation of infant formula. One of the probe questions to examine current behaviour was: do you use the manufacturers scoop to measure out formula? This study found a high level of compliance with following instructions regarding the preparation of infant formula, though it did not specifically comment on whether caregivers used the enclosed scoop.

Although reconstitution errors were identified in the literature there is little evidence that this was related to use of the wrong measuring scoop (for the particular product) when preparing powdered formula, or of a lack of understanding among caregivers that the scoops are not transferrable. A number of studies identified that the key factors contributing to safe preparation of infant formula products are the knowledge and behaviour of caregivers. A component of this knowledge is the information provided to caregivers by official sources and the caregiver's interpretation of that information. Manufacturer information on packages of infant formula regarding scoop use is supplemented by guidance from health agencies, which also often emphasises the importance of using the scoop and instructions provided with each can.

4.3.3 Previous consideration under Proposal P93

During P93, ANZFA was asked to consider whether the scoop size should be standardised and mandated. There was also a suggestion that the dilution should be standardised to one scoop of formula to 30 mL of water across all brands and products. The assessment concluded that standardising the dilution factor and the scoop size was not appropriate because of the different product densities. There were many technical difficulties in setting a standard scoop size, and it would require all products to have the same powder density which was not feasible. Standardising the dilution factor would also have required some

reformulation of products. The requirement that the scoop must be suitable for use in accordance with the directions contained in the label on or attached to the package was retained. This assessment is still valid.

4.3.4 International and overseas regulations

FSANZ is not aware of any international or overseas regulations that standardise the scoop size for powdered infant formula. In the UK, infant formula companies tend to specify that one scoop of powder should be added for every 30 mL of water, though this is not a regulatory requirement. The scoop sizes still vary depending on product density.

4.3.5 Summary

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, as discussed above, 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, it is FSANZ's preliminary view that 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*'.

4.4 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 (see section 4.3 on 'measuring scoop').

4.4.1 Stakeholder views

Four submitters (two jurisdictions, one health group and one individual) raised concerns about volume indicators on bottles used to feed infants. One submitter recommended that FSANZ work with the National Measurement Institute (NMI) to explore the possibility of developing regulatory requirements for the accuracy of volume of feeding bottles. Two other submitters proposed that the Code should require an accurate measuring container for water be included in the package of infant formula powder, similar to the scoop.

4.4.2 Evidence of inaccurate volume measure indicators

In a submission to the 2012 Consultation paper, information was provided by the New Zealand Ministry of Health and Consumer Affairs (within the Ministry of Business, Innovation and Enterprise (MBIE)) which cited a survey undertaken in 2011 by Consumer Affairs. The research found that a number of infant feeding bottles sold in New Zealand had inaccurate volume measurement levels, ranging from -10 mL to +40 mL for a 100 mL measure. The research indicated the problem was mainly with low cost bottles, rather than the better known

brands. FSANZ is also aware of similar tests being undertaken in Australia which have identified some problems with the accuracy of volume measure indicators.

4.4.3 Current regulations

There is no specific standard in Australia or New Zealand that mandates that volume measure indicators on containers used in a domestic setting, such as infant feeding bottles, need to be accurate. However, both Standards Australia and Standards New Zealand refer to European Standard EN14350 (Child use and care articles – Drinking equipment), which outlines specifications for products including single use and re-usable feeding bottles. Part 1 (of the two part standard) includes requirements for volumetric labelling and accuracy, including test methodology. The standard requires the 100 mL volume indicator to be accurate within 5%. Some infant feeding bottles sold in Australia and New Zealand voluntarily comply with this European Standard, though these bottles are generally more expensive.

FSANZ has engaged with relevant government departments and agencies in Australia and New Zealand to determine the regulatory requirements for the accuracy of volume measure indicators on infant feeding bottles. Infant feeding bottles can be used to feed infant formula, breast milk or water in older infants. Their use is not limited specifically to infant formula.

Thus, infant feeding bottles are ‘consumer goods’ in both Australia and New Zealand, as they are goods which are sold to consumers. In Australia, consumer goods are subject to the general provisions of the *Competition and Consumer Act 2010*. There is no specific Australian mandatory standard for infant feeding bottles. Representations about bottles, such as what they are produced from or other characteristics such as volume indicators should be truthful and accurate. If a bottle is found to be defective or unsafe, various provisions of the Act would apply, such as statutory guarantees for consumers, supplier liability and product safety recall provisions.

Similarly, in New Zealand, the *Consumer Guarantees Act 1993* would apply, which has a blanket requirement that any goods sold in New Zealand must be safe. While the bottles themselves may not be unsafe, there may be scope for consumers to claim that the bottles are not ‘fit for purpose’ to accurately measure water to prepare infant formula.

4.4.4 Use of infant feeding bottles

Infant feeding bottles are used for both infant formula and breast milk. When used for preparation of infant formula, Ministry of Health officials have anecdotal information from the Royal New Zealand Plunket Society and from New Zealand paediatric dietitians that many caregivers use the volume indicators on infant feeding bottles to measure water when preparing infant formula.

4.4.5 Summary

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 consumer goods and not covered in 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.

Questions to submitters:

Q2.2 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.

5 Warning, advisory and other statements

The term ‘warning statement’ is defined in Standard 1.1.1 (section 1.1.2—3 in Standard 1.1.2 in the revised Code) to mean: “a statement required to be expressed in the text as so prescribed in the Code”, and specifically identifies those statements required in subclauses 14(1) and 14(3) of Standard 2.9.1 as warning statements.

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations (Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations in the revised Code) specifies mandatory information that must be provided for all food, where applicable. At present, only those generic labelling requirements listed in clause 4 of the Standard (section 1.2.4—1 in the revised Code) that relate to the declaration of allergenic substances are relevant to infant formula.

Standard 2.9.1 sets out statements that are specific to infant formula products. These include the warning statements described in paragraphs 14(1)(a), (b) and (c) in relation to following preparation instructions, and in subclause 14(3) in relation to the ‘breast is best’ statement (all paragraphs in subsection 2.9.1—19(1) in the revised Code). Standard 2.9.1 also sets out requirements for mandatory statements of an advisory nature for infant formula; these are described in the relevant sections below. The Guidelines attached to Standard 2.9.1 also recommend that advice about additional vitamin and mineral supplementation is provided on the label of a package of infant formula product. As the Guidelines are not part of the legally binding Standard, this advice is not mandatory.

This section outlines the elements of the Code that relate to warning statements and other statements for infant formula. This includes a full review of all existing requirements for statements, and the general legibility of such statements. Stakeholders have raised issues with some statements, and these along with related issues are discussed in this section.

5.1 Legibility requirements for warning statements

General legibility requirements for all foods, including infant formula, are regulated in Standard 1.2.9 – Legibility Requirements in the Code. Subclause 2(1) of Standard 1.2.9 states that “unless otherwise expressly permitted by this Code, each word, statement, expression or design prescribed to be contained, written or set out in a label must, wherever occurring, be so contained, written or set out legibly and prominently such as to afford a distinct contrast to the background, and in the English language”. Clause 3 of Standard 1.2.9 mandates the size of type for warning statements, based on the surface area of the label. In the revised Code, these requirements are set out in Division 6 – Legibility requirements in Standard 1.2.1 – Requirements to have labels or otherwise provide information.

Clause 15 of Standard 2.9.1 (section 2.9.1—20 in the revised Code) sets out specific requirements for print and package size for the warning statements prescribed by subclauses 14(1) and 14(3) (subsection 2.9.1—19(1) in the revised Code). Packages of infant formula with a net weight of more than 500 g must display the warning statements in size of type no less than 3 mm. Packages with a net weight of 500 g or less must display the same warning statements in size of type no less than 1.5 mm. These specific requirements override the general legibility requirements in Standard 1.2.9.

The intent of these general and specific requirements is to ensure prescribed information is readily accessible to the consumer before purchase and during the life of the product. The larger size of type is intended to be read more easily and alert consumers to important safety information.

In submissions on the 2012 Consultation paper, industry stakeholders, some government agencies and an organisation representing health professionals, commented that existing legibility requirements relating to the size of type for warning statements were satisfactory for the labelling of infant formula products and did not need to change.

A number of individuals and health professionals commented that bolding and capitalisation should be mandated for statements on infant formula labels. Also, the placement and size of type should be mandated such that statements can be easily seen and read by consumers. Many of these comments were in relation to the 'breast is best' statement (see section 5.4 for further discussion on the 'breast is best' statement).

FSANZ has not identified any evidence to indicate that the current legibility requirements for infant formula requirements are inadequate, and its preliminary view is to maintain the existing requirements set out in Standard 2.9.1. FSANZ seeks stakeholders' views on this position.

5.2 Adding other foods to formula

Infant formula is designed to meet the nutritional requirements of the infant at the intended concentration. 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 (NHMRC 2012; MoH 2013). The addition of other foods to infant formula modifies its composition, and consequently it may not meet the nutritional requirements of the infant or may be too concentrated with adverse effects to health.

5.2.1 Current regulation

In Standard 2.9.1, paragraph 14(1)(a) (paragraph 2.9.1—19(1)(a) in the revised Code) requires the label on a package of powdered infant formula to include the following warning statement:

Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill.

The warning statement for concentrated infant formula is the same, except the word 'concentrate' is used in place of 'powder'. The warning statement for 'ready to drink' infant formula products differs slightly (third sentence of paragraph 14(1)(c)), stating: *Do not dilute or add anything to this 'ready to drink' formula except on medical advice.* This has been replicated in paragraph 2.9.1—19(1)(c) in the revised Code.

5.2.2 Stakeholder views

This issue was raised in submissions to the 2012 Consultation paper with some government and public health submitters citing 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.

Submitters recommended that additional instructions be included on the product label to discourage this practice, for example: *Only put formula and water in the bottle. Do not add foods such as cereal and sugar.* One submitter suggested paragraph 14(1)(a) in the current Code be amended to include a similar statement to that in paragraph 14(1)(c) for 'ready to drink' products.

5.2.3 Evidence on adding other foods to formula

FSANZ has undertaken a literature search to identify relevant data on the practice of caregivers adding cereal and other foods to infant formula. The literature suggests this may be common practice, including in Australia and New Zealand, though it is not possible to estimate the prevalence of this behaviour. It is also not possible to determine from the studies whether it differs by product form (i.e. powdered, liquid concentrate or 'ready to drink'), though powdered infant formula is the most commonly used form of product in Australia and New Zealand. For further analysis of the evidence, see Attachment 2.

Options to communicate to caregivers that other foods should not be added to infant formula may need to be considered (for example, a label statement or education material provided by health agencies etc). New Zealand research (Winstanley and Cressey 2008) found that many caregivers experienced difficulties in obtaining information on infant formula, particularly information on preparation.

FSANZ is seeking stakeholder comments on the following questions to assist with its assessment of this issue.

Questions to submitters:

Q2.3 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 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 What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

5.3 Statement on protein source

Clause 18 of Standard 2.9.1 (paragraph 2.9.1—3(1)(a) in the revised Code) requires the infant formula label to contain a statement of the specific source, or sources, of protein in the product. Standard 2.9.1 specifies requirements for the quality and quantity of protein in infant formula but does not prescribe the protein source. The requirement to list the protein source ensures correct identification of products suitable for infants with particular dietary requirements.

Codex STAN 72-1981 requires the sources of protein to be clearly shown on the label. If cow's milk is the only protein source, the product may be labelled 'Infant Formula Based on Cows' Milk'.

Several submissions to the 2012 Consultation paper supported maintaining the requirement for a mandatory declaration of the protein source. One submission noted this declaration is important for infants with allergies. It provides consumers with information on the infant formula content and reduces the risk of fraudulent practices. Two submissions were of the

view that protein sources were not clearly identified across all brands. One of these suggested that Standard 2.9.1 should include a list of approved protein sources for use in infant formula and that must be declared in the mandatory protein source statement (for example, cow's milk, soy protein isolate and goat's milk). As protein quality and quantity is regulated for health and safety reasons, FSANZ does not consider that there is a need to mandate a list of permitted protein sources for declaration on the label. We note current practice of infant formula companies is to be very specific about the type of protein used (e.g. soy, casein-dominant, whey dominant, goat etc).

FSANZ's preliminary view is to maintain the current requirement to label the protein source as it ensures correct identification of products suitable for infants with particular dietary requirements. FSANZ seeks stakeholders' views on this position.

5.4 Co-location of protein source statement with the name of the food

Clause 18 of Standard 2.9.1 (paragraph 2.9.1—23(1)(a) in the revised Code) requires the mandatory statement about protein source to be located immediately adjacent to the name of the infant formula. In the current Code, an editorial note to clause 18 provides a signpost to labelling requirements for the name of the food. In the revised Code, the note refers to the labelling provisions in Standard 1.2.1. The intent of the note (in both versions of the Code) is to clarify that the name of the food to which the protein source must be immediately adjacent is the prescribed name 'Infant Formula'.

The Code does not specify where the prescribed name (and by association, the protein source statement) should be located on the label. This approach aligns with the approach taken for other foods that have a prescribed name (for example 'formulated supplementary sports food', 'fermented processed meat – heat treated', or 'honey'). As a result, the prescribed name and protein source information may be separate from (and less prominent than) the brand name of the product.

5.4.1 Stakeholder views

One industry submission to the 2012 Consultation paper did not support the requirement to place the statement of protein source(s) "immediately adjacent" to the name of the product, noting that it provides no apparent benefit to consumers. This submission stated that the editorial note to clause 18 (in the current Code) creates confusion and highlighted the current inconsistencies in how the statement on protein source is expressed on different product labels.

Two submissions, from a health professional and a consumer group, agreed there were inconsistencies across infant formula brands in how the protein source was declared on the label. They believed the protein source statement should be clearly stated on the front of the label using consumer friendly language. The consumer group noted that the Code did not mandate the location of the prescribed name (and therefore the protein source statement) on the label.

5.4.2 Current industry practice

FSANZ reviewed a range of current labels of packaged infant formula and found that the location of the protein source statement differs between products. Some products display the statement on the front of the product but separately from the prescribed name (such as near the bottom edge of the label). Other products locate the protein source statement and prescribed name within or alongside other required information, such as other mandated statements, usually on the back of the product. For example, a product may state 'Infant

formula made from whey-dominant cow's milk', followed by some of the mandated warning statements.

The exception to these labelling practices appeared to be products made from protein sources other than cow's milk (e.g. soy). These products tended to display the protein source information together with the brand or product name (which may include the prescribed name) in a prominent position, and in large font, on the front of the label. The protein source can be a key point of difference between these products, particularly those products that are intended for use in the management of intolerances and allergies, or are made from less traditional protein sources such as goat's milk, and standard types of infant formula.

5.4.3 Consumer use of the statement on protein source

Recent evidence from consumer research (see Attachment 2) suggests the protein source statement is useful for some caregivers seeking out infant formula not made from cow's milk (for example, because their infant has a food allergy), or who believe a whey-based infant formula will be best for their infant. However, there is no evidence available to determine whether caregivers have trouble finding the protein source statement which, in practice, may not appear on the front of infant formula product labels.

5.4.4 Summary

The variation in labelling practices and stakeholder comments suggest there is a lack of regulatory clarity regarding:

- the requirement to use the prescribed name as the name of the food
- its co-location with the protein source statement
- the position of this information on the label.

FSANZ's preliminary view is to maintain the existing requirement that the protein source statement must be immediately adjacent to the name of the food, and will consider how to make it clearer in the Code that the name of the food is the prescribed name.

While the position on the label of the protein source statement and the prescribed name is not regulated, infant formula companies are, however, including this information prominently on the labels of products made from protein sources other than cow's milk. FSANZ currently has no evidence that the current labelling practice is failing to meet the needs of those caregivers who require specific information for managing various health conditions. Stakeholder views are therefore being sought for the following questions.

Questions to submitters:

- Q2.6 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 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 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 What are the cost and trade implications of prescribing the position of the statement of protein source on the label?

5.5 Warning statement about following instructions exactly

Subclause 14(1) of Standard 2.9.1 (paragraphs 2.9.1—19(1)(a) to (c) in the revised 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. For powdered and concentrated forms, the warnings specify that the proportions must not be changed except on medical advice. For ‘ready-to-drink’ formula, the warning is not to dilute or add anything to the formula.

Infant formula is formulated for use as the sole source of nutrition for a young infant and incorrect preparation can negatively impact the health of the infant. The intent of these warning statements is to alert caregivers to the importance of following instructions about the essential hygiene measures for equipment (e.g. teats and bottles) and using the correct concentration. The wording of these warning statements is prescribed. The WHO Code and the Codex STAN 72-1981 both specify the need for a warning about the health hazards of inappropriate preparation, storage and use.

5.5.1 Stakeholder views

As noted in section 5.2 (adding other foods to formula), submissions from government and public health professionals cited anecdotal evidence that caregivers add other foods when preparing infant formula. One government submission suggested this is often a deliberate practice to address infant hunger and prolong sleep; this behaviour is not necessarily evidence of misunderstanding the label statements. Some evidence suggests carers are more likely to add cereal to the bottle as the infant grows older (see Attachment 2). Suggestions were made in submissions to either amend the existing statement on following instructions exactly, or to require an additional warning statement that discouraged this practice.

No particular issues were raised about the existing statement for ‘ready to drink’ products. FSANZ assumes this is because the warning statement specifically instructs caregivers to not dilute or add anything to the product. Other general stakeholder comments were made in relation to preparation instructions. One health professional submission indicated some caregivers choose not to heed the warning, for example they over-dilute formula to make it last longer, because the formula is costly.

One government submission referred to a New Zealand qualitative survey (Winstanley & Cressey 2008) in which a high level of compliance with the information on the preparation of infant formula in general was reported. Several industry submissions noted that, from feedback through customer information services (telephone ‘Carelines’), the majority of caregivers generally understand and follow instructions on the label.

5.5.2 Caregiver practices

Some research suggests that caregivers tend to rely most heavily for information on preparing infant formula on the formula package as they find it difficult to obtain information from health professionals on infant formula. Caregivers mentioned that health professionals believed they were ‘not allowed’ to provide information on formula feeding. Recent studies suggested that caregivers referred to preparation instructions, particularly when first using the formula, as these were very important elements of the label (Watson 2012; Yockney and Comfort 2013; Redmond and Griffith 2013d). In contrast, two studies found that the preparation instructions on infant formula cans were not a main source of information for caregivers (Labiner-Wolfe et al., 2008; Smith 2010). Research findings suggest that most caregivers report finding the instructions and statements easy to understand when they are

read (Labiner-Wolfe et al., 2008; Fein and Falci 1999). No studies were found which tested caregivers' understanding of preparation instructions on infant formula packages.

5.5.3 Summary

FSANZ considers the existing warning statement is effective. Therefore, FSANZ's preliminary view is to maintain the current requirement, and is seeking stakeholders' views on this position.

5.6 Warning statement that 'breast is best'

Subclause 14(3) of Standard 2.9.1 (paragraph 2.9.1—19(1)(d) in the revised Code) requires the label on a package of infant formula product 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* under a heading of 'Important Notice' (or any word or words that have the same or similar effect). This is often referred to as the 'breast is best' statement. This statement is subject to the specific legibility requirements set out in clause 15 (section 2.9.1—20 in the revised Code).

The intent of this requirement is related to alignment with the WHO Code principles and public health messages about the superiority of breastfeeding compared to formula feeding.

5.6.1 Stakeholder views

In response to the 2012 Consultation paper, a number of health professionals, consumer groups and individual submitters commented on the issue of amending the 'breast is best' statement to become a risk-based statement about the risks to infant health of *not* breastfeeding. Those submitters in support of a risk-based statement noted that there is a growing body of evidence about the benefits of breastfeeding, particularly in relation to reduced incidence of infectious diseases and potential reduced risk of chronic disease for infants. They want the superiority of breast milk compared to formula to be clear to caregivers, with the primary purpose to promote breastfeeding and maintain (or increase) current breastfeeding rates.

Other submitters were opposed to a risk-based statement approach. This included two consumer groups representing caregivers who have chosen to formula feed their infants. These submitters considered that the evidence to support such statements is inconclusive and therefore would be misleading if it were present on the label. They also noted that studies show that caregivers who formula feed their babies experienced negative emotions, such as guilt, anger, worry, uncertainty and a sense of failure, and that this type of risk-based statement on formula products could amplify these feelings. Additionally, one consumer group noted the findings of a survey of its members supporting the view that health-based risk warnings are not very effective.

Two submissions considered that a risk-based statement may amplify the experience of postnatal depression. One of these submitters conducted a survey of 100 respondents drawn from online networks that provide support for women with, or recovering from, postnatal depression. Some respondents believed risk-based statements about not breast feeding were potentially harmful, for example they could increase feelings of guilt in women already struggling with depression.

Other points made by submitters included that risk-based statements would give the impression that the product itself poses a health risk, that these types of statements do not actively promote breastfeeding, and that statements on a label would come too late in the decision making process about whether to breast feed or formula feed to be effective. One

government submitter noted that infant formula is a safe product due to its specific compositional requirements and that warning and advisory statements should be used only if there are health and safety concerns associated with the consumption of a food.

5.6.2 Evidence for/against a change

A review of existing literature by FSANZ has found that, for the majority of women, the decision about whether to breastfeed or formula feed is made either before they conceive or during pregnancy (Attachment 2). FSANZ has also examined the literature comparing gain-framed messages (emphasising the benefits of breastfeeding) and loss-framed messages (emphasising the risks of formula feeding). There is, however, insufficient information to determine whether either loss-framed or gain-framed messages would have an impact on caregivers' breastfeeding intentions or outcomes (Attachment 2).

5.6.3 Summary

FSANZ recognises that there is a body of evidence supporting the importance of breastfeeding for infants, including the provision of optimal nutrition, in assisting physical and emotional development, in reducing incidence and severity of infectious diseases, and the potential reduced risk of chronic disease (Ministry of Health 2008; NHMRC 2012). However, it is FSANZ's preliminary view that there is sufficient rationale to retain the existing statement in Standard 2.9.1. This view is on the basis that:

- once the decision is made not to breastfeed, then a risk-based statement could be considered contrary to infant feeding guidelines that state that infant formula is the only suitable and safe alternative when infants are not breastfed
- based on available evidence (see Attachment 2) a risk-based statement is unlikely to influence the decision about whether to breastfeed or formula feed, as research shows that the majority of women make this decision either before they conceive or when pregnant.
- the current statement is consistent with the WHO Code and the corresponding Australian and New Zealand agreements, and the Codex infant formula standard.
- caregivers already receive information about the advantages and disadvantages of breastfeeding and formula feeding from a multiple information sources, particularly in the prenatal period, to assist in their decision about whether to breastfeed or formula feed their infant (e.g. antenatal classes, midwives and other health professionals, and educational materials from government health departments).
- research on loss-framed messages (e.g. emphasising the risks of formula feeding) and gain-framed messages (e.g. emphasising the benefits of breastfeeding) has had mixed findings thus there is insufficient information available to determine whether either message type would have an impact on caregivers' breastfeeding intentions or outcomes.

FSANZ is seeking stakeholders' views on its preliminary position that the existing 'breast is best' statement is appropriate and that the existing requirement should be maintained.

5.7 Statement that infant formula product may be used from birth

Paragraph 14(5)(a) of Standard 2.9.1 (paragraph 2.9.1—19(4)(a) in the revised Code) requires a statement indicating that the infant formula product may be used from birth, in the case of infant formula. The purpose of this statement is to inform caregivers of the age

'suitability' of infant formula for infants aged from birth and is intended to be read in conjunction with other mandated statements such as the 'breast is best' statement. Codex STAN 72-1981 specifies that products shall be labelled in such a way as to avoid risk of confusion between infant formula, follow-up formula, and formula for special medical purposes. Stakeholder submissions to the 2012 Consultation paper did not raise any issues in relation to this statement.

FSANZ's preliminary view is that the statement remains relevant and that the existing requirement should be maintained.

5.8 Statement about age to offer foods in addition to formula

Paragraph 14(5)(c) of Standard 2.9.1 (paragraph 2.9.1—19(4)(c) in the revised Code) requires a statement on infant formula product labels (except packages for pre-term formula), indicating that infants over the age of six months should be offered foods in addition to the infant formula product. The statement is intended to provide advice to the consumer that additional foods should be included in the diet, in order to reduce the risk of ill health due to poor nutrition.

Part 9.6.4 of Codex STAN 72-1981 requires "information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months. "

Submissions to the 2012 Consultation paper did not contain any comments on this specific requirement.

FSANZ notes the statement is consistent with current Australian and New Zealand infant feeding guidance (NHMRC 2012; MoH 2008). These guidelines refer to 'around six months' as the age for introducing solid foods; they also mention that solid foods become an increasingly important part of an infant's diet beyond six months of age. Introducing solid foods too late can cause growth to falter, micronutrient deficiencies, compromised immunity and a delay in motor skills development (e.g. chewing). The statement is also consistent with Codex. FSANZ's preliminary view is that this labelling statement is appropriate and should be maintained without change. FSANZ seeks stakeholders' views on this position.

5.9 Guidance statement about additional vitamin and mineral supplementation

The Guidelines attached to Standard 2.9.1 (Schedule 29—10 in the revised Code) include a guideline on advice regarding additional vitamin and mineral supplementation that states:

Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations are not necessary.

As this is guidance only, infant formula companies can choose whether to provide this advice on their product labels. This guidance statement reflects the vulnerability of infants and the potential risks associated with excess intake of vitamins and minerals. The relevance of this advice today in the context of public health and safety will be considered in this Proposal, though as part of a future report.

The following information is provided as background to this issue and identifies current gaps in the evidence base.

5.9.1 Stakeholder views

FSANZ has not previously consulted on this issue. The 2012 Consultation paper identified this statement as being part of the voluntary Guidelines, though its relevance in the context of public health today and whether the statement was fit for purpose was not discussed.

However, one jurisdiction commented that the Guideline advice 'that consumption of vitamin and mineral preparations is not necessary' remains relevant today and that the requirement for the statement should be incorporated into Standard 2.9.1 (and therefore made mandatory). It also considered that this statement should include the proviso 'unless medically indicated'. The basis for this view was anecdotal evidence from paediatric dietitians that some parents give formula-fed infants vitamin and mineral supplements believing them to be beneficial.

5.9.2 History of the statement

Before the joint Code was developed, both Australian and New Zealand food regulations required infant formula labels to display a statement that formula-fed infants do not require additional vitamin and mineral supplements. The need for this statement was reviewed during P93, at which time it was determined that the statement would assist in protecting against the risk of toxicity arising from excessive vitamin and mineral intakes. However, it was noted that international and overseas regulations did not require such a statement, and so it could constitute a technical barrier to trade if mandated in Australia and New Zealand (ANZFA 2002). Therefore it was agreed the statement would be voluntary. It was included in the Guidelines to the Standard to encourage infant formula companies to display this information on product labels.

FSANZ is not aware of any international or overseas regulations that require or recommend infant formula product labels to display advice about use of vitamin or mineral preparations for infants.

5.9.3 Current labelling practice

FSANZ examined a range of products available on the Australian and New Zealand market. The majority of infant formula sold in Australia and New Zealand do not display the recommended advice about additional vitamin and mineral supplementation. Of the products that do, most display this information in conjunction with the mandatory preparation and use instructions for the product.

5.9.4 Infant feeding guidelines

The statement that 'consumption of vitamin and mineral preparations are not necessary' is consistent with current national infant feeding guidelines in Australia and New Zealand. The respective Australian and New Zealand infant feeding guidelines (NHMRC 2012; MoH 2008) advise that infants, both breastfed and formula-fed, generally do not require dietary supplements, including vitamin and mineral supplements.

