Nestlé Submission

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

2 September, 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 regulatory approaches 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 FSANZ's proposed approaches following an assessment of A1155 and submissions to CFS1.

Permissions for use in infant formula products and FSFYC.

> FSANZ's approach is to permit the addition of 2′-FL alone or combined with LNnT to infant formula products. Consideration of the proposed levels of use in infant formula products is discussed in section 2.3.3.1 below.

> FSANZ's approach is to permit the addition of 2′-FL alone or combined with LNnT to FSFYC. Consideration of the proposed levels of use in FSFYC is discussed in section 2.3.3.2 below.

Nestlé fully supports FSANZ's safety and technical assessment which "…*concludes that the requested addition of 2′-FL alone or combined with LNnT in FSFYC is safe and supported by appropriate evidence in providing potential beneficial health outcomes*", in both 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 in more than 50 countries.

The permission to add such ingredients structurally identical to 2'-FL and LNnT in breastmilk 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.

Nestlé also supports FSANZ's latest proposal to link permission to the following gene-gene donor information specific to the production of the oligosaccharides:

- 2'-FL derived from *E.coil* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*
- LNnT derived from *E.coli* K-12 containing the gene for beta-1,3-N-acetylglcosaminyltransferase from *Neisseria meningitides* and the gene for beta-1,4-galactosyltransferase from *Helicobacter pylori.*

In terms of FSANZ proposing to amend Schedule 26 to add a new, separate table for these ingredients of microbial origin –

- Nestlé still considers it more relevant for these non-traditional foods to be regulated within FSC 1.5.1 (Novel foods), as originally described in the Administrative Assessment Report (12 January 2018). This is also consistent to the approach of other international regulatory authorities with the EU, USA, Singapore and Israel who have regulated them as novel foods.
- If it is to be regulated within Schedule 26, Nestlé considers that the presentation of the *conditions of use* is inconsistent to the preceding section on plant-based sources, and therefore not necessary as permission for addition is already inherent in the Code when regulated as used as a nutritive substance. Regarding the exclusive capturable commercial benefit term under Conditions of use, Nestlé supports this however as the term is only 15 months we question whether it is necessary to place it in the form of a table that is inconsistent to the other sections of Schedule 26, or whether it may be better placed within the Specifications in Identity and Purity (Schedule 3) or a preceding clause in Schedule 26.

Used as a nutritive substance

> FSANZ's approach is to permit both 2'-FL and LNnT to be *used as a nutritive substance*, and as *food produced using gene technology* linked to the gene-gene information specific to the production of the oligosaccharides, for use in infant formula products and FSFYC.

Nestlé supports 2'-FL and LNnT as being *used as a nutritive substance*. As mentioned already above, Nestlé prefers for international consistency that 2'-FL and LNnT are regulated as novel foods. We support however the approval being based on gene-gene information being specific to the production of the oligosaccharides.

Maximum use levels and units of expression

A minimum permitted amount is not proposed as this was not requested in the application and has not been determined by FSANZ.

FSANZ's approach is to permit the following maximum levels for addition to infant formula products:

- If only 2′-FL added – not more than 96 mg/100 kJ of 2′-FL
- If both 2′-FL and LNnT added – not more than 96 mg/100 kJ of 2′-FL and LNnT combined, of which contains not more than 24 mg/100 kJ of LNnT.

FSANZ's approach is to permit the following maximum levels for addition to FSFYC:

- If only 2′-FL added – not more than 0.55 g/serving
- If both 2′-FL and LNnT added – not more than 0.55 g/serving of 2′-FL and LNnT combined, of which contains not more than 0.14 g/serving of LNnT.

Nestlé supports no minimum regulated amount, which is consistent to how these ingredients are regulated internationally. Additionally, we consider that minimum amounts should only be mandatory where the ingredient is necessary for essential composition that delivers normal growth and development, and without minimums, these health outcomes would be impacted. 2'-FL and LNnT are optional ingredients.

Nestlé supports the above approach for maximum use levels and FSANZ's previous conclusions 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 still significantly lower than the total oligosaccharide concentration present in breastmilk, and are also far lower than the existing GOS and ITF permissions in the code. With the proposed prohibition on combination of 2'-FL or LNnT with existing GOS and ITF permissions in the Code, we agree with FSANZ that there would be no cumulative increase to the total oligosaccharide load consumed by infants.

Regarding the units of expression, while Nestlé has no objections to the proposed unit of measure of mg/100kJ, 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.

