INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

19 August 2021

INC SUBMISSION ON CALL FOR SUBMISSIONS ON APPLICATION A1190 – 2'-FL IN INFANT FORMULA AND OTHER PRODUCTS

INTRODUCTION

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents manufacturers, marketers and suppliers of infant formula and toddler milk dinks (formulated supplementary foods for young children) and, is the key industry stakeholder in the advancement of infant nutrition representing over 95% of the volume manufactured and marketed in in Australia and New Zealand.
INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula product and toddler milk drink industry in Australia and New Zealand.

INC is a responsible group that voluntarily restricts its marketing practices for infant formula products to support government policies for the protection and promotion of breastfeeding.

INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants who do not receive breast milk.

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Call for Submissions – Application A1190: 2'-FL in infant formula and other products.*

Yours sincerely

[redacted]

INFANT NUTRITION COUNCIL SUBMISSION ON Call for Submissions: – Application A1190: 2'-FL in infant formula and other products

EXECUTIVE SUMMARY

1. INC supports safe and nutritious infant formula products and toddler milk drinks (formulated supplementary foods for young children (FSFYC)), and effective regulatory provisions for these product categories that adhere to the principle of minimum effective regulation; are clear and consistent and provide sufficient information for consumers to make informed choices.

2. INC supports the FSANZ decision to approve the voluntary addition of new substances that have been shown to be safe and suitable for addition to infant formula products and FSFYC.

3. INC notes that permission exists in the Australia New Zealand Food Standards Code (the Food Standards Code) for '2'-Fucosyllactose' (2′-FL) from Application A1155. As the source and specifications of the A1190 2′-FL (Chr. Hansen) are different FSANZ was required to undertake a pre-market assessment to recommend its permission and assess it is eligible for an exclusivity period of 15 months.

4. INC supports the FSANZ decision to permit the addition of the Chr. Hansen 2'-FL to infant formula products at the levels proposed "up to a maximum of 2.4 g/L". 2'-FL occurs naturally in human milk and this 2'-FL is structurally identical to those oligosaccharides naturally occurring.

5. INC does not support the FSANZ decision to exclude permission of the Chr. Hansen 2'-FL to FSFYC. INC supports Option 3 as outlined in the *Call for Submissions – Application A1190: 2'-FL in infant formula and other products* (CFS).

6. INC supports FSANZ's decision to apply generic ingredient labelling requirements, consistent with the general approach in the Australia New Zealand Food Standards Code (the Food Standards Code).

7. INC continues to be of the view that prohibition of terms such as 'human identical milk oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of infant formula products and FSFYC is entirely at odds with the decision to apply generic ingredient labelling requirements. INC continues to oppose this prohibition of generic terms that have been in use in the scientific literature for over 25 years and that continue to be used widely. The standard containing this prohibition;

    a. ignores not only the existing protections in the Food Standards Code
    b. ignores other consumer-related legislative provisions that serve to protect consumers
    c. ignores the decisions that manufacturers might make concerning compliance and truthfulness, and
    d. Ignores other international standards that allow such terms, creating inconsistency

8. INC is concerned that the labelling prohibition will stifle innovation and adversely impact trade. In relation to exports, the impacts include substantially reducing competitiveness with other global traders in relation to cross-border e-commerce (CBEC) (which in China, requires compliance with the country of origin under specific conditions). This then has potential longer-term flow-on impacts to general exports in general trade. In relation to imports, it creates a trade barrier to importing products made and labelled in other countries, with significant, additional costs to companies where the label is required to be changed specifically for the Australia and New Zealand market.

9. INC strongly recommends further consideration is given to the drafting variation proposals for Schedule 3 in the interests of improved consistency of general approach and more specifically with regard to 2'FL.

DETAILED COMMENTS

Variation to Standard

10. INC supports Option 3 as outlined in the FSANZ Call for submissions – Application A1190 (FSANZ CFS).

11. INC considers that the FSANZ draft variation to the *Australia New Zealand Food Standards Code* (the Food Standards Code) to permit the level of the Chr. Hansen 2'-FL "up to a maximum of 2.4 g/L" in infant formula products is appropriate for implementation of option 2. This is consistent with the currently approved level of 2'-FL in Standard 2.9.1--7 and Schedules 3, 26 and 29. INC does, however, have reservations about the changes within the draft variation in relation to Schedule 3. Please refer to comments below under the heading 'Identity and Purity'.

12. INC does not support the FSANZ assessment that the draft variation will not permit the addition of the Chr. Hansen 2'-FL to FSFYC. INC made the same comment in relation to this exclusion in Application A1155.

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 (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*.

14. INC argues 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.

15. 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 (Lewis et al. 2015, Morrow et al. 2004 and Siziba et al. 2021), reduce risk for lower respiratory tract illnesses through a protective effect on mucosal barrier function (Sprenger et al. 2019) and an immunomodulation role in prevention of allergic diseases in early life (Zuurveld et al. 2020).

