

1 November 2016
[27–16]

Supporting document 2

Assessment against the Policy Guidelines – Application A1124

Alternative DHA-rich Algal Oil for Infant Formula Products

1 Regulation of Infant Formula Products

FSANZ has had regard to the Ministerial Policy Guideline on the *Regulation of Infant Formula Products* (the Policy Guideline) 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 in relation to these specific policy principles, with particular focus on the principles for composition.

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
<i>Overarching</i>		
(a) The regulation of infant formula products should recognise that breastfeeding is the normal and recommended way to feed an infant.	FSANZ acknowledges in this report that breastfeeding is the recommended way to feed an infant.	Not applicable

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
(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 change is not inconsistent with current national nutrition polices and guidelines for infant feeding.	Not applicable
(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 assessed the Application using a risk analysis approach. A comparative nutritional safety assessment approach was taken for the assessment of this Application.</p> <p>The Risk and Technical assessment considered the safety of the optional addition of the new alternative DHA-rich oil to infant formula products. The risk management considered the vulnerability of the intended population (i.e. formula-fed infants).</p> <p>The identity and purity specifications were considered and will be set for the new oil derived from the new production strain of <i>Schizochytrium</i> sp. (ATCC PTA-9695).</p>	Yes
Composition		
(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 Risk and Technical assessment concluded that DHA-rich oil derived from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is a safe and suitable alternative oil source of DHA for use in infant formula products.	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
<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>Yes</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 permission is for optional addition of DHA-rich algal oil to infant formula products.</p>	<p>Not applicable</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 permission is for optional addition of DHA-rich algal oil to infant formula products.</p>	<p>Not applicable</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>DHA and other LC-PUFA are normal components of breast milk. The Risk and Technical assessment found that the reported average quantity of DHA in breast milk of Australian mothers consuming typical (not supplemented) diets ranges from 0.14 to 0.28% of total fatty acids. Worldwide average DHA concentration in breast milk is approximately 0.34% of total fatty acids.</p>	<p>Yes</p>

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
<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"> 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 form/structure, or is produced using a substantially different technique or technology. 	<p>DHA-rich algal oil from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is similar to other marine micro-algal oils which have a history of safe use in infant formula products in Australia and New Zealand, but is derived from a new source thus a pre-market assessment was undertaken.</p>	<p>Yes</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>The Risk and Technical assessment concluded that the consumption of infant formula products supplemented with this new form of DHA-rich algal oil is equivalent to the other permitted DHA-rich algal oils used in infant formula. The reported average quantity of DHA in breast milk of Australian mothers consuming typical (not supplemented) diets ranges from 0.14 to 0.28% of total fatty acids.</p> <p>Bioequivalence studies concluded that increases in DHA levels of plasma and red blood cells were similar dose-dependent in the piglets fed DHA-B oil compared to those fed a difference DHA-rich algal oil.</p>	<p>Yes</p>
<p>Labelling and advertising</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>Not applicable to this Application. Amendments to current labelling requirements for DHA-rich algal oils in infant formula products are not proposed as part of this Application.</p>	<p>Not applicable</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>		

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles?
(m) The labelling and advertising of infant formula products should provide information on the appropriate and safe use of those products.		
(n) The Authority should: <ul style="list-style-type: none"> 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 appropriate common, descriptive or generic name of the DHA-rich algal oil added to the formula must be declared on a label of an infant formula product in the same manner as other DHA-rich algal oils. The current prohibition on nutrition claims and health claims will also apply.	
Relevant international agreements		
The regulation of infant formula products in Australia and New Zealand should be consistent to the greatest extent possible with: <ul style="list-style-type: none"> • relevant World Health Organization agreements; and • relevant World Trade Organization agreements, Codex standards and guidelines 	FSANZ has taken account of the relevant World Trade Organization agreements, Codex standards and guidelines. DHA-rich algal oil from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is permitted and used in infant formula products sold overseas.	Yes

2 Novel foods

The table below summarises how FSANZ has had regard to the Ministerial to the Policy Guideline on Novel foods.

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles
High Order Principles		
To ensure that priority is given to the protection and improvement of public health and safety in relation to food matters.	FSANZ has undertaken a Risk and Technical assessment (refer to SD1) based on the best available evidence. Based on this assessment, FSANZ has concluded that oil derived from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is as safe as other LC-PUFA oils already permitted to be added to infant formula products.	Yes
To ensure that consumers have access to sufficient information to enable informed and healthy food choices.	Not applicable to this Application. Amendments to current labelling requirements for DHA-rich algal oils in infant formula products are not proposed as part of this Application.	Not applicable
Be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion.	The proposed change is not inconsistent with current national nutrition policies and guidelines for infant feeding.	Yes
To draw on the best elements of international regulatory systems (i.e. protocols, standards, guidelines, assessment processes) and be responsive to future trends and developments (i.e. CODEX, WHO/FAO).	Marine micro-algal oils have been used as a source of the LC-PUFAs in infant formula products around the world since the 1990s. Several assessments (by FSANZ and many other regulators around the world) have considered their safety and suitability for use in infant formula products over the years. Thus the assessment process for this Application was confirmed to consideration of whether this new DHA-rich oil was as safe and suitable for use in infant formula products as those currently permitted.	Yes

Specific Policy Principles	Approach	Does the assessment meet the Policy Principles
To provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade.	DHA-rich algal oil from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is permitted and used in some infant formula products sold overseas. Permitting the use of this oil as a novel food in Australia and New Zealand is transparent and consistent with minimum effective regulation. The permission also encourages industry growth, innovation and international trade.	Yes
Specific Principles		
To ensure that public and industry confidence in the food system is maintained.	<p>Infants are a vulnerable population. FSANZ has undertaken premarket assessment using a risk analysis approach.</p> <p>FSANZ's assessment concludes that oil derived from <i>Schizochytrium</i> sp. (ATCC PTA-9695) is as safe as other LC-PUFA oils derived from micro-algae already permitted to be added to infant formula products.</p>	Yes
To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.	Not applicable to this Application.	Not applicable
To ensure consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.	The Risk and Technical Assessment has compared oil derived from <i>Schizochytrium</i> sp. (ATCC PTA-9695) to previously approved DHA-rich algal oils. The nutrition assessment also considered the compositional and bioequivalence of this oil compared to other DHA-rich oils when fed to healthy term infants.	Yes