One of the required statements on an infant formula label states that a health worker should be consulted before the use of infant formula. Given the guidance for health workers includes information on how infants do not need to consume vitamin and mineral preparations in addition to infant formula, consideration needs to be given to the need for this statement on an infant formula label. Such information could be provided by the health worker or through other means such as health education resources targeted at consumers. Manufacturers may voluntarily provide such information in their information provided to health professionals, or as part of information provided to consumers, e.g. websites, Carelines.

5.9.5 Supplement intake in Australian and New Zealand infants

There is limited data on dietary supplement intake of Australian and New Zealand infants. No relevant data for the infant age group was identified for New Zealand. The *New South Wales Population Health Survey: 2007–08 Report on Child Health* (NSW Department of Health, 2010) reported that among children less than seven months of age who were being breastfed, 19.6% had received vitamin or mineral supplements or medicines in the previous 24 hours. However there was no breakdown of the results for vitamin or mineral supplements alone in the results reported.

The practice of caregivers adding vitamins and minerals directly to infant formula does not appear to be common, although it has not been extensively explored in the literature. From the available evidence, see Attachment 2, no conclusion can be reached about the likely prevalence of caregivers adding vitamins and mineral to infant formula in Australia and New Zealand.

5.9.6 Current market for vitamin and mineral preparations for infants

A number of vitamin and mineral preparations designed specifically for infants are available from pharmacies in Australia and New Zealand. The product labels identify them as products for infants and/or children, providing an age range for use and in some cases the term 'infant' is used in the product name. All identified products were in liquid (drop) form.

Of the vitamin and mineral products identified, they contained approximately 450 µg vitamin A, 10 µg vitamin D and 10 µg iron per recommended daily dose, as well as other nutrients, equating to between 40-75% of the relevant upper level of intake. None of the products identified provided guidance on the label about their use for formula-fed infants (or breastfed infants).

5.9.7 Summary

FSANZ is 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.

Questions to submitters:

- Q2.10 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 Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?
- Q2.12 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 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 What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

5.10 Prescribed name

Under generic requirements in Standard 1.1.1 the term ‘prescribed name’ is defined to mean a name by which a food is defined or described in a Standard, and is declared in this Code to be a prescribed name. In the revised Code, the term ‘prescribed name’ is defined in subsection 1.1.2—2(3) to mean, for a particular food, ‘a name declared by a provision of the Code to be the prescribed name of the food’.

Paragraph 1(1)(a) of Standard 1.2.2 – Food Identification Requirements requires the label on a package of food to include the prescribed name of the food, where the name of the food is declared in this Code to be a prescribed name. In the revised Code, paragraph 1.2.2—2(2)(a) states that the name of the food is the prescribed name if the food has a prescribed name.

Clause 12 of Standard 2.9.1 (subsection 2.9.1—17(a) in the revised Code) states that ‘Infant Formula’ is a prescribed name. Clause 11 of this Standard (section 2.9.1—16 in the revised Code) states that a product cannot be represented as an infant formula product unless it complies with Standard 2.9.1. The intent of this latter clause (section) is that it includes meeting the definition for ‘infant formula’. 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. This is particularly important from a health perspective for formula-fed infants who may rely on infant formula as the sole source of nutrition. The prescribed name ‘Infant Formula’ is consistent with Codex STAN 72-1981, where section 9.1.2 specifies the name of the product shall be either ‘Infant Formula’ or any appropriate designation indicating the true nature of the product, in accordance with national usage.

Stakeholders who responded to the 2012 Consultation paper considered the prescribed name ‘Infant Formula’ appropriate and supported continuing the requirement for it to be included on the label. FSANZ’s preliminary view is to maintain this requirement.

6 Nutritive substances and novel foods in infant formula

The regulation of nutritive substances and novel foods in the Code, particularly their definitions, has come under scrutiny in recent years. FSANZ is currently working (through [Proposal P1024 – Nutritive Substances and Novel Foods](#)) to clarify current provisions to allow for improved compliance and enforcement with the Code.

Proposal P1028 will consider the regulation of nutritive substances and novel foods in infant formula, because infant formula products (and food for infants) are excluded from the scope of Proposal 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.

6.1 The Code

The intent of the Code is that pre-market approval is required for all nutritive substances, novel foods, food additives and processing aids proposed for use in infant formula. The use of novel foods or nutritive substances as ingredients or components of food are prohibited unless there are express permissions in the Code. Prior to use in infant formula, nutritive substances and novel foods need to be established as safe and be demonstrated that they provide a nutritive or health benefit for formula-fed infants. This approach means infant formula companies or other applicants seeking permission to add a new substance to infant formula must make a pre-market application to FSANZ. An application is also needed to extend a permission for a substance, for example to raise the maximum permitted amount.

The use of nutritive substances and novel foods in infant formula is covered by several overarching provisions in the Code. The relevant provisions in the current Code are:

- Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions: includes a definition of nutritive substance and a prohibition on the addition of nutritive substances to food unless they are expressly permitted in the Code (clause 9).
- Standard 1.5.1 – Novel Foods: includes a definition of novel food and a prohibition on the sale of a novel food (as food or for use as a food ingredient) unless it is listed in the table to the Standard.
- Standard 2.9.1 – Infant Formula Products: Clause 6(1) prohibits the addition of a vitamin, mineral, food additive or nutritive substance to infant formula product unless: (a) expressly permitted by the Code; or (b) it is naturally present in an ingredient of the infant formula product. Clause 7 provides a list of nutritive substances permitted to be added to infant formula products on a voluntary basis.

Under the revised Code, the relevant provisions for nutritive substances and novel foods have been revised slightly to reflect the overall structure and drafting conventions followed in the revised Code. These changes are explained in the [Approval Report for P1025 – Code Revision](#) (FSANZ, 2014b). A summary of the definitions for nutritive substance and novel food in the current Code, and the variations in the revised Code, are reproduced in subsections 6.2.1.1 and 6.2.1.2 respectively.

6.2 Problems with the current Code provisions

6.2.1 Definitions

6.2.1.1 Definition of nutritive substance

The New South Wales Supreme Court (December 2009) identified a number of ambiguous terms in the definition of nutritive substance that made interpretation very difficult³. The definition includes terms that are themselves not clearly defined. In particular, terms like 'normally consumed', 'nutritive purpose' and 'ingredient' are not defined in the Code. The definition for nutritive substance is amended under the revised Code to 'used as a nutritive substance', however due to the limited scope of the revision, the above individual terms were not amended pending further consideration of these issues in relevant proposals. The lack of clear meaning of these terms creates uncertainty and ambiguity in the overarching definition of nutritive substance. This uncertainty makes it difficult to decide which substances need pre-market approval before they can be added to infant formula.

In the context of infant formula, substances are either added for their use as a nutritive substance or to perform a technological function. The major difficulty arises for substances that may be subject to the definition. Vitamins and minerals and other substances that are specifically referred to in the Code as nutritive substances are straightforward as they are clearly identified as nutritive substances. However, substances that are not specifically identified in the Code as being nutritive substances are subject to an interpretation.

New food substances are being developed as the food industry continues to innovate in the area of functional foods. Many of these substances may be considered to be added for nutritional purposes. It is not possible to predict the exact nature of nutritive substances that may be developed in the future. The current definition attempts to overcome the absence of knowledge of substances yet to be developed by the inclusion of terms like 'normally consumed as a food', and 'achieve a nutritional purpose', which provide flexibility at the expense of certainty.

Table 6.1: Definitions of nutritive substance

Location	Definition
Current Code (Standard 1.1.1)	Nutritive substance means a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides.

³ The revised Code definition of 'used as a nutritive substance' replaces the definition of 'nutritive substance'. However, the revised definition maintains the terminology referred to by the Court. Addressing the issues associated with these terms has been reserved for Proposal P1024.

Location	Definition
Revised Code (Section 1.1.2—12)	<p>(1) In this Code, a substance is used as a nutritive substance in relation to a food if it is added to the food:</p> <p>(a) to achieve a nutritional purpose; and</p> <p>(b) it is a substance identified in subsection (2).</p> <p>(2) For subsection (1), the substances are:</p> <p>(a) any substance that is identified in this Code as one that may be used as a nutritive substance; and</p> <p>(b) a vitamin or a mineral; and</p> <p>(c) any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food.</p>

6.2.1.2 Definition of novel food

Proposal P1024 is addressing issues related to Standard 1.5.1, including the definition of novel food. However, the lack of clarity in relation to use of novel foods in infant formula needs to be considered in this Proposal. The current definition of novel food includes two arms as shown below.

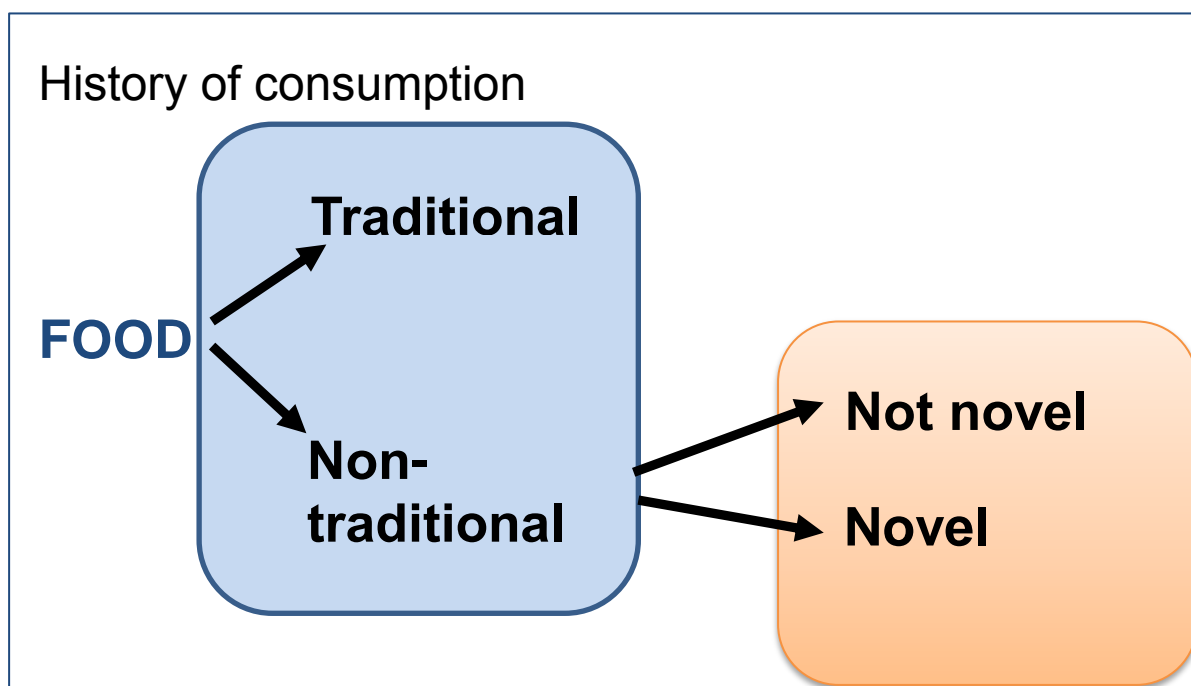


Figure 6.1: Operation of the current definition of novel food

The first arm is a definition of ‘non-traditional food’. The second arm is a definition of ‘novel food’, which is a subset of ‘non-traditional food’. A food must be considered non-traditional before it can be considered novel. The definitions for *non-traditional food* and *novel food* in the current Code, and replicated in the revised Code (section 1.1.2—8) are shown in the table below.

Table 6.2: Elements of the novel food definition

Non-traditional food	<p>means –</p> <ul style="list-style-type: none"> (a) a food that does not have a history of human consumption in Australia or New Zealand; or (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.
Novel food	<p>means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to:</p> <ul style="list-style-type: none"> (a) the potential for adverse effects in humans; or (b) the composition or structure of the food; or (c) the process by which the food has been prepared; or (d) the source from which it is derived; or (e) patterns and levels of consumption of the food; or (f) any other relevant matters.

The definition of ‘non-traditional food’ includes the term *history of human consumption*, which is not defined in the Code. As such, the definition of non-traditional food is subject to a similar level of uncertainty and ambiguity as the definition of nutritive substance. Therefore, it is difficult to be certain which foods should be considered non-traditional and therefore whether they should be subject to the second arm of the definition of novel food.

The second arm defines a novel food as a non-traditional food that *requires an assessment of the public health and safety considerations having regard to* (a number of matters which are set out). This phrase is also considered to be ambiguous and not clearly defined elsewhere in the Code. However, this ambiguity raises an additional problem to those identified above for the definitions of nutritive substance and non-traditional food.

Applying the phrases of non-traditional and novel to substances is at times subjective and is a matter of judgement as to whether an assessment is required. In the context of infant formula, determining whether a substance is ‘traditional’ or not in relation to breast milk or dairy milk is particularly uncertain. FSANZ has received enquiries as to whether substances produced from dairy milk that are identified in breast milk would be traditional or ‘non-traditional’ when added to infant formula. For example, human colostrum is traditionally consumed by infants in the first days of life; however, bovine colostrum would not be traditionally consumed by infants. Another relevant example from the literature is glycomacropeptide, a sialic acid rich peptide⁴ that occurs naturally in small amounts in bovine milk and which can be isolated from whey protein by the action of rennet (chymosin) during the manufacture of cheese and other dairy food processing (Neelima et al 2013). Although not present in human milk, glycomacropeptide is formed during digestion of breast milk (Sandstrom et al 2008), and thus may be considered traditional by some.

The issues with these definitions mean that the requirements of the standard itself are based on uncertainty when they should be objective and clearly interpretable. In addition, the

⁴ Glycomacropeptide (GMP) is a C-terminal part (f 106–169) of kappa-casein. The literature suggests that the composition of GMP is variable depending on the particular whey source and the fractionation technology used to isolate it.

Standard fails to make it clear who is responsible for determining whether an assessment is required and subsequently who should undertake the assessment. Food enforcement agencies have advised FSANZ that this aspect of the definition presents difficulties when determining whether a food is novel or not, particularly in relation to who makes that decision. While a food enforcement agency may consider that an assessment is required (i.e. the substance is novel), it is possible for an infant formula company or food business to argue that they have done the relevant assessment and on that basis the food they are supplying is safe and therefore not novel.

6.2.2 Category overlap

Novel food and nutritive substance are not mutually exclusive categories. An increasing number of substances intended to be added to infant formula could be considered to meet both the nutritive substance and novel food definitions. Substances can be produced through a novel process or from a novel source with the intended use to act as a nutritive substance in infant formula. For example, oil rich in DHA derived from the micro-algae species which is a novel ingredient permitted for use in infant formula in the European Union, or phospholipids derived from egg yolk to provide arachidonic acid (AA) and DHA (US FDA 2012).

This overlap of categories has caused confusion for stakeholders and potential uncertainty around the appropriate regulation of substances in infant formula. It has added to the difficulty in determining whether a new ingredient or substance may require an application to FSANZ for regulatory pre-market approval if no current permission exists in the Code.

6.2.3 Nutritive substances naturally present in an ingredient

Standard 2.9.1 prohibits the addition of vitamins, minerals, food additives and nutritive substances to infant formula, unless expressly permitted, through subclause 6(1)(a) in the current Code. Subclause 6(1)(b) states this prohibition does not apply if the vitamin, mineral, food additive or nutritive substance is naturally present in an ingredient of the infant formula product.

FSANZ is aware that there are differing interpretations of subclause 6(1)(b) for those substances *naturally present in an ingredient of the infant formula product*. For example, for a nutritive substance naturally present in the milk powder used to make the product, the following interpretations of subclause 6(1)(b) have been shared with FSANZ:

- an extracted form of this nutritive substance can be added back to the infant formula to the level that may be found in the original ingredient (i.e. milk)
- an extracted form of this nutritive substance can be added to increase the levels beyond what would be seen in milk
- the substance may be present with no action required on the part of the manufacturer to remove it, but the manufacturer cannot add more of that substance.

It is important that the intent of subclause 6(1)(b) is clarified as improvements in technology mean that components in dairy products can now be identified and then extracted, refined and purified as substances. Infant formula companies may want to add some of these components to infant formula for various purposes. For example, alpha-lactoalbumin can lower total protein content while maintaining the amino acid profile (Lonnerdal, 2014; Kelleher et al. 2003) to better meet the mandatory macronutrient requirements for infant formula, or could potentially provide a nutritive or health benefit for the formula-fed infant. Similarly, addition of another whey protein component, lactoferrin, to infant formula could potentially make the composition of the product closer to breast milk, and enhance iron absorption (McSweeney et al, 2013).

The revised Code has retained the intent of the prohibition, though the use of nutritive substances is now expressed as a permission with certain conditions that must be met. Subsection 2.9.1—5(1) provides the permission for use of nutritive substances, and paragraph 2.9.1—5(1)(b) clarifies the original intent for substances naturally present in an ingredient and are still present in the final product (i.e. have not specifically been added). However, there is still a lack of clarity around substances that are extracted through milk processing, and whether they may be added to infant formula or back to milk powders used in infant formula and at what levels.

6.3 Stakeholder views

The 2012 Consultation paper asked submitters: *What provisions in the Code for the composition of infant formula and follow-on formula are unclear and ambiguous? What are the specific issues and how would you suggest the intent of the specific provision be clarified?*

Four jurisdictional submitters considered greater clarity is required in relation to adding new substances to infant formula. They noted concerns with the definition of ‘nutritive substance’ and with paragraph 6(1)(b) of Standard 2.9.1 which, in their view, could lead to uncontrolled and potentially excessive addition of nutritive substances to products. The lack of an appropriate definition for these substances was considered to be a major issue for enforcement. One submitter stated that they were not necessarily in support of retaining a definition for ‘nutritive substance’, instead preferring a new approach to permitting new ingredients consistent with Ministerial policy guidance. All government submissions supported a restrictive approach to regulating new substances in infant formula in line with the relevant Ministerial Policy Guideline (see section 6.4.1), specifically in relation to specific policy principles (i) and (j) and the pre-market assessment requirements.

Industry submitters noted different interpretations of the pre-market assessment requirements for nutritive substances. They also noted confusion with the way Standard 2.9.1 regulates substances, macronutrient components or ingredients in infant formula. Examples included problems with:

- the definition of nutritive substance and ingredients added for a nutritional purpose or biologically active substances added for specific developmental or functional purposes
- ingredients that contribute to the macronutrient composition of the formula (i.e. protein, fat and carbohydrate sources) that are added for specific developmental or functional purposes above and beyond the basic macronutrient profile.

There was also comment that Standard 2.9.1 should not attempt to expressly list every safe and suitable substance that may be added to infant formula. Industry submissions did not support the need for pre-market assessment of every prospective new ingredient in infant formula. These considered that nutritive substances and novel foods for use in infant formula should be regulated in the same manner as for general foods in the Code. A number of other submissions took the opposite view, stating that the types of substances that may be added to infant formula should be treated differently to ‘nutritive substances’ in general foods in the Code. Pre-market assessment requirements should apply to all prospective new ingredients as per the policy guidelines.

6.4 Current regulatory environment

6.4.1 Ministerial Policy Guideline

The [Ministerial Policy Guideline on the Regulation of Infant Formula Products⁵](#) (the Policy Guideline) was developed to address two concerns identified by the then Food Regulation Standing Committee (FRSC). These related to the regulation of new optional substances added to infant formula. The issues were defined as (FRSC WG on the Regulation of Infant Formula Products, 2009):

- incomplete regulatory oversight of the addition of substances to infant formula products
- a lack of a process to substantiate that a substance added to infant formula provides a nutritional or health benefit to the infant, or has a role in normal growth and development.

The Policy Guideline specifies that regulations for infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula-fed infants (specific policy principle (c)). Accordingly, the Policy Guideline states that any new substance proposed for use in infant formula without a history of safe use, or any substance modified or produced by different technology from one that has a history of safe use, should be subject to pre-market assessment (specific policy principle (i)). It specifies that these substances should have a substantiated beneficial role in the normal growth and development of infants or children. 'Substantiated' is given to mean that appropriate evidence should exist to link biochemical, physiological, and/or functional effects to specific health outcomes in infancy or childhood (specific policy principle (j)). The Policy Guideline acknowledges that it might not always be possible to substantiate clear links between beneficial health outcomes and biochemical, physiological and/or functional effects. In such cases, it guides FSANZ to apply particular caution.

The other specific policy principles for the composition of infant formula products are:

- d) and e) Infant formula should strive to achieve the normal growth and development of healthy, full term, breastfed infants in the same age group as those for whom the product is intended. Normal growth and development should be determined by appropriate and measurable physiological, biochemical and functional outcomes.
- f) and g) The essential (mandated) composition must satisfy the nutritional requirements of infants and be shown to be essential for normal growth and development
- h) Breast milk composition should be a primary reference for determining formula composition.

As previously mentioned, the current regulatory approach in the Code requires the pre-market approval of all new substances proposed to be added to infant formula although this is difficult in practice. One interpretation of the Policy Guideline would require pre-market assessment of *all* new substances and ingredients i.e. any change to formulation. Such an approach may considerably expand the scope of regulatory oversight beyond that currently required for novel foods and permitted substances to any change to an infant formula formulation. If routinely adopted, this approach has the advantage of removing the uncertainty about which substances need pre-market assessment, but conversely could increase the regulatory involvement in any changes to the formulation of an infant formula.

⁵ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/Pages/default.aspx>

A more pragmatic interpretation would require pre-market assessment of only *certain* substances, which is more consistent with the current approach in the Code and with that proposed under P1024.

6.4.2 International and overseas approaches

FSANZ has reviewed the regulatory approaches of Codex and major overseas jurisdictions for the addition of substances to infant formula. The regulatory frameworks in the European Union (EU), the United States (USA) and Canada are described, and a summary of approaches is provided at Attachment 3. Specifically, the definitions used to identify types of substances, the process for approval to use new substances in infant formula, and notification procedures for new/reformulated products is considered. These regulatory approaches, or elements of them, may help consider potential approaches to regulating nutritive substances and novel foods in infant formula in Australia and New Zealand.

6.4.2.1 Definitions

The regulatory definitions used in the EU, USA and Canada for novel foods and nutritive substances (or equivalent terms), if they exist, are provided in the summary tables in Attachment 3. To FSANZ's knowledge there is no definition for either novel food or nutritive substance in any Codex Alimentarius standards, guidelines or codes of practice. In the USA, the overarching term 'food additive' is used for any substance that is intentionally added to food. 'Novel food' is defined in the Canadian regulations, but no formal definition is provided in either the USA or EU regulations. However, generally the concept of novel food in these jurisdictions is similar to its use in Australia and New Zealand, in relation to types of substances captured and whether the substance has a history of human consumption. Neither Canada nor the EU defines 'nutritive substance' (or similar) in their regulations, though the term is used in the Canadian regulations.

6.4.2.2 Approval of new substances

The addition of new substances to infant formula historically has been tightly regulated in Australia and New Zealand, and universally in all like economies due to the inherent health risks for formula-fed infants.

The scope of Codex STAN 72-1981 does not extend to outlining a framework for considering new substances for addition to infant formula. The Standard includes two clauses on the addition of optional ingredients. These clauses state:

...other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to the outcomes of breastfed babies.

The suitability for the particular nutritional uses of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect, taking into account levels in human milk.

The use of a pre-market assessment framework in Australia and New Zealand is broadly consistent with the approaches taken by major overseas jurisdictions.

In the USA, for a substance to be used in infant formula it needs to either be accorded a status as generally recognised as safe (GRAS) for use in infant formula, approved as a food additive for use in infant formula, or authorised by a prior sanction. The process for each route differs, ranging from a GRAS self-determination (though this can be reviewed by FDA at any time) to a formal pre-market approval with the substance listed in regulation. A new GRAS substance can be used in food when "it is generally recognised, among qualified

experts, as having been adequately shown to be safe under the conditions of its intended use". The evidence that establishes the substance is safe under the conditions of its intended use must be widely available. The GRAS system does not require notification to the FDA or a response from the FDA prior to use of the new substance in foods.

The EU and Canada each have a specific novel food regulation and pre-market approval process, which applies to novel foods for use in infant formula. The EC is currently reviewing the legislation for the authorisation and use of novel foods and novel ingredients in the EU. Similarly, pre-market assessment by national competent authorities is required in the EU for other substances (i.e. other than vitamins, minerals, amino acids etc) for use in infant formula to ensure the substance is safe and suitable for infants based on generally accepted scientific data. The Canadian approach prohibits the addition of other new substances (i.e. other than novel foods and food additives, which are regulated separately) unless they meet certain criteria. The criteria includes that the nutritive substance is normally contained in human milk and the amount added is equal to that present in human milk.

The information requirements set by each of the major jurisdictions for the pre-market assessment of new substances for use in infant formula is similar to that required in Australia and New Zealand. As shown in Attachment 3, although there are differences in the description of substances that can be optionally added to infant formula in the major overseas jurisdictions, all require the safety of these substances for infants to be established. For nutritive-type substances, the USA, Canada and the EU all require evidence to demonstrate efficacy of the substance to deliver the nutritional or physiological effect, and evidence to show that the formula has the ability to support normal physical growth in infants.

6.4.2.3 Notification of new/reformulated products

In the USA, Canada and the EU, food businesses must notify the relevant national authority of any new or modified infant formula product that will be marketed. In the USA and Canada, this must be done prior to the product being placed on the market, and the information submitted must include details on the composition of the product and assurances that it is safe and suitable for its intended use. Whereas in the EU, the notification is made at the time the product is placed on the market with a model of the label of the product forwarded to the competent authority in the Member State where it will be marketed.

Pre-market notification at the product level is not currently required in Australia and New Zealand.

6.4.3 Proposal P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods

The recent 1st call for submissions for P1024 seeks to improve the regulation of nutritive substances and novel foods to ensure appropriate pre-market safety assessment of these foods before they are sold in Australia and New Zealand. The options presented include (1) retain the status quo, (2) retain the status quo but with amended definitions for nutritive substances and novel foods, and (3) develop an alternative framework. Although the approach implemented under P1024 for general foods may be able to be considered for infant formula, FSANZ will consider infant formula separately given the vulnerability of formula-fed infants and the current regulatory environment.

6.5 Summary

The review of the regulatory approach for the addition of new substances to infant formula will progressively develop over the course of this Proposal. The ambiguity associated with the definitions of nutritive substance and novel food has resulted in confusion about whether a substance is subject to pre-market approval by FSANZ, and therefore creates uncertainty

in the market place. There is also a lack of clarity around substances that are extracted through milk processing, and whether these may be added to infant formula without pre-market approval.

As a first step, the principles for the overarching regulatory approach for infant formula need to be established. The regulatory approach could range from an all-encompassing prohibition to an open permission, or involve a graduated approach commensurate with the risk posed by a substance to infant health. Future reports will address how the preferred regulatory approach might be achieved in the Code, and the information requirements for the pre-market assessment of new substances if necessary.

Questions to submitters:

Q2.15 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 What would be the cost and trade implications of your preferred position?

Q2.17 If only *certain* substances for use in infant formula should require pre-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 If only *certain* substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

7 Contaminants

Chemical contaminants may occur at low concentrations in all foods, including infant formula. It is not possible to avoid the presence of very low level contamination in some cases, for example for certain metal contaminants that are ubiquitous in the environment. As a general principle, the levels of contaminants and natural toxicants in all foods should be kept As Low As Reasonably Achievable (the ALARA principle). Where the Code serves an effective risk management function, Maximum Levels (MLs) have been established for some contaminants in infant formula consistent with protecting public health and safety.

Generally when considering changes to the Code, FSANZ routinely has regard to the standards of Codex. For some foods, concentrations of contaminants in Australia and New Zealand may differ from concentrations in food produced overseas; however, this is not considered to be the case for infant formula, which is an internationally traded product. Thus, following safety considerations, harmonisation with Codex would generally be the preferred approach.

