



6 November 2012

Project Officer Regulation of Infant Formula Products
Food Standards Australia New Zealand
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Dear Sir/Madam

Consultation Paper – Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code

Thank you for the opportunity to comment on this Consultation Paper. The Ministry for Primary Industries (MPI) has the following comments to make. MPI has consulted the New Zealand Ministry of Health (MoH) during the preparation of this submission. Specific comments from the MoH officials are identified in this submission. In addition, the Ministry of Business, Innovation and Enterprise (MBIE), provided information in response to Questions 24 and 27, and the Commerce Commission provided information in response to question 27.

We have provided responses to the majority of the questions. In addition, comments have been made about other matters. These additional comments are provided at the end of the submission.

General comments from MPI and MoH

MPI and MoH officials strongly support the three primary objectives identified in section 2.1.2 of the Consultation Paper, and the supporting paragraph in this section which highlights that these primary objectives are of paramount importance, given that formula-fed infants are vulnerable because these products provide the sole source of nutrition during the first months of life.

Response to Questions contained in Attachment A – Summary of Questions to Submitters

1. *What is the total volume of each of infant formula, follow-on formula and Infant Formula Products for Special Dietary Uses (IFPSDU) manufactured in Australia New Zealand for domestic consumption and export? What proportion of the total volume is for export only?*

MPI can provide the following information.

Over the past ten years, New Zealand's infant formula export increased from \$74.2 million (13,979 tonnes) to \$361.7 million (30,020 tonnes) from year ended Sep 2001 to 2012. This average annual growth rate of export value and volume are 19% and 10% respectively.

This information is based on harmonised system codes and is an indication only of export volumes. It is likely to be an underestimate of export volumes and dollar values.

Export volumes are of course critical to the economy of New Zealand.

Domestic requirements should provide a robust platform for exports, acknowledging that some countries will have different requirements to New Zealand and Australia.

2. *What is the total volume of each of infant formula, follow-on formula and IFPSDU imported into Australia and New Zealand? Where are these products imported from?*

MPI does not hold this information.

3. *What is the value for each component listed in Q1 and Q2?*

Please see the information provided in question 1.

4. *Is the current structure of Standard 2.9.1 (i.e. organised from general to specific requirements by division) logical and easy to use? What changes would you suggest are made to the structure of Standard 2.9.1 and why?*

MPI considers that the structure of Standard 2.9.1 could be improved. Currently the standard is structured in a way where the essential compositional requirements are not listed until Division 2 of the standard. Calculations, permissions for optional additions, and labelling and packaging requirements all come before the essential compositional provisions.

MPI supports a structure which firstly presents the definitions and interpretation of the standard, followed by the essential compositional requirements (and calculations associated with the essential composition), with permissions for the addition of 'optional ingredients' (permitted nutritive substances, lactic acid cultures, inulin-derived substances and GOS) coming after this. The labelling and packaging requirements could follow the compositional clauses.

MPI considers that the Purpose statement at the beginning of the standard could be strengthened to outline the policy intent of the standard. Text could be taken from the Purpose Statements in the Policy Guidelines. A purpose statement then 'sets the scene' for the standard, and emphasises that the standard is there to protect a vulnerable

population group, for which infant formula may be the sole source of nutrition, and that infants are reliant on adults for feeding. The Purpose Statement can then act as a reference point when determinations need to be made about the safety of ingredients used to manufacture the formula, safety considerations for the preparation of the formula, and labelling.

5. *Are the current definitions in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see made?*

MPI and MoH officials support amending the definitions of 'infant formula' and 'follow-on formula' and using the definitions that were developed for the Infant Formula Products Policy Guideline, as set out below.

infant formula means an infant formula product represented as a breastmilk substitute for infants and which satisfies, as the sole source of nourishment, the nutritional requirements of infants up to six months of age

follow-on formula means an infant formula product represented as either a breastmilk substitute or replacement for infant formula and which can constitute the principal liquid source of nourishment in a progressively diversified diet for infants aged from six to 12 months of age

We are of the view that the above definitions add regulatory clarity around the intended age group for each product category, as well as clarifying that infant formula must satisfy the complete nutritional requirements of infants up to the age of six months. Note, it is our interpretation that the above definitions would allow for 'infant formula' to still be marketed up to an age of 12 months.

6. *What additional terms, if any, do you consider should be defined in Standard 2.9.1? Why? How would you suggest we define these terms?*

MPI's view is that Standard 2.9.1 should stand alone (to the extent that this is possible), and not create ambiguity. For example, health claims are referenced elsewhere in the Code as not permitted on infant products (currently Standard 1.1A.2), yet health claims are not defined. We are of the view that any prohibition on health and nutrition claims on infant formula products should be stated in Standard 2.9.1. The updated definitions for health and nutrition claims (under development in Proposal P293) could be included in the standard so that it is clear what constitutes a claim, and what references are therefore prohibited.

