19 August 2022

Project Manager
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6143
NEW ZEALAND

Email: submissions@foodstandards.gov.au

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for Submissions – Application A1251: 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products.*

Yours sincerely

[redacted]

[redacted]

[redacted]

CALL FOR SUBMISSIONS – APPLICATION A1251: 2'-FL COMBINED WITH GALACTO-OLIGOSACCHARIDES AND/OR INULIN-TYPE FRUCTANS IN INFANT FORMULA PRODUCTS

Submission by the New Zealand Food & Grocery Council

19 August 2022

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("**NZFGC**") welcomes the opportunity to comment on the.

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.

OVERARCHING COMMENTS

3. Neutral and acid oligo- (and poly) saccharides are the third main solid component in human milk after lactose and fat. Neutral oligosaccharides such as 2'-fucosyllactose ("**2'-FL**") are the predominant oligosaccharides in human milk. Inulin and oligofructoses have been assessed as safe and regulated as unstandardised foods for almost 30 years. 'Unstandardised foods' such as inulin-type fructans ("**ITF**"), fructo-oligosaccharides and substances normally consumed as foods are taken not to be nutritive substances.

4. Food Standards Australia New Zealand ("**FSANZ**") concluded from its overall *risk and technical assessment* (safety, toxicological and microbiological assessments and dietary and nutrition assessments) that consumption of infant formula containing a combination of 2′-FL, galacto-oligosaccharides ("**GOS**") and/or ITF was safe and well tolerated.

5. In light of existing permissions and labelling requirements, no additional labelling requirements were proposed, a position NZFGC agrees with. NZFGC nonetheless continues of the view that 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.

6. We support FSANZ's commitment to reviewing new evidence on the beneficial role of 2′-FL (alone, or in combination with LNnT) in the normal growth and development of infants.

7. 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 and for export. As well, the alignment of regulations with international standards encourages consideration of future investments in innovation in Australia and New Zealand. Alignment will result after the 15 month exclusivity period.

8. NZFGC has no comments to make on the exclusivity of this particular Application. We are, however, concerned about the ad hoc nature of the expanding scope of exclusivity in the broader food supply.

9. To date, an exclusive capturable commercial benefit has been applied by way of proposal to novel foods and as part of a category-specific application (infant formula) to nutritive substances. The current category-specific application for an exclusive period of use is for a branded food that contains a previously approved nutritive substance and unstandardised foods (GOS and/or ITF).

10. NZFGC is concerned that the scope of “exclusive capturable commercial benefit” is being expanded by applications on a case-by-case basis rather than in a more transparent and regularised way. Without this, the broader food industry is unaware of the opportunity to comment on various implementation pathways of the concept of exclusivity.

11. NZFGC is supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this has to deliver on investment for the food industry and for innovation. We are concerned, however, at the ad hoc way in which the concept appears to be implemented and suggest a more consistent approach be applied in order to ensure visibility for the broader food industry.

DETAILED COMMENTS

The application

12. Nutricia and Chr. Hansen A/S ("**Hansen**") have applied to FSANZ to amend the Australia New Zealand Food Standards Code ("**the Food Standards Code**") to permit 2'-FL to be added to infant formula products in combination with GOS and/or ITF. Nutricia and Hansen have also requested an exclusive use permission for a period of 15 months for their combination of 2′-FL with GOS and/or ITF.

Content of human milk

13. 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. Neutral oligosaccharides such as 2'-FL are the predominant oligosaccharides in human milk and the permitted addition in infant formula products satisfies Policy Principle (h) relating to composition in the Policy Guideline on *Regulation of Infant Formula Products*.

14. Inulin and oligofructoses have been assessed as safe and regulated as unstandardised foods since 1993 in Australia and 1995 in New Zealand. 'Unstandardised foods' can be added to any food that does not have specific compositional requirements. From Standard 1.1.2, ITF, fructo-oligosaccharides and substances normally consumed as foods are taken not to be nutritive substances.

