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

Due date of submission – 31 January 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 *A1233 - 2′-FL from new GM source for infant formula* seeks to permit a new source organism and specification for 2′-fucosyllactose (2′-FL) for addition to infant formula products.

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 granted in November 2020. Given the different source and specifications of the 2′-FL under Application A1233, a pre-market assessment is required.
- The applicant, Friesland Campina Ingredients, is requesting a new source organism for 2′-FL: a genetically modified (GM) *Escherichia coli* K-12 derived strain expressing the α-1,2-fucosyltransferase gene from *Bacteroides vulgatus*. New specifications are also being requested that are different to those that currently apply for 2′-FL.
- FSANZ concludes there are no safety or nutritional concerns with 2′-FL, including from this new source and with the proposed specifications.
- The conditions put in place for the existing 2′-FL permission will apply to the new form 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.
- The permission will also be subject to review by FSANZ by 26 March 2026 to determine 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.
- 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 'Aequival® 2′-FL', commencing on the date of gazettal of the variation.

The departments support the progression of A1233.