# Nestlé Submission

# Consultation Paper for Application 1155 (A1155)
# 2′-FL and LNnT
# in infant formula and other products

**16th January, 2019**

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# A1155: 2′-FL and LNnT in infant formula and other products

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

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 consultation paper for Application 1155 (A1155), and welcomes the opportunity to consider the issues and preliminary views proposed, and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Regulation of the voluntary use of 2′-O-Fucosyllactose (2′-FL) alone or in combination with Lacto-N-neotetraose (LNnT). We thank FSANZ for their consideration of the comments, issues and views raised in this submission.

## Comments on the Consultation Paper

Nestlé will provide specific comments in response to the Summary of FSANZ's preliminary position on regulatory measures (pg 18 of CFS).

**Summary of FSANZ's preliminary position on regulatory measures**

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| Permit both 2′-FL and LNnT to be *used as a nutritive substance*, and as *food produced using gene technology* derived specifically from the GM production strains *E.coli* SCR6 (for 2′-FL) and *E.coli* MP572 (for LNnT), for use in infant formula products and FSFYC. |

**Permissions for use in infant formula products and FSFYC.**
Nestlé fully supports FSANZ's safety and technical assessment which "*…concluded that there are no public health and safety concerns associated with the addition of the applicant's 2′-FL and LNnT in infant formula products and FSFYC at the levels requested, or at higher levels consistent with levels in human milk*" and "*…has the potential to confer certain beneficial health outcomes in infants and young children*".

2′-FL and LNnT have also been pre-market assessed by the European Food Safety Authority (EFSA) to be safe and the United States Food and Drug Administration (USFDA) issued 'no questions' responses to the applicant's self-assessed Generally Recognized as Safe (GRAS) notifications. Other international regulatory authorities have also approved these ingredients.

Internationally, infant formula products and toddler milk drinks containing these ingredients have already been launched and consumed by infants and young children with no evidence of market failure.

The permission to add such ingredients structurally identical to 2'-FL and LNnT facilitates innovation and trade and is an advance in current nutrition that is in the interests of infants fed formula when breastfeeding or feeding breastmilk is not possible.

Therefore, Nestlé supports the proposed permission to voluntarily add 2'-FL and LNnT to infant formula products and FSFYC.

**Used as a nutritive substance**
Nestlé supports 2'-FL and LNnT as being *used as a nutritive substance*.

**As a food produced using gene technology**
Nestlé does NOT support the food being regulated within FSC 1.5.2 (Food produced using gene technology) and considers it more relevant to be regulated within FSC 1.5.1 (Novel foods), as originally described in the Administrative Assessment Report (12 January 2018). We consider 2'-FL and LNnT are non-traditional foods. This approach is also consistent with the EU, USA, Singapore and Israel who have regulated them as novel foods.

Set a maximum permitted use level of 2.4 g/L for 2'-FL alone; and a total maximum level of 2.4 g/L for 2'-FL and LNnT combined with no more than 0.6 g/L of LNnT. For consistency with existing voluntary permissions for infant formula products and FSFYC, these levels will be expressed in mg/100 kJ and g/serving as follows:

Infant formula products:

- If only 2'-FL added – no more than 96 mg/100 kJ of 2'-FL
- If both 2'-FL and LNnT added – no more than 24 mg/100 kJ of LNnT; and no more than 96 mg/100 kJ of 2'-FL and LNnT combined.

FSFYC:

- If only 2'-FL added – no more than 0.56 g/serving
- If both 2'-FL and LNnT added – no more than 0.14 g/serving of LNnT; and no more than 0.56 g/serving of 2'-FL and LNnT combined.

Nestlé supports the proposed maximum use levels and FSANZ's conclusion that these levels are safe based on a lack of adverse effects on growth in the clinical studies review and limited gastrointestinal absorption of 2'-FL and LNnT. These levels are significantly lower than the total oligosaccharide concentration present in breastmilk.

While Nestlé has no objections to the proposed units of measure of mg/100kJ for infant formula products and g/serving for FSFYC, we would prefer to use g/L as the unit of measure. This is because it is aligned to the relevant units of expression for breastmilk and in clinical studies as well as the approved units of measure in the EU and USA. Alignment helps to promote harmonisation and trade.

