Submission – Consultation Paper 1 – Safety and food technology

Proposal P1028 – Infant Formula

Comments from Public Health Services, Department of Health, Tasmania,
7 July 2021

Public Health Services, Department of Health, Tasmania (PHS) appreciates the opportunity to comment on Proposal P1028 – Infant Formula, Consultation paper 1.

General comments

It is well recognised that breastfeeding is the normal and recommended way to feed an infant and that the regulation of breastmilk substitutes, such as infant formula has implications for health outcomes for all infants, formula fed and breastfed.

As stated in the FSANZ paper the overarching goal of Proposal P1028 is to '*ensure that infant formula remains safe and suitable, takes account of current science, market developments, and the international regulatory context'*.

To ensure the regulation of infant formula remains safe for all infants FSANZ needs to have regard for the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*. It clearly states in this policy that infants are a vulnerable population group and for these reasons there is a greater level of risk that needs to be managed. The regulatory framework for infant formula products needs to be commensurate with this risk. This risk is not only for the infant that is consuming the breast milk substitute but also to ensure the labelling and advertising of infant formula products does not undermine the promotion of breastfeeding. This is consistent with the World Health Organisation International Code of Breast Milk Substitutes.

PHS is concerned that P1028 and consultation paper 1 excludes follow-on formulas. The issues raised in this paper including food additives, contaminants, labelling, and preparation and use are equally relevant to follow-on formulas. Standard 2.9.1 currently includes all infant formula products for infants under 12 months [(infant formula, follow-on formula and Infant Formula Products for Special Dietary Use (IFPSDU)]. It is not clear why these current safety assessments have only been applied to two out of three of these product categories. PHS recommends that all comments below be applied to all infant formula products and that the remaining consultation papers for P1028 includes all three categories as defined in Standard 2.9.1. PHS strongly supports follow-on formulas remaining in Standard 2.9.1 as these products (along with Infant formula) are the primary source of nutrition for infants from 6-12 months even with the introduction of solids.

Section 2 – Food Additives

PHS supports FSANZ's risk management framework for food additive permissions for infant formula products and its three principles:

1. Protection of infant health and safety
2. The number of food additives used in infant formula should be the least number necessary to achieve the required technological functions
3. Consideration of harmonisation with international standards

2.2 Food class system for food additive permissions

PHS supports in principle FSANZ's proposed approach (Option 3, Figure 2.3) as this not only simplifies the regulation of food additives but is consistent with the approach taken in Codex and in the EU. PHS recommends infant formula products as described in Figure 2.3 are defined as infant formula and follow-on formula. PHS also recommends that the category be renamed from Infant Formula Products for Special Dietary Use (IFPSDU) to Infant Formula Products for Special Medical Purposes (IFPSMP). This naming is consistent with the EU and Codex and better reflects that these formulas have been designed for special dietary purposes under the guidance of medical supervision.

2.4 Harmonisation of food additive permissions

PHS supports in principle FSANZ's proposed approach to amend the Code to align with Codex and EU (Option 2). This is particularly relevant for IFPSDU, many of which are imported into Australia from the EU. However, PHS supports Option 2 subject to principles 1 (protection of infant health and safety) and principle 2 (justification of need) being met.

Acidity Regulators

PHS supports FSANZ's safety assessment and justification of use in infant formula and IFPSDU and supports alignment with permitted levels in Codex and the EU.

PHS strongly supports a condition statement being applied to food additive permissions to protect infant health and reduce the potential risk of exceeding maximum levels. This would not be inconsistent with Codex and the EU.

Citric and fatty acid esters of glycerol (CITREM)

PHS support FSANZ's approach.

Starch sodium octenylsuccinate (INS 1450)

PHS support FSANZ's approach.

Locust bean (carob bean) gum (INS410)

PHS does not support FSANZs preferred approach to maintain the permission for locust bean gum in all infant formula products up to 1000mg/L due to no clear rationale for their addition in general infant formulas. This approach is not consistent with FSANZ's risk management framework:

- Principle 2 - justification of use and the minimum amount necessary, and
- Principle 3 - harmonisation with international standards as currently the EU only permits this additive in special purpose formula for the management of gastro-oesophageal reflux.

PHS noted in FSANZ's report that EFSA are currently calling for toxicological data to support the re-evaluation of the use of locust bean gum in foods for infants below 16 weeks of age. This supports principle 1 of FSANZ's risk management framework and the outcomes of this research should be considered when FSANZ makes their final recommendation.

