Submission from the New Zealand Ministry for Primary Industries (MPI), including comments from the New Zealand Ministry of Health (MoH).

Attachment 1 – Summary of questions to submitters

Before agreeing to all of FSANZ's preliminary views, MPI will reserve our position until we have had the opportunity to consider the issues fully, giving consideration to issues (including trade and compliance matters) raised by other stakeholders. We look forward to providing further comment at the next round of public consultation.

Comment on the Consultation paper – Section 4.7.2. The last sentence in the final paragraph contains a summary of the MPIs s export requirements with regard to labelling, but this needs to be updated to refer to the Notice that comes into force on 18 June 2016. SD3, Section 1.2.4, contains the updated information. There is no longer an exemption for labelling, and labelling requirements are contained in the new Notice.

Supporting Document 1: Definitions and Nutrient Composition

No.	Section of the SD	Question
Q1.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

RESPONSE:

Macronutrient Composition

- MPI supports retaining the current total protein content and range in Standard 2.9.1 to align with Codex, that being 0.45 – 0.7 g/100 kJ.
- MPI does not support FSANZ's preliminary view that only two nitrogen conversion factors should be specified in Standard 2.9.1 – that being 6.25 for mammalian milk, and 5.71 for soy protein. MPI requests that Standard 2.9.1 retain the nitrogen conversion factor for milk proteins of 6.38. This aligns with the approach taken footnote 2 within 3.1.3 (a) of the Codex Infant Formula Standard which allows for the use of a different conversion factor if *'scientific justification is provided for the use of a different conversion factor for a particular product'.* MPI supports the inclusion of the conversion factor of 5.71 for soy proteins to align with Codex.
- MPI is aware that there may be some issues around FSANZ's preliminary view on amino acids which requires further consideration and reserves our position at this time.
- MPI supports lowering the maximum fat content from 1.5 to 1.4 g/100kJ to align with the Codex IF Standard.
- MPI supports the continuation of the voluntary addition of DHA to infant formula and ratio of AA:DHA as per the Codex requirements. As described below, we reserve our position on the suitability of amending the current maximum limit to a GUL.
- MPI supports the principle of lowering the maximum proportion of TFA's to align with Codex, however as the methods of analysis are different (Codex vs Food Standards Code), we support accepting and acknowledging that while dairy ingredients contribute TFA's, it is the 'manufactured' TFA's potentially added as a fat source that should be avoided. We support further analysis of this issue, taking into account the methods of analysis, for consideration at the next stage of consultation.
- We support lowering the maximum energy density to 2950 kJ/L as per Codex.

Guidance Upper Levels

No.	Section of the SD	Question
• FSANZ has provided a comprehensive overview of the current Food Standards Code (FSC) recommended maximum amounts, hereafter referred to as Guidance Upper Levels (GUL), specified within Section 29-10. • Currently the FSC specifies maximum amounts for 15 micronutrients and GULs for 14 micronutrients. The current Codex Standard for Infant Formula specifies maximum amounts for 5 micronutrients, and a GUL for a further 20 micronutrients. In addition to these, FSANZ have proposed amending the maximum limits of some essential fatty acids and nutritive substances to GUL. • The concept of a GUL is described in the Codex STAN 72-1981 with the following footnote: *Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in infant formulas should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.* • MPI supports the concept that all mandated nutrients have some form of upper limit specified within the FSC but wishes to reserve our position on how this concept is portrayed within the Schedule. • It is our view that there is some regulatory uncertainty around the purpose and application of GULs, for which we consider further discussions are warranted. Prior to supporting the continued inclusion and extension of GULs we would like to ensure that there is clarity on the practical application of these GULs to essential fatty acids, micronutrients and nutritive substances. • MPI retains the view that any upper limit must be safe and nutritionally suitable, in addition to ensuring that it is also technologically feasible. Any upper limit should take into account natural variation in the nutrient content of ingredients (e.g cow's milk and soy), bioavailability, processing losses and shelf-life stability of the ingredients, and formula matrix. • Regarding the FSANZ preliminary view that it is appropriate for some micronutrient levels to be amended from the prescribed maximum to a GUL within the Standard, MPI acknowledges that there is a paucity of evidence that can guide the derivation of maximum limits for this specific application. Despite the limited evidence, MPI considers it is important that a maximum limit is retained for those micronutrients for which a tolerable upper limit has been derived by the NHMRC/MoH for this age group (2006). These micronutrients include: selenium and zinc. Of those nutrients for which a UL has been set, MPI supports the continuation of a regulatory maximum as per FSANZ's preliminary view (Vitamin A, vitamin D and iron). • MPI notes that although ULs could not be established for infants with certainty for some micronutrients by the NHMRC/MoH, it was recommended that intakes of these nutrients should **only** be from breast milk, infant formula or food; (niacin, vitamin B6, folic acid, choline, vitamin E, copper, sodium, magnesium, iodine and phosphorous). The current maximum levels within the Standard ensure that excessive amounts of these nutrients are not provided to infants. Of those nutrients highlighted above, all have ULs derived for other age groups (including young children 1-3 years) by the NHMRC/MoH. Further consideration should be given to the continuation of maximum limits for iodine, vitamin E, vitamin B6, magnesium, iodine, copper and zinc for which excessive intakes are to be avoided.		
Q1.2	2.2	Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula? (1) "satisfies by itself the nutritional requirements of infants less than 6 months of age" (2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding " (3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of

No.	Section of the SD	Question
		infants from 6 months of age (4) no change

RESPONSE:

MPI supports alignment where possible with the Codex Infant Formula Standard. MPI's preferred definition is Option 2 as presented below (to align with Codex and to move away from specifying a set age):

Infant Formula: An infant formula product that:

(a) is represented as a breast milk substitute for infants; and
(b) satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding

The Ministry of Health (MoH) however supports Option 1 followed by Option 3. The definition of infant formula would therefore read as follows:

Infant Formula: An infant formula product that:

(a) is represented as a breast milk substitute for infants; and
(b) satisfies by itself the nutritional requirements of infants less than 6 months of age and as part of a progressively diversified diet, for infants from 6 months of age.

The MoH supports the above revised definition because firstly, it clarifies the intended age range for use of infant formula and purpose in the diet of infants depending on their age; and secondly, it is in alignment with both New Zealand and Australian infant feeding guidelines that recommend introducing solid foods at around 6 months of age.

Q1.3	3.1	Do you support a higher minimum of 0.5 g/100 kJ for infant formula based on isolated soy protein? Please provide your rationale?

RESPONSE:

Yes, MPI supports a higher minimum protein level of 0.5g/100 kJ for infant formula based on isolated soy protein, to align with Codex, and as per recent EFSA (2014) recommendations.

Q1.4	4.3	Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

RESPONSE:

Linoleic and alpha-linolenic acid requirements

FSANZ's preliminary view is that alignment with Codex STAN 72-1981 is appropriate and unlikely to pose a risk to infants for the following essential fatty acids provisions:

- maximum (GUL) for LA: although Codex GUL amount for LA is lower than the current maximum, depending on current manufacturing practice, reformulation of products may not be required as it is a guidance (advisory) level rather than a mandatory amount.
- minimum amount for ALA with no prescribed maximum for ALA
- LA:ALA ratio range.

MPI reserves its view on whether the fatty acid requirements for LA, ALA should be aligned with the Codex requirements. We note FSANZ has commented that adopting the Codex minimum for LA (70 mg/100 kJ) which is lower than that stipulated in the Code (90 mg/100 kJ) requires further review with regards to nutrient requirements. MPI therefore supports further assessment of the issues for consideration at the next stage of consultation. Furthermore we note that the compositional requirements for minimum and maximum LA and ALA are interlinked and as such all aspects should be considered together, particularly with regard to the suitability of the LA:ALA ratio.