In this section, we have reviewed the current MLs for infant formula in the Code and in both Codex STAN 72-1981 and the Codex General Standard for Contaminants and Toxins in Food and Feed (Codex STAN 193-1995). In this review, FSANZ has taken account of the Risk Profile of Contaminants in Infant Formula at Attachment 4. We have focused on the contaminants that have MLs applicable to infant formula, either in the Code and/or Codex. In addition, arsenic was considered because of a recent international assessment. These contaminants are discussed in alphabetical order. Other issues relating to current regulation of contaminants in the Code, specifically the location of MLs in the Code, and ML concentration units used for infant formula are also discussed in this section.

7.1 Background

7.1.1 The Code

The Code defines a maximum level (ML) as meaning:

the maximum level of a specified contaminant, or specified natural toxicant, which is permitted to be present in a nominated food expressed, unless otherwise specified, in milligrams of the contaminant or the natural toxicant per kilogram of the food (mg/kg).

The Code currently includes MLs for the metals: arsenic, cadmium, lead, and mercury; in addition, for all food there are MLs for acrylonitrile and vinyl chloride and for canned food, an ML for tin. MLs for contaminants in infant formula are located in both Standards 1.4.1 – Contaminants and Natural Toxicants (and Schedule 19 – Maximum levels of contaminants and natural toxicants in the revised Code) and 2.9.1.

In March 1999, FSANZ reviewed the provisions for Maximum Permitted Concentrations (MPCs⁶) of metal contaminants in food in order to develop Standard 1.4.1. The approach agreed to by the then Australia New Zealand Ministerial Council⁷ was that MLs would be set in the following circumstances:

- only for those contaminants that present a significant risk to public health and safety
- only for those foods that significantly contribute to the dietary exposure of the contaminant
- to ensure that levels are as low as reasonably achievable
- consistent with Codex levels, where possible. However, harmonisation with Codex is secondary to measures put in place to protect the public health and safety of Australians and New Zealanders.

These principles underpin the MLs that are currently in the Code.

7.1.2 Codex Alimentarius

At the international level, Codex sets either MLs or Guideline Level (GL). In infant formula both MLs and GLs have been established. The Codex Committee on Contaminants in Foods (CCCF) establishes or endorses permitted maximum levels or guidelines levels for contaminants and naturally occurring toxicants in food and feed taking into consideration any risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

A GL is the maximum level of a substance in a food or feed commodity which is recommended by Codex to be acceptable for commodities moving in international trade. When a GL is exceeded, the Codex STAN 193-1995 states that governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. Codex GLs are 'historical' levels which the Codex has decided should be reviewed if appropriate for their possible conversion to MLs after a risk assessment performed by the JECFA. In contrast to GLs, MLs are the maximum concentration of the substance recommended by Codex to be *legally permitted* in that commodity. Codex STAN 193-1995 was last reviewed in 2009 and last amended in 2013.

⁶ Now known as maximum limits (MLs)

⁷ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation

There are some differences between the Code and Codex in which type of infant formula the ML applies to; this is discussed further in the relevant sections below. Table 7.1 provides a summary of the comparison between the Code and Codex.

7.1.3 Stakeholder views

The 2012 Consultation paper sought views on whether full alignment of infant formula contaminant levels with Codex infant formula contaminant levels is appropriate. Some submitter comments are discussed under the issue heading in the following subsections. In general, many of the submissions supported the harmonisation and alignment of the Code with the Codex standards. A number of industry submissions also supported the consolidation of all contaminant MLs in one location in the Code i.e. Standard 1.4.1.

Several submissions drew attention to the more comprehensive list of MLs (i.e. additional substances) for infant formula in the EU regulations. However, they did not suggest full alignment at this stage on the basis that the lack of alignment was not creating trade difficulties.

Table 7.1: Contaminant provisions applicable to infant formula in the Code compared to Codex

Contaminant Name	The Code		Codex		Potential amendments to the Code to align with Codex
	Maximum Level	Food(s)	Maximum Level	Food(s)	
Acrylonitrile	0.02 mg/kg	All food	0.02 mg/kg (GL)	Food	Already aligned with Codex - no amendments required.
Aluminium	0.1 mg/100 mL	Soy-based formula	Not applicable		No amendments to Code to align with Codex.
	0.05 mg/100 mL	Infant formula other than soy-based infant formula			
Arsenic	Not applicable		Not applicable		Already aligned with Codex - no amendments required
Melamine	Not applicable		1 mg/kg	Powdered infant formula	FSANZ does not propose to introduce MLs for melamine.
			0.15 mg/kg	Liquid infant formula as consumed	
Lead	0.02 mg/kg	Infant formula*	0.01 mg/kg (lowered from 0.02 mg/kg at 2014 CAC)	Infant Formula (ready to use)	Reduce ML to 0.01 mg/kg to align with Codex.
Tin	250 mg/kg	All canned food	250 mg/kg	Canned foods (other than beverages)	Already aligned with Codex - no amendments required
Vinyl chloride	0.01 mg/kg	All food excluding packaged water	0.01 mg/kg (GL)	Food	Already aligned with Codex - no amendments required.

7.2 Acrylonitrile

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as a packaging material. Standard 1.4.1 includes a ML of 0.02 mg/kg for acrylonitrile in all foods. The ML for acrylonitrile therefore also applies to infant formula. Codex STAN 193-1995 has established a GL for acrylonitrile in all foods that is identical to the ML in the Code of 0.02 mg/kg.

One submission supported the retention of the current ML in the Code as it already aligns with the Codex GL. Acrylonitrile does not have a health based guidance value (HBGV), it is considered a possible human carcinogen. As discussed in the contaminant risk profile, acrylonitrile is now rarely detected in foods and is unlikely to be present at detectable levels in infant formula. Thus dietary exposure to acrylonitrile in infant formula is not considered to pose a health risk.

However, acrylonitrile is still an approved starting material (e.g. in US food packaging regulations) for the production of a wide range of plastics, coatings and adhesives, so there is still the potential for migration of residual acrylonitrile into packaged foods, including infant formula. This, in combination with the possible carcinogenicity in humans, supports FSANZ's preliminary view to retain the intent that the MLs in the general contaminants standard (Standard 1.4.1) would apply to infant formula as a *default* if a specific contaminant is *not* specifically listed in Standard 2.9.1.

7.3 Aluminium

Aluminium can be present in food as a result of its natural occurrence in the environment, leaching from food contact materials, and the use of aluminium-containing food additives.

Standard 2.9.1 (clause 10 in the current Code, section 2.9.1—8 in the revised Code) includes limits on the maximum concentration of aluminium permitted in infant formula. Infant formula must contain no more than 0.05 mg of aluminium per 100 mL, with the exception of soy-based formula which must contain no more than 0.1 mg of aluminium per 100 mL.

Codex does not specify an ML for aluminium in infant formula. The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) has not specifically considered the need for MLs for aluminium in infant formula as part of its work.

Several submissions supported locating the aluminium ML in the same location in the Code as all other contaminant MLs. Several industry submissions also supported removal of the ML from the Code, noting Codex has not adopted such a level for infant formula. Other submissions noted studies published overseas which have identified aluminium in infant formula, thus removal of the aluminium ML would need to be justified by a risk assessment, particularly for premature infants who have reduced renal function. Other submissions queried the potential risk to infants from exposure to aluminium in infant formula.

The current ML in the Code for aluminium in soy-based formula is higher because, at the time of the previous review of the infant formula standard, it was considered that the lower limit achievable for non-soy based formula may not be achievable (ANZFA 1995). The literature suggests that aluminium in infant formula comes from several possible sources, however noting that prior accumulation in the soybean plant can be a major contributor (Bhatia & Greer, 2008; Burrell and Exley, 2010; Chuchu et al. 2013). One study noted that aluminium levels in soy-based infant formula have decreased over time (Dabeka et al., 2011).

The 23rd and 24th Australian Total Diet Studies (ATDSs) both included an assessment of aluminium levels in infant formula. In the 23rd ATDS, for 9 month old infants, estimated dietary exposure to aluminium was < 40% (FSANZ 2011). In the 24th ATDS, for the same age group estimated dietary exposure was 50% of the Provisional Tolerable Weekly Intake (PTWI) (FSANZ 2014). Thus the risk profile concludes that the current aluminium limits in Standard 2.9.1 are therefore considered to be health protective. Further details are included in the Risk Profile at Attachment 4.

Given the relatively low HBGV, and the ongoing international discussions on limiting aluminium dietary exposure, it is FSANZ's preliminary view that the retention of the existing ML for aluminium is appropriate.

We are considering whether one ML of 0.05 mg/100 mL could be set in the Code for all infant formula; information on the feasibility of this for soy-based infant formula is sought from stakeholders. It is also FSANZ's preliminary view that the existing ML for aluminium should be transferred from Standard 2.9.1 to Standard 1.4.1. FSANZ is seeking stakeholder comments on the following questions.

Question to submitters:

Q2.19 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 What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?

7.4 Arsenic

Arsenic occurs in various inorganic and organic forms which are found in the environment both from natural occurrence and from anthropogenic activity. The organic forms are of relatively low toxicity while inorganic arsenic has been identified as a human carcinogen from epidemiological studies of populations exposed to inorganic arsenic in drinking water (WHO 2001).

There is no current ML for arsenic (inorganic) or 'arsenic, total' in the Code for infant formula. There is no ML for arsenic (inorganic) in infant formula adopted by Codex. No specific comments were made in submissions in relation to arsenic.

Arsenic was considered at a recent (2011) JECFA meeting but a HBGV for arsenic (inorganic) was unable to be established because JECFA was unable to establish the threshold under which exposure is safe.

Total arsenic has been included as an analyte in infant formula in the 19th, 20th and 23rd ATDSs (ANZFA 2001; FSANZ 2003, 2011) and in the 2009 New Zealand TDS (MAF 2011). Arsenic was detected in only one infant formula sample in these four analytical surveys at a level of 2.7 µg/kg. Concentrations in all other samples were below the limit of reporting. 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, FSANZ's preliminary view is that there is no specific need to establish an ML for arsenic (inorganic) for infant formula in the Code. This approach is consistent with Codex.

7.5 Lead

Lead is an element that occurs naturally and is widely found in the environment. The total elimination from food is therefore not generally possible. Standard 1.4.1 includes a ML of 0.02 mg/kg for lead in infant formula. Codex STAN 72-1981 contains a maximum level for lead of 0.02 mg/kg (in the ready to use product).

In July 2014, the Codex Commission agreed to revoke the current ML of 0.02 mg/kg for lead in infant formula (Codex 2015a). This followed the Codex Committee on Contaminants in Foods (CCCF) recommendation based on JECFA's withdrawal of the Provisional Tolerable Weekly Intake (PTWI) following assessment in 2011, as JECFA was unable to establish the threshold under which exposure is safe. Thus Codex STAN 193-1995 was amended recently to include the revised maximum level for lead in infant formula of 0.01 mg/kg (as consumed). The CCCF also requested the CCNFSDU to remove this ML from the section on contaminants in the Codex STAN 72-1981 and instead make reference to the Codex STAN 193-1995. This will be considered by the CCNFSDU in 2015.

One industry submission supported the current ML (0.02 mg/kg) in the Code. However, there were many industry submissions which favoured harmonisation with the lower level in the Codex standards (0.01 mg/kg).

Recent levels reported in Australian and New Zealand Total Diet Studies support the lower levels (ANZFA 2001; FSANZ 2003, 2011; MAF 2011). Similar advice on achievability of the lower levels was provided by the infant formula industry to the Australian and New Zealand CCCF delegations.

In view of the withdrawal of the PTWI by JECFA, it is important to ensure the ML for lead in infant formula is as low as reasonably achievable. Given the recent Codex adoption of the lower ML, FSANZ's preliminary view is that this reduced ML would be appropriate and achievable in infant formula available in Australia and New Zealand.

Question to submitters:

Q2.21 What are the cost and trade implications of reducing the ML for lead in infant formula?

7.6 Melamine

Melamine has several industrial uses, including the production of laminates, glues, dinnerware, adhesives and coatings and was used as an adulterant in food products to give a higher apparent protein content in the 2008 infant formula incident in China (WHO 2008; Skinner et al., 2010).

No MLs have been established for melamine in the Code. Codex STAN 193-1995 includes a ML for melamine in powdered infant formula of 1 mg/kg and liquid infant formula ("as consumed") of 0.15 mg/kg. The Codex standard allows for the presence of melamine from its non-intentional and unavoidable presence in food and feed. Concentrations of melamine above the Codex MLs would be indicative of adulteration.

No specific comments were made about melamine in submissions, although there was general support for harmonisation with Codex.

There is no evidence indicating that melamine is still being used as an adulterant in milk used in the production of infant formula. The 2008 infant formula incident in China appears to be an isolated one. Testing of melamine at the border in 2012 did not report the presence of melamine in a range of foods for infants and some other specific foods (e.g. rice husks, candy, biscuits) imported into Australia. New Zealand is no longer monitoring foods for melamine content at the border. Infant formula was not specifically tested because quarantine restrictions did not permit the import of infant formula from China.

The Australian state and territory Food Acts require food to be *safe and suitable*. These provisions allow enforcement to be undertaken in the event of any future adulteration events (adulterated food is not suitable and possibly not safe). Similar provisions exist in the New Zealand legislation. Setting a ML would result in ongoing enforcement costs which do not appear to be justified on the basis of risk.

Based on the absence of any associated risk, and that the Codex ML was specifically set to control illegal adulteration of infant formula, it is FSANZ's preliminary view that there is no rationale for the incorporation of the Codex ML for melamine into the Code.

Question to submitters:

Q2.22 What if any, issues are associated with not including the Codex ML in the Code for melamine?

7.7 Tin and inorganic tin compounds

Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in cationic form (stannous and stannic compounds) or as anions (stannites and stannic compounds).

Standard 1.4.1 (Schedule 19 in the revised 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)".

One submission sought clarity on the requirements for Testing for Tin in the Code (Table to clause 2 in Standard 1.4.1) querying whether the tin ML was intended to apply to low moisture powdered products. Submissions identified that there is no definition of canned foods in the Code. Some suggested that infant formula could be considered as a food retorted in cans, thus it is not clear whether infant formula packed in metal cans are or are not a canned food.

The current ML for tin in the Code relates to all canned foods. Previous consideration during Proposal P157 – Metal Contaminants set the ML for tin for all canned foods, noting that tin is used to cover the inside of food and beverage containers (ANZFA, 1999b). As most powdered infant formula is packaged as a food in a can, FSANZ concludes that this would be within the scope of the current Standard.

It is FSANZ's preliminary view that there is no case for the exception of infant formula *per se* from the scope of the tin ML of Standard 1.4.1. The general contaminant definition for tin as a metal in Standard 1.4.1 should be applied to infant formula.

7.8 Vinyl chloride

Vinyl chloride is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods.

Standard 1.4.1 includes a ML of 0.01 mg/kg for vinyl chloride in all foods except packaged water. The ML for vinyl chloride therefore also applies to infant formula. Codex has established a GL in Codex STAN 193-1995 for vinyl chloride that is identical to the MLs in the Code of 0.01 mg/kg.

Only one stakeholder commented specifically on vinyl chloride stating they supported the retention of the current ML in the Code as it already aligns with the Codex GL.

FSANZ's preliminary view is that the current ML for vinyl chloride remains relevant, and that no amendment to the level in the Code is necessary.

7.9 Location of MLs in the Code

Several industry submissions supported the transfer of the ML for aluminium from Standard 2.9.1 to Standard 1.4.1.

Therefore, the consolidation of all the MLs into Standard 1.4.1 would appear desirable since all contaminant standards would then be in the same place in the Code. This is also consistent with the approach adopted in the revised Code (developed under P1025) and also by Codex, where MLs for all commodities are being migrated, as the opportunity arises, into Codex STAN 193-1995.

Based on the previous stakeholder support, FSANZ's preliminary view is to consolidate all MLs for contaminants in Standard 1.4.1 (Schedule 19 in the revised Code) including those set for infant formula.

7.10 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. Clause 2 of Standard 2.9.1 (section 2.9.1—4 in the revised Code) specifies that the compositional requirements of the Standard apply to powdered or concentrated form that has been reconstituted as per directions or in ready to drink form. Thus, the ML for aluminium currently included in Standard 2.9.1 is expressed in terms of mg/100 mL.

As discussed in section 7.9, FSANZ's preliminary view is to consolidate all MLs for contaminants in Standard 1.4.1. However, the consistency of expression of these MLs is yet to be determined and views are sought on this approach.

Also, as mentioned the compositional requirements of Standard 2.9.1 apply to either ready to drink formula or reconstituted powdered or concentrated formula. In Standard 2.9.1 a limit of aluminium for infant formula products is given generally, with specific limits for the subcategories of soy-based formula, and pre-term formula. There is no specific reference to calculating these permitted contaminant levels on the basis of reconstitution of dried product/formula with water, or a calculation based on "the mass of the food (or ingredients of the food) prior to drying, dehydration..." as is the case for the ML concentrations in Standard 1.4.1. However, the Full Assessment Report for P93, which established the ML, indicates that the intent was that the level applies to "human milk substitutes in ready-to-feed form, or when reconstituted from powder or liquid concentrate using aluminium-free water" (ANZFA, 1995).

Therefore, FSANZ's preliminary position is to apply all MLs for infant formula to a reconstituted ready-to-feed form, rather than to a product *prior to drying, dehydration or concentration*.

Question to submitters:

Q2.23 Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.

7.11 Contaminant definition

The term 'Contaminant definition' is one that refers to the form of the analyte to which the ML applies or which may or should be analysed in commodities (as noted in the Explanatory Notes for Codex STAN 193-1995).

In the Code, subclause 1(2) of Standard 1.4.1 specifies that "where food contains a metal and any other chemical species of that metal, all chemical species of that metal must be expressed as the metal." In the revised Code, this is captured in paragraph S19—3(1)(a) as "a reference to a metal is taken to include a reference to each chemical species of that metal". In addition, subclause 1(1) specifies that "arsenic is considered to be a metal".

Codex standards for MLs and GLs routinely specify the *contaminant definition*. The current MLs in the Code do not usually specify a *contaminant definition*. In some case, this may lead to confusion as to the nature of the analyte for which testing is applicable. However, it is noted that for clarity, inclusion of a contaminant definition could be useful for some of the metals relevant to infant formula.

It is FSANZ's preliminary view to not change the definition of analytes which are common to both infant formula and other foods but will address this as part of a proposed future review of Standard 1.4.1.

Questions to submitters:

Q2.24 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 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?

7.12 Other contaminant issues from submissions

Issue	Response
Why there is a ML for aluminium but not for cadmium	<p>The Code does not include a ML for cadmium in infant formula. It is noted that the Provisional Monthly Tolerable Intake (PMTI) for cadmium is higher than that for aluminium (for which an ML has been established), moreover there is no Codex ML or MLs established in many other developed countries (i.e. Canada, EU and USA) for cadmium in infant formula. In addition, in recent total diet studies, cadmium has only been detected at extremely low levels in infant formula: max of 0.0006 mg/kg (FSANZ, 2011) and a max of 0.0007 mg/kg (MAF 2011).</p> <p>In view of these considerations, it is FSANZ's preliminary view that the introduction of new MLs for cadmium in infant formula is not necessary.</p>
Are aflatoxins covered within the Code as they are commonly found in animal feed items	<p>Standard 1.4.1 includes MLs for aflatoxins in certain foods. However, no aflatoxin ML has been established for infant formula in the Code. Codex has adopted an ML of 0.5 µg/kg in milk for aflatoxin, but has not established a level in infant formula. FSANZ tested for aflatoxin M1 in infant formula in the 23rd ATDS, and this analyte was not detected in any composite sample. In view of these considerations, it is FSANZ's preliminary view that the introduction of new MLs for aflatoxin in infant formula is not necessary.</p>
Current levels in the Code reflect the ANZ environmental conditions and agricultural practices and are appropriate. Any differences should be identified and assessed.	Noted. This has been considered in the assessment above.

8 Food additives

Food additives play an important part in ensuring our food is safe and meets the needs of consumers. Food additives perform roles such as improving the taste and appearance of processed foods, improving their keeping quality, stability and shelf life, and ensuring added substances (e.g. nutrients) are mixed and remain homogeneous in the final product. Some of these functional properties are very important for infant formula.

The Code specifies which food additives are permitted and their maximum permitted amounts for different food products. Before a food additive is permitted for use in food, FSANZ ensures the food additive is both safe to eat at the permitted level in the particular food and that there is a good technological reason for its use.

The approach taken compares the current permissions in the Code for food additives in infant formula with the equivalent Codex infant formula food additive provision (Codex STAN 72-1981 and Codex STAN 192-1995), and considers aligning the Code permissions with Codex for consistency. The Code permissions are not directly evaluated against other overseas infant formula standards. This approach is consistent with stakeholder views expressed in previous FSANZ consultation activities, which supported aligning the Code permissions for food additives infant formula with Codex infant formula food additive provisions for ease of international trade. Other issues relating to current food additive permissions are also discussed in this section, specifically the application of the carry-over

principle for food additives and infant formula, carrageenan permissions, and other areas of the Code for clarification.

8.1 Background

8.1.1 The Code

Food additive permissions for infant formula are provided in Schedule 1 of Standard 1.3.1 – Food Additives (Schedule 15 in the revised Code), specifically food category 13.1 (infant formula products). Standard 1.3.4 – Identity and Purity (Schedule 3 in the revised Code) lists the appropriate specifications for food additives. A food additive may only be added to infant formula if permitted in the Code.

8.1.1.1 Hierarchical system for food additive permissions

Schedule 1 of Standard 1.3.1 (section S15—5 of Schedule 15 in the revised Code) uses a hierarchical food category system for food additive permissions. For each class of food identified by a numbered heading in the schedule for food additives, the food additives listed directly under the heading and any listed directly under a higher-level heading are permitted for use in that food. That means a food in a subcategory is permitted to have added to it the food additives in its subcategory plus those categories directly above it.

In the case of infant formula, the highest level heading is 13.1 – infant formula products with three subclasses of foods listed below (i.e. soy-based infant formula, liquid infant formula products and IFPSDU based on protein substitutes). Under the revised Code, these subclasses of infant formula products are numbered 13.1.1, 13.1.2 and 13.1.3 respectively to make it clear that the hierarchical system applies to infant formula products. For example liquid infant formula products (subcategory 13.1.2) are also permitted to have the food additives listed for infant formula products (category 13.1), but not those listed for subcategories 13.1.1 and 13.1.3.

8.1.1.2 History of the food additive permissions

The infant formula food additive permissions were determined under two Proposals, P150 – Australia New Zealand Standard for Food Additives and P93 – Review of Infant Formula, which established Standard 1.3.1 and Standard 2.9.1 respectively. Standard 1.3.1 was published in December 2000 when the new joint Code was originally published, and was based on a review of the earlier standards in the former Australian *Food Standards Code* and the New Zealand *Food Regulations 1984*. Therefore, the last comprehensive review of the permissions was prior to December 2000. Standard 2.9.1 was incorporated into the Code in June 2002. At Preliminary Inquiry for P93, ANZFA proposed to include the Codex provisions for food additive use in infant formula, with adjustment for the recommendations by the European Commission’s Scientific Committee for Foods. Permissions were established on the principle that the number of food additives used in infant formula should be restricted to the minimum necessary to achieve the required technological functions (ANZFA, 1999b).

8.1.2 Codex Alimentarius

There are several Codex documents that are relevant to food additive provisions for infant formula. Part 4 of Codex STAN 72-1981 lists some food additive permissions for infant formula (either all types of infant formula or specifically for hydrolysed protein or amino acid based formulas). The Codex *General Standard for Food Additives* (GSFA) (Codex STAN 192-1995) lists additional food additive permissions for infant formula. This Standard uses a hierarchical food category system, meaning that when an additive is recognised for

use in a general category, it is recognised for use in all its sub-categories, unless otherwise stated. Similarly, when an additive is recognised for use in a sub-category, its use is recognised in any further subcategories.

Codex STAN 192-1995 categories for infant formula differ from the Code as shown below:

13.0 Foodstuffs intended for particular nutritional uses

13.1 Infant formulae, follow-on formulae, and formulae for special medical purposes for infants

13.1.1 Infant formulae

13.1.2 Follow-up formulae

13.1.3 Formulae for special medical purposes for infants

The subcategory 13.1.1 Infant formulae is described as including product in liquid form, either as a ready-to-eat product, or as reconstituted from a powder.

The Codex *Guideline on Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989) lists the International Numbering System for Food Additives (INS). The INS is intended as a harmonised naming system for food additives, to provide an alternative to the use of specific food additive names.

The *List of Codex Specifications for Food Additives* (CAC/MISC 6-2015) details all the specifications for food additives adopted by reference by Codex. The specifications have been prepared by JECFA and are published in the Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 and subsequent monographs (2014, monograph 16).

8.1.2.1 Recent amendments to Codex food additive provisions for infant formula

Following safety evaluations by JECFA in 2014, the CCNFSDU and the Codex Committee on Food Additives (CCFA) considered amendments to the Codex food additive lists for infant formula. Subsequently CODEX STAN 72-1981 was amended to reflect the outcomes of the thirty-eighth session of the Codex Alimentarius Commission in July 2015. The amendments were to:

- permit the use of citric and fatty acid esters of glycerol (INS 472c) at a maximum level of 0.9 g/100 mL of the product ready for consumption in all types of liquid infant formula, and a maximum level of 0.75 g/100 mL of the product ready for consumption in all types of powdered infant formula
- permit the use of starch sodium octenyl succinate (INS 1450) at a maximum level of 2 g/100 mL of the product ready for consumption in hydrolysed protein and/or amino acid based infant formula only.

JECFA also evaluated the safety of two other food additives for use in infant formula products – pectin (INS 440) and carrageenan (INS 407), both of which are used as a thickener in infant formula. The JECFA determined that more data were required before the assessment on pectin could be finalised.

Use of carrageenan in infant formula has been contentious due to uncertainty around its safety. It has been subject to international consideration for some time and has been reviewed by JECFA several times; at its thirteenth (1970), seventeenth (1974), twenty-eighth (1984), fifty-first (2000), fifty-seventh (2002) and sixty-eighth (2007) meetings. Up until the sixty-eighth meeting (2007) the ADI (Acceptable Daily Intake) for carrageenan (summed with processed *Eucheuma* seaweed) was “not specified”, thus both the Code (established in

2000) and Codex STAN 72-1981 (adopted in 1981) listed carrageenan as a food additive for use in liquid infant formula. However, at its sixty-eighth meeting, JECFA reiterated that: *As a general principle, the Committee considers that (any) ADI is not applicable to infants under the age of 12 weeks, in the absence of specific data to demonstrate safety for this age group.* For carrageenan JECFA concluded that:

It is inadvisable to use carrageenan or processed Eucheuma seaweed in infant formula intended for infants up to and including 12 months of age. No studies were available addressing effects of carrageenan on the immature gut, and it is not possible to draw conclusions on whether carrageenan might be absorbed by the immature gut (JECFA, 2008).

Previously, a footnote in CODEX STAN 72-1981 stated: *Not endorsed by the 39th session of the CCFA. JECFA evaluation is pending. National authorities may restrict its use until JECFA evaluation has been completed.* In 2014, carrageenan was considered safe after assessment for its use as a thickener in infant formula. JECFA concluded that its use in infant formula at concentrations up to 1000 mg/L is “not of concern”. One change to the Codex carrageenan provisions is that the associated footnote was deleted following the thirty-eighth session of the Codex Alimentarius Commission in July 2015. The CCFSDU and CCFA agreed to retain the current permissions for use of carrageenan as a food additive in infant formula.

8.2 Aligning food additive permissions in the Code with Codex

FSANZ is considering whether to align the infant formula food additive provisions in the Code with those of Codex. The Codex infant formula food additive provisions have been revised more recently than those in the Code, and there are differences.

In the Code, food additive maximum permitted levels for all different food commodities are given using consistent units; either as mg/kg or mg/L (in the table to section S15—5). Codex food additive provisions relating to infant formula are given in different units depending on the Standards in which they are located. It is not considered appropriate to provide them as mg/100 mL in the Code, just for infant formula as this would create an inconsistency.

