Comments from the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 19 August 2022

The Victorian Departments of Health and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this application to amend the Australia New Zealand Food Standards Code (the Code).

Application *A1251 - 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products* seeks to change the Code to permit 2'-FL and galacto-oligosaccharides and/or inulin-type fructans (with pre-existing voluntary permissions in infant formula products to be added separately) to be added in combination.

From the Food Standards Australia New Zealand (FSANZ) Assessment report it is understood that:

- The applicants, Nutricia Australia Pty Ltd and Chr. Hansen A/S are requesting to amend the Code to permit the voluntary combination of 2'-fucosyllactose (2'-FL) with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) in infant formula products.
- Chr. Hansen has a pre-existing exclusive use granted for its form of 2'-FL until early 2023.
- There are pre-existing voluntary permissions for adding GOS and ITF to infant formula products.
- FSANZ has assessed the safety and tolerance of the proposed combination through a literature search on infant growth. Four studies are outlined that used 0.2 to 1 g/L 2'-FL together with 1.4 to 8 g/L of GOS/ITF. These showed no statistically significant increase in adverse events as secondary outcomes.
- FSANZ has concluded adding the maximum of 2.4g/L of 2'-FL and 8g/L GOS/ITF is safe and suitable and has proposed a variation to amend Standard 2.9.1 to this effect.
- FSANZ states no conclusions can be drawn on whether there are any additional benefits arising from supplementation with a combination of 2'-FL and GOS and/or ITF.
- The applicants have requested 15 months' exclusive use of the combination of Chr. Hansen 2'-FL and GOS/ITF and FSANZ has agreed.
- Following the 15 month exclusive period, the voluntary permission to combine 2'-FL together with GOS/ITF will be open to all manufacturers and all forms of 2'-FL.

Comments

Evidence of safety and tolerance

The departments note that the studies reviewed only provide evidence of safety and tolerance of combined 2'-FL and GOS/ITF using up to 1g/L of 2'-FL. FSANZ has assumed safety of up to 2.4g/L of 2'-FL (together with up to 8g/L GOS/ITF). This results in permitted maximum oligosaccharides exceeding previous levels permitted in the Code. FSANZ suggests that, because breastmilk can contain higher levels of total oligosaccharides, it should be inferred the proposed levels in infant formula are safe. The departments do not agree that the safety and tolerance of breastmilk, which contains up to 200 oligosaccharides (known to operate synergistically and to have different functions) can be automatically extrapolated to an infant formula containing a combination of

oligosaccharides, some of which do not exist in breastmilk, at levels which have not been tested in trials.

Given the particular vulnerability of the population and the expectation that the regulation of infant formula should be commensurate with this level of risk, the departments consider that amendments to the permitted composition of infant formula should be based on direct evidence showing safety and tolerance of an infant formula containing the relevant ingredients at the proposed maximum levels.

Exclusivity

The departments' question whether exclusivity should be granted in this application. The ability to apply for exclusive permissions was introduced for novel foods to protect commercially sensitive information released during the application process and allow businesses to realise the commercial benefit of their investment into food innovation. The departments are not convinced exclusivity should be granted because:

- the ingredients in question having pre-existing permissions. GOS and ITF are not novel. The original application for 2'-FL requested exclusive use as a novel food and was granted for 2'-FL produced from specific source organisms and gene-gene donor combinations. The applicant already has exclusive use of Chr. Hansen 2'-FL.
- the research relied on to demonstrate safety of the combined ingredients has been funded by other bodies and companies, and
- granting exclusivity will disadvantage domestic infant formula producers.