16. 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. The Therapeutic Goods Administration permits use of 2'FL in

supplements for young children from age one through to senior adults (ARTG IDs: 362438, 320165, 320164, 320162).

17. FSANZ states that the applicant's 2'-FL is structurally and chemically identical to the form of this substance in human milk. This is significant as it is a scientifically accurate description and confirms that 'human identical milk oligosaccharides' (HiMO) accurately describes these substances.

International status

18. FSANZ states in the CFS 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.

19. 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 young children as well as infants.

Risk and Safety Assessment

20. As noted, there is already a permission to add 2′-FL in the Food Standards Code. As the source and specifications of Application A1190 for the Chr. Hansen 2′-FL derived from *Escherichia coli* (*E. coli*) BL-21 to be added to infant formula products and FSFYC 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.

21. The Chr. Hansen 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.

22. 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.

23. 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.

24. 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.

25. 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 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. 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 (Lewis et al. 2015, Morrow

et al 2004 and Siziba et al 2021), reduce risk for lower respiratory tract illnesses through a protective effect on mucosal barrier function (Sprenger et al. 2019) and an immunomodulation role in prevention of allergic diseases in early life (Zuurveld et al. 2020).

26. Additionally, Fonvig et al (2021) concluded that in a parallel, randomised, double blind placebo-controlled trial (RCT) of 75 children with overweight, that subjects receiving 2'FL or a mix of LNnT and 2'FL showed an increase in bifidobacteria in intestinal microbiota and also that the supplementation was well tolerated.

27. 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* BL21 and produced by microbial fermentation, to infant formula products and FSFYC, at the requested level of 2 g/L, or at higher estimated dietary intakes based on the existing permitted level in the Food Standards Code (2.4 g/L).

28. INC notes an error in the Risk Assessment that FSANZ might reconsider: the inclusion of the phrase "(less if combined with LNnT)" (p10 CFS). The limit in the EU Regulation (EU) 2017/2470 of 20 December 2017 is the same for 2'-FL whether with or without LNnT so long as a ratio of 2:1 is maintained. It is not clear that there is evidence to support the statement in the Food Standards Code. The text in the EU reads: "*1,2 g/l alone or in combination with up to 0,6 g/l of lacto-N-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer".*(EU Regulation 2017/2470).

Risk Management

29. Although FSANZ's safety assessment indicated no concerns with the addition of 2′-FL produced by microbial fermentation to infant formula products and FSFYC and concluded that there were plausible beneficial health outcomes for infants and young children in consuming 2′-FL (though the evidence was weaker in young children), FSANZ's recommendation for addition of 2'-FL derived from *E. coli* BL21 is limited to infant formula products.

30. FSANZ states that taking account of all that proceeded during the course of approval for 2'-FL (and LNnT) under Application A1155, the absence of any new data or information on the beneficial health effects for 2′-FL in young children, it proposed not to permit the applicant's 2′-FL in FSFYC.

31. To reach this conclusion, "FSANZ also noted the applicant's justification for 2′-FL addition in FSFYC does not *directly* align with the intention of FSFYC (i.e. because 2′-FL is naturally found in human milk only, and FSFYC is not a human milk substitute)". Oligosaccharides are in fact found in the milk of a wide variety of mammalian milk from cows', goat, sheep, buffalo and camel through giraffe, bear, lion, elephant, wombat, possum, echidna and koala to whales and dolphins (eg Leong et al. 2019).

Permissions to add 2'-FL to infant formula products

32. INC 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*. INC therefore supports the decision of FSANZ to permit the voluntary addition of 2'-FL derived from *E. coli* BL21 to infant formula products. The Chr. Hansen 2'-FL is structurally identical to the 2'-FL that occurs naturally in human milk. INC 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.

Permissions to add 2'-FL to FSFYC

33. INC supports permissions for voluntary addition of new substances that have been shown to be safe for addition to FSFYC and that meet the Policy Guideline on the *Intent of Part 2.9*. INC therefore reiterates the support it expressed in its submissions on Application A1155 for the addition of 2'-FL to FSFYC and **opposes** the proposal of FSANZ in relation to A1190 to prohibit the voluntary addition of 2'-FL in FSFYC.

34. The scope of the Policy Guideline on the *Intent of Part 2.9* states that the standards for special purpose foods:

    "prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups"

    and that

    "physiological vulnerability relates only to situations where there is risk of dietary inadequacy to support the physical and physiological need arising from specific life stages … that occasion the use of special purpose food."

35. In the absence of other more specific Policy Guidelines such as exists for infant formula products, the test is 1) a risk of dietary inadequacy and 2) physiological need.

