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Danone welcomes the opportunity to make this Submission in response to the FSANZ 2nd Call for submissions – *Application A1155 – 2'-FL and LNnT 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.

Danone, as a member of the Infant Nutrition Council, also provide 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 Peter Sutherland, Head of Regulatory and Industry Affairs on

Yours sincerely

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DANONE

SUBMISSION: ***Application A1155 – 2'-FL and LNnT in infant formula and other products***

Danone supports the need for the *Australia New Zealand Food Standards Code* (the Code) to ensure that infant formula products 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.

As a Member of the Infant Nutrition Council (INC), Danone wish to provide our support for the views expressed in their Submission.

DANONE SUPPORT

In relation to FSANZ's proposed regulatory measures Danone support the following:

- 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 donor information specific to the production of the oligosaccharides, for use in infant formula products and FSFYC.

- Set a maximum permitted use level of 2.4 g/L for 2'-FL alone; and a total maximum level of 2.4 g/L for 2'-FL and LNnT combined with no more than 0.6 g/L of LNnT. For consistency with existing voluntary permissions for infant formula products and FSFYC, these levels are expressed in mg/100 kJ and g/serving.

- Set specifications for 2'-FL and LNnT based on the specifications provided by the applicant (without specific methods of analysis).

- Provide 15 months exclusivity from the date of gazettal of the variation for the applicant's brand of 2'-FL and LNnT.

DANONE WISH TO RAISE CONCERN OVER

<u>Prohibition of Terms</u>

Danone wish to raise concern with regards to the following FSANZ's proposed regulatory measure:

- Prohibit the following terms on the label of infant formula products and 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.

The Submissions in response to the 1st CFS that objected to the use of the terms above raised concern that the use of these terms infer equivalence to human breast milk, none appear to have provided evidence of this being true. FSANZ in the 2nd CFS has presented limited flawed research to support the proposed prohibition. The INC Submission clearly outlines the significant issues with the research FSANZ sited. Considering the significant implications that rendering these terms unusable has, this

should instigate further investigation into which terms are meaningful and in the best interest of customers.

Danone strongly supports INCs comment's relating to the opposition to the proposed prohibition of terms words such as 'human milk identical oligosaccharide' or 'HiMO' (or similar words or abbreviations) on the labels of infant formula products and FSFYC.

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*". As stated in the INC Submission the term 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.

In addition to this FSANZ has itself used and defined the term Human Milk Oligosaccharides in the Final Report Assessment Report for P306 as "*a collective term used throughout this Report to refer to the oligosaccharide and polysaccharide content of human breast milk*". This Report follows on to recognise that "*the definitions of 'inulin-derived substances' and 'galacto-oligosaccharides' in the drafting are not intended to act as prescriptive names for labelling purposes. 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*." An important link between Proposal P306 – Addition of Inulin / FOS & GOS to Food and Application A1155 is that inulin-derived substances, galacto-oligosaccharides (GOS), 2'-FL and LNnT are all part of the oligosaccharide family.

Danone would support a similar approach as was outlined in the First Review Report for Proposal P306 for all oligosaccharides: "*use the terms inulin-derived substances and GOS to clarify the compositional permissions, but do not prescribe the terms to be used in labelling. This approach allows manufacturers to use the terms of their choice on labels thus promoting consistency with the varying international terms used for inulin-derived substances*." Also noted in this Report the terminology used "*is not consistent with international terminology used for these carbohydrates and may confuse industry, particularly importers, as to whether products approved in other jurisdictions may lawfully be imported into Australia. The Australian and New Zealand food regulatory system should strive for consistency between our food standards and international food standards, especially where international standards clearly protect public health and safety*." Similar considerations have not been given in FSANZ's assessment of A1155.

As highlighted in the First Review Report for Proposal P306, FSANZ proceeding with this regulatory measure could significantly impact importation of product and deviate from greater global alignment of food standards. This could influence the availability of innovative nutritious products for infants and young children in Australia and New Zealand due to conflicts in labelling requirements. 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. This does not support the statement made on page 39 of the 2nd CFS "*promotion of consistency between domestic and international food standards promote greater compatibility between domestic and overseas foods standards*".

