



5 July 2023

Project Manager
Food Standards Australia New Zealand
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NEW ZEALAND

Email: submissions@foodstandards.gov.au

Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the *Call for submissions – Application A1265: 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products.*

Yours faithfully

A handwritten signature in blue ink, appearing to be "Raewyn Bleakley". The signature is stylized and cursive.

Raewyn Bleakley
Chief Executive



**CALL FOR SUBMISSIONS – APPLICATION
A1265: 2'-FL/DFL, LNT, 6'-SL SODIUM
SALT AND 3'-SL SODIUM SALT AS
NUTRITIVE SUBSTANCES IN INFANT
FORMULA PRODUCTS**

**Submission by the New Zealand Food & Grocery
Council**

5 July 2023

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (**NZFGC**) welcomes the opportunity to comment on the *Call for submissions – Application A1265: 2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products*.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$40 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$34 billion in export revenue from exports to 195 countries – representing 65% of total good and services exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 45% of total manufacturing income. Our members directly or indirectly employ more than 493,000 people – one in five of the workforce.

THE APPLICATION

3. Glycom A/S (**Glycom**) has applied to Food Standards Australia New Zealand (**FSANZ**) to amend the Australia New Zealand Food Standards Code (**the Food Standards Code**) to permit the voluntary addition of four human-identical milk oligosaccharide (**HiMO**) products for use as nutritive substances in infant formula products. The substances and their proposed maximum permitted amounts are:
 - A mixture of 2'-fucosyllactose (**2'-FL**) and difucosyllactose (**DFL**) (**2'-FL/DFL**) (96 mg/100 kJ);
 - lacto-N-tetraose (**LNT**) (32 mg/100 kJ);
 - 6'-sialyllactose sodium salt (**6'-SL**) (16 mg/100 kJ); and
 - 3'-sialyllactose sodium salt (**3'-SL**) (8 mg/100 kJ).
4. Glycom has also requested an exclusive use permission for a period of 15 months for their combination of the above four HiMO branded substances after gazettal.

COMMENTS

5. The HiMOs 2'-FL/DFL; LNT; 6'-SL and 3'-SL are all components of the human milk oligosaccharide (**HMO**) fraction of human milk. 2'-FL and DFL are oligosaccharides that contain the sugar fucose (a hexose deoxy sugar with the chemical formula C₆H₁₂O₅) and so are called 'fucosylated' HMOs. 2'-FL and DFL are always found together in human milk.
6. Glycom produces these oligosaccharides via a microbial fermentation process to produce the HiMOs. The fermentation is performed using a GM strain of *Escherichia coli* (**E. coli**) K-12. This method is the same as for that of the Application A1155 for the production of 2'-FL and LNnT and, based on the FSANZ previous assessment as part of A1155 and the data provided by the Applicant, a biotechnology assessment of this production strain was not required.
7. FSANZ concluded from its overall *risk and technical assessment* (safety, toxicological and microbiological assessments, dietary and nutrition assessments and beneficial health assessment) that consumption of infant formula products containing the Applicant's 2'-FL/DFL, LNT, 6'-SL and 3'-SL alone or in combination at the levels requested was safe and well tolerated and would have a beneficial outcome.
8. NZFGC supports the FSANZ decision to permit the addition of the Applicant's 2'-FL/DFL, LNT, 6'-SL and 3'-SL alone or in combination at the levels requested to infant formula products. NZFGC also supports the proposal to remove the current prohibition in Standard

2.9.1 on the addition to IFP of galacto-oligosaccharides (GOS) and/or inulin-type fructans (IFT) in combination with lacto-N-neotetraose (LNnT).

9. In light of existing permissions and labelling requirements, no additional labelling requirements were proposed. NZFGC agrees with this position but agrees with the Infant Nutrition Council (**INC**) that the prohibition on the use of the term, 'human identical milk oligosaccharides' or HiMO, is counter to building consumer confidence in, and understanding of, labelling information.
10. We strongly support FSANZ's commitment to reviewing new evidence on the beneficial role of a range of HiMOs in the normal growth and development of infants.
11. Harmonisation with international standards, that are based on relevant science and scientific expert opinion, is essential to allow the manufacture and availability of these types of products for consumers in Australia and New Zealand and for export. As well, the alignment of regulations with international standards encourages consideration of future investments in innovation in Australia and New Zealand. Alignment will result after the 15 month exclusivity period.