As noted previously, MPI reserves its position on the proposed amendment from a maximum to GUL for linonelic acid. At the time of the ESPGHAN review it was considered necessary to establish maximum

No.	Section of the SD	Question
limit for LA to prevent high intakes which *may induce untoward metabolic effects with respect to lipoprotein metabolism, immune function, eicosanoid balance and oxidative stress*[1].		
Q1.5	4.5	What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale

RESPONSE:

Standard 2.9.1 does not specify or prohibit any particular sources of fat (or particular oils) used in infant formula. The Standard does however state that nutritive substances cannot be added to infant formula unless there is an express permission.

MPI is of the view that clarity is needed in relation to what can and cannot be used to manufacture infant formula with respect to the addition of certain fats. MPI provides β -palmitin as an example of an ingredient where we think greater certainty is required.

MPI has received a number of queries regarding β -palmitin. While we note it was considered by the Novel Foods Advisory Committee, this was in relation to a novel substance (the determination around its use as a nutritive substance was not in the scope of this consideration). Beta-palmitin is an example of a source of fat that requires clarification in the revised standard for infant formula. While a source of added fat may not result in any conflicts with the fatty acid requirements, the same fat source could arguably fall within the definition of novel foods or nutritive substances.

Medium Chain Triglycerides (MCTs)
MPI notes the FSANZ preliminary view, and supports a detailed assessment for consideration at the next stage of consultation (noting of course that use levels as a processing aid are significantly lower than levels that might be contributed via fats as ingredients).

Q1.6	4.6.5	What amount of lecithin is used in infant formula for technological purposes?

RESPONSE:

We do not have this information.

MPI supports the FSANZ preliminary view that the total phospholipid level should be restricted. We support further assessment, including a consideration of the appropriate maximum level. MPI has received several queries regarding the addition of phospholipids to infant formula, and we have not been able to provide definitive views. We also note that in some cases the phospholipids can be sources of other nutrients, such as serine or choline. Therefore, it is important that any permissions for phospholipids are clear, and clarify how contributions to other nutrient levels (where relevant) are calculated.

We note that the EU Directive (and the new Regulation that has replaced the Directive) and the Codex infant formula standard permit phospholipids, but with no particular source specified (with maximum levels). MPI therefore supports an approach whereby the regulatory status of ingredients such phospholipids is clarified (as outlined by FSANZ in SD1 4.6.5).

However, as with any ingredient, evidence is required regarding the reason/s for adding phospholipids, and the optimum level of addition.

Q1.7	5.1	Should the concept of dietary fibre or its prescribed methods of analysis apply to infant formula?

No.	Section of the SD	Question
RESPONSE: In our view, this requires clarification and consideration at the next stage of the consultation process. Dietary fibre permissions are regulated via specified methods of analysis, which could unintentionally capture a wide range of substances that might require pre market assessment. MPI agrees that the link between permitted dietary fibres (via the methods of analysis) and any application to infant formula does need to be clear. If the dietary fibre permissions (via methods of analysis) extended to infant formula, substances could be permitted for which there is no safety assessment for infants. MPI raised the potential overlap in our submission on A1055, in regard to other special purpose foods. There are potential regulatory overlaps, if the dietary fibre methods apply. It would therefore be inconsistent to apply the dietary fibre methods to infant on the one hand, and specifically regulate and premarket assess other dietary fibres (such as FOS, inulin-derived substances), on the other hand.		
Q1.8	5.3	What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.
RESPONSE: MPI supports an assessment of aligning with Codex, which states that “Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula, because of potential life-threatening symptoms in young infants with unrecognised hereditary fructose intolerance”.		
Q1.9	7.2.1	Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

No.	Section of the SD	Question
RESPONSE: As noted in the FSANZ proposal, the absorption efficiency of folate is lower than that of folic acid and is best considered using the unit dietary folate equivalents. In the Codex Standard for Infant Formula (CODEX STAN 72-1981) and recently agreed essential composition of follow-up formula for older infants at Step 4 (REP15/NFSDU, Appendix III) the essential compositional requirements for folate are specified as folic acid only. MPI supports the alignment with the Codex Standard for Infant Formula for which the minimum only applies to **folic acid** added to infant formula, and not any naturally occurring folate from ingredients. At present, folic acid is the only permitted form of folate to be added to infant formula products and the contribution of folate from cows' milk is generally considered to be minimal and also variable. Therefore it is not considered necessary to include the contribution from cows' milk which is less efficiently absorbed and problematic to analyse. This approach is similar with the exclusion of β-carotene from the calculation of vitamin A due to uncertainties with the efficiency of absorption and utilisation of β-carotene. MPI considers that the FSANZ's preliminary view to include folate (ug) would require further clarity. As units for folate are not currently used in the FSC it is unclear what units would be measured under this scenario and how comparable they would be to the Codex Standard and EU legislation if units are not specified? Use of folic acid (ug) only will ensure consistency with the Codex Standard, be clear as to the appropriate units and analyte to be measured. Furthermore there is not sufficient evidence presented by FSANZ to deviate from the approach outlined by Codex. *Maximum/GUL* It is noted that a tolerable upper level has not been established by the NHMRC/MoH for the 0-12 month age group and the following statement is provided: *Not possible to establish for supplemental folic acid. Source of intake should be milk, formula and food only.* It is noted that ULs have been established for folic acid for all other age groups in the population. While the basis for the UL is to prevent the masking of vitamin B12 deficiency in the elderly, it is also important to note that provision of folic acid in excess of requirements can lead to the presence of unmetabolised folic acid in the blood and this was also considered by the IOM, EFSA and NHMRC/MoH when deriving ULs. MPI notes that the consequence of unmetabolised folic acid in the blood is uncertain, but it is prudent that excessive intakes of folic acid in this population group should be avoided and suitable limits required. MPI reserves its position at this time as to the suitability of listing the upper permitted range as a maximum or GUL within the Standard.		
Q1.10	7.2.1	If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.
RESPONSE: MPI does not consider that DFEs should be included in Standard 2.9.1. as alignment with the Codex Standard for Infant formula should be sought. At the present time the FSC does not include any reference to DFEs.		
Q1.11	7.3.2	Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio? Please provide a rationale in support of your view.

No.	Section of the SD	Question
RESPONSE: FSANZ's preliminary view is that it is appropriate to change the current phosphorous maximum (25 mg/100 kJ) in Standard 2.9.1 to a GUL of 24 mg/100 kJ in alignment with Codex. FSANZ also proposes to adjust Standard 2.9.1 to align with the minimum Ca:P ratio of 1:1 as the nutrition assessment indicates that such a change would be unlikely to pose a risk to infant health, and the shift required to align is small. MPI agrees with the FSANZ preliminary view to align the Ca:P ratio to 1:1 with that of Codex and to amend the upper limit of the permitted range of phosphorous to 24 mg/100 kJ. As stated in response to Q1.1, MPI reserves its view as to the suitability of amending the maximum to a GUL at this time. We would like to highlight that ULs have been derived by the NHMRC/MoH for phosphorous for young children and that in general excessive intakes should be avoided as a precautionary approach for this age group.		
Q1.12	7.3.3.1	Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.

No.	Section of the SD	Question

RESPONSE:

MPI supports the inclusion of an elevated vitamin C max/GUL to that currently contained within the Standard and in general supports alignment with the Codex Standard for Infant Formula.

In the review of vitamin C compositional requirements for follow-up formula for older infants several eWG members have provided information on the shelf life stability of vitamin C. A summary of which is replicated below for FSANZ's consideration.

MPI reserves its position at this time as to the suitability of listing the upper permitted range as a maximum or GUL within the Standard.

Codex EWG Review of the standard for follow-up formula: 2nd Consultation Paper. June 2016

A study by MacLean and colleagues[1] compared analytical nutrient concentrations in infant formulas to the Codex Infant Formula Standard. Within this study the range of means (+2 standard deviations) of 27,920 infant formula products was 15-39 mg/100 kcal (18-72 mg/100 kcal). The paper highlights that vitamin C is *one of the most challenging nutrients for infant formula manufacture due to its considerable and variable lability. Loss over shelf life is variable, and can depend on the product form, package and is said to be considerably greater in liquids than in powders. Powder products are generally packed under nitrogen and the available oxygen that remains in the powder after packaging quickly drops to close to nothing during the first week as the antioxidants in the product react with it. Liquid products generally do not have this stability after the first week and, depending on package and shelf life, typical losses of 30–50% are not out of the ordinary; losses may go as high as 75%. Loss of vitamin C also occurs after the product has been opened. One manufacturer reported there was a loss of 35% in 72 h after ready-to-use product had been opened. By contrast, "open can" studies of powder (cans left open at room temperature for a period of up to 4 weeks) by the same manufacturer showed losses of 8–10%*[2].

