18 August 2021

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NUTRICIA AUSTRALIA LTD SUBMISSION ON
Call for Submissions: – Application A1190:
2'-FL in infant formula and other products

Nutricia welcomes the opportunity to make this Submission in response to the FSANZ Call for submissions – *Application A1190 – 2'-FL in infant formula and other products*.

Our comments on the Call for submissions document and draft variation to amend the Code are contained in the attached Submission.

Nutricia, as a member of the Infant Nutrition Council, also provides support for the views expressed in the INC Submission.

We thank FSANZ for its consideration of our Submission. If you have any questions or require any further information, please contact [redacted], [redacted] on [redacted]

Yours sincerely

[redacted]

[redacted]

NUTRICIA AUSTRALIA LTD SUBMISSION
Application A1190 – 2'-FL in infant formula and other products

Nutricia Australia Ltd (Nutricia) supports the need for the *Australia New Zealand Food Standards Code* (the Code) to ensure that infant formula products (IFP) and formulated supplementary foods for young children (FSFYC) on the market in Australia and New Zealand protect the health and safety of formula-fed infants and young children.

Nutricia's comments on Application A1190 are expressed in the following.

Additionally, as a Member of the Infant Nutrition Council (INC), Nutricia wishes to provide its support for the views expressed in the INC Submission, having participated in the preparation of that submission.

SUBMISSION SUMMARY

In relation to FSANZ's proposed regulatory measures, Nutricia's comments are:

1. **Supports Option 3** –the voluntary addition of the Chr. Hansen 2'-FL to IFP and FSFYC. Nutricia does not support the FSANZ assessment that the draft variation will not permit the addition of the Chr. Hansen 2'-FL to FSFYC.

2. **Supports** the setting a maximum permitted use level of 2.4 g/L for Chr. Hansen 2′-FL alone, consistent with the permission allowed from A1155 for Glycare 2'-FL.

3. **Opposes** FSANZ's recommendation to prohibit the use of terms such as "human identical milk oligosaccharide", "HiMO" or "HMO" (or other similar words or abbreviations) on labels of IFP and FSFYC.

4. **Concerned** that the proposed regulatory measures will adversely stifle and impact innovation and trade for these products both manufactured in ANZ and imported from other countries.

5. **Supports** harmonisation of standards within the Code with international standards, that are based on relevant science and scientific expert opinion, that allows human milk oligosaccharides, such as 2'-FL, to be added to both IFP and FSFYC.

6. **Supports** provision of 15 months exclusivity from the date of gazettal of the variation in the Code for the Chr. Hansen 2′-FL.

NUTRICIA DETAILED COMMENTS

1. **Support for Option 3**
   Nutricia supports the voluntary addition of the Chr. Hansen 2'-FL to IFP and FSFYC. Nutricia does not support the FSANZ assessment that the draft variation will not permit the addition of the Chr. Hansen 2'-FL to FSFYC.

   Nutricia made similar comments in its submission to Application A1155 and reiterates these comments again in relation to this submission. Recommending the prohibition of the

voluntary addition of an ingredient to FSFYC that has been determined to be safe and suitable is contrary to government policy, as outlined in the Policy Guideline on the Intent of Part 2.9 (Special Purpose Foods).

Nutricia, as a member of the INC, highlights and fully supports the comments made on this issue in the INC submission, notably;

"INC is strongly of the view that there is increasing evidence of risk of dietary inadequacy in young children in Australia and New Zealand (Atkins et al. 2016, Johnston K 2017, Leonard D et al. 2017, Spence AC et al. 2018, Starship Hospital 2016, Tonkin E et al. 2020), that those subject to such risk would benefit from FSFYC (Wall et al. 2019, Lovell et al. 2019), and that there is no evidence to support prohibiting the addition of 2'-FL to FSFYC.