Table 8.1 compares the current infant formula food additive permissions in the Code with those in Codex STAN 72-1981(Part 4) and Codex STAN 192-1995 (food category 13.1.1 Infant formulae). The different classification categories for the various types of infant formula products noted above means direct comparison is difficult. The Codex maximum permitted levels have been converted to the same units as those in the Code (i.e. mg/L), for ease of comparison.

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 MPLs, and revision of some nomenclature and INS numbers. These are discussed in the following sections.

8.2.1 Stakeholder views

Industry submitters on the 2012 Consultation paper supported alignment with Codex food additive permissions for infant formula, while also maintaining all existing food additive permissions for infant formula in the Code (i.e. no restrictions on current permissions). Their support for harmonisation with Codex related to ease of international trade for products.

Two industry submissions specifically requested citric and fatty acid esters of glycerol (INS 472c), which are currently permitted in one of the IFPSDU subcategories (i.e. infant formula products for specific dietary use based on a protein substitute), be extended to infant formula.

It was noted by some submitters that Codex does not differentiate between food additives and processing aids. However, there was support to retain the separation between food additives and processing aids in the Code as this clarifies the purpose for use of these substances in infant formula.

Although industry submitters supported the approach for alignment with Codex, we need to determine whether all the food additives listed in Codex STAN 72-1981 are required by infant formula companies and for what technological purpose before any future assessment process.

8.2.2 Additional and extension of food additive permissions

Table 8.1 provides an overview of the infant formula permissions in Codex STAN 72-1981 and Codex STAN 192-1995, and the amendments to the Code that would be required if the Code was to align with Codex. In summary, Codex lists 14 food additives that are not currently permitted as food additives for use in infant formula in the Code.

Table 8.1: Comparison of the infant formula food additive permissions in the Code and Codex standards

The Code				Codex Alimentarius (cell entries only if different from the Code)				Amendments that would be required if Std 2.9.1 in the Code was to align with Codex
Food additive name	INS	MPL ¹ (mg/L)	Food(s)	Food additive name ²	INS	MPL ¹ (mg/L) ³	Food(s)	
Ascorbyl palmitate	304	10	All infant formula products		304i	10		Amend INS number to 304i.
Tocopherols concentrate, mixed	307b	10	All infant formula products	Mixed tocopherol concentrate	304i			
Carrageenan	407	300	Liquid infant formula products			300	Regular milk- and soy-based liquid infant formula	
Citric acid	330	GMP	All infant formula products					No change
Citric and fatty acid esters of glycerol	472c	9000	Infant formula products for specific dietary use based on protein substitutes			7500	All types of powder infant formula	Amend to provide a permission for citric and fatty acid esters of glycerol to be used in powder and liquid infant formula with MPLs of 7500 mg/L and 9000 mg/L respectively.
						9000	All types of liquid infant formula	
Guar gum	412	1000	All infant formula products				Liquid formulas containing hydrolysed ⁴ protein	Consider this in later work which looks at IFPSDU.

The Code				Codex Alimentarius (cell entries only if different from the Code)				Amendments that would be required if Std 2.9.1 in the Code was to align with Codex
Food additive name	INS	MPL ¹ (mg/L)	Food(s)	Food additive name ²	INS	MPL ¹ (mg/L) ³	Food(s)	
Lecithin	322	5000	All infant formula products	Lecithins		5000 ⁵	All types of infant formula	Amend the name of the food additive to 'Lecithins' (plural); this incorporates 'lecithin, partially hydrolysed'.
Locust bean (carob bean) gum	410	1000	All infant formula products	Carob bean gum (Locust bean gum)			All types of infant formula	Amend the name of the food additive to 'Carob bean gum (Locust bean gum)'.
Mono- and di- glycerides of fatty acids	471	4000	All infant formula products	Mono- and di-glycerides		4000 ⁵	All types of infant formula	No change
Starch sodium octenyl succinate	1450	No permission				20000	Hydrolysed ⁴ protein-based infant formula	Consider this in later work which looks at IFPSDU.
Sodium phosphates	339	No permission		Sodium dihydrogen phosphate	339i	450 ⁶	All types of infant formula	Amend to provide new permissions for all sodium phosphates and potassium phosphates, singly or in combination to a MPL of 450 mg/L. Amend names and INS numbers (i.e. separate individual chemicals with Roman numeral suffixes; noting the Code currently does not do this).
				Disodium hydrogen phosphate	339ii			
				Trisodium phosphate	339iii			

The Code				Codex Alimentarius (cell entries only if different from the Code)				Amendments that would be required if Std 2.9.1 in the Code was to align with Codex
Food additive name	INS	MPL ¹ (mg/L)	Food(s)	Food additive name ²	INS	MPL ¹ (mg/L) ³	Food(s)	
Potassium phosphates	340	No permission		Potassium dihydrogen phosphate	340i			
				Dipotassium hydrogen phosphate	340ii			
				Tripotassium phosphate	340iii			
Distarch phosphate	1412	5000	Soy-based infant formula			5000	Soy-based infant formula	Remove the qualification statement that subclause 6(1) applies, as it automatically applies for all four of the starches. Lower the MPL for hydroxypropyl starch (1440) for use in soy-based infant formula from 25000 to 5000 mg/L, singly or in combination.
Phosphated distarch phosphate	1413	5000 ⁷	Soy-based infant formula					
Acetylated distarch phosphate	1414	5000 ⁷	Soy-based infant formula					
Hydroxypropyl starch	1440	25000 ⁷	Soy-based infant formula					
Potassium citrate	332	GMP	All infant formula products					No change
Sodium citrate	331	GMP	All infant formula products	Sodium dihydrogen citrate	331i			Amend the name and INS number (i.e. separate individual chemicals with Roman numeral suffixes; noting the Code currently does not do this).
				Trisodium citrate	331iii			
Sodium carbonates	500	No permission		Sodium carbonate	500i	2000 ⁶	All types of infant formula	Amend to provide new permissions for all, except calcium hydroxide which is

The Code				Codex Alimentarius (cell entries only if different from the Code)				Amendments that would be required if Std 2.9.1 in the Code was to align with Codex
Food additive name	INS	MPL ¹ (mg/L)	Food(s)	Food additive name ²	INS	MPL ¹ (mg/L) ³	Food(s)	
				Sodium hydrogen carbonate	500ii			<p>already permitted.</p> <p>Adopt a MPL of 2000 mg/L singly or in combination, including for calcium hydroxide for which GMP currently applies.</p> <p>Amend names and INS numbers (i.e. separate individual chemicals with Roman numeral suffixes; noting the Code currently does not do this).</p>
Potassium carbonates	501	No permission		Potassium carbonate	501i			
				Potassium hydrogen carbonate	501ii			
Potassium hydroxide	525	No permission						
Calcium hydroxide	526	GMP	All infant formula products					
Sodium hydroxide	524	No permission				2000 ⁶	All types of infant formula	

Notes:

1. Maximum Permitted Level (MPL).

2. See section 8.2.3 for discussion of impact of nomenclature changes

3. Codex STANZ 72-1981 expresses the Maximum Permitted Level (MPL) for food additives in g/100 mL. The Codex MPLs have been converted from g/100 mL to mg/L to make the comparison easier with the associated MPLs in the Code.

4. Food additive permissions in Codex STAN 72-1981 refer to formulas containing 'hydrolysed protein'. In footnote 6 to 3.1.3(a), it refers to hydrolysed vs non-hydrolysed protein; therefore without further qualification, hydrolysed is taken to mean any extent of hydrolysis.

5. From Codex STAN 72-1981: If more than one of the substances INS 322, 471 are added the maximum level for each of those substances is lowered with the relative part as present of the other substances (comparable to clause 6 of Standard 1.3.1 of the Code).

6. Singly or in combination and within the limits for sodium, potassium, calcium and phosphorus in section 3.1.3 (e) of the Standard (STAN 72-1981) in all types of infant formula.

7. Clause 6(1) of Standard 1.3.1 applies: Where a food contains a mixture of food additives that perform the same technological function, the sum of the proportion of these additives in the food must not be more than 1.

8.2.2.1 Acidity regulators

The following 12 food additives are listed in Codex STAN 72-1981 as acidity regulators:

- Sodium dihydrogen phosphate (INS 339i)
- Disodium hydrogen phosphate (INS 339ii)
- Trisodium phosphate (INS 339iii)
- Potassium dihydrogen phosphate (INS 340i)
- Dipotassium hydrogen phosphate (INS 340ii)
- Tripotassium phosphate (INS 340iii)
- Sodium carbonate (INS 500i)
- Sodium hydrogen carbonate (INS 500ii)
- Potassium carbonate (INS 501i)
- Potassium hydrogen carbonate (INS 501ii)
- Sodium hydroxide (INS 524)
- Potassium hydroxide (INS 525).

These are listed for use either singly, or in combination, provided their addition is within the sodium, potassium, calcium and phosphorus limits of Codex STAN 72-1981; as they perform the same function to adjust and regulate the acidity of the food. These 12 substances are not currently permitted in the Code as food additives for infant formula.

Many of these acidity regulators are listed in Schedule 2 of Standard 1.3.1 (section S16—2 of Schedule 16 in the revised Code) as food additives that can be used in accordance with Good Manufacturing Practice (GMP). In the Code, Schedule 2 food additives are also generally permitted processing aids as per subclause 3(b) of Standard 1.3.3 (subsection 1.3.3—4 in the revised Code). Thus, as processing aids, they are generally permitted for use in the production of infant formula if such a technological purpose for their use exists. Note that processing aids differ from food additives in that they perform their technological purpose during the processing or manufacture of the final food but they do not fulfil a technological purpose in the final food. All of these acidity regulators are current permitted forms of minerals for use in infant formula; as per Schedule 1 to Standard 2.9.1 (section S29—7 of Schedule 29 in the revised Code). Therefore, these 12 substances could be used as either food additives (technological purpose of acidity regulators), processing aids or as permitted forms of minerals in the manufacture of foods. FSANZ therefore needs information on how these substances are used in the manufacture of infant formula. This is particularly important if their permissions and use is different in overseas markets and such products could be exported to Australia and New Zealand.

We are seeking further information in order to consider whether to permit these substances as food additives in infant formula in the Code to align with Codex. If it is determined that there is a technological purpose and need for these food additives then FSANZ may consider their safety and suitability by conducting a safety and technical assessment of them at the next stage of this Proposal.

8.2.2.2 Citric and fatty acid esters of glycerol

Citric and fatty acid esters of glycerol (INS 472c) were recently adopted by Codex for use in infant formula (see section 8.1.2.1). They have been listed for use in all types of powdered and liquid infant formula. In the Code they are only permitted for use in infant formula products for specific dietary use based on protein substitutes which are a subcategory of IFPSDU. These food additives are also permitted at GMP in Schedule 2 of Standard 1.3.1 (section S16—2 of Schedule 16 in the revised Code).

FSANZ could potentially consider an extension of use for these food additives as part of future work within this Proposal if there was a justification for the use, and information could be provided in submissions to enable an assessment. Such information would need to be consistent with the Application Handbook requirements for an extension of use of a food additive. This should note the recent JECFA assessment on the use of these food additives in infant formula.

8.2.2.3 Starch sodium octenyl succinate

Starch sodium octenyl succinate (INS 1450) is permitted by Codex only for hydrolysed protein-based infant formula products, so at this stage is considered out of scope for this Proposal.

Questions to submitters:

Q2.26 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 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 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 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?

8.2.3 Updates to nomenclature and INS numbers

Codex uses the INS (as listed in CAC/GL 36-1989), thus permissions in Codex STAN 72-1981 and Codex STAN 192 - 1995 are listed by the specific name and INS number for individual food additives. The INS usually consists of three or four digits with some additives further subdivided by numerical subscripts which identify sub-classes (e.g. INS 500i). The Code refers to chemical families written as the plural term with the same INS number. For example, the Code uses the term 'sodium carbonates' and INS 500, while Codex lists the specific chemicals, namely sodium carbonate (INS 500i) and sodium hydrogen carbonate (INS 500ii). If the Code were to align with Codex, the following amendments to nomenclature and INS numbers would be required:

- Prescribe the specific food additive name and number of individual additives rather than refer to chemical families, or the plural form of additives. For example, use the terms: Sodium carbonate (500i) and Sodium hydrogen carbonate (500ii), rather than Sodium carbonates (500)
- Amend references to 'lecithin' (322) to the plural form, 'Lecithins' (322) to incorporate 'Lecithin, partially hydrolysed'
- Replace Sodium citrate (331) with Sodium dihydrogen citrate (331i) and Trisodium citrate (331iii)

- Rename ‘Locust bean (carob bean) gum’ as ‘Carob bean gum (Locust bean gum)’.

To align the Code with Codex for food additive names and nomenclature relevant to infant formula would have flow on consequences for other food categories, as these food additives are also permitted for use in other foods. To make amendments to infant formula permissions alone would result in inconsistencies in food additive names and nomenclature across the Code. Similarly, if the amendment were to apply to the food additive, rather than the food category, then the change would impact a wider group of food categories than infant formula (e.g. labelling changes would be required across a broad range of food products).

Updating the Code in relation to food additive names and INS numbers to be consistent with Codex, in particular Standards 1.3.1 and 1.2.4 (Schedules 8, 15 and 16 in the revised Code), is beyond the scope of this Proposal. FSANZ may prepare a proposal at a later date to address this issue.

Question to submitters:

Q2.30 What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?

8.2.4 Changes to maximum permitted levels

As shown in Table 8.1 there is a difference in the MPL for hydroxypropyl starch between the Code and Codex. To align with Codex the MPL for hydroxypropyl starch for use in soy-based infant formula would need to be lowered from 25000 to 5000 mg/L, singly or in combination. The MPL of hydroxypropyl starch (INS 1440) in soy-based infant formula is 25000 mg/L, which is understood to be an error. The recommended MPL in Proposal P93 was 5000 mg/L (ANZFA, 2002). The limit in Codex is also 5000 mg/L. Lowering the MPL for hydroxypropyl starch (1440) would create consistency with Codex and with the original intent of the decision made in Proposal P93.

Question to submitters:

Q2.31 Will lowering the MPL of hydroxypropyl starch to 5000 mg/L create any difficulties for infant formula companies?

8.3 Carry-over principle for food additives and infant formula

In general terms ‘carry-over of food additives’ (the carry-over principle) refers to food additives used in ingredients or raw materials which are used in production of a final food being ‘carried-over’ into the final food. Often in food production, food additives used in ingredients are found in the final food. This fact of food production is behind the carry-over principle for general foods. There has been confusion around how this carry-over principle operates for infant formula in the Code This situation can be open to interpretation so FSANZ is therefore considering whether clarification is required.

8.3.1 The Code and Codex standards

Clause 7 of Standard 1.3.1 in the Code (subsection 1.3.1—3(2) in the revised Code) allows (with conditions) carry-over of food additives from a raw material or an ingredient used in the

manufacture of food, that are not specifically permitted in that food in the Code. Specifically, clause 7 states:

7 Carry-over of food additives

A food additive may be present in any food as a result of carry-over from a raw material or an ingredient, provided that the level of the food additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice.

Subclause 6(1) of Standard 2.9.1 states:

6 Restrictions and prohibitions

(1) *A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless –*

- (a) *expressly permitted by this Code; or*
- (b) *it is naturally present in an ingredient of the infant formula product.*

This subclause has been interpreted by some stakeholders as meaning carry-over of food additives is not permitted for infant formula products, notwithstanding clause 7 of Standard 1.3.1.

Clause 4 of Codex STAN 72-1981 states that only food additives permitted for use in the foods covered by the Standard may be present as a result of carry-over from raw material or other ingredients (including food additives) used to produce the food. In addition, clause 4.3 of Codex STAN 192-1995 explicitly prevents the carry-over of food additives in the infant formula food category.

8.3.2 Stakeholder views

Comments received on the 2012 Consultation paper from four industry stakeholders supported aligning the Code with the Codex carry-over provisions.

The comments mainly focused on ensuring that food additives permitted for use under Codex are permitted under the Code. It was noted that trade barriers may exist where additives are permitted to be carried over from raw material under Codex (i.e. if permission for the food additive exists; not due to carry-over *per se*) but not under the Code.

8.3.3 Previous FSANZ consideration

Proposal P93 recommended that carry-over of food additives be permitted for infant formula products like all other food categories, when it finalised Standard 2.9.1. There was limited discussion reported on this matter under P93. At the time Codex did not have an exception for the carry-over of food additives for infant formula products. However, the former New Zealand *Food Regulations 1984* did not allow carry-over of food additives from ingredients unless there were already permissions for those additives. The Australian *Food Standards Code* was silent on the issue of carry-over of food additives.

8.3.4 Summary

Because of the confusion of stakeholders including infant formula companies that exists, clarification is required. Codex does not permit the carry-over of food additives in raw material and ingredients used in the manufacture of infant formula, unless permission for the

food additive in infant formula already exists. Infant formula companies generally agree that the Code should be consistent with Codex. Therefore, FSANZ's preliminary view is that it is appropriate to not allow the carry-over principle to apply to infant formula, and seeks stakeholders' views on this position.

Question to submitters:

Q2.32 Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

8.4 Clarifications to the Code

There are also a number of anomalies in the Code relating to permissions for food additives in infant formula that should be clarified.

8.4.1 Carrageenan permission for liquid soy-based infant formula products

As shown in Table 8.1, carrageenan is permitted as a food additive in both the Codex infant formula standard and in the Code.

Codex STAN 72-1981 sets one maximum level for regular milk and soy-based infant formula. 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 only listed for liquid infant formula (sub-category 13.1.2) and there is no permission for carrageenan in soy-based infant formula (sub-category 13.1.1). As noted above, JECFA's 2014 assessment supported its use in all forms of infant formula products.

FSANZ is aware that there is some confusion about whether the subcategories of infant formula are mutually exclusive. In order to determine whether amendments are required, we are seeking information from interested parties in relation the current use of carrageenan and how they apply the current permissions.

8.4.2 Permitted starches, removal of qualification statements

Subclause 6(1) of Standard 1.3.1 (section 1.3.1—6 in the revised Code) states that: “where a food contains a mixture of food additives that perform the same technological function, the sum of the proportion of these additives in the food must not be more than 1”.

In Schedule 1 of Standard 1.3.1 the qualification column indicates subclause 6(1) applies to only three of the four permitted starches in soy-based infant formula. The limitation appears to have been made as an outcome from P93, with the intention of being consistent with the Codex standard at the time. However, the use of the qualification statement for only three of the starches is inconsistent as all four starches perform the same technological function. This approach also exists within section S15—5 in the revised Code for food category 13.1.1 (soy-based infant formula).

Subclause 6(1) is comparable to Codex STAN 72-1981 qualification that the four starches can be used singly or in combination with the maximum permitted limit applying to the total starch addition.

FSANZ's preliminary view is that the qualification statement that subclause 6(1) applies is unnecessary since this subclause applies to all food additives used to perform the same function in a food. It should be removed from the qualification column for the subcategory of

soy-based infant formula in Schedule 1 of Standard 1.3.1 (and in category 13.1.1 in section S15—5 in the revised Code).

Questions to submitters:

Q2.32 Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?

Q2.33 Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?

Q2.34 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?

9 Processing aids

Processing aids differ from food additives in that the substance is added to perform a technological function during the manufacture or processing of the food, but not in the final food. This section summarises the processing aid permissions for infant formula, comparing the Code with Codex where relevant.

9.1 Current regulation

9.1.1 The Code

Processing aids are regulated in the Code by Standard 1.3.3 – Processing Aids (Standard 1.3.3 and Schedule 18 in the revised Code). A general prohibition on the use of processing aids in food applies unless expressly permitted in this Standard. There are a variety of different types of processing aids that can be used for different types of foods, or all foods, with or without qualifications. There are also a variety of different technological purposes that processing aids can perform during processing or manufacturing of food. There is no specific list of processing aids that can only be used in the manufacture of infant formula. Nutrient carriers are considered processing aids and not food additives in the Code; see clause 10 of Standard 1.3.3 (within section S18—3 of Schedule 18 in the revised Code).

All Schedule 2 food additives in Standard 1.3.1 (section S16—2 of Schedule 16 in the revised Code), are also generally permitted processing aids due to subclause 3(b) of Standard 1.3.3 (section 1.3.3—4 in the revised Code). This means these substances may be used as processing aids in the manufacture of infant formula.

9.1.2 Codex

Codex has a set of Guidelines on Substances Used as Processing Aids (CAC/GL 75-2010) that outline principles for the safe use of substances used as processing aids. Unlike the Code, Codex does not have a separate standard which lists the permissions for processing aid use in foods or for use in infant formula.

Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979) also includes an advisory list for food additives for special nutrient forms in section D (page 20).

9.2 Comparison between Code and Codex permissions

FSANZ notes that the Codex Advisory Lists (CAC/GL 10-1979) includes an advisory list for specific food additives (gum Arabic, silicon dioxide, mannitol, starch sodium octenyl succinate and sodium ascorbate) which have the technological function as carriers for nutrients. As noted above, nutrient carriers are considered as processing aids in the Code, not food additives. These five substances are all Schedule 2 food additives in Standard 1.3.1 (section S16—2 of the revised Code), so are generally permitted processing aids.

9.2.1 Stakeholder views

Submitters to the 2012 Consultation paper noted that Codex does not have a permitted list of processing aids for infant formula products, nor does it have a processing aid standard. They also noted examples where Codex considers some substances as food additives while the Code considers them as processing aids. In the Code, the Schedule 2 food additives in Standard 1.3.1 are also generally permitted processing aids. Some substances may have a number of technological functions, as a food additive, a processing aid or even a nutrient; the function will depend on how it is used in the product.

9.2.2 Summary

We are not aware of any issues relating to the permissions for processing aids in the Code for the manufacture of infant formula. Accordingly, at this stage, we are not considering any changes to Standard 1.3.3 or processing aids in the manufacture of infant formula under this Proposal.

10 Other issues from submissions

10.1 Issues to be addressed during further consideration of P1028

Issue	Details	FSANZ Response
<p>Statements on dental fluorosis</p>	<p>Standard 2.9.1 does not prescribe a maximum level for fluoride in infant formula. However, subclause 19(2) of Standard 2.9.1 requires packaged infant formula to contain statements indicating that consumption of the formula has the potential to cause dental fluorosis, and recommending that the risk of dental fluorosis should be discussed with a medical practitioner or other health professional. These statements apply only when powdered or concentrated infant formula contains more than 17 µg of fluoride per 100 kJ prior to reconstitution or 'ready to drink' formula contains more than 0.15 mg of fluoride per 100 mL.</p> <p>Submitters to the 2012 Consultation paper expressed diverse views on issues relating to fluoride in infant formula. Some submitters supported alignment with Codex provisions (i.e. maximum level of 24 µg/100 kJ 'ready to drink'), while others considered the level should be lowered. Some questioned the need for the dental fluorosis statements, and others considered these statements should be amended and made mandatory on products. A number of submitters, from various backgrounds, called for a review of public health and safety concerns relating to fluoride in infant formula.</p>	<p>FSANZ will consider this issue in a future report for P1028.</p> <p>The issue of fluoride will be considered from a risk assessment perspective, and clause 19 requirements will be considered based on the outcome of this assessment.</p>

10.2 Issues that will not be considered further in P1028

Issue	Details	FSANZ Response
Suggested advisory statement – independent contact details	A public health advocacy group requested that Standard 2.9.1 mandate the contact details and/or website links for independent information on the safe use and preparation of infant formula on the product label.	Subclause 14(2) of Standard 2.9.1 requires the product label to display directions for the preparation and use of infant formula. These requirements apply to all infant formula products, and so are independent of any one manufacturer or brand. Therefore, FSANZ considers it unnecessary to mandate the contact details for an independent provider of this information on the product label.
Suggested advisory statement – concentration of infant formula	A health professional requested that infant formula labels display an instruction to titrate the prepared amount of formula during the first seven days of feeding.	The compositional requirements in Standard 2.9.1 are set to provide sufficient nutrition during the first 12 months of life, including during the first seven days. If a formula-fed infant requires a different concentration of formula for medical reasons, then this should be undertaken under the guidance of a medical professional. Therefore, FSANZ does not support a new labelling requirement for preparation instructions specific for an infant's first seven days of life.
Suggested advisory statements in relation to infant feeding practices	<p>Two government submitters suggested mandating advisory statements to address the following issues:</p> <ul style="list-style-type: none"> • Feeding a baby when it is hungry but not to force the baby to finish the bottle. • If breastfeeding, then topping up with infant formula could reduce breast milk supply. • Detailed information on how to recognise infant hunger cues. 	FSANZ does not support mandating these suggested statements. Currently, Standard 2.9.1 requires statements on product labels that relate to health risks from improper preparation and storage of the formula, or warnings about the other health risks associated with the use of infant formula. The feeding practices mentioned in the suggested statements do not relate specifically to any health risk directly associated with infant formula use. In addition, there are other sources of information on appropriate infant feeding practices such as advice from health professionals and the national infant feeding guidelines.
Suggested advisory statement that the formula is not sterile	A health professional and a consumer group suggested an advisory statement that the infant formula product is not sterile.	Infant formula is safe to consume when the current directions for use and storage set out in subclause 14(2) are followed. FSANZ does not consider such a statement to be necessary.
Suggested advisory statement for aluminium content	A health professional requested that infant formula labels display the aluminium content of the product. This suggestion was linked to issues around composition and safety of infant formula, noting that aluminium is a contaminant.	Clause 10 of Standard 2.9.1 sets maximum limits for aluminium in infant formula. As this requirement already ensures that aluminium contents are within a safe limit, FSANZ does not consider that mandating the declaration of aluminium content on the label is necessary.

Issue	Details	FSANZ Response
Declaration of vitamins and minerals	A government submitter suggested that the permitted forms of vitamins and minerals should be declared on the label.	<p>FSANZ notes that, in accordance with clause 4 of Standard 1.2.4, all ingredients must be declared using one of the following: the common name of the ingredient, a name that describes the true nature of the ingredient, or a generic name for the ingredient (where applicable). The names of ingredients should be accurate and sufficiently detailed to ensure that they are not false, misleading or deceptive, or likely to mislead or deceive.</p> <p>Additionally, clause 8 of Standard 1.2.4 requires a food additive to be declared by its class name, followed by the prescribed name or International Numbering System (INS) number in brackets. Clause 9 of this Standard permits vitamins and minerals to be declared in accordance with clause 8 using the class name 'vitamin' or 'mineral'. If this provision is relied on, the prescribed name of the food additive set out in Schedule 2 of the Standard must be declared if the INS number is not.</p> <p>These different methods of declaring ingredients (including vitamins and minerals) provides flexibility to infant formula companies, including being able to shorten ingredient lists when label space is limited. This flexibility extends to all packaged foods, including infant formula.</p> <p>FSANZ does not consider there is sufficient rationale for making a special case for declaring the permitted forms for vitamins and minerals in the ingredient lists of infant formula products.</p>

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Attachments

A1 – Microbiological safety of powdered infant formula

A2 – Rapid evidence assessment on infant formula preparation, perceptions and label use

A3 – Overseas regulatory approaches to the addition of substances to infant formula

A4 – Risk profile of contaminants in infant formula

Attachment A2.1 – Microbiological safety of powdered infant formula

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1 Introduction

The manufacture of powdered infant formula does not include a processing step that can eliminate all microbiological hazards – it is not a sterile product (Agnostoni et al 2004). This means that the microbiological safety of powdered infant formula must be ensured through good hygienic practices during both manufacture and use. The Code includes various risk reduction strategies which aim to reduce microbiological hazards associated with the preparation, use and storage of infant formula.

1.1 Scope

This Attachment considers the information relevant for risk reduction strategies related to the preparation and use risks of infant formula, including labelling.

