Nestlé Submission

Application A1190 – 2'-FL in infant formula and other products:

19 August 2021

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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'), and formulated supplementary foods for young children (otherwise known as Toddler Milk Drinks), regulated in section 2.9.3 of the Code.).

Nestlé thanks FSANZ for the A1190 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 (2'-FL) in infant formula and other 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.

Executive summary

Nestlé supports the Application and the permission for 2'FL[1] in infant formula products (IFP).

Nestlé does not support the omitting of permission for use of 2'FL in FSFYC (formulated supplementary foods for young children)/toddler milks.

Nestlé recommends that 2'FL be also permitted for use in FSFYC /toddler milks.

> 2'FL is recognised as promoting bifidogenic and anti-infective effects against invasive *C. jejuni*. There are no safety concerns.
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> The bifidogenic and anti-infective properties of human milk oligosaccharides are not restricted to infants alone. That is, HMOs can play an important role in toddler and child immune functionality.
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> The reason given for not including 2'FL in FSFYC (FSANZ CFS1 A1190 p 13) is unsound. FSFYC are not breast milk substitutes, however it is not logical to use this as the reason for excluding 2'-FL from addition to FSFYC. Further, the addition of 2'-FL as a voluntary ingredient to FSFYC does not change the intended purpose of the food as a supplement to the diet when energy or nutrient intakes are inadequate.
>
> 2'FL is permitted in toddler milk drinks in a range of countries including those in Europe, USA, Israel, and Taiwan and omitting the permission for FSFYC sets up an inconsistency with international permissions.

It is recommended that where human identical milk oligosaccharides have already been approved for IFP, these permissions are also extended FSFYC. This would apply to 2'FL and LNnT[2] that have already been approved for use in infant formula products.

It is requested that the common terms 'human identical milk oligosaccharide' or 'HiMO' are permitted on the labels of infant formula and as this reflects the true nature of the ingredient and enables consumers to make informed choices.

Conclusion

It is Nestlé's view that not permitting the use of 2'FL for toddlers ignores the growing body of evidence in support of 2'FL functionality and is denying toddlers, and their parents and caregivers the potential benefits arising from consumption of this important human milk oligosaccharide.

Nestlé respectfully asks that this element of the decision be reviewed and that 2'FL (and other already permitted HiMOs) are permitted in FSFYC.

[1] 2'FL 2'-O-fucosyllactose

[2] Lacto-N-neotetraose LNnT

Discussion

Nestlé supports the Application and the permission for 2'FL in infant formula products IFP). This is consistent with the permission given to Glycom arising from Application A1155.

Nestlé does not support the omitting of permission for use of 2'FL in FSFYC /toddler milks, for the following reasons:

1. **2'FL, a significant component of human milk oligosaccharides in breastmilk, is recognised as promoting bifidogenic and anti-infective properties. There are no safety concerns.**

The Call for Submissions (CFS) to this Application (A1190) supports this statement where in CFS 1 – Executive Summary, FSANZ notes that it 'has no safety concerns with the addition of the applicant's 2-FL produced by microbial fermentation to both IFP (infant formula products) and FSFYC (formulated supplementary foods for young children)'.

FSANZ also notes in that Executive Summary that from its assessment of beneficial health outcomes concluded that 'there is evidence to support a role for 2′-FL in promoting a bifidogenic effect in infants and limiting infection by pathogenic strains of *Campylobacter jejuni* in infants and young children. However, the evidence base for such effects in young children is fairly limited.'

2. **The bifidogenic activity (and potential immune modulating functionality) of human milk oligosaccharides' including 2'FL and LNnT is not restricted to infants alone.**

HMOs have been shown to contribute to improved immune outcomes in infancy, childhood and on to adulthood. That is, HMOs can play an important role in infant and child nutrition and immune functionality. The following illustrates:

Fonvig *et al* (2021) concluded that in a parallel, randomised, double blind placebo-controlled trial (RCT) of 75 children with overweight, that subjects receiving 2'FL or a mix of LNnT and 2'FL showed an increase in bifidobacteria in intestinal microbiota and also that the supplementation was well tolerated.

