Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

2 September 2019

INC SUBMISSION ON 2nd CALL FOR SUBMISSIONS ON APPLICATION A1155 – 2'-FL AND LNnT IN INFANT FORMULA AND OTHER PRODUCTS

INTRODUCTION

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing and/or manufacturing infant formula products and toddler milk drinks (formulated supplementary foods for young children) 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.

Members:

- A2 Infant Nutrition Ltd
- Aspen Nutritionals Australia Pty Ltd
- Danone Nutricia Early Life Nutrition
- Fonterra Co-operative Group Ltd
- H J Heinz Company Australia Ltd and H J Heinz Company (New Zealand) Ltd
- Nestlé Australia Ltd and Nestlé New Zealand Limited
- Synlait Milk Ltd

Associate Members:

- Abbott Australasia Pty Ltd
- Adams Australia Pty Ltd Australian Dairy Park
- Bakels Edible Oils (NZ) Ltd
- Bayer Ltd
- Blend and Pack Pty Ltd
- Bodco Dairy Ltd
- Bubs Australia Ltd
- Burra Foods
- Cargill Australia
- Dairy Goat Co-operative Ltd
- DSM Pty Ltd
- Freedom Foods
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- Great Ocean Ingredients Pty Ltd
- GrainCorp Ltd
- Jamestrong Packaging Pty Ltd
- Mataura Valley Milk Ltd
- NIG Nutritionals
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Nu-Mega Ingredients
- Oceania Dairy

- Reckitt Benckiser
- Saputo Dairy Australia Pty Ltd
- Snow Brand Aust Pty Ltd
- Spring Sheep Milk Co
- Tatura Milk Industries
- The H&H Group
- Wattle Health Australia Ltd
- Westland Co-operative Dairy Company Ltd
- Winston Nutritional New Zealand
- Yashili Dairy New Zealand

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 *2nd Call for Submissions – Application A1155: 2'-FL and LNnT in infant formula and other products.*

Yours sincerely

INFANT NUTRITION COUNCIL SUBMISSION ON Second Call for Submissions: – Application A1155: 2'-FL and LNnT in infant formula and other products

FINAL 2 SEPTEMBER 2019

EXECUTIVE SUMMARY

1. INC supports safe and nutritious infant formula products and toddler milk drinks (formulated supplementary foods for young children), 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 for addition to infant formula products and formulated supplementary foods for young children (FSFYC).

3. In particular, INC supports the FSANZ decision to permit the addition of '2'-Fucosyllactose' (2'-FL) alone or combined with Lacto-N-neotetraose (LNnT) to both infant formula products and FSFYC at the levels proposed. Both occur naturally in human milk and 2'-FL and LNnT are structurally identical to those oligosaccharides naturally occurring.

4. INC supports FSANZ's decision to apply generic ingredient labelling requirements, rather than prescribed ingredient names previously proposed, consistent with the general approach in the Australia New Zealand Food Standards Code (the Food Standards Code).

5. INC strongly believes that no additional prohibited representations should be introduced. 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 completely at odds with the decision to apply generic ingredient labelling requirements. INC strongly opposes 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 draft variation standard containing this prohibition ignores not only the existing protections in the Food Standards Code, but also ignores other consumer-related legislative provisions that serve to protect consumers and the decisions that manufacturers might make concerning compliance and truthfulness.

6. The process that FSANZ has applied in arriving at the regulatory prohibition does not have the depth or breadth of consumer research support that would be required to sustain compliance with good regulatory practice (limited consumer sample populations in even more limited research). In particular, extending the prohibition to FSFYC is setting policy outside statutory policy development processes, pre-empts work in Codex and, in proposing to extend it to FSFYC, is contrary to the protections and provisions in Standard 1.2.7. Overall, INC considers the FSANZ process in arriving at the proposed determination inadequate.

7. INC is absolutely and very strongly opposed to the prohibition on the label of FSFYC of common terms for 2'FL and LNnT. The strength of this opposition is because making such

a prohibition undermines the policy process set out in the *FSANZ Act 1991* and is additional to all the existing protections applying to labelling the substances in FSFYC.

8. Such an extension to the prohibition creates a precedent targeting a group of food products for young children out of all the foods in the general food supply that can be consumed by this age group. It is setting policy outside the accepted practice for policy decision-making, it pre-empts work in Codex and is contrary to the protections and provisions in Standard 1.2.7.

