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FSANZ Consultation paper – Proposal P1028: Infant formula

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Food Standards Australia New Zealand

Proposal P1028: Infant formula

The opportunity to provide a submission about the revision and clarity of standards relating to infant formula is very timely given the recently released World Health Organisation, UNICEF, and International Baby Food Action Network (IBFAN), report on the marketing of breast-milk substitutes that revealed the status of national laws to protect and promote breastfeeding and to protect infants being fed on breast-milk substitutes in 194 countries. [1]

135 countries, out of the 194 analysed in the status report, have in place some form of legal measure related to the International Code of Marketing Breast-Milk Substitutes, [2] and subsequent, relevant World Health Assembly resolutions,[3] [4] and this number has increased by 35 since the last analysis which was carried out in 2011. The International Code is now 35 years old, so it is disappointing to note that only 39 countries out of the 194 reviewed have laws that enact all International Code provisions. The International Code, and the essential updates in the form of the World Health Assembly resolutions, are designed to not only protect breastfeeding by stopping inappropriate and misleading marketing of breast-milk substitutes, bottles and teats, but to also protect infants fed on breast-milk substitutes. Just as parents should have access to unbiased, commercial-free, information about infant feeding, health professionals also need a source of unbiased, scientific and factual information. Interested and well informed health professionals also need their views to be taken into account when they are providing evidence and research-based information to contribute to the health and well-being of infants. As highlighted in this consultation process there is a serious shortage of research conducted in the area of parental/caregiver understandings and infant formula usage practices (2.3-2.7).

A recent Lancet Series on breastfeeding contained the economic argument for breastfeeding, and the need for protection of breastfeeding and infant feeding, via the International Code of Marketing of Breast-Milk Substitutes. McFadden et al, called for a coordinated global action to combat inappropriate and misleading marketing. [5] In the 'Marketing of breast-milk substitutes: National implementation of the International Code – Status report 2016', WHO/UNICEF and IBFAN urge countries who have not yet adopted legal measures to do so. With the aggressive and

misleading marketing of breast-milk substitutes continuing largely unabated, and the global sales revenue of US$44.8 billion, which is expected to rise to US$70.6 billion by 2019, the report highlights the need for urgent action to regulate and protect parents from misleading information, thereby enabling some protection for babies being fed with formula products. This includes the need for attention to all aspects of product labeling, product content, added ingredients, misleading health claims and preparation instructions.

The International Code contains a key statement that relates to the reason why there was a need to develop such a Code, and why there is a need to continue to update the Code regularly via the World Health Assembly resolutions.

"… in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products." [6]

On March 3rd 2015 the Commerce Commission released a draft determination with a preliminary decision to grant authorisation for the restricted practices sought by the Infant Nutrition Council (Formula Marketers Association), and on April 2nd the final determination was released with the final approved authority.[7] The Commerce Commission determination represents possibly the only attempt to estimate health care savings related to breastfeeding rates in New Zealand and this was modelled on the UNICEF UK commissioned report by Renfrew et al, from 2012.[8]

The Infant Nutrition Council (Formula Marketers Association) stated that an increase in their marketing activities would have the, "... overall effect of a reduction in the rate of breastfeeding of infants."[9] This is an admission of industry awareness of the power and influence of their marketing, which needs to be taken into account during any consultation process regarding formula products and standards. Submissions to the Commerce Commission, during this authorisation process, from health organisations also pointed out that although the Infant Nutrition Council (Formula Marketers Association) weak code of practice needed to be supported in this instance, due to the historic and current lack of government regulation or legislation, a preference for regulation and legislation to enact the International Code of Marketing of Breast-milk Substitutes, along with the subsequent, relevant, World Health Assembly resolutions was recommended.

With these critical issues in mind the feedback on the questions posed by FSANZ is below. I have removed questions related to ingredients that fall out of my area of expertise but in question 3.1 I have added information from EFSA.[10]

A number of changes to standards so that they align better with international standards, along with alignment to the International Code of Marketing of Breast-Milk Substitutes and subsequent, relevant World Health Assembly resolutions are recommended.