Microbiological criteria are not being considered as part of this Proposal, as these are currently under review through Proposal P1039 – Microbiological Criteria for Infant Formula.

2 Background

2.1 Microbiological limits

Although microbiological criteria are outside of the scope of this Proposal, it is important to note that Proposal P1039 is reviewing Standard 1.6.1 – Microbiological Limits in Food (and Schedule 27 of the revised Code). P1039 aims to include food safety microbiological criteria for powdered infant formula products that align with international standards, current scientific knowledge and best practice manufacturing practices. The application of appropriate microbiological criteria to verify that appropriate hygiene measures have been met during production and that product is safe, is an important risk management tool.

2.2 Current regulation – preparation and use instructions

Subclause 14(2) of Standard 2.9.1 (subsection S2.9.1—19(3) of the revised Code) includes labelling requirements for guidance on the safe preparation and storage of powdered infant formula. The purpose of this information on the label is to inform carers on using the product in a manner that minimises the risks from pathogens. The subclause requires that the label on a package of infant formula product must include directions for its preparation and use, which include words and pictures instructing:

- a) that each bottle should be prepared individually; and
- b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
- c) that potable, previously boiled water should be used; and
- d) where a package contains a measuring scoop, that only the enclosed scoop should be used; and
- e) that formula left in the bottle after a feed must be discarded.

2.3 Australian and New Zealand infant feeding guidance

Australia and New Zealand have each developed their own national evidence based guidelines on infant feeding.

In Australia, the National Health and Medical Research Council (NHMRC) undertook a literature review to consider whether any updates needed to be made to the previous guidance. The summary of the literature review is available online. The revised version of the *Infant Feeding Guidelines – Information for Health Workers* was then released in 2012.

The New Zealand guidance is part of the *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2)*, which were published by the Ministry of Health (MoH) in 2008 and updated in December 2012. The MoH has also published education materials for health professionals and consumers.

Despite having slightly different purposes and target audiences, both the Australian and New Zealand guidance documents on infant feeding include a set of instructions on the preparation, handling and storage of infant formula. This advice is summarised in Table A1.1.

Table A1.1: Preparation instructions contained in Infant feeding guidelines in Australia and New Zealand

Type of advice	Australian Guidelines	New Zealand Guidance
Washing of feeding equipment	Pay careful attention to washing bottles, caps, teats and knives.	Wash thoroughly in hot soapy water. Scrub bottles and teats to ensure all remaining formula is removed.
Sterilisation advice	Boil feeding equipment for 5 minutes or use an approved sterilising agent/device.	Boil feeding equipment for 5 minutes or use a commercial home steriliser.
Boiling of preparation water	Boil water and allow to cool until lukewarm. Water heating appliances should only be used with water that meets Australian Standards.	Boil clean drinking water for infants younger than 3 months. Always boil bore water for use in infant feeding.
Cooling of preparation water	Cool to a safe temperature and allow the water to sit for 30 minutes	Cool water by placing it in a covered, sterilised container and into a refrigerator for up to 24 hours.
Addition of non-formula substances	Not mentioned	Do not add any food, beverage or medicine unless on the advice of a medical practitioner.
Number of bottles to prepare	One at a time	Formula is best made up fresh for each feed and for immediate consumption.
Order of reconstitution	Add water to the bottle first, then formula powder	Add water to the bottle first, then formula powder
Use of measuring scoop	Always use the enclosed scoop to measure out formula	Always use the enclosed scoop to measure out formula
Use of labels	Always follow manufacturer's preparation instructions on the product label	Always follow manufacturer's preparation instructions on the product label
Method of feeding	Feed formula immediately after preparation and for no more than one hour. Do not leave the infant to consume formula on their own, or to go to sleep while feeding.	Not mentioned
After feeding practice	Discard unused formula, or formula that has been at room temperature for longer than one hour	Discard unused formula, or formula that has been at room temperature for longer than two hours

Type of advice	Australian Guidelines	New Zealand Guidance
Storage of prepared formula	A prepared formula that has been at room temperature for less than one hour can be stored in a refrigerator (<5°C) for up to 24 hours in a sterile container. Applies to ready to drink formulas.	Prepared formula may be stored at up to 4°C in the lower half of the fridge, at the back, but should be kept for only a maximum of four hours.
Warming of stored formula	Warm formula by standing the bottle in a container of warm water. The use of a microwave is discouraged.	Place the bottle in hot water and gradually warm. Test that the formula is warm to the touch on a wrist. Do not warm formula in a microwave.
Transporting formula	The best option is to prepare formula at the destination. Prepared formulas can be transported if they have been refrigerated and carried in an insulated bag with ice. Transported formula must be used within two hours.	The best option is to prepare formula at the destination. Prepared formulas can be transported if they have been refrigerated and carried in an insulated bag with ice. Transported formula must be discarded if it has been out of a refrigerator for more than two hours.
Formula product containers	When a container of formula is empty, throw out both the formula and the scoop	Not mentioned

2.3 International regulations and guidelines

2.3.1 Codex Alimentarius

The Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP66-2008) (CoHP) provides practical guidance and recommendations to governments, industry, health care professionals/caregivers of infants and young children, as appropriate, on the hygienic manufacture of powdered formula and on the subsequent hygienic preparation, handling and use of reconstituted formulae. The CoHP has an emphasis on the control of microbiological hazards, in particular *Salmonella* and *Cronobacter* species.

The CoHP identifies relevant control measures at the various steps in the food chain that can be employed to reduce the risks for infants and young children that are associated with the consumption of powdered formulas. The CoHP notes that various hygienic measures can be used together in different risk reduction strategies, each of which reduces the risk to infants from *Cronobacter* species. Although the underpinning risk assessments focussed on reducing the risk from *Cronobacter* species, the basic control principles for this microorganism also hold true for *Salmonella* spp.

In addition, section 9.5 of Codex STAN 72-1981 states that adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, must appear on the label and in any accompanying leaflet. It also requires clear graphic instructions illustrating the method of preparation of the product, and notes that powdered products should be reconstituted with water that is safe or has been rendered safe by previous boiling.

International risk assessments

SD2 for the 1st call for Submissions for [Proposal P1039](#)⁸ provides an overview of the international risk assessment work undertaken to inform the Codex CoHP. In summary, the FAO and WHO convened two expert consultations (in 2004 and 2006) to identify the organisms of concern in powdered infant formula and the approaches that could be used to reduce risk associated with powdered infant formula.

Findings from the consultations in 2004 and 2006 identified *Cronobacter* species and *Salmonella* as the primary organisms of concern in powdered infant formula and considered the relevant control measures at various steps in the food chain to reduce the risks for infants and young children associated with the consumption of powdered infant formula. These steps included consideration of labelling and preparation risk reduction strategies, and the establishment of microbiological food safety criteria for *Cronobacter* species and *Salmonella* species.

Although infections of *Cronobacter* species in infants appear to be rare, the consequences can be severe. *Cronobacter* species is widely found in the environment, so exposure may occur from a range of sources. The population identified by the FAO/WHO risk assessment as being at risk for *Cronobacter* species infection were all infants (less than 12 months of age). Subgroups at greatest risk include: infants less than two months of age, pre-term and low-birthweight infants (less than 2500 g); and immunocompromised infants.

The FAO/WHO commissioned the development of a risk assessment model for [Cronobacter species in Powdered Infant Formula](#). The web-based risk assessment model estimates the effectiveness of different risk reduction strategies for *Cronobacter* species in powdered infant formula based on a number of model inputs⁹, including:

- the concentration of *Cronobacter* species in the infant formula powder
- the ambient temperature during preparation of the formula and feeding of the formula
- the temperature of the water used to reconstitute the formula
- the temperature of the refrigerator in which prepared formula is stored
- the method of cooling to storage temperature (e.g. ice bath, refrigeration with forced cool air, or still air)
- whether bulk prepared formula is stored in individual bottles or a large container
- the temperature at which the formula is fed to the infant
- the duration of the processes of: reconstitution of the formula, storage of prepared formula, reheating or cooling of the formula, and feeding.

2.3.2 World Health Organization Guidelines

The World Health Organization (WHO) updated its guidelines on the [Safe Preparation, Storage and Handling of Powdered Infant Formula](#) (the WHO PIF guidelines) in 2007. These guidelines were based on the 2006 FAO/WHO microbiological risk assessment. The WHO PIF guidelines recommend specific guidance on the most appropriate practices in the different steps during the preparation of PIF for care and [home settings](#). The guidance for caregivers specifies the following methods to prepare and use powdered infant formula products:

⁸ <http://www.foodstandards.gov.au/code/proposals/Pages/P1039MicroReviewInfantFormula.aspx>

⁹ http://www.fstools.org/ESAK/RunModel_PrepGuidance.aspx

- Prepare powdered infant formula with water at a temperature of no less than 70°C, which can be achieved by allowing the preparation water to sit for up to 30 minutes after boiling.
- Once the product has been reconstituted, it should be cooled to feeding temperature by holding the bottle under running water or placing in a container of cold or iced water.
- Any feed that has not been consumed within two hours should be discarded.
- Store prepared formula at no higher than 5°C. Formulas can be stored at this temperature for up to 24 hours.

3 Risk mitigation options

As discussed earlier, the Code includes a combination of risk reduction strategies which aim to reduce microbiological hazards associated with the preparation, use and storage of infant formula. The preparation and use instruction labelling requirement on the product is one of these strategies. The intent is to communicate to the caregiver the importance of good hygiene practice through all of the preparation steps and in storage of the formula. Two specific issues related to the microbiological safety of reconstituting infant formula are discussed, namely storage time of prepared formula, and temperature of water used for preparation of powdered infant formula.

3.1 Storage time of prepared formula

During the development of Standard 2.9.1, FSANZ's assessment determined it was microbiologically safe to make up several bottles of formula at one time provided they were stored refrigerated ($\leq 5^{\circ}\text{C}$) for not more than 24 hours prior to use. Based on this analysis, paragraph 14(2)(b) requires a statement or pictures instructing that if a bottle of formula is made up and stored prior to use, it must be refrigerated and used within 24 hours.

As shown in Table A1.1 the guidance in the *Australian Infant Feeding Guidelines for Health Workers* and New Zealand guidance on storage time of prepared formula differ slightly. The Australian guidelines align with the labelling requirements in the Code. The New Zealand guidance states that the prepared formula may be stored at up to 4°C in the lower half of the fridge, at the back, but should be kept for only a maximum of four hours. The recommendation for the maximum storage time in the refrigerator in the New Zealand guidelines were based on a risk assessment undertaken by the Ministry for Primary Industries (MPI) which utilised the FAO/WHO risk assessment model (FAO/WHO 2004, 2006). The model was used to generate a risk reduction strategy appropriate for New Zealand conditions, including ambient temperatures in New Zealand.

3.1.1 Use of the FAO/WHO risk assessment model

To investigate the impact of different preparation and storage conditions on the relative risk of *Cronobacter* species infection in infants, FSANZ ran a number of scenarios using the FAO/WHO risk assessment model. Three different refrigerated storage scenarios (2, 4 and 24 hours) were modelled using three different reconstitution temperatures (10, 30 and 45°C)¹⁰. Prepared formula left unrefrigerated (2 hours ambient) was also modelled for the different reconstitution temperatures. The baseline scenario for comparison was reconstitution at 45°C with no storage time (i.e. immediately consumed). Inputs for all other preparation and handling parameters were kept the same for all scenarios (refer table A1.2).

¹⁰ The temperature of water used to reconstitute the powdered infant formula

Table A1.2: Inputs used in the FAO/WHO risk assessment model

Stage	Temperature (°C)	Duration (h)
Preparation of formula	25	0.25
Active rewarming/cooling	37	0.25
Feeding	25	1

Using the assumptions built into the model, a probability of illness of between 1×10^{-5} (1 in 100,000) – 1×10^{-10} (1 in 10,000,000,000) is predicted for the baseline scenario, indicating the uncertainty in the model¹¹ (Table A1.3).

Table A1.3: Model outputs presented as relative risk reduction. Baseline scenario shaded

Reconstitution temperature (°C) [#]	Storage time (h)	Relative risk reduction*
45	0	1.0
	2 h ambient	0.018
	2 h refrigerated	0.16
	4 h refrigerated	0.13
	24 h refrigerated	0.081
30	2 hrs ambient	0.2
	2 h refrigerated	1.0
	4 h refrigerated	1.0
	24 h refrigerated	0.56
10	2 hrs ambient	1.0
	2 h refrigerated	1.0
	4 h refrigerated	1.0
	24 h refrigerated	1.0

[#] Temperature of the water used to reconstitute the powdered infant formula

*A relative risk reduction of less than 1 represents an increased relative risk

When reconstituted with cool water (10°C) there was no change in relative risk between the different storage scenarios (ambient and 2, 4 and 24 h storage at 6°C) compared with the baseline scenario (formula consumed immediately following reconstitution). Storage time also had minimal effect on risk when using 30°C water to reconstitute PIF, with 24 h storage at 6°C resulting in a 1.8 fold increase in risk (i.e. a worst case change in risk from 1 in 100,000 to 1.8 in 100,000).

Reconstituting PIF with 45°C water and storing for any period of time is predicted to have an increased relative risk, ranging from 6–12-fold increase (relative risk reduction of 0.16–0.081) between 2–24 h refrigerated storage. This is due to *Cronobacter* species being able to grow while the temperature of the reconstituted formula cools to 5°C. Once the temperature of the reconstituted formula reaches refrigeration temperature, there will be no to limited growth of the organism.

For comparison purposes, the model was also run to simulate reconstituted formula held at room temperature for two hours. This scenario estimated a 55-fold increased relative risk compared to the baseline.

¹¹ http://www.who.int/foodsafety/publications/micro/RA_Overview.pdf

3.1.2 Summary

For all refrigerated storage scenarios modelled, there was relatively small difference (approximately 1-log₁₀) in the relative risk from the baseline scenario.

Based on this analysis, we consider that the direction for storage time of refrigerated, made up infant formula up to 24 hours is still appropriate. This aligns with the approach in the WHO PIF guidelines.

3.2 Temperature of water used for preparation of powdered infant formula

The WHO PIF guidelines advocate the use of water at no less than 70°C for preparing formula. The rationale for the use of water at a temperature of no less than 70°C to reconstitute formula is to inactivate *Cronobacter* species potentially present in the powder. Consequently, this reduces the risk to all infants, including those in warm climates where refrigeration may not be readily available (e.g. developing countries).

However, there are some other issues that need to be considered around the use of water at no less than 70°C. These include:

- the potential risk of serious burns and scalding to the infant and caregiver
- the potential that the content of heat-labile vitamins (thiamine, vitamins B₁, B₆ and B₁₂, folic acid, and vitamin C) may be lost through inactivation or degradation
- activation of *B. cereus* or other bacterial spores in the formula
- clumping of the powder
- destruction of added probiotics.

The Codex CoHP notes that various hygienic measures can achieve a significant reduction in risk. In situations where there is high confidence in the microbiological quality of the product, the combination of hygienic preparation and safe storage of reconstituted formula can be appropriate risk management strategies. Similarly, when there are heat-labile components in the powdered formula alternative risk management strategies (which do not involve the use of water at no less than 70°C for reconstitution) may be appropriate. Neither the Australian nor New Zealand infant feeding guidance has adopted the recommendation to use water at temperatures no less than 70°C during formula preparation for these reasons. A number of developed countries have not adopted this recommendation for these same reasons (Agnostoni et al. 2004).

Very few studies have been conducted in Australia or New Zealand on the prevalence or levels of *Cronobacter* in PIF. A survey of 91 powdered formula products and three ready-made formulas conducted by the New South Wales Food Authority in 2010 failed to detect any *Cronobacter* or *Salmonella* (NSWFA, 2011). Similarly, no *Cronobacter* was detected in 34 samples of PIF surveyed in New Zealand in 2009 (NZFSA, 2009).

There are no concerns with the current Code labelling requirements relating to instructions for the preparation and use of infant formula. This is underpinned by food safety requirements that should ensure infant formula products are produced to a stringent level of hygiene.

4 Summary

The risk management approach when developing the current Code requirements for preparation and use of infant formula focused on ensuring the information and instructions on the label were clear and easy to follow for the general community. The intent was to ensure that the essential risk reduction elements were clear e.g. only use potable water that has

previously been boiled, and advice on refrigeration of reconstituted formula for up to 24 hours and discarding unused/leftover formula.

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Attachment A2.2 – Rapid evidence assessment on infant formula preparation, perceptions and label use

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1 Introduction

A rapid evidence assessment (literature review) was conducted to examine:

- formula preparation, specifically whether caregivers:
 - boil water before using it to prepare formula
 - store formula at room temperature or in the refrigerator
 - discard unfinished feeds
 - add cereal or other foods to formula
 - add vitamins and minerals to formula
 - use the scoop enclosed with the formula
 - use and understand the preparation instructions on formula products
- the influence of breastfeeding intentions on breastfeeding initiation and duration
- caregivers' understanding of the prescribed term 'infant formula'
- whether the framing of a message about the benefits of breastfeeding (as a gain-framed or loss-framed message) is likely to impact caregiver perceptions or infant feeding choices
- whether the format in which nutrition information is presented will impact on caregiver use or understanding of the information (see SD3 for this section)
- whether caregivers use the protein source statement and whether they encounter difficulties locating it.

Appendix A2.1 is the protocol for the rapid evidence assessment. It includes further detail on the scope of the literature review, the search strategy used and the inclusion and exclusion criteria.

The findings of the rapid evidence assessment follow. These findings are also summarised in the relevant sections of SD2 and SD3.

2 Infant formula preparation

A literature search was conducted to find studies which examined caregivers' infant formula preparation practices. Studies were included if they examined self-reported preparation practices (qualitative or quantitative), used observations of caregivers preparing formula, or tested samples of formula reconstituted by caregivers. Only studies from developed countries were included. Further details on the search strategy are available in Attachment 1. Results reported in this review relate to how caregivers prepare powdered infant formula, unless the study did not specify what type of formula was used.

2.1 Background to the studies

2.1.1 Study methods

Most of the studies examining the infant formula preparation practices of caregivers were conducted in either the USA (10 studies) or the UK (13 studies¹²), rather than Australia (five)

¹² NB: Four of these studies were from the same report prepared for the UK Food Standards Agency: Redmond E, Griffith C (2013) An investigation into the attitudes and behaviours of consumers and caregivers in the preparation, handling and storage of powdered infant formula inside and outside the home. Food Standards Agency Research Project B13008. <https://www.food.gov.uk/science/research/foodborneillness/b13programme/b13list/b13008>, accessed 30

or New Zealand (three). One study was conducted in the Republic of Ireland and one in Italy. The majority of studies were quantitative surveys (23 studies), followed by qualitative studies (six studies), literature reviews (three studies), laboratory analysis of infant formula samples (two studies), two observational studies, and one study that used temperature dataloggers on infant formula bottles with diaries kept by parents. The surveys included two examples of longitudinal studies. These were the Infant Feeding Practices studies conducted in the USA in 1993-94 (Baydar et al. 1997; Fein and Falci 1999) and 2005-07 (Labiner-Wolfe et al. 2008), and the UK Infant Feeding Survey conducted in 2000 (Hamlyn et al. 2002), 2005 (Bolling et al. 2007) and 2010 (McAndrew et al. 2012).

Of the qualitative studies, four used focus groups, two used interviews and one used an online forum.

Generally the studies relied on participants self-reporting how they prepared infant formula. However, two studies (Bennett and Gibson 1990; Lucas et al. 1991) conducted laboratory testing on samples of infant formula prepared by caregivers and two studies used observations of caregivers preparing infant formula (Herbold and Scott 2008; Redmond and Griffith 2013a). In one of the UK Food Standards Agency's (UKFSA) studies, parents prepared bottles of powdered infant formula at home and attached temperature dataloggers to the bottles to measure the temperatures prepared infant formula was exposed to (Redmond and Griffith 2013b).

2.1.2 Sample characteristics

Of the surveys, six were population surveys, 14 used convenience samples (such as participants drawn from clinics or local areas), two used research panels and one used quota sampling.

Three of the qualitative studies recruited participants through community groups or people who work with parents and their infants. One recruited parents through parent/baby groups and 'on-street' recruitment outside shopping centres. One recruited participants through a consumer panel, and one did not specify how participants were recruited.

The two laboratory studies used convenience samples of parents, as did the two observational studies.

Five of the surveys focused on the preparation practices of low income caregivers (O'Malley et al. 1991; Daly et al. 1998; Kwon 2002; Kavanagh and Springer 2007; Trepka et al. 2007) rather than the general population of caregivers.

2.2 Findings on preparation, handling and use of infant formula

2.2.1 Boiling water before mixing with formula

The proportion of caregivers who boiled water before using it to mix infant formula varied widely between studies (see Table A2.1, below), with one finding that 43% of caregivers using tap water did not boil the water, even when preparing formula for young infants (Baydar et al. 1997; Labiner-Wolfe et al. 2008). In contrast, an observational study conducted in the UK found that 100% of parents boiled water before using it to prepare formula (Redmond and Griffith 2013a).

In some of the studies from the USA, caregivers reported using bottled water (Kwon 2002; Herbold and Scott 2008; Labiner-Wolfe et al. 2008). In the UK Infant Feeding Survey studies, the proportion of caregivers following UK recommendations to boil water and use within 30 minutes increased from 59% in 2005 to 71% in 2010 (Bolling et al. 2007; McAndrew et al. 2012). No data on Australian or New Zealand caregivers could be located for this behaviour. Based on the findings from overseas studies, it is likely that a substantial minority of Australian and New Zealand caregivers are not boiling water before using it to prepare infant formula.

Table A2.1: Boiling water before mixing with formula

Study	Year collected	Study type	Country	Finding
Baydar et al. (1997), Fein & Falci (1999)	1993-94	Survey	USA	When infant was 2 months old, 43% of mothers did not boil tap water before use.
Kwon (2002)	Unknown	Survey	USA	19% of mothers used boiled water. 36% used filtered or bottled water.
Define Research & Insight (2006)	2006	Qualitative (focus groups)	UK	Majority reported they boiled water, then let it cool for 30-40 minutes. Some added boiling water to formula
Bolling et al. (2007)	2005	Survey	UK	59% of mothers followed recommendations to use water boiled and left to cool for less than 30 minutes. 40% left it to cool for longer than 30 minutes
Carletti & Cattaneo (2008)	2006	Survey	Italy	22% of parents used water at 70 degrees Celsius or warmer to prepare formula
Herbold & Scott (2008)	2004	Observational study	USA	40% of observed participants brought the water to the boil before use. One used bottled water ¹³
Labiner-Wolfe et al. (2008)	2005-07	Survey	USA	When infant was 1.5–4.5 months old, 30% of mothers boiled tap water before use
Lennox et al. (2011)	2011	Survey	UK	When making up formula, 68% used water that had been boiled and left to cool for no more than 30 minutes.
McAndrew et al. (2012)	2010	Survey	UK	71% of mothers (of 4–10 week old infants) used water that had been boiled and left to cool for 30 minutes or less 29% left it to cool for longer than 30 minutes ¹⁴
Redmond & Griffith (2013c)	2007-08	Qualitative (focus groups)	UK	All parents reported preparing feeds with boiled water.

¹³ Frequencies from this study should be interpreted with caution as the study sample was small (15 mothers).

¹⁴ NB: Respondents were not given the option of indicating that they did not boil water for mixing with infant formula. Response options all related to how long caregivers left boiled water to cool before using.

Study	Year collected	Study type	Country	Finding
Redmond & Griffith (2013a)	2010	Observational study	UK	100% of parents prepared the feeds used boiled tap water. 70% followed the recommendation to cool the water for less than 30 minutes before using it to prepare the formula ¹⁵ .
Redmond & Griffith (2013b)	2010	Temperature datalogger/diary		15% of feeds were prepared with boiled water cooled for less than 30 minutes. 85% prepared using boiled water cooled for more than 30 minutes.

2.2.2 Storing prepared infant formula at room temperature

Caregivers were generally aware that infant formula should not be kept at room temperature once prepared (see Table A2.2, below), and most reported only leaving prepared infant formula at room temperature for two hours or less. However, no Australian or New Zealand studies explored this behaviour.

Table A2.2: Storing prepared infant formula at room temperature

Study	Year collected	Study type	Country	Finding
Fein & Falci (1999)	1993-94	Survey	USA	15% reported leaving prepared infant formula at room temperature for more than 2 hours
Define Research & Insight (2006)	2006	Qualitative (focus groups)	UK	Some parents kept prepared formula at room temperature for up to 4 hours. Most stored prepared formula in the refrigerator. Participants were confused as to whether prepared formula need to be discarded after using, after warming or just if left at room temperature
Trepka et al. (2006)	2005	Survey	USA	79% of mothers reported never or rarely leaving prepared infant formula or breastmilk at room temperature for more than 2 hours. 10 % reported doing this some of the time.
Carletti & Cattaneo (2008)	2006	Survey	Italy	10% of parents reported storing prepared formula at room temperature
Herbold & Scott (2008)	2004	Observational Study	USA	73% of mothers thought prepared formula could be kept at room temperature for less than 1 hour. 20 % reported that 3-4 hours was safe ¹⁶ .

¹⁵ The researchers note that more than half of parents used methods to cool the boiled water before adding the formula, in these cases the water would be below the 70°C recommended by the WHO.

¹⁶ Frequencies from this study should be interpreted with caution as the study sample was small (15 mothers).

Study	Year collected	Study type	Country	Finding
Labiner-Wolfe et al. (2008)	2005-07	Survey	USA	6% reported leaving prepared infant formula at room temperature for more than 2 hours. 17–23% (depending on infant age) reported that they never left prepared formula at room temperature
Redmond & Griffith (2013c)	2007-08	Qualitative (focus groups)	UK	Some parents reported preparing infant formula ahead of time with hot water and leaving it at room temperature to cool. In some cases the infant preferred room temperature formula, and so the formula was left at room temperature until this was reached.
Redmond & Griffith (2013d)	2008	Survey	UK	71% of parents agreed with the statement “I am happy to cool a made-up bottle of powdered formula milk at room temperature”. Once formula has been prepared, 12% of parents reported storing the formula at room temperature before feeding. When feeding away from home, 45% of parents prepare a bottle of formula and take it with them. Of these parents, 52% store this in an insulated compartment of a baby bag to keep it warm. 30% store it in a non-insulated bag
Redmond & Griffith (2013a)	2010	Observational study	UK	Of the 10 bottles of reconstituted formula for feeding away from home, only one was cooled and stored in a cool-bag with freezer packs. Some parents used an insulated bag to keep the prepared formula warm.
Redmond & Griffith (2013b)	2010	Temperature datalogger/diary	UK	The longest a prepared feed was stored at room temperature was 21 hours and 15 minutes. Some of the feeds prepared for using away from home were stored with no insulation or freezer packs for up to 8.5 hours. Of the feeds that were refrigerated, the time between reconstitution and refrigeration ranged from 26–679 minutes.

Although the above findings are not based on Australian or New Zealand studies, it seems that the importance of not storing prepared infant formula at room temperature is generally understood by caregivers.

2.2.3 Storing prepared formula in the refrigerator

Findings regarding how caregivers stored formula that has been prepared were positive, with all finding that the majority of caregivers store prepared formula in the refrigerator (Table A2.3). Only one study examined how long caregivers thought prepared formula could be stored at refrigerator temperatures (Herbold and Scott 2008). The findings of this were positive, with over 80% of participants believing that formula could be kept in the refrigerator for 24 hours or less (Herbold and Scott 2008). No studies examining refrigeration of prepared infant formula were found that were conducted in Australia or New Zealand.

Redmond and Griffith (2013c) reported that many of the focus group participants had noticed that ready to use infant formula (which is sterilised) had instructions on the label saying it could be stored (once open) in the refrigerator for up to 24 hours. They assumed because of this that powdered infant formula reconstituted with water would have the same storage time.

