

**22 November 2018**

**[65-18]**

## **Supporting document 2**

Assessment against Ministerial Policy Guidelines – Application A1155

2'-FL and LNnT in infant formula and other products

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FSANZ has had regard to two Ministerial Policy Guidelines relevant to Application A1155, as required under subsection 18(2) of the FSANZ Act:

- Regulation of Infant Formula Products
- Intent of Part 2.9 - Special Purpose Foods

The tables below summarise our assessment against the specific policy principles of these policy guidelines.

### **1 Regulation of Infant Formula Products**

FSANZ has had regard to the policy guideline on the Regulation of Infant Formula Products in our assessment of this application. The policy guideline includes specific policy principles relating to composition, labelling and advertising, as well as overarching principles. The table below summarises our assessment against these specific policy principles for the proposed use of 2'-FL alone and in combination with LNnT in infant formula products (includes infant formula, follow-on formula and infant formula for special dietary use).

Specific Policy Principles	Assessment
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	FSANZ acknowledges in the 1 <sup>st</sup> Call for submissions (CFS) report that breastfeeding is the recommended way to feed an infant.
(b) The regulation of infant formula products should not be inconsistent with the national nutrition policies and guidelines of Australia and New Zealand that are relevant to infant feeding.	The proposed voluntary addition of 2'-FL and LNnT is not inconsistent with current national nutrition policies and guidelines for infant feeding.
(c) The regulation of infant formula products should be based on risk analysis, taking into account the vulnerability of the population for whom they are intended and the importance of these products in the diets of formula fed infants.	<p>FSANZ has assessed the application using a risk analysis approach.</p> <p>The safety, technical and health effects assessment (SD1) considered the safety of the voluntary addition of 2'-FL alone and with LNnT to infant formula products. This included the safety of these substances derived from the applicants GM production strains, and a comparative assessment with the substances naturally present in human milk.</p> <p>The risk management considered the vulnerability of the intended population (i.e. formula fed infants).</p> <p>The identify and purity specifications were considered and will be set for 2'-FL and LNnT.</p>
(d) The composition of infant formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical and/or functional outcomes) of healthy full term exclusively breastfed infants when infant formula used as the sole source of nutrition up to six months of age.	The safety, technical and health effects assessment, which included an assessment on infant growth, concluded that there are no public health and safety concerns associated with the addition of 2'-FL alone or with LNnT, at levels up to 2.4 g/L of 2'-FL or 0.6 g/L of LNnT, to infant formula products (includes infant formula, follow-on formula and infant formula for special dietary use). FSANZ notes that 2'-FL is secreted by the majority of women worldwide and LNnT is always present in human milk, providing a history of safe exposure to these substances for breastfed infants. The applicant's 2'-FL and LNnT are structurally and chemically identical to those secreted in human milk.

<p>(e) The composition of follow-on formula must be safe, suitable for the intended use and must strive to achieve as closely as possible the normal growth and development (as measured by appropriate physiological, biochemical or functional outcomes) of healthy full term breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.</p>	<p>See comments for specific policy principle (d).</p>
<p>(f) The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.</p>	<p>Not applicable to this application as the proposed permission is voluntary.</p>
<p>(g) Compositional requirements for infant formula and follow-on formula products should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.</p>	<p>Not applicable to this application as the proposed permission is voluntary.</p>
<p>(h) The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula.</p>	<p>The safety, technical and health effects assessment examined the natural occurrence of 2'-FL and LNnT in human milk. The risk management considered this natural occurrence in developing the proposed regulatory measures (see section 2.2.3 of the 1<sup>st</sup> CFS report, and comments in specific policy principle (j) below).</p>
<p>(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance proposed to be used in infant formula and follow-on formula that:</p> <ul style="list-style-type: none"> <li>i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or</li> <li>ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.</li> </ul>	<p>Although 2'-FL and LNnT are naturally occurring components in human milk, these substances produced by microbial fermentation do not have a history of safe use in infant formula products in Australia and New Zealand, thus a pre-market assessment was undertaken.</p>

<p>(j) Substances subject to pre-market assessment for use in infant formula and follow-on formula should have a substantiated beneficial role in the normal growth and development of infants or children, or a technological role, taking into account, where relevant, the levels of comparable substances in breast milk. A substance's role in normal growth and development is substantiated where there is appropriate evidence to link the physiological, biochemical and/or functional effects of the substance to specific health outcomes for infants, in infancy or childhood. Particular caution should be applied by the Authority where such links are less clear.</p>	<p>Based on the available evidence and taking account of the comparable levels and wide range of ratios of 2'-FL and LNnT in mature human milk, FSANZ concludes that the voluntary addition of 2'-FL alone or with LNnT to infant formula products at a higher level of 2'-FL than requested (i.e. 2.4 g/L alone rather than 1.2 g/L, and 2.4 g/L combined rather than 1.8 g/L) is supported by appropriate evidence in providing potential beneficial health outcomes in infants. FSANZ has applied caution in its assessment noting that evidence was demonstrated as both plausible health effects and potential beneficial health outcomes.</p> <p>See sections 2.2.1 and 2.2.3 of the 1<sup>st</sup> CFS report.</p>
<p>(k) The labelling and advertising of infant formula products should be consistent with the World Health Organization International Code of Marketing of Breast Milk Substitutes as implemented in Australia and New Zealand.</p>	<p>The term 'human milk-identical' (or similar terms) is prohibited on infant formula products (section 2.9.1—24 of the Code).</p> <p>Additionally, to ensure consistent disclosure of these substances on infant formula products (as well as FSFYC), FSANZ proposes to prescribe the ingredient names '2'-fucosyllactose' and 'Lacto-N-neotetraose' when used in infant formula products and FSFYC (see section 2.2.5.1 of the 1<sup>st</sup> CFS report).</p>
<p>(l) The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better than, breast milk.</p>	<p>See comments for specific policy principle (k) above.</p>
<p>(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.</p>	<p>The proposed voluntary addition of 2'-FL and LNnT to infant formula products would be subject to existing specific labelling requirements in Standard 2.9.1 (see section 2.2.5 of the 1<sup>st</sup> CFS report). These requirements help consumers to make informed purchasing decisions.</p>
<p>(n) The Authority should:</p> <ul style="list-style-type: none"> <li>i. ensure that the prohibitions and restrictions on nutrient content, health, therapeutic, and prophylactic claims in the Food Standards Code are clear and effective for infant formula products; and</li> <li>ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.</li> </ul>	<p>The existing labelling requirements, including the prohibition for nutrition content claims and health claims for infant formula products, would apply to the proposed addition of 2'-FL and LNnT (see section 2.2.5 of the 1<sup>st</sup> CFS report). No changes are proposed to these arrangements.</p>

