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

Due date of submission – 19 August 2021

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 *A1190 – 2'-FL in infant formula and other products* seeks to permit addition of an oligosaccharide, 2'-FL, from a specific source to infant formula products and formulated supplementary foods for young children (FSFYC).

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

- A voluntary permission under the Code to add 2'-FL to infant formula products up to 2.4g/L, as consumed, was recently granted. Given the different source and specifications of the 2'-FL under Application A1190, a pre-market assessment was required.
- Application A1190 sought the addition to both infant formula products and FSFYC. FSANZ has determined, in light of the decision on A1155 to not permit 2'-FL in FSFYC (on the basis that 2'-FL is naturally found in human milk only, and FSFYC is not a breast milk substitute) that the permission will apply to infant formula products only.
- While the Applicant sought a permission up to 2g/L, the existing permission up to 2.4g/L (96 mg/100 kJ) will apply.
- The conditions put in place for the existing 2'-FL permission will apply to the new version of 2'-FL, including the prohibition on adding 2'-FL together with galacto-oligosaccharides and inulin-type fructans; and a prohibition on the use of the words 'human milk identical oligosaccharide' or 'human milk oligosaccharide', and abbreviations 'HMO', 'HiMO', or any word or words or abbreviations having the same or similar effect.
- 2'-FL is manufactured by fermentation, using a unique genetically modified bacterium, from E. coli BL21, which is a non-pathogenic, non-toxigenic microorganism with a history of use of industrial compounds and human therapeutics.
- An exclusive permission to use the applicant's 2'-FL will apply for a period of 15 months, linked to the applicant's brand name 'CHR. HANSEN™ 2'-FL', commencing on the date of gazettal of the variation.

The departments **support the progression of A1190**.

In agreeing to the permission for 2'-FL and LNnT to infant formula products, Food Ministers also introduced a condition that within five years of gazettal (26 March 2021), FSANZ must examine, and report back to Food Ministers, as to whether there is sufficient evidence of a 'substantiated beneficial role in the normal growth and development of infants, or a technological role' to justify the continuation of the permission. This review was considered necessary because the evidence of benefit of 2'-FL and LNnT to infants was weak.

FSANZ should make this review date of 26 March 2026 clear to all prospective applicants seeking addition of a form of 2'-FL or LNnT.