This was supported from the findings of the survey, in which 27% of parents agreed with the statement “Made-up powdered formula milk can be safely stored for the same length of time as opened cartons of ready-to-use formula” (Redmond and Griffith 2013d).

Table A2.3: Storing prepared formula in the refrigerator

Study	Year collected	Study type	Country	Finding
Kwon (2002)	Unknown	Survey	USA	94.6% stored prepared infant formula in the refrigerator as soon as it is made. A further 1.6% freeze it.
Define Research & Insight (2006)	2006	Qualitative (focus groups)	UK	Most of those who prepared in advance stored the formula in the refrigerator.
Herbold & Scott (2008)	2004	Observational Study	USA	80% of mothers thought a prepared bottle could be kept in the refrigerator for up to 24 hours, 7% for 12 hours. One respondent (7%) thought it was safe for more than 5 days ¹⁷ .
Labiner-Wolfe et al. (2008)	2005-07	Survey	USA	85% believed it was very important to follow the label directions to refrigerate or discard prepared formula
Redmond & Griffith (2013c)	2007-08	Qualitative (focus groups)	UK	Many parents reported preparing feeds in advance and storing them in the refrigerator for up to 24 hours. However, more typical storage times were 9–12 hours. No parents reported monitoring the temperature of their refrigerator. Some parents who prepared feeds for feeding away from home used a cool bag with freezer packs to keep the formula cool.
Redmond & Griffith (2013d)	2008	Survey	UK	Once feeds have been prepared, 23% of parents reported storing them in the refrigerator before use. (Most parents reported feeding the prepared feeds immediately). Of parents who prepared feeds ahead of time for feeding away from home, only 4% used a cool bag with freezer packs to keep the bottle cool
Redmond & Griffith (2013a)	2010	Observational study	UK	Of parents who prepared formula feeds ahead of time, the majority reported that they would leave the prepared feed at room temperature before refrigeration. Usually this was for less than 1 hour. Of the 10 parents that demonstrated preparing a feed ahead of time to feed away from home, only one used a cool bag with a freezer pack.

¹⁷ Frequencies from this study should be interpreted with caution as the study sample was small (15 mothers).

Study	Year collected	Study type	Country	Finding
Redmond & Griffith (2013b)	2010	Temperature datalogger/diary	UK	Of the 143 feeds prepared, 62% spent at least some time in a refrigerator. Refrigeration storage times ranged from 2 hrs 17 minutes to 19 hrs and 44 minutes.

Again, the findings regarding caregivers storing prepared infant formula in the refrigerator suggest the importance of this is well understood. Although there are no Australian or New Zealand studies examining this, all four studies did have similar (positive) findings.

2.2.4 Discarding unfinished feeds

Only four studies investigated whether caregivers discarded unfinished formula, left over from a feed (see Table A2.4). These found caregivers generally discarded the formula, although one New Zealand study found that some parents did not throw it away, generally because they were concerned about wasting money. No Australian studies examined whether caregivers discarded leftover infant formula.

Table A2.4: Discarding unfinished feeds

Study	Year collected	Study type	Country	Finding
Define Research & Insight (2006)	2006	Qualitative (focus groups)	UK	Participants tended to throw unfinished milk away immediately. Although some left it for 30–60 minutes before discarding or using it.
Labiner-Wolfe et al. (2008)	2005-07	Survey	USA	85% of mothers believed it was very important to follow instructions to refrigerate or discard prepared formula
Winstanley & Cressey (2008)	2008	Qualitative (focus groups)	NZ	Parents generally discarded unfinished feeds. Among those who did not, this was generally for cost reasons
Redmond & Griffith (2013d)	2008	Survey	UK	73% of parents were aware of the recommendation to “Discard any feed that has not been used within two hours”. 73% also considered this recommendation to be realistically achievable.

In research commissioned by the UKFSA (Define Research & Insight 2006), some caregivers did not understand the recommendation to “throw away any leftover milk”. This was both because they were not clear what the rationale for and consequences of keeping the milk were, and because it was not clear to them how soon after preparing the formula it must be thrown away.

Of the four studies that examined whether caregivers discard unfinished feeds, two were qualitative and so did not report the proportion of caregivers following the recommendation to throw away left over feeds.

Given the paucity of evidence on the prevalence of this behaviour (particularly quantitative data), no conclusion can be reached as to whether Australian and New Zealand caregivers are aware of, understand, or follow this recommendation.

2.2.5 Using the scoop enclosed with the formula product

Only two studies examined whether caregivers used the scoop enclosed by the manufacturer to measure infant formula powder before reconstitution (Herbold and Scott 2008; Watson 2012). These both found a high rate of compliance. In the observational study by Herbold and Scott (2008) all of the mothers were observed to use the scoop enclosed by the manufacturer. In Watson's (2012) survey 95.5% of parents reported using the enclosed scoop. Most of the remainder did not use powdered infant formula (i.e. they used to ready to feed formula) (Watson 2012).

However, these results should be interpreted with caution. This is because Herbold and Scott had a small sample size, of only 15 mothers. In addition, Watson used a convenience sample of caregivers, collected by promoting the survey on Facebook.

2.2.6 General findings regarding infant formula preparation

Caregivers tend to become more relaxed about following the recommended formula preparation instructions as the infant gets older (Lucas et al. 1991; Baydar et al. 1997; Guthrie and Parnell 1998; Fein and Falci 1999; Labiner-Wolfe et al. 2008; Winstanley and Cressey 2008; Yockney and Comfort 2013; Redmond and Griffith 2013c; Redmond and Griffith 2013d). In particular, caregivers are less likely to sterilise feeding equipment as the infant grows older (Fein and Falci 1999; Yockney and Comfort 2013), and are more likely to use a dishwasher for sterilising bottles (Guthrie and Parnell 1998). They are less likely to boil water for mixing with formula (Labiner-Wolfe et al. 2008; Yockney and Comfort 2013) and more likely to add cereal to the bottle as the infant grows older (Baydar et al. 1997). Lucas et al. (1991) also found that mothers were more likely to over-concentrate feeds when the infant was older. In contrast, Lennox et al. (2011) found that caregivers were more likely to prepare multiple feeds ahead of time with younger infants (4–6 months of age) than with older infants (aged 7 months and over); this may be connected to the lower number of bottles older infants would consume in a day.

Caregivers may understand that younger infants are more vulnerable and that the preparation of formula for them requires more care (Define Research & Insight 2006). Infants who had been born premature were regarded as particularly at risk, and their caregivers were more likely to be fastidious in following preparation instructions (Define Research & Insight 2006). Redmond and Griffith (2013c) found that many parents felt they have been given little or no information by health practitioners on infant formula preparation, with the exception of parents of 'at-risk' infants. Parents of these infants were given information and demonstrations of proper infant formula preparation in the hospital and had a positive attitude to this support.

Fein and Falci's (1999) research also supports the finding that caregivers are intentionally more careful with younger infants. Mothers in their study who had received instructions from health professionals on preparing infant formula were more likely to follow recommended practices, but this effect was only found among younger infants (when mothers were surveyed two months postpartum) and disappeared as the infant grew older (Fein and Falci 1999).

In one study, conducted in New Zealand, some caregivers noted that they were less careful regarding hand hygiene and the cleanliness of the infant formula preparation environment for subsequent children than they were for their first child (Winstanley and Cressey 2008).

Some studies have found that caregivers tend to assume that powdered infant formula is sterile until before it is reconstituted with water (Define Research & Insight 2006; Winstanley and Cressey 2008; Redmond and Griffith 2013c; Redmond and Griffith 2013d). One of these

was conducted with New Zealand caregivers (Winstanley and Cressey 2008). Some parents even believed that powdered infant formula remained sterile after the package had been opened (Redmond and Griffith 2013c; Redmond and Griffith 2013d). One UK study found that 22% of parents agreed with the statement “There is no association between Salmonella and powdered infant formula” (Redmond and Griffith 2013d).

The lack of awareness that infant formula can contain bacteria (i.e. is not sterile) may partly explain why caregivers do not always follow the preparation instructions exactly. However, despite not being aware that powdered infant formula can contain bacteria, caregivers do seem to understand that leaving prepared formula at room temperature and storing leftover formula after a feed is risky despite not fully understanding why (Define Research & Insight 2006; Winstanley and Cressey 2008).

Research conducted in the UK found that some parents were confused by new UK guidelines recommending that parents use boiled water, cooled for 30 minutes or less to prepare powdered infant formula (Redmond and Griffith 2013d). The majority of the parents were not aware that this recommendation was designed to kill bacteria in the infant formula

2.2.7 The use of preparation instructions on infant formula labels

Caregivers tend to rely most heavily for information on preparing infant formula on the formula package (Bennett and Gibson 1990; Define Research & Insight 2006; Herbold and Scott 2008; Winstanley and Cressey 2008; Redmond and Griffith 2013c). Australian and New Zealand based research suggests that formula feeding parents feel they do not receive sufficient information and support from health care providers on the use of infant formula (Guthrie and Parnell 1998; Winstanley and Cressey 2008; Smith 2010; Wirihana and Barnard 2011). For example, Fenwick et al. (2013) found the educators in antenatal classes in Australia generally do not discuss infant formula, except when referring to the health risks of infant formula feeding in comparison with breastfeeding. Caregivers may not seek out information prior to birth on infant formula preparation because they expect to breastfeed, and therefore feel they will not need this information (Winstanley and Cressey 2008; Smith 2010). However, this then leaves them feeling unprepared if they encounter difficulties in breastfeeding and need to supplement with formula or switch to formula feeding (Winstanley and Cressey 2008; Smith 2010).

Winstanley and Cressey (2008) found that many caregivers experienced difficulties in obtaining information on infant formula, particularly information on preparation. The formula tin became the main source of information, and was considered available, authoritative and trusted. Many of the caregivers in this study also attempted to access information from health professionals on infant formula, but in many cases they were unwilling or unable to provide it. Caregivers mentioned that health professionals believed they were ‘not allowed’ to provide information on formula feeding.

Caregivers in Yockney and Comfort’s (2013) research reported that they referred to preparation instructions the first few times they prepared formula, but generally did not refer to them again unless they changed formulas. They noted that preparation instructions are most important for caregivers that are new to preparing formula. Caregivers saw instructions on how to sterilise bottles, to use cooled boiled water and the ratio of powder to water to be the three most important components of the preparation instructions.

In contrast, Smith (2010), found that infant formula cans were not a main source of information mentioned by formula feeding mothers. Some participants in the study were sceptical of the information on formula cans, particularly as formula companies were not seen as objective.

In Labiner-Wolfe et al.'s (2008) research (conducted in the USA), caregivers were asked when their infant was two months old which parts of the preparation instructions they had read on infant formula cans. They found 11.7% of mothers had not read the preparation instructions on the label, 25% had not read instructions on storing formula after it is prepared, 30% had not read the directions for left over formula after feeding, 31% had not read instructions for storing the formula package after opening, and 34% had not used the pictures on the label which demonstrate how to prepare the formula. Of the mothers who had read the preparation instructions, most reported that they understood them (only 3% reported finding them difficult to understand), however 9% reported that they were too small to read easily. The earlier Infant Feeding Practices Study also found that all (100%) of mothers who responded found the preparation instructions easy to understand (Fein and Falci 1999).

In an online survey by Watson (2012) of Australian formula feeding caregivers, 62% reported strictly following the instructions on the formula packaging, and 29% followed the instructions on the formula packaging but not strictly. The majority of respondents indicated that they would change how they prepared formula if there was a change to the instructions on the packaging.

In a survey of parents in the UK, 71% disagreed with the statement "Following preparation and storage instructions on cans of powdered formula is not essential" (Redmond and Griffith 2013d) whereas 18% agreed with the statement, with the remaining 11% neither agreeing nor disagreeing.

Caregivers who do not follow preparation instructions may or may not be aware that they are preparing infant formula incorrectly. For example, a few participants in the research above appear to have deliberately over concentrated formula (O'Malley et al. 1991; Fein and Falci 1999). They may be unaware of recommended preparation practices because they did not read the instructions, or because they read the instructions but did not understand them or later forgot them. For those who are aware they are preparing infant formula incorrectly, this may be because they believe the risk is low (for example, because the infant is older (Winstanley and Cressey 2008) or because they believe the formula powder is sterile (Define Research & Insight 2006)), because correct preparation takes too long or is too much effort, because they have been preparing infant formula incorrectly for some time and do not believe this has harmed their infant (Define Research & Insight 2006), or because they have received conflicting information from other sources.

A survey conducted in the UK of parents using infant formula found that 90% believed that there was a very low risk of illness for their infant from powdered infant formula that they themselves had prepared (Redmond and Griffith 2013d). The parents surveyed tended to perceive formula prepared by other people (e.g. other parents, day care staff) as riskier.

2.2.8 Adding cereal and other foods to infant formula

The addition of cereal to the bottles of infants, particularly young infants, is not recommended (National Health and Medical Research Council 2012; Ministry of Health 2013). The review found this was a common practice, although no recent studies from Australia or New Zealand were found which examined this (see Table A2.5).

Both of the longitudinal studies included a question regarding substances other than infant formula or breastmilk added to feeds in their earlier waves (Baydar et al. 1997; Fein and Falci 1999; Hamlyn et al. 2002). However, publications on the subsequent waves of these studies do not mention foods added to infant formula or breastmilk, suggesting the question was dropped in the later surveys (Bolling et al. 2007; Labiner-Wolfe et al. 2008; McAndrew et al. 2012).

Table A2.5: Adding cereal and other foods to infant formula

Study	Year collected	Study type	Country	Finding
O'Malley et al. (1991)	1987	Survey	USA	Only one instance of feeding an infant cereal in a bottle was observed. However, this was collected from an open ended question.
Retallack et al. (1994)	1992	Survey	AU	Of mothers using infant formula, 13% added cereal, crushed biscuit or a sweetening agent to the formula
Baydar et al. (1997), Fein & Falci (1999)	1993-94	Survey	USA	Baydar et al. found 11% of infants at 1 month had other foods or liquids added to their formula. At 3 months this was 24% of infants. Fein & Falci found that among 2 and 5 month old infants, 35% had other foods added to their formula, the most common of which was cereal. At 7 months 28% of infants had other foods added. At 2 months of age, 21% of infants had cereal added to bottle. At 5 months of age, 22% had cereal added to their bottle. At 7 months, 15% had cereal added.
Daly et al. (1998)	Unknown	Survey	UK	47% added cereal to the infant's bottle, particularly with the last feed at night time
Hamlyn et al. (2002)	2000	Survey	UK	At 4–10 weeks of age, 5% of infants were having substances other than formula or water added to their bottle (most commonly colic drops and gripe water) At 4–5 and 8–9 months 6% of infants were having substances other than formula or water added to their bottle (most commonly substances that would thicken the milk, such as baby rice)
Carletti & Cattaneo (2008)	2006	Survey	Italy	31% added cereal to the bottle
Herbold & Scott (2008)	2004	Observational Study	USA	47% had added cereal to the infant's bottle ¹⁸
Lakshman et al. (2009)	2008	Literature review	USA, UK, AU, NZ	6 studies looked at adding cereal to the bottle. Only 2 of these were published from 1990 onwards. From all of the studies examining addition of cereal, the proportion of caregivers doing so ranged from 4–47 %.
Tarrant et al. (2013), Tarrant et al. (2010)	2004-06	Survey	Ireland	At 6 weeks, 3.8% of parents were adding solid foods, such as baby rice or cereal to the infants' bottles. At 6 months this was 6% of parents.

None of the studies examining the addition of foods to infant formula examined whether this differed by type of infant formula (powdered infant formula, liquid concentrate or 'ready to drink') used. However, where the article provided information on the types of formula used by participants (in general, not specifically for caregivers adding foods to bottles of infant formula), powdered infant formula was the most common type used¹⁹. For example, in the

¹⁸ Frequencies from this study should be interpreted with caution as the study sample was small (15 mothers).

¹⁹ The predominance of powdered infant formula is likely due to the cost differential, as powdered infant formula is

population study by Hamlyn et al. (2002) in the UK 80-86% of infants were fed powdered infant formula. Similarly, in Herbold and Scott's (2008) observational study conducted in the USA, 80-86% of caregivers were using powdered infant formula²⁰. The survey by Carletti and Cattaneo (2008) was conducted exclusively with users of powdered infant formula.

Due to the predominance of powdered infant formula use, it seems likely that many of the instances of cereal (and other foods) being added to formula that were mentioned in the literature, were added to powdered infant formula. However, it is not possible to conclude from the available evidence whether this behaviour is more common among caregivers using powdered infant formula than those using ready to drink or liquid concentrate formula.

The proportion of caregivers adding cereal and other foods to infant formula varied widely between studies. Some of the studies noted that the rate of this behaviour varied between demographic groups (e.g. Baydar et al. 1997 noted that African American mothers were more likely to add foods to bottles of infant formula than other ethnic groups). Given the variation between studies it is not possible to estimate the prevalence of this behaviour in Australia or New Zealand.

Baydar et al. (1997) found that the addition of other foods to infant formula appeared to rise between one month and three months (this was not tested for statistical significance). However, other authors found the rate of addition of other foods to be fairly stable over the infants' first nine months (Hamlyn et al. 2002; Tarrant et al. 2013).

2.2.9 Adding vitamins and minerals to infant formula

Only three of the studies on infant formula preparation examined whether caregivers gave their infants vitamin and mineral supplements (Retallack et al. 1994; Daly et al. 1998; Fein and Falci 1999).

Retallack et al. (1994), in a convenience sample of mothers in Australia, found that no formula fed infants aged 0–8 months were receiving a multivitamin supplement. Two per cent of formula fed 8.1–10 month olds and 10.1–12 month olds were receiving a multivitamin supplement. Retallack et al. do not state whether the multivitamin supplements were being added to the infants' bottles.

The study by Daly et al. (1998) was conducted in the UK. Daly et al. found that 9% of mothers in their sample gave their child drops containing vitamins. However, the authors did not specify whether the drops were added to bottles of infant formula or given directly. The study focused on infants aged 0–12 months living in deprived inner city areas who had been given pasteurised cow's milk before 12 months.

The third study, by Fein and Falci (1999), found that "A few mothers added vitamins or minerals to bottles of formula" (pg. 1237). No further information is provided about these mothers (e.g. demographic information) or on the proportion of the sample they represented.

The issue of vitamin or mineral supplements being added to infant formula by caregivers has not been explored in the literature (with the exception of Fein and Falci's brief mention of it). However the few studies which included questions on supplement use generally found that it was not common. However, they were all relatively old (the most recent was published 16 years ago).

substantially cheaper than liquid concentrate and ready to drink formula (McAndrew et al. 2012).

²⁰ Frequencies from this study should be interpreted with caution as the study sample was small (15 mothers).

Based on the available evidence, no conclusion can be reached about the likely prevalence of caregivers adding vitamins and minerals to infant formula in Australia and New Zealand.

2.3 Conclusion

For many infant formula preparation practices there was little or no Australian or New Zealand research. Preparation behaviours where the research identified the highest proportion of caregivers not following recommendations were: whether caregivers used cooled boiled water, and the addition of cereal or other substances to infant formula.

For some issues: discarding leftover feeds, the addition of other foods (e.g. cereal) to infant formula, and the addition of vitamins and minerals to infant formula, there was insufficient evidence to reach a conclusion as to whether this was an issue in Australia or New Zealand.

Preparation instructions on infant formula cans are clearly an important source of information for caregivers learning how to safely prepare infant formula. Many Australian and New Zealand caregivers using infant formula felt that they did not receive sufficient information on how to prepare formula for their infants. Caregivers will generally refer to preparation instructions on the package only the first few times they prepare formula. Caregivers generally report following the infant formula preparation instructions on the package.

Two surveys examined whether caregivers understood preparation instructions on the can (Fein and Falci 1999; Labiner-Wolfe et al. 2008). However these both relied on respondents' self-report. No studies were found which actually tested caregivers' understanding of instructions.

Where caregivers do not follow recommended preparation practices it is not clear to what extent this is due to lack of awareness or other reasons, for example the extra time or effort that some correct preparation practices require. Therefore it is not clear to what extent changes in the preparation instructions may alter caregivers' preparation practices.

3 Use of the statement of protein source

Research participants discussed protein in infant formula in three of the studies found in the literature search (Fein and Falci 1999; Caroline Walker Trust 2009; Yockney and Comfort 2013).

The only study to examine whether caregivers used the statement of protein source was a qualitative study commissioned by the New Zealand Ministry for Primary Industries (Yockney and Comfort 2013). Participants in the study ranked seven label elements found on infant formula products from those they found the most useful to those they found least useful. The study did not specifically explore the effect of the location of the protein source statement on caregivers' understanding or use of the statement.

The 'Declaration of protein type' ranked as less useful than most of the other label elements by participants in both Australia and New Zealand. In Australia, the declaration was considered less useful than: age information; brand; production description; claims²¹; and ingredients. The only label element it was more useful than was trademarks. Similarly, among New Zealand respondents, the declaration was less useful than: age information; ingredients; brand; and product description. However, it was more useful than both claims and trademarks. Yockney and Comfort (2013) noted that many participants "do not know

²¹ NB: Respondents were shown examples of claims from toddler milk and infant formula products sold in Australia/New Zealand. It is possible that some of these claims may not comply with the Code.

what 'protein type' is" (pg. 57), and so therefore it was not useful for them. However, caregivers with infants who had intolerances or allergies (and therefore needed to avoid certain types of formula) did find the information useful. A few Australian caregivers reported that they used the declaration of protein type to identify whey-based infant formulas which they believed were easier for the infant to digest than casein-based infant formulas.

The second study in which participants discussed protein in infant formula was conducted in the USA (Fein and Falci 1999). Mothers in the survey were asked about the ingredients they looked for on infant formula products. Mothers tended to look for: iron (the most common), fats, sugar, vitamins, protein and calcium. It is not clear from the article where mothers were looking on the infant formula packaging for protein, i.e. whether they were looking at a protein declaration, in the ingredient list, or in the nutrition panel. It is also not clear whether they were concerned about the source of the protein (e.g. from cow's milk) or some other aspect, such as the quantity of the protein in the formula.

In the third study, researchers examined posts on a UK parenting internet forum (Caroline Walker Trust 2009). Some forum participants mentioned protein, but not the source of the protein, and they did not refer to the protein source declaration. Instead, the discussion focused on the benefits of 'long chain proteins'.

In conclusion, the protein source statements appear to be useful for some caregivers that are seeking out infant formula not made from cow's milk (e.g. because their infant has a food allergy), or who believe a whey-based infant formula will be best for their infant. However, no evidence is available to determine whether caregivers have trouble finding the protein source statement which, in practice, may not appear on the front of infant formula products.

4 Understanding of 'infant formula'

Only one study (Yockney and Comfort 2013) examined caregivers' understanding of the term 'infant formula. Yockney and Comfort's (2013) research found that caregivers differed in the terms they used to distinguish between formula products designed for different age ranges. To refer to infant formula products, some used the term 'infant formula', others used 'Stage 1 formula' and some referred to the age range 'from birth to 6 months'. Caregivers understood that infant formula could be used as a sole source of nutrition for infants, and that (in contrast) follow on formulae and toddler milks were for older infants (in the case of follow on formula) or children (in the case of toddler milks) who would be receiving other sources of nutrition.

5 Influence of breastfeeding intentions on breastfeeding initiation and duration

Women's stated infant feeding intentions are some of the strongest predictors of whether they will breastfeed (Losch et al. 1995; Dennis 2002; Meedyia et al. 2010). The majority of women make a decision on whether to breastfeed or formula feed either before they conceive or in pregnancy (Scott et al. 2001; Binns and Scott 2002; Sheehan et al. 2003; Morton et al. 2010). Australian and New Zealand research has found that women's intentions to breastfeed, whether mentioned antenatally (Forster et al. 2006; Baghurst et al. 2007; Wen et al. 2009; Morton et al. 2012) or postnatally (Scott et al. 1999; Vogel et al. 1999; Scott et al. 2001; Heath et al. 2002; Forster et al. 2006; McGrath and Phillips 2009; Kervin et al. 2010) are strong predictors of a woman's future infant feeding practices. Intentions to breastfeed predict whether women will initiate breastfeeding (Scott et al. 2001; Heath et al. 2002; Morton et al. 2012) and also how many months they will breastfeed for (Scott et al. 1999; Vogel et al. 1999; Scott et al. 2001; Forster et al. 2006; Baghurst et al. 2007).

Similarly, women who report intending to feed their infant formula (and no breastmilk) before their child's birth will generally follow through with this (Australian Institute of Health and Welfare 2011; Morton et al. 2012). A study by AIHW (2011) found that, of the 5% of Australian women who intended to formula feed their infant, three quarters did so. The authors also note that "nearly all mothers whose prior intention was to breastfeed their child did provide breastmilk to their child", although they do not provide a percentage that did so. These findings are similar to Morton et al.'s (2012) that, of the 1.9% of the New Zealand women in their study who did not intend to breastfeed, 62% did not feed their infant any breastmilk after birth.

6 Loss-framed versus gain-framed messages

Some authors have suggested that the emphasis in infant feeding health communication should shift from the benefits of breastfeeding to the risks of formula feeding (Wiessinger 1996; Berry and Gribble 2008; Akre 2010; Howard 2010). In other words, messages should emphasise the potential losses from formula feeding (e.g. higher risk of gastroenteritis) rather than the potential benefits of breastfeeding (e.g. lower risk of gastroenteritis). This issue was also raised by some submitters in an inquiry conducted by the House of Representatives Standing Committee on Health and Ageing (2007) into breastfeeding. Berry and Gribble (2008) have argued that the emphasis on the 'breast is best' message (rather than the risks of formula feeding) may mean that women who encounter difficulties in breastfeeding are less likely to persist with it. Similarly, McNeil et al. (2010) has argued that by expressing research findings in terms of the risks of infant formula (rather than the benefits of breastfeeding) would lead families to perceive these risks as too high, thereby making them more likely to choose exclusive breastfeeding. They also suggest that this would create a social norm of breastfeeding.

Some submitters to the 2012 Consultation paper advocated changing the statement currently required on infant formula labels in Standard 2.9.1 – Infant Formula Products from "Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice" to a statement regarding the risks of formula feeding.

The proposed change would move the warning statement from a gain-framed message (emphasising the benefits of breastfeeding) to a loss-framed message (emphasising the risks of formula feeding). Only one peer-reviewed study has examined the effect of gain-framed versus loss-framed messages in relation to infant formula and breastfeeding (Ebert Wallace and Taylor 2011). However, the study used male and female university students rather than a sample of pregnant women or mothers of young children and was conducted in the USA. Participants were exposed to either a gain-framed message about the benefits of breastfeeding, (e.g. "Compared with formula-fed children, those who are breastfed are healthier and have fewer symptoms and shorter illnesses when they do get sick"), a loss-framed message emphasising the risks of formula feeding (e.g. "Compared with breast-fed children, those who are formula fed are sicker and have more symptoms and longer illnesses when they do get sick") or no text (control group). The researchers found that the message framing (loss-framed or gain-framed) did not have any impact on their intentions to breastfeed future children. In addition, breastfeeding intentions did not differ between the treatment groups (loss-framed and gain-framed messages) and the control group who were not exposed to messages about infant formula and breastfeeding.

Watson (2012) conducted a survey using a convenience sample gathered through an online formula feeding community, in part to examine responses to how caregivers perceived loss-framed messages regarding breastfeeding. Respondents were asked "If the message on formula packaging was not 'Breast is Best' but instead a risk based statement (e.g. 'Formula feeding increases risk of') would that have changed your need/choice to use formula to feed your baby?". Only 5% of respondents answered 'yes', 66% answered 'no'. Respondents

also gave free text comments regarding the potential change, many of which explained that the message would make no difference to women who cannot breastfeed (for example, due to insufficient breastmilk or health issues).