9. INC is also 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. Outside CBEC, if different labelling is needed on export packaging compared to domestic product this adds significantly to production costs. In relation to imports, the labelling restrictions will influence/restrict importation, and thus the availability, of innovative nutritious products for infants and young children in Australia and New Zealand.

10. Finally, INC raises concerns about harmonisation and consistency of the specification for inclusion in Schedule 3 *Identity and Purity* in the Food Standards Code.

DETAILED COMMENTS

Content of human milk

11. After lactose and fat, the third main solid component in human milk is neutral and acid oligo- (and poly) saccharides. These oligosaccharides occur in concentrations between 5-10 g/L (Aggett et al 2003). The structure of about 200 human milk oligosaccharides has been identified (Kunz et al, 2000). Neutral oligosaccharides such as 2'-FL and LNnT are the predominant oligosaccharides in human milk and permitted addition is in line with Policy Principle h) relating to composition in the Policy Guideline on *Regulation of Infant Formula Products*.

12. FSANZ states (section 2.2.1, p22 CFS 2) that "the applicant's 2'-FL and LNnT are structurally and chemically identical to the forms of these substances in human milk". This is significant as it is a scientifically accurate description and confirms that 'human milk identical oligosaccharides' accurately describes these substances.

Permissions to add 2'-FL and LNnT

13. INC supports permissions for voluntary addition of new substances that have been shown to be safe for addition to infant formula products and formulated supplementary foods for young children (FSFYC) 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 alone or combined with LNnT to both infant formula products and FSFYC. Both are structurally identical to 2'-FL and LNnT that occur naturally in human milk. INC also supports the level of additions as proposed by FSANZ for both infant formula products and FSFYC noting that these are within the ranges naturally present in mature human milk.

Labelling

14. INC supports FSANZ's decision to apply generic ingredient labelling requirements, rather than prescribed ingredient names previously proposed, consistent with the provisions in Standard 1.2.4—4:

    "Ingredients to be listed by common, descriptive or generic name

    A statement of ingredients must identify each ingredient:

(a) in the case of offal—in accordance with section 2.2.1—6; or
(b) in any other case, using any of:
    (i) a name by which the ingredient is commonly known; or
    (ii) a name that describes the true nature of the ingredient; or
    (iii) a generic name for the ingredient that is specified in Schedule 10, in accordance with any conditions specified in that Schedule."

15. We note that the last provision in 1.2.4—4 has no applicability to the Application since there are no applicable generic terms in Schedule 10.

16. The provisions of Standard 1.2.4—4 (b) (i) and (ii) support the use of common names and names that describe the true nature of the ingredient.

Prohibited representations

Infant formula products

17. INC strongly supports the current provisions reflected above and strongly opposes the introduction of an additional prohibition on the label of infant formula products. The draft variation to the Code prohibits use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' and the abbreviations, 'HMO', 'HiMO' (or similar words or abbreviations). This prohibition is completely at odds with the decision to apply generic ingredient labelling requirements. These ingredients have been commonly known by the above generic terms in the scientific literature for over 25 years. Not being able to choose to use them to describe the true nature of the substances in the ingredients list and nutrition information is misleading for consumers. The use of accurate terms enables manufacturers to meet the provisions in Standard 1.2.4—4 and support consumer understanding of the product.

18. The prohibition on the use of the term, 'human milk identical oligosaccharides' and words having similar meanings (and abbreviations thereof) makes it effectively impossible to apply the generic labelling provisions in Standard 1.2.4—4 and is counter to building consumer confidence in, and understanding of, labelling information.

19. 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.

20. It is the manufacturer's responsibility to choose an appropriate term to describe an ingredient in accordance with the Food Standards Code and other applicable legislation. INC considers the proposed prohibition is unwarranted given the existing protections outlined. Further this prohibition is inconsistent with the provisions applying to other similar ingredients approved in the past such as inulin-type fructans or galacto-oligosaccharides which are labelled according to Standards 1.2.4, 1.2.8 and relevant product standards 2.9.1 and 2.9.3.

21. The process that FSANZ has applied in arriving at the prohibition appears to ignore science (commonality of use in the literature over 25 years), balance and standard expectations of substantiation applied in other areas of the Food Standards Code. The consumer research to justify the prohibition relies on very limited consumer sample populations (especially in Malek *et al*), labours the consumer impact and is limited to just a couple of papers. There is a significant dearth of support, relying heavily on Malek and a number of papers by Berry *et al* which reflect author conclusions and inferences rather than explicit data. That is, Berry *et al* provide a view based on descriptive suppositions

rather than conclusive evidence of a connection between the term 'formula' and advertising for toddler milk and explicitly in at least two papers makes clear that generalisations cannot be drawn from the results.

