7 July 2023

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Dear Sir/Madam

Attached are the comments that the New Zealand Food and Grocery Council wishes to present on the *Second Call for Submissions – Proposal P1028 Infant Formula*

Yours faithfully

[redacted]

Second Call for Submissions – Proposal P1028 Infant Formula

Submission by the New Zealand Food and Grocery Council

7 July 2023

NEW ZEALAND FOOD AND GROCERY COUNCIL

1. The New Zealand Food and Grocery Council (**NZFGC**) welcomes the opportunity to comment on the *Second call for submissions – Proposal P1028 Infant Formula* (**CFS2**).

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

COMMENTS

3. NZFGC considers that breast feeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. However, when an infant is not given breastmilk, the only suitable and safe alternative is a scientifically developed infant formula.

4. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health and provide flexibility and incentive for innovation for continuous improvement of infant formulas.

5. This review has been formally underway for a decade and was preceded by 5 year's development of the policy guidance from the then Australia New Zealand Food Regulation Ministerial Council. NZFGC is pleased to see it nearing completion so that infants in Australia and New Zealand can better benefit from many developments overseas that have, until now, passed us by.

6. NZFGC provides conditional support for the two category framework. For category one, we support infant formula and follow-on formula containing partially hydrolysed protein from a compositional perspective noting there is no reason for a distinction between infant formula and follow-on formula. For category two Special Medical Purpose Products for infants (**SMPPi**) NZFGC is supportive of restricted sale of high-risk products. Such products are almost all exclusively imported, they currently have limited availability often only through hospitals (and restricted accessibility), they are very costly and are often available only with subsidisation and on prescription. However, not all SMPPi are high risk. The products for special dietary use in the current Food Standards Code for transient conditions are low risk.

7. Category two is proposed to be restricted for sale but since only pharmacies are proposed to sell SMPPi to the general public, this restriction is limited by availability within pharmacies. Geography and time limits access, increases cost and potentially increases risks to infants. A general restriction on the sale of SMPPi will have an impact on three major areas:
   - a negative effect on some health outcomes for infants who require these products and the parents and caregivers who support the infant
   - less accessibility and availability of these products for parents and carers, and
   - supply chain logistics.

8. The restriction on sale of low-risk products also has the potential to be inequitable and unsafe for those in need, particularly due to limited access in rural and remote communities. INC commissioned research by IQVIA to examine the impact of this

restriction across each of Australia and New Zealand. Those in regional/rural or remote areas such as characterises much of the New Zealand's South Island outside Christchurch are particularly affected.

9. NZFGC recommends low-risk SMPPi products that are used for gastrointestinal conditions and feeding problems are exempt from the restriction of sale. These are infant formula products represented as being specially formulated for the dietary management of the gastrointestinal conditions, gastroesophageal reflux/regurgitation, colic, constipation and lactose intolerance.

10. In many other areas covered by P1028, NZFGC is supportive. This includes definitions proposed for infant formula products and related terms, SMPPi and protein substitute, the removal of certain terms (such as 'soy based formula' and 'preterm'), changes proposed for novel foods (noting we support reactivation of P1024 to provide industry and stakeholders regulatory clarity), maintaining the current permission on L(+) lactic acid producing microorganisms (**LAM**), all the food additive proposals except for those identified by INC that require further amendment (INS 301, 307c, 333, 338-341, 410, 415 and 472e) and no further changes to processing aids.

11. NZFGC does not support reducing the aluminium maximum limit (**ML**) for soy because the reduced ML may not always be met due to varying natural levels in soy ingredients. The current level is safe as it's in line with the JECFA recommendation (2mg/kg bw/week).

12. In relation to nutrient composition, NZFGC supports the alignment with Codex and the EU on many aspects. However, this the minimum amounts of amino acids histidine, methionine and tryptophan values should be 9.8, 5.7 and 7.9 respectively. As well, the ability to combine the aromatic amino acids (AAA – phenylalanine and tyrosine), and the sulphur amino acids (SAA – methionine and cysteine) should be provided for to achieve the minimum amino acid requirements because to do otherwise may lead to unnecessary addition of L--amino acids.

