New Zealand Food Safety
Haumaru Kai Aotearoa

Project Officer Proposal A1265
Food Standards Australia New Zealand
PO Box 10559
The Terrace
Wellington 6036

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Tēnā koe,

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

New Zealand Food Safety (NZFS) welcomes the opportunity to comment on the Call for Submissions (CFS) for Application A1265 – 2'FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products.

NZFS acknowledges that breastfeeding is the recommended way to feed infants. For infants who are not breastfed, a safe and nutritious substitute for breast milk is needed. Infant formula products are the only safe and suitable alternative to breast milk.

This Application from Glycom A/S seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the voluntary addition of four human-identical milk oligosaccharides (HiMO) for use as nutritive substances in infant formula products. These substances are produced by microbial fermentation using a genetically modified strain of *Escherichia* coli K-12. Glycom A/S has also requested an exclusive use permission for their brand of each substance for a period of 15 months after gazettal.

NZFS provides its preliminary support to permit the voluntary addition for each of 2'-FL/DFL, LNT, 6'-SL and 3'-SL to be 'used as a nutritive substance' and as 'food produced using gene technology' in infant formula products at a maximum permitted amount of:

- 2'-FL/DFL mixture – 96 mg/100 kJ;
- LNT – 32 mg/100 kJ;
- 6'-SL sodium salt – 16 mg/100 kJ; and
- 3'-SL sodium salt – 8 mg/100 kJ.

We also provide our preliminary support to grant Glycom A/S a 15-month exclusive period of use for their brand of each substance, and for FSANZ to remove the current prohibition on use of GOS and/or ITF with LNnT in infant formula products.

Overall, we consider there are no public health and safety concerns with the requested HiMO permissions. The assessment is based on best available evidence and meets the specific policy principles for composition and labelling outlined in the Ministerial Policy Guideline on the Regulation of Infant Formula Products. The new HiMO permissions would promote consistency between domestic and international standards, and support innovation and trade.

We have the following specific comments on the risk assessment and proposed approach detailed in the CFS:

Risk assessment

NZFS supports the findings of the four risk assessments undertaken by FSANZ to evaluate the food technology, safety, nutrition and beneficial health effect aspects of this Application.

NZFS agrees with FSANZ's conclusion that there are no public health and safety concerns. We agree that the substances 2′-FL/DFL, LNT, 6′-SL and 3′-SL are chemically and structurally identical to the naturally occurring forms of these substances in human milk, and that the production of these substances using GM strains of *E. coli* K-12 presents no public health risk.

NZFS supports FSANZ's conclusion of the dietary intake assessment, which shows that the concentrations of 2'-FL/DFL, LNT, 6'-SL and 3'-SL requested to be added to infant formula products are within the range of mature human milk concentrations. We commend FSANZ on considering total oligosaccharide amounts and potential cumulative effect given other existing permissions for HiMOs in the Code. We note the combined maximum amount of HiMOs added to infant formula products (accounting for existing HiMO permissions and the additional permissions requested in this Application) would be 0.15 g/100 kJ, which is less than the lower limit of average total oligosaccharide concentration reported in mature human milk (0.34 – 0.51 g/100 kJ).

NZFS agrees the available evidence indicates that infants achieve normal growth when they are fed HiMOs at the levels normally present in human milk. However, we suggest a minor amendment to the wording of the final sentence of the section 'Key findings of the nutrition assessment'. Due to the relatively small number of directly relevant studies, words to the effect of "unlikely to pose a risk to growth" or "…is not indicated to pose a risk to growth" may be appropriate. We also request that FSANZ clarify their summary of findings for the study by Cohen et al (2022). From the description provided, it is unclear whether or not there were statistically significant differences in daily body weight gain, though it is clear that any differences were not clinically significant (i.e. within the margin of ±3 g/day).

NZFS supports FSANZ's conclusion that beneficial health effects to the gut microbiota, anti-pathogenic effects and immunomodulation effects have been established for the HiMOs requested in this Application. We also agree that the inclusion of a wider range of HiMOs to infant formula products enables the microbiota profile to more closely resemble that of breast-fed infants.

Labelling requirements

NZFS supports the approach for labelling and representation of infant formula products with added HiMO, including the existing generic ingredient labelling requirements, declaration of nutritive substances in the nutrition information statement, prohibition on the use of words and abbreviations for HiMOs, and the prohibition on nutrition content and health claims for infant formula products. These requirements will help ensure caregivers have adequate information to make an informed choice, and will help prevent misleading or deceptive conduct.

Exclusivity

We note Glycom A/S's request for an exclusive use permission for their brand of each HiMO substance based on the company's research and investment in developing these highly refined substances via proprietary manufacturing processes. This appears a reasonable request and aligns with the intent of exclusivity to provide an incentive to industry for innovation, and to provide

a benefit to an applicant that has expended significant resources into the development of the product.

Thank you for the opportunity to comment on this Application and we welcome any questions on issues raised in our submission.

Nāku noa, nā