2 September 2019

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *2nd Call for Submissions: – Application A1155: 2'-FL and LNnT in infant formula and other products*.

Yours sincerely

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

Submission by the New Zealand Food & Grocery Council

2 September 2019

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the ***2nd Call for submissions – Application A1155: 2'-FL and LNnT in infant formula and other products*** (2nd CFS).

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. Some of our members produce and market infant formula and other food products suitable for infants.

OVERARCHING COMMENTS

1. NZFGC 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). This includes 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.

2. We also support 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). However, we strongly believe that no additional prohibited representations should be introduced. The proposed prohibition of common terms that have been in use in the scientific literature for over 25 years, such as 'human milk identical oligosaccharide' or 'HiMO', is contrary to the decision to apply generic ingredient labelling requirements. The draft variation standard containing this prohibition on terminology 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.

3. The process that FSANZ has applied in arriving at the regulatory prohibition does not have the level of substantiation of consumer research support that would be required to sustain compliance with good regulatory practices. We oppose both the prohibitions for infant formula products and their extension to FSFYC. The prohibitions set policy outside the 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, NZFGC considers the FSANZ process in arriving at the proposed determination inadequate.

4. We are very particularly and strongly opposed to the prohibition on the label of FSFYC of common terms for 2'FL and LNnT. 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. NZFGC members produce many food products for young children but this prohibition singles out one group of all those 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.

5. NZFGC 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) 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.

6. Finally, NZFGC notes the concerns INC has raised in its submission 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

7. After lactose and fat, the third main solid component in human milk is neutral and acid oligo- (and poly) saccharides. Neutral oligosaccharides such as 2'-FL and LNnT are the predominant oligosaccharides in human milk. The permitted addition meets the Policy Guideline on *Regulation of Infant Formula Products,* and particularly Policy Principle h) relating to composition: "The composition of breastmilk should be used as a primary reference for determining the composition of infant formula and follow-on formula."

8. FSANZ acknowledges (section 2.2.1, 2nd CFS) 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 identical milk oligosaccharides' accurately describes these substances.

Permissions to add 2'-FL and LNnT

9. NZFGC supports permissions for voluntary addition of new substances that have been shown to be safe for addition to infant formula products FSFYC 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 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. NZFGC 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

10. NZFGC 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. The provisions of Standard 1.2.4—4 (b) (i) and (ii) relating to a name by which the ingredient is commonly known and a name that describes the true nature of the ingredient support the use of common names.

Prohibited representations

Infant formula products

11. NZFGC 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 contrary to the decision to apply generic ingredient labelling requirements.

12. The ingredients 2'-FL and LNnT 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. Such a prohibition is contrary to a consumer's right to know about the composition of food products they are purchasing for their infants.

13. 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 descriptions by manufacturers.

14. 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. NZFGC considers the proposed prohibition is unwarranted given the existing protections outlined.

15. NZFGC is particularly concerned at the process that FSANZ has applied in arriving at the prohibition including the use common terms in the literature over 25 years and the very limited level of consumer research relied on to justify the prohibition (a set of papers by one group of researchers and a paper by another). These papers appear to rely heavily on author conclusions and inferences rather than explicit data and we note that two of the Berry *et al* papers make it clear that generalisations cannot be drawn from the results.

16. 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.

17. In the paper "It's all formula to me" (Berry *et al* 2010) the sample is 15 women recruited in 2007 from antenatal classes on the Central Coast. Just three of four women who responded to a question about advertising suggested an equivalence between 'formula' and breastmilk. This paper notes "that the small sample sizes associated with qualitative enquiry constitute an inherent limitation to the generalisability of the findings."

18. In the paper "Relax, you're soaking in it" (Berry *et al*, 2011) the sample is 17 women including some grandmothers recruited via an Anglican church and concludes that the study "is exploratory in nature and cannot be generalised to the wider populations of Australian mothers, grandmothers or primary health care providers".

19. In the paper "Toddler milk advertising in Australia" (Berry *et al*, 2012) the sample 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, but 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."

20. In the Malek *et al* paper "Informed choice or guessing game" (Malek *et al*, 2019), 21 focus group discussions with a total of 136 caregivers of infants aged less than 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". The paper actually reports, however, that only two respondents out of 136 hold the view that infant formula might be best for their baby. One was a regional New Zealand caregiver who 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 was an Australian caregiver (PSE/metro) who stated that the claims on infant formula products motivated her to use formula to top up breast-feeds. This could be a disproportionately low representation of the sample and as such could be an 'outlier'.

21. The Malek *et al* paper goes on to state: "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".

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

Extending the prohibition on representations to Formulated Supplementary Foods for Young Children

23. NZFGC is particularly 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.

24. 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.

25. 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.

26. 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".

27. 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.

28. The lack of evidence for such a prohibition as discussed above 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.

29. 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.

30. 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 infant and child population and for the industry in terms of international competitiveness. This makes sense – why innovate if a company is prohibited from explaining to consumers the benefit of that innovation?

31. In line with the foregoing, NZFGC 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

32. 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. Both countries will not only lose consideration of future investments in innovation, but will also lose the public health benefits of such innovation. This will consign our infants and young children to less than optimal foods in the future. This should be of concern to all current and prospective parents.

Trade impacts

33. In addition to the above, trade may be adversely impacted by the labelling prohibition. This impacts both exports and imports in the event that other manufacturers from other markets have the ability to describe the benefits of their products accurately in export markets.

34. In relation to exports, our competitiveness with other global products will be impacted, most particularly in relation to cross-border e-commerce or CBEC since this trade relies on compliance with the country of origin (in this respect – the Australia New Zealand Food Standards Code). Constraints applied in Australia and New Zealand that are not required to be applied by other foreign products, such as not being able to communicate the common and true nature of the innovative ingredient, will have the inevitable consequence of our export trade not competing with the developments that other countries permit and eroding the ability to remain competitive in an international market.

35. Also in relation to exports, if there is a need to provide different labelling on export packaging that meets overseas country legislative permissions than the labelling of product sold in New Zealand or Australia, there are cost impacts 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.

36. In addition to trade impacts on exports, NZFGC has very real concerns about impacts on imports. Proceeding with the proposed measures will raise conflicts in labelling provisions elsewhere that will influence and 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 FSANZ Act aims of promoting consistency between domestic and international food standards.

Identity and Purity

37. NZFGC supports the INC views on the longevity of the proposed identity and purity criteria. The proposed specification does not appear to align with the most recent revision of the EU regulations which is stated as the basis for the specification. Some NZFGC 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'.

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