Further, voluntary addition of inulin-like fructans and galacto-oligosaccharides to FSFYC is permitted to infant formula products and FSFYC. These non-digestible ingredients are added to these products to provide some of the beneficial effects provided by HMOs in human milk but cannot substitute all HMO functions (Akkerman, et al. 2019). Yet, now there are production processes available that allow the production of some human milk identical oligosaccharides, such as 2'-FL, the Code permits voluntary addition of approved HiMOs to infant formula products but not to FSFYC.

There are various studies that have made comparison between GOS and 2'-FL that are reporting benefits from 2'-FL that are not seen from GOS. For example, Salli et al (2020) found that 2'-FL limits the growth and inhibits adhesion of S. mutans, a bacteria involved with dental caries, is an example.

This exclusion of permitting 2'-FL ingredients precludes young children, who are not being fed breast milk, gaining any potential benefits from supplementation of FSFYC with these oligosaccharides, that include bifidogenic and gut and immune system benefits for their age-group. FSANZ acknowledges in the CFS that there is evidence in the scientific literature for these effects in young children as a part of their diet. Therefore, the 2'-FL is safe and suitable and does provide benefit and should be allowed to be added, as a voluntary ingredient, to FSFYC.

INC notes that FSANZ "acknowledges the importance of ensuring caregivers are not confused around the purpose or intent of FSFYC and do not buy foods that are not needed" (CP2 p18). INC disagrees that consumers are confused around the purpose or intent of FSFYC. A key transition from breast feeding to another form of liquid in a young child's diet from 1 year of age is the availability of a nutritional source of liquid. Based on data collected by industry in 2019, cows' milk accounts for up to 70% for those leaving the journey of breastmilk and/or infant formula. Further, industry data for Australia records that up to 35% of young children at 1 year of age consume FSFYC declining to 15% as children age through to 4 years of age (Nutricia research 2019). This percentage of use, combined with the significant volume of sales in ANZ does not indicate that parents or caregivers are confused, but that FSFYC provides an important product for consideration of use in the diet of young children.

It is not FSANZ's role to decide that caregivers should 'not buy foods that are not needed' or completely remove the choice from caregivers to access better FSFYC. Consumers

would not purchase a product more expensive than cows' milk if there was no benefit and providing choice to caregivers should be the major driver once safety is confirmed. People should be able to spend their money as they see fit and have the choice to make purchasing decisions".

Additionally, there is no prohibition provided in Standards in the Code for other ingredients in foods that could be fed to young children that could be considered foods that are not needed, based on a lack of good nutritional science or benefits for consumption of such foods (eg: highly processed snack foods).

There is a number of international standards that permit the voluntary addition of 2'-FL to IFP and FSFYC. These standards base these permissions on relevant science and expert scientific opinion.

Lastly, as further evidence demonstrating the safety and efficacy of 2'-FL for young children, Australia's Therapeutic Goods Administration (TGA) approved the first 2'-FL ingredient for use as a prebiotic ingredient in March 2021 for use in dietary supplements. The specific applications include;

- Up to 5 g of 2'-FL daily to individuals aged 18 years and older;
- Up to 2 g of 2'-FL daily to individuals aged between 4 to 17 years (inclusive); and
- Up to 1.2 g of 2'-FL daily to individuals aged between 1 to 3 years (inclusive).

This 2'-FL ingredient has been available globally for digestive health in dietary supplements and functional nutrition since 2019. There is a TGA ARTG listed dietary supplement (362438 effective April 2021) with the 2'-FL for young children, with the following permitted indications;

- Maintain/support healthy growth and development in children
- Aids/assists teeth development in children
- Aids/assists healthy bone development/growth/building in children
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children
- Helps stimulate a healthy immune system response in children

There are other dietary supplements through to senior adults in the ARTG listings. (ARTG IDs:, 320165, 320164, 320162).