The definition of "nutritive substance" in Standard 1.1.1 is relevant, because the addition of nutritive substances to infant formula products is not permitted, except for those listed in clause 7 *permitted nutritive substances* of Standard 2.9.1. The FSANZ review of the definition of "nutritive substance" could significantly affect the type of substances that may be added to infant formula products and the impact on Standard 2.9.1 must be considered.

MPI does not necessarily favour the continuation of the term 'nutritive substance', and supports a new approach to permitting new ingredients consistent with the Policy guidelines.

Consideration should therefore be given to delinking permissions in Standard 2.9.1 for the addition of substances to infant formula products with any other type of "nutritive substance" defined in the Code. Suitability of these substances should take into consideration the Ministerial Council Policy Guidelines, and in particular the principle in (j) where substances subject to a pre-market assessment should have a substantiated beneficial role in the normal growth and development of infants and children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk.

This Policy Guideline is in itself enough justification for delinking the types of substances that may be added to infant formula products, from other “nutritive substances” in the Code.

The lack of an appropriate definition for substances added to infant formula products detracts from the fitness for purpose of Standard 2.9.1. This is a major issue for MPI.

MPI is aware of number of substances that lack regulatory clarity, and would be pleased to discuss this with FSANZ.

7. *What provisions in the Code for the composition of infant formula and follow-on formula are unclear and ambiguous? What are the specific issues and how would you suggest the intent of the specific provision be clarified?*

Determination of essential composition:

As a general comment, MPI and MoH officials suggest that consideration is given to how the essential composition of infant formula products is specified in the new standard. For example:

- How will the Australia New Zealand Nutrient Reference Values (NRVs) be incorporated into the standard?
- How will the ‘base composition’ of all infant formula and follow-on formula be defined in the new standard? Formula can of course be derived from a large number of ingredients, and the protein source is usually dairy (bovine), goats milk, or soy. Taking cows milk derived formula as an example, it is traditionally made from milk powders and proteins, and vegetable fats. However it is possible that as technology develops, the components used to make formula could be increasingly fractionated, and combined to produce formula, using lesser quantities of the non-fractionated traditional ingredients. Consideration needs to be given to how the new standard is future proofed for new technologies that are used to produce formula. For example, is it sufficient to set out the gross composition, or is more detail required in the standard to specify what ingredients are permitted to make up the essential composition? It is important to acknowledge that while there are different protein sources, cows milk derived formula is the dominant product on the market, and is expected to continue to be so. A ‘reference’ or benchmark for this product could be considered, including a list of acceptable ingredients that could be used to manufacture this formula. MPI appreciates that the development of a positive list of ingredients is probably not a solution to this, but consideration of acceptable ingredients needs exploration as the new standard is drafted.
- At some point in time, optional ingredients (usually defined as nutritive substances under the current standard) are added to most products, or evidence becomes available that their addition to all infant formula products is desirable, in order to better mimic the composition of breast milk or health outcomes related to formula feeding. Therefore, it is important that the standard is reviewed periodically, and an assessment is made of when optional ingredients become essential. MPI would like to see this approach included in the review of the standard.

Unclear and ambiguous provisions:

MPI is seeking to have clause 6 (1) (b) clarified to make the intent clearer in the text of the infant formula standard thus no longer leaving room for disparate interpretation.

The Food Standards Code regulates the use of nutritive substances in food, including in infant formula products. Generally, nutritive substances are not permitted to be added to food unless expressly permitted in the Food Standards Code (clause 9 of Standard 1.1.1).

Standard 2.9.1 – Infant formula products reaffirms this general prohibition in clause 6(1) but it has an additional phrase not present in Standard 1.1.1, the entire clause 6(1) is quoted below:

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.

The context of the issue applies to any nutritive substance which is naturally present in milk (or any other ingredient for that matter that might be used to make infant formula products, such as soy products or vegetable oils).

One point of view is that if a nutritive substance is already naturally present in an ingredient of the infant formula product (e.g. in the base milk powder) then its extracted form can be added to increase the amount of that substance beyond what is naturally present. “Naturally present” would mean that the source of the extracted nutritive substance being added to the infant formula product needs to be the same as the food ingredient in which it is naturally present.

The second point of view is that if a non-approved nutritive substance is naturally present in an ingredient in infant formula product then no action is required on the part of the manufacturer to remove it, but the manufacturer cannot add more of that substance.

The first point of view opens the infant formula standard to uncontrolled and potentially excessive addition of nutritive substances. MPI acknowledges the ambiguity of clause 6(1)(b) when read without the background policy and drafting context, i.e. that both the liberal and restrictive interpretations are plausible.

MPI also takes the view that the more restrictive interpretation of this clause is the one most consistent with the general purpose of the Food Standards Code, and the infant formula standard in particular, and is the one most consistent with the drafting and policy documents behind this standard.