More recently, a nationally representative survey was conducted in the United States whereby fifteen high consumption infant formula products were purchased from retailers at twelve different locations around the country[3]. In the US the Food and Drug Administration (FDA) require a minimum of 8 mg of vitamin C per 100 kcal of infant formula. Of the infant formulas analysed all contained more than the minimum requirement and met the label declared amounts[3]. All formulas contained less than the Codex Infant Formula Standard GUL of 70 mg/100 kcal containing between 12 and 54 mg of vitamin C per 100 kcal despite one company exceeding the declared label vitamin C value by 3.5-5.5 times[3].

A shelf study has been conducted on the nutrient levels of two varieties of infant formula (containing vitamin A as either retinol acetate or retinol palmitate) under different storage conditions (25°C and 40°C) over a period of 18 months[4]. Following storage, constant decreases in vitamin C were observed under all conditions. After 18 months of storage at 25°C losses of 20% and 34% of vitamin C were observed in the infant formula containing retinol acetate and retinol palmitate, respectively. In the infant formula containing vitamin A as retinol acetate analytical values were consistently above the declared label value under all conditions. In the formula containing retinol palmitate, vitamin C were lower than that declared after nine months at 25°C[4].

As noted by some eWG members and the evidence submitted to date, during normal storage conditions significant losses in vitamin C can occur during the shelf life of product, ranging from 20 – 50 % in powdered products. Factors affecting the stability of vitamin C can include the packaging, form of formula (powdered or liquid) and fortificants added. As such over fortification is required to ensure that adequate amounts of vitamin C can be provided during the shelf life. The GUL of 70 mg/100 kcal agreed to by the Committee at CCNFUSD37 appears adequate to ensure minimum requirements are met.

Q1.13	7.3.3.2	Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

RESPONSE:

MPI supports retaining the current minimum (0.1 mg/100 kJ) and maximum (0.5 mg/100 kJ) iron levels, particularly with regards to retaining a maximum limit. It is considered important that maximum limit is established to ensure that excessive amounts are not added to infant formula. Taking this approach separate minimum and maximum limits for formulas based on isolated soy protein are not required.

No.	Section of the SD	Question
Although there have been some studies which have shown an association between excessive iron intakes in iron replete infants with increased risk of infection, reduced growth[5], and the potential negative effective on neurodevelopment at 10 years[5,6(merged)] the levels within the current standard appear suitable based on currently available evidence[7]. At the time of the EFSA review on establishing the essential composition of formula products it was considered that the evidence was limited and does not allow conclusions to be drawn for the establishment of maximum iron content in infant formula and follow-up formula[8]. MPI notes the evidence provided by FSANZ on the review of iron requirements for infant formula and the difficulty in establishing minimum and maximum values. MPI would like to seek clarification on the following statement: *Overall, there is no international consensus on the minimum amount of iron in infant formula. Formula-fed infants have a lower risk of ID or IDA than breastfed infants and that there is evidence for inadequate iron status in some population groups of older infants*. (para 7, page 50 of SD1-Attachment 1) Is this statement referring to evidence of inadequate iron status for all infants (including breast-fed infants) as per paragraph 6, page 50 of SD1-Attachment 1? It would be useful if FSANZ could contact the researchers (Conn et al 2009; Atkins et al 2016; Wall et al 2009) involved in the studies referred to in the SD to provide further sub-group analysis on the iron status of formula-fed infants' fed infant formula within the current range of fortification in Standard 2.9.1. It should be noted that the reference to EFSA's Scientific Opinion on the Essential Composition of Infant Formula and Follow-on formula also established separate elevated iron requirements for follow-up formula for older infants noting that complementary foods cannot provide sufficient iron to cover iron requirements. EFSA recommend that i*f the same formula is to be used from the first months of infancy, and is to be suitable for the whole first year of life, the minimum iron content should be 0.6 mg/100 kcal (0.14 mg/100 kJ) for formulae based on intact cow's and goat's milk protein and formulae containing protein hydrolysates, and 0.9 mg/100 kcal (0.22 mg/100 kJ) for formulae containing ISP*[8]*.* A minor error has been made in the statement referring to the EFSA opinion in the SD 1 which implies that EFSA had suggested that ¾ of iron requirements should be met by complementary foods (para 4, page 50, SD1-Attachment 1).		
Q1.14	7.3.3.3	Do you support raising the minimum and maximum amount of selenium required in infant formula? Please provide your rationale.

No.	Section of the SD	Question
RESPONSE: MPI supports raising the minimum and maximum amount of selenium required in infant formula, in accordance with the evidence presented by FSANZ. The current minimum does not provide adequate selenium intakes to meet the selenium requirements derived by the NHMRC/MoH or other recognised authoritative scientific bodies including the IOM and EFSA[9-11]. In addition to this, the evidence from randomised controlled trials in Australia supports the need to elevate the minimum to at least 0.46 ug/100 kJ to reach selenium sufficiency[12]. MPI notes that an elevation in the minimum value from that specified by Codex and Standard 2.9.1 would be aligned with the recent revisions of both the EU[13] and US[14] regulation on the selenium requirements of infant formula products, in addition to the recommendations of Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for follow-up formula for older infants (REP15/NFSDU, Appendix II). • FSC Standard 2.9.1: Minimum amount 0.25 ug/100 kJ; maximum 1.19 ug/100 kJ • Codex IF (Codex STAN 72-1981): Minimum amount 0.24 ug/100 kJ; GUL 2.2 ug/100 kJ • Revised EU 2015: Minimum amount 0.72 ug/100 kJ; maximum 2.0 ug/100 kJ • US 2015: Minimum amount 0.48 ug/100 kJ; maximum 1.7 ug/100 kJ • Codex Follow-up Formula older infants (Step 4): Minimum 0.48 ug/100 kJ; GUL 2.2 ug/100 kJ As stated in the nutritional assessment the selenium content of breast milk content is highly geographically variable based on soil selenium levels. In Australia and New Zealand the selenium content of breast milk is lower than in other selenium sufficient countries. The recommendations of EFSA, which informed the EU regulation, were based on selenium content of human milk from selenium sufficient European mothers and to meet the selenium requirements of infants (12.5 ug/day) in the first half-year of life and rounded up to 0.72 µg/100 kJ[8]. The US FDA recently updated the selenium requirements of infant formula to 0.48 ug/100 kJ[14]. This value is based on meeting the Institute of Medicine's AI level for selenium 15 µg/day from an intake of 500 kcal per day[10], and a recent randomised controlled trial which demonstrated the improvement in circulating biochemical indicators of selenium status in selenium supplemented with both 1.9 and 3.1 µg /100 kcal[12]. The infants consuming formulas containing at least 0.46 µg selenium/100 kcal received sufficient selenium to meet their nutritional needs, however those consuming formulas containing 0.75 µg /100 kcal excreted significantly more urinary selenium, suggesting that this level may be superfluous to requirements[12]. MPI notes the difficulty in establishing a maximum/GUL based on scientific evidence where there is limited evidence available. As stated previously, MPI considers it is prudent to retain a maximum level for selenium to ensure that formulations are not consistently exceeding the UL. In addition to this MPI notes that any maximum level that is established must be technologically feasible and as such support an upper limit of 2.2 ug/100 kJ (Codex Infant Formula Standard (Codex STAN 72-1981)) which has a history of safe use and permits a reasonable range of selenium. Further insights from industry may be required on the technological feasibility of this range given the variable selenium content of cows' milk as selenium was not included in the review by MacLean and colleagues. In conclusion MPI supports further consideration of elevating the minimum selenium content of infant formula to 0.48 ug/100 kJ and aligning the maximum/GUL with the Codex Standard for Infant Formula (Codex STAN 72-1981) GUL of 2.2 ug/100 kJ.		
Q1.15	7.3.3.3	Do you support moving the maximum amount to a GUL? Please provide your rationale

No.	Section of the SD	Question
RESPONSE: MPI reserves its position at this time as to the suitability of continuing to have guidance levels specified within the standard. As discussed previously MPI notes that establishing a maximum based on scientific evidence is difficult. However, it important to take into account that tolerable upper levels have been established for selenium for infants in the Australia and New Zealand population and excessive intakes should be avoided. In general, MPI supports retaining maximum levels for those nutrients for which tolerable upper limits have been established by the NHMRC/MoH[9].		
Q1.16	7.3.3.4	Do you support aligning with the higher Codex minimum and maximum amount and converting the maximum to a GUL? Please provide your rationale.

