COMMITTEE PAPER FOR DISCUSSION **ACNFP/131/03**
ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

DHA RICH ALGAL OIL FROM SCHIZOCHYTRIUM SPECIES T18

Issue

The Committee reviewed this application at the meetings in November 2016 and February, April and July 2017. When the application was last considered further information was requested by the Committee on which to base their assessment. Members are invited to consider the response from the applicant and whether it recommends authorisation of the extension of use of the product.

Background

1. The substantial equivalence of the Mara Renewables DHA oil also known as T18 was assessed and authorised by the Irish competent authority for the existing authorised uses of this form of algal oil (DHA –S).

2. An application has now been submitted to the UK by the company, for an extension of use authorisation of its DHA rich algal oil in the EU. The applicant proposes to incorporate the DHA rich oil into additional product categories namely fruit and vegetable purees, infant formula, other foods for special groups and baby foods.

3. At the last meeting the Committee requested further information on toxicology and whether exposure of infants via breast feeding had been taken into account in the intake assessment.

4. A letter outlining the request for further information from the discussion at the July meeting is provided in **Annex A**. The applicant has now provided a response to the Committee's questions (**Annex B)**. A draft opinion has been prepared for consideration in **Annex C**. To assist in the Committee's consideration a summary of the issues considered to date are provided in **Annex D**.

Toxicological information on the novel food

5. Previously the Committee has requested clarification of whether the exposure assessments provided included the potential exposure of infants through breast milk. The question was raised on whether complementary feeding scenarios had been considered in the assessment. The applicant was asked to evidence the basis of their intake assessment to inform the assessment of the margin of exposure identified.

6. In their response the applicant explains that in preparing the intake assessment it was assumed that DHA would be present at the requested levels in all the food categories requested at every eating occasion. To estimate intake by infants from breast feeding information on the mother's exposure and the DHA content of human milk was used. This resulted in an estimate of 35-44mg/100ml of DHA with all DHA assumed to be from the novel ingredient. For those under 6 months the applicant estimates for infants were based on government guidelines and therefore the groups would either be exclusively breastfed or fed fortified infant formula. The applicant suggested this would result in very similar exposure by infants to DHA / the novel ingredient from the two routes of exposure.

7. The assessment was rerun using the European consumption data to confirm whether previous estimates were correct, this resulted in very slight changes to the intake levels for average consumers in the infants and toddlers group. There applicant suggests there was no impact on the high consumers due to the limited data on breastfeeding in some countries for which data was available and the food category with the most impact in the high consumers group differed between Member States.

8. The applicant explains that in toddlers, due to limits on calorific intake, one source of DHA is most likely to be replaced by another food. Inclusion of the revised breastmilk intake figures had less impact due to the lower level of breastmilk consumption in this age group.

9. In the response the margins of safety provided previously have been updated to reflect the revised findings of the updated intake assessment.

COMMITTEE ACTION REQUIRED

a) The Committee is asked whether the response from the applicant is sufficient to address the questions raised to date.

b) If so, the Committee is asked whether it is content to recommend approval of the extension of use of DHA oil from *Schizochytrium sp.* A draft opinion is provided for consideration.

c) If not, the Committee is asked to indicate what feedback should be given to the applicant.

Secretariat
September 2017

Annexes attached:

Annex A - Letter providing feedback to the applicant from the July meeting of the ACNFP.

Annex B - The applicant's response to the request for further information.

Annex B Appendix 1 – The revised intake assessment

Annex B Appendix 2 – Modelling approach used to develop intake assessment

Annex C – Draft opinion for the Committee's input.

Annex D – Summary of issues raised in the assessment to date and the applicant's responses.

Annex D - Summary of Committee's consideration to date:

