FSANZ Consultation Paper – Proposal P1028 Infant formula

Responses to questions to submitters

[redacted]

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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.
The main point of difference is in point 4.3 related to the current minimum requirement for LA in infant formula. See below. We have deleted the points where we have no comment.		
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
We suggest option 2 and 3: "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding, as part of a progressively diversified diet, of infants from **around** 6 months of age"		
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.
We consider that 9% total fatty acids is too high a minimum. The minimum level to prevent LA deficiency is <1% total fatty acids. We are able to supply additional information if required.		
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
We have no issues with this statement.		
Q1.27	9.2	Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.
Not without clinical data to support this.		

Supporting Document 2: Safety and Food Technology

No.	Section of the SD	Question
Q2.1	All	For all views presented in this SD, do you agree with FSANZ's preliminary view? If so, indicate this in your submission and provide your reasons where appropriate. If not, indicate this in your submission and provide your reasons including additional relevant evidence, current practice in complying with the Code, impact on manufacture or trade, technical justification or other relevant information.
Q2.2	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?
We do not have any specific evidence of foods being added to infant formula, however 9.7% of infants less than 3 months old were reported to have received soft/semi-solid/solid food in the previous 24 hours in the 2010 Australian National Infant Feeding Survey. No questions were asked about how these foods were given, and it is possible that some infants were receiving foods in their formula. Risk factor for obesity. Anecdotally parents report adding food to infant formula when interviewed in the clinic setting.		
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?
We cannot provide evidence to support this statement.		
Q2.4	5.2.	What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?
We cannot provide evidence to support this statement.		
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?
We only have anecdotal evidence to support this statement.		
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?
We only have anecdotal evidence to support this statement.		
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?
This information should be on the front of the can. eg "based on modified cow's milk" or "based on soy".		
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?
We are not aware of any data collection in this area.		
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?
From a health care professional perspective, vitamin and mineral supplementation is not indicated unless there are insufficiencies eg Vit D or iron.		

No.	Section of the SD	Question
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?
Consumers purchase formula in the assumption that all of the ingredients have been proven to be safe to feed their infants. Novel ingredients not traditionally included in infant formula should be tested.		
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?
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?
We consider that new or novel ingredients not traditionally included in infant formula should have pre-market assessment, as should existing ingredients where large changes in dose are proposed (outside the normal range of consumption of a breast or formula fed infant).		
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?
We consider that consistent nomenclature of food additive names is essential for a small number of infants who may potentially be intolerant or allergic to these additives.		

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?
Our opinion is that claims apart from content of specific ingredients should not be allowed on packaged infant formula.		
Q3.2	2.3	Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?
Yes, as health professionals this is useful, particularly related to essential fatty acid content.		
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?
Yes.		
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).
We consider that it is not necessary to specify subgroups of proteins or specific proteins, and this may be confusing for consumers.		
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).
Information related to fat composition would be useful. eg Total fat / DHA / AA.		

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?
Yes, there is potential for confusion.		
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?
We are not aware of any evidence, but it is logical to expect that the more information there is on a label the more room for confusion and potential error there is.		
Q3.9	2.4	Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?
Yes, as this is potentially confusing for consumers.		
Q3.10	2.5	Which base units of expression do stakeholders find to be of greatest value?
Grams per 100g of powder is very useful clinically, especially in cases where an infant requires a prescribed amount of protein or other nutrient. This should be included as a minimum. Grams per 100ml is also useful.		
Q3.11	2.5	Is there any evidence that caregivers are confused by the use of different base units of expression?
We are not aware of any evidence to support this question.		
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?
Yes.		
Q3.14	2.5	Should the voluntary use of the base unit of per 100 kJ be permitted?
Yes, however we consider this to be confusing. If not on the can the information should be available to health professionals as needed.		
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'?
We consider that there would be no impact.		
Q3.16	2.7	Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?
There is anecdotal evidence to suggest that this may often be the case.		
Q3.17	2.7	Would a consistent approach to format across product labels assist consumer understanding of this information?
We consider that a consistent approach to labelling would enable consumers to more easily compare products.		
Q3.19	2.8	How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?
We agree that advertising formula composition changes on front of can could be seen as advertising. A notice on the lid of changes to formulation could be useful to alert consumers and health professionals.		
Q3.20	2.8	What information about the change in composition would caregivers and health professionals find useful?
Any change in composition, or scoop size changes should be communicated. This information is particularly valuable for the Nutrition and Dietetics, Gastroenterology and Metabolic departments in major paediatric hospitals as formulation changes may potentially have clinical implications.		