Fonterra Submission: FSANZ Call for Submissions on P1028 Infant Formula, Consultation Paper 1

07/07/2021

About Fonterra:

Fonterra is a global dairy nutrition company owned by 10,000 farmers and their families. With a can-do attitude and collaborative spirit, we are a world leading dairy exporter. We draw on generations of dairy expertise and are one of the world's largest investors in dairy research and innovation, to produce more than two million tonnes annually of value-added advanced dairy ingredients, foodservice and consumer products for over 140 markets.

Fonterra has a long history in the manufacture of paediatric nutrition, with more than 50 years of experience in producing world class infant formula and young child formulas globally. Fonterra produces formula and ingredients for large multinational and major regional paediatric companies and is one of the world's largest contract manufacturers of paediatric nutrition formula and ingredients.

Introduction:

Fonterra welcomes the opportunity to provide comments and information to FSANZ on **P1028 – Infant Formula, Consultation Paper 1 – Safety and Food Technology**. Fonterra has supported development of the Infant Nutrition Council (INC) submission. In light of this, and rather than repeat INC responses in full, Fonterra have selected key areas of P1028 where we are well placed to provide elaboration on certain topics related to general infant formula. We thank FSANZ for the consideration of the comments outlined in both ours and the INC submission. If there are any queries relating to this submission, please contact Sarah Lochrie, Regulatory Manager (sarah.lochrie@fonterra.com).

Fonterra supports the continued protection of breastfeeding noting the many benefits this has for both mothers and infants. For non-breast fed infants that are fed infant formula, Fonterra supports a regulatory approach that ensures the best possible nutrition for infants. This includes measures to ensure appropriate food safety and protection of public health, while allowing for continued innovation including scientific and technical development of infant formula. Fonterra supports harmonization with relevant Codex standards as a means of reducing trade barriers, unless there is strong scientific justification for a different approach.

General Comments:

There are several proposals made within CP1 that are not expressly covered by the questions. We will provide comments on each of these in turn under the relevant headings and then comment specifically on the questions related to the topic.

CP1 covers many regulations which are shared with the Follow-on Formula within Standard 2.9.1. While we appreciate the focus of this paper is specifically on Infant Formula, we would encourage FSANZ to consider how to manage any changes where the regulations are shared (e.g., additive permissions, labelling etc.).

Food Additives

2.2 Food class system for food additive permission

Fonterra appreciates that FSANZ has considered three options for the number of classes of food additives. We support option 3 to simplify, by reducing the number of subclasses as the best way to address clarity issues and be consistent with international approaches.

2.3 Carry-over principles for food additives and infant formula products

Fonterra supports and prefers the continuation of the carry-over principle for food additives (i.e. status quo) in infant formula. If however, FSANZ continues to seek alignment with the Codex framework for carry over, we note that further changes in alignment with Codex are necessary to ensure permissions at Codex are reflected in The Code. Fonterra supports permissions for all food additives and nutrient carriers included in Codex STAN 72-1981 Section 4 Food Additives, and the Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children CAC/ GL 10-1979, which may be present in infant formula products as a result of carry-over from raw material or direct addition and consider appropriate provisions should continue to allow for these ANZ Infant Formula products. Additionally, we have also made a recommendation in question six on food additive permissions for nutrient forms.

Food additives are technologically necessary for the quality of the ingredients and finished product. To facilitate innovation and harmonisation of trade, Fonterra consider the list of food additives permitted in infant formula should be expanded to include those already permitted under Codex for which safety and technological justification have already been established.

We understand that FSANZ has conducted a risk assessment and made recommendations on acidity regulators and ten other food additives which were considered individually as summarised in Table 2.17 of the consultation paper. We support the FSANZ proposals regarding these additives.

2.4 Harmonisation of food additive permissions

Fonterra supports and refers to the INC submission on harmonisation proposals for food additives.

2.6 Updates to nomenclature and INS numbers

Fonterra supports FSANZ's proposal to address these inconsistencies as part of a targeted review on food additives.