Issue Raised	Applicants response	Committee's response from the minutes of the discussion
Specification of the novel food		
• The Committee were keen to understand how the novel ingredient's composition compares to other authorised DHA rich oils in order to understand if it would be nutritionally disadvantageous.	• In their response the applicant has provided composition information, based on multiple batches, compared to the other authorised DHA rich oils. This includes the DHA -S to which the product has gained a substantial equivalence authorisation. This is subject to further discussion in the paper above.	The Committee commented that the novel ingredient could be less nutritious than other forms of DHA rich oils used in infant formula which were already on the market. However, it was accepted that this would be managed in the case of infant formula containing the novel ingredient as these are blended to meet regulatory nutritional requirements.
• The Committee also requested information on the anti-oxidants listed as ingredients to the novel product.	• Information has been provided on the antioxidants that are commonly used as ingredients in the oil.	This was noted and no further action required.
Production process and level of undesirable substance		
• The Committee had sought a further explanation from the applicant on the choice of algal toxins for analysis in their dossier. Of interest was whether the selection was a function of the production process and whether regular testing once in full production was planned to manage any risk of algal toxin production.	The applicant's response comments that algal toxins have not been identified in the *Thraustochytriaceae* family to which *Schizochytrium sp* belong. However, further testing of microalgae toxins from the wider kingdom of microalgae were undertaken to demonstrate that these were not produced in this production system. The applicant therefore considers that it is unnecessary to undertake regular testing for the presence of microalgal toxins.	The information provided on the algal toxins produced during the production process was considered and it was suggested that this was not a risk.
• Questions were also raised on how it would be ensured that the system would not be contaminated with other microorganisms.	An explanation of the microbial controls used in the system was provided by the applicant.	The Committee was content with the information supplied by the applicant on the production process and HACCP plans to manage the risks of microbial contamination.
Nutritional information on the novel food		
The Committee requested a comparison of the novel	In their response the applicant has compared the fatty acid	See specification point above.

ingredient's composition compared to that of oils currently used in infant formulas as a source of DHA.	composition of the novel ingredient to both the authorised DHA rich oil that can be used in infant formulas (DHA-B) and Tuna oil an alternative source of DHA in this food category. Further information on this is provided in the paper above.	
Toxicology		
Margin of safety assessment The applicant was asked to provide an assessment of the Margin of Safety between the intakes calculated and the NOAEL's seen in the toxicological studies The Committee questioned the choice of NOAEL and whether infant exposure via breast milk had been considered in the exposure assessment.	In response they have highlighted that the safety of microalgae oils has been demonstrated by a number of studies and that their novel ingredient is similar in composition to those already marketed. For this novel ingredient toxicological testing suggested a NOAEL at the highest dose tested, 5% of the diet, in a 90 day study of 3305 and 3679 mg/kg bw/day in males and females respectively. The consumption levels seen in the intake assessment vary between population groups between 8-60mg/kg bw/day which is 55-413 times lower than the NOAEL. The applicant therefore argues that the use of the oil is safe. Further information on this point is outlined in the paper above.	The Committee considered the toxicological information provided by the applicant had addressed many of the outstanding questions on the NOAEL selection. The Committee noted that the NOAEL was based on the top dose in the study. This was a conservative value as no effects were seen at this dosage. The Committee was satisfied that while the margin of safety presented was less than would normally be sought, the conservative nature of the NOAEL would support this the lower value. Consideration ongoing
Long term exposure Members noted that the longest toxicological study undertaken on the novel food has been 3 months in duration. It was recognised that infants, could have life-long exposure to the novel ingredient from the range of permitted uses. The applicant was asked to comment on the safety of long term use of the novel ingredient.	The applicant argues that DHA rich oils have been used safely in infant formula since the 1990's and the safety of this type of oil is well established. The same uses as currently sought were evaluated for other DHA rich oils and felt to be sufficient to support safety. The applicant has commented that for the highest intakes to be maintained over the longer term, infants would need to consume the ingredient at the maximum level of addition, which it is argued is overly conservative.	Conclusion not made but no further questions have been raised on this topic.
Level of silicon in the novel product It was noted that the levels of silicon in the mineral analysis of the novel ingredient were	The level of silicon in the novel ingredient was reported to be 51-110mg/kg. The applicant has calculated potential exposure for infants based on consuming	The Committee accepted the information from the applicant that the level of silicon in the product as consumed was unlikely to be a safety concern.

higher than the other minerals in the oil. The applicant was asked to comment on the silicon levels that the end user would experience in the final product and to compare this to the level of silicon from other dietary sources to understand if this would be of health concern.	400mg DHA oil per day the daily exposure to silicon would be approximately 0.011mg/day; 15,636-18,727 times lower than seen in the case study described in Nishizono et al 2004 where there were detrimental health effects from high levels of silicon in the diet. On this basis the applicant does not consider that the level of silicon is a health concern.	