Prohibit the use of 2′-FL alone or with LNnT in combination with existing permissions for GOS and ITF for infant formula products and FSFYC (i.e. permissions for 2′-FL and LNnT would be used as alternatives to GOS and ITF).

Within the scope of this Application, Nestlé supports prohibiting the use of 2′-FL and LNnT in combination with existing permissions for GOS and ITF, and agrees with FSANZ's current evaluation that the maximum amounts of scFOS and GOS currently permitted in the Code were not tested (to date) in the clinical studies.

In the event that future scientific substantiation could be provided to facilitate a proposed combination of 2′-FL and LNnT in combination with existing permissions and maximum use levels for GOS and ITF, this could be reviewed through a separate new Application to change the Code based on new scientific evidence. Nestlé is not opposed in the future to combine human identical milk oligosaccharides with current 'mimics' derived from inulin or lactose or other permitted sources, despite the current permissions not occurring naturally in human milk, since the current permissions intend to 'mimic' the outcomes and purpose of similar ingredients of breastmilk. It is our view however, that it is not appropriate to consider combination within the scope of A1155.

Prescribe the ingredient names '2′-fucosyllactose' and 'Lacto-*N*-neotetraose' for infant formula products and FSFYC.

Nestlé does NOT support prescribing the ingredient names 2'-Fucosyllactose and Lacto-N-neotetraose. ITF and GOS that are somewhat similar substances - do not have prescribed ingredient names.

Nestlé is also disappointed by the FSANZ view that the term 'human milk-identical' or similar terms, is prohibited. We consider the appropriate intent is for the consumer not to perceive the product as a whole to be equivalent to human milk. In this case, these are single ingredients that are structurally identical to 2'FL and LNnT in human milk therefore we consider this to be technically correct in a list of ingredients and in addition, it could be a more easily understandable term for the consumer, as opposed to 2'-Fucosyllactose and Lacto-N-neotetraose. We note a recent study, commissioned by FSANZ and conducted in an Australian-New Zealand context (Malek *et al*., 2018) which found that *"…caregivers commonly experience difficulties when using labelling information, particularly when trying to identify and understand key differences between products".* Additionally, *"…mandated labelling information, particularly ingredient and nutrition information, needs to be clear and comprehensible to be effective".* The study also found *"…that explaining the scientific names/acronyms using simple 'layman's' terms would allow the information to be understood by those without a scientific background and who may be sleep-deprived".*

We are not proposing that human identical milk oligosaccharides would necessarily replace labelling 2'-Fucosyllactose and Lacto-N-neotetraose in a list of ingredients. Rather, we consider both could complement one another. Labelling requirements for infant formula products would exclude this term from being used on the tin in any place other than the ingredient list, and therefore it is unlikely that the consumer would understand it to apply to the whole product.

Set specifications for 2′-FL and LNnT using the specifications provided by the applicant.

Nestlé supports the regulation of specifications within Schedule 3 (Identify and Purity) and supports the specifications that are provided in Tables 2.3 for 2'-FL and 2.4 for LNnT to be based on specifications regulated by the EU and USA, with the exception of Methods of Analysis. Nestlé does not support prescribing the Methods of Analysis in Regulation as this does not facilitate innovation in method improvements.

Nestlé would additionally propose for the strain to be located together with the specification in Schedule 3, and would propose the strain to be prescribed as *E. coli* K-12 DH1 MDO. Nestlé does NOT support prescribing the strain at a production strain level (*E. coli* K-12 (DH1) SCR6 and *E. coli* K-12 (DH1) MP572) as this does not facilitate innovation on continuous improvements through elimination of current limitations (example: elimination of plasmids, elimination of antibiotic resistance genes, elimination of IPTG use). These improvements do not have any impact to the genes being expressed to produce 2'-FL and LNnT and therefore the safety elements of the assessment.

Reference

Malek, L., Fowler, H., Duffy, G., & Katzer, L. *Informed choice or guessing game? Understanding caregivers' perceptions and use of infant formula labelling*. Public Health Nutrition, 2018, Nov 27: 1-14.