8. *Is alignment of the compositional requirements for infant formula products in the Code with the relevant Codex standards appropriate? What is the rationale for your view to align/not align with Codex?*

Alignment with Codex facilitates trade in these products as it encourages the development of harmonised standards across national legislation. In countries where there is no alignment of domestic standards with Codex, diversification of national regulations for infant formula products may present significant issues for the international trade of these products. New Zealand and Australian manufacturers may be faced with additional regulatory difficulties when manufacturing product for export to, and sale in, these countries. If these difficulties become too costly, there may be an impediment to the manufacture of these added value products for export in these countries or a negative impact on revenue.

Standard 2.9.1 goes across two Codex standards, the Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981 (Rev.2007))) which has recently been reviewed and updated and the Codex Standard for Follow-up Formula (CODEX STAN 156-1987) which has not been substantially updated since its development. There have been scientific and technological developments in nutrition for infants, and the production of substances that may be suitable to include in follow-up formula products since 1987. As a result, CODEX STAN 156-1987 is considered out of date and is currently under consideration for review at CCNFSDU. While the principle of alignment with CODEX STAN 72-1981 (Rev.2007) and CODEX STAN 156-1987 is important, a flexible approach to the review of Standard 2.9.1 will be needed to allow for consideration of

CCNFSDU's decision on the proposal to review CODEX STAN 156-1987, as well as any technological and scientific changes to the Codex standard that might result from a review should it proceed.

It would be useful to have detailed information in the up coming Proposal on the amendments made to the CODEX STAN 156-1987 in 1989 and 2011.

Section 4.3.1 comment – MPI supports the discussion in this section of the consultation document which states that FSANZ will consider alignment of the vitamin, mineral and electrolyte requirements in the Code with those set by Codex and appropriate Australian and New Zealand nutrient reference values for infants.

As a principle; MPI considers that where FSANZ has already considered an application for change to Standard 2.9.1, conducted a risk assessment and amended the standard as a result, these provisions should be retained in Standard 2.9.1 even if they do not align with Codex e.g. the Standard 2.9.1 provisions for inulin derived substances, galacto-oligosaccharides, and lutein should be retained.

9. *Should there be different compositional requirements for infant formula and follow-on formula? If yes, for which nutrients? Please provide evidence to support your view.*

MPI considers that the option of different compositional requirements for infant formula and follow-on formula should be considered for the 0 to 6 month, and 6 to 12 month age groups respectively. Expert evidence should be obtained from relevant health professionals, such as paediatric nutritionists, for advice on suitable compositional requirements for the two age groups. The Codex standards should be taken into consideration, in addition to the recommendations in the report coordinated by the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) for the composition of infant formula based on current scientific evidence (Koletzko et al. 2005, as referenced in the Consultation Paper). MPI is not averse to the continuation of two different product categories; infant formula and follow-on formula, while acknowledging that infant formula could be marketed as suitable from birth to up to 12 months.

MPI considers that priority should be given to the development of the standard for infant formula. While the Standards for follow-on formula (and possibly toddler milks) could be considered concurrently, an updated standard for infant formula (as the sole source of nutrition) is MPI's priority in the review of these products.

10. *Should the two nitrogen conversion factors (6.25 and 6.38; for different protein sources) continue to be prescribed in Standard 2.9.1 for the calculation of protein content of products? If only one nitrogen conversion factor was to be prescribed, which factor (i.e. 6.25, 6.38 or other) would you recommend and why?*

Yes, Standard 2.9.1 should use appropriate nitrogen factors. This would align with the Codex infant formula standard. Section 4.2.1 of the FSANZ Consultation Paper explains that the Codex standard uses a single nitrogen conversion factor of 6.25 (unless there is a scientific justification to use a different factor for a particular product). However, the Codex infant formula standard clearly distinguishes between a suitable conversion factor for milk protein and for soy protein (and as such this could be clearer in the Proposal report that will be prepared).

From CODEX STAN 72-1981 (Rev.2007):*"For the purpose of this standard, the calculation of the protein content of the final product prepared ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products".*

Standard 2.9.1 should retain the protein nitrogen conversion factor for milk proteins of 6.38. Consideration could also be given to an additional conversion factor of 5.71 for soy proteins to align with Codex.

MoH and MPI officials support the continued mandatory declaration of protein source. This is important for those with allergies, as well as for providing consumers with content information and to reduce the risk of fraudulent practices.

11. *Is alignment of the minima and maxima for vitamins, minerals and electrolytes in the Code with those specified in the Codex infant formula standard appropriate? What is the rationale for your view to align/not align with Codex?*

Yes. See response to question 8.

Consideration should be given to listing choline, inositol and L-carnitine as essential. Since the development of Standard 2.9.1, the National Health and Medical Research Council (NHMRC) and New Zealand Ministry of Health have listed choline as an essential nutrient and set an Adequate Intake for infants (2006). The Codex infant formula standard (2011a) lists choline, inositol and L-carnitine as essential, based on the approach recommended by ESPHGAN (Koletzko et al. 2005, as referenced in the Consultation Paper).