2. Setting a maximum permitted use level of 2.4 g/L for Chr. Hansen 2′-FL

This is supported by Nutricia, based on FSANZ dietary intake assessment and it being consistent with the permission currently allowed for a 2'-FL in the Infant Formula Standard 2.9.1. Nutricia again reiterates that the use of 2'-FL, up to the proposed maximum level for IFP, should also be allowed in the FSFYC Standard 2.9.3.

3. Proposed Prohibition of Terms

Nutricia has concerns with regards to the FSANZ's recommendation to prohibit the use of terms such as "human identical milk oligosaccharide", "HiMO" or "HMO" (or other similar words or abbreviations) on labels of IFP and FSFYC. Nutricia does not agree with the recommendation.

These terms are meaningful and in the best interest of consumers in understanding what ingredients are added to IFP and FSFYC. It provides specifically for consumers the identification of a voluntarily permitted ingredient in the composition of a product that they

are feeding to their infants and young children. In some ways it is more misleading and deceptive to consumers to prohibit the use of these terms or abbreviations.

The proposed regulatory measure is at complete odds with decision to apply generic ingredient labelling requirements. The FSANZ Guide to Standard 1.2.4 – Ingredient Labelling of Foods states "*the names of ingredients should be accurate and sufficiently detailed to ensure that they are not false, misleading or deceptive, or likely to mislead or deceive*". Clause 4 of Standard 1.2.4 – Labelling of Ingredients allows for the declaration of ingredients in the statement of ingredients using either the common name of the ingredient or a name that describes the true nature of the ingredient. The term HMO or HiMO has been used in scientific literature for over 25 years and continues to be used widely. These terms are currently used on product labels in both the EU and the USA, where regulations allow for the use of these terms on label.

The proposed change to the Code containing the prohibition;

a. ignores not only the existing protections in the Food Standards Code,
b. it ignores other consumer-related legislative provisions that serve to protect consumers, and
c. ignores the decisions that manufacturers might make concerning compliance and truthfulness, and
d. ignores other international standards that allow such terms, creating inconsistency, and
e. will add significant, additional re-labelling costs for IFP and FSFYC products manufactured overseas and imported into ANZ, where the label using these terms is required to be changed specifically to comply with the Food Standards Code. The costs will be similar to the costs estimated for changes commented on in the Nutricia submission to Proposal P1044 – Plain English Allergen Labelling. Given the relatively small size of the market in Australian and New Zealand, shared labels are often used to make it viable to export product to this region of the world. The prohibition proposed could prevent this from being possible. These costs include update of existing labels for IFP (including IFPSDU), FSFYC, product write-off due to not meeting the minimum order quantities for products, updating education materials for healthcare professionals and trade for all products and potentially loss of business for products that become financially non-viable to import into ANZ.

4. Impact innovation and trade

Nutricia asserts that if FSANZ proceeds with its regulatory recommendations this could significantly stifle innovation and impact importation of some IFP products. This could then influence a decline in local manufacture and the availability of innovative nutritious products for infants and young children in Australia and New Zealand.

The regulatory recommendations could see future investment in innovative products in ANZ being curtailed, to the detriment of the infant and young child populations who consume IFP and FSFYC products as part of their diets. This includes not being able to access public health benefits of consuming these products.

In relation to trade, exports and imports of products will be impacted. The competitiveness of exports will be lessened and limit expansion of trade. The impact on imports may be more significant, with implicated products not being able to be imported into ANZ, due to non-compliant compositional and labelling requirements.

5. **Harmonisation of standards within the Code with international standards**
   Nutricia is concerned that the proposed regulatory measures will deviate or not harmonise with other international standards. International standards that permit the voluntary addition of 2'-FL to IFP and FSFYC base these permissions on relevant science and expert scientific opinion. At least 37 overseas countries permit the addition of 2'-FL in IFP alone or both IFP and FSFYC. As previously stated in this submission, deviations for permissions can have impacts on product availability and denies benefits to infants and young children in ANZ. It also impacts import availability with products deviating from greater global alignment of food standards.

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