Pectins (INS 440)

PHS does not support FSANZ's proposed approach to permit pectins in IFPSDU at a MPL of 5000mg/L based on principle 1 (protect infant health and safety). JECFA concluded that the consumption of pectins at a maximum of 2000mg/L does not raise safety concerns however, ESFA has raised additional concerns at higher levels and has recommended additional clinical trials to be generated to assess the safety of pectins in IFPSDU.

To meet FSANZ's risk management framework, PHS would like to see more evidence of the safety of pectins over 2000mg/L

Xanthan gum (INS 415)

PHS support FSANZ's proposed approach to allow the permission of xanthan gum in IFPSDU only, to align with the EU and allow for the importation of these specialised products. However, PHS does not support the higher MPL of 1200mg/L at this stage. Industry requested consideration of xanthan gum up to 1000mg/L and JECFA have assessed the safety of xanthan gum at a proposed maximum of 1000mg/L. To meet both principle 1 and 2 PHS requests additional data on 1) the safety at a higher MPL and 2) whether a lower level will cause a regulatory barrier to Australia and New Zealand.

Guar gum (INS 412)

PHS supports FSANZ's proposed approach to remove permission for guar gum in infant formula and to be only permitted in IFPSDU. This is consistent with principle 2 and 3 of FSANZ risk management framework.

PHS notes that EFSA are conducting further re-evaluation of guar gum and have called for toxicological data to assess the safety of its use for infants under the age of 16 weeks. PHS supports FSANZ awaiting the outcomes of this safety assessment before establishing permission in IFPSDU and setting an MPL.

Sodium alginate (INS 401)

PHS does not support the addition of sodium alginate to IFPSDU without clear evidence on safety and justification of need. Sodium alginate is a functional class of thickener, stabilizer and emulsifier and there appears to be other additives on the market that meet this need.

A greater understanding of the impact of not permitting this additive is required before PHS supports this proposed change to the Code.

Sodium carboxymethycellulose (INC 466)

PHS supports FSANZ's approach.

Sucrose esters of fatty acids (INC 473)

PHS does not support FSANZ's proposed approach without additional data to on the safety and justification for need for this additive.

Diacyltartaric and fatty acid esters of glycerol (472e)

PHS supports FSANZ's approach.

2.5 Clarifications to the Code

PHS supports FSANZ's approach to amendments of the Code in this section.

3. Contaminants

PHS supports an approach to MLs that protects infant's health and safety. Infants are a vulnerable population group and for this reason there is a greater level of risk that needs to be managed. As a result, PHS supports aligning with MLs where they exist in Codex or the EU to ensure both imported and Australian infant formula contaminant levels remain low.

PHS does not support FSANZ's proposed approach to not establish an ML for a number of contaminants (mycotoxins, polycyclic aromatic hydrocarbons, perchlorate, chloropropanol, glycidol and their esters). The EU has set a ML for these contaminants and PHS considers harmonisation with the EU as an important measure to protect infant's health and safety. This approach should not have any trade barriers and will protect infants in Australia and New Zealand from a situation where products that exceed contaminant levels overseas are able to be sold in Australia. This is particularly the case for IFPSDU of which the majority are imported from the EU.

4. Lactic acid Producing Microorganisms

PHS notes that the original intent of the permission for L (+) lactic acid producing cultures was as a food additive (ie acidity regulator and pH adjustment). Over the years the permission in the Code has lost the link and is now being used as optional ingredients for other purposes (e.g. probiotics) by manufacturers. This was not the intention. PHS does not support L-lactic acid microorganisms being used for this purpose and supports clarity on the role to be as a food additive.

If L-lactic acid microorganisms are to be used for a purpose other than what it was originally permitted for then a full risk analysis should be undertaken by FSANZ. This will include FSANZ having regard for the *Ministerial Policy Guideline for Infant Formula Products*, in particular specific policy principles i) and j) where pre-market assessment is required and that the substance should have a substantiated beneficial role in the normal growth and development of infants.

PHS is concerned that there is currently a potential loophole in the system where a food additive can be deemed safe to be included for a technological purpose and then later used for

an alternative purpose without a full risk assessment. Infants are a vulnerable population group and as such a greater level of risk needs to be managed.

PHS notes that FSANZ concludes that there are no potential public health and safety risks associated with fermented infant formulas. PHS does not support this view without a more detailed risk assessment.

5. Labelling

5.3.1 Directions for preparation and use

PHS supports FSANZs proposed approach to maintain without change the mandatory requirements for directions:

- To prepare bottles individually
- Instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours

PHS supports FSANZs proposed amendments:

- To include the word '**cooled**' potable, previously boiled water when reconstituting a powdered infant formula. The addition of 'cooled' reduces the ambiguity and ensures greater safety for infants, particularly when noting that only 33% of caregivers in an online survey used cooled water.

