19 August 2021

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for Submissions on Application A1190 – 2'-FL in infant formula and other products.*

Yours sincerely

[redacted]

[redacted]

[redacted]

Call for Submissions on Application A1190 – 2'-FL in infant formula and other products

Submission by the New Zealand Food & Grocery Council

19 August 2021

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Call for Submissions on Application A1190 – 2'-FL in infant formula and other products.*

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. At the outset, NZFGC wishes to state that it supports government policies for the protection and promotion of breastfeeding and recognises the role of scientifically-developed infant formula product as the only suitable and safe alternative when breast milk is unavailable for an infant.

4. We also support FSANZ's decision to approve the voluntary addition of new substances that have been shown to be safe and suitable for addition to IFP and FSFYC. The addition of optional ingredients is the mechanism by which the move to mandatory additions is often made as we are seeing in Codex and the EU with the likes of choline.

5. NZFGC has received a copy of the Infant Nutrition Council of Australia and New Zealand (INC) submission and we strongly support the positions taken by the INC as stated in its submission. We share the concerns that the INC has described in detail and which we comment on in more general terms below.

6. NZFGC supports Option 3 permitting the use of the applicant's 2′-FL in both infant formula products and formulated supplementary foods for young children (FSFYC).

7. We note an exclusive permission period of 15 months would apply, linked to the applicant's brand name 'CHR. HANSEN™ 2′-FL', commencing on the date of any gazettal of the variation.

8. NZFGC has reviewed the following assessments undertaken by FSANZ:
   - ***biochemical assessment*** determined the 2′-FL sourced from the microbial fermentation was shown to be chemically and structurally identical to the naturally occurring 2′-FL in human milk
   - ***microbiological assessment*** concluded that the host strain had a recognised safe history of use
   - ***biotechnology assessment*** found the production strains were safe
   - ***nutritional assessment*** concluded the addition of 2′-FL to infant formula was not expected to affect the growth profiles of infants and there was no evidence to indicate concern at concentrations that were typically observed in human milk
   - ***benefit assessment*** that there was evidence to support a role for 2′-FL in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. Although the evidence base for these effects in young children was found to be limited, there was evidence for an effect in young children.

9. We also note that FSANZ has previously assessed 2′-FL (separately and in combination with LNnT in Application A1155 – *2'-FL and LNnT in infant formula and other products* in which FSANZ confirmed the safety of the substances**.**

10. NZFGC therefore **fully supports** FSANZ's safety assessment and the resulting decision to permit the voluntary addition of 2'-FL, at the levels proposed of up to a maximum of 2.4 g/L, to infant formula products.

11. NZFGC **does not support** the FSANZ decision to exclude permission of 2'-FL to FSFYC.

12. NZFGC continues to have concerns with the prohibition of adding 2'-FL to FSFYC. FSFYC may provide ingredients, found in breastmilk, that may contribute a benefit to young children as part of their diet. As stated above, FSANZ found evidence of a beneficial effect in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children.

13. NZFGC is firmly of the view that 2'-FL should be allowed to be added to FSFYC products. Allowing a human milk oligosaccharide such as 2'-FL to be voluntarily added to FSFYC products could allow young children, who do not continue to breast feed beyond 12 months, for whatever reason, to receive benefits, including bifidogenic and immune system effects.

14. As the most prevalent of the HMOs found in human breast milk, 2'-FL is reported to have a role in the gut and immune system of infants, reduce risk for lower respiratory tract illnesses through a protective effect on mucosal barrier function and an immunomodulation role in prevention of allergic diseases in early life.

15. FSFYC products are not breastmilk substitutes but may provide ingredients, including those found in breastmilk, that can continue to be a benefit to young children as part of their diversified liquid diet.

16. NZFGC previously raised in relation to Application A1155, concerns regarding the decision to prohibit the use of the terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on infant formula products and FSFYC with permissions otherwise available in Standard 1.2.7. Nutrition, Health and Related Claims.

17. FSANZ is proposing a regulatory measure that allows the addition of a nutrient, which has demonstrated health benefits into a food, but is prohibiting food companies providing the best information to consumers of its presence.

18. The proposed prohibition of terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of infant formula products and FSFYC is a barrier for care givers and health professionals alike.

19. NZFGC considers FSANZ should apply generic ingredient labelling requirements, rather than prescribed ingredient names previously proposed, consistent with the general approach in the Food Standards Code. Standard 1.2.4—4 requires ingredients to be identified using a name by which they are commonly known, or a name that describes its true nature, or a generic ingredient name if one is specified in Schedule 10 – Generic names of ingredients and conditions for their use.

20. NZFGC notes that approval of this Application provides harmonisation with international standards, and encourages local manufacturers to access to the latest technologies and to invest in innovative products with appropriate safeguards that will deliver benefits for both the domestic and export markets.

21. The 2'-FL compound, as outlined, when added to infant formula products and FSFYC will result in products better able to support infant nutrition and health. These products will be competitive in international markets, and will ensure that Australian and New Zealand manufacturers can compete directly with international infant formula product and toddler milk manufacturers.

22. In summary, NZFGC is supportive of FSANZ's decision to permit the voluntary addition of '2' Fucosyllactose' (2'-FL) to infant formula products at the levels proposed in A1190. However, we are opposed to excluding permission of 2'-FL to FSFYC, and the prohibition of the use of terms such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of infant formula products and FSFYC.