International status

15. 2′-FL as individual ingredients are permitted in similar products without prohibition of the combination, or with the combination expressly permitted, in a range of countries overseas. 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 and for export.

16. Alignment of regulations to permit ingredients that are safe and permitted internationally encourages consideration of future investments in innovation in Australia and New Zealand. Both countries gain consideration of future investments in innovation if regulations continue to align. Without such investment we stand to lose the public health benefits of such innovation and consign our infants to less than optimal foods in the future.

Risk and Safety Assessment

17. Inulin and oligofructose have been assessed as safe and regulated as unstandardised foods since the mid-1990s. As also noted, there are already permissions to add 2′-FL to infant formula products in the Food Standards Code. The source and specifications of the Chr. Hansen 2′-FL derived from *Escherichia coli* (*E. coli*) BL-21 (Application A1190) to be added to infant formula products to a maximum level of 2.4 g/L appears in the Food Standards Code.

18. FSANZ's ***toxicology assessment*** noted there were no safety concerns associated with
    - the addition of 2′-FL to infant formula products at concentrations up to 2.4 g/L
    - the addition of a total level of 8 g/L of ITF and/or GOS, alone or in combination at any ratio, to infant formula products
    - the addition of various combinations of 2′-FL and ITF and/or GOS.

19. FSANZ's ***microbiological assessment*** noted that a literature review covering the period 2008–2021 confirmed that there were no microbiological safety concerns from the addition of GOS and/or ITF to infant formula products.

20. According to FSANZ's ***nutritional assessment,*** 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. Similarly, the addition of GOS and/or ITF alone or combined, at any ratio in infant formula products was unlikely to pose a risk to young infants. One multi-centre (Belgium, Hungary, Poland, Spain and Ukraine) study involving almost 200 infants has indicated that equivalence in daily weight gain from baseline to 17 weeks in infants receiving test and control formula was achieved. From all these, FSANZ has concluded that, based on the available evidence, no difference in growth is likely to occur in infants fed formula that contains 2′-FL and GOS and/or ITF at previously permitted levels.

21. FSANZ's **dietary intake assessment** concluded that, based on the maximum permitted concentration levels in the Food Standards Code, the estimated mean and P90 intakes of 2′-FL combined with GOS and/or ITF from infant formula and follow-on formula range between 5 and 17 g/day and that these intakes are less than the estimated mean and P90 intakes of HMOs from human milk.

22. FSANZ's **health effects assessment** considered anti-pathogenic and bifidogenic effects and concluded that there was no evidence that implied any antagonistic effects between the individual components. FSANZ did note that the evidence was insufficient to draw conclusions on how the magnitude of the effects due to the combination of 2′-FL and GOS and/or ITF compares to the effects of the individual components.

23. FSANZ concluded from its overall ***risk and technical assessment*** that consumption of infant formula containing a combination of 2′-FL GOS and/or ITF was safe and well tolerated.

Risk Management

24. On **labelling**, in light of existing permissions and labelling requirements whereby ingredients must be declared and nutrition information provided and certain representations are prohibited, no additional labelling requirements were proposed, a position NZFGC agrees with.

The five-year review for 2'-FL in infant formula products

25. We note FSANZ is committed to reviewing any new evidence on the beneficial role of 2′-FL (alone, or in combination with other ingredients) in the normal growth and development of infants. NZFGC is very supportive of this work.

Trade impacts

26. In 15 months (after the exclusivity period), Australia and New Zealand will be aligned with other jurisdictions where 2'FL, GOS and ITF are approved both individually and in combination.

Food industry impacts

27. NZFGC makes no comments on the exclusivity of this particular Application. We are, however, concerned about the ad hoc nature of the expanding scope of exclusivity in the broader food supply.

