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Health

Proposal 1028 Infant formula Consultation paper 2 – Nutrient Composition

Submission

NSW appreciates the opportunity to comment on Proposal 1028 Infant Formula – Consultation paper 2 Nutrient Composition. Due to the COVID-19 pandemic and NSW investment in response, it has not been possible to review the consultation paper in detail. However, NSW offers the following high-level comments.

Infant health and safety is a key policy driver for the NSW Health. The First 2000 days Framework (the Framework) is a strategic policy which outlines the importance of the first 2000 days in a child's life (from conception to age 5) and what action people within the NSW health system need to take to ensure that all children have the best possible start in life. Through effective and collaborative support and intervention during the first 2000 days, there is an opportunity to give children the best possible start in life physically, developmentally, socially and emotionally, and to address the escalating prevalence of adult disease and morbidity.

NSW sees the work undertaken by Food Standards Australia New Zealand in reviewing the infant formula standard to be essential to ensure this vulnerable group is protected. While NSW recognises breastfeeding as the usual and recommended way of feeding infants, for parents unable to breastfeed and for infants requiring specialist feeds, infant formula must be safe, provide a sole source of complete nutrition, and be an effective alternative to breast milk. Infant formula regulations can have long term health impacts, so careful consideration is vital to ensure that infants' health and safety are the primary focus of regulatory decisions.

Ministers' views on infant formula are clear. The Ministerial Policy Guidelines on Infant Formula Products sets a precautionary approach to infant formula regulations. There *'is a greater level of risk to be managed for infants compared to other population groups. The regulatory framework for infant formula products should include requirements commensurate with this level of risk for the composition, labelling, advertising and promotion of infant formula products.'*

Targeted health professional consultation required due to COVID impacts

Due to the evolving COVID-19 situation and response, NSW Health is unable to engage with relevant clinical stakeholders (physicians, dietitians, maternal child health nurses, researchers). These clinicians have the expertise to assist with the technical elements of the paper.

For this reason it is essential that FSANZ undertakes targeted consultation and facilitates engagement with the complex material, for example, by facilitating workshops with relevant paediatric clinicians as part of this current review process when it is safe and appropriate to do so. NSW is concerned that many clinicians, especially those in paediatrics, normally interested in providing submissions, will not be able to due to COVID. This could result in FSANZ considering these people do not have input on the important issue of nutrient composition of infant formula. NSW suggests it is important these stakeholders have the opportunity to add their expertise to the further consideration of Proposal 1028.

We note specifically FSANZ is seeking further information from health professionals on nutritional adequacy concerns related to the current linoleic acid minimum requirement in Standard 2.9.1 (S29—8) (page 35) so it is imperative to facilitate opportunities for health professionals' input at a more appropriate time.

Insufficient regard is given to infant health and safety in the current approach

The infant formula regulations require updating to keep pace with scientific gains about breast milk composition and health outcomes, and the nutritional needs of infants, as well as to work towards closing the health outcome gaps between formula-fed and breastfed infants. NSW is concerned FSANZ is having insufficient regard to the Ministerial Policy Guidance's clear direction on the vulnerability of infants and placing too much emphasis on aligning with international regulations. For instance, nutrient levels are being proposed based on international regulations with limited or no assessment whether these levels met infants' nutritional needs. FSANZ has stated, 'the primary objective of the P1028 proposal is to align with international regulations unless safety or other concerns do not support alignment'. NSW does not agree alignment with international regulations should be the primary objective, it should be secondary after ensuring infant health and safety. These infant formula regulations should be based on up-to-date science to remain fit for purpose.

Alignment with Codex when EU regulations are based on more up-to-date science

NSW supports the intent of the Ministerial Policy Guideline, that infant health and safety is best protected by aligning with the best nutrient criteria to meet the nutrient needs of infants based on the evidence. The 2014 EU regulations for infant formula were reviewed using more up dated science than Codex, so should be considered when determining if compositional requirements are suitable to meet infant nutrient needs. This is also relevant given the significant trade in infant formula manufactured in the EU.