<p>(o) Infant formula products for special dietary use must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended.</p>	<p>See comments for specific policy principle (d). FSANZ also notes that approval of 2'-FL and LNnT would provide alternative options to galacto-oligosaccharides and inulin-type fructans currently permitted for use in infant formula products which includes such products for special dietary use. These latter substances are not present, or only present in trace amounts, in human milk.</p>
<p>(p) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.</p>	<p>FSANZ has used the best available scientific evidence to assess the application.</p> <p>The Code requirements for infant formula products for special dietary use (IFSDU) provide a flexible approach, based on the composition of infant formula, to allow products formulated for particular conditions. Care is taken by food businesses to formulate products for specific dietary uses.</p>
<p>(q) The labelling and advertising of infant formula products for special dietary uses should clearly specify the special dietary or medical uses for which the product is intended.</p>	<p>Existing labelling requirements specific to IFSDU would apply where products formulated for certain conditions are required to state the condition, disease or disorder for which the product has been formulated (sections 2.9.1—13 and 2.9.1—14 of the Code). No changes are proposed to these requirements.</p>
<p><b>Expert Group</b></p>	
<p>FSANZ should consider establishing an independent scientific expert group that may provide advise prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:</p> <ul style="list-style-type: none"> <li>i. a substance proposed to be added to infant formula products has a history of safe use in infant formula or follow-on formula in Australia and New Zealand; and</li> <li>ii. there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.</li> </ul>	<p>FSANZ considers that an independent group is not necessary for our assessment of this application, noting that we have assessed the application using a risk analysis approach.</p> <p>See comments to specific policy principle (i) above.</p> <p>See comments to specific policy principle (j) above.</p>

<b>Relevant international agreements</b>	
<p>The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:</p> <ul style="list-style-type: none"> <li>• relevant World Health Organization agreements; and</li> <li>• relevant World Trade Organization agreements, Codex standards and guidelines</li> </ul>	<p>FSANZ has taken account of the relevant agreements and Codex standards and guidelines. 2'-FL and LNnT (derived from GM strains <i>E.coli</i> SCR6 and <i>E.coli</i> MP572 respectively) are permitted and used in infant formula products sold overseas.</p>

## 2 Intent of Part 2.9 – Special Purpose Foods

FSANZ has had regard to the policy guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code. The policy guideline includes specific policy principles for standards contained within Part 2.9 of the Code. The table below summarises our assessment against these specific policy principles for the proposed use of 2'-FL alone and in combination with LNnT in formulated supplementary foods for young children (FSFYC).

<b>Specific Policy Principles</b>	<b>Assessment</b>
a) Special purpose foods should be targeted to specific population groups who meet the criteria outlined in the policy guideline	This application does not amend the range of special purpose foods in Part 2.9 of the Code. Special purpose foods relevant to this application are infant formula products (as assessed against the specific policy above) and FSFYC.
b) The composition of special purpose food should be consistent with the intended purpose	FSFYC are specifically formulated for children aged 1 to <4 years as a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements. Whilst the proposed voluntary addition of 2'-FL and LNnT to FSFYC may not strongly align with the intended purpose of these foods, the addition is safe, provides potential beneficial health outcomes in toddlers, and allows alternative options to existing non-digestible oligosaccharide permissions (see section 2.2.1 of the 1 <sup>st</sup> CFS).

Specific Policy Principles	Assessment
c) Adequate information should be provided, including through labelling and advertising of special purpose foods	The proposed voluntary addition to FSFYC would be subject to generic labelling requirements in the Code (see section 2.2.5 of the 1 <sup>st</sup> CFS report), and specific labelling requirements in Standard 2.9.3, Division 4. In addition to existing requirements, FSANZ is proposing to prescribe the ingredient names '2'-fucosyllactose' and 'Lacto- <i>N</i> -neotetraose' when used in FSFYC (same for infant formula products) (see section 2.2.5.1 of the 1 <sup>st</sup> CFS report). The existing and proposed labelling requirements will enable consumers to make informed purchasing decisions.
d) Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety	Access to FSFYC on the market is currently not restricted. The safe addition of 2'-FL and LNnT to these foods does not warrant any change to these arrangements.