No.	Section of the SD	Question

RESPONSE:

FSANZ preliminary view is to align with the higher Codex minimum (2.5 ug/100 kJ) and maximum (GUL) (14 ug/100 kJ) amount of iodine in infant formula.

Minimum

MPI is supportive of elevating the current minimum level to at least that specified by Codex (2.5 ug/100 kJ) to ensure that infant formula provides a significant contribution to iodine requirements. Ideally iodine requirements would be met through consumption of average quantities of infant formula (0.8 L/day). However, MPI notes that iodine requirements for infants in Australia and New Zealand are higher than those established in other countries and have not been considered in the recent review of iodine nutrient reference values by the NHMRC (2015).

It is also important to note that in the revised EU regulation the iodine composition of infant formula was amended to: minimum 3.6 ug/100 kJ and maximum of 6.9 ug/100 kJ[13].

The EFSA scientific opinion was based on the iodine requirements of infants, whereby 70 ug per day is considered adequate for the majority of infants from birth to 12 months of age[8]. Assuming that infants consume approximately 500 kcal/day it was recommended to establish a minimum of 3.6 ug/100 kJ[8].

Consumption of formula at the revised EU minimum iodine level in formula (3.6 ug/100 kJ) would equate to a concentration of 98.1 ug/L and daily intake of 78 ug (assuming the midpoint of the energy (2725 kJ/L) and average intake of 0.8 L).

A balance of meeting iodine requirements and providing a wide enough range to ensure technological feasibility is important.

Maximum/GUL

MPI supports the continued need for a regulatory maximum limit of iodine in infant formula. The level specified in the Codex Standard for Infant Formula of 14 ug/100 kJ could be appropriate.

While the NHMRC has not established an UL for iodine for infants this is accompanied by the following statement: *Not possible to establish. Source of intake should be milk, formula and food only*[9]*.* ULs derived by the NHMRC/MoH have been established for all other age groups, including young children (1-3 years) based on the evidence that excess iodine has a critical effect on thyroid function[9].

The same conclusion was also reached by the IOM (Institute of Medicine) where it is determined that a UL was *judged to not be determinable because of insufficient data on adverse effects in this age group and concern about the infant's ability to handle excess amounts. To prevent high intake, the only source of intake for infants should be from food and formula*[15].

As noted by FSANZ the FAO/WHO have derived probably safe upper limits for infants.

In the regulations in the USA and in Australia and New Zealand, maximum levels of iodine have been set for the composition of infant formula. This current scenario ensures that infants are not exposed to excessive amounts of iodine.

It should also be noted that the infant formula for export from New Zealand must also meet domestic regulation unless a 60 B exemption has been requested and as such it is important to ensure that no safety concerns could occur by removing a regulatory maximum limit. Excessive iodine intakes leading to elevated urinary iodine excretion, and subclinical hyperthyroidism has been observed in other countries where iodine levels in the soil are high.

It is also important to note that despite the variability of iodine with cows' milk used in the manufacture of infant formula, an industry led review of the Codex maximum and GULs stated that the current Codex Standard for Infant Formula GUL is technologically feasible[2]. As such MPI would consider it prudent to maintain a maximum level to ensure the safety and nutritional suitability of infant formula at a level that is technologically feasible to manufacture.

No.	Section of the SD	Question
Q1.17	7.3.3.5	Can you provide data on the chromium levels in commercially available infant formula in Australia and New Zealand? This information can be provided as 'Commercial in confidence' if required.
RESPONSE: MPI is collecting chromium data in infant formula as part of its element screen in the 2016 New Zealand Total Diet Study. The full dataset will be available in early 2017.		
Q1.18	7.3.3.6	Can you provide any data on the molybdenum levels in commercially available infant formula in Australia and New Zealand? This information may be provided as confidential commercial information.
RESPONSE: MPI is collecting molybdenum data in infant formula as part of its element screen in the 2016 New Zealand Total Diet Study. The full dataset will be available in early 2017.		
Q1.19	7.3.3.8	What information can you provide on the phytic acid content of soy-based infant formula?
RESPONSE: MPI is unaware of any specific studies on the phytic acid content of soy-based infant formulas and the uptake of phytic acid reducing technologies in ready-to-feed formula. The following studies have been published recently which may be of interest: **Vandenplas**, Y.; Guiterrez Castrellon, P.; Rivas, R et al. Systematic review with meta-analysis: safety of soya-based infant formulas in children. British Journal of Nutrition (2014), 111, 1340–1360 States that soya-based infant formulas contain 1-2% phytates. None of the studies included in the meta-analysis showed any negative impact of the content of phytates in soya-based infant formulas on anthropometric growth, Hb levels, and Ca and Zn serum levels in soya-based infant formulas fed, cows' milk formula-fed children or breast-fed infants. It is also noted that soy-based formulas contain higher levels of iron and zinc. FSANZ may wish to consider an additional review on the effect of zinc on iron absorption: **Olivares**, M., Pizarro, F., Ruz, M., Lopez de Romana, D. Acute inhibition of iron bioavailability by zinc: studies in humans. Biometals (2012) 25:657–664 This review found no negative interaction between iron and zinc when provided in infant formula.		
Q1.20	7.3.3.8	Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?
RESPONSE: MPI is not aware of any technical issues, but notes that if the Codex approach to defining copper minimum and maximum values is taken, then a zinc to copper ratio would not be appropriate.		
Q1.21	7.3.3.8	Should a Zn:Cu ratio be retained. If so, what should it be and why? If not, what is your rationale?

No.	Section of the SD	Question
RESPONSE: MPI supports FSANZ's preliminary view that a zinc to copper ratio is not necessary. Regarding the maximum zinc content of formula, MPI supports retention of a maximum level to ensure that zinc fortification does not markedly exceed the tolerable upper level established by the NHMRC/MoH and lead to impaired copper absorption. Both the Codex Standard for Infant Formula and current FSC maximum exceed the UL for infants (4-5 mg/day). The UL for zinc for this age group has been noted as being inappropriately low due to the large numbers of children with usual intakes greater than the UL with no known adverse consequences, and due to the paucity of data available to derive the UL[16,17]. The current Codex and FSC maximum/GUL are able to accommodate the higher levels of zinc in soy-based formulas.		
Q1.22	8.1.1	What is the justification to retain β-carotene as a provitamin A form?
RESPONSE: MPI supports the preliminary view that β-carotene should not contribute to the calculated vitamin A activity of infant formula, as per the Codex Standard for Infant Formula. We are unaware of the justification to add β-carotene as a provitamin A form and await further discussion on this issue prior to determining if β-carotene should continue to be permitted for use in infant formula within the FSC.		
Q1.23	8.3	What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?
RESPONSE: MPI has no comments.		
Q1.24	9.1	Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.
RESPONSE: MPI supports FSANZ's preliminary view that choline should be listed as a mandatory substance in infant formula within a range of 1.7–12 mg/100 kJ. MPI supports further consideration as to whether the upper end of the range is listed as a maximum of GUL, particularly with regards to the establishment of ULs for other age groups. This view is aligned with the Codex Standard for Infant Formula and recently reviewed EU legislation.		
Q1.25	9.1	What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
RESPONSE: MPI has no information to support the technological justification for the use of choline citrate and/or choline hydrogen tartrate in infant formula.		
Q1.26	9.1	If you have provided a technological justification for these forms of choline can you provide: (a) reference to a specification for choline citrate and/or choline hydrogen tartrate in an internationally accepted monograph of specifications (including those referenced in Standard 1.3.4)? (b) evidence to demonstrate safety can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?
RESPONSE:		