Suligoj *et al* (2020) showed using a Simulator of the Human Intestinal Microbial System (SHIME) that in addition to their bifidogenic activity HMOs (2'FL and LNnT) had the capability of modulating immune function and the gut barrier, supporting the potential to provide health benefits in adults.

Iribarren *et al* (2020), in an RCT 4-week trial with 58 patients, showed that a mix of 2'FL and LNnT induced an increase in beneficial *Bifidobacteria* spp without aggravating gastrointestinal symptoms in patients with irritable bowel syndrome.

Palsson *et al* (2020), in a multicentre, 12-week, open label trial recruiting patients with IBS (irritable bowel syndrome) from 17 sites across the United States, found that in a total of 317 patients (245 completed), when a mix of 2'FL and LNnT was orally administered, there was a significant improvement in stool consistency, with the most improvement in the first 4 weeks of the trial.

It can be concluded from the above and the growing body of evidence that the beneficial health effects apply not only to infants, but to other population groups from children up to adults. That is, the evidence supports effects across all age groups, and that the exclusion of permission for FSFYC from this assessment should be reconsidered.

3. **The reason given for not including 2'FL in FSFYC (FSANZ CFS1 A1190 p 13) is unsound.**

Nestlé agrees that FSFYC are not breast milk substitutes, however it is not logical to use this as the reason for excluding 2'-FL from addition to FSFYC.

Firstly, the key issues are the safety and suitability of 2'FL as a component of toddler milks. There is ample evidence supporting the safety and suitability for permitting 2'FL in FSFYC.

Secondly, it has been shown that 2'FL can confer nutritional and physiological benefits beyond infancy (see point 2 above).

Further, the addition of 2'-FL as a voluntary ingredient to FSFYC does not change the intended purpose of the food as a supplement to the diet when energy or nutrient intakes are inadequate, in keeping with the Policy Guideline on the intent of Part 2.9 – Special Purpose Foods. Rather, these ingredients allow for product differentiation and consumer choice, they support competition in the market (offering consumers an alternative to inulin type fructans and galacto-oligosaccharides) and innovation.

Not permitting 2'FL (chemically and physiologically identical to the 2'FL in human milk) in FSFYC is denying toddlers the opportunity to benefit from today's science.

4. **2'FL is permitted in toddler milk drinks in a range of countries**

The countries include those in Europe, USA, Israel, and Taiwan and omitting the permission for FSFYC sets up an inconsistency with international permissions. Australia and New Zealand will be out-of-step and at a competitive disadvantage with its international competitors, leading to substantial, negative flow-on effects in trade.

It is recommended that where human identical milk oligosaccharides have already been approved for IFP, these permissions are also extended FSFYC. This would apply to 2'FL and LNnT that have been approved for use in infant formula products.

Prohibition of the terms 'human identical milk oligosaccharide' or 'HiMO' is contrary to the provision of adequate information relating to food to enable consumers to make informed choices.

The use of the terms 'human identical milk oligosaccharide' or 'HiMO' on the labels of infant formula products (as current Code permissions for other nutritive substances in the ingredient list and nutrition information panel) reflects the common name and true nature of the ingredient. Such generic terms are widely used in the scientific literature and are in use on products in various international jurisdictions.

Conclusion

Nestlé supports the Application and the permission for 2'FL in infant formula products.

It is Nestlé's view that not permitting the use of 2'FL for toddlers ignores the growing body of evidence in support of 2'FL functionality and is denying toddlers, and their parents and caregivers the potential benefits arising from consumption of this important substance.

Nestlé respectfully asks that this element of the decision be reviewed and that 2'FL (and other already permitted HiMOs) are permitted in FSFYC.

References

Fonvig C E *et al*, 2021. *Human Milk Oligosaccharides Moderate Fecal Microbiota and are Safe for Use in Children with Overweight: An RCT.* Journal of Pediatric Gastroenterology and Nutrition, Publish Ahead of Print. DOI: 10.1097/MPG.0000000000003205

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