Submission – Proposal P1028 – Infant Formula

Comments from the Department of Health and Human Services, Tasmania,
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The Department of Health and Human Services, Tasmania (the Department) appreciates the opportunity to comment on Proposal P1028 – Infant Formula. This submission will address a number of the specific questions raised in the consultation paper along with a discussion on the preliminary views of FSANZ throughout the submission.

The Department supports the continued prohibition for nutrition content claims and health claims for Standard 2.9.1 which is in line with the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*. The Department's views are further discussed in Section 2 of Supporting Document 3.

The Department acknowledges the scope of P1028 is limited to the product category of infant formula with follow-on formulas and toddler milks out of scope. However, within the category of infant formula it is important that these products be clearly differentiated from other similar products for the safety and protection of infants. A number of suggestions have been put forward for FSANZ to consider in Section 5 of Supporting Document 2.

The Department supports pre-market assessment of any new substance proposed to be used in infant formula as outlined in the *Ministerial Policy Guideline on the Regulation of Infant Formula Products.* The Department agrees with FSANZ to exclude infant formula products from the scope of Proposal P1024 – nutritive substances and novel foods and recommends that infant formula should be regulated differently to general foods in the Code as a result of infants' increased vulnerability. This is further discussed in Section 6 of Supporting Document 2.

Supporting Document 1: Definitions and Nutrient Composition

Section 2 – Definition and terminology

Q1.2 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

The Department supports the following definition which is in line with option 1 and 3 - "satisfies by itself the nutritional requirements of infants up to 6 months of age, and as part of a progressively diversified diet from around 6 months to 12 months of age"

This is consistent with the *Infant Feeding Guidelines* (NH&MRC, 2012) which states that by around 6 months of age nutritional requirements are no longer satisfied by breast milk or infant formula alone.

The Departments also supports the additional qualifying statement that infant formula is still recommended from 6 to 12 months of age as this is in line with the *Infant Feeding Guidelines* that state 'breast milk or infant formula should be continued while introducing solids, with other drinks, except cooled boiled water, avoided until the infant is 12 months old' (NH&MRC, 2012). Whilst the definition of infant is clearly defined in Standard 1.1.2 to mean 'a person under the age of 12 months' by including it as part of the definition in Standard 2.9.1 the purpose of infant formula is more clearly articulated.

Section 3 - Protein

For all views presented in this section, do you agree with FSANZ's preliminary view?

The Department does not support FSANZ's preliminary view that the source of protein does not need to be regulated in the standard if the quantity and quality of protein is regulated. This has the potential to allow new sources of protein to be used in infant formula without pre-market assessment. Some plant based sources of protein may contain anti-nutrient factors that can interfere with nutrient absorption which needs to be carefully considered before being added to infant formula. The *Ministerial Policy Guideline on the Regulation of Infant Formula Products* clearly states that pre-market assessment should be required for any substance that does not have a history of safe use in Australia and New Zealand. By clearly defining what is meant by protein source the ambiguity of what substances require pre-market assessment is removed.

Supporting Document 2: Safety and Food Technology

Section 3 – Preparation, use and storage directions to manage microbiological hazards

For all views presented in this section, do you agree with FSANZ's preliminary view?

The Department agrees with the following preliminary views of FSANZ:

- The statement that each bottle should be prepared individually should be retained.
- That the current requirements [Standard 2.9.1-19 (3)] to include the preparation and use instructions on the label remain appropriate.
- That it is safe to store prepared formula for up to 24 hours in the refrigerator, if the refrigerator temperature is operating at 4 C or less.

The Department agrees that consistency in the placement and content of consumer messages will generally assist consumers in their search for, and acquisition of such messages such as the preparation instructions on infant formula. To reduce safety risk associated with incorrect formula preparation consideration to prescribed words and pictures has the potential to benefit consumers.

Section 4 – Other safe preparation and storage issues

For all views presented in this section, do you agree with FSANZ's preliminary view?