13. NZFGC recommends amendments to:
    a) Docosahexaenoic Acid (DHA) – the following permitted sources of DHA be retained: dried marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA), oil derived from marine micro-algae (Schizochytrium sp.) rich in docosahexanoic acid (DHA) and oil derived from marine micro-algae (Ulkenia sp.) rich in docosahexanoic acid (DHA).
    b) Long Chain Fatty Acids – for the variation to Schedule 29—4, retain the maximums for long chain omega 6 series fatty acids (C> = 20) and long chain omega 3 series fatty acids (C> = 20)
    c) Follow-on Formula Vitamin D Maximum – adopt the draft Codex Follow up Formula for Older Infants and EU maximum for follow-on formula of 0.72 µg /100kJ
    d) the wording for the sucrose/fructose prohibition – limit the prohibition in infant formula and follow on formula for added fructose and/or added sucrose <u>as a carbohydrate source</u>
    e) Medium Chain Triglycerides to clarify that naturally occurring MCTs in vegetable oils (which are not intended to be included within the scope of the prohibition)
    f) the use of GULs – retain the word 'usually' in the note on the use of GULs as is the case in Codex
    g) a higher GUL for L-carnitine to better reflect naturally occurring levels in dairy ingredients.

14. For the composition of SMPPi, many highly specialised products are imported from other countries and a continuous supply is critical to infants who require these products for the

dietary management of their condition. NZFGC supports FSANZ's proposal to allow the composition of SMPPi products to deviate from the specific compositional requirements for infant formula products, where required to address the product's special medical purpose.

15. In relation to labelling our key concerns are the prohibitions on:
    - using certain prescribed labelling terms such as 'lactose free', 'low lactose', 'partially hydrolysed', animal or plant sources of protein and the voluntary stage labelling on the back of pack as well as the front
    - provenance labelling associated with ingredient labelling.

16. The prohibition of applying prescribed or permitted voluntary terms on the back of the pack when they are permitted on the front makes no sense. We fail to see how such terms suddenly become claims by moving 15cm to the back of pack. If a term is prescribed for the front or permitted for the front, then its use on the back is confirmatory and raises awareness for the carer selecting the product. We note duplication of stage labelling can be important an driver for consumer awareness as was well recognised during the plain English allergen labelling discussions which now require allergens to be labelled multiple times within the ingredients list and in summary statements.

17. NZFGC very strongly opposes the proposed further restriction on so-called ingredient claims that are more accurately described as provenance statements. Provenance related statements do not imply nutrition or health benefits to consumers. The inability to put "made with New Zealand milk" on a can will restrict the provision of information to consumers to make informed choices and have substantial implications for the competitiveness of the New Zealand infant formula industry in export markets. This restriction does not support the adequate description of products to ensure those purchasing the product are not misled but rather, are provided with adequate information.

18. NZFGC considers provenance related statements to not imply any nutrition or health benefits to consumers and we believe they have been inadvertently captured by the general nature of the draft variation. The same is true of other general statements such as "high -quality ingredients" or "sustainably sourced ingredients". The inability to put "made with New Zealand milk" on a can will have substantial implications for the competitiveness of the New Zealand infant formula industry.

19. In relation to the mandated format of the Nutrition Information Statement (**NIS**), NZFGC supports many aspects but does not support the following:
    - Units for Vitamin E and A. Those shown in Schedule 29—6 should be Vitamin E as mg α-TE and Vitamin A as µg RE.
    - Folate, not folic acid to be in NIS – folic acid is used in the Ministry of Health pregnancy guidelines and on general food nutrition information panels and to argue greater familiarity for carers with the term 'folate' is simply not substantiated
    - Voluntary use of unit quantities of 100mL as consumer in addition to the mandated 100g. This would be consistent with the mandatory requirement in Codex (both 100mL and 100g) and the EU to allow for harmonisation with markets that have adopted mandatory Codex provisions. This is especially important for Pacific Island nations and would be inequitable to those markets for New Zealand to do otherwise
    - Prohibition on use of common terms, acronyms/abbreviations and additional information. There is no evidence that acronyms should not be used on labels and we especially support the acronyms for docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), linoleic acid (LA), alpha linoleic acid (ALA) and arachidonic acid (ARA)

- An explicit list, prescription of wording and format of the voluntary declaration of macronutrient sub-groups. This would greatly assist carers who already have some familiarity with the headings.

20. NZFGC supports the provision for infant formula that is represented as partially hydrolysed, requiring the words 'partially hydrolysed' immediately adjacent to the statement of protein source and permitting the words 'partially hydrolysed' in the statement of ingredients. However, NZFGC does not support the explicit prohibition of the words elsewhere on the label (as they are prescribed terms) nor the prohibition of the words on follow-on formula. Similarly, NZFGC supports the provision of the use of stage numbering to enable caregivers to differentiate between infant formula and follow on formula but does not agree that this information should only appear on front of pack.

