



Supporting document 2 – Assessment of the Application in relation to Specific Policy Principles for the Regulation of Infant Formula Products

Approval Report – Application A1055

Short Chain Fructo-oligosaccharides

Executive summary

This Supporting document provides a summary of FSANZ's consideration of this Application against the specific policy principles in the Ministerial Policy Guideline on the Regulation of Infant Formula Products.

Assessment of the Application in relation to the Specific Policy Principles for the Regulation of Infant Formula Products

INFANT FORMULA PRODUCTS Specific Policy Principles – Overarching Principles	Approach	Does the assessment meet the Policy Principles
a) <i>The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant</i>	FSANZ acknowledges that breastfeeding is the recommended way to feed an infant.	
b) <i>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</i>	Not relevant to this Application.	Not applicable
c) <i>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.</i>	<p>FSANZ assessed the Application using a risk analysis approach. The risk and technical assessment considered the safety, functional effects and benefits of the optional addition of short chain FOS to infant formula products. The chemical specifications for short chain FOS were also considered, and cover short chain FOS_{sucrose} and short chain FOS_{inulin} because they are functionally equivalent in the gut.</p> <p>The risk management considered the vulnerability of the intended population (i.e. formula-fed infants).</p>	Yes
Specific Policy Principles – Composition		

<p>d) <i>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 6 months of age.</i></p>	<p>The risk and technical assessment concluded that short chain FOS_{sucrose} is as safe as IDS (including short chain FOS_{inulin}) which is already permitted to be added to infant formula products. The assessment also concluded that scFOS_{sucrose} is technologically suited to its proposed use, and complies with international specifications.</p> <p>The addition of short chain FOS_{sucrose} to infant formula products aims to align the stool characteristics of formula fed infants with their breastfed counterparts which are typically softer. The risk and technical assessment concludes that the addition of scFOS_{sucrose} has the potential to soften infant stools and may reduce the incidence of constipation.</p> <p>The assessment also concluded that the consumption of short chain FOS-supplemented formula supports normal growth in infants.</p>	<p>Yes</p>
<p>e) <i>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 and/or functional outcomes) of healthy full term exclusively breastfed infants at the appropriate age when follow-on formula used as the principal source of liquid nourishment in a progressively diversified diet.</i></p>	<p>See response for Policy Principle (d)</p>	<p>Yes</p>
<p>f) <i>The essential composition of infant formula and follow-on formula should be prescribed in regulation and must satisfy the nutritional requirements of infants.</i></p>	<p>Not applicable to this Application, as the permission is for optional addition of short chain FOS_{sucrose} to infant formula products.</p>	<p>Not applicable</p>
<p>g) <i>Compositional requirements for infant formula and follow-on formula products should only be <u>mandated in regulation</u> where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants.</i></p>	<p>Not applicable to this Application, as the permission is for optional addition of short chain FOS_{sucrose} to infant formula products.</p>	<p>Not applicable</p>
<p>h) <i>The composition of breast milk should be used as a primary reference for determining the composition of infant formula and follow-on formula</i></p>	<p>The risk and technical assessment used the composition of breast milk as a primary reference for determining the composition of inulin-type fructans in infant formula products. The approved permitted amount is well below the amount of oligosaccharides found in breast milk.</p>	<p>Yes</p>

<p>i) <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:</i></p> <p>i. <i>Does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or</i></p> <p>ii. <i>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.</i></p>	<p>Short chain FOS_{sucrose} does not have a history of safe use in infant formula products in Australia and New Zealand and thus required a pre-market assessment.</p>	<p>Yes</p>
<p>j) <i>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 substances 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.</i></p>	<p>The risk and technical assessment concluded that there was no discernible difference in infant growth patterns between infants consuming formula containing short chain FOS_{sucrose} and infants fed unsupplemented formula.</p> <p>The quantity of poly- and oligosaccharides present in breast milk is ~ 25 g/L following birth, and decreases to around 15 g/L from one to four months.</p> <p>The risk and technical assessment concluded that short chain FOS_{sucrose} has the potential to soften infant stools and may reduce the incidence of constipation, both of which are considered beneficial effects.</p> <p>FSANZ has applied caution in developing the proposed regulatory measure, which is an extension of the current permissions for IDS.</p>	<p>Yes</p>
<p>Specific Policy Principles – Labelling and Advertising</p>		
<p>k) <i>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</i></p>	<p>Not applicable to this Application</p>	<p>Not applicable</p>
<p>l) <i>The labelling and advertising of infant formula products should not represent those products as an equivalent to, or better food than, breast milk</i></p>	<p>Not applicable to this Application.</p>	<p>Not applicable</p>
<p>m) <i>The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products</i></p>	<p>Not applicable to this Application.</p>	<p>Not applicable</p>

<p>n) <i>The Authority should:</i></p> <p>i) <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</i></p> <p>ii) <i>consider whether the current labelling regime is leading to consumers being misled about the quality or effectiveness of an infant formula product.</i></p>	<p>The appropriate common, descriptive or generic name of the inulin-type fructans added to the formula must be declared on a label of an infant formula product in the same manner as inulin-derived substances. The current prohibition on nutrition claims and health claims will also apply to short chain FOS_{sucrose}.</p>	<p>Yes</p>
<p>Expert Group</p>		
<p><i>FSANZ should consider establishing an independent scientific expert group that may provide advice prior to pre-market assessment, based on scientific criteria established by the Authority, on whether:</i></p> <p>i) <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</i></p> <p>ii) <i>there is evidence available that the substance has a substantiated beneficial role in the normal growth and development of infants or children.</i></p>	<p>FSANZ has sought advice from its independent Infant and Child Health Scientific Advisory Group on the risk assessment.</p>	<p>Yes</p>
<p>Relevant international agreements</p>		
<p><i>The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with:</i></p> <ul style="list-style-type: none"> • <i>relevant World Health Organization agreements; and</i> • <i>relevant World Trade Organization agreements, Codex standards and guidelines</i> 	<p>FSANZ has taken account of the relevant World Trade Organization agreements, Codex standards and guidelines. Short chain FOS_{sucrose} is permitted and used in some infant formula products sold overseas.</p>	<p>Yes</p>