No.	Section of the SD	Question
Q1.2	2.2	***Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?*** ***(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"*** ***(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding "*** ***(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age*** ***(4) no change*** A different definition is necessary to provide clarity, and to align with the World Health Organisation's recommendations for optimal infant feeding, and the Global Strategy for Infant and Young Child Feeding.[11] An infant is a child from birth to age one year and the Australia/NZ definition needs to reflect this urgently. Global optimal recommendations for infant feeding remain six months of exclusive breastfeeding (or formula feeding) before the introduction on appropriate complementary foods.[12] Therefore a definition could be - '*satisfies the nutritional requirements of infants up to six months of age and then as part of the diet from six months of age, after the introduction of appropriate complementary foods, until one year of age when formula is no longer needed*' This would align with the current thinking on follow on, or follow up milks as being unnecessary and used as a marketing ploy. [13] [14] A recent Lancet editorial publication highlighted that follow on milks are not necessary and should be regulated just the same as other breast-milk substitutes. [15]
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?*** If soy is included in formula products then a labelling requirement for genetically modified ingredients is also necessary to make it possible for parents to make informed decisions about the exposure of their infants to GM 'foods'. Agostoni et al, suggest that soy is a source of protein that is inferior to cows' milk, with a lower digestibility and bioavailability and no nutritional advantage over

No.	Section of the SD	Question
		cows' milk protein formulae. There is also a concern about high concentrations of phytate, aluminum, and phytoestrogens (isoflavones), which the authors considered might have untoward effects. [16] Agostoni also suggested that soy protein plays no role in allergy prevention and there is no evidence to suggest a role in regurgitation prevention, colic or prolonged crying prevention or management. Therefore the addition of isolated soy protein could be reconsidered along with the amount of protein contained in products. Marketing claims made about 'benefits' of soy should also be considered.
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.*** The amount of iron absorbed in formula is an ongoing issue. The iron in breast milk is absorbed due to the protein/enzyme lactoferrin. When making decisions about the maximum amount of iron in formula products caution is necessary to avoid excess iron in the infant system. A study which enrolled 835 healthy, full-term infants was conducted in Santiago, Chile. From 6-12 months infants were fed iron-fortified (mean 12.7mg/L) or low-iron (mean 2.3mg/L) formula milk. At 10 years of age 473 (56.6%) of the children were assessed for IQ, spatial memory, arithmetic achievement, visual-motor integration, visual perception, and motor functioning. Compared with the low-iron group, the iron fortified group scored lower on every 10 year outcome.[17] Ljung et al, also found some issues with iron when they assessed concentrations in, and intake of, toxic and essential elements from formulas and foods intended for infants during their first 6 months of life. The researchers suggested that evaluation of potentially adverse effects of the elevated element concentrations in infant formulas and foods are warranted.[18] Kaur et al, also looked at iron elevation and found that mice administered iron at doses equivalent to those found in iron-fortified human infant formula during a developmental period equivalent to the first human year of life displayed progressive midbrain neurodegeneration and enhanced vulnerability to toxic injury. The authors suggested this may have major implications for the impact of neonatal iron intake as a potential risk factor for later development of Parkinson's disease. [19]

Supporting Document 2: Safety and Food Technology

No.	Section of the SD	Question
Q2.3	5.2	***What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?*** Anecdotal evidence only from parents. The Growing Up in New Zealand study found a 6% exclusive breastfeeding rate at 6 months of age but the reasons for loss of exclusivity, although recorded as a loss by 4 months did not provide dietary details. However, it is