No.	Section of the SD	Question
MPI has no further information to provide.		
Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
RESPONSE: MPI supports FSANZ's preliminary view that L-carnitine should be listed as a mandatory substance in infant formula containing a minimum of 0.3 mg/100 kJ. This view is aligned with the Codex Standard for Infant Formula and recently reviewed EU legislation. MPI supports further consideration as to whether a maximum or GUL is required, taking into account the natural variation of L-carnitine in cows' milk and technological feasibility. It is noted that the recently reviewed EU legislation does not contain a maximum limit.		
Q1.28	9.2	What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
RESPONSE: MPI has no further information to provide.		
Q1.29	9.2	If you have provided a technological justification for these forms what evidence to demonstrate safety can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?
RESPONSE: MPI has no further information to provide.		
Q1.30	9.3	Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.
RESPONSE: MPI supports FSANZ's preliminary view that inositol should be listed as a mandatory substance in infant formula containing 1.0-9.5 mg/100 kJ. This view is aligned with the Codex Standard for Infant Formula and recently reviewed EU legislation. We supports further consideration as to whether the upper end of the range is listed as a maximum of GUL.		
Q1.31	9.3	Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?
RESPONSE: MPI supports either approach.		
Q1.32	9.4	Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?
RESPONSE: At this time, we are unaware of any issues related to the drafting of the maximum amount of nucleotides in the revised Code.		

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No.	Section of the SD	Question
Q2.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.

RESPONSE:

Comments relating to section 3 of SD 2

- Both MPI and MoH support retaining the labelling requirement and instruction to prepare each bottle of infant formula individually as this aligns with WHO Guidelines and New Zealand Formula Feeding Guidance.
- Both MPI and MoH support retaining the existing requirement for the label of infant formula to include words and pictures instructing that formula left in the bottle after a feed must be discarded.
- At this stage of the consultation, both MPI and MoH support FSANZ's preliminary view to maintain the existing overarching requirement in subsection 2.9.1 – 19(3) which does not prescribe the words and pictures for the instructions that must be used on the label. MoH considers that whilst standardised directions may assist consumers by giving consistent advice across infant formula brands, MPI and MoH do not have any evidence to support the notion that consumers are confused by different presentations of this information between products. MoH appreciates that it would be difficult to implement a standardised approach as New Zealand and Australian infant feeding guidelines differ, and therefore there would need to be agreement on the directions. In addition, the preparation ratio of scoops to water may vary across brands so this advice could not be standardised.
- MPI notes the FSC requirement for a label of infant formula to include a direction instructing that if a bottle of made up infant formula is to be stored before use, it must be refrigerated and used within 24 hours. MPI can support this direction *provided* that this instruction also states the temperature at which the fridge must be operating if storage for this duration is to be safe, that being at or less than 4ºC. MPI therefore requests that the FSC stipulates that the label of infant formula must include a direction instructing that if a bottle of made up formula is to be stored prior to use, it must be refrigerated **at or less than 4ºC** and used within 24 hours.
- However, MoH notes that the current requirement in the FSC differs to current advice for New Zealand, which states that reconstituted infant formula should be stored in the bottom of the fridge, at the back (2 – 4 degrees Celsius) for no more than 4 hours. This advice was confirmed in a recent review on the microbiological safety of reconstituting powdered infant formula published on the MoH website at:
  http://www.health.govt.nz/our-work/environmental-health/food/microbiological-safety-reconstituting-powdered-infant-formula
  The basis for MoH advice is that reconstitution temperature impacts on relative risk associated with subsequent handling parameters, eg storage, and from a risk perspective, a shorter storage time is required to restrict pathogen growth in formula following reconstitution with water at ambient temperature compared with water at 70◦C. In response to MPI's request to stipulate a refrigeration temperature at or less than 4ºC on the label, the MoH does not consider that inclusion of this information will reduce risk to infants. Surveys confirm that less than half of domestic refrigerators in New Zealand households operate in the ideal range of 2 - 4ºC and a significant proportion have temperatures > 6ºC (Gilbert S, Whyte R, Bayne G, et al, 2007 Survey of internal temperatures of New Zealand domestic refrigerators. British Food Journal; 109: 323-329).
- MPI and MoH request that consideration is given to extending the direction 'that each bottle should be prepared individually' to state that it should also **ideally be consumed immediately.** MPI also supports an approach whereby the FSC clearly articulates that manufacturers may specify a time of less than 24 hours on the label.
- Suggested drafting is shown below:

  a) that each bottle should be prepared individually, and **ideally consumed immediately**
  b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated **at or less than 4ºC** 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.

- Section 3.4.5 of SD 2 states that the current requirement in the FSC is to use '*cooled* previously boiled water'. This is not the case. MPI and MoH note that paragraph 2.9.1 -19 (3)(c) requires that the label instruct that 'potable, previously boiled water should be used'. Note the absence of the word *'cooled'.* It does however raise the issue as to whether the FSC should specify the temperature at which water should be for the reconstitution of powdered infant formula, such as 'cooled to room temperature' to avoid insufficient cooling of water which may result in reconstitution of powdered infant formula at the peak temperature range (37 – 43° C) for optimum Cronobacter growth. New Zealand does not support aligning with the WHO recommendation to use water at or above 70 degrees.
- The MoH comments that while they support retaining (e) as above relating to discarding formula, they suggest adding "within 2 hours', to minimise misinterpretation.

Comments relating to section 4 of SD2

- Section 4.1 - MPI agrees that the current requirements should be maintained, that is, that infant formula should be required to have a date mark. In response to FSANZ's question about issues, MPI can report that we do receive queries regarding the date mark used, ie should it be a use-by or a best-before. MPI has provided advice that a use-by could be more appropriate, as the nutritional value could deteriorate after a certain period of time, and after that time a best-before date would not be appropriate. MoH also supports the use of a 'use-by-date' in preference to a 'best-before date'. As infant formula provides the sole or principal source of nutrition to infants, MoH is of the view it should be treated differently to other packaged foods. The rationale for this approach, it that the nutrient content of powdered infant formula diminishes over time. MPI supports further consideration of this point – if the date mark is always a use by, this should be specified.

  MPI supports retaining the current requirement for infant formula to include storage instructions covering the period after the product has been opened on the label. This aligns with Codex requirements, and helps to ensure safety of the product after opening.

  <u>*Inaccurate volume indicators on infant feeding bottles*</u>
  MoH notes that the issue has been deemed by FSANZ as out of scope. MoH is of the view that ensuring that the correct volume of water is used to reconstitute formula is the infant formula manufacturer's responsibility. MoH therefore propose that the standard includes a requirement for an accurate measuring container/device to be included with the powdered infant formula container (similar to the scoop).

Comments relating to section 5 of SD2

- Clarity is required so that it is clear that the 'name of the food' relates to the prescribed name 'Infant Formula' and not the brand name.
- MPI and MoH support maintaining the current FSC requirement to label the protein source on the label of infant formula – immediately adjacent to the name.
- MPI and MoH support mandating that both the prescribed name 'Infant Formula' and the protein source which should be immediately adjacent (or more clearly articulated as co-located) with the prescribed name, and should appear on the front panel of the label (front of pack). This is consistent with the Codex General Standard for Food Labelling, which requires the name of the food to be in a prominent position (paragraph 8.1.4).
- The FSC is not clear as to whether the requirement to label the protein source on the label of infant formula immediately adjacent to the name should occur every time that the prescribed name appears on the label. We are of the view that the requirement to label the protein source needs to only appear once on the label, provided this statement is in a prominent place – such as on the front of pack and co-located with the prescribed name.
- Section 5.3 clarifies the detail on protein source, and that sometimes more detail is provided voluntarily (e.g. casein dominant is stated, whereas the minimum requirement is to state that the source is cow's milk). In our view, the current FSC is not clear, and this requirement should be clarified in any revised standard.
- MPI supports retaining the existing warning statement regarding 'breast is best'.

