17 January 2019

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 A1155 – 2'-FL and LNnT as novel foods in infant formula and other products***

Yours sincerely

Katherine Rich
Chief Executive

Call for Submissions – Application A1155 – 2'-FL and LNnT as novel foods in infant formula and other products

Submission by the New Zealand Food & Grocery Council

17 January 2019

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the *Call for Submissions – Application A1155 – 2'-FL and LNnT as novel foods 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 $34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

Application A1155

3. Glycom A/S, Denmark, proposes a novel food permission to amend Schedule 25 of the Australia New Zealand Food Standards Code (the Food Standards Code) to include 2'-*O*-fucosyllactose (2'-FL) and lacto-*N*-neotetraose (LNnT) as novel foods for use as ingredients in infant formula, follow-on formula, and formulated supplementary foods for young children (specifically milk products). Both 2'-FL and LNnT are oligosaccharides that occur naturally in human breastmilk (collectively termed "human milk oligosaccharides" (HMOs) or "human identical milk oligosaccharides" (HiMOs)), with 2'-FL representing the most abundant HiMO.

4. Glycom A/S's 2'-FL and LNnT ingredients, produced by microbial fermentation, are intended to complement the range of other non-digestible oligosaccharide ingredients such as inulin-type fructans and galacto-oligosaccharides that are already permitted for addition to foods for infants and young children in Australia and New Zealand. Based on this Application for a novel food permission, Glycom A/S has applied for an exclusive permission for its brand of 2′-FL and LNnT for a period of 15 months after gazettal.

OVERARCHING COMMENTS

5. NZFGC supports the addition of permissions in the Food Standards Code for Glycom's 2'-FL and LNnT. We agree with FSANZ's conclusion concerning safety aspects of 2'-FL and LNnT and support the maximum levels proposed by FSANZ for 2′-FL alone, for LNnT and for their combined use in the range of products covered by the application. We also support a specification for 2'-FL and LNnT within Schedule 3 *Identity and Purity*, based on what is regulated by the EU in its most recent regulatory revision.

6. There are several areas where NZFGC does not support the FSANZ approach. We do not support the proposal to regulate 2'-FL and LNnT in the Food Standards Code under Standard 1.5.2 and Schedule 26 *Food produced using Gene Technology.* Instead we support alignment with the international community particularly the EU and the US where 2'-FL and LNnT are regulated as novel foods.

7. NZFGC does not support prescribing use of the ingredient names '2-fucosyllactose' and 'lacto-N-neotetraose' but rather strongly supports the application of Standard 1.2.4—4 *Ingredients to be listed by common, descriptive or generic name* as is the case for the vast majority of foods and ingredients used in the food supply. We also do not support the inclusion of Methods of Analysis in the specification as this does not facilitate method improvement and adds unnecessary cost to amend.

8. While NZFGC supports the permission for both 2'-FL and LNnT to be voluntary additions to foods including infant formula and formulated supplementary foods for young children,

we consider that categorising them to each be *used as a nutritive substance* is inconsistent with the approach taken in the Food Standards Code for both galacto-oligosaccharides (GOS) and inulin-type fructans which are very similar substances. We also consider that the term 'human identical milk oligosaccharide' should be able to be used for this group of substances since this would be particularly helpful for consumers

DETAILED COMMENTS

International status

9. Glycom's 2′-FL and LNnT have been approved in the EU as novel food ingredients for use in a variety of food products including infant formula, follow-on formula, processed cereal-based food and baby food for infants and young children, milk-based drinks and similar products intended for young children, dietary foods for special medical purposes and meal replacements as well as a range of other food groups for the general population. They have also been ganted Generally Recognized as Safe (GRAS) status for these same food uses in the US. We understand that 2'-FL and LNnT have recently been granted approval for use in infant formula and growing up milks in Singapore, and 2'-FL has been authorised for use in infant formula in Israel.

Safety assessment

10. FSANZ undertook a comprehensive safety and technical assessment of Glycom's 2′-FL and LNnT. 2′-FL and LNnT are naturally present in human milk in a range of concentrations and ratios, providing a history of safe human exposure to these substances for breastfed infants. FSANZ concluded that there were no public health and safety concerns associated with the addition of 2′-FL and LNnT in infant formula products and formulated supplementary foods for young children at the levels requested, or at higher levels consistent with levels in human milk. This was based on 2′-FL and LNnT being chemically and structurally identical to the naturally occurring oligosaccharides in human milk and to chemically synthesised oligosaccharides, and the toxicological and clinical evidence not presenting concerns at the levels proposed by the applicant.

11. FSANZ also confirmed that intestinal absorption was limited, and a significant proportion of human milk oligosaccharides including 2'-FL and LNnT reach the large intestine where they are fermented by the microbiota or excreted unchanged in the faeces. The substances were not genotoxic and no adverse effects were observed in relevant studies on toxicity.

