Government of **Western Australia**
Department of **Health**

Food Standards Australia New Zealand

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Submission DUE by 6 pm (Canberra time) on 2 September 2019

SUBMISSION ON APPLICATION - A1155
2nd Call for submissions paper
2'FL and LNnT in infant formula and other products

The Department of Health Western Australia (DOH) would like to thank Food Standards Australia New Zealand (FSANZ) for seeking comment on Application A1155 products. This submission has been prepared by the Food Technical Policy Team, Environmental Health Directorate.

The DOH notes that this application, by Glycom A/S, seeks permission to add 2'-O-Fucosyllactose (2'-FL) and/or Lacto-N-neotetraose (LNnT) to infant formula, and to formulated supplementary foods for young children (FSFYC) on a voluntary basis.

The DOH acknowledges that breast feeding is the normal and recommended way of feeding infants. Where an infant is not breastfed or is partially breastfed, commercial infant formulas are the alternative source of essential nutrition required for growth and development. The DOH considers that infant health and safety are the pivotal drivers for all decision making concerning to regulatory changes to infant formula composition, labelling and representation. The DOH further considers issues relating to the marketing of infant formula are of great importance.

Comments in response to the second Call for Submissions consultation paper detailed below, are underpinned by the Ministerial Policy Guideline – Regulation of Infant Formula Products (Policy Guideline); along with the principle that infants are a highly vulnerable population that rely on infant formula as their only source of nutrition. Regulation of infant formula has potential health impacts for formula fed infants, and on rates of breast feeding. The DOH is committed to protection, promotion and support of breastfeeding. Due to an infant's immature body systems, it is essential to ensure infants are not burdened with unnecessary substances in infant formula.

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In summary. In response to the FSANZ Assessment report and supporting documents, the DOH:

- **does not support the permission for voluntary addition of 2'FL and LNnT in infant formula; and**
- **does not support the permission for voluntary addition of 2'FL and LNnT in FSFYC.**

Rationale:

The DOH considers that the proposed amendment:

1. is not consistent with the Ministerial Policy Guideline – Regulation of Infant Formula Products.
2. does not demonstrate the protection of health and safety at the proposed concentration levels.
3. is not supported by sufficient scientific evidence.
4. potentially confounds evidence of a 'potential' or 'plausible' health effect with the level of evidence required to **substantiate** a health effect (i.e the totality of evidence required).
5. Controlled trials are required to investigate the health benefits of adding 2'-FL and LNnT to infant formula.

General comment

The DOH is concerned about the level of evidence that FSANZ considers sufficient in this application. In particular, FSANZ has used the premise that 'possible' or 'plausible' effects is all that is required to meet the scientific evidence criteria of a 'substantiated beneficial role in the normal growth and development of infants'.

The DOH is aware that FSANZ provided a response to concerns previously raised by jurisdictions, in the second Call for Submissions consultation paper. The DOH, however, does not consider the FSANZ response adequately addresses the issues raised by jurisdictions in the first round of consultation on this application, and does not have sufficient regard to the Policy Guideline. For reference, the Specific Policy Principle j) states:

> *j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breastmilk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.*

1. Addition of 2'-FL and LNnT to infant formula

The DOH considers that FSANZ has not provided the necessary and appropriate level of evidence to show that adding 2'-FL and LNnT to infant formula leads to a physiological, biochemical and/or functional effect in infants, and has not shown that these effects are themselves linked to particular health outcomes.

Health Benefit

- The DOH does not consider demonstrating plausibility (possible or plausible that *Camplylobacter jejuni* could bind) provides sufficient evidence to link the physiological, biochemical and/or functional effects of 2'-FL and LNnT to specific health outcomes in

infants. Additionally, the DOH considers FSANZ has not applied an adequate level of caution given that the links are not clear.