Prohibition of use with existing oligosaccharide permissions

FSANZ's approach is to prohibit the addition 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).

Per our response to CFS1, 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.

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 for GOS and ITF, this could be reviewed through a separate new Application to change the Code based on the latest available

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.

LABELLING

Statement of Ingredients on a label of infant formula products

> FSANZ's approach is to specifically prohibit the following terms on the label of infant formula products:
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> - the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect
> - the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect.

Nestlé is strongly AGAINST specific prohibitions on the words "human milk oligosaccharide", "human milk identical oligosaccharides", "HMO" or "HiMO" or any words or abbreviations having the same or similar effect, on a label of an infant formula product. We consider the proposed additional Clause is not necessary.

Nestlé is disappointed by the FSANZ view that the term 'human milk-identical' or similar terms,are prohibited. Including the name in a list of ingredients is not suggesting or claiming the product is 'humanised', or equivalent to breast milk. It is simply a statement of scientific fact, and mirrors use of these terms in scientific literature for more than 20 years, and it is now common usage.

We consider the appropriate regulatory intent is for the consumer not to perceive the 'product as a whole' to be claimed as 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 is likely to be a more easily understandable term for the consumer, as opposed to 2'-Fucosyllactose and Lacto-N-neotetraose. We are of the view that using the scientifically correct term for the human identical milk oligosaccharides in the ingredient listing or NIP is not in contravention of Standard 2.9.1 or the WHO International Code of Marketing of Breast Milk Substitutes as it is not *claiming* that the product is humanised or maternalised, but is simply a *neutral* statement of fact.

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 preclude this

term from being used on the tin in any place other than the ingredient list, and therefore it is most unlikely that the consumer would understand it to apply to the whole product.

Nestlé also understands the concerns are specifically on the word 'human' (*alone),* for infant formula products. However, the above proposal introduces issues with regulatory clarity as it might be conservatively interpreted that even the term 'galacto-oligosaccharides' used for similar currently permitted substances (but derived from lactose), is prohibited. We consider this strictest interpretation of this proposed Clause, due to the use of the words '*having the same or similar effect*', certainly does not appear to be the regulatory intent and will be in conflict with FSC 1.2.4-4. See insert taken from proposed draft variations to the Code, Attachment A, page 44 of the 2nd CFS for Application A1155:

> The label on a package of a formulated supplementary food for young children must not contain:
> (a) the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or any word or words having the same or similar effect; or
> (b) the abbreviations 'HMO' or HiMO' or any abbreviation having the same or similar effect;

Fundamentally, there is a need for the consumer to understand the 'common name' and true nature of the ingredient. We are of the view that this perspective is absolutely aligned with the requirements set out in 'High Order Policy principle 1(b) in the Policy Guidelines on Regulation of Infant Formula Products':

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
    a) the protection of public health and safety; and
    b) the provision of adequate information relating to food to enable consumers to make informed choices; and
    c) the prevention of misleading or deceptive conduct;

and clauses b(i) and b(ii) of

Standard 1.2.4—4 Ingredients to be listed by common, descriptive or generic name
A statement of ingredients must identify each ingredient:
(a) in the case of offal—in accordance with section 2.2.1—6; or
(b) in any other case, using any of:
(i) a name by which the ingredient is commonly known; or
(ii) a name that describes the true nature of the ingredient; or
(iii) a generic name for the ingredient that is specified in Schedule 10, in accordance with any conditions specified in that Schedule.

Technical names like 2'-Fucosyllactose and Lacto-N-neotetraose will certainly not facilitate consumer understanding, nor will the health care professional be likely to adequately point out to the consumer which products contains these ingredients. The current vast scientific literature and consumer articles refer to these ingredients as human milk oligosaccharides or human identical milk oligosaccharides. Nestlé considers such terms reflect the common name and true nature of the ingredient and when used in a list of ingredients and nutritional information panel, is not promotional in nature. As an analogy - a chair is a chair and nothing else.