For example, with regard to linoleic acid we note FSANZ prefers to retain the current minimum requirements for linoleic acid (LA) of 90mg/100kJ. However, the EU requires a minimum of 120mg/100kJ which is more closely aligned with breast milk minimums of 110-140mg. Current formulas on the market range from 146-267mg/100kJ so manufacturers are already able to meet the EU minimum standard of 120mg/100kJ. This may be in part again because many infant formulas are manufactured in the EU. The NSW position is to support composition that is more closely aligned to that of breast milk.

There are other nutrients noted where Codex maximum levels equate to infant intakes that would exceed upper limit levels such as zinc and vitamin A. While for iodine it is

proposed to retain the current maximum as it reflects current products in the market, however, this level exceeds upper limits set by the EU. Beta carotene is proposed to be permitted as a form of Vitamin A, despite unclear infant bioconversion of beta carotene into vitamin A, but will not be counted as vitamin A on labels. This could be misleading to parents.

Regulatory changes are proposed for 0-6mths formulas only, yet infants are defined as 0-12months.

The scope of Proposal P1028 includes requirements for infant formula products in Standard 2.9.1 *excluding follow-on formula*. Proposed changes to regulatory provisions will only apply to infant formula (0-6months), which will create two sets nutritional composition permissions -- one for infant formula and one for follow-on formula. This is without scientific justification and also has potential trade/manufacturing implications. NSW is concerned that changing the regulatory approach for follow on formula products means a new regulatory problem definition that would need justification and risks and benefits analysis. Standard 2.9.1 must retain consistent nutritional compositional requirements across both infant formula and follow-on products to avoid creating confusion for manufacturers, enforcers and parents. If this progresses, NSW requests clarity and certainty that follow-on formula will be addressed in a timely manner.

NSW notes there appears to be no scientific basis for different infant formulas with different protein and energy levels for 7- to 12-month-olds when breastmilk composition is considered relatively stable at that age. The provision of unnecessary additional protein may contribute to excess energy which may present an obesity risk, and parents may be misled to believe a different formula is required at this stage.

Voluntary ingredients and premium products – all formula fed infants deserve to receive nutrients found in breast milk

If a nutrient is found in breast milk and is considered safe and effective for infant health and nutrition, it must be included in all formula products as standard. The development of premium products with additional ingredients has the potential to mislead parents into believing they need to buy premium products with additional ingredients, or their infant will miss out on essential nutrients.

For instance, long chain omega 3 (DHA) is present in human breast milk and has been allowed as a voluntary addition to infant formula for 20 years. The evidence for health benefits is mixed and may relate to individual genetics and metabolism. A thorough review of the evidence is required; if this ingredient is assessed as safe and effective it should be available to all infants, if not, permission to add voluntarily should be removed.

Lutein, another example, has been permitted in infant formula products since 2011. FSANZ should review the evidence in the intervening 10 years to determine if it is an essential nutrient that should now be mandatory in all infant formula products.

A review of the NSW 2016 submission identified two further issues we still consider worth noting:

- 1) Glucose – we note FSANZ's preferred option in the 2021 consultation paper is Option 2 to limit sucrose and fructose additions. However, our preferred option

is Option 3 limits on sucrose, fructose and glucose. Glucose forms Maillard products and increases osmolality which may impact infant gut health.

- 2) Folate units - NSW requested FSANZ consider using Dietary Folate equivalents (DFE) in calculating folic acid/folate values for labels in 2016. This is a similar issue to that noted above with beta carotene. That by not including all forms of vitamin A, and in this case, all forms of folate, it could lead to misleading information on the label and higher levels of these nutrients present than described. Given the EU has changed its regulations and requires DFEs to include all folate forms, and the lack of consistent results and evidence of processing that removes folate from ingredients, NSW preferred DFEs for folate units consistent with DFE for other food product labels

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.