No.	Section of the SD	Question
		possible that data about formula feeding and associated practices was recorded. [20] The only other study that I am aware of about parents and formula feeding did not report on this topic either. [21]
Q2.4	5.2	***What evidence can you provide on whether this practice is more common with powdered infant formula products compared to liquid concentrate or 'ready to drink' products?*** Liquid/RTF is not available in NZ apart from in small amounts in some retail outlets and in small, not for sale, bottles in maternity facilities.
Q2.5	5.2.	***What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?*** Anecdotal evidence only. Parents add cereal to bottles of formula with the intent of promoting longer sleep. Again there appears to be no data available. Formula stretching is another issue and this is done to make the product last longer and reduce costs. See 3.17.
Q2.6	5.4	***What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?*** The only study I am aware of about parents and formula feeding in NZ is the Winstanley and Cressey 2008 survey which suggests that some parents do read labels but again, what they are looking for on the labels is largely unknown.
Q2.7	5.4	***What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?*** No evidence that I am aware of, but consistent labelling across all products would likely make it easier for parents to understand labels.
Q2.9	5.4	***What are the cost and trade implications of prescribing the position of the statement of protein source on the label?*** Trade implications are secondary to the health of infants and the support for parents when making decisions about infant feeding.
Q2.15	6	***Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?*** All substances used in infant formula should have pre-market assessment due to the vulnerability of infants and potential short and long term adverse effects.
Q2.16	6	***What would be the cost and trade implications of your preferred position?*** Costs to industry and trade implications are secondary to the health

No.	Section of the SD	Question
		and safety of vulnerable infants.
Q2.20	7.3	***What are the cost and trade implications of reducing the ML for aluminium in soy-based formula?*** Costs to industry and trade implications are secondary to the health and safety of vulnerable infants
Q2.21	7.5	***What are the cost and trade implications of reducing the ML for lead in infant formula?*** Costs to industry and trade implications are secondary to the health and safety of vulnerable infants
Q2.22	7.6	***What if any, issues are associated with not including the Codex ML in the Code for melamine?*** Limits for melamine in formula are necessary as per Codex. [22] [23] The issue concerned is in regards to safety and contamination.
Q2.23	7.10	***Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.*** It should apply to RTF products also. With food is intended for use by vulnerable infants, no exceptions should be allowed.
Q2.24	7.11	***Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?*** Yes
Q2.25	7.11	***Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?*** Yes
Q2.33	8.4	***Is there a technological justification for permitting carrageenan in liquid soy-based infant formula products?*** Carrageenan is a controversial ingredient that needs further assessment.

Supporting Document 3: Provision of Information

No.	Section of the SD	Question

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, nutrition and health claims should not be permitted as they are misleading to parents and health care workers, and they are without scientific and factual evidence. Their prime purpose is marketing and this is unacceptable as infants are vulnerable and should be protected. First Steps Nutrition Trust provides an excellent over-view of these claims.[24] EFSA also stated in 2014 - [25] *"Breastmilk is the preferred food for all healthy infants. Whereas the composition of infant formula remains stable over time, breastmilk composition changes continuously and therefore infant formula cannot imitate breastmilk. Human milk composition can provide guidance on the composition of formula, but compositional similarity to human milk is not the only determinant or indicator of safety and nutritional suitability of formula. The mere presence of a substance in human milk does not necessarily indicate a specific benefit of this substance for the infant, nor do the concentrations of nutrients in human milk necessarily reflect infants' dietary requirements because they may mirror maternal intakes rather than infants' needs, or because absorption efficiency of certain nutrients differ between breastmilk and formula. Infant formula cannot imitate breastmilk with respect to its energy and protein content."*[26] Further comments from EFSA – *"Nutrients and substances should be added to formulae for infants only in amounts that serve a nutritional or other benefit. The addition in amounts higher than those serving a nutritional or other benefit or the inclusion of unnecessary substances in formulae* ***may put a burden on the infant's metabolism or on other physiological functions****, as substances which are not used or stored have to be excreted."* [27] *"There is a lack of studies designed to investigate the short- or long-term health consequences of consumption of formulae containing the currently permitted maximum amounts of nutrients in infant formula."* EFSA also stated the following ingredients were unnecessary in formula – ***Arachidonic acid (ARA), Eicosapentaenoic acid (EPA), Non-digestible oligosaccharides (prebiotics. GOS/FOS mixtures), Probiotics, Synbiotics (a mix of prebiotics and probiotics), Chromium Fluoride, Taurine, Nucleotides, Phospholipids as a source of long-chain polyunsaturated fatty acids instead of triacylglycerols and Triacylglycerols with palmitic acid predominantly esterified in the sn-2 position***