Contaminants

3.3 Maximum Levels (ML) for contaminants

Fonterra supports the range of contaminant proposals discussed in CP1. Please refer to the below table for Fonterra's views.

Contaminant	Proposal	Fonterra Response
Acrylonitrile	No change to the ML of 0.2mg/kg for all foods incl. IF	Support
Aluminium	Retention of a single ML of 0.05mg/100mL for all IF products	Do not support retention of a ML for Aluminium and as ML's should be based upon risk to address public health concerns. The toxicological understanding of aluminium has evolved since JEFCA's 2011 assessment derived a Provisional Tolerable Weekly Intake (PTWI) of 2mg/kg-bodyweight. In 2017, the EU established a Tolerable Daily Intake (TDI) for aluminium of 0.3 mg/kg-bodyweight/day[1]. It is not apparent how FSANZ has calculated the ML of 0.05 mg/100 mL from either the JECFA or EU health-based guidance value (HBGV). Nor is it apparent that current dietary exposure to aluminium from infant formula comes close to any

[1] https://ec.europa.eu/health/sites/default/files/scientific_committees/scheer/docs/scheer_o_009.pdf

		toxicologically-based limits. Therefore, we request further information that helps demonstrate what (if any) public health benefit this ML achieves. The ADS dietary information that was shared to support the ML suggests that older infants (9 months) have most of their dietary exposure to aluminium from baked goods (muffins, scones, cakes, slices). INC considers it important to recognise that infant formula is for 0 to -6 months where formula is a sole source of nutrition, and that baked goods are irrelevant to the dietary intake of this age-group. Any assessment of risk should take this into consideration. Hence, Fonterra is of the view that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995). The EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006). In the US, limits for aluminium as a contaminant metal in infant formula are also not included (CFR, Chap 21, parts 106 & 107).
Arsenic	No ML for IF products – consistent with Codex	Support
Cadmium	2 options: • Do not establish a ML for IF • Harmonise with EU ML's on the basis for soya protein isolates, alone or in a mixture with cows milk proteins	Support option 1, not to establish a ML for IF.
Lead	Reduce the ML from 0.02mg/kg to 0.01mg/kg in IF and apply this level on a ready ready-to-feed basis. Aligned with ML in Codex.	Support reduced ML to align with Codex.
Melamine	Not to establish an ML, despite ML's in place for Codex	Support
Tin and inorganic tin	No change in the code ML of 250mg/kg - set for all canned foods would also apply to IF products	Support
Vinyl chloride	No change	Support
Mycotoxins: Aflatoxins B1 and M1	Introducing MLs is not necessary	Support
Mycotoxins: Ochratoxin A	Not to establish MLs	Support
Polyaromatic hydrocarbons	Not to establish ML	Support
Perchlorate	Not to establish ML	Support
3- and 2-MCPD and GE	No ML added to the code. But will continue to work with international agencies, sharing data and information with a view of identifying further mitigation measures.	Support

3.4 MLs for infant formula in the dry powder form or as consumed

While ML's applied to a powder basis are more practical for implementation, we can align with Codex if other stakeholders have strong views on this proposal.

3.5 Contaminant definition

Fonterra support consideration for the definition of analytes to be more appropriate within a future review of Standard 1.4.1

Questions for Additives & Contaminants:

1. **FSANZ has proposed two options in relation to the ML for cadmium (Section 3.3.4). FSANZ ask stakeholders for views on these options.**

Fonterra support option 1, not to establish a ML for IF.

2. **Table 2.17 lists the proposed approach for food additives. It includes some food additives where it is proposed to align with EU regulations but FSANZ has noted that there is a lack of safety information and therefore, it is not possible to draw a conclusion on the safety of these substances at the proposed levels in the target population. In these cases (all relate to IFPSDU which are generally imported into the Australian and New Zealand market), we request further information from health professionals about the need to permit addition of these food additives to IFPSDU and information from manufacturers about industry use of these food additives in Australian and New Zealand. The food additives that this question pertains to are:**
    - **Locust bean gum**
    - **Pectins**
    - **Xanthan gum**
    - **Sodium alginate**
    - **Sodium carboxymethylcellulose**
    - **Sucrose esters of fatty acids**

Fonterra supports and refers FSANZ to the INC response in relation to this question.