12. *Is alignment with Codex for the permitted forms of nutrients appropriate? What is the rationale for your view to align/not align with Codex?*

The permitted forms of vitamins, minerals and electrolytes in Standard 2.9.1 should be extended to include all of the compounds on the Codex advisory list of nutrients. This would mean additional permitted forms for copper, folate, iron, magnesium, manganese, niacin and pantothenic acid. This would be a larger list of permitted forms than the Codex list because there are already additional forms of vitamin A, D E and K permitted in Standard 2.9.1 compared with Codex.

13. *Do manufacturers follow the guideline upper levels (GULs) for certain vitamins and minerals specified in the Guidelines attached to Standard 2.9.1?*

MPI does not have information on this question.

14. *Would it be appropriate to include the GULs for vitamins and minerals in the legally binding Standard?*

MPI supports the inclusion of GUL's in association with the standard but further consideration of the establishment of GUL and maximum levels in the Standard is required. If the GULs are to be included in the standard they must be legally enforceable and would therefore be maximum levels in the Standard. Therefore consideration should be given to which nutrients require a maximum level from the list of GULs in the Guidelines so as not to place a metabolic or physiological burden on the infant, as identified in the Policy Guideline. Consideration will also need to be given to whether the maximum level is applicable to both infant and follow-on formula.

If the GULs are not included in the Food Standards Code, we suggest there is a reference in the standard to the GUL's, which could be provided in a separate user guide.

The Codex infant formula standard has maximum levels or GULs for all vitamins and minerals except iron (which is left to individual country requirements). The Codex follow up formula standard does not specify a maximum, except for Vitamin A and D, and iron and sodium where there is a food safety risk. This leaves over 20 vitamins and minerals with no upper limit, or GUL, which does not seem appropriate for a standard for infants in the 6 to 12 month age group. This is an area where an alternate approach to alignment with the Codex standard should be considered.

MPI considers that maximum limits of some sort for contributors to renal solute load – protein, sodium, potassium, phosphorus and chloride – are particularly important.

15. What additional forms of vitamins, minerals and electrolytes would you like permitted in Standard 2.9.1? Why?

MPI supports extension of the permitted forms of vitamins, minerals and electrolytes in infant formula products to include all of the compounds on the Codex advisory list of nutrients. This would mean additional permitted forms for copper, folate, iron, magnesium, manganese, niacin and pantothenic acid. This would be a larger list of permitted forms than Codex because there are already addition forms of vitamin A, D E and K permitted in Standard 2.9.1 compared with Codex.

Any other additional forms of vitamins, minerals and electrolytes must have a safety assessment based on consumption by infants of 0 to 12 months of age. Safety assessments for older populations may not be suitable for extrapolation to formula products for infants.

16. Are the current food additive permissions in Standard 1.3.1 fit for purpose? If no, why not and what changes would you like to see made?

MPI is interested in the views of industry and other stakeholders on the adequacy of current food additive permissions.

17. What additional food additives do you consider should be permitted in the Code? What is your rationale for these?

MPI is interested in the views of industry and other stakeholders on the need for new or revised food additive permissions.

18. Are the current permissions for processing aids for use in the manufacture of infant formula products fit for purpose? If not, why not and what changes would you like to see made?

MPI is interested in the views of industry and other stakeholders on the adequacy of current processing aid permissions, or the need for new and revised permissions.

19. *Is alignment of the microbiological limits in the Code with international approaches as developed by Codex under the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children appropriate?*

MPI and MoH officials suggest that these could be updated to align with the Codex criteria in the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, for the following additional pathogens:

- *Cronobacter sakazakii*
- Salmonella

Alignment with this Codex Code for *Salmonella* will require careful consideration. The Codex Code criteria requires 60 x 25g samples to be taken and tested. This is a significant increase over the current Food Standards Code criteria for 10 x 25g samples, representing a significant increase in costs for manufacturers. In New Zealand a number of smaller scale operations have been started. We have limited information as to the size of smaller production lots, and the impact that a 6-fold increase in sampling and testing costs for *Salmonella* will have. Further, the Codex Code criteria is applied with the underlying assumption that the history of the lot is unknown, and the criteria are being used on a lot-by-lot basis. The Codex Code further suggests that where (as in New Zealand) the product is produced under a fully documented HACCP system, alternate sampling criteria may be feasible.

It is also important to note that alignment with the Codex Code will mean that the Food Standards Code requirements for Salmonella become 'out-of-sync' with product safety limits under the Animal Products Act (APA). In New Zealand both the Food Standards Code (FSC) and the APA apply microbiological limits to final infant formula products. The limits in FSC only apply to product sold in Australia and/or New Zealand whereas the limits in the APA apply to product produced in New Zealand for sale anywhere in the world. In most cases the APA requirements are the same as, or more stringent than, requirements in the FSC. It is MPI's preference that this continues to be the case, and if changes to microbiological limits are proposed that they be underpinned by sound science demonstrating the need for such changes. The current APA criteria for the above microorganisms are:

- Salmonella – Not detected in a 250g composite of [final product] samples collected throughout the production run
- Cronobacter spp – Not detected in 300g composite of [final product] samples collected throughout the production run (or 30 x 10g samples).