36. INC is strongly of the view that there is increasing evidence of risk of dietary inadequacy in young children in Australia and New Zealand (Atkins et al. 2016, Johnston K 2017, Leonard D et al. 2017, Spence AC et al. 2018, Starship Hospital 2016, Tonkin E et al. 2020), that those subject to such risk would benefit from FSFYC (Wall et al. 2019, Lovell et al. 2019), and that there is no evidence to support prohibiting the addition of 2'-FL to FSFYC.

37. Further voluntary addition of inulin-like fructans and galacto-oligosaccharides to FSFYC is permitted to infant formula products and FSFYC. These non-digestible ingredients are added to these products to provide some of the beneficial effects provided by HMOs in human milk but cannot substitute all HMO functions (Akkerman, Faas, and de Vos 2019). Yet, now there are production processes available that allow the production of some human milk identical oligosaccharides, such as 2'-FL, the Food Standards Code permits voluntary addition of approved HiMOs to infant formula products but not to FSFYC.

38. There are various studies that have made comparison between GOS and 2'-FL that are reporting benefits from 2'-FL that are not seen from GOS. For example, Salli et al (2020) found that 2'-FL limits the growth and inhibits adhesion of *S. mutans* a bacteria involved with dental caries is an example. Dental caries in young children is of particular concern (Schluter P et al. 2020; Bach K and Manton DJ 2014; Gussy et al 2016).

39. This is inconsistent and precludes young children gaining any potential benefits from supplementation of FSFYC with these oligosaccharides, that include bifidogenic and gut and immune system benefits.

40. INC notes that FSANZ "acknowledges the importance of ensuring caregivers are not confused around the purpose or intent of FSFYC and do not buy foods that are not needed" (CP2 p18). INC's view is that consumers are not confused around the purpose or intent of FSFYC. A key transition from breast feeding to another form of liquid in a young child's diet from 1 year of age is the availability of a nutritional source of liquid. Based on data collected by industry in 2019, cows' milk accounts for up to 70% for those leaving the journey of breastmilk and/or infant formula. Further, industry data for Australia records that up to 35% of young children at 1 year of age consume FSFYC declining to

15% as children age through to 4 years of age. This percentage of use does not indicate that parents or caregivers are confused, but that FSFYC provides an important product for consideration of use.

41. It is not FSANZ's role to decide that caregivers should 'not buy foods that are not needed' or completely remove the choice from caregivers to access better FSFYC. Consumers would not purchase a product more expensive than cows' milk if there was no benefit and providing choice to caregivers should be the major driver once safety is confirmed. People should be able to spend their money as they see fit and have the choice to make purchasing decisions.

Labelling

42. INC 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.

43. 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. The prohibition ignores the existing protections in:
    - the Food Standards Code which includes a number of existing prohibitions such as are contained in Standard 2.9.1—24) and
    - other legislation in New Zealand and Australia such as the *Fair Trading Act 1987* and the Australian Consumer Laws in the *Competition and Consumer Act 2010* concerning truthfulness of the description of ingredients by manufacturers.

44. The above terms and abbreviations are 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.

45. There is currently an inconsistent approach in Schedule 3 with microbiological criteria included in some and not others. This also applies to other parameters. We are concerned to know how FSANZ decides what parameters to include in the interests of a more consistent approach. Our recommendation is that microbiological criteria and limits for heavy metals are not included within specifications in Schedule 3 unless there is a compelling reason for inclusion for specific substances.

46. 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 consider that there might 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 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).

47. Further, we are concerned about the disparity between the microbiological criteria currently in S3—43 and proposed for inclusion in S3-45 which raises questions about the

value of including this information. Our preference is that the microbiological criteria are not included so that the onus is fully on manufacturers to assess microbiological suitability for their particular application.

Investment in innovation

48. If regulations stifle the communication of innovation and the application of developments that are safe and permitted elsewhere, there is little point in pursuing investment in innovations in Australia and New Zealand. Not only will both countries lose consideration of future investments in innovation, we will lose the public health benefits of such innovation and consign our young children to less than optimal foods in the future.

Trade impacts

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

50. 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.

51. In addition to trade impacts on exports, INC has very real concerns about impacts on imports. Proceeding with the proposed measures will raise conflicts in labelling requirements elsewhere that will influence/restrict the importation, and thus the availability, of innovative nutritious products for infants and young children in Australia and New Zealand. Generic labels that meet requirements across several countries are often used to make exports of product viable especially in relation the small markets of Australia and New Zealand. The prohibition proposed could prevent this in future. Such an approach is inconsistent with the statement made on page 39 of the Call for Submissions: '*promotion of consistency between domestic and international food standards promote greater compatibility between domestic and overseas foods standard*s'.

Drafting

52. In S3—45 (u)(i) should capitalise '*Salmonella*' and in (u)(iv) should capitalise '*Cronobacter sakazakii*'.

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