PHS supports FSANZ's proposed approach to discard unfinished formula within a specified time. However FSANZ is recommending 'within 2 hours' when the NH&MRC Infant Feeding Guidelines (2012) state 'A *feed should take no longer than 1 hour – any formula that has been at room temperature for longer than 1 hour should be discarded*' . This is in contrast to the New Zealand Infant Feeding Guidelines and the WHO preparation of Infant formula that state 'within two hours'. PHS recommends FSANZ undertake a microbiological risk assessment on the length of time an infant formula product is 'safe' at room temperature and provide easy to understand wording to that effect. PHS recommends this time period is explained from the start of feeding as infants vary in the length of time they take to feed.

PHS supports FSANZs proposed approach to not apply the following directions to ready-to-drink infant formula:

- That each bottle be prepared individually
- To refrigerate formula and use within 24 hours
- To use potable, previously boiled water

5.3.2 Standardised wording and pictures for directions for preparation and use

PHS acknowledges that the changes recommended above such as using the word 'cooled', to refrigerate formula and use within 24 hours and clearer instructions on discarding formula once it has been finished will assist in reducing risk to infants. However, FSANZ's consumer research still indicates there is confusion in understanding instructions. To reduce safety risk associated with incorrect formula preparations considerations to prescribed words and pictures has the potential to benefit consumers and ensure infants remain safe. A level of flexibility could be included to enable infant formula product suppliers to ensure there is enough flexibility for their particular product whilst ensuring a level of consistency for consumers to aid understanding.

5.4.3 Measuring scoop

PHS supports FSANZs proposed approach to maintain existing requirement for only using the enclosed scoop and not mandating a standard scoop size. However, PHS supports a standardised ratio for preparations (e.g. 1 scoop per 30ml water across all products, regardless of scoop size) to ensure that when consumers change infant formula, they can use the same ratio. The evidence presented by FSANZ suggests that consumers rarely recheck the instructions when they change brands. By having a standardised ratio this would reduce the safety risks of over or under concentration that is more likely to occur with groups with lower literacy or English language skills.

If this option is not feasible PHS supports prescribed words and pictures to illustrate the ratio in bold font to ensure this is clearly understood that the ratio may be different to their previous formula.

5.5 Warning statements

PHS supports FSANZ's proposed approach to maintaining legibility requirements for generic or specific warning statements.

PHS supports FSANZ's proposed approach to insert text into the existing warning statement to make it clear not to add anything to infant formula.

Whilst PHS notes FSANZ proposes to retain the words 'breast is best' PHS would like it noted that this is not contemporary health communication language and can be counterproductive in protecting breastfeeding. Research[1] suggests that the 'breast is best' message idealises breastfeeding as optimal rather than the 'normal' way to feed infants. PHS does support the intent of the statement that it is there to highlight the superiority of breastfeeding but suggests FSANZ consider undertaking additional research on more appropriate language to covey this message.

5.6 Product Identification

PHS strongly supports that the prescribed name 'infant formula' be retained and the ambiguity about using the brand name is removed. This will assist in distinguishing these products from follow on formulas and toddler milks that without the words 'infant formula' clearly labelled can make it difficult for consumers to distinguish these products from each other. In the current market place the labelling of infant formula is only differentiated from follow-on formula and toddler milks by a numbering system, otherwise the products are almost identical. We strongly recommend that labelling of infant formula is distinctive from follow-on formula and toddler milks to prevent carers from purchasing the wrong product accidently.

PHS supports FSANZ's proposed approach to retain the requirements that infant formula are suitable from birth and that it is recommended that infants from the age of 6 months be offered foods in addition to infant formula products.

PHS supports FSANZ's proposed approach to retain the requirement for the label to state the specific source of the protein (i.e. cow's milk) and not the protein fractions (e.g. whey, casein).

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[1] Berry N.J., Gribble K.D., (2008) Breast is no longer best: promoting normal infant feeding. Maternal and Child Nutrition 4 pg 74 -79

Clarification of this will ensure that protein fractions cannot be used as a potential nutrition content claim.

PHS supports FSANZ's proposed approach to retain the requirement for the co-location of the protein source and the name of the product (Infant formula). Consideration to ensuring the name of the food (i.e. infant formula) be given a prominent position as currently it can appear on different areas of the label which may not always be prominent. This will reduce the safety risks for those with allergies but also ensuring that caregivers do not accidently choose a product that is not suitable for infants (e.g. toddler milks).