22. Social research methodology should be rigorous (in terms of sample size and representation of the population, data collection, and data analysis techniques) for the result to be reliable and dependable for policy and regulatory decisions. The references presented do not substantiate a policy nor regulatory change of the magnitude proposed.

23. Comments relating to the Berry *et al* papers:
"It's all formula to me" (Berry *et al* 2010) is qualitative research of 15 women recruited in 2007 from antenatal classes on the Central Coast. This is a very small sample from one region who are not yet mothers. FSANZ cites this paper and states "three of four respondents…believed the advertisement suggested an equivalence between 'formula' and breastmilk". This is correct, just 3 of the 4 women responded in this way. This paper by Berry *et al* concludes "It should be noted that the small sample sizes associated with qualitative enquiry constitute an inherent limitation to the generalisability of the findings…Quantitative enquiry is required…"

"Relax, you're soaking in it" (Berry *et al*, 2011) is qualitative research comprising 17 women including some grandmothers recruited via an Anglican church. The Paper contains no further information on the selection of the balance of the sample which included one GP and one dietitian. The Paper reports in conclusion: "The study reported in the paper is exploratory in nature and cannot be generalised to the wider populations of Australian mothers, grandmothers or primary health care providers".

"Toddler milk advertising in Australia" (Berry *et al*, 2012) is a quantitative study of 439 parents of children under 5 years of age (or expecting a child) recruited from the Sydney pregnancy, babies and children expo in 2008. No limitations were reported in the Paper, however an earlier report of the same research (Berry 2012) concluded "This was a cross-sectional study that recruited a convenience sample by intercept at a retail trade show aimed at parents and expectant parents in a large Australian city. Parents who live in rural or remote areas might be expected to hold different views about infant feeding."

24. Comments relating to take the Malek et al Paper:
"Informed choice or guessing game" (Malek *et al*, 2019) held 21 focus group discussions with a total of 136 caregivers of infants aged <12 months. FSANZ states, in citing this Paper that "it is possible that caregivers who believe an infant formula product is closer in composition to breastmilk may be more likely to use infant formula in place of or in addition to breastfeeding".

25. Closer analysis of the Malek *et al* 2019 Paper shows that "…one regional NZ caregiver acknowledged claims about 'best breast-milk substitute' were a strong driver of product choice as it alleviated her guilt about choosing to formula-feed rather than breast-feed; and one Australian caregiver (PSE/metro) stated the claims on IF products motivated her to use formula to top up breast-feeds". It seems therefore that two respondents out of 136 hold the view that infant formula might be best for their baby. This could be a disproportionately low representation of the sample and as such could be an 'outlier'.

26. Conversely, the Paper states "There was widespread acknowledgement by caregivers (in all subgroups and all individual focus groups apart from one 'other ethnicity' focus group) [that is in 20 of the 21 discussion groups] that they do not understand the nutrient content claims (names or acronyms) … it was believed that explaining the scientific names/acronyms using simple 'layman's' terms would allow the information to be understood by those without a scientific background and who may be sleep deprived".

27. Overall, INC considers the FSANZ process in arriving at the proposed new prohibition inadequate and strongly believes that no additional prohibited representations should be introduced.

Formulated Supplementary foods for young children

28. INC is absolutely and very strongly opposed to the prohibition on the label of FSFYC in the draft variation of "the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect" and to the prohibition on the use of "the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect." This is because strong protections are already in place in the Food Standards Code and additional prohibitions are unnecessary. Additionally, we are strongly opposed because the proposal undermines the explicit policy process available in the food regulatory system by setting policy on the labelling of the general food supply outside that process as provided in the *FSANZ Act 1991* for such purposes.

29. The Policy Guideline on the *Regulation of Infant Formula Products* does not extend to foods for FSFYC and the Policy Guideline on the *Intent of Part 2.9 – Special Purpose Foods* does not include prohibitions but rather the reverse, placing emphasis on the provision of adequate information through labelling to "assist consumers understanding of the specific nature of the food". There is no rationale, in fact, for extension of the proposed prohibition for Infant Formula Products to FSFYC. No such prohibition on statements (or claims) is made in relation to the terminology on labelling of products for FSFYC containing ingredients derived from (or identical to) other sources of food. It is also inconsistent with the provisions relating to inulin-type fructans and galacto-oligosaccharides.