The Department agrees with the following preliminary views of FSANZ:

- Maintain existing requirements for date marking on infant formula.
- Maintain existing requirements for storage instructions covering the period after the infant formula has been opened.
- Agrees there is insufficient evidence to regulate a standard scoop size.
- Given that there is insufficient evidence that there is a problem with use of scoop and that from FSANZs research all infant formulas in Australia and New Zealand currently have on their labels '*only the enclosed scoop should be used*' there does not appear to be any reason to mandate at this stage.

The Department acknowledges that the accuracy of infant feeding bottles is regulated as consumer goods and not covered in the Code, however the over concentration or dilution of infant formula can have acute and chronic negative health effects for the infant. Serious consideration should be given to the inclusion of an accurate measuring container for water in the package of infant formula powder. This would reduce the health inequity associated with the low cost bottles being less accurate than the better known brands.

Section 5 – Warning, advisory and other statements

For all views presented in this section, do you agree with FSANZs preliminary view?

The Department agrees with the following preliminary views of FSANZ:

- That the current warning statements about following the instructions exactly to ensure correct preparation are adequate.
- The existing 'breast is best' statement is appropriate and should be maintained.
- That the statement 'suitable from birth' should be maintained.
- That the statement that infants over the age of six months should be offered foods in addition to the infant formula product should be maintained.

The Department agrees with FSANZ's preliminary view to maintain the current requirement to label the protein source as it ensures correct identification of products suitable for infants with particular dietary requirements. However, the Department would like FSANZ to consider how protein source is prescribed. Currently companies can be very specific about the type of protein which blurs the line between what is a legitimate claim for protein source and what is a nutrition content claim. Names such as whey dominant or casein dominant could be considered a nutrition content claim. Consideration should be given to using the primary protein source words such as cow's milk, goat's milk, soy milk, and not subgroups of protein.

The Department agrees with FSANZ's preliminary view that the protein source statement must be immediately adjacent to the name of the food (i.e. Infant Formula). The Department also agrees that the prescribed name 'Infant Formula' should also be maintained.

Infant formula needs to be clearly distinguished from follow-on formulas and toddler milks to reduce the safety risk associated with the wrong formula being given to an infant under the age of 12 months. In the current market place the labelling of infant formula is only differentiated from follow-on formulas and toddler formulas by a numbering system, otherwise the products are almost identical. We have anecdotal evidence of incidents where parents have bought follow-on or toddler formula thinking it is infant formula. While we have not been able to find any substantial published evidence to support our anecdotal evidence we believe this issue is worthy of consumer research.

Infants are a vulnerable population and for some infants infant formula may be the sole or principal source of nutrition. For these reasons there is a greater level of risk to be managed and it is essential that consumers are able to clearly differentiate infant formula from other similar products to reduce the safety risks associated with infants accidently being given an inappropriate formula or toddler milk. This is in line with the scope/aim of the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*.

Section 6 – Nutritive substances and novel foods.

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position.

The Department supports the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*, specific policy principles (i) and (j) that

- pre-market assessment should be required for any new substance proposed to be used in infant formula that does not have a history of safe use; or
- has a history of safe use but has a different form/structure or is produced using different technology; and
- any substance that is subject to pre-market assessment for use in infant formula should have a substantiated beneficial role in normal growth and development.

This policy guideline clearly states that infants are a vulnerable population group because they have immature immune systems and organs, and for some infants, infant formula may be the sole or principal source of nutrition. The regulatory framework for infant formula should therefore include requirements commensurate with this level of risk. As a result the Department supports all substances in infant formula requiring pre-market assessment. Whist this may increase the regulatory involvement in changes to the formulation of an infant formula this approach has the advantage of removing the uncertainty about which substances need pre-market assessment. This would also reduce the need to define or characterise a certain group of substances that should require pre-market assessment.