For health professionals, please provide information to the following questions:

3. **In addition to the above list, what new evidence (if any) do you have for the potential health impacts for infants of changing any of the current permissions for any other food additives, discussed in this paper?**
4. **In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants?**
5. **To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need? Please provide evidence where possible.**

No comments as these questions (3-5) are for health professionals

For industry, please provide information to the following questions:

6. **Would there be any practical barriers to complying with new permissions and limits as proposed in this document for any formula products that have not yet been identified? How might such barriers be overcome?**

There is a barrier to compliance in terms of the permissions of vitamins and minerals that also can serve an additive function. Under Codex, there is an explicit reference to the advisory lists (CXG 10-1979) in the additive section of the infant formula standard:

> *"Only the food additives listed in this Section or in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions: [...]"*

There is no equivalent in FSANZ, which leaves a gap between FSANZ and Codex carry-over permissions for IF. For example, a nutrient form might not be a directly permitted additive for food category 13.1 of Schedule 15. Under the proposals, that nutrient form would not be permitted to be carried over into IF and IPFSDU as an additive, even when it is directly permitted in IF and IPFSDU as a nutrient.

Our proposed solution is to add a food additive section to Standard 2.9.1 with the following text:

> *"Only the food additives listed in the sub-food categories 13 of Schedule 15 or in Schedule 29—7[1] may be present in the foods described in Standard 2.9.1—3 as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food"*
>
> *[1] Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes*

7. **What (if any) implications might overcoming any practical barriers have for production costs per product line? Please quantify where possible.**

N/A

8. **Might smaller or else larger businesses be disproportionately impacted if a new permission does not align with international regulations or standards? If so can you specify how by providing quantitative evidence where possible?**

N/A

9. **Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how?**

Food category 0 in Schedule 15 includes all additives permitted at GMP, along with a list of specific substances. From the list of additives permitted at GMP, there are some that are used in the preparation of other additives that are then used in infant formula. These food additive preparations may have functions such as being an anti-oxidant (e.g. sodium ascorbate has antioxidant function) for another additive or mixture of additives.

Given that the technological function for the substances in food category 0 in Schedule 15 relate to their function in other additives, rather than the infant formula or IFPSDU product, we do not think it is necessary to review or re-evaluate their appropriateness as part of this consultation.

10. **What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper?**

If the FSANZ proposals aligned more fully with Codex regarding carry-over with respect to carry-over of permitted nutrient forms when they are used as additives (refer to question 6 response), there will be no additional steps required to ensure compliance.

11. Do you have any more information on how much ensuring compliance would cost per effected product?

N/A

12. Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle?

N/A

Lactic Acid Producing Microorganism

13. Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic. Do these need to be explicitly excluded (or non-pathogenic specifically permitted) or is the base 'safe and suitable' requirement considered sufficient to manage this risk?

Fonterra do not consider that L(+) lactic acid producing microorganisms requires clarification to specify 'non-pathogenic'. This is because there is an overarching requirement in the code for all food to be safe and suitable. Further, Codex refers to L(+) lactic acid producing cultures without further clarification and there is no market failure with this approach.

If there is a strong preference by other stakeholders, Fonterra is not opposed to the inclusion of 'non-pathogenic' in the code.

Labelling – directions for preparation and use

14. Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach?

The labelling section recommends a range of proposals. Please see Fonterra's comments below:

5.3.1 Directions for preparation and use

Proposal	Fonterra Response
Maintain existing direction to prepare bottles individually.	Support
Maintain recommend maximum storage time of 24 hours when refrigerated.	Support
Revise water used to reconstitute powder to specify 'cooled'	We support inclusion of the word 'cooled' to be included within the directions for use provided the wording continues to provide flexibility by not being prescribed. This would allow manufacturers to use terms with similar meaning such as 'room temperature' or 'lukewarm'.
Revise discarding left over formula to specify within 2 hours	Support the inclusion of 'within 2 hours' or similar wording that reflects this maximum or less. As determined appropriate by the manufacturer and or to be consistent with local country feeding guidelines where appropriate: • Australia[2]: "*any formula that has been at room temperature for longer than one hour should be discarded"* • New Zealand[3]: "*Discard made up formula that is not used after two hours at room temperature*."
Removal of labelling requirements not applicable to ready to drink formula's	Support, requirements are not relevant to ready to drink formula's.

