31 January 2022

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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 – Application A1233: 2'-FL from new GM source for infant formula.*

Yours sincerely

[redacted]

[redacted]

[redacted]

Call for Submissions – Application A1233: 2'-FL from new GM source for infant formula

Submission by the New Zealand Food & Grocery Council

31 January 2022

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Call for Submissions – Application A1233: 2'-FL from new GM source for infant formula.*

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.

THE PROPOSAL

3. Friesland Campana applied to amend the Australia New Zealand Food Standards Code (the Food Standards Code) permit the sale and use of 2'-fucosyllactose 2 (2′-FL) derived from a genetically modified *Escherichia coli* (*E.coli*) strain as a nutritive substance in infant formula products covering infant formula, follow-on formula and infant formula products for special dietary use.

4. The application also requested an amendment to Schedule 3 of the Code to reference or include a specification published by the European Union for this 2'-FL.

COMMENTS

5. NZFGC supports the Application and FSANZ's draft variation to the *Australia New Zealand Food Standards Code* (the Food Standards Code) to permit the level of the Friesland Campina Ingredients 2'-FL "up to a maximum of 2.4 g/L" in infant formula products is appropriate. This is consistent with the currently approved level of 2'-FL in Standard 2.9.1--7 and Schedules 3, 26 and 29.

6. NZFGC strongly supports the submission made on this application by the Infant Nutrition Council Australia and New Zealand.

Content of human milk

7. After lactose and fat, the third main solid component in human milk is neutral and acid oligo- (and poly) saccharides. The structure of about 200 human milk oligosaccharides has been identified and many more are present, at least in small quantities. These oligosaccharides occur in concentrations between 10-15 g/L in mature breast milk and up to 20 g/L in colostrum (Kunz et al. 2000 and Thurl et al. 2017). Neutral oligosaccharides such as 2'-FL are the predominant oligosaccharides in human milk and the permitted addition in infant formula products is in line with Policy Principle h) relating to composition in the Policy Guideline on *Regulation of Infant Formula Products*.

8. 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.

9. FSANZ states that the applicant's 2'-FL is structurally and chemically identical to the form of this substance in human milk. This is a scientifically accurate description

International status

10. FSANZ states in the Call for Submissions that 2′-FL produced by microbial fermentation and by chemical synthesis are permitted for use in infant formula products, FSFYC and many other foods in at least 37 overseas countries at a range of levels. EFSA (EFSA 2015) provided an opinion on the safety of 2'-FL in 2015 that concluded that it was safe for infants (up to one year of age) and young children (older than one year of age) when added to infant and young children drinks.

11. Harmonisation with international standards, that are based on relevant science and scientific expert opinion, is essential to allow the manufacture and availability of these types of products for consumers in Australia and New Zealand. Other jurisdictions including EU, Switzerland, USA, Israel and Taiwan permit the addition of 2'-FL in products for infants as well as young children.

12. 2'FL produced using *Escherichia coli* (*E. coli)* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus* has received EU novel food approval. The Netherlands has determined that the 2'-FL produced through fermentation with *E. coli* K-12 strain E997 by Friesland Campina is substantially equivalent to synthetic 2'FL previously authorised in the EU (EFSA 2015).

13. In the USA, the Food and Drug Administration (FDA) responded with a 'no questions' to Friesland Campina's self-assessment that 2'FL produced using *E. coli* K-12 strain E997 is Generally Recognized As Safe (GRAS).

Risk and Safety Assessment

14. As noted, there is already a permission to add 2′-FL in the Food Standards Code. As the source and specifications of Application A1233 for the Friesland Campina Ingredients 2′-FL derived from *E. coli* K-12 strain E997 to be added to infant formula products, it required a separate pre-market assessment. The maximum level of addition of 2'-FL is 96 mg/100 kJ or 2.4 g/L.

15. The Friesland Campina Ingredients 2′-FL is manufactured by fermentation, using a unique genetically modified bacterium. FSANZ's ***microbiological assessment*** concluded that the host strain had a recognised safe history of use and its ***biotechnology assessment*** found the production strains were as stated by the applicant and were safe.

16. FSANZ's ***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.

17. FSANZ's ***dietary intake assessment*** determined the requested level of 2′-FL was within the normal range of 2′-FL reported in human milk (0.6 – 7.8 g/L). FSANZ's previous ***toxicological assessment*** of 2′-FL concluded there were no safety concerns associated with the addition of 2′-FL at concentrations up to 2.4 g/L. Further assessment of new studies as a part of this application did not indicate a reason to change this conclusion.