Research on the framing of health messages more generally has had mixed findings regarding whether loss-framed or gain-framed messages are more effective. The effect of health messages on attitudes, intentions and behaviour may depend on whether the message is about preventing or detecting a condition. Rothman and Salovey (1997) have hypothesised that gain-framed messages may be more effective in encouraging disease prevention behaviours (such as breastfeeding) and loss-framed messages may be more effective for disease detection behaviours (such as undergoing screening for a disease). For example, a meta-analysis by O'Keefe and Jensen (2009) found that loss-framed messages were somewhat more persuasive than gain-framed messages at encouraging disease detection behaviour. Another meta-analysis by the same authors (O'Keefe and Jensen 2007) found that gain-framed messages tended to be more effective at encouraging disease prevention behaviours. However, the authors note that these results are largely attributable to studies on dental hygiene behaviours.

Studies examining messages regarding diet and nutrition behaviour have so far found no overall difference in efficacy between gain- and loss-framed messages (Aldridge 2006). Aldridge (2006) suggests this may be due to the complexity of dietary behaviours, or because they require long-term lifestyle changes. No studies were found which examined the effect of gain- or loss-framed messages relating to children's health on the behaviour of caregivers. However, one study examined the effect of gain- and loss-framed messages on women's attitudes and intentions to use folic acid supplements in the future when they would be trying to become pregnant (Brug et al. 2003). The study found the message frame had no significant impact on intentions or attitudes.

Aldridge (2006) has noted that the research examining the effect of gain-framed and loss-framed messages often only examines self-reported intentions, or attitudes. Druckman (2001) has also suggested that much of the research on framing effects is unrealistic because it creates an environment in which decision makers are basing decisions solely on information provided by researchers. In reality, people will have multiple information sources, some of which they believe are more trustworthy or reliable than others.

Further research on message framing is investigating how individuals' personalities influence how they react to gain- and loss-framed messages (Latimer et al. 2007). However, these findings would be less applicable to infant formula labelling which is standardised and cannot be adapted to individuals' characteristics.

In conclusion, insufficient information is available from research on loss-framed and gain-framed messages to determine whether either would have an impact on caregivers' breastfeeding intentions or outcomes. The literature search found no studies which examined the effects (if any) of including the current 'Breast is best...' statement on infant formula packaging (compared to no message) on breastfeeding intentions or outcomes.

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Appendix A2.1 – Protocol for literature review on infant formula for P1028

1 Background

The purpose of this literature review is to examine the following issues relating to the labelling of infant formula and follow on formula:

- formula preparation, specifically whether caregivers:
 - boil water before using it to prepare formula
 - store formula at room temperature or in the refrigerator
 - discard unfinished feeds
 - add cereal or other foods to formula
 - add vitamins and minerals to formula
 - use the scoop enclosed with the formula
 - use and understand the preparation instructions on formula products
- the influence of breastfeeding intentions on breastfeeding initiation and duration
- caregivers' understanding of the prescribed term 'infant formula'
- whether the framing of a message about the benefits of breastfeeding (as a gain-framed or loss-framed message) is likely to impact caregiver perceptions or infant feeding choices
- whether the format in which nutrition information is presented will impact on caregiver use or understanding of the information
- whether caregivers use the protein source statement and whether they encounter difficulties locating it.

2 Methods

This project is a rapid evidence assessment. The literature search was designed to uncover articles on formula preparation, use and understanding of formula labels, and caregivers' perceptions of infant formula and follow on formula.

Literature on other topics²² were drawn from:

- previous literature searching conducted on the topic
- papers uncovered by the literature search noted above that was carried out for the other topics
- papers cited by relevant articles
- papers citing relevant articles.

Searching was done with literature databases, and citations found using these were exported to EPPI-Reviewer 4, a web-based software program for managing and analysing data for literature reviews.

Duplicates were excluded using EPPI-Reviewer 4 duplicate management tools. Following the elimination of duplicates, a first screening of articles based on titles was conducted, and then a second on abstracts (where abstracts were available). The purpose of the first and second

²² Other topics were:

- influence of breastfeeding intentions on breastfeeding initiation and duration
- loss-framed versus gain-framed messages presentation of nutrition information in table format

screenings was to eliminate the following types of articles that were not in scope, for example:

- articles not in English
- articles published prior to 1990
- articles on the composition of infant formula (or breastmilk)
- articles on the health effects of infant formula use
- articles on foods other than infant formula
- articles on contaminants in infant formula (or breastmilk)
- articles on dietary surveys
- articles on the use of formulas to address particular conditions (such as food allergies)
- articles on the nutritional requirements of infants
- articles on assistance or advice given on breastfeeding.

3 Inclusion criteria for types of studies

Different inclusion criteria were developed for each of the key topics explored. These are detailed individually.

3.1 *Instructions for the preparation and use of infant formula product*

Types of studies that were eligible to be included were:

- quantitative surveys
- qualitative studies
- lab testing of infant formula prepared by caregivers (e.g. to test reconstitution)
- observation of infant formula preparation practices
- literature reviews.

Australian and New Zealand studies which examined the information sources available to caregivers on infant formula preparation were also eligible.

Studies could be either Australian, New Zealand, or international²³.

To be eligible for inclusion, studies needed to include one of the following outcome measures:

- self-reported preparation practices (qualitative or quantitative)
- proportion of caregivers following a recommended practice (either self-report or observed)
- proportion of caregivers preparing formula to the correct concentration (i.e. a lab study).

3.2 *Infant feeding intentions*

Types of studies that were eligible to be included were:

- quantitative surveys
- qualitative studies
- literature reviews.

²³ International studies included studies from developed countries only. Studies from Turkey, Brazil and South Africa were excluded. The final literature review(s) included studies from New Zealand, Australia, the UK, the Republic of Ireland, the USA, and Italy.

Studies could be Australian, New Zealand, or international.

3.3 *Caregivers' understanding of the prescribed term 'infant formula'*

Types of studies that were eligible to be included were:

- quantitative surveys
- qualitative studies
- literature reviews.

Studies could be Australian, New Zealand, or international.

3.4 *Loss-framed and gain-framed health messages*

Types of studies that were eligible to be included were:

- quantitative surveys or experiments on health messages relating to breastfeeding or infant formula feeding
- literature reviews on loss-framed and gain-framed health messages
- individual studies drawn from the literature reviews on topics related to infant feeding (for example studies examining loss-framed and gain-framed nutrition messages)
- individual papers drawn from the literature reviews in which the authors comment on loss-framed and gain-framed message research in general.

Studies could be Australian, New Zealand, or international.

3.5 *Impact of nutrition information format on caregiver use or understanding of the information*

Types of studies that were eligible to be included were:

- quantitative surveys
- qualitative studies
- observational studies of label use
- literature reviews.

3.6 *Caregiver use the protein source statement and whether they encounter difficulties locating it*

Types of studies that were eligible to be included were:

- quantitative surveys
- qualitative studies
- observational studies of label use
- literature reviews.

4 Inclusion criteria for types of participants

Studies which gathered information from caregivers and pregnant women were the focus of this review. Studies which only included formula technicians were excluded.

However, for research on loss-framed and gain-framed messages there was no exclusion by type of participant.

5 Data synthesis and analysis

The literature findings were split into the topics listed under the Background section.

For all topics, where there were gaps in the available literature (for example, a lack of Australian or New Zealand studies) this is noted in the text.

6 Search strategy

6.1 Search avenues

Searches were undertaken in the following databases in September 2013:

- Food Science Source (via EBSCOhost)
- Food Science and Technology Abstracts (via EBSCOhost)
- Medline (via EBSCOhost)
- EconLit (via EBSCOhost)
- SocINDEX
- Psychological and Behavioral Sciences Collection (via EBSCOhost)
- Nutrition Abstracts & Reviews (via CAB Direct)
- PsycINFO
- JSTOR
- E-Journals
- Open Grey (System for Information on Grey Literature in Europe)
- Academic Source Premier
- a database of references held by FSANZ.

The reference lists of relevant articles were also scanned for literature to include.

6.2 Search restrictions

Search strings used a combination of index terms and text words. Restrictions which were used in specific databases (such as limiting to primary sources, research articles, reviews) are noted below.

6.3 Search terms

Search terms used in Medline (via EBSCOHost)

- "Infant Formula" AND "Food Labeling"
- "Infant Formula" AND "Marketing"

Search terms used in Food Science and Technology Abstracts (via EBSCOHost)

- ("infant formulae" OR "infant formulas" OR "infant milk formulas") AND labelling
- ("infant formulae" OR "infant formulas" OR "infant milk formulas") AND marketing

Search terms used in Food Science Source (via EBSCOHost)

- "infant formula" OR "infant formula feeding" OR "infant formula market" OR "infant formula powder" OR "infant formula rebates" OR "infant formula use" OR "infant formula" OR "infant formulae" OR "infant formulas" AND label

Search terms used in EconLit (via EBSCOHost)

- infant AND (milk OR formula)

Psychological and Behavioral Sciences Collection (via EBSCOHost)

- "infant formula industry" OR "infant formula industry -- law & legislation" OR "infant formulas" OR "infant formulas -- government policy" OR "infant formulas -- law & legislation" OR "infant formulas -- marketing"
- (caregiver OR parent OR mother OR father OR carer) AND (preparation OR prepare) AND (infant* OR baby) AND (formula* OR milk*)

Nutrition Abstracts and Reviews (via CAB Direct)

- ("infant formulae" OR "infant formulas") AND ("labeling" OR "labeling controls" OR "labelling" OR "labelling controls" OR "labels")
- ("infant formulae" OR "infant formulas") AND marketing
- (caregiver OR parent OR mother OR father OR carer) AND (preparation OR prepare) AND (infant* OR baby) AND (formula* OR milk*)

Search terms used in E-Journals (via EBSCOHost)

- infant formula AND label*
- infant formula AND market*

Search terms used in combined searching of EconLit, Food Science Source, Food Science and Technology Abstracts, and SocINDEX (via EBSCOHost)

- "Bottle Feeding" AND label*
- "Bottle Feeding" AND market*
- (caregiver OR parent OR mother OR father OR carer) AND (preparation OR prepare) AND (infant* OR baby) AND (formula* OR milk*)

Search terms used in Open Grey (System for Information on Grey Literature in Europe)

- (advertis* OR market* OR label*) AND (infant* OR baby) AND (formula* OR milk*)

Search terms used in JSTOR, limited to primary sources, research articles, reviews.

- (advertis* OR market* OR label*) AND (infant* OR baby) AND (formula* OR milk*)

Search terms used in Academic Source Premier, limited to academic journals and reviews

- (advertis* OR market* OR label*) AND (infant* OR baby) AND (formula* OR milk*)

Search terms used in PsycINFO

- (advertis* OR market* OR label*) AND (infant* OR baby) AND (formula* OR milk*)

Attachment A2.3 – Overseas regulatory approaches to the addition of substances to infant formula

1 Summary of USA regulatory approach to the addition of substances to infant formula

Regulations, terminology and general permissions/prohibitions:	
Regulations	<p>Infant formula is regulated under section 412 of the Federal Food, Drug and Cosmetic Act (FFDCA) and the US Food and Drug Administration's (FDA's) implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR).</p> <p>Relevant parts of 21 CFR are:</p> <ul style="list-style-type: none"> • 106 – Infant formula requirements pertaining to current good manufacturing practice, quality control procedures, quality factors, records and reports, and notifications. • 107 – Infant formula • 170 – Food additives
Terminology	<p>The term <i>'food additive'</i> is used for any substance that is reasonably expected to become a component of food, unless the substance is generally recognised as safe (GRAS) or meets one of the other exclusions from the food additive definition in section 201(s) of the FFDCA.</p> <p>The term <i>'generally recognised as safe' (GRAS)</i> is used for substances that are generally recognised, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use.</p> <p>No formal definition for <i>'novel foods'</i> in regulation. The FDA considers food ingredients as novel as those "that have not previously been used as food ingredients"; prior to 1958.</p>
Permission/prohibition on the addition of substances to infant formula	<p>Substances need to be either:</p> <ol style="list-style-type: none"> (a) accorded a status as GRAS for use in infant formula; (b) approved as a 'food additive' for use in infant formula; or (c) authorised by a prior sanction (part 181 21 CFR).

Pre-market assessment of <i>substances</i> for use in infant formula:		
Process	GRAS for use in infant formula	Food additive for use in infant formula
	<p>For a substance to be GRAS, the scientific data and information about the use of a substance must be widely known and there must be a consensus among qualified experts that those data and information establish that the substance is safe under the conditions of its intended use.</p> <p>Manufacturers may either submit a GRAS notification to FDA or they can self-affirm GRAS (not submit a notification) and keep the information in their records. Any GRAS self-determination can be reviewed by FDA at any time.</p> <p>When FDA reviews a GRAS notification, it either issues a letter that does not question the basis of the notifier's determination (but might raise pertinent issues such as related to labelling) or one that cannot support the conclusion of the notifier.</p>	<p>A person may file a petition with the FDA seeking pre-market approval for a food additive.</p> <p>Notice of the proposed regulation is published by the FDA within 30 days after filing of the petition.</p> <p>The FDA then either (a) establish a regulation for the use of the food additive, with conditions of use, or (b) deny the petition. This step is completed within 90 days after the petition is filed. This timeframe can be extended to not more than 180 days.</p>
Data & information requirements for inclusion in any notification/assessment documents:	<p>Information requirements for affirmation of GRAS status are outlined in section 170.35 of 21 CFR.</p> <p>Details on how to submit a GRAS notice is available at: http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083062.htm</p>	<p>Guidance documents to help prepare the scientific documentation to support the safety of a food additive: http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/default.htm</p>
i. Must show evidence to support safety	✓ Safe and suitable for intended use	✓ Safe and suitable for intended use
ii. Must show evidence of efficacy (level/form to achieve stated purpose)	✓ The substance must be bioavailable and it must be demonstrated (through a clinical growth monitoring study) that the formula has the ability to support normal physical growth (as required in 21 CFR 106.96)	✓ The substance must be bioavailable and it must be demonstrated (through a clinical growth monitoring study) that the formula has the ability to support normal physical growth (as required in 21 CFR 106.96)

iii. Must show evidence of nutritional considerations (including growth and development)	✓ See above	✓ See above
iv. Must be referenced to human milk	✓ A relationship between the substance and human milk would be expected, and similarly that the proposed level would be modelled after human milk.	✓ A relationship between the substance and human milk would be expected, and similarly that the proposed level would be modelled after human milk.
Transparency of permissions	Part 182 of 21 CFR lists some common substances that are generally recognised as safe. The GRAS Notice Inventory on the FDA web site contains GRAS notices received from companies since 1998, and FDA's response.	Approved food additives are issues a regulatory number (parts 170-180 of 21 CFR). Food Additive Status List is also available on the FDA website at: http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm091048.htm
Post-market monitoring	Although a substance may have GRAS status, the FDA may at any time prohibit its use or conduct further studies to determine its safety if new evidence suggests that a product already in use may be unsafe or if consumption levels have changed.	The status of a food additives may be amended or removed from regulation if there are safety concerns, in accordance with 21 CFR 571.130(a).

Pre-market notification of an infant formula *product*:

Process	<p>Prior to marketing a new infant formula in the US, a manufacturer must register with, must notify, and must submit written verification to, FDA (sections 106.110 and 106.120 of 21 CFR).</p> <p>The notification must occur at least 90 days before marketing the product.</p> <p>A 'new infant formula' includes an infant formula manufactured by a person which has previously manufactured infant formula and in which there has been a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer.</p>
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Data & information requirements for inclusion in any notification/ assessment documents	<p>Section 106.120 of 21 CFR outlines that the notification must include:</p> <ul style="list-style-type: none"> • The quantitative formulation of the infant formula; • A description of any reformulation of the formula or change in processing of the infant formula; • Assurances that the infant formula will not be marketed unless it meets the quality factors and the nutrient requirements of the Act; and • Assurances that the processing of the infant formula complies with good manufacturing practices, including quality control procedures.
i. Must show evidence of Safety	✓
ii. Must show evidence of efficacy	✓ Need to provide a scientific rationale, including efficacy information, that supports the purpose of the addition
iii. Must show evidence of Nutritional consideration (including growth and development)	✓
Post-market monitoring	Inspections and regular batch testing required under part 106 of 21 CFR.

2 Summary of EU regulatory approach to the addition of substances to infant formula

Regulations, terminology and general permissions/prohibitions	
Regulations	<p>Infant formula – current:</p> <ul style="list-style-type: none"> • Directive 2009/39/EC on foodstuffs intended for particular nutritional uses; sets the general requirements for foods under its scope, including infant formula. • Directive 2006/141/EC on infant formulae and follow-on formulae; sets the specific requirements for infant formula and follow-on formula. <p>Infant formula – future:</p> <ul style="list-style-type: none"> • Regulation (EU) No 609/2013 on food intended for infants and young children; sets general requirements, and will repeal Directives 2009/39/EC and 2006/141/EC as of 20 July 2016. • Delegated Regulation on infant formula and follow-on formula to be adopted in the coming months; will set the specific requirements. The draft delegated Regulation was notified to WTO with reference G/TBT/N/EU/291 and is available on the Commission's website http://ec.europa.eu/growth/tools-databases/tbt/en/. Until the new delegated Regulation is in force, Directive 2006/141/EC remains applicable. <p>Novel foods:</p> <ul style="list-style-type: none"> • Regulation (EC) No 258/97 concerning novel foods and novel food ingredients; currently under review.
Terminology	<p>Although 'novel food' is not specifically defined in regulation, <i>Regulation (EC) No 258/97</i> applies to <i>the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community</i> (i.e. within the EU before 1997). This includes foods and food ingredients: with a new or intentionally modified primary molecular structure; that consist of or are isolated from micro-organisms, fungi or algae; that consist of or are isolated from plants and food ingredients isolated from animals; whose nutritional value, metabolism or level of undesirable substances has been significantly changed by the production process.</p> <p>The term 'nutritive substance' is not used in regulation. The term 'substance' is used in Regulation (EU) No 609/2013 to refer to specific categories of substances (e.g. vitamins, amino acids) but is not defined in the regulation.</p>
Permission/prohibition on the addition of substances to infant formula	<p>Infant formula – current:</p> <ul style="list-style-type: none"> • Novel foods: Infant formula products may contain novel foods and novel food ingredients, provided the novel substance fulfils the conditions under Regulation (EC) No 258/97.

Regulations, terminology and general permissions/prohibitions

- Substances that belong to the categories of mineral substances, vitamins, amino acids and other nitrogen compounds, and other substances having a particular nutritional purpose: permitted for use in infant formula if they are listed in Annex III (Article 8 of Directive 2006/141/EC).
- Other substances (not belonging to those categories): may be added to infant formula provided that they are safe and suitable for infants based on generally accepted scientific data; case-by-case assessment by the national competent authorities.

Infant formula – future:

- Novel foods: Infant formula products may contain novel foods and novel food ingredients, provided the novel substance fulfils the conditions under Regulation (EC) No 258/97 for being placed on the market (Article 9(4) of Regulation (EU) No 609/2013).
- Substances that belong to the categories of vitamins, minerals, amino acids, carnitine and taurine, nucleotides, and choline and inositol: permitted for use in infant formula if they are listed in the Union List in the Annex (Article 15 of Regulation (EU) 609/2013).
- Other substances (not belonging to those categories): may be added to infant formula provided that they satisfy the general requirements set out in Articles 6 and 9 (i.e. safe, suitable and satisfy the nutrition requirements for the persons for whom it is intended), and the specific requirements established in accordance with Article 11 (i.e. the future delegated Regulation). It is expected that the specific requirements for optional substances in infant formula will be the same as in current Directive 2006/141/EC.

Pre-market assessment of <i>substances</i> for use in infant formula:			
Process	Novel foods	Substances that belong to specified categories (e.g. vitamins, minerals, amino acids)	Other optional substances
	<p><i>Pre-market authorisation required for new novel foods and novel ingredients:</i></p> <p>Application prepared by the applicant and sent to Competent Authority in Member State.</p> <p>Initial assessment report circulated for comments and objections to all Member States. Applicant notified of whether there is no reasoned safety objections (and the product may be placed on the market) or that there are reasoned safety objections. If reasoned safety objections, then authorisation decision required by the EC. If further risk assessment is required then this is undertaken by EFSA. The novel food/ingredient may then be placed on the market with conditions, or it may not be approved for use.</p> <p>The approval to market the novel food or novel food ingredient is granted to the applicant (i.e. individual authorisation).</p> <p><i>Simple notification to a Competent Authority in a Member State for a novel food that is ‘substantially equivalent’:</i></p> <p>Another applicant may notify the EC of the placing on the market of a novel food that is ‘substantially equivalent’ to an authorised food.</p>	<p><i>Current procedure under Directive 2006/141/EC to amend Annex III:</i></p> <p>Upon receipt of a dossier, the Commission submits it to EFSA who evaluates safety and bioavailability. A decision is then taken by the Commission on whether or not to include the new chemical form in the Annex.</p> <p><i>Future procedure under Regulation (EU) No 609/2013 to amend the Union list in the Annex:</i></p> <p>Article 16 of Regulation (EU) No 609/2013 relates to updating the Union list. The Commission is empowered to add or remove substances from the Union list. It may also add, remove or amend the elements of the Union list (e.g. the description of the substance, the conditions of use of a substance, the applicable purity criteria).</p>	<p><i>Compliance check by national competent authorities (i.e. no preauthorisation):</i></p> <p>Compliance with the requirements of safety and suitability is checked by national competent authorities on a case-by-case basis.</p> <p>Operators place the products on the market and notify a copy of the label to national competent authorities. They need to hold a dossier proving compliance with the legislation. If a national competent authority, after looking into the dossier, believes that compliance is not verified, it can ask the operator to make the necessary changes.</p>

Pre-market assessment of <i>substances</i> for use in infant formula:			
<p>Data & information requirements for inclusion in any notification/assessment documents:</p>	<p>Article 6 of Regulation (EC) No 258/97 requires the applicant to provide information to demonstrate that the food or food ingredient does not:</p> <ul style="list-style-type: none"> • Present a danger for the consumer • Mislead the consumer • Differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer <p>Commission Recommendation 97/618/EC outlines the scientific aspects and the presentation of information necessary to support applications for novel foods and novel food ingredients.</p> <p>EFSA is currently working on new scientific guidance on novel foods in view of the upcoming new novel food regulation.</p>	<p>Information requirements are detailed in the <i>Administrative Guidance on Submissions for Safety Evaluation of Substances Added for Specific Nutritional Purposes in the Manufacture of Foods</i>:</p> <p>http://ec.europa.eu/food/safety/docs/labelling_nutrition-vitamins_minerals-adm_guidance_safety_substances_en.pdf</p>	<p>Recital 8 of Directive 2006/141/EC gives some examples on how to carry out studies to prove compliance with the requirements.</p> <p>It is the responsibility of operators to prove that every specific substance is safe and suitable for infants. Such suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.</p>
<p>i. Must show evidence to support safety</p>	<p>✓</p>	<p>✓</p> <p>Safe for particular use</p>	<p>✓</p>
<p>ii. Must show evidence of efficacy (level/form to achieve stated purpose)</p>	<p>✗</p>	<p>✓</p> <p>Shall be bioavailable for use by the human body, have a nutritional or physiological effect and be suitable for whom the food is intended</p>	<p>✓</p>
<p>iii. Must show evidence of</p>	<p>✗</p>	<p>✓</p> <p>Systematic review of the available data for</p>	<p>✓</p>

Pre-market assessment of <i>substances</i> for use in infant formula:			
nutritional considerations (including growth and development)		expected benefits	
iv. Must be referenced to human milk	x	~ Not specifically, though expected that this would be considered when evaluating the suitability of a substance for use in infant formula	~ Not specifically, though expected that this would be considered when evaluating the suitability of a substance for use in infant formula
Transparency of permissions	The Novel Food Catalogue lists products of animal and plant origin and other substances subject to the Novel Food Regulation, based on information provided by the EU Member States: http://ec.europa.eu/food/safety/novel_food/catalogue/index_en.htm A list of novel food authorisations granted in the EU is provided on the EC website: http://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations/index_en.htm	Current permissions are listed in Annex III of Directive 2006/141/EC. Future permissions will be listed in the Union list in the Annex to Regulation (EU) 609/2013.	No publicly available list. Information can be obtained from national competent authorities.
Post-market monitoring	Member States may temporarily suspend or restrict the marketing/use of substances if there is evidence that they may be unsafe. Regulation (EC) No 178/2002 sets provisions in cases of non-compliance of foods with EU food law.		

