



Nestlé Submission

Application A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans 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 thanks FSANZ for the A1251 consultation paper and welcomes the opportunity to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Regulation of the voluntary use of 2'-fucosyllactose combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products. We thank FSANZ for their consideration of the comments, issues and views raised in this submission.

Introduction:

Breast milk is the best nutrition for infants. Nestlé fully supports this and optimal breastfeeding for optimal health outcomes for infants. We welcome the consultative effort of FSANZ to determine the best nutrition advice and outcomes for Australian and New Zealand 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 voluntary use of 2'-fucosyllactose (2'-FL) combined with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF) to be added infant formula products (IFP).

We note that removal of the current prohibition will align the Code closer to international food standards, which do not restrict 2'-FL combined with GOS/ITF in infant formula products. Nestlé supports consistency of the Code with international food regulations.

Exclusivity

Nestlé supports the intent of exclusive use permissions for novel foods as described in *Proposal P305 – Permission for Exclusivity of Use of Novel Foods* (2007) and extended to nutritive substances as part of *Application A1155 – 2'-FL and LNnT in infant formula and other products* (2020). Exclusivity supports innovation by providing a commercial benefit to applicants who have invested considerable resources into the research and development of a novel food or a new nutritive substance.

Nestlé understands that a period of exclusive use for a specific brand or class of food can be requested by applicants requesting approval of a novel food or a new nutritive substance. We note that the background and current approach to exclusivity of use for novel foods and nutritive substances is described in a recently published page on the FSANZ website¹.

However, we note that A1251 is not an application requesting approval of a novel food or new nutritive substance – permission currently exists within the Code for GOS and ITF and for 2'-FL developed by Chr. Hansen to be added to infant formula products. Rather, this application is requesting a change to the condition of use of a nutritive substance.

Considering publicly available information, Nestlé is concerned that there is insufficient justification to support the potential precedent set in this application regarding exclusivity. We would like to seek further clarity from FSANZ on the rationale for exclusivity of use permission detailed in this application.

We are also concerned that a precedent regarding exclusivity for use is being set for all foods, through individual applications. The topic may have broader stakeholder relevance for future consideration.

Conclusion

Nestlé supports extending the permission for 2'-FL combined with ITF/GOS in infant formula products.

However, due to our concerns detailed above, we would like to seek regulatory clarity around granting a further exclusivity of use period to novel foods and nutritive substances already permitted by the Code, including those in this Application.

¹ <https://www.foodstandards.gov.au/industry/novel/Pages/Exclusivity-of-use-for-novel-foods-and-nutritive-substances.aspx>