



# Infant Nutrition Council

Industry supporting both  
Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

13 December 2016

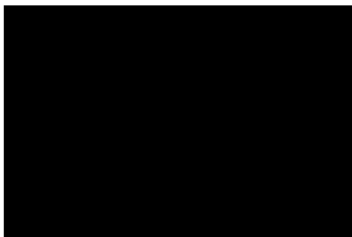
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Dear Sir/Madam

Attached are the comments that the Infant Nutrition Council wishes to present on the ***Call for Submissions – Application A1124: Alternative DHA-rich Algal Oil for Infant Formula Products.***

Yours sincerely



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Chief Executive

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# **Call for Submissions – Application A1124: Alternative DHA-rich Algal Oil for Infant Formula Products**

## **Submission by the Infant Nutrition Council (INC)**

13 December 2016

### **Summary**

1. INC supports the approval of an additional, replacement and alternative oil source of docosahexaenoic acid (DHA) for use in infant formula products.
2. The product that is the subject of Application A1124 known as DHASCO®-B or DHA-B is approved for use in the European Union, the USA and Canada. FSANZ's nutrition, technological and risk assessments of the DHASCO®-B/DHA-B application did not identify any issues of concern.
3. INC considers that DHASCO®-B/DHA-B will provide manufacturers of infant formula products with more safe choices for the benefit of infants in Australia and New Zealand.

### **Detailed Comments**

#### **Previous Assessments and Current Permissions for DHA-rich oils**

4. FSANZ has previously assessed several marine micro-algal DHA-rich oils for use in infant formula products. Standard 1.5.1 – *Novel foods* and Schedule 25 – *Permitted novel foods* contain permissions for the sale of novel foods that have already been assessed and approved by FSANZ. Schedule 3 – *Identity and purity* includes specifications for the following oils derived from marine micro-algae species and fungi rich in DHA:
  - oil derived from the algae *Cryptocodinium cohnii* rich in DHA
  - oil derived from marine micro-algae (*Schizochytrium* sp.) rich in DHA
  - oil derived from marine micro-algae (*Ulkenia* sp.) rich in DHA

#### **The Application**

5. Application A1024 is for a DHA-rich oil marine micro-algal oil derived from a new production strain of *Schizochytrium* sp. known as American Type Cell Culture (ATCC) PTA-9695. DSM Nutritional Products, the Applicant, has advised FSANZ that this strain is more productive than other marine algal DHA-rich oils currently in the market and that the oil will be sold under the trade names DHASCO®-B or DHA-B.
6. This alternative DHA-rich algal oil is proposed to be added to infant formula products at levels consistent with the current use of DHA oils and within the maximum 1% level of n-3 LC-PUFAs permitted in Standard 2.9.1. The composition of the new strain of *Schizochytrium* sp. micro-algae and its oil are comparable to other currently permitted sources of DHA.

#### **Nutrition Assessment**

7. FSANZ recently (for its Proposal P1028 *Review of Infant Formula*) undertook a nutrition assessment of the evidence for supplementing infant formula with DHA as an optional ingredient, an optional addition process that has been undertaken since 1998.

8. For the current application, FSANZ reported on essential fatty acids, LC-PUFAs, fats and fatty acids in different milk sources the composition of DHASCO®-B/DHA-B.
9. INC notes that FSANZ concluded there was no evidence that voluntary DHA addition posed a risk to infant health:
  - the fatty acids in DHA-B were normal components of edible oils
  - in general, the fatty acid composition of DHASCO®-B/DHA-B was comparable to that of other micro-algal oils on the market. The DHA component was similar; the main difference between the products was the ratio of DHA to EPA but these were insignificant because the limit on the maximum amount of n-3 LC-PUFA that can be added to infant formula products (less than 14 mg/100 kJ)
  - an analytical method (AOCS Ce 1b-89) was available for compliance.

#### **Risk assessment**

10. The FSANZ risk and technology assessment was conducted to evaluate the safety of this new production strain of *Schizochytrium* species algae. It was also intended to assess the safety and suitability of DHASCO-B/DHA-B as an additional, replacement or alternative DHA oil source for infant formula products noting that the composition of the new strain of *Schizochytrium* sp. micro-algae and its oil are comparable to other currently permitted sources of DHA.

#### **Technology Assessment**

11. The technology assessment considered a range of food technology issues: identity, chemical properties, method for detection, product specification, manufacturing process and product stability. The conclusion was that DHASCO®-B/DHA-B was a suitable additional, alternative or replacement DHA oil source in infant formula products. Its stability is assured, the manufacturing process appropriate and an analytical method for detection available.

#### **Hazard Assessment**

12. The hazard assessment considered the history of human exposure, genotoxicity studies, experimental studies in animals and studies in humans.
13. FSANZ concluded that DHASCO®-B/DHA-B was a safe source of DHA for supplementation of infant formula products based on:
  - omega 3, LC-PUFAs (including DHA, EPA and DPA) were normal components of breast milk
  - A number of infant formula products contain such oils and analyses overseas had not identified any changes in adverse gastrointestinal events over time
  - no evidence was found of risk of genotoxicity, reproductive or developmental toxicity, or toxicity as a consequence of subchronic dietary consumption of either dried *Schizochytrium* or DHASCO®-B/DHA-B by experimental animals.
  - there were no adverse effects of DHASCO®-B/DHA-B there was no evidence to suggest that absorption, distribution, metabolism and excretion of DHASCO®-B/DHA-B would be different to that of the other marine micro-algae oils.

#### **Overseas approvals**

14. In the United States, DHASCO®-B oil was the subject of a New Dietary Ingredient Premarket Notification submitted to the Food and Drug Administration (USFDA) by DSM Nutritional Products and approved for use February 2014

15. In 2015, DHASCO®-B received approval as a novel food ingredient in the European Union for use in various food categories, including infant formula and follow-on formula.
16. DSM submitted a novel food pre-market notification to Health Canada for DHASCO®-B which was approved for use in infant formula, follow-on formula, and foods for special dietary use for children under 3 years old in August 2015.

**Industry use**

17. As noted above, a number of infant formulas now contain such oils and the appropriateness of LC-PUFAs, and DHA oil in particular, to support infant growth and development is widely accepted (DHA is an essential component of nerve and retinal cells and is involved in normal brain and visual function; and it accumulates in brain cells in the first two years of life). Micro-algal DHA-rich oil use is accepted within the scientific and industry communities for addition to infant formula and follow up formula.

**Conclusions**

18. In light of the FSANZ risk, nutrition and technology assessments, the approvals overseas and the continuing use by industry of adding DHA-rich oil to infant formula and follow on formula, INC supports the approval of this new source of micro-algal DHA-rich oil.