Pre-market notification of an infant formula <i>product</i>:	
Process	<p>Under Article 9(1) of current Directive 2006/141/EC, when a food business operator places an infant formula on the market he shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product.</p> <p>The national competent authorities have the right to ask operators to show data proving compliance with the legislation. In cases of proven non-compliance, national competent authorities may require the operator to di the necessary changes or withdraw the product from the market.</p> <p>In the future, the delegated Regulation will contain provisions on notification, which will be very similar to those of current Directive 2006/141/EC.</p>
Data & information requirements for inclusion in any notification/ assessment documents:	<p>Commission Directive 2006/141/EC requires a model of the label of the product must be forwarded to the competent authority of the Member State where the product is being marketed.</p> <p>It is the responsibility of the food business operator to make sure that infant formula they place on the market is safe and suitable, and to hold the data to prove this (Articles 4-6 of current Directive 2006/141/EC, and Article 9 of Regulation (EU) No 609/2013 together with Article 3 of the draft delegated Regulation).</p>
i. Must show evidence of safety	✓
ii. Must show evidence of efficacy	✓
iii. Must show evidence of nutritional consideration (including growth and development)	✓
Post-market monitoring	<p>Application of EU law is a responsibility of Member States.</p> <p>The Food and Veterinary office, within the European Commission, carries out inspections on how Member States are performing in this respect and can issue recommendations and corrective actions. In case of inaction from Member States, the Commission can take adequate measures (including referral to the Court of Justice of the EU for Member States' failure to comply with EU law).</p>

3 Summary of Canadian regulatory approach to the addition of substances to infant formula

Regulations, terminology and general permissions/prohibitions	
Regulations	Canadian Food and Drug Regulations Divisions B.25 (Infant formula) and B.28 (Novel food)
Terminology	<p>'Novel food' is defined in Division B.28 as:</p> <ul style="list-style-type: none"> (a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that: <ul style="list-style-type: none"> (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that: <ul style="list-style-type: none"> (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (<i>aliment nouveau</i>) <p>The term 'nutritive substance' is used (e.g. in Division B.25.055) but is not defined in the <i>Food and Drug Regulations</i>.</p>
Permission/ prohibition on the addition of substances to infant formula	<p>Novel foods require pre-market notification prior to sale (Division B.28.002).</p> <p>Section B.25.056 prohibits the addition of new substances to infant formula unless they meet the criteria of B.25.056 (a) and (b). Criteria (a) allows for nutritive substances normally contained in human milk to be added to infant formula if the amount of the substance in the product is equal to the amount present (per 100 available kilocalories) in human milk.</p>

Pre-market assessment of <i>substances</i> for use in infant formula:		
Process	<p>Pre-market notification for a new novel food (Division B.28.002-3):</p> <p>The manufacturer or importer of the novel food must notify the Director (of Health Canada) in writing of their intention to sell or advertise for sale the novel food, with accompanying information.</p> <p>Within 45 days after receiving a notification, the Director will review the information and either notify the applicant that the information is sufficient to establish that the novel food is safe for consumption, or that additional information is necessary in order to assess the safety of the novel food.</p> <p>Within 90 days of receiving the additional information requested the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the applicant in writing that the information is sufficient.</p>	<p>Pre-market assessment for new substances other than novel foods and food additives:</p> <p>Presently there is no published pre-market assessment procedure for new substances (other than novel foods and food additives) for use in infant formula. Specific guidance is provided on a case-by-case basis to companies.</p> <p>Health Canada also reviews packaging materials for infant formulas, and this review and approval is considered as a pre-requisite to submitting a pre-market notification for an infant formula product.</p>
Data & information requirements for inclusion in any notification/assessment documents:	<p>Assessment criteria is outlined in the <i>Guidelines for the Safety Assessment of Novel Foods</i>: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php</p> <p>If a manufacturer/seller of the novel food wishes for it to be used in infant formula, then evidence for safety in infants is required.</p>	<p>At present, there is no relevant published guidance for the pre-market assessment for new substances. However, a pre-market notification for an infant formula product would not be accepted by Health Canada unless the following information had been assessed.</p>
i. Must show evidence to support safety	✓	✓

Pre-market assessment of <i>substances</i> for use in infant formula:		
ii. Must show evidence of efficacy (level/form to achieve stated purpose)	<p>✘</p> <p>While the novel food regulations are silent on efficacy, a pre-market notification for an infant formula product must include evidence relied on to establish that the infant formula is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions of use.</p>	<p>✓</p> <p>Form and amount of the substance in achieving the stated purpose would be considered.</p>
iii. Must show evidence of nutritional considerations (including growth and development)	<p>✓</p> <p>As above</p>	<p>✓</p> <p>As for novel foods</p>
iv. Must be referenced to human milk	<p>Not specifically</p>	<p>✓</p> <p>B.25.056 (a) allows for nutritive substances normally contained in human milk to be added to infant formula if the amount of the substance in the product is equal to the amount present (per 100 available kilocalories) in human milk</p>
Transparency of permissions	<p>A table of novel food decisions is available on the Health Canada website at: http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php</p>	<p>Nutritive substances normally contained in human milk are not listed in regulation; except those referred to in paragraph B.25.054(1)(a).</p>
Post-market monitoring	<p>Health Canada may request manufacturers to submit post-marketing surveillance data on a case-by-case basis to monitor or track any possible adverse reactions, or other safety or efficacy data.</p>	

Pre-market notification of an infant formula <i>product</i>:	
Process	<p>Pre-market notification of new infant formula products and any product that has undergone a major change (to the formulation, or the processing or packaging that is expected to have an adverse effect on the levels or availability of nutrients in, or the microbiological or chemical safety of, the infant formula product (Division B.25.046 and B.25.048).</p> <p>The manufacturer may sell an infant formula 90 days after the date of the pre-market notification. Section B.25.060 provides 'stop sale' provisions if needed.</p>
Data & information requirements for inclusion in any notification/ assessment documents:	<p>Information requirements are outlined in sections B.25.046 and B.25.048, and include the evidence relied on to establish that the new human milk substitute is nutritionally adequate to promote acceptable growth and development in infants when consumed in accordance with the directions for use.</p> <p>Upon request, the Food Directorate at Health Canada can provide additional guidance on the evidence requirements to support a pre-market notification of an infant formula product. Health Canada intend to publish a guidance document in the future.</p>
i. Must show evidence of Safety	✓
ii. Must show evidence of efficacy	✓
iii. Must show evidence of nutritional consideration (including growth and development)	✓
Post-market monitoring	<p>The Canadian Food Inspection Agency (CFIA) is responsible for all monitoring and compliance activities for foods, including infant formula. The CFIA addresses complaints about infant formula products and labelling, and may also carry out nutrient composition testing of infant formulas.</p>

Attachment A2.4 – Risk profile of contaminants in infant formula

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Executive Summary

This risk profile considers those contaminants for which standards exist in the Code and/or Codex Alimentarius that are applicable to infant formula. These contaminants are acrylonitrile, aluminium, lead, melamine, tin and vinyl chloride. Information on arsenic is also provided because the Provisional Tolerable Weekly Intake (PTWI) for inorganic arsenic has been withdrawn by JECFA and there is a recently published study reporting levels of inorganic arsenic in infant formula purchased in the USA.

Acrylonitrile and vinyl chloride are potentially carcinogenic substances used in the production of certain packaging materials and migration of these substances into various foods has been reported, notably in the 1970s and 1980s. No studies have been located reporting the analysis of infant formula for acrylonitrile or vinyl chloride, however they are now rarely detected in any packaged foods. Potential dietary exposure to acrylonitrile and vinyl chloride from infant formula is therefore considered to pose a negligible health risk.

Aluminium can be present in infant formula as a result of its natural occurrence in the environment and migration from food contact materials. JECFA has established a PTWI for aluminium based on adverse effects in laboratory rodents. Upper estimates of dietary exposure to aluminium based on levels determined in infant formula from recent Australian Total Diet Studies (ATDSs) are below the PTWI. Dietary exposure to aluminium in infant formula is therefore not considered to pose a health risk.

Arsenic occurs in various inorganic and organic forms which are found in the environment both from natural occurrence and from anthropogenic activity. The organic forms are of relatively low toxicity while inorganic arsenic has been identified as a human carcinogen. JECFA withdrew the PTWI for inorganic arsenic in 2010 and made a number of recommendations to facilitate future quantitative risk assessment. No data have been located on the levels of inorganic arsenic in infant formula sold in Australia and New Zealand and there are only minimal international data for inorganic arsenic in infant formula. However, in Australia and New Zealand total diet studies, arsenic in all forms (total arsenic) has been detected in only one composite sample of infant formula.

Lead occurs in the environment both naturally and from anthropogenic activities. In 2010, JECFA withdrew the lead PTWI because a threshold could not be established for the association of lead dietary exposure with reduced IQ in children. Lead levels in infant formula available in Australia and New Zealand have been shown to be similar, and data from the 23rd ATDS indicates that estimated dietary exposure in infants consuming infant formula as a sole source of nutrition is similar to that for 9-month old infants consuming a mixed diet. Risk characterisation for lead in infant formula is not possible because the JECFA analysis of IQ was based on a 20 kg child, which corresponds to the average weight of a 5 to 6 year old.

Melamine is an organic base with several industrial uses, including the production of laminates, glues, dinnerware, adhesives and coatings. Low concentrations of melamine can occur in food due to migration from such materials. In 2008, melamine was used in China as an infant formula adulterant in order to boost its apparent protein content. Melamine levels exceeded 1000 mg/kg in some samples of infant formula. In contrast, baseline levels of melamine in infant formula, including product sold in Australia and New Zealand, have been shown to be less than 1 mg/kg, a concentration which results in estimated dietary exposure below the Tolerable Daily Intakes (TDIs) for melamine established by the USFDA and WHO. It is concluded that levels of melamine in infant formula available in Australia and New Zealand do not raise health concerns.

Tin coatings are used to prevent corrosion of steel cans and the main source of dietary exposure to tin is via ingestion of inorganic tin from canned foods. International and Australian data indicate levels of tin in infant formula of less than 0.02 mg/kg. Dietary exposure to tin in infant formula products is very low relative to the PTWI and is therefore not considered to pose a health risk.

1 Background and scope

This risk profile considers those contaminants for which standards (maximum levels: MLs) exist in the Code and/or Codex Alimentarius that are applicable to infant formula. These contaminants are acrylonitrile, aluminium, lead, melamine, tin and vinyl chloride²⁴. Information on arsenic is also provided because the health-based guidance value for inorganic arsenic has been withdrawn by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and infant formula has been analysed for arsenic in Australian and New Zealand total diet studies. In addition, there are extensive recent data on arsenic levels in infant formula sold in the EU and a published US study reporting levels of inorganic arsenic in infant formula.

For each contaminant, information on hazard (e.g. health-based guidance values), contaminant levels in infant formula and estimated dietary exposure to the contaminant from infant formula consumption is provided (where available). The focus is on the available data on contaminant levels in infant formula available in Australia and New Zealand.

2 Contaminants

2.1 Acrylonitrile

Acrylonitrile monomer is a starting substance for the production of certain resins and plastics. Substances derived from acrylonitrile may contain residual amounts of the monomer which can potentially migrate into food.

2.1.1 Hazard information

An assessment by the Australia New Zealand Food Authority (ANZFA) concluded that acrylonitrile is carcinogenic in rats when administered via the oral route (ANZFA 1999b), consistent with an earlier JECFA evaluation (WHO 1984). ANZFA further concluded that there was no evidence of adverse health effects resulting from low level exposure via food, however the potential for carcinogenicity requires that exposure should be kept as low as possible. It was therefore proposed to retain the existing ML for all food which was set at the limit of detection (LOD) of 0.02 mg/kg (ANZFA 1999b).

2.1.2 Dietary exposure

No studies have been located reporting the analysis of infant formula for acrylonitrile and there are limited data on acrylonitrile levels in other foods. In a FSANZ analytical survey, a range of foods packaged in plastic were tested for acrylonitrile. The foods tested included full fat milk, minced beef, yogurt, tomato sauce, pre-prepared meals, orange juice and still water. The analytical method had a limit of quantification (LOQ) ranging from 0.001 to 0.01 mg/kg depending on the food matrix. There were no detections of acrylonitrile in any food (FSANZ 2011a).

Reports from the 1980s indicated parts-per-billion (ppb = µg/kg) levels of acrylonitrile in some foods. An absence of detectable acrylonitrile in foods analysed in the above FSANZ study is consistent with the reported large improvements in the formulation and production of food packaging materials (ATSDR 1990; NICNAS 2000).

²⁴ Standard 1.4.1 (Schedule 19 in the revised Code) includes MLs for acrylonitrile and vinyl chloride for “all food” and “all food except packaged water”, respectively. MLs for these contaminants are therefore applicable to infant formula. Standard 1.4.1 includes a tin ML for “all canned foods”. The ML is therefore applicable to canned infant formula.

2.1.3 Conclusion

Acrylonitrile is now rarely detected in foods and is unlikely to be present at detectable levels in infant formula. Potential dietary exposure to acrylonitrile from infant formula is therefore considered to pose a negligible health risk.

2.2 Aluminium

Aluminium can be present in food as a result of its natural occurrence in the environment, migration from food contact materials, and the use of aluminium-containing food additives²⁵.

2.2.1 Hazard information

JECFA has established a Provisional Tolerable Weekly Intake (PTWI) of 2 mg/kg bodyweight (bw) for aluminium based on adverse effects on reproduction and development in laboratory rodents. The previous PTWI of 1 mg/kg bw was withdrawn. JECFA concluded that there were no appropriate epidemiological studies available for risk assessment (WHO 2011c).

2.2.2 Dietary exposure

The level of aluminium in infant formula products was addressed as part of ANZFA Proposal P93 - Review of Infant Formula (ANZFA 2002). The report cited data indicating substantially lower aluminium levels in infant formula available at the time compared to levels reported in 1986 and 1992. It was concluded that almost all infant formula on the market in Australia had aluminium levels below 1 mg/L for soy-based formula and 0.2 mg/L for non-soy formula. The generally higher levels of aluminium in soy-based formula relative to non-soy formula was consistent with the data reported in 1986 and 1992.

Aluminium levels in infant formula were determined for the 23rd and 24th Australian Total Diet Studies (ATDSs) (FSANZ 2011b; FSANZ 2014). These studies also included aluminium as an analyte in a range of other foods in order to calculate estimates of total dietary exposure to aluminium for five age groups, ranging from 9 month old infants to adults (17 years and above). In the 23rd ATDS, four composite samples of non-soy infant formula products were analysed resulting in minimum, maximum and mean aluminium levels of 0.18, 0.53²⁶ and 0.29 mg/kg, respectively. For 9 month old infants, estimated dietary exposure to aluminium was less than 40% of the PTWI at 90th percentile consumption levels (high consumers) with infant formula the major contributor (29%) to aluminium dietary exposure followed by the food category 'cakes, muffins and puddings' (19%). For the 24th ATDS, additional foods and beverages were selected to supplement data on aluminium levels from the 23rd ATDS. Four composite samples of soy-based infant formula products were analysed resulting in minimum, maximum and mean aluminium levels of 0.26, 0.36 and 0.30 mg/kg, respectively. Estimated dietary exposure to aluminium for 9 month old infants was 50% of the PTWI at 90th percentile consumption levels. Infant formula was the second highest contributor (21%) to aluminium dietary exposure. No information was located on the levels of aluminium in infant formula sold in New Zealand.

Dietary exposure calculated using the highest aluminium level found in the above ATDSs (0.53 mg/kg) and an upper estimate of daily infant formula consumption [200 mL per kg bw; IOM 1991] is 0.1 mg/kg bw/day, or 0.7 mg/kg bw/week, which is 35% of the PTWI.

²⁵ There are no Code or Codex provisions for the use of aluminium-containing food additives in infant formula.

²⁶ This equates to 0.55 mg/L assuming an infant formula density (as consumed) of 1.03 kg/L (Ljung et al 2011).

Dietary exposure calculated using the highest aluminium limit in Standard 2.9.1 (1 mg/L for soy-based formula) and the same upper estimate of daily infant formula consumption is 0.2 mg/kg bw/day, or 1.4 mg/kg bw/week (70% of the PTWI).

2.2.3 Conclusion

Dietary exposure to aluminium calculated using an upper estimate of infant formula consumption and the highest aluminium level found in recent ATDSs is well below the aluminium PTWI. Dietary exposure to aluminium from the consumption of infant formula is therefore not considered to pose a health risk. In addition, high level consumption of infant formula which complies with the aluminium limits in Standard 2.9.1 also results in dietary exposure which is below the PTWI. The aluminium limits in Standard 2.9.1 are therefore considered to be health protective.

2.3 Arsenic

2.3.1 Hazard information

Arsenic occurs in various inorganic and organic forms which are found in the environment both from natural occurrence and from anthropogenic activity. One food additive for use in infant formula in Standard 1.3.1 (carrageenan) has a JECFA specification that includes a limit for arsenic. The organic forms of arsenic are of relatively low toxicity while inorganic arsenic has been identified as a human carcinogen from epidemiological studies of populations exposed to inorganic arsenic in drinking-water (WHO 2001). The most recent JECFA assessment of inorganic arsenic concluded that an estimated dietary exposure of 3 µg/kg bw/day (range: 2–7 µg/kg bw/day) was associated with a 0.5% increased incidence of lung cancer. The Committee concluded that the PTWI for inorganic arsenic (15 µg/kg bw; equivalent to 2.1 µg/kg bw/day) was no longer health protective because the above estimated dietary exposure was in the same range as the PTWI value. The PTWI for inorganic arsenic was therefore withdrawn (WHO 2011a).

2.3.2 Dietary exposure

Compared to total arsenic there are far less data on the levels of inorganic arsenic in food, including infant formula. No data were located on the levels of inorganic arsenic in infant formula sold in Australia or New Zealand. Regarding international data, the WHO/GEMS database contains 306 records²⁷ on total arsenic levels in infant formula (powder and liquid) but no data on inorganic arsenic levels in infant formula. A 2014 EFSA report included data on total arsenic in 123 infant formula samples but no data on inorganic arsenic levels in infant formula (EFSA 2014).

A study published in 2012 concluded that arsenic in a range of infant formula products was exclusively inorganic. The study measured levels of total arsenic in 15 infant formula products from five major brands purchased in the USA. Inorganic arsenic levels were determined in the 9 infant formula powder samples with the highest levels of total arsenic. Arsenic was reported to be 100% inorganic for each of these 9 samples, with levels ranging from 7 to 12 µg/kg powder (Jackson et al 2012). This would give an inorganic arsenic level of approximately 0.9 to 1.5 µg/L for reconstituted formula (assuming no arsenic contribution from water). For comparison, these values are well below the maximum arsenic concentration of 10 µg/L in the Australian Drinking Water Guidelines (NHMRC 2011).

²⁷ GEMS database searched on 19 November 2014.

Levels of total arsenic in infant formula have been examined in several Australian and New Zealand analytical surveys. The 23rd ATDS included arsenic (total) as an analyte in four composite samples of infant formula and a range of other foods (FSANZ 2011b). Arsenic was detected in only one infant formula composite sample, at a level of 2.7 µg/kg which was slightly above the limit of reporting (LOR) for the assay (2.5 µg/kg). Only seafood was assayed for inorganic arsenic in this study. The 19th and 20th ATDSs each included arsenic (total) as an analyte in 9 samples of infant formula and there were no detections in any sample using an analytical method with an LOR of 10 µg/kg (ANZFA 2001; FSANZ 2002).

In the 2009 New Zealand Total Diet Study (NZTDS), eight samples of infant formula and follow-on formula were analysed for total arsenic with no detections using a method with an LOD of 1 µg/kg (MAF 2011).

2.3.3 Conclusion

No data have been located on the levels of inorganic arsenic in infant formula sold in Australia and New Zealand. However, in Australia and New Zealand total diet studies, arsenic in all forms (“total”) has been detected in only one composite sample of infant formula (at a level of 2.7 µg/kg, as consumed).

2.4 Lead

Lead occurs in the environment both naturally and from anthropogenic activities such as mining, smelting, battery manufacturing and the use of leaded petrol. Lead contamination of food arises mainly from the environment or from food processing, food handling and food packaging. Atmospheric lead can contaminate food through deposition on agricultural crops. Water is another source of lead contamination of food. All food additives for use in infant formula in Standard 1.3.1 have JECFA specifications that include limits for lead.

2.4.1 Hazard information

The most recent evaluation of lead by JECFA considered the previously established PTWI of 25 µg/kg bw (WHO 2011b). JECFA reaffirmed that because of the neurodevelopmental effects, fetuses, infants and children are the population subgroups that are most sensitive to lead. Based on data from cohort studies following subjects from birth or early infancy to 5–10 years of age (Lanphear et al 2005), JECFA estimated that dietary exposures of 0.3, 0.6 and 1.9 µg/kg bw per day are associated with decreases of 0.5, 1 and 3 intelligence quotient (IQ) points, respectively, for a 20 kg child (i.e. 5 to 6 years of age). A three-point reduction in IQ was considered important on a population basis and dietary exposure of 1.9 µg/kg bw/day is lower than the previously established PTWI (which is equivalent to daily dietary exposure of 3.6 µg/kg bw). JECFA therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn. Because the dose-response analyses do not provide an indication of a threshold for the key effects of lead, JECFA concluded that it was not possible to establish a new PTWI that would be considered health protective.

2.4.2 Dietary exposure

Lead levels in infant formula have been examined in several Australian and New Zealand analytical surveys. The 19th and 20th ATDSs each included lead as an analyte in 9 composite samples of infant formula and there were no detections in any sample using an assay with an LOR of 10 µg/kg (ANZFA 2001; FSANZ 2002). The 23rd ATDS included lead as an analyte in four composite samples of infant formula (FSANZ 2011b). Lead was detected in three of the composite samples using an analytical method with an LOR of 0.5 µg/kg. Lead levels in these composite samples were 0.9, 1.1 and 2.5 µg/kg. A lead concentration of zero was assumed for the composite sample below the LOR, resulting in median and mean lead

levels for the four composite samples of 1.0 and 1.1 µg/kg, respectively.

Estimates of total dietary exposure to lead were greatest in the youngest age-group considered in the study (9-month old infants), with mean and 90th percentile exposures of 0.22 and 0.44 µg/kg bw/day, respectively.²⁸ Infant formula contributed to 28% of total estimated dietary exposure to lead in 9-month old infants.

In the 2009 NZTDS, mean and maximum lead levels in infant formula (0.9 and 2.0 µg/kg, respectively) were similar to the values reported in the 23rd ATDS (MAF 2011).

Dietary exposure to lead calculated using the mean and maximum levels determined in the 23rd ATDS (1.1 and 2.5 µg/kg, respectively), and an upper estimate of daily infant formula consumption (200 mL per kg bw; IOM 1991), is 0.22 and 0.50 µg/kg bw/day, respectively. These values are similar to those reported in the 23rd ATDS for 9-month old infants consuming a model diet (0.22 and 0.44 µg/kg bw/day, respectively).

2.4.3 Conclusion

It is concluded that estimated dietary exposure to lead in infants consuming infant formula as a sole source of nutrition is similar to that of older infants consuming a mixed diet (i.e. those aged 9 months). Risk characterisation for lead in infant formula is not possible because the JECFA analysis of the association with lead dietary exposure and reduced IQ was based on a 20 kg child, which corresponds to the average weight of a 5 to 6 year old.

2.5 Melamine

Melamine is an organic base with several industrial uses, including the production of laminates, glues, dinnerware, adhesives and coatings. Low concentrations of melamine can occur in food due to migration from such materials. In addition, degradation of certain herbicides, pesticides and feed additives can result in melamine formation and residual levels may remain in food (WHO 2009a). Melamine is not an approved food additive.

In 2008, melamine was used in China as an infant formula adulterant in order to boost its apparent protein content (WHO 2008, FSANZ 2008). Prior to the infant formula incident, a pet food adulteration incident involving melamine resulted in the deaths of cats and dogs in North America (Brown et al 2007).

2.5.1 Hazard information

In 2007, the USFDA published an interim assessment of the risk to human health associated with eating pork, chicken, fish and eggs from animals consuming feed that may have been adulterated with melamine and its analogues (cyanuric acid, ammelide and ammeline). Based on a 13-week rat study, a Tolerable Daily Intake (TDI) for melamine of 0.63 mg/kg bw was derived that incorporated a 100-fold safety factor (USFDA 2007). Following the infant formula adulteration incident, the USFDA set a 10-fold lower TDI of 0.063 mg/kg bw applicable to infants (USFDA 2008). A subsequent expert meeting convened by WHO resulted in the establishment of a higher TDI of 0.2 mg/kg bw which was applicable to the whole population, including infants (WHO 2009b).

²⁸ Estimated lead dietary exposure at the 90th percentile in the other age groups was 0.40 (2–5 yrs), 0.27 (6–12 yrs), 0.18 (13–16 yrs) and 0.23 µg/kg bw/day (17 yrs and above).

Illness in infants consuming adulterated formula in China was characterised by urinary tract crystals and stones and, less frequently, by renal impairment from tubular injury and obstructive uropathy (Skinner et al 2010).

2.5.2 Dietary exposure

Following the adulteration incident in China, data were collected on baseline levels²⁹ of melamine in infant formula sold in several countries (WHO 2009a). Health Canada analysed 80 infant formula products available on the retail market. Melamine was detected in 60 products with concentrations ranging from 0.00053 to 0.069 mg/kg (as consumed). New Zealand reported the analysis of 121 infant formula samples with all values below the LOR of 1.0 mg/kg. The USFDA reported results on 44 domestically manufactured infant formulas consisting of powdered, liquid concentrated and liquid ready-to-use formulas. Although there were some positive detections, all were below the LOQ of 0.25 mg/kg. In 2010, FSANZ published a report on a national coordinated survey of melamine in food and beverages. Five infant formula products were analysed with all results below the LOR of 0.05 mg/kg (FSANZ 2010).

To estimate the level of melamine that does not raise public health concerns, the USFDA used a worst case exposure scenario in which all of an infant's total daily dietary intake (assumed to be 0.15 kg powdered infant formula) is contaminated with melamine. It was concluded that if 100% of the diet was contaminated at a melamine level of 1 mg/kg, an infant's daily exposure would be less than the infant TDI of 0.063 mg/kg bw (USFDA 2008).

The WHO expert meeting also concluded that a limit of 1 mg/kg for melamine in powdered infant formula would provide a sufficient margin of safety for dietary exposure relative to the TDI of 0.2 mg/kg bw established at that meeting (WHO 2009b).

2.5.3 Conclusion

Baseline levels of melamine in infant formula sold in Australia and New Zealand have been shown to be less than 1 mg/kg, a concentration which results in estimated dietary exposure below the melamine TDIs established by the USFDA and WHO. It is concluded that baseline levels of melamine in infant formula available in Australia and New Zealand do not raise health concerns.

2.6 Tin and inorganic tin compounds

The main source of dietary exposure to tin is via ingestion of inorganic tin from canned foods. Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in cationic form (stannous and stannic compounds) or as anions (stannites and stannic compounds) (WHO 2006). Steel cans used in the food industry are coated in a thin layer of tin and/or a lacquer. The tin and lacquer acts to prevent corrosion of the steel. Although tin is corrosion resistant, acidic food like fruits and vegetables can cause corrosion of the tin layer of unlacquered cans resulting in transfer of inorganic tin into the food. Dietary exposure to inorganic tin is greatly reduced when cans are lacquered.

2.6.1 Hazard information

In 1989, JECFA established a PTWI for inorganic tin of 14 mg/kg bw (WHO 1989). The most recent JECFA evaluation of inorganic tin stated that the basis for the previously established PTWI was unclear and may have been derived from intakes associated with acute effects (WHO 2006). In assessment published in 1999 by ANZFA considered the various MLs for tin

²⁹ Baseline levels refer to levels that do not result from adulteration or misuse.

in force at the time and concluded that there are limited concerns to public health and safety other than acute gastric disturbances when levels of tin in food exceed 250 mg/kg (ANZFA 1999a).

2.6.2 Dietary exposure

There are minimal data on the levels of inorganic tin in infant formula. In the 19th ATDS, tin was not reported in any infant formula sample using a method with an LOR of 0.02 mg/kg (ANZFA 2001). Tin has not been included as an infant formula analyte in any subsequent ATDS. The WHO GEMS/Food³⁰ database contains only non-detects for tin in infant formula (limit of detection 0.01 mg/kg).

Assuming a tin concentration in infant formula of 0.02 mg/kg (i.e. the LOR from the 19th ATDS) and an upper estimate of daily infant formula consumption (200 mL per kg bw; IOM 1991), calculated dietary exposure to tin is approximately 0.03 mg/kg bw/week which is only 0.2% of the PTWI.

2.6.3 Conclusion

International and Australian data indicate levels of tin in infant formula of less than 0.02 mg/kg. Dietary exposure to tin in infant formula products is therefore very low relative to the PTWI, and is not considered to pose a health risk.

2.7 Vinyl chloride

Vinyl chloride is a starting substance for the production of polyvinylchloride (PVC) plastics used in the manufacture of food packaging materials, and small amounts may remain in such materials.

2.7.1 Hazard information

An assessment by ANZFA concluded that vinyl chloride is carcinogenic in rats when administered via the oral route (ANZFA 1999b), consistent with an earlier JECFA evaluation (WHO 1984). ANZFA further concluded that there was no evidence of adverse health effects resulting from the low level of exposure to vinyl chloride via food, however the potential for carcinogenicity requires that exposure should be kept as low as possible. An ML of 0.01 mg/kg (set at the LOD) applicable to all food was established (ANZFA 1999b). Vinyl chloride is considered by the International Agency for Research on Cancer to be a human carcinogen based on epidemiological data from occupational exposure (IARC 2008).

2.7.2 Dietary exposure

No studies have been located reporting the analysis of infant formula for vinyl chloride and there are limited data on vinyl chloride levels in other foods. In a FSANZ analytical survey, a range of foods packaged in plastic were tested for vinyl chloride. The foods tested included full fat milk, minced beef, yogurt, tomato sauce, pre-prepared meals, orange juice and still water. The analytical method had a limit of quantification (LOQ) ranging from 0.001 to 0.01 mg/kg depending on the food matrix. There were no detections of vinyl chloride in any food (FSANZ 2011a).

³⁰ Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (<https://extranet.who.int/gemsfood>)

Reports from the 1970s indicated parts-per-million levels of vinyl chloride in some foods (e.g. up to 98 mg/L in vinegar, 1.8 mg/L in edible oils, and 8.4 mg/L in alcoholic beverages) when these foods were packaged and stored in PVC containers (ATSDR 2006). An absence of detectable vinyl chloride in foods analysed in the above FSANZ study is consistent with the reported large improvements in the formulation and production of PVC packaging materials (ATSDR 2006).

2.7.3 Conclusion

Vinyl chloride is now rarely detected in foods and is unlikely to be present at detectable levels in infant formula. Potential dietary exposure to vinyl chloride from infant formula is therefore considered to pose a negligible health risk.

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