12. FSANZ reviewed the effect on infant growth and concurred with the applicant that the addition of 2′-FL, alone or in combination with LNnT, to infant formula products had no effect on growth at the levels requested by the applicant.

13. NZFGC agrees with FSANZ's conclusion concerning safety aspects of 2'-FL and LNnT.

Regulated as a Food Produced using Gene Technology

14. Glycom A/S produces 2′-FL and LNnT by microbial fermentation using production strains *Escherichia coli* (*E.coli*) SCR6 and *E.coli* MP572 respectively. FSANZ found there was no safety concern but proposes that the permission be for *food produced using gene technology* and that this was required in accordance with Standard 1.5.2 – Food produced using gene technology (rather than novel food permission in Schedule 25).

15. NZFGC does not support FSANZ's proposed position to regulate 2'-FL and LNnT in the Food Standards Code under Standard 1.5.2 and Schedule 26 *Food produced using Gene Technology*, and instead supports that they are regulated under Standard 1.5.1 and Schedule 25 *Novel Foods* as the applicant sought. Further comments on this view are provided below.

Risk Management

16. Health effects in terms of benefit were considered by FSANZ in addition to safety. FSANZ considered the benefits presented by Glycom A/S of anti-infective effect; bifidogenic effect; and immune modulation, improved intestinal barrier function and alleviation of allergic responses.

17. FSANZ concluded that substances naturally present in breast milk (such as 2′-FL and LNnT) are options for voluntary addition to infant formula products, where the evidence supports their provision of potential beneficial health outcomes in infants. The proposed addition is consistent with the defined purpose for infant formula products in the Australia New Zealand Food Standards Code and satisfies the relevant Ministerial policy guidelines.

Used as a Nutritive Substance and Novel Foods

18. FSANZ's preliminary position is to permit both 2'-FL and LNnT to be *used as a nutritive substance*, and as *food produced using gene technology* derived specifically from production strains *E.coli* SCR6 (for 2'-FL) and *E.coli* MP572 (for LNnT), for use in infant formula products and formulated supplementary foods for young children.

19. NZFGC supports the permission for both 2'-FL and LNnT to be voluntary additions to infant formula and formulated supplementary foods for young children. We note, however, that both galacto-oligosaccharides (GOS) and inulin-type fructans which are similar substances are NOT categorised as to be *used as a nutritive substance.* This creates an inconsistency in the Food Standards Code which in turn creates confusion and additional complexity for both manufacturers and regulators. In any case, the same labelling provisions should apply to infant formula products and formulated supplementary foods for young children for this group of oligosaccharide substances.

20. As noted above, FSANZ found there was no safety concern with the production of 2'-FL and LNnT but proposes that the permission be for *food produced using gene technology* rather than as a *novel foods*.

21. NZFGC does not support FSANZ's proposed position to regulate 2'-FL and LNnT in the Food Standards Code under Standard 1.5.2 and Schedule 26 *Food produced using gene technology*. NZFGC strongly supports alignment with the approaches taken in both the EU and the US and elsewhere where they are categorised as novel foods which recognises the innovation of use. NZFGC supports the regulation of 2'-FL and LNnT within the Food Standards Code under Standard 1.5.1. and Schedule 25 *Novel Foods*.

22. We note that other foods listed in Schedule 26 (Foods produced using gene technology) mainly relate to commodities such as canola and potatoes. The raw materials covered by Application A1155 are not derived from a commodity altered using gene technology. 2'-FL and LNnT are more aligned to foods listed in Schedule 25 which also provides for conditions of use to be listed. As well, within the trans Tasman regulatory system, 2'-FL and LNnT meet the definition of non-traditional foods and therefore should be considered novel foods.

23. We are concerned that all future innovation employing such technology to create substances identical to breastmilk substances (rather than the 'mimics'), would be captured under Standard 1.5.2 rather than aligned with the categorisation internationally and reflective of the novel approach and innovation covered by Standard 1.5.1. We also note that the exclusivity applied for was under the provisions of Standard 1.5.1 *Novel Foods* and this is not available under Standard 1.5.2 *Foods Produced using gene technology.*

Maximum use levels

24. FSANZ considered the maximum levels proposed by Glycom S/R of 2′-FL and LNnT including estimated dietary intakes and naturally occurring levels in human milk and at higher levels. FSANZ found that higher levels of 2′-FL could potentially enhance the protective effect of this substance against invasive *C. jejuni* infection in infants (and toddlers) and that a level of use double that requested (i.e. 2.4 g/L rather than 1.2 g/L) in infant formula and follow-on formula provides dietary intakes of 2′-FL similar to 3 and 9 month old breastfed infants. Approving a higher level of 2.4 g/L of 2′-FL alone would provide greater compatibility with a greater range of overseas food standards and allow for a more efficient and internationally competitive food industry given the high level of international interest in these substances.

