COMMITTEE PAPER FOR DISCUSSION **ACNFP/127/01**
ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

DHA RICH ALGAL OIL FROM SCHIZOCHYTRIUM SPECIES T18

ISSUE

The Committee reviewed this application for the first time in November 2016 and requested further information 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. An application has been submitted to the UK by Mara Renewables, 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.

2. A non confidential version of the dossier was subject to a 30 day public consultation. This ended on the 2nd February 2017 and the comments received are summarised in **Annex A** for the Committee's information.

3. At the November teleconference Members requested further information in a number of areas

    a) specifications

    b) Effect of the production process applied to the novel food

    c) Nutritional information on the novel food and

    d) toxicology

4. A letter outlining the concerns raised with the applicant is provided in **Annex B**. The applicant has now provided a response to the Committee's questions **Annex C**.

a) Specification of the novel food

5. The Committee in considering the application had noted that the product that is subject to the extension of use has previously received a substantial equivalence authorisation. However, they were keen to understand how the novel ingredient's composition compares to other authorised DHA rich oils. The Committee also requested information on the anti-oxidants listed as ingredients to the novel product.

6. 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 –O to which the product has gained a substantial equivalence authorisation. They have also provided fatty acid profile information for the novel ingredient compared against the other authorised DHA rich oils. Information has been provided on the antioxidants that are commonly used as ingredients in the oil.

b) Effect of the production process applied to the novel food

7. 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.

8. 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. They explain that the system is closed and therefore additional organisms cannot penetrate the system. The applicant therefore considers that it is unnecessary to undertake regular testing for the presence of microalgal toxins.

c) Nutritional information on the novel food

9. The Committee requested a comparison of the novel ingredient's composition compared to that of oils currently used in infant formulas as a source of DHA. In their response the applicant has compared the fatty acid 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.

d) Toxicological information on the novel food

10. The Committee had considered the additional toxicological assessment that had been made as part of the extension of use application and raised several questions for clarification.

Margin of safety assessment

11. The applicant was asked provide an assessment of the Margin of Safety between the intakes calculated and the NOAEL's seen in the toxicological studies. 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.

12. 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.

Long term exposure

13. 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.

14. 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.

Level of silicon in the novel product

15. It was noted that the levels of silicon in the mineral analysis of the novel ingredient were 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.

16. 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 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.

COMMITTEE ACTION