Department of Health

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Tasmanian Government

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A1265 - Call for submissions

A1265 – 2'FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as a nutritive substances in infant formula products

Thank you for the opportunity to comment on the call for submissions for Application *A1265 – 2'FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as a nutritive substance in infant formula products.*

Application A1265 seeks to permit the voluntary combination of four human-identical oligosaccharide (HiMO) ingredients produced by microbial fermentations, alone or in combinations as nutritive substances in infant formula products, namely:

- Mixture of 2'-fucosyllactose (2'-FL) and difucosyllactose (DFL) ("2' FL/DFL")
- Lacto-N-tetraose (LNT)
- 6'-Sialyllactose (6'-SL) sodium salt; and
- 3'-Sialyllactose (3'-SL) sodium salt

The Applicant (Glycom A/S) also requested exclusive use permission for a period of 15 months for this combination.

The draft variation by FSANZ, if approved, would also remove the current prohibition in Standard 2.9.1 on the addition to infant formula products of galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in combination with lacto-N-neotetraose (LNnT).

Public Health Services notes FSANZ has assessed that the weight of evidence for these four HiMO to be added to infant formula products supports beneficial health effects, notably an increase in the abundance of Bifidobacterium spp. in the infant gut microbiota, anti-pathogenic effects, inflammatory suppression and facilitation of appropriate immune responses and antigenic memory.

Whilst the evidence appears to include a number of clinical trials, only one of these assessed the health effects; the remainder reported only on safety, tolerance, and infant growth. PHS queries if this is enough evidence to substantiate beneficial role in normal growth and development.

PHS acknowledges it is not defined in the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* (2011) the level of evidence required to substantiate benefit, but it is expected this will be clarified as part of the review of A1155.

PHS requests that these new HiMO and their combinations be included as part of the review of A1155 to determine if the level of evidence for a beneficial role in normal growth and development can be substantiated.

PHS supports the need to maintain prohibition on labelling for nutrition content claims and health claims and supports the prohibited representations outlined in 2.9.1-24 (1) (ca) prohibits the use of the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect. In addition, PHS supports paragraph 2.9.1—24(1)(cb) prohibits the use of the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect.

Summary

Public Health Services is concerned about extending permissions for the addition of HMOs or the combination of HMOs with other ingredients to infant formula products if it does not provide a beneficial role in normal growth and development. Adding substances to infant formula that provides minimal benefit (and presumably add to the cost) is misleading to caregivers of formula fed infants. FSANZ has noted from their literature review to inform P1028 that caregivers preferred longer ingredient lists, as they were perceived to be more nutritionally complete (FSANZ 2022). There is a risk that the addition of HiMO to infant formula products will be perceived as 'beneficial' simply because they have been added. It is important that the evidence is clear of their beneficial role in normal growth and development to warrant their addition.