Queensland Government

Queensland Health

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7 July 2021

Standards Management Officer
Food Standards Australia New Zealand
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Dear Sir / Madam

Submission – Proposal P1028—Infant formula – Consultation paper 1

Thank you for the opportunity to provide a submission on *Consultation paper 1 – Safety and food technology* of Proposal P1028.

This submission provides comments on the proposed changes to the *Australia New Zealand Food Standards Code* (the Code). It was prepared by health professionals from Children's Health Queensland Hospital and Health Service, Health and Wellbeing Queensland, Preventive Health Branch and Food Safety Standards and Regulation Unit. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government should notification be made by the FSANZ Board to the Food Ministers' Meeting.

This submission aligns with the Queensland Government's commitment towards protecting, promoting and supporting breastfeeding and optimal infant nutrition consistent with:

- Australian National Breastfeeding Strategy: 2019 and beyond
- NHMRC Infant Feeding Guidelines
- NHMRC Australian Dietary Guidelines
- Australian Government Draft National Preventive Health Strategy 2021-2030

The Queensland Government aims to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution, in line with the WHO International Code of Marketing Breastmilk Substitutes (1981) and subsequent World Health Assembly resolutions.

The Queensland Government recognises that infant formula and other breastmilk substitutes have a legitimate role to play in circumstances where an infant cannot be breastfed.

Responses to questions for submitters

Q1. The level of cadmium in soy based infant formula in Australia is unknown. If there is ANY degree of potential risk for consumption of cadmium for any length of time, then there should be an established maximum level (ML). Harmonising with the European Union's ML is safer and justifiable to allow higher levels in soy products.

Q2. Food additives

- ***Locust bean gum***: Safety data is not available for the use of this product at the proposed levels of 10,000 mg/L. In addition there is limited evidence for the use of thickeners in improving gastrointestinal reflux (Pediatric Gastroesophageal Reflux Clinical Practice Guidelines, Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition, 2018). Given there are safety concerns raised regarding the use of these thickeners in very young infants we would not support increasing the use of locust bean gum in infant formula.
- ***Pectins:*** Due to the reports of delayed gastric emptying with the use of pectins in animals we do not support the addition of pectins to infant formulas.
- ***Xanthan gum***: We support the addition of up to 1000 mg/L in line with the JECFA risk assessment and recommendation.

Q5. Perceived delays in Special formula: Our suggestion is to not request any tightening of restrictions as this will unlikely have any impact on the supply of special infant formulas.

Q13. Concern is raised that pathogenic L+ lactic acid producing microorganisms may be added to infant formula, especially to infant formula provided to immunocompromised and premature infants. At a minimum, the standard should be amended to clarify the permission for L(+) lactic acid producing microorganisms only applies to non-pathogenic varieties now that this has been identified as a risk, so that it cannot be used as a defence, rather than rely solely on 'safe and suitable' requirements in state and territory Food Acts.

Since infants are a vulnerable population and infant formula products may be their sole or a main source of nutrition, we are concerned there is not a specific regulated premarket assessment process for the evaluating the safety of microorganisms added to infant formula, other than Standard 1.5.1 *Novel Foods,* which has been difficult to apply and enforce in practice. Any assessment process should also include the evaluation of substances produced by these organisms after their addition. It uncertain how FSANZ should manage the addition of microorganisms to infant formula products for probiotic purposes. It is suggested FSANZ should undertake further work to consider whether the addition of microorganisms to food should explicitly be prohibited unless permitted by the Code (without reliance on Standard 1.5.1 Novel foods), and that a microorganism only be permitted to be added to infant formula if a safety assessment has concluded it is safe for the intended purpose and set any necessary conditions for its safe use.

Q14. Support is given in principle to labelling changes that standardise labelling instructions across other national guidelines such as the Infant Feeding Guidelines.

- ***2.9.1—19(1) Warning statements and directions***
    - Support is given to continuing to include in 2.9.1—19(1) a clear explanation of the risks associated with incorrect preparation of infant formula products and that this be expanded to include risks of poor handling and storage practices of infant formula and other breastmilk substitutes, for example "Incorrect preparation, handling and storage can make your baby very ill".

- ***2.9.1—19(3)(b) 'if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours':***
    - Inclusion of such a statement is supported because there is often the misconception by consumers that the "make up per bottle" relates to not being able to make up formula ahead of time.
    - In regard to reconstituting and storing prepared powdered infant formula, it is suggested the requirement include the word 'prepared' before refrigerated, i.e. 'it must be prepared, refrigerated and used within 24 hours'.
- ***2.9.1—19(3)(c) 'potable, previously boiled water should be used':***
    - It is noted that the Consultation Paper states the Australian infant feeding guidelines also state that plain unopened bottled water can be used and it is noted that FSANZ is not proposing to change the advice that (cooled) boiled water be used. Conventional bottled water is not a sterile product and, depending on its source and how the water is treated prior to bottling, it may still contain some microorganisms that could be a source of infection for severely immunocompromised patients. Experience in Queensland has shown that bottled water sourced from groundwater springs may contain low levels of microbiological contamination from naturally occurring bacteria such as *Ralstonia* and *Cupriavidus*.
    - It is suggested 2.9.1—19(3)(c) be amended to include the word cooled in the description of potable previously boiled water. This would support the conclusions of the FSANZ modelling of increased risk from *Cronobacter spp*. growing in reconstituted powdered infant formula made with water above 40°C, and possibly reduce scalding risks. However, consideration may need to be given to any increased difficulty in dissolving infant formula powder in cold water. It is suggested the use of the term 'cooled' is sufficient, while terms such as 'refrigerated' and 'chilled' are not appropriate due to possible increased difficulty dissolving and dispersing powdered infant formula in chilled water and not be practical when it is being prepared for immediate use.
- ***2.9.1—19(3):***
    - Clear and unambiguous directions in words and pictures for how to prepare and use infant formula are already required. However, consideration of either prescribing exact wording, or requiring that manufacturers' wording aligns with a literacy level of readability Grade 6 (typically ages 11–12 years) and be suitable for consumers with a low education level or from diverse backgrounds, could minimise risks of incorrect use.

It is noted that views on labelling for informed choice will be canvassed in subsequent consultation papers. Exclusive breastfeeding to around six months of age is recommended, with continued breastfeeding until 12 months of age and beyond, for as long as the mother and child desires. However, any breastfeeding is beneficial to the infant and mother. To support optimal infant feeding, it is suggested an additional requirement be included in Standard 2.9.1 stating images or text that idealise the use of breastmilk substitutes should not be used.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Department of Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au

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