18. FSANZ's ***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 a nutritional concern at concentrations that were typically observed in human milk.

19. FSANZ concluded through a ***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. Additionally, there is evidence to support

immune system effects. 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.

20. FSANZ concluded that 2′-FL was naturally present in human milk in a range of concentrations, providing a history of safe human exposure. It also concluded that there were no safety concerns associated with the addition of 2′-FL derived from *E. coli* K-12 strain E997 and produced by microbial fermentation, to infant formula products at the requested existing permitted level in the Food Standards Code (2.4 g/L).

Risk Management

21. FSANZ's safety assessment indicated no concerns with the addition of 2′-FL produced by microbial fermentation to infant formula products and concluded that there were plausible beneficial health outcomes for infants in consuming 2′-FL. FSNZ therefore proposed to permit the applicant's 2′-FL in infant formula.

Permissions to add 2'-FL to infant formula products

22. NZFGC supports permissions for voluntary addition of new substances that have been shown to be safe for addition to infant formula products and that meet the Policy Guidelines on *Regulation of Infant Formula Products* and *Intent of Part 2.9*. NZFGC therefore supports the decision of FSANZ to permit the voluntary addition of 2'-FL derived from *E. coli* K-12 strain E997 to infant formula products. The Friesland Campina Ingredients 2'-FL is structurally identical to the 2'-FL that occurs naturally in human milk. NZFGC also supports the level of additions as proposed by FSANZ for infant formula products noting that these are within the ranges naturally present in mature human milk.

Labelling

23. NZFGC notes FSANZ's decision to apply the same ingredient labelling requirements as were approved for 2'FL under Application A1155. We continue to disagree that '2′-fucosyllactose' is the only name by which the ingredient is commonly known and is therefore inconsistent with the provisions in Standard 1.2.4—4 (b)(i) and (ii) that provides for the use of a name by which the ingredient is commonly known, in this case 'human identical milk oligosaccharide' or HiMO.

24. The prohibition on the use of the term, 'human identical milk oligosaccharides' or HiMO is counter to building consumer confidence in, and understanding of, labelling information. This term and abbreviation is allowed to be used on labels under other internationally recognised standards.

Identity and purity

Schedule 3 covers Identity and Purity. None of the primary sources of specifications listed under S3—2 (Food Additive Specifications, FAO JECFA Monographs, Food chemicals Codex and Commission Regulation (EU) No 231/2012) include microbiological parameters. Schedule 3—4 provides default limits for heavy metals for substances not covered by the primary references.

25. There is currently an inconsistent approach in Schedule 3 with microbiological criteria included in some and not others. FSANZ needs to address such inconsistency.

26. The consultation paper states that that the applicant's 2'-FL is structurally and chemically identical to the form of this substance in human milk. We suggest that there might be value in there being just one entry for this substance in Schedule 3 with one definition followed by additional information specific to each permitted source. We note that in the EU novel

food list (EU2017/2470 consolidated to 16.05.21) there is one entry for 2'Fucosyllactose from microbial sources with one definition, followed by information relating to the two permitted sources (and that this follows immediately after definition for 2'Fucosyllactose (synthetic).

Investment in innovation

27. Regulations should not stifle the communication of innovation and the application of developments that are safe and permitted elsewhere. To do so applies a brake on the pursuit of investment in innovations in Australia and New Zealand. Not only would both countries lose consideration of future investments in innovation, we would lose the public health benefits of such innovation and consign our infants to less than optimal formula products in the future.

Trade impacts

28. In addition to the above, trade may be adversely impacted by the labelling prohibition. This impacts both exports and imports.

29. In relation to exports, the impacts include the competitiveness with other global products. In the short to medium term, a key area of potential non-competitiveness is in relation to cross-border e-commerce or CBEC. If constraints are applied in Australia and New Zealand that are not applied to other foreign products, then our export trade will not compete with the developments that other countries permit. In the longer term, there will be a sustained impact on expanding trade and recognition of products from Australian and New Zealand origin. The inevitable consequence is an erosion of the ability to remain competitive in an international market, and potentially significant trade impacts for Australia and New Zealand.

References

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods consolidated to 16.05.21. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R2470-20210516&from=DE

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