Q2.2	5.2	What evidence can you provide that could be used to estimate the prevalence of

No.	Section of the SD	Question
		the practice of caregivers adding other foods to infant formula in Australia and New Zealand?
RESPONSE: MPI has no comments.		
Q2.3	5.2	What evidence can you provide on whether this practice is more common with powdered infant formula products compared to liquid concentrate or 'ready to drink' products?
RESPONSE: MPI has no comments		
Q2.4	5.2.	What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?
RESPONSE: MPI has no comments		
Q2.5	5.4	What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?
RESPONSE: MPI has no comments		
Q2.6	5.4	What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?
RESPONSE: MPI has no comments		
Q2.7	5.4	If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?
RESPONSE: Please see response above, where we provide our view that the protein source declaration should be on the front panel, in association with the prescribed name of the food (Infant Formula). Another reason for this added requirement is to avoid confusion by caregivers as to the product. Line marketing of products means labels have reference to other products, so a prominent name of the product on the front panel helps avoid confusion by caregivers. MPI suggests that if no evidence or information is forthcoming as a result of this consultation, that research could be undertaken to further inform this question to stakeholders.		
Q2.8	5.4	What are the cost and trade implications of prescribing the position of the statement of protein source ion the label?
RESPONSE: MPI has no comments.		
Q2.9	5.9	What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?
RESPONSE: MPI has no comments.		
Q2.10	5.9	Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?

No.	Section of the SD	Question
RESPONSE: MPI has no comments.		
Q2.11	5.9	What data are available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements (in addition to their normal diets)?
RESPONSE: MPI has no comments.		
Q2.12	5.9	What advice is given by health care professionals and/or state and territory government agencies on whether vitamin and mineral supplementation is needed for formula-fed (or breastfed) infants?
RESPONSE: The New Zealand Ministry of Health Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2): A background paper - Partially revised December 2012, states the following: *'Full-term infants fed breast milk or infant formula should not require supplements of vitamins, minerals or other nutrients. A mother with a very poor diet can have relatively low levels of iodine, some B vitamins and vitamin C in her breast milk (Fomon and McCormick 1993), but even in extreme cases, it would usually be better to give the vitamin supplements to the mother rather than to the infant. In New Zealand, there is no evidence of benefit from giving nutritional supplements to infants and toddlers who are adequately fed. Those who do develop a vitamin deficiency have usually had a diet inadequate in quality or quantity. In these cases, a change in diet is the correct course of action.'*		
Q2.13	5.9	What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?
RESPONSE: MPI has no comments.		
Q2.14	6	Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

No.	Section of the SD	Question
RESPONSE: Section 6 provides a summary of the problems associated with the current FSC definitions and application of the terms nutritive substance and novel foods. FSANZ has summarised the issues clearly, and MPI concurs that the issues identified are ones that are regularly faced by MPI. We appreciate that P1024 (Nutritive and Novel Substances) could inform the regulation of these substances in infant formula. Substances in infant formula will of course need to be regulated differently, given the vulnerable population group (as identified by FSANZ in Section 6.4.3). In moving to a new regulatory regime it is important to identify what substances/ingredients can be added without explicit permissions, compared to those requiring a premarket safety and suitability assessment. MPI does not support applying the regulatory principles to be developed under P1024 to infant formula, as the policy guideline clearly states that substances used in infant formula require a higher level of regulation, than those in general purpose foods. Additionally, infant formula is a sole source of nutrition for a vulnerable population group. Section 6.4.1 articulates two points of view with respect to the intent of the policy guideline, and the premarket assessment of substances. MPI agrees with the second interpretation provided by FSANZ, ie that premarket assessment is required of only certain substances (and is not intended to apply to every formulation adjustment). MPI notes (i.e the summary in Section 6.5) that FSANZ is yet to develop its approach to the regulation of novel foods and nutritive substances in infant formula, and that the regulatory approach for the addition of new substances to infant formula will progressively develop over the course of this Proposal. Question Q2.15 asks if all or only certain substances proposed for use in infant formula require premarket assessment. All substances do require an assessment of safety, but a framework needs to be developed that guides this – some will need a premarket assessment, others will fall into the already approved ingredients and substances. For example, if the types of fats that are safe and suitable are more clearly described, some may fall into existing permissions and not require preapproval. We note that clause 6 of Regulation (EU) 2016/17 states that the voluntary addition to infant formula of ingredients not covered by specific requirements of the Regulation should be possible to allow for innovation and product development. The proviso is that: *'All ingredients used in the manufacture of infant formula and follow-on formula should be suitable for infants and their suitability should have been demonstrated, when necessary, by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities to consider, on a case-by-case basis, whether this is the case. Guidance on the design and conduct of appropriate studies has been published by expert scientific groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Such guidance should be taken into consideration in the manufacturing of infant formula or follow-on formula'.* As articulated above, a framework needs to be developed to guide what ingredients/substances would require premarket assessment. MoH is of the view that all substances proposed for use in infant formula should require a pre-market assessment due to the vulnerability of infants and their reliance on infant formula as a sole or principle source of nutrition. Rationale for this position is that any substance used in infant formula needs to be safe and proven to provide a benefit to formula-fed infants.		
Q2.15	6	What would be the cost and trade implications of your preferred position?
RESPONSE: The position described above is not detailed enough to be able to respond to this question at this time. However, we support consistency with regimes applying internationally, in order to facilitate trade.		
Q2.16	6	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?

No.	Section of the SD	Question
RESPONSE: We support further development of the definitions for novel foods and nutritive substances (or an all-encompassing term or framework that clearly defines what they are). This will ensure regulatory clarity, and therefore where the line is drawn between those substances that meet the definition (and therefore require a premarket assessment), and those that do not.		
Q2.17	6	If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

RESPONSE: As noted above, we think this can be achieved by improvements to the definitions for novel foods and nutritive substances (or an alternative term or framework).		
Q2.18	7.3	What evidence can you provide as to whether this proposed ML would/would not be achievable in soy-based formula? Reference should be made to relevant concentration data in soy-based formula products where possible.
RESPONSE: In relation to section 7.1, and the table 7.1, MPI comments that the last column headed "potential amendments to the Code to align with Codex' is confusing with regard to Aluminium. While Codex does not set an ML, JECFA has recognised that aluminium is a contaminant of concern. JECFA has set a PTWI and commented that MLs need to be compatible with that PTWI. MPI supports MLs aluminium. Reference to the JECFA PTWI should be included in the summary table. Additional comment on section 7.1. In relation to arsenic, we note the FSANZ preliminary view, which is that there is no specific need to establish an ML for arsenic (inorganic). However, Codex does set an ML for inorganic arsenic in polished rice and is in the process of adopting a limit for husked rice. We are not aware of rice being used in infant formula (eg a non-dairy infant formula), but if it were to be, then an ML would be appropriate.		
Q2.19	7.3	What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?
RESPONSE: MPI has no comment on this.		
Q2.20	7.5	What are the cost and trade implications of reducing the ML for lead in infant formula?
RESPONSE: MPI support the reduction in the lead ML to harmonise with that set by Codex. Previous industry advice provided to MPI in advance of the Codex ML change was that the new ML was readily achievable.		
Q2.21	7.6	What if any, issues are associated with not including the Codex ML in the Code for melamine?
RESPONSE: MPI considers that FSANZ should not rule out the setting of an ML for melamine in infant formula. As FSANZ notes, Codex has set limits for melamine in infant formula. Melamine can be detected in powdered dairy products, as a result of filters that have a melamine component. The Codex levels are above the limit of detection of melamine, and are achievable. We therefore support further consideration of an ML for melamine, consistent with Codex.		
Q2.22	7.10	Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.
RESPONSE: MPI supports continued application of MLs to the products as consumed. This avoids having two values in the FSC – one for powder, and one for the ready-to-drink product.		
Q2.23	7.11	Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?