The APA criteria for *Cronobacter sakazakii* are aligned with the Codex Code criteria therefore MPI would have no objection to aligning the Food Standards Code with Codex for *Cronobacter sakazakii*.

20. *Is it appropriate to include criteria that verify good hygiene practice (e.g. indicators) as regulatory standards in the Code or should these be established as reference or guidance criteria?*

This needs further consideration amongst experts. If the indicator approach is continued these should be updated to align with the Codex Code of Hygienic Practice for Infant Formula criteria for process hygiene for:

- Mesophilic Aerobic Bacteria
- Enterobacteriaceae.

The indicator bacteria are primarily expected to be used as an in-process verification tool, therefore it may be more appropriate to consider alignment with the Codex Code in the relevant production and processing standards (e.g under the Animal Products Act in New Zealand). The review will need to consider whether it is realistic to expect infant formula product with added lactic acid bacteria to meet the current Standard Plate Count (SPC) limits. One

approach to consider is to remove SPC limits from the Food Standards Code criteria, and include only pathogens in the microbiological criteria.

21. Can you provide evidence to suggest that the maximum potential renal solute load (RSL) has not been effective in minimising the risk of dehydration illness from formulas with high protein and electrolyte contents?

MPI and MoH officials suggest that expert opinion is sought on this issue, which could include the advice of paediatric dietitians and other health professionals (for example, Dietitians New Zealand Paediatric Special Interest Group).

We agree that this issue needs to be fully explored in the review, including information on why there is an absence of RSL criteria in the Codex standard.

22. Is full alignment of the Code with the Codex contaminant standard appropriate? Or is there a rationale for only partial alignment of maximum contaminant levels with those set by Codex?

It is confusing to have maximum levels for contaminants in two different standards within the Code e.g. Standard 1.4.1 for lead and Standard 2.9.1 for aluminium. They should be placed in one standard in the Code.

Aluminium levels were included in Standard 2.9.1 for sound reasons at the time the standard was developed. A review of the requirement, along with a summary of the rationale for Codex not including such a limit, will be helpful for submitters at the Proposal stage of the consultation process.

23. What evidence can you provide to support an amendment to the current requirements for storage and/or disposal of made-up formula?

MPI and the MoH officials are considering the current recommendations for reconstitution, storage and disposal of made-up formula, in particular recommendations in the Code for the storage time in the refrigerator (24 hours). We will provide further comment at the next consultation round.

As noted in the Consultation Paper, the advice provided by the MoH is not consistent with the requirements in Standard 2.9.1. The advice was developed in consultation with MPI, in 2008. This advice was based on MPI's interpretation of the Codex recommendations, applying a New Zealand context.

Comments on the text in the Consultation Paper (section 6.1):

MoH officials note that the following additional blue text should be included, in paragraph 3 of Section 6.1. MoH Guidelines specify storing formula (if it cannot be given straight away): " in the [bottom half](#) of the fridge at the back (2-4°C) for no more than four hours" .

MPI officials note that the last sentence on section 6.1 states that "There is no specific direction or prescribed wording for direction and storage outlined in the Codex infant formula standard". While this is correct for STAN 72, the Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (Codex 2009, as referenced in the Consultation Paper) gives clear direction on risk reduction strategies stating the feeding period should be minimised and not exceed 2 hours; leftover formula should be discarded (captured in 14(2) (e)); any formula prepared for use should be refrigerated immediately and used within 24 hours (captured in 14(2) (b)).

24. *What evidence can you provide on how caregivers currently prepare formula? Do they follow the instructions on the packaging? If not, is there evidence to show that changes to the instructions on labels of products could potentially influence how caregivers prepare formula?*

MPI (formerly the New Zealand Food Safety Authority) commissioned research in this area in 2008, and the report can be found at the following link:

<http://www.foodsafety.govt.nz/elibrary/industry/powdered-infant-formula/>

This report is called 'Information Sources and Practices – Preparation of Powdered Infant Formula in New Zealand – Qualitative Research'. The report noted the high level of compliance with information on the preparation of infant formula. Some deviations were identified and these were mostly driven by cost (affecting decisions around discarding unfinished feeds), pragmatism or an increasingly relaxed attitude with increased age of the infant. Decisions to relax practices did not appear to be driven by conscious knowledge derived from guidance material; these decisions were often consistent with guidelines that include stricter hygiene measures during the first three months of life.

The research reported that caregivers viewed information on infant formula tins as authoritative and trusted. It was also the major information source for most caregivers.