[2] National Health and Medical Research Council (2012) Infant Feeding Guidelines. Canberra: National Health and Medical Research Council.
[3] Ministry of Health. 2008. Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2): A background paper (4th Ed) – Partially Revised December 2012. Wellington: Ministry of Health.

5.3.2 Standardised wording or pictures for directions for preparation and use

Fonterra supports flexibility for words and imagery which is consistent with Codex. It is appropriate for the words and imagery to be applicable to the product and aligning with infant feeding guidelines in the applicable countries.

5.4.1 Date marking

Fonterra supports retention of existing date marking requirements.

5.4.2 Storage instructions for infant formula

Fonterra supports retention of existing storage instruction requirements.

5.4.3 Measuring scoop

Fonterra supports the status quo with directions instructing to only use the scoop enclosed.

5.5 Warning statements

5.5.1 Legibility for warning statements

Fonterra support no change to the legibility requirements for warning statements on infant formula products.

5.5.2 Warning statements about following instructions exactly

Fonterra do not support the inclusion of '*or add anything to this formula*' to the warning statement.

The current statement is considered fit for purpose and adding any additional words to a statement with prescribed legibility at 3mm takes up valuable space on cans.

As noted by the MPI commissioned research, there is limited evidence of caregivers adding foods to formula (5-6% of respondents), furthermore, it is not clear whether this practice relates to infant formula or follow on formula products. The additional proposed text could create concern or confusion for the majority of caregivers who would ordinarily not consider this practice.

Further, we note the MOH draft dietary guidelines include advice not to "add anything else to the bottle, for example, cereal or baby rice" and explains in more detail the need to prepare bottles correctly for caregivers and healthcare professionals.

Fonterra propose it would be more appropriate to include clarifying text in the preparation instructions, which eye tracking results indicated caregivers spent more time reading. We propose the wording "*do not change proportions of powder **and water***" would clarify that only powder and water should be used and reinforce the importance of following the individual product directions.

5.5.3 Warning statement 'breast is best'

Fonterra supports the continued use of the 'breast is best' warning as support for the best way to feed infants.

5.6 Product Identification

5.6.1 Prescribed name

Fonterra supports continued use of 'infant formula' as the prescribed name.

5.6.2 Statement that infant formula products may be used from birth

Fonterra supports maintenance of the existing statement.

5.6.3 Statement about age to offer foods in addition to formula

Fonterra does not support the continued use of the existing labelling statement i.e. " *It is recommended that infants from the age of6 months should be offered foods in addition to the infant formula product.*".

We propose the wording is changed to "*It is recommended that infants from **around** the age of6 months should be offered foods in addition to the infant formula product*", noting that 'around' aligns to both the NZ and Australia MOH draft dietary guidelines for infants and toddlers. This also acknowledges that advice regarding the recommended age for introducing solids has changed over time.

In 2002 the World Health Organisation updated its guidelines from introducing solids between 4 to 6 months of age, to "at 6 months of age". More recently, In ANZ[4,5], Food and Nutrition Guidelines advise to introduce weaning foods around 6 months and in the EU, ESPGHAN[6] (The European Society for Paediatric Gastroenterology Hepatology and Nutrition) reviewed evidence on complementary feeding and recommended solids should not be introduced before 4 months of age, but should not be delayed beyond 6 months of age.