- The DOH does not consider there is sufficient scientific evidence to support the stated anti-infective health benefits for the addition of 2'-FL and LNnT (i.e. to substantiate a health effect). The evidence to support the anti-infective is weak, as it lacks robust human studies to justify a substantiated health benefit. FSANZ has described **one** human infant study to support this health effect. This study involved breastfed infants, with breast milk contributing 49% of feeds, and not an infant formula which contained 2'-FL and LNnT. The infants were also fed infant formula and other foods. As such, it is not possible, nor valid, to assign the health effect of these feeds to the specific elements of 2'-FL and LNnT.
- Evidence reviews have not substantiated the promoted health effects of human milk oligosaccharides. Breast milk contains numerous protective substances; and adding particular human milk oligosaccharides does not account for the role of many other oligosaccharides naturally present in human milk.
- The DOH does not consider FSANZ has substantiated the bifidogenic health outcomes in this second Call for Submissions, nor in previous work (refer to Proposal P306 and Application A1055).
  - In the review of Proposal P306, FSANZ stated that there was insufficient evidence to demonstrate benefit or efficacy for the addition of inulin/FOS/GOS in infant formula products, infants foods and FSFYC. As such, FSANZ has not satisfied the Policy Guideline specific policy principle j).
  - In A1055, the only health effect assigned was stool softening effect of short chain fructo-oligosaccharides (scFOS). FSANZ concluded that the studies presented did not establish an effect of scFOS on the level of *Bifidobacteria* (genus) in the infants' guts (many of these studies found no effect).
  - In A1155, FSANZ has not established the health benefit in formula fed infants of promoting *Bifidobacteria* genus over other genus in a stool, nor a particular sub-species of *Bifidobacteria* over another, such as *B. longum subsp. infantis* over *B. adolescentis* (i.e major species found in adults stool).

Safety

- The DOH does not consider there is sufficient justification of FSANZ's decision to propose extending the maximum limit for 2'-FL level tested in the toxicity and feeding studies, described in the second Call to Submissions. Whilst FSANZ has theorised that the higher maximum levels are safe, evidence to demonstrate this position has not been provided.

2. Addition of 2'-FL and LNnT to FSFYC

The DOH considers there is insufficient evidence to support the stated nutritional benefits for the addition of 2'-FL and LNnT for this age group (13 to 47 months). The DOH also considers that the addition of 2'-FL and LNnT to FSFYC, has not had sufficient regard for the Policy Guideline 'Intent of Part 2.9' where the composition of special purpose food should be consistent with the intended purpose.

- The purpose of FSFYC is to supplement toddlers' diet where there is an inadequate dietary intake of energy and nutrients.
- Unlike infant formula, FSFYC is not a breast milk substitute.
- FSANZ notes that the addition of 2'-FL and LNnT may not have strong alignment with the definition of the FSFYC category.
- In FSANZ assessment, while plant based oligosaccharaides may promote *Bifidobacteria* sub-species dominant in children and adolescent's guts; 2'-FL and LNnT were not shown to promote these sub species. As such adding plant based oligosaccharides is consistent with supplementing inadequate plant fibre intake; whereas adding 2'-FL and LNnT is not.

3. Labelling

3.1 Labelling of 2'-FL and LNnT in infant formula

In the event that FSANZ establishes appropriate level of evidence on the safety and beneficial health effect for the addition of 2'-FL and LNnT to infant formula, the DOH would be supportive of the prohibitions that FSANZ proposed on the use of the terms, including related terms or acronyms, for 'human milk oligosaccharides'. There is a need to fully investigate future proofing these proposed prohibitions, such as how to deal with potential impact of trademarking.

3.2 Labelling of 2'-FL and LNnT in FSFYC

The DOH has concerns that there may be risks associated with cross-marketing of FSFYC and infant formula. In particular, in contrast to infant formula, FSFYC does not have the prohibitions on labelling, claims, references to breast milk and/or humanising elements. Should the addition of 2'-FL and LNnT in FSFYC be permitted, there is a need to fully investigate future proofing these proposed prohibitions, such as how to deal with the potential of trademarking.

Thank you for considering the above comments. If you have any queries, please contact Food Technical Policy Team, Environmental Health Directorate or (08) 9222 2000.

Yours sincerely

ENVIRONMENTAL HEALTH DIRECTORATE