ABBOTT NUTRITION SUBMISSION ON APPLICATION A1155 2'-FL AND LNnT IN INFANT FORMULA AND OTHER PRODUCTS

August 30, 2019

INTRODUCTION

This submission has been prepared by Abbott Nutrition. Abbott Nutrition believes that proper nutrition is the foundation for living the best life possible. Our aim is to make every stage of life a healthy one which is why we are dedicated to developing science-based nutrition products for people of all ages.

Abbott Nutrition is committed to ethically marketing our products and supports the voluntary restriction of marketing practices for infant formula products to support government policies which protect and promote breastfeeding. Abbott Nutrition believes that breastfeeding provides the best nutrition for infants and supports, educates and encourages mothers to breastfeed for as long as possible. When breastmilk is not given to an infant, infant formula is the only safe and recommended alternative.

We have reviewed Application A1155 – 2'-FL and LNnT in infant formula and other products and welcome the opportunity to provide comments to the Food Standards Australia New Zealand (FSANZ) in response to the 2nd Call for Submissions.

COMMENTS

Prohibition of use with Existing Oligosaccharide Permissions

Abbott Nutrition does not support the proposed prohibition of 2'-FL alone, or with LNnT, in combination with existing permissions for galacto-oligosaccharide (GOS) and inulin-type fructans (ITF) for infant formula products and formulated supplementary foods for young children (FSFYC).

Infant formula manufacturers are under regulatory obligation to ensure that the products they market are safe and suitable, and this requirement extends to combinations of ingredients. A prohibition of the use of 2'-FL and LNnT with GOS or ITF would be inconsistent with how these ingredients have been approved under other regulatory frameworks, where no such prohibition exists. This misalignment between the proposed FSANZ regulatory measure and the authorizations elsewhere could have significant impacts on trade since infant formulas containing a combination of 2'-FL or LNnT with GOS or ITF have been on market in other countries for several years. As discussed in the second consultation, FSANZ has reviewed available clinical evidence on the safety of formulas containing 2'-FL and either GOS or scFOS (a permitted ITF) and concluded there were no adverse effects.

Therefore, we would encourage FSANZ to consider allowing the combinations of these ingredients, with the inclusion of additional limitations as necessary to reflect what has been demonstrated to be safe and what is currently on market.

Permitted Use as a Food Produced Using Gene Technology

Abbott Nutrition does not support the proposal to regulate 2'-FL and LNnT under Standard 1.5.2 and Schedule 26 - Food produced using gene technology.

We encourage FSANZ to reconsider its assertion that the 2'-FL and LNnT ingredients produced with a Genetically Modified Microorganism (GMM) meet the definition of "food produced using gene technology" (section 1.1.2 – 2). Classifying these ingredients in this way would establish an unfortunate precedent that would be misaligned with other global regulatory frameworks. Under other global regulatory frameworks, the use of a GMM as a processing aid does not define an ingredient as being "derived from" a genetically modified organism. Instead, these other regulatory frameworks restrict the definition of "derived from" to align with the foods that are currently listed in Schedule 26 Food produced using gene technology. We encourage FSANZ to harmonize their definition of "derived from" with these other regulatory frameworks to ensure better consistency with how these food substances are defined globally.

Examples of how other global regulatory frameworks have incorporated this distinction into their regulations include:

- **European Union (Regulation (EC) No 1829/2003)** – "This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation."
- **Canada (CAN/CGSB-32.315-2004)** – "Under this standard, processing aids, enzymes below 0.01% by weight in a food as offered for sale (exception, see par. 6.2.7 a), veterinary biologics, animal feeds, and substrates for micro-organisms (where the substrate itself is not present in the finished food product) do not affect whether a food or ingredient is considered to be or not to be a product of genetic engineering."
- **United States (7 CFR 66.1)** – "(2) A food that meets one of the following factors and conditions is not a bioengineered food. (i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3)."
    - **21 CFR 101.100(a)(3)** – "Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. For the purposes of this paragraph (a)(3), incidental additives are: (ii) Processing aids, which are as follows: (a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form."

Thus, we would encourage FSANZ to consider aligning their interpretation of "derived from" with these other regulatory frameworks to ensure consistency of interpretation by considering these two ingredients "produced with" a GMM, and therefore outside of the scope of "food produced using gene technology. It should also be noted that none of the countries listed above include these GM processing aids in their lists of approved GMO organisms.

Prohibited Representations on Infant Formula Products and Formulated Supplementary Food for Young Children

Abbott Nutrition does not support the proposal to prohibit reference to 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO', 'HMO' or words or abbreviations of similar effect on the label of infant formula and FSFYC products.

Introducing this prohibition would add further restriction to being able to call out the common and true nature of the ingredient on the list of ingredients and nutrition information panel. These ingredients are structurally identical to the oligosaccharides (2'FL and LNnT) in human milk and should be able to be listed as such. This nomenclature is also aligned with use by the scientific community for 20+ years. Additionally, this prohibition is inconsistent with existing conditions for other oligosaccharides which are labelled in accordance to Standards 1.2.4, 1.2.8 and relevant product standards 2.9.1 and 2.9.3.

For infant formula products, we note that there are already existing prohibitions in Standard 2.9.1-24 which prevent manufactures from using the terminology, 'human milk identical oligosaccharide' or other similar terms.

For FSFYC products, we note that adequate consumer research is not currently available to conclude that presence of such terms would mislead consumers. Additionally, this proposed prohibition is inconsistent with the current policy process required to introduce new food labelling requirements and preempts work being done at Codex.

Therefore, we would encourage FSANZ to reconsider the proposed prohibited representation on infant formula and FSFYC.

CONCLUSION

In the absence of public health and safety concerns and considering the evidence supporting health benefits, Abbott Nutrition:

- agrees with FSANZ's conclusion regarding public health and safety concerns
- does NOT support the prohibition of use with existing oligosaccharide permissions
- does NOT support the regulation of 2'-FL and LNnT as a food produced using gene technology
- does NOT support the prohibitions on the words "human milk oligosaccharide" or other similar words on infant formula products and FSFYC