30. This prohibition for FSFYC would create a precedent for a group of foods for this age group out of all the foods in the general food supply that can be manufactured for the group. It is setting policy outside the accepted practice for policy decision-making. It pre-empts work in Codex and, in addition to the reasons for opposing the terminology that is proposed to be prohibited for infant formula products, for the prohibition to be extended to FSFYC is contrary to the protections and provisions in Standard 1.2.7.

31. The lack of evidence for such a prohibition as discussed in paragraphs 21 to 26 are even more relevant in relation to FSFYC. Closer analysis of the Malek *et al* 2019 paper makes it clear there is no evidence presented to substantiate the view that representations on FSFYC influence product choice and decisions around breast-feeding.

32. .Further, the provision in Standard 1.2.1—23 relating to the application of labelling provisions to advertising states "If this Code prohibits a label on or relating to food from including a statement, information, a design or a representation, an advertisement for that food must not include that statement, information, design or representation." If use of the term 'human milk identical oligosaccharides' is prohibited on labels, this could be interpreted to extend to more comprehensive product information on websites for example. If the rationale for addition of these substances cannot be explained to the consumer, manufacturers could be accused of withholding information or misleading the consumer by remaining silent.

33. Such prohibitions will also not facilitate future innovation in the category, and the impacts on failures to innovate will be significant for the Australian and New Zealand population and for the industry in terms of international competitiveness.

34. In line with the foregoing, INC strongly opposes additional prohibitions in the mandatory nutrition information labelling descriptions to those already in the Food Standards Code for both Infant Formula Products and FSFYC.

Investment in innovation

35. 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 infants and young children to less than optimal foods in the future.

Trade impacts

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

37. In relation to exports, the impacts include:
    - 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. For CBEC trade in Australia and New Zealand's largest trading partner (China) for these categories of products – products reflect compliance with the country of origin (in this respect – the Australia New Zealand Food Standards Code). CBEC is particularly beneficial to new entrants to the general export trade, to test the market and begin building product recognition of Australian and New Zealand origin, before expansion and investment into export to general trade. 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. Therefore if Australian and New Zealand products are unable to communicate the common and true nature of the innovative ingredient, whereas foreign products from EU, USA and other countries sold in CBEC China are able to, 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.

    - Cost – The need to provide different labelling on export packaging that meets overseas country legislative permissions and the labelling of product sold in New Zealand or Australia is costly for production and for labelling/packaging inventory. In New Zealand, exporters have available a provision whereby a permission explicit in the legislation of an importing country can result in an exemption to the New Zealand labelling provisions. With global breakthrough developments, legislation may take time to catch up giving brands from other countries in those markets a strong advantage over Australian and New Zealand exports.

38. 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'.

Identity and Purity

39. INC questions the longevity of the proposed identity and purity criteria. INC supports a specification for 2'-FL and LNnT within Schedule 3 (Identity and Purity), based on what is regulated by the EU but it appears the proposed specification does not align with the most recent revision of the EU regulations.

40. We note that in the Call for Submissions document under section 1.3.2.2, FSANZ states that since the first Call for Submissions, new EU regulations had come into force which modified the specification to a more generic one "based on equivalence notifications to the EU Commission from other manufacturers … and further amendment requests by Glycom." INC repeats that it supports a specification that is aligned with the current EU regulation.

41. Some INC members are also concerned about the lack of consistency in the parameters of the proposed variation for identity and purity that will sit in Schedule 3 of the Food Standards Code, especially in relation to the inclusion of a number of microbiological limits and the terminology that results in the use of 'absent' instead of 'not detected'.

42. We would encourage FSANZ to consider these harmonisation and consistency issues.

References

Aggett P, Leach JL, Rueda R, MacLean WC. 2003 "Innovation in infant formula development: a reassessment of ribonucleotides in 2002". *Nutrition* 19(4):375-84, 2003.

Kunz C, Rudloff S, Baier W, Klein N, Strobel S. 2000 Oligosaccharides in human milk: structural, functional, and metabolic aspects". *Annual Review of Nutrition*; 20:699-722, 2000. DOI:10.1146/annurev.nutr.20.1.699