25. In terms of the combined use of 2′-FL and LNnT, ratios differ widely in breastmilk. FSANZ proposes that a maximum combined total of 2.4 g/L for 2′-FL and LNnT in any ratio so long as LNnT does not exceed 0.6g/L, is safe and suitable for addition to infant formula products. FSANZ proposes that for toddler milk, the maximum levels be 0.56 g/serving for 2'-FL alone or in combination with LNnT and a maximum of 0.14 g/serving for LNnT.

26. NZFGC supports the maximum levels proposed by FSANZ for the individual substances and for their combined use in both infant formula products and formulated supplementary foods for young children.

Prescribing the ingredient names

27. FSANZ proposes to prescribe ingredient names of '2′-fucosyllactose' and 'Lacto-*N*-neotetraose'. In its view, the acronyms are unnecessary although their voluntary use in association with the relevant prescribed ingredient names would be permitted. FSANZ states that such an approach is aligned with the approach taken by the EU which requires the substances to be identified as '2′-fucosyllactose' and 'lacto-*N*-neotetraose' on the label of the final food.

28. NZFGC does not support prescribing the ingredient names '2-fucosyllactose' and 'lacto-N-neotetraose' and considers this inconsistent with the treatment of other oligosaccharides and likely all other ingredients in infant formula, follow-on formula and toddler milk drinks. Reliance for food and other substance names is generally through the application of Standard 1.2.4—4 *Ingredients to be listed by common, descriptive or generic name*. The prescribed names proposed are very consumer unfriendly. Manufacturers are most likely to voluntarily label the ingredients as 2'-fucosyllactose and lacto-N-neotetraose together with the associated acronyms 2'-FL and LNnT in the list of ingredients. In addition to the prescribed names being consumer unfriendly, prescribing them would preclude the use of acronyms in the nutrition information panel which have significant space constraints and likely negative consumer reaction.

Specifications for 2'-FL and LNnT

29. FSANZ proposes that the specification in the Food Standards Code includes Methods of Analysis as proposed by the applicant. NZFGC does not support the inclusion of Methods of Analysis in the specification as this stifles method improvement and creates unnecessary costs for either analytical method developers to make application to amend the Food Standards Code or for FSANZ to raise a proposal for this purpose. We suggest some form of guidance might suggest methods of analysis used to date especially those publicly available.

30. We understand that the specifications proposed by FSANZ are now out of step with the EU since the revision of its regulations (European Commission, 2017) and that realignment might be considered. NZFGC supports INC supports a specification for 2'-FL and LNnT within Schedule 3 (Identity and Purity) that is based on what is regulated by the EU.

Other comment – Labelling – "Human identical milk oligosaccharides"

31. FSANZ considers that the term 'human identical milk oligosaccharides' is currently prohibited due to the existing requirements in Standard 2.9.1, section 2.9.1—24. NZFGC does not agree that 'human identical milk' in relation to a group of ingredients is prohibited under section 2.9.1—24. The basis of section 2.9.1—24 is the WHO Code of Marketing and relates to marketing not ingredient description. The term 'human identical milk oligosaccharides' is technically correct for the group of oligosaccharides, is used internationally, and is much more consumer friendly. The group term would better inform consumers about the nature of these ingredients if such a description, together with its acronym of HiMO, was able to be used to complement, and be used in conjunction with, their technical names.

CONCLUSION

32. In summary and in the absence of safety concerns, NZFGC:
    - agrees with FSANZ's conclusion concerning safety aspects of 2'-FL and LNnT
    - does not support FSANZ's proposal to regulate 2'-FL and LNnT in the Food Standards Code under Standard 1.5.2 and Schedule 26 *Food produced using Gene Technology* and strongly supports alignment with treatment in the USA and the EU where 2'-FL and LNnT are regulated as novel foods not as GM foods
    - supports the permission for both 2'-FL and LNnT to be voluntary additions to infant formula and formulated supplementary foods for young children but that categorising them to each be *used as a nutritive substance* is inconsistent with the approach taken in the Food Standards Code for both galacto-oligosaccharides (GOS) and inulin-type fructans which are similar substances.
    - supports the maximum levels proposed by FSANZ for 2′-FL alone, for LNnT and for their combined use in both infant formula products and formulated supplementary foods for young children
    - does not support prescribing use of the ingredient names '2-fucosyllactose' and 'lacto-N-neotetraose' but rather strongly supports the application of Standard 1.2.4—4 *Ingredients to be listed by common, descriptive or generic name* as is the case for the vast majority of food and ingredients used in the food supply, including infant formula and toddler milk drinks and their ingredients
    - considers the term 'human identical milk oligosaccharide' should be able to be used and that use of such a description in addition to the technical names would be helpful for consumers
    - does not support the inclusion of Methods of Analysis in the specification as this does not facilitate method improvement and adds unnecessary cost to amend
    - supports a specification for 2'-FL and LNnT within Schedule 3 (Identity and Purity), based on what is regulated by the EU in its most recent regulatory revision.

REFERENCE

European Commission (2017). *Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.* European Commission: Brussels, Belgium.
https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32018R1023