Preparing formula with hot water was actively discussed with study participants, with participants in agreement that this recommendation was impractical and potentially dangerous due to the risk of scalding.

In addition to this qualitative research, MoH officials have provided anecdotal information as follows:

MoH officials have anecdotal information from Plunket and from New Zealand paediatric dietitians that many caregivers measure water volumes for making up formula using baby bottle markings.

The MoH officials point out that the provision of a scoop to enable correct measurement of formula is important and MPI officials support this. However there is no regulatory requirement in New Zealand that volume measurement indicators (for example, infant feeding bottles) used in a domestic setting need to be accurate. Limited research undertaken by the Ministry of Consumer Affairs in 2011 (now called Consumer Affairs, which is part of the Ministry of Business, Innovation and Enterprise – MBIE) has shown that a number of baby bottles sold in New Zealand have inaccurate volume measurement levels, some up to 40% inaccurate, potentially concentrating formula feeds by 40% (or diluting formula feeds by 10%). MBIE's research indicates the problem is mainly with low cost bottles, rather than the better known brands. Unintentionally concentrating formula, especially to this degree, could have significant acute and chronic negative effects on the infant. MoH officials propose that the infant formula standard includes a requirement for an accurate measuring container for water to be included with the infant formula powder container (similar to the scoop). The information provided by MBIE is provided at Appendix 1. The testing of the bottles was carried out in Wellington and Auckland, and the bottles were sourced locally for each test. This gives a fairly good representation of the bottles available on the NZ market at the time of testing.

MPI notes that the volume of water added to powdered formula is of course critical and notes the importance of this being correct.

Manufacturers may choose to voluntarily include a measuring device in addition to a scoop. Relying on measuring utensils found in the home (e.g. measuring cups) may not be accurate and cannot be relied on.

MoH and MPI officials request that FSANZ considers options to address this issue in the Proposal report.

25. *What evidence can you provide on whether caregivers use measuring scoops other than those supplied with the product, and whether they understand that scoop size (and therefore number of scoops per volume of water) differs between brands?*

MPI notes that as it is very important that the correct scoop is used when following directions, instructions must be very clear about using the correct scoop. It may be necessary to consider prescribing these instructions if there is evidence that this is not understood.

26. *What evidence can you provide on:*

- (a) *how consumers choose between infant formula products?*
- (b) *whether or not nutrition claims, by providing additional information, would 'enable consumers to make informed choices' (or choices that are more informed than they currently are) and/or*
- (c) *how their choice might be affected by the presence of nutrition claims?*

MPI and MoH officials support the continued prohibition on health claims on infant formula products. As stated earlier, this prohibition needs to be clearer, and contained within the standard itself (and cross referenced to the health claims standard).

MPI notes the arguments that are presented in section 6.3 of the Consultation Paper, and considers that the ability to make nutrition content claims could be given further consideration by FSANZ. Some options would be to:

- restrict such claims to optional ingredients only, and
- to limit the number of claims that could be made (for example, there could be a maximum of three nutrition content claims, such as: contains lutein, GOS and probiotics), and
- to prohibit the linking of nutrition content claims to a physiological function or health effect (so it would not be permissible to link lutein with eye health, for example).

MoH officials do not support making nutrition content claims on infant formula, especially for substances such as lutein, GOS and probiotics, as they are not terms that are well understood by consumers or many health workers so would be likely to confuse consumers.

27. *What evidence can you provide on whether consumers perceive trademarks on food labels in a similar way to health claims?*

MPI is of the view that trademarks should not be permitted as a way of making labelling statements that are not permitted. For example, it should not be possible to trade mark a name that implies a health effect or applies to a health condition, and is effectively a health claim.

MPI has consulted with the Commerce Commission, and has the following comment to make (as provided by the Commerce Commission):

- We are not able to directly answer Question 27 as we have no evidence on whether consumers perceive trade marks on food labels in a similar way to health claims. However, we take the view that, under the Fair

Trading Act, a trade mark or the name of a company or product may constitute a representation. Section 13 of the Fair Trading Act prohibits certain types of false or misleading representations about goods. Whether or not a trade mark or name might be liable or likely to mislead consumers is dependent on the facts and the overall impression given by the labelling. So in relation to infant formula labels, if the representations on a label (including any words, pictures, or images) create the impression or imply there is a certain health benefit associated with the product and that is either inaccurate or the benefit is overstated, then it may breach the Fair Trading Act. However, if any health claims are accurate, then it is not likely that the Fair Trading Act will have been breached.

- Section 16 of the Fair Trading Act specifically prohibits certain conduct in relation to trade marks, such as forging trade marks or falsely applying any trade mark or sign so nearly resembling a trade mark as to be likely to mislead or deceive.

The Intellectual Property Office within MBIE is responsible for the registration of Trade Marks in New Zealand. MPI welcomes the consideration of the use of trade marks within the infant formula review.