In addition to this, Danone also support the comments made in the INC Submission in relation to effects on trade. Specifically, the following statement: "*If constraints are applied in Australia and New Zealand that are not applied to other foreign products, then our export trade will not compete with the developments that other countries permit. In the longer term, there will be a sustained impact on expanding trade and recognition of products from Australian and New Zealand origin. Therefore, if Australian and New Zealand products are unable to communicate the common and true nature of the innovative ingredient, whereas foreign products from EU, USA and other countries sold in CBEC China are able to, the inevitable consequence is an erosion of the ability to remain competitive in an international market, and potentially significant trade impacts for Australia and New Zealand*".

FSANZ has previously entrusted industry to understand their customers and use terms relating to ingredients on labelling and other materials that they believe to be meaningful and truthful to their customers.

Use of 2'-FL alone or with LNnT in combination with existing permissions for GOS and ITF

Danone wish to raise concern with regards to the following FSANZ's proposed regulatory measure:

- Prohibit the use 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).

FSANZ's risk assessment of the Application found "*the assessment of effect on infant growth concluded that the addition of 2'-FL, alone or in combination with LNnT, to infant formula products has no effect on growth at the levels requested by the applicant. 2'-FL has been tested in formula in combination with short-chain fructooligosaccharide (scFOS) or galactooligosaccharide (GOS) or LNnT. The highest tested concentrations of 2'-FL and LNnT were 1.2 and 0.6 g/L, respectively. None of the studies examined by FSANZ found a difference in infant growth compared to a control formula*." This finding does not translate to the proposed regulatory measure above.

Danone understands that this may not have specifically been requested to be considered in the Application and note that FSANZ state that permission was not given as "*no evidence was provided which investigated the use of 2'-FL combined with both GOS and scFOS*", as well as the fact that "*this combination does not occur naturally in human milk*".

Danone wish to make FSANZ aware of research presented at the European Society for the Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Congress in June on the effect of 2'-FL when combined with scGOS and lcFOS. The following papers provide information on the use of these combinations:

- Overbeek S et al. JPGN. 2019; 68:995 (N-O-008); and
- Goh C.Y. et al. JPGN. 2019; 68:1164 (N-P-114).

The Application references the high concentration and variety of oligosaccharides human breast milk: "*human milk contains as its third largest solid component a faction consisting of a complex family structurally related oligosaccharides*". In addition to this the First Review Report for Proposal P306 recognises the breadth and diversity of the oligosaccharides in human breast milk:

- "*approximately 1-2% of human milk is made up of oligo- and polysaccharides";*
- *"to date over 200 HMOs have been identified in breast milk, but it is thought that the total number may be in the thousands"; and*
- "*there is a large variation in the breast milk concentration of HMOs among individual women, as much as a four-fold difference; due in part to genetic variations*."

This Report also states commonalities between HMOs and inulin-derived substances and GOS "*similar to naturally-occurring human milk oligosaccharides (HMOs), inulin-derived substances and GOS are undigested in the small intestine. When they reach the large intestine, mostly intact, there is a small beneficial increase in osmotic potential in the colon. This increase in osmotic potential from inulin-derived substances and GOS is similar to that observed from HMOs and therefore no more likely to cause dehydration*." Further to this, although the Final Report Assessment Report for P306 acknowledges "*inulin-derived substances/FOS are not present in breast milk",* it recognises that GOS is found *"in trace amounts*" in human breast milk. This Report states "*long-chain inulin and GOS are added to infant formula to mimic the effects of oligosaccharides in breast milk*".

Therefore, in permitting a combination for all four discussed oligosaccharides would be in line with the composition principles of the Australia and New Zealand Food Regulatory Ministerial Council Food Regulatory Standing Committee Regulation of Infant Formula Products, which states that for infant formula and follow-on formula "*the composition of breastmilk should be used as a primary reference for determining the composition*".

Danone wish to understand FSANZ's reason in deciding to propose this regulatory measure. Is it their intent that any new oligosaccharides in the future would require review with currently approved structures at a variety of levels? Danone requests FSANZ's guidance in understanding which nutrients require further evidence of compatibility. It is unclear why FSANZ has decided to specifically look at ITF and GOS and decided not to consider other nutrients which could impact the tolerability of LNnT and 2'-FL. Danone believes this proposed regulatory measure could set precedence.

This proposed prohibition does not allow for greater innovation within the product categories considered therefore limiting the potential for further nutrients in the diets of formula-fed infants and young children in Australia and New Zealand. As well as limiting the competitiveness in and with overseas markets.

As stated in the previous Section this regulatory measure would also create the same issues regarding Australian and New Zealand trading with overseas markets, through deviating from greater global alignment of food standards.