However, Recent Health Bodies/Guidelines are generally consistent in outlining that weaning foods should not be delayed beyond 6 months of age and should not be initiated prior to 4 months. In summary:

- It is not recommended to introduce solids prior to 4 months of age (17 weeks, beginning of the 5th month)
- It is not recommended to delay the introduction of solids past 6 months of age (26 weeks)
- There is some evidence of a link between delayed introduction of 'allergenic' solid foods (such as peanut butter, cooked egg, dairy and wheat) in the first year of life and increased risk of food allergy.
- Fewtrell 2017[6] highlights emerging evidence of an allergy 'tolerance' window for egg at 4-6 months

As there may be some introduction of solids in the 5th month, the inclusion of 'around' would help provide clarity for parents who may have been advised to start solids prior to 6 months by a healthcare professional.

5.6.4 Statement on protein source

Fonterra do not support FSANZ's proposed clarification of the protein source statement and supports maintenance of the status quo which allows for references to protein fractions in addition to protein source (origin).

There is no evidence the protein origin is not being included within current labelling practices to comply with the current code, suggesting there is no need to further clarify the intent. The protein source statement is different from an allergen statement and should not be used by consumers as a means to assess the allergens present. This is because not all allergens in a product will be derived from the main protein sources (origin) within the product (e.g. **soy** lecithin in a cow's milk formula).

We support consumers and healthcare professionals being able to clearly differentiate protein origin, we also consider that allowing other information related to protein fractions (such as 'whey-dominant' or 'hydrolysed' etc.) is important. This supports truth in labelling to ensure consumers understand the true nature of the product.

Furthermore, anecdotally we receive consumer queries requesting information on the protein fractions within our products. This suggests this information is useful and sought out by interested parties and should therefore continue to be available at point of purchase.

5.6.5 Co-location of protein source statement with the name of the food

Fonterra support the maintenance of the current requirement to co-locate the protein source statement and the prescribed name of the food.

In relation to proposals related to this, refer to section 5.6.1 and 5.6.4 above.

15. Are you aware of any further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products?

Fonterra are not aware of any additional data.

[4] National Health and Medical Research Council (2012) Infant Feeding Guidelines. Canberra: National Health and Medical Research Council.
[5] Ministry of Health. 2008. Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0–2): A background paper (4th Ed) – Partially Revised December 2012. Wellington: Ministry of Health.
[6] Fewtrell et al (2017). Complementary Feeding: A Position Paper by the European Society for Paediatric gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition. J Pediatr Gastroenterol Nutr. 2017 Jan;64(1):119-132.

16. **How often do you change labels on your products voluntarily for marketing or other purposes?**

Product renovations are driven by changing consumer needs and innovations in the paediatric nutrition sector. This is a highly regulated category where changes to products can cause consumer concern. Based on this and due to the significant impact to resources, time and costs involved, changes are not frequent.

17. **If the proposed changes were made at the same time as a voluntary label change, how much extra would it cost to change each product's labels (on average)?**

It is strongly preferable that if label changes are required that we bundle these together to minimise cost with a long lead time so this could be built into any other product renovation. If proposed label changes were to go ahead as part of a brands voluntary label change, there may be minimal additional costs depending on the type of change.

18. **If the proposed changes could not be made at the same time as a voluntary change, how much extra would it cost to change each product's labels (on average)?**

Fonterra can provide this information as commercial in confidence if required.

19. **Apart from any costs, would there be any other practical challenges of changing your products' labels as proposed?**

While it is preferred that we use of all existing labels, depending on the type of change (soft vs. hard change) write off's may be required, this means finding sustainable solutions to dispose of unneeded packaging. This is particularly important when considering transition periods for change.

It is important to recognise that labels updates impact more than the individual label. Any changes made to labels requires update of associated material such as website content and other collateral to ensure consistency which can require substantial resource to manage changes.

General questions related to the consultation paper

20. **In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence and quantify impacts where possible.**

CP1 covers many regulations which are shared with the Follow-on Formula within Standard 2.9.1. While we appreciate the focus of this paper is specifically on Infant Formula, we would encourage FSANZ to consider how to manage the impacts where the regulations are shared (e.g., additive permissions, labelling etc.) to ensure continued alignment where appropriate.

FSANZ should consider a transition period that is commensurate with the complexity of product reformulation and labelling change lead times. We recommend a five-year transition period allowing for stock in trade to allow sufficient time to update product in line with proposals.