28. Are the current prescribed names in Standard 2.9.1 fit for purpose? If not, why not and what changes would you like to see made?

MPI considers that the prescribed names are appropriate; noting that we would support the name 'follow-up formula' as an alternative to 'follow-on' formula (i.e. either option could be used). MoH officials note that follow-on is the term that has regularly been used in New Zealand since these products were introduced so if a change is proposed it should be tested during public consultation.

We think however that it is confusing to have a standard titled "Infant Formula Products" which contains within it standards for prescribed names for two products "Infant Formula" and Follow-on Formula". It would be clearer to call Standard 2.9.1 "Formula products for infants" instead of "Infant Formula Products". The difficulty is in using the term Infant Formula (identified later in the standard as a prescribed name) in the title of a standard for Infant Formula (prescribed name), and Follow-on Formula (prescribed name). Put simply, it should be clear whether follow-on formula is a separate product, as the prescribed name suggests, or a subset of an Infant Formula as the standard title suggests.

If prescribed names are used, the alignment of composition with these names should be clearly set out in the compositional tables.

29. Would it be appropriate to include the nutrition information format requirements in the Guidelines attached to Standard 2.9.1 in the legally binding Standard?

MPI considers that the standard needs to be clear on what the nutrition information requirements are, and where there is a need for a standardised and prescribed approach, this should form part of the standard. There may be some aspects where flexibility in presenting the information is acceptable, and this should be shown by way of a guideline.

30. Do you consider that there is a rationale for revising the current requirements for size of type relating to mandatory warning statements on labels?

MPI is not aware of any problems with the current requirements.

31. *Should other presentation requirements (e.g. prescription of the use of bolding and capitalisation for certain statements) be considered as part of the proposal?*

The proposal should consider the compositional and labelling aspects in their entirety, even if a review shows that the status quo should be maintained.

32. *Is the current location of the provisions for IFPSDU in Standard 2.9.1 appropriate? If not, why?*

Yes.

33. *Do you consider that any of the labelling provisions of Standard 2.9.5 should apply to IFPSDU products? If yes, which requirements and what is your rationale?*

One point for consideration is the regulation of names and claims made on products that are not IFPSDU's, or mainstream infant formula products. Examples are products that claim to be 'sleepy time' formulae or 'hungry baby' formulae. MPI considers that these products need to be strictly regulated, in the same way as other infant formula products. Furthermore, names of products should not contravene the infant formula products regulations, or be misleading under the Fair Trading Act.

34. *Are there any additional labelling requirements (e.g. advisory statements) that should be displayed on the labels of IFPSDU that are not already required by either Division 3 of Standard 2.9.1, or by Standard 2.9.5? If yes, why?*

MPI will consider this further at the Proposal stage. As stated above, we are concerned about the numbers of products falling into a grey area between regular infant formula, and IFPSDU, and the names these products are given.

Additional comments on matters covered in the Consultation Paper, not relating to the specific questions (identified by the paragraph heading)

Section 2.1.3. MoH officials have provided the following additional information, which should be considered in the Proposal that is prepared following the Consultation Paper:

- In New Zealand, the WHO Code is implemented through four codes, with 1, 3 and 4 relating to manufactures, marketers and distributors:
 1. *Infant Nutrition Council's (INC) Code of Practice for the Marketing of Infant Formula*
 2. *Code of Practice for Health Workers (Ministry of Health 2007)*
 3. *Australia New Zealand Food Standards Code (2002) (legislative code)*
 4. *Code for Advertising of Food Advertising Standards Authority (ASA 2006)*

The WHO Code in New Zealand is overseen by the MoH. In addition the Ministry oversees the monitoring of compliance with Codes 1 and 2 via a compliance panel and independent adjudicator

- A review of the WHO Code in New Zealand is currently underway so FSANZ should ensure alignment of the Foods Standards Code and the WHO Code in New Zealand.

Section 2.2.1. MoH and MPI officials are aware of a number of other companies that are not listed in this section, and these include Best Health Products Ltd and HomeCare Health Ltd.

Section 7.1 Line Marketing and Section 7.2 Proxy advertising. MoH and MPI officials are concerned that the current practice of line marketing as described in section 7.1 and proxy advertising in section 7.2 of the Consultation Paper is undermining the intent of the WHO Code, and the research provided in the Consultation Paper supports this. We do not have the solution to this problem, however, we support consideration by FSANZ of these issues in the Proposal that results from this Consultation. These matters may not be able to be regulated in the Food Standards Code, and may be a matter for other agencies to consider.

Other matters

Labelling of added vitamins and minerals - MPI has been asked for guidance on how added vitamins and minerals are declared on the label of infant formula products. Our view is that the Code provides for several options.