The Department agrees with FSANZ to exclude infant formula products from the scope of Proposal P1024 and recommends that infant formula should be regulated differently to general foods in the Code as a result of infants' increased vulnerability.

FSANZ seeks clarification around the wording of Standard 2.9.1 – (1) (b) for substances that are extracted through milk processing and whether they may be added to infant formula without requiring pre-market approval. As clearly stated in the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*, these substances would require pre-market assessment if a different form/structure is used or a different technology or technique. If a different level of these substances were to be added pre-market assessment would also be required if it was not already clearly stated in the Code the min/max levels.

Supporting Document 3: Provision of Information

Section 2 – Issues under consideration

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?

The Department strongly opposes claims about specific ingredients being permitted on packaged infant formula. The intent of the *Ministerial Policy Guideline on the Regulation of Infant Formula Product* was to provide sufficient information about the composition, labelling and advertising of infant formula products to ensure the protection of public health and safety without undermining the key message that breastfeeding is the normal and recommended way to feed an infant. It also states that the labelling and advertising of infant formula products should be consistent with the World Health Organisation International Code of Marketing of Breast Milk Substitutes.

The WHO International Code of Marketing of Breast Milk Substitutes under Article 9 - Labelling states that 'Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding'.

Nutrition content claims and health claims on infant formula would place a disproportionate emphasis on these individual components in infant formula. This may mislead consumers in the belief that infant formula has an advantageous ingredient in it that breast milk doesn't. Infant formula should not imply superiority over breast milk by labelling their products with claims such as 'fish oil to help brain and eye development'.

FSANZ's review of current labels of packaged infant formula highlights the proliferation of nutrition content claims and/or health claims despite Standard 1.2.7 clearly stating that a nutrition content claim or health claim must not be made about an infant formula product. Current industry practice appears to be around 'ingredient' claims which suggest there is a need for regulatory clarity as the intent of the policy guideline and the Code was to prohibit such claims.

The Department recommends greater clarity is provided in the Code to state that ingredient claims cannot be made and prescribe where the declaration of ingredients can be made on a label. The Department strongly supports ingredient claims should only be made on the back of a label underneath a mandated Nutrition Information Table.

Q 3.3 Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in 2.9.1 – 21) in the nutrition information statement?

The Department acknowledges that the inclusion of macronutrient sub-groups would constitute a nutrition content claim as the Standard now applies. The Department is concerned that the inclusion of macro-nutrient subgroups in the nutrition information statement may mislead consumers on the nutritional benefits of infant formula. If this was to proceed the Department would strongly recommend Standard 2.9.1 included a prescribed format (ie font size, colour etc) that was mandated for infant formula to reduce consumer confusion by the potential overemphasis of particular subgroups in the nutrition information statement.

Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement?

The Department does not support mandatory declaration of specified macronutrient subgroups as this information would be clearly stated in the list of ingredients.

Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula fed infants to be misled about the nutritional values of formula?

The Department believes there would be the potential for caregivers of formula fed infants to be misled about the nutritional value of formula depending on the way the macronutrients were presented on the label. If these subgroups were bolded, in different font or enlarged to draw attention to them this may mislead consumers on the importance of these subgroups. The Department would only support this information being included on the nutrition information statement if a prescribed format was mandated.

Q 3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?

The Department supports the view that a consistent approach to format across product labels for infant formulas would assist consumer's understanding. As stated in the FSANZ paper a mandated format allows easier comparisons of nutrition information between products. In addition consumers are familiar with the tabular format of the NIP which is used for general purpose foods and therefore a similar format for infant formula may assist consumers with their understanding of this information.

Q3.19 How can changes in the compositional in an infant formula product be communicated to caregivers and health professionals

The Department does not support the inclusion of compositional changes in the front of an infant formula label as this would constitute a nutrition content claim. Whilst consumers may want to know these changes alternative methods need to be examined. Notifications of changes could occur on an industry web-page or through the use of an over-sticker located at the back on the nutrition information statement.