



Nestlé Submission in response to

Call for Submissions CFS - Application A1265 (Glycom A/S)
2'-FL/DFL, LNT, 6'-SL sodium salt and 3'-SL sodium salt as nutritive substances in infant formula products

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Limited.

Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets and is globally one of the largest manufacturers of infant formula products and other foods. Nestlé currently imports and markets infant formula products which are regulated in section 2.9.1 of the Australia New Zealand Food Standards Code ('the Code').

Nestlé welcomes the opportunity to consider the issues and views proposed in the call for submissions (CFS) for Application A1265, and to provide comment and information to Food Standards Australia New Zealand (FSANZ).

We thank FSANZ for its consideration of the comments, issues and views expressed in this submission.

Breast milk is the best nutrition for infants

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants.

In situations where the infant cannot receive breast milk, an infant formula is the only suitable and safe alternative, as a sole source of nutrition. Nestlé advocates a science-based approach to formulating products for the health and well-being of infants and young children. It is important that health recommendations and regulations focus on the best interests of the child and are based on the latest body of scientific evidence.

Discussion

Nestlé supports the Application and the permission for 2'-FL/DFL, LNT, 6'-SL and 3'-SL alone or in combination at the levels requested to infant formula products.

Nestlé supports FSANZ's proposal to remove the current prohibition in Standard 2.9.1 on the addition of galacto-oligosaccharides (GOS) and/or inulin-type fructans (IFT) in combination with lacto-N-neotetraose (LNnT) to infant formula products.

Nestlé requests consideration of removing the current restriction that LNnT must be used in combination with 2'FL.

Comments on the Call for Submission document (CFS)

1. *Nestlé supports FSANZ assessment of safety / nutrition / beneficial health effect of these human identical milk oligosaccharides (HiMOs).*

Nestlé notes the favourable findings of the risk assessment of the HiMOs (the subject of the Application) in relation to safety (toxicology, microbial, clinical), the comparability of pharmacokinetics to HMO's from breast milk, and the consistency and weight of evidence supporting beneficial health effects. Beneficial health effects include bifidogenic, anti-pathogenic and anti-infective properties. Further, post market surveillance data did not identify any safety concerns.

2. *Nestlé supports the levels proposed for addition of 2'-FL/DFL, LNT, 6'-SL and 3'-SL*

Nestlé notes the finding that mean estimated dietary intakes of 2'-FL, DFL, LNT, 6'-SL and 3'-SL from IFP were comparable to mean estimated dietary intakes from mature human milk, and FSANZ's conclusion in respect of safety, technical and health effects assessment that there are no public health and safety concerns associated with the addition of the Applicant's 2'-FL/DFL, LNT, 6'-SL and 3'-SL in IFP at the levels proposed. These levels are comparable to those of human milk. Accordingly, Nestlé supports the proposed levels of addition.

3. *Nestlé supports exclusivity of use as these are new nutritive substances*

Nestlé notes that FSANZ is proposing to provide to the Applicant 15-month exclusivity for the newly permitted forms of 2'-FL/DFL, LNT, 6'-SL and 3'-SL. Nestlé supports this exclusivity, as it recognises the considerable research and development investment that has been required to bring these substances to the marketplace, and the importance of receiving a return on that investment.

4. *Nestlé supports FSANZ proposed risk management measures*

Nestlé notes that the proposed risk management measures including purity specifications for each HiMO in Schedule S-3, measures related to ingredient labelling and mandatory nutrition labelling relating to permitted nutritive substances.

Nestlé supports these measures as appropriate for the newly permitted forms of 2'-FL/DFL, LNT, 6'-SL and 3'-SL and which are consistent with existing HiMO permissions.

Nestlé supports FSANZ proposal to remove the current prohibition in Standard 2.9.1 on the addition of GOS and/or IFT in combination with LNnT to infant formula products.

5. *Nestlé requests consideration of removing the current restriction that LNnT must be used in combination with 2'FL*

In addition, Nestlé suggests consideration is given to removing the current restriction that LNnT must be used in combination with 2'-FL.

LNnT is currently permitted for use in IFP in combination with 2'-FL with an individual maximum use level of 24 mg/100kJ. This is within the range of mean concentrations of LNnT reported in human milk (Soyyilmaz *et al.*, 2021). The combined maximum 2'-FL or 2'-FL/DFL, LNT, LNnT, 6'-SL and 3'-SL permitted for addition to IFP would be 0.18 g/100 kJ which remains well below the lower limit of average total oligosaccharide concentration reported in mature human milk calculated by FSANZ (from Zhang *et al.*, 2021) as 0.34 to 0.51 g/100 kJ.

LNnT is a separate HiMO ingredient from 2'-FL (i.e., it is not produced as a mixture with 2'-FL, unlike DFL). It is already permitted as a single ingredient in IFP in countries where permissions exist including a recent update in the European Union ((EU) 2023/961) to remove a prescribed ratio with 2'FL.

Hence, based upon the same principle of minimum effective regulation, more efficient assessment of future applications for HiMO-type ingredients and international consistency, Nestlé requests that this restriction is removed.

References

Commission Implementing Regulation (EU) 2023/961 of 12 May 2023 amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food Lacto-N-neotetraose

Soyyılmaz B, *et al.* (2021) The mean of milk: a review of human milk oligosaccharide concentrations throughout lactation. *Nutrients*. 13(8):2737.

Zhang S, *et al.* (2021) Gold standard for nutrition: a review of human milk oligosaccharide and its effects on infant gut microbiota. *Microb Cell Fact*. 20(1):108.