RESPONSE: MPI supports a future review being undertaken of contaminant definitions for contaminants applying specifically to infant formula.		
Q2.24	7.11	Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?
RESPONSE: MPI supports a future review being undertaken of contaminant definitions for those substances which apply to general foods, including infant formula.		
Q2.25	8.2.2	What is the technological purpose for using the following 12 substances in the production of infant formula – INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525? i.e. are they best described as food additives, processing aids or permitted forms of minerals? Please explain and provide examples of how they are used in the manufacture of infant formula.
RESPONSE: We support the approach, ie that FSANZ seeks information on the technological purpose of the additional additives permitted in the GSFA. However, JECFA is currently considering which additives permitted in the GSFA (for infant formula) might not have an acceptable JECFA assessment. This could mean that some additives currently permitted in the GSFA for infant formula might ultimately be removed. The relevant wording in the 2016 CCFA meeting report (paragraph 15)is as follows: *The JECFA Secretariat noted that it would report on the status of JECFA safety assessments of food additives in infant formula at the next session of the Committee*. It is important to note this review by JECFA, when considering what new permissions are appropriate in the FSC. It would be premature to adopt all Codex permissions for additives in infant formula, when some might be revoked due to the JECFA work outlined above. We do however support the provision of information by industry on the technological need for Codex-approved additives, not currently permitted in the FSC.		
Q2.26	8.2.2	What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?
RESPONSE: We support the approach, ie that FSANZ seeks information on the technological purpose of the additional additives permitted in the GSFA.		
Q2.27	8.2.2	What, if any, information can you provide to support an assessment of an extension of use of a food additive in infant formula?
RESPONSE: We support the approach, ie that FSANZ seeks information on the technological purpose of the additional additives permitted in the GSFA.		
Q2.28	8.2.2	To what extent is 472c used in IFPSDU? Is it widely used, and are the levels used close to the maximum permitted level in the Code?
RESPONSE: We support the approach, ie that FSANZ seeks information on the technological purpose of the additional additives permitted in the GSFA.		
Q2.29	8.2.3	What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?
RESPONSE: We support the alignment of food additive class names with Codex. INS class names are updated on an ongoing basis, and the Food Standards Code should be updated when these changes occur so they can		

be incorporated. However, we see this as a separate exercise and it should update all food additives nomenclature. A further point is that the additive provisions under Codex, some additives are further subdivided by numerical subscripts such as I, ii, iii. These identify sub-classes which are covered by separate Codex specifications. The effect of the Food Standards Cdoe using "parent" additive names without further specification is that when Codex adds more forms of the additives to these (as noted above, these are usually designated with lower case Roman numerals (eg i ii,iii,iv etc) these are automatically picked up in our FSC. For example, sodium citrate covers sodium dihydrogen citrate, disosdium monohydrogen citrate and trisodium citrate (ie 331 i, ii, and iii). Interestingly in this case, the Codex GSFA does not permit disodium citrate INS 331(ii) including in infant formula. MPI believes that FSANZ could consider updating the INS numbers in the review of infant formula, so that the additive permissions align with Codex. This will ensure consistency with Codex, and ensure that product is not manufactured (including for export) with additives not permitted under Codex (such as INS 331 (ii)). At some point, MPI considers that this task should be completed for the Food Standard Code as a whole.		
Q2.30	8.2.4	Will lowering the MPL of hydroxypropyl starch to 5000 mg/L create any difficulties for infant formula companies?
RESPONSE:		
Q2.31	8.3	Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

RESPONSE:

The '**carry-over principle'** should not apply to infant formula. See however comments below on when **'carry-over'** can apply.

We agree with the reasons FSANZ has noted in SD2 (i.e. consistency with the Codex GSFA and Infant Formula Standard). We support the interpretation that the current FSC does not permit carry over of additives (unless there is an express permission for that additive to be added directly to infant formula). In our view, additives in infant formula should have an express permission. Tighter controls should apply to additives used in infant formula, as the food can be the sole source of nutrition for a vulnerable population group.

Under Codex:

GSFA: Section 4.3 of the GSFA prohibits infant formula from having non-permitted food additives, as a result of carry-over from ingredients used.

Codex Infant Formula Standard (STAN 72-1981) : Section 4 of the Codex Infant Formula Standard (STAN 72-1981) does not permit carry-over of food additives in infant formula, unless the additives are permitted additives. In addition, some additives are listed as permitted additives in nutrient preparations, as listed in CAC/GL 10-1979 (see below for more discussion).

We believe there is some confusion regarding the use of the term 'carry-over' and the 'carry-over principle'. It is important to communicate to stakeholders that by **not** applying the carry-over principle to infant formula (i.e as per Codex), then:

- 'Carry-over' (from raw materials to the final food) is **not** permitted when there is no specific permission for the food additive in the standard
- 'Carry-over' (from raw materials to the final food) is permitted when there is a specific permission for the food additive in the standard.

Codex Guideline CAC/GL 10-1979 (Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children)

Codex Guideline CAC/GL 10-1979 allows a limited number of food additives (as listed in Section D) to be permitted in **nutrient preparations** added to infant formula (and other infant or young children products). This document is also referred to in CODEX STAN 72-1981, Section 4.

The only relevance of CAC/GL 10-1979 to the FSANZ consultation for P1028 is to permitted food additives in **nutrient preparations**, and is not a specific provision allowing for carry-over of the additives listed in Section D, in other ingredients.

MPI's view is that the list of additives in Section D of CAC/GL 10-1979 should be considered for inclusion under P1028, but only with respect to added nutrients/nutrient preparations. This ensures consistency with Codex.

Additives in additive preparations

Another consideration, is the use of additives in additive preparations (i.e. Food Category 0 in the Food Additive schedule, of the Food Standards Code – previously Food Category 0.1`in the former Code), used in infant formula products. It is our view that the current Food Standards Code might require that additives in additive preparation should not be contained in infant formula. This might not be the intent, and is another aspect of the regulation of food additives that requires consideration and clarification in any revised standard for infant formula. For example, the scope of Food Category 0 could be limited, to exclude infant formula. A risk analysis could be conducted, to determine if this approach is warranted. While such an approach might appear onerous, it avoids the situation of unexpected additives in the end product of an infant formula, and possible restrictions on sale when traded or sampled in Australia or New Zealand under routine testing.

Furthermore, we note that in some cases, the additives used in additives could be treated as processing aids. For example, some of these may function as "carriers" to help blend the additive or nutrient into the final food. This may be seen as being consistent with the definition of substances used as a processing aid in that they have no effect in the final food.

In summary, we note that food additives can be added directly to infant formula to perform a technological function in the formula. Direct addition is clearly limited to specific additives and is subject to maximum levels in the final formula. The same additives could be added to:

- an ingredient to perform a technological function in that ingredient, or

		• to a preparation of an additive or nutrient or • as a processing aid in an ingredient or additive or nutrient. In our view, regardless of how food additives are introduced into infant formula, they should be limited to those that are allowed to be directly added and such that maximum levels set for direct addition are not exceeded.
Q2.32	8.4	Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?
RESPONSE: Before responding to this question, the last sentence of section 8.1.2.1 correctly states that the CCNFSDU and CCFA agreed to retain the current permission for use of carrageenan in infant formula. It is important to note the restriction that applies, being that it is only permitted for use in the liquid ready to drink products (as sold). A technological need has not been demonstrated for its use in **powdered** infant formula. While JECFA's conclusion related to safety *per se*, the only permission under Codex is for the 'liquid ready to drink' form, which has a demonstrated technological purpose. Regarding the details of the technological justification for carrageenan in liquid ready to drink soy formula, we defer to information that industry will provide. MPI suggests that future references to 'liquid' infant formula use the term 'ready to drink' infant formula (as this is the term used currently, and is clearer).		
Q2.33	8.4	Do submitters believe the current permissions in the Code permit carrageenan in soy-based infant formula?
RESPONSE: We agree that the current FSC is unclear in this respect. We suggest that the original proposal is consulted, as this might establish the intent. However, it would seem reasonable that if there is a technological need for carrageenan in liquid ready to drink dairy based formula, the same technological justification could apply to liquid ready to drink soy based formula.		
Q2.34	8.4	Will the correction of the hydroxypropyl starch MPL to the lower level of 5000 mg/L cause any issues? Are you aware of any infant formula marketed in Australia and New Zealand that uses hydroxypropyl starch as a food additive at levels above?
RESPONSE: We support the provision of this information from industry, for consideration at the next consultation.		