No.	Section of the SD	Question
Q3.2	2.3	***Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?*** Information is only of value when evidence-based and health workers require a source on non-commercial information so they can provide unbiased information to parents.
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).*** All ingredients should be declared.
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?*** Yes, many health professionals, in my experience, know very little about ingredients and need access to an unbiased source of information/education. First Steps Nutrition Trust provides useful publications for the UK that explain about ingredients, and although the publications are designed for the UK they are useful for both NZ and Australia as the ingredients, if not the product names, are the same. [28] As stated by 1st Steps - *"In order to protect breastfeeding it is important that all those who offer advice to families have accurate and unbiased information about infant feeding, including clear information about infant formula, follow on formula and other infants milks marketed in the early years. First Steps Nutrition Trust provides a regularly updated guide for health professionals which summarises the composition of infant milks available in the UK. We also provide information on specialised milks, fortified milks for older children and on making up milks safely."*
Q3.9	2.4	***Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?*** Yes. Labels should be easy to understand and consistent
Q3.16	2.7	***Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?*** Yes. Misleading health and nutrition claims influence some caregiver's choices and some caregivers do read the information on the tin. .

No.	Section of the SD	Question
Q3.17	2.7	***Would a consistent approach to format across product labels assist consumer understanding of this information?*** Yes. This should include preparation instructions also. A study of families in the US in 2012 found that both food insecurity and formula stretching were common. [29] Formula stretching happens when parents try to make formula powder last longer and they hold back feeds or dilute them to the detriment of nutrition and infant development. One of the issues mentioned in this US study was that parents bought expensive branded formula products and saw the cheaper generic products as not being equivalent. Formula literacy can be elusive in the face of misleading industry marketing, but parents using formula should know that they do not need to purchase the expensive products, nor do they need to use any formula milk after their babies reach one year of age. Consistent instructions on labels are necessary in terms of preparation. A small survey of formula labels in three NZ supermarkets found a confusing range of information and using the WHO guidelines would eliminate the range of different information found, as below - • BOIL FRESH DRINKING WATER AND ALLOW TO COOL UNTIL LUKEWARM • BOIL FRESH DRINKING WATER FOR 5 MINUTES AND ALLOW TO COOL • BOIL SAFE DRINKING WATER AND ALLOW TO COOL TO 40-60 ℃ • BOIL DRINKING WATER FOR 5 MINUTES. ALLOW TO COOL TO 40 ℃ • BOIL CLEAN WATER AND COOL TO 40 ℃ • BOIL FRESH DRINKING WATER. ALLOW TO COOL 30-40 MINS UNTIL TEMP REACHES 50-60 ℃
Q3.18	2.7	***If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?*** Industry and trade considerations are secondary to the health and well being of infants.
Q3.19	2.8	***How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?*** It is the responsibility of the Ministry of Health to ensure any information about products is communicated to all agencies and health workers who have contact with families.
Q3.20	2.8	***What information about the change in composition would caregivers and health professionals find useful?*** All changes should be notified

No.	Section of the SD	Question
Q3.21	2.8	***What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?*** Industry and trade considerations are secondary to the health and well being of infants

Although this review is not looking at preparation instructions it is important to note the differences between New Zealand guidelines for preparation of powdered formula and the WHO optimal guidelines.[30]

There are many countries using this safety information without any reported issues and it is of interest that New Zealand goes against this evidence based optimal practice. The NHS guide to bottle feeding states '*to reduce the risk of infection make up each feed as your baby needs it, using boiled water at a temperature of 70 degrees Centigrade or above. Water at this temperature will kill any harmful bacteria that may be present. Remember to let the feed cool before giving it to your baby.*' The booklet also contains pictures and simple instructions on how to ensure that the water is boiled and remains at a 70 degree temperature. [31] [32]

Another issue not covered in this consultation is nanoparticles and as this seems to be an emerging issue in formula products it is to be hoped that this issue will be examined in the near future. [33] [34]

Thank you

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