There is also a need to clearly differentiate from other 'similar' type ingredients – Galacto-oligosaccharides (GOS) and Inulin-Type Fructans (ITF). Structurally, HMOs are considerably different from other oligosaccharides such as GOS and ITF. HMOs have far more complex structures compared

to the linear structures of FOS and GOS. Because of these clear structural differences, the oligosaccharides from human milk (HMO) are viewed differently from other oligosaccharides which originate from plants. In the 2017 expert consensus statement on prebiotics (Gibson *et. al*., 2017), HMOs are clearly separated from these other oligosaccharides, rather than being put together under an 'oligosaccharides' label. HMOs are *highly characteristic* for human milk in regards to structure and the quantities found, unlike the milk oligosaccharides of insignificant amounts of animal origin. As such we consider that labelling needs to clearly differentiate the different types of oligosaccharides, that are permitted to be added by the FSC. By using the term 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO' or 'HMO' (or words or abbreviations of similar effect) we can differentiate sufficiently from confusing 'like' ingredients and provide consumers with adequate information and transparency. This will then help to facilitate innovation and consumer informed choice.

Finally, the introduction of such a clause is not harmonised to international regulations, and may have potential impact on harmonisation and trade for Australia and New Zealand. In large export markets that facilitate trade for Australia and New Zealand, particularly those utilizing the cross border e-commerce avenue, this will impede (and not facilitate) effective competition from other international brands, and may cause consumer confusion when labelled differently to other international brands.

Nestlé primary position is that the proposed Clause to prohibit such terms is not necessary, nor warranted or justified. As a secondary position and compromise approach, Nestlé would propose to address the concerns by requesting FSANZ regulate a statement to the effect that when added to an infant formula product, the label must reference that these ingredients are 'Not sourced from human milk'. This statement however, should not be prescriptive.

Statement of Ingredients on a label of formulated supplementary food for young children

FSANZ's approach is to specifically prohibit the following terms on the label of FSFYC:

- the words 'human milk oligosaccharide', 'human milk identical oligosaccharide' or any word or words having the same or similar effect
- the abbreviations 'HMO' or 'HiMO' or any abbreviation having the same or similar effect.

Nestlé is strongly AGAINST specific prohibitions on the words "human milk oligosaccharide", "human milk identical oligosaccharides", "HMO" or "HiMO" or any words or abbreviations having the same or similar effect, on a label of a formulated supplementary food for young children. Nestlé does not support the inclusion of a clause with such prohibitions on FSFYC.

In addition to all the reasons outlined already above for infant formula products, this would set a first-time precedent that limits expression of a nutrient content claim on a label of a formulated supplementary food for young children. This would be inconsistent to FSC 1.2.7 (Nutrition, health and related claims standard), which was debated for many years, as well as international regulations. The Policy Guideline on the intent of Part 2.9 - Special Purpose Foods does not indicate such prohibitions are relevant for formulated supplementary foods for young children.

Standard 2.9.1 prohibits Infant formula products from making claims whereas claims on FSFYC (toddler milk drinks) are regulated by Standard 1.2.7. We note that FSANZ has drawn on a number of published papers to support extending the prohibitions on using the words human milk

oligosaccharide' to toddler milks, where it is suggested that mothers and caregivers mistakenly attribute claims made on toddler milks to infant formula products. We are concerned that FSANZ does not appear to have looked more broadly for corroborating (or not), evidence on which to make such an important determination. As such we consider the substantiation not sufficiently robust to drive Policy and Regulatory change of this magnitude.

In summary, Nestlé considers the reasons outlined by FSANZ and the resulting prohibition is part of a broader topic that is not appropriate to be considered within the scope of a remit of an Application, and that it is not appropriate to 'make policy' in the processing of an application. As a policy matter, it should be handled separately from A1155.

FSANZ's approach is to set specifications for 2′-FL and LNnT in the Code using those provided by the applicant (without specifying the methods of analysis).

Nestlé supports the inclusion of risk-assessed specifications in the Code, and supports the specifications that are provided by the Applicant (without specifying the methods of analysis). However, we would suggest that the revised risk-assessed specifications from the EU are reflected instead, in Schedule 3 for Identity and Purity, in order to allow for a harmonised approach to the EU.

FSANZ's approach is to provide 15 months exclusivity from the date of gazettal for the applicant's brand of 2′-FL and LNnT.

Nestlé supports FSANZ's approach to provide 15 months exclusivity from the date of gazettal for the Applicant's brand of 2'-FL and LNnT. As a principle - this facilitates innovation and investment into the Application process.

References

Gibson, G.R., Hutkins R., Sanders M.E., Prescott S.L. Reimer, R.A., Salminen, S.J., Scott, K., Stanton, C., Swanson, K.S., Cani, P.D., Verbeke, K., Reid, G. (2017). Expert consensus document. The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on the definition and scope of prebiotics.

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.