Supporting Document 3: Provision of Information

No.	Section of the SD	Question
Q3.1	2.1	Should claims about specific ingredients be permitted on packaged infant formula? • If no, then why not? • If yes, then how should they be regulated?

No.	Section of the SD	Question
RESPONSE: FSANZ has stated that they are not proposing to change the prohibition contained within Standard 1.2.7 – Nutrition, Health and Related Claims, which states that infant formula products are not permitted to carry nutrition content claims and health claims. MoH supports the continuation of the prohibition on health claims and nutrient content claims. MPI however wishes to make the following comments: FSANZ has communicated that claims on infant formula products were 'extensively considered and consulted on' as part of Proposal P293. MPI notes that the 2007 Preliminary Final Assessment Report for P293 states: *'The function of the health claims proposal is to develop a horizontal standard, not focus on vertical applications such as Part 2.9 Standards. When Part 2.9 is addressed, if the horizontal provisions for claims as provided by Standard 1.2.7 are not considered suitable, specific provisions around claims can be provided in the Part 2.9 Standards and these will automatically override Standard 1.2.7'.* Rather than look at individual declarations (such as permitting claims about specific ingredients) MPI would support an approach whereby the totality of issues relating to declarations about nutrients and nutritive substances, ingredient claims, nutrition content claims, communication of product reformulation, declaration of macronutrient subgroups etc. are considered, consulted on, and discussed in an open and transparent manner, allowing all stakeholders to express their view, and giving due consideration as to whether the prohibition on claims for infant formula products should remain Whilst MPI supports the continued prohibition on health claims on infant formula, we would support consideration of 'nutrient content claims' in an open and transparent manner. Such an approach would entail consideration of what (if any) nutrition content claims are permitted (on mandatory and optional ingredients), and setting out of the permissions and prohibitions in the revised standard. The current standard can be viewed as ambiguous, in relation to the declarations that can be made about nutrients, nutritive substances, macronutrient subgroups, ingredients etc. A thorough review of 'claims' on infant formula would provide an opportunity for this ambiguity to be removed and clarity provided around the permissions and prohibitions. Further to this, Section 1.2.4 of SD3 states that *'FSANZ must have regard to the promotion of consistency between domestic and international food standards'*. With respect to the provision of information on the label of infant formula, it appears that SD3 only looks to relevant Codex documents as an international comparator. New Zealand suggests that it would be beneficial to look wider than Codex, especially to infant formula regulations for New Zealand's major trading partners for this commodity to see what 'provision of information' (including content claims) is permitted. This would provide a more global picture. Section 2.1 of SD 3 discusses the uncertainty around referencing particular ingredients on the label. An interpretation is that references to ingredients usually imply some sort of property about the food, so are implied references to nutrients (and are therefore not permitted). An example would be reference to fish oil, which is implied to be a reference to omega 3. As there is regulatory uncertainty, consideration should be given as to how this could be managed.		
Q3.2	2.3	Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

No.	Section of the SD	Question
RESPONSE: MPI does not have the necessary data with which to respond to this question. Independent research to collect such data would be warranted. It is critical to know whether the provision of this information would be helpful, neutral or confusing to caregivers and health professionals, before consideration to proceed with allowing its provision. MoH recommends FSANZ consult with relevant groups within the health sector including Plunket, Dietitians New Zealand and NZ College of Midwives on this issue to gain a better understanding of whether the provision of this information would be useful.		
Q3.3	2.3	Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?
RESPONSE: Yes. In our view, providing additional information in the Nutrition Information Statement could be permitted if this would provide further clarity for consumers and health professionals. To facilitate this, the FSC would need to be amended to allow this, without it being regarded as a nutrition content claim. However, in order for this to be not misleading, this would need further consideration, as FSANZ has already identified in the questions which follow. We note that clause 14 of Regulation (EU) No 2016/127 allows infant formula manufacturers to voluntarily include more detailed information on the label for protein, carbohydrate and fat present in the infant formula as this additional information could provide 'useful information for parents, caregivers and healthcare professionals' and as such it should be allowed. MPI supports consideration of such an approach. If subgroups of macronutrients are added to the infant formula or declared in the ingredient list, it could be viewed by some as misleading the consumer/purchaser if this declaration is made in the ingredient list but the amount of the added ingredient is not declared in the NIS, particularly if the level of addition is insignificant.		
Q3.4	2.3	Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).
RESPONSE: This does require further consideration, as the omission of certain subcategory information could become misleading (for example, if certain undesirable fat or carbohydrate subgroups were omitted). Therefore, our preliminary view is that while this concept is appealing, it requires careful consideration by stakeholders, in order to ensure the transparent declaration of all components.		
Q3.5	2.3	If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).
RESPONSE: At this preliminary stage, MPI considers that this should be based around defined principles. In order to help stakeholders form a view, we suggest that different options are developed, based on the compositional requirements and provided for consideration at the next stage of public comment.		
Q3.6	2.3	If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

No.	Section of the SD	Question
RESPONSE: In our view, this is a possibility, however to be sure, the ultimate proposal developed on this system would need to be consumer tested. However, in the absence of this information and details of the principles that might apply, we think the benefits (i.e. more information provided) could outweigh any potential issues around misleading caregivers.		
Q3.7	2.3	What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?
RESPONSE: FSANZ may wish to consider an approach whereby permission for declaration of subgroups of macronutrients in the NIS is permitted, but not mandated, allowing manufacturers to comply with labelling requirements of overseas markets.		
Q3.8	2.4	Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?
RESPONSE: MPI does not have any information to provide.		
Q3.9	2.4	Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?
RESPONSE: MPI is not aware of any issues with the current requirements, and therefore is not aware of reasons to change the approach.		
Q3.10	2.5	Which base units of expression do stakeholders find to be of greatest value?
RESPONSE: MPI has no comments		
Q3.11	2.5	Is there any evidence that caregivers are confused by the use of different base units of expression?
RESPONSE: MPI has no comments		
Q3.12	2.5	In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?
RESPONSE: MPI is not aware of any issues with the current requirements, and therefore are not aware of reasons to change this approach.		
Q3.13	2.5	What would the cost and trade implications be of mandating these base units?
RESPONSE: MPI has no comments		
Q3.14	2.5	Should the voluntary use of the base unit of per 100 kJ be permitted?
RESPONSE: MPI is not aware of any reasons why the information could not be provided voluntarily.		
Q3.15	2.6	What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?

No.	Section of the SD	Question
RESPONSE: MPI considers that consistency with other wording in the FSC is desirable. Clarity is however required on the levels of nutrients that are required during shelf life (and degradation). Does average quantity mean the average amount added (allowing for batch variation), and is this average quantity required to be detected during the shelf life of the product? It is our understanding that any declared label values should be present at the end of the products shelf life.		
Q3.16	2.7	Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?
RESPONSE: MPI has no comments		
Q3.17	2.7	Would a consistent approach to format across product labels assist consumer understanding of this information?
RESPONSE: MPI is not aware of any confusion with the current approach (whereby the format is not consistent).		
Q3.18	2.7	If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?
RESPONSE: MPI has no comments		
Q3.19	2.8	How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?
RESPONSE: MPI agrees that this question does require a consideration of options, so that caregivers are informed, but the communication is not used as a method to make nutrient content or health claims. A prescribed format or wording could be considered, to communicate such changes.		
Q3.20	2.8	What information about the change in composition would caregivers and health professionals find useful?
RESPONSE: MPI has no comments		
Q3.21	2.8	What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?
RESPONSE: MPI has no comments		

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