28. We note that exclusivity of use for novel foods has been in place since 2007 and was, at that time, subject to a specific proposal and consultation in *Proposal P305: Permission for*

exclusivity of use of novel foods. This arose from requests from the Food Regulation Standing Committee ("**FRSC"**) and the Australia and New Zealand Food Regulation Ministerial Council (now the Food Ministers Meeting). FSANZ was requested to consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 – Novel Foods of the Food Standards Code. FSANZ was also requested to consider that an exclusive permission, if granted, should be limited to a period of 15 months, after which any exclusive approvals would revert to generic approvals within the Novel Foods Standard. A note is now included in Standard 1.5.1 Novel Foods that states:

> "Novel foods are added to the table to section S25—2 by variations to the Code. When added for the first time, the conditions may include some that apply to the novel food only during the first 15 months after gazettal of the variation."

29. This provides clarity for users of the Food Standards Code about the implementation of the capacity for exclusive permissions for novel food products and prospective 15-month time limits on exclusive permissions.

30. We are aware that Section 8 in the *FSANZ Act 1991* provides that:

> "an exclusive capturable commercial benefit is conferred upon a person who applies for the development of a food regulatory measure or the variation of a food regulatory measure under section 22".

31. To date, an exclusive capturable commercial benefit has been applied by way of proposal to novel foods and as part of category-specific application (infant formula) to nutritive substances. The current category-specific application for an exclusive period of use is for a branded food (manufactured by Nutricia Australia Pty. Ltd) that contains a previously approved nutritive substance (2′-fucosyllactose sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126) and unstandardised foods (GOS and/or ITF). The approved 2'-FL is currently subject to a 15 month exclusivity period which concludes in 2023.

32. NZFGC is concerned that the scope of "exclusive capturable commercial benefit" is being expanded by applications on a case-by-case basis rather than in a more transparent and regularised way so that the entire food industry is aware of the opportunity to comment on, various implementation pathways of the concept of exclusivity. Once approved, the broader food industry has no awareness of that approval if the category of food is not within their product range. Any future combinations of foods (not necessarily novel foods or nutritive substances) could be subject to exclusivity through an application.

33. For example, exclusivity of use for nutritive substances was introduced in 2020 with the finalisation of Application A1155. There was no proposal to consider exclusivity for nutritive substances as there had been for novel foods. Consequently, others in the broader food industry without an interest in infant formula had no awareness of the opportunity to comment on exclusivity for nutritive substances.

34. NZFGC is very supportive of the concept of exclusive capturable commercial benefit and fully recognises the value that this has to deliver on investment for the food industry and for innovation. We are concerned, however, at the ad hoc way in which the concept appears to be implemented and suggest a more consistent approach be applied in order to ensure visibility for the broader food industry.

35. In June 2022, FSANZ published a statement *Exclusivity of use for novel foods and nutritive substances* which states that applicants requesting approval of a novel food or nutritive

substance may also apply for a period of 'exclusive' use to apply to a brand or class of food for up to 15 months. Because of ad hoc approvals, this could soon be out of date.

36. Finally, while we are aware of the particular complexities associated with Application A1155, we note it was a FSANZ decision in response to the Application that led to FOS and GOS not being permitted to be used with HMOs on the basis that the applicant did not specifically request it. In the Application, Glycom had stated it was seeking approval of 2'FL and LNnT as novel foods with the intention for use in infant formula, follow on formula and formulated supplementary foods. It would have appeared reasonable to Glycom at the time that, as FOS and GOS were already approved for use in these products, there would not be a need to make a specific request for use in combination
    - it is not as though any other ingredient with specific approval was requested or excluded from use if using 2'FL and LNnT.

37. NZFGC has examined many of the responses to the Application A1155 Call for submissions and has not seen any that even expressed a view on such a prohibition.

38. This situation adds to our concerns of future uncertainty.

Drafting – Variation to Standard

39. NZFGC agrees with the FSANZ draft variation to the Food Standards Code to permit 2'-FL in combination with GOS and/or ITF in infant formula products.