

Project Officer Application A1155
Food Standards Australia New Zealand
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2 September 2019

Dear Sir/Madam

Application A1155 2'-FL and LNnT in infant formula and other products – 2nd Call for Submissions

Thank you for the opportunity to comment on this application. New Zealand Food Safety (NZFS) has consulted with the New Zealand Ministry of Health (MoH) on the labelling aspects of this application. This submission notes where comments include the views of MoH.

SAFETY

NZFS has no concerns regarding the safety of the voluntary addition of 2'-O-fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT) to infant formula products and formulated supplementary foods for young children (FSFYC) at the levels proposed by FSANZ. We maintain our view (as per the NZFS submission dated 17th January 2019) that the food technology and GM safety assessments are well detailed and provide confidence that 2'-FL and LNnT are structurally and chemically equivalent to the naturally occurring forms and present no public health risks.

LABELLING

NZFS and MoH note that many of the current labelling provisions within Standard 2.9.1 enforce in law New Zealand's commitment as a signatory to the World Health Organization Code of Marketing for Breastmilk Substitutes (WHO Code). In New Zealand, this Code is applied to infant formula products for infants below 12 months of age.

Generic ingredient labelling

NZFS supports the FSANZ proposal to apply generic ingredient labelling requirements, rather than prescribed ingredient names (as previously proposed), consistent with the general approach in the Food Standards Code.

Infant Formula Products

Specific prohibition of words on the label

NZFS and MoH are not opposed to the approach proposed by FSANZ, that is to specifically prohibit the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or the abbreviations 'HMO' or 'HiMO' (or any word or words having the same or similar effect) on the label of infant formula products.

MoH and NZFS note that Standard 2.9.1 – 24: *Prohibited representations* states that the label on a package of infant formula product must not contain;

- c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect
- e) information relating to the nutritional content of human milk

NZFS and MoH consider that these provisions already prohibit the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or the abbreviations 'HMO' or 'HiMO' (or any word or words having the same or similar effect) on the label of infant formula products.

NZFS is of the view that in this context, the prohibition on the word 'humanised' (or word(s) having the same or similar effect) means making something more human, by giving human character to, or portraying or endowing products or ingredients with human characteristics or attributes. Using the word "human" itself in the ingredient name inherently does this. Infant formula products and/or ingredients associated with the words "human milk oligosaccharide" are inherently "humanised" or rather, those words have a humanising effect. Similarly the words "human milk identical oligosaccharide" portray or endow the product by association with the human characteristics or attributes of those naturally occurring substances in human breast milk. Again this has a humanised or humanising effect in relation to the product.

NZFS and MoH therefore consider that the use of the words 'human milk' as a qualifier for the oligosaccharides 2'-FL and LNT is in breach of the prohibition on the use of the term 'humanised'. This view is consistent with the New Zealand position taken and our international obligations as a signatory to the WHO Code.

NZFS is also mindful that the draft Codex Follow-up Formula Standard (for older infants), includes similar provisions to those in the Food Standards Code. The draft Codex Standard also prohibits any picture, text, or representation that makes a comparison to breast milk, or suggest that the product is similar, equivalent to or superior to breast milk, as well as a prohibition on the use of terms "humanized", "maternalized" or other similar terms on the label of follow-up formula for older infants (6 – 12 months). Therefore NZFS considers that the proposed prohibition is also in line with the current and generally accepted international approach.

Whilst NZFS can support the proposed explicit prohibition which provides regulatory clarity, in order to future proof the standard, and to avoid a long list of possible ingredients that may in the future be 'human milk identical' we suggest that an alternative approach could be considered. That would be to specifically prohibit the qualifying terms; 'human milk' or 'human milk identical' (or abbreviations of these), so as to capture any ingredient not just human milk identical oligosaccharides.

Formulated Supplementary Foods for Young Children (FSFYC)

Specific prohibition of words on the label

FSANZ is proposing that the prohibition of the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' or the abbreviations 'HMO' or 'HiMO' (or any word or words having the same or similar effect) be extended to the label of FSFYC.

FSANZ is of the view that the words 'human milk oligosaccharide' or 'human milk identical oligosaccharide' (or their abbreviations) on the label on a package of FSFYC would be confusing to caregivers if they are present on FSFYC labels and not on infant formula products, and that the presence of such terms could mislead consumers.

NZFS notes that there are no mandatory labelling requirements for FSFYC to be labelled that they are not suitable for infants (<12 months), nor is there a mandatory requirement to label the age of the intended

consumer. NZFS considers that the prescribed name 'formulated supplementary food for young children' itself does not convey sufficiently to the caregiver the intended consumer of the product. NZFS is of the view that extending the prohibition to FSFYC is justified in order to avoid any potential for confusion. Furthermore, for consistency with infant formula products, NZFS considers that the label of a FSFYC should not include words or information that could convey equivalence to breastmilk, or imply that the product is a substitute for breastmilk.

At the upcoming meeting of the Codex Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU41, November 2019), the Committee will be discussing the draft labelling provisions for Follow-up Formula for Young Children (12 – 36 months). It is currently proposed that the terms 'humanized', 'maternalized' or other similar terms must not be used on the label of such products. New Zealand supports the inclusion of the proposed prohibition of these terms in this Codex Standard.

Additionally, NZFS notes Attachment B – Draft Explanatory Statement states that the proposed prohibition is not intended to prohibit the use of the term 'oligosaccharide' on its own on the label on a package of FSFYC. NZFS supports this intent.

ADDITIONAL COMMENTS

NZFS notes that FSANZ is proposing to permit 2'-FL and LNnT to be used as nutritive substances and that the permissions for 2'-FL and LNnT would be used as alternatives to existing permissions for galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) in the Food Standards Code. We are of the view that this potentially warrants reconsideration of the classification of GOS and ITF, however note that it is not within the scope of this application.

NZFS also notes that FSANZ is reviewing Standard 2.9.1 with the aim of reflecting the latest scientific evidence and harmonising the Standard with international regulations. This review will also consider the application of the Ministerial Policy Guideline on Infant Formula Products. NZFS consider that this work should be progressed as a matter of priority.

Yours sincerely

Director Food Science and Risk Assessment