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NUTRICIA AUSTRALIA LTD SUBMISSION ON
Call for Submissions: – Application A1233:
2'-FL from new GM source for infant formula

Nutricia welcomes the opportunity to make this Submission in response to the FSANZ Call for submissions – *Application A1233 – 2'-FL from new GM source for infant formula.*

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]

Yours sincerely

[redacted]

[redacted]

NUTRICIA AUSTRALIA LTD SUBMISSION
Application A1223 – 2'-FL from new GM for infant formula

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

Nutricia's comments on Application A1233 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 the draft variation to the code to permit the voluntary addition of Aequival®2'-FL to infant formula.**

2. **Supports** the setting a maximum permitted use level of 2.4 g/L for Aequival®2'-FL alone or in combination with LNnT. This is consistent with consistent with the permission allowed from A1155 for Glycare 2'-FL and A1190 for Chr. Hansen 2'-FL.

3. **Continues to oppose** 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. This opposition was voiced in previous submissions for A1155 and A1190.

4. **Concerned** that the proposed regulatory measures in relation to wording on label (see point 3 above) 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 Aequival®2'-FL.

NUTRICIA DETAILED COMMENTS

1. **Supports the draft variation to the code to permit the voluntary addition of Aequival®2'-FL to infant formula.**
   Nutricia supports the voluntary addition of the Aequival®2'-FL to IFP. Nutricia continues to support the addition of this and previously approved 2'-FL to FSFYC.

   In continuing to support the addition to FSFYC, Nutricia considers FSANZ 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). This issue was raised in the consultation for A1155 and A1190. FSANZ states in the A1233 CFS that 2'-FL produced by microbial fermentation and by chemical synthesis are permitted for use in infant formula products, FSFYC and many other foods in at least 37 overseas countries at a range of levels. EFSA (EFSA 2015) provided an opinion on the safety of 2'-FL in 2015 that concluded that it was safe for infants (up to one year of age) and young children (older than one year of age) when added to infant and young children drinks.

Nutricia, as a member of the INC, highlights and continues to fully support the comments made and evidence provided on this issue in the INC A1233, A1190 and A1155 submissions, reinforcing the position for 2'-FL being permitted in products for FSFYC.

2. **Supports the setting a maximum permitted use level of 2.4 g/L for Aequival®2'-FL alone or in combination with LNnT.**
   This is supported by Nutricia, based on FSANZ dietary intake assessment and it being consistent with the permissions currently allowed for a 2'-FL in the Infant Formula Standard 2.9.1.

3. **Proposed Prohibition of Terms on Labels**
   Nutricia continues to have 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. 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), 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 on innovation and trade

Nutricia asserts that if FSANZ proceeds with its regulatory recommendations, particularly in regard to labelling, 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, formula fed populations who consume IFP 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.

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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.