The relevant clauses are:

- Std 1.3.2, clause 2. This states that vitamins and minerals need express permission, and must be in a permitted form as specified in std 1.1.1 (ie only particular chemical forms of the vitamin or mineral are permitted)
- Std 1.2.4, clause 4 requires ingredients to be listed by common, descriptive or generic names. Using this clause, the added vitamins or minerals might be labelled along the following lines: calcium (calcium carbonate), mineral (calcium carbonate), vitamin C (L-ascorbic acid) or vitamin (vitamin C - L ascorbic acid), mineral (calcium), etc
- Std 1.2.4, clause 9 This provides the *option* of labelling vitamins and minerals in accordance with the way food additives are declared. An example of this method would be mineral (calcium carbonate) or vitamin (L-ascorbic acid). This method is not particularly helpful, as if the class name vitamin or mineral is used, and the permitted form is put in brackets, there does not appear to be scope to say that the mineral is calcium, or the vitamin is vitamin C (for example).
- Std 2.9.1, clause 24

There are two competing interpretations of the provisions. Firstly, that the provisions provide a number of options in which an ingredient (such as a vitamin or mineral) can be declared, i.e. using the 'common name', and secondly, that added vitamins and minerals should be declared using their full (permitted form) name in the ingredient list. On the balance of arguments, it is more likely that the first view has more substance due to being supported by the applicable provisions in the Food Standards Code (clause 4 of Standard 1.2.4).

While clause 9 of standard 1.2.4 provides the *option* of labelling added vitamins and minerals in accordance with the way food additives are declared, clauses 4 and 9 do not appear to create any preference as to the manner in which ingredients should be declared on an ingredient list; there is no hierarchy towards declaring the permitted form of a vitamin or mineral.'

MPI can see reasons in support of both methods of labelling added vitamins and minerals. It could be argued that consumers are not fully informed if nutrient names such as 'iron' or 'calcium' are on the ingredient list without the full chemical name, as iron and calcium in their native states are not the substances consumed. It is the permitted form (i.e. the chemical) that is added, e.g. ferrous citrate, calcium carbonate. This argument (i.e. being technically correct) needs to be balanced against what is meaningful to the consumer. Another point is that it is very difficult to assess imported products for compliance with the permitted form provisions of the Food Standards Code where the full chemical name is not on the label.

The full information package is relevant, i.e. the vitamins and minerals that are added and described on the ingredient list, and the nutritional information that is provided in the nutrition information panel.

MPI requests that this issue is considered in the upcoming Proposal report, with particular regard to infant formula products. We acknowledge that this issue is common to all foods, but there may be a case for being more explicit when labelling infant formula products.

MPI has welcomed the opportunity to provide comment at this pre-proposal stage, and looks forward to further opportunity for comment as the proposal progresses.

Yours sincerely

Appendix 1: Ministry of Consumer Affairs' (which is now part of the Ministry of Business, Innovation and Enterprise (MBIE) 2011 survey results.

MAPSS is the Measurement and Product Safety Service, which is a unit within Consumer Affairs

MAPSS Baby Bottles Test Results

Bottle size	Reference	Made in...	Volume water added	Indicated volume	Difference (ml)
150ml	1	not given	100ml	just below 90ml	-10
250ml	2	?	100ml	90ml	-10
250ml	3	?	100ml	92ml	-8
275ml	4	China	100ml	94ml	-6
150ml	5	Germany	100ml	94ml	-6
250ml	6	Thailand	100ml	96ml	-4
120ml (Glass)	7	Mexico	100ml	97ml	-3
250ml	8	Thailand	100ml	97ml	-3
250ml	9	China	100ml	97ml	-3
250 ml	10	China	100ml	below 100ml	-2
240ml (Glass)	11	Germany	100ml	98ml	-2
270ml	12	Austria / EU	100ml	99.5ml	-0.5
300ml	13	China	100ml	100ml	0
250ml	14	Thailand	100ml	100ml	0
250ml	15	China	100ml	100ml	0
240ml	16	China	100ml	100ml	0
330ml	17	?	150ml*	150ml	0
260ml	18	China	100ml	100ml	0
250ml	19	Thailand	100ml	100ml	0
150ml	20	Switzerland	100ml	100ml	0
250ml	21	Thailand	100ml	100ml	0
125ml	22	England	100ml	101ml	+1
250ml	23	Thailand	100ml	102.5ml	+2.5
250ml	24	China	100ml	estimated 100ml	+3
300ml	25	Taiwan	100ml	103.5ml	+3.5
275ml	26	China	100ml	106ml	+6
140ml	27	China	100ml	106ml	+6
120ml	28	China	100ml	110ml	+10
240ml	29	China	100ml	110ml	+10
120ml	30	New Zealand	100ml	110ml	+10
125ml	31	China	100ml	below 125ml	+20
240ml	32	China	100ml	120ml	+20
125ml	33	China	100ml	below 125ml	+20
240ml	34	China	100ml	140ml	+40
240ml	35	China	100ml	140ml	+40
35 Bottles					
9 accurate					
10 are 10% or more out, in range -10ml to +40ml					