

22 July 2019

[86–19]

Supporting document 2

Assessment against Ministerial Policy Guidelines – Application A1155

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

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. The tables have been revised since the 1st Call for Submissions (CFS), following consideration of submissions and targeted consultation.

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 and high order principles. The table below summarises our assessment against the specific policy principles for the proposed addition of 2'-FL alone and in combination with LNnT to 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 2 nd 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 whether addition of 2'-FL alone or combined with LNnT to infant formula products would pose a public health and safety risk to the intended population (i.e. formula-fed infants). This assessment included consideration of the safety of these substances derived from the applicant's GM production strains, effect on infant growth, toxicological and dietary intake assessments, and a comparative assessment with the substances naturally present in human milk.</p> <p>The risk management considered the vulnerability of the intended population.</p> <p>The identity and purity specifications for 2'-FL and LNnT were considered and are proposed to be prescribed in the Code.</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.	<p>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 the levels requested, or at higher levels up to 2.4 g/L of 2'-FL, to infant formula products (includes infant formula, follow-on formula and infant formula for special dietary use), noting:</p> <ul style="list-style-type: none"> - 2'-FL is secreted by the majority of women worldwide and LNnT is always present in human milk, providing a history of safe intakes for breastfed infants. - The applicant's 2'-FL and LNnT are structurally and chemically identical to those secreted in human milk and the maximum levels proposed are within the range of concentrations found in mature human milk. - Intestinal absorption of 2'-FL and LNnT is limited.

Specific Policy Principles	Assessment
	<ul style="list-style-type: none"> - No adverse effects were observed at high doses in suitable animal studies of an appropriate age, or in infant studies.
(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.	See comments for specific policy principle (d).
(f) The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.	Not applicable to this application as the proposed permission is voluntary.
(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.	Not applicable to this application as the proposed permission is voluntary.
(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>The safety, technical and health effects assessment examined the natural occurrence of 2'-FL and LNnT in human milk (see SD1). The risk management considered this natural occurrence in developing the proposed regulatory measures, noting that the maximum levels proposed by FSANZ are within the range of concentrations present in mature human milk (see section 2.3.3 of the 2nd CFS report, and further comments to specific policy principle (j) below).</p> <p>FSANZ also notes that approval of 2'-FL and LNnT would provide alternative options to galacto-oligosaccharides (GOS) and inulin-type fructans (ITF) currently permitted at higher levels for use in infant formula products. These latter substances are not present, or only present in trace amounts, in human milk – the proposed permission allows alternative substances which are also naturally present in human milk.</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: <ul style="list-style-type: none"> i. does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or ii. has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different 	As 2'-FL and LNnT are naturally occurring in human milk, and the levels proposed are within the range found in human milk, there is a history of safe intakes for breastfed infants. However, noting the application is for 2'-FL and LNnT produced by microbial fermentation for use in infant formula products, a pre-market assessment has been undertaken.

Specific Policy Principles	Assessment
form/structure, or is produced using a substantially different technique or technology.	
(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>FSANZ has concluded that the addition of 2'-FL alone or combined with LNnT is supported by appropriate evidence, for the purpose of voluntary compositional permission, in providing potential beneficial health outcomes in infants.</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 proposes 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).</p> <p>FSANZ has applied caution in its assessment, as referred to in this specific principle, noting that:</p> <ul style="list-style-type: none"> - The proposed voluntary addition is safe. - 2'-FL and LNnT are naturally present in human milk at levels proposed (noting human milk is used as the primary reference as per specific principle (h)). - Evidence demonstrated biological and mechanistic plausibility of the anti-infective and bifidogenic effects for the purpose of compositional permission and supported a link to potential beneficial health outcomes. <p>See sections 2.3.1 and 2.3.3 of the 2nd CFS report.</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>Existing labelling requirements which would apply to the proposed addition of 2'-FL and LNnT support this specific policy principle (see section 2.3.5 of the 2nd CFS report for existing labelling requirements).</p> <p>A specific prohibition of terms such as 'human milk identical oligosaccharide' is now also proposed – see further comments to specific principle (l) below.</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>Following consideration of submissions, FSANZ now proposes to specifically prohibit reference to 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO' or 'HMO' (or words or abbreviations of similar effect) on infant formula products.</p> <p>Although the intent of subsection 2.9.1—24(c) of the Code is to prohibit such terminology on the label of infant formula products, FSANZ considers a</p>

Specific Policy Principles	Assessment
	specific prohibition would communicate more clearly that such terminology is inconsistent with specific policy principle (l).
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.	The proposed voluntary addition of 2'-FL and LNnT to infant formula products would be subject to existing labelling requirements in Standard 2.9.1 which provide information on the safe and appropriate use of infant formula products.
(n) The Authority should: 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 ii. consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.	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. FSANZ is also proposing to specifically prohibit terminology such as 'human milk identical' (see policy principle (l) above) to avoid misleading consumers by the addition of 2'-FL and LNnT to infant formula products. See section 2.3.5 of the 2 nd CFS report.
(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.	See comments for specific policy principle (d). FSANZ also notes that approval of 2'-FL and LNnT would provide alternative options to GOS and ITF currently permitted at higher levels 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) The composition of infant formula products for special dietary uses should be based on appropriate scientific evidence.	FSANZ has used the best available scientific evidence to assess the application. 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.
(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.	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.

Specific Policy Principles	Assessment
Expert Group	
<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> <ol style="list-style-type: none"> 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 ii. there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children. 	<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 and applied particular caution.</p> <p>See comments to specific policy principle (i) above.</p> <p>See comments to specific policy principle (j) above.</p>
Relevant international agreements	
<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"> • relevant World Health Organization agreements; and • relevant World Trade Organization agreements, Codex standards and guidelines 	<p>FSANZ has taken account of the relevant agreements and Codex standards and guidelines. The applicant's 2'-FL and LNnT are permitted and used in infant formula products sold overseas.</p> <p>The proposed addition supports international consistency and a competitive food industry (in accordance with high order policy principles 2(b) and (c)), providing trade opportunities (see section 2.5.1.1 of the 2nd CFS report).</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 and high order policy principles for standards contained within Part 2.9 of the Code. The table below summarises our assessment against the specific policy principles for the proposed addition of 2'-FL alone and in combination with LNnT to formulated supplementary foods for young children (FSFYC).

Specific Policy Principles	Assessment
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.

Specific Policy Principles	Assessment
<p>b) The composition of special purpose food should be consistent with the intended purpose</p>	<p>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 this food category, the addition is safe and provides potential beneficial health outcomes in toddlers. The proposed addition also supports international consistency and a competitive food industry (in accordance with high order policy principles 2(b) and (c)), and provides alternative options to ITF and GOS currently permitted at higher levels in FSFYC (see section 2.3.1 of the 2nd CFS).</p>
<p>c) Adequate information should be provided, including through labelling and advertising of special purpose foods</p>	<p>The proposed voluntary addition to FSFYC would be subject to generic labelling requirements in the Code (see section 2.3.5 of the 2nd CFS report), and specific labelling requirements in Standard 2.9.3, Division 4. These existing requirements will enable consumers to make informed purchasing decisions.</p> <p>In addition to existing requirements, following consideration of submissions, FSANZ now proposes to specifically prohibit reference to 'human milk identical oligosaccharide', 'human milk oligosaccharide', 'HiMO' or 'HMO' (or words or abbreviations of similar effect) on FSFYC. The intent of this prohibition is to prevent consumers being misled or confused about the use of such terminology on FSFYC (see section 2.3.5.2 of the 2nd CFS report).</p>
<p>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</p>	<p>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.</p>