21. NZFGC supports the prohibition of representation made in infant formula or follow-on formula about information relating to another product (a name, number, picture, image, word or words) and is generally supportive of the labelling proposals for SMPPi except in relation to labelling of nutrient modification and prohibited representations. In both cases, these would have the potential to be trade barriers due to misalignment with international regulation and the unintended consequence of prohibiting, or delaying, import of specialty infant formula products for infants. An alternative approach would be for companies to provide this information to healthcare professionals upon request.

22. In relation to costs and benefits, NZFGC does not consider that all major impacts of the proposed changes to the Standard have been identified. NZFGC does not agree with assessments that suggest lower costs nor that restricted sales of specialised formula may cause only some inconvenience. This severely understates the impact of removing the two/thirds of these products in Australia and New Zealand that are sold through supermarkets. INC commissioned IQVIA analysis of the SMPPi market which suggests higher costs in pharmacies ($6 per can in Australia and $3 per can in New Zealand (although $7 per can in the lower South Island)) and fewer choices as a result of restricted sales. However, NZFGC considers the estimates for the quantifiable costs to industry are fair estimations and agrees that industry will generally benefit from greater alignment with international infant formula products

23. In terms of impacts on consumers, it is a certainty that there will be an impact for consumers from restricting sales channels on price and availability. Assumptions in these areas and in relation to online sales need correcting.

24. In relation to industry impacts, trade costs require further consideration especially in relation to seeking exemptions in New Zealand and for both Australia and New Zealand for specific labelling prohibitions related to provenance of some ingredients.

25. FSANZ states that "The standards are not expected to result in a change to market access nor significantly reduce market viability for infant and follow-on formula products. FSANZ expects that very few products would be unable to adapt to the new standards and that competition between manufacturers would not be significantly affected." (p33 SD4). The issue for market access is not about adapting to the local market but rather being able to import inputs that are made for global destinations and remaining competitive in global markets. Of particular concern are the labelling restrictions. It is costly and difficult to seek exemptions for export labelling from domestic standards. Such requirements also limit product placement into the domestic market should that be necessary in the future (such as in a future pandemic situation). The restrictions also impact the ability of domestic products to compete in the global marketplace via cross-border e-commerce channels.

26. New Zealand imports 30-40% of infant formula inputs and exports a significant proportion of both finished product and base powder for infant formula manufacture off-shore. Infant formula exports from New Zealand are around 141,000t or $1.93bn.

27. The prohibition of label statements relating to the provenance of ingredients such as "made with New Zealand milk" do not infer specific nutritional benefit and therefore, should not be prohibited. Rather such statements provide adequate information relating to trust in the food to enable consumers to make informed choices in accordance with a FSANZ stated objective. The prohibition of such label statements is:

    a) extremely detrimental in ensuring that New Zealand maintains an efficient and internationally competitive dairy and infant formula industry since the prohibition disadvantages New Zealand manufacturers in overseas markets where such restrictions are not placed on our in-market competitors who manufacture in other jurisdictions

    b) particularly of concern for CBEC exporters who compete in overseas markets where regulation on ingredients is not prohibited

    c) removing the mechanism for communicating consumer trust and informing consumers on the difference related to our products versus others on the market.

28. In the current environment, export product must meet FSANZ requirements unless exempt. If the prohibition of ingredient claims is progressed, New Zealand products sold via export and CBEC channels would both be significantly impacted. This proposed prohibition would put New Zealand exporters at a significant disadvantage to exporters from other countries. The cost cannot be calculated but a loss of even 1% of New Zealand's $1.93bn export value of infant formula alone would be $19.3m.

29. NZFGC believes the costs of changes could be higher in the short run (5 years). Only if the prohibitions do not proceed for provenance related labelling statements, would NZFGC agree that benefits in the long run (10 years) could be higher than costs.

30. Communication of changes to healthcare professionals and caregivers regularly during the transition period will be very important. Any changes to product can cause carers significant anxiety. Due to the application of the INC Code of Marketing in New Zealand, there are restrictions on our members communicating changes about infant formula products. The risk for industry is that consumers will believe that individual businesses have chosen to make wholesale changes when that is not the case. FSANZ and the New Zealand (and Australian state and Territory Governments) need to be supporting the changes over the transition and to provide clear communication of these changes to carers in order to reduce their anxiety over this period. Industry could then point to these when consumers contact them expressing concerns.

31. NZFGC continues to support INC's recommendation of a transition period of 5 years plus 2 years stock-in-trade. This greater period will reduce cost of change and smooth the impact for consumers.