Comments from the Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action.

Due date of submission – 7 July 2023

The Victorian Departments of Health and Energy, Environment and Climate Action (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application A1265 seeks to permit the voluntary addition of four human-identical milk oligosaccharides (HiMO) as nutritive substances to infant formula products. The HiMOs and the proposed maximum permitted levels are outlined in **Table 1**.

Human-identical milk oligosaccharide (HiMO)	Maximum permitted level
2'-fucosyllactose (2'-FL) and difucosyllactose (DFL)	96 mg/100 kJ
lacto-N-tetraose (LNT)	32 mg/100 kJ
6'-sialyllactose sodium salt (6'-SL)	16 mg/100 kJ
3'-siallyllactose sodium salt (3'-SL)	8 mg/100 kJ

Table 1: HiMOs and proposed maximum permitted levels for voluntary addition to infant formula products

Based on the assessment of safety, nutritional impact and health benefits, Food Standards Australia New Zealand (FSANZ) has proposed a draft variation to the Code to permit the requested HiMOs with conditions on maximum permitted use as outlined in Table 1.

Comments

Total permitted oligosaccharide content

Although not requested by the Applicant, FSANZ also proposes to remove the prohibition on the addition of galacto-oligosaccharides (GOS) and/or inulin-type fructans (IFT) in combination with lacto-N-neotetraose (LNnT) to infant formula products. This will in effect allow all permitted HiMOs to be added in combination with GOS and/or ITF. The departments previously raised concern under Application A1251 that the removal of the prohibition on combined use of 2'-FL and GOS and/or ITF would permit these substances to be added at levels higher than the studies included in the safety assessment. The proposed removal of the prohibition on combined use of HiMOs with GOS and/or ITF extends the permitted maximum levels of oligosaccharides without further evidence of safety. While FSANZ considered the cumulative effect of the combined substances, this appears to focus on the levels of HiMOs and total oligosaccharides as a proportion of total carbohydrate content, and it is unclear how this demonstrates safety of the total oligosaccharide quantity in infant formula products. The departments' request further information on the cumulative safety assessment, particularly the level of safety of total oligosaccharide content that will be permitted under this Application. In addition, the departments seek further information from FSANZ on the considerations required to set a maximum total amount for total added oligosaccharides.

Evidence of substantiated health benefit

The departments note that FSANZ has commenced the review of evidence for a substantiated health benefit of 2'-FL and LNnT in infants, which is due to be completed by March 2026. Given the number of recent applications for voluntary addition of human milk

oligosaccharides to infant formula products, the departments request FSANZ clarify the scope of the review and its inclusion of the cumulative benefit of subsequent HiMO approvals such as 6'-SL and 3'-SL. The departments support a complete review which includes all currently permitted HiMOs and their individual and combined health effects.

Exclusivity

The departments remain concerned by the granting of exclusive use permissions for substances that are demonstrated to benefit infant health and development outcomes. As noted in our previous comments to Application A1253, exclusivity permissions limit availability and is inconsistent with the Policy Guideline on the Regulation of Infant Formula Products which states that the composition of infant formula and follow-on formula should strive to achieve as closely as possible the growth and development of breastfed infants. However, we note FSANZ has previously granted exclusive use of nutritive substances in infant formula products under Applications A1155, A1251 and A1253. It is therefore consistent and equitable to extend exclusivity permission under Application A1265.

The departments support the progress of this Application subject to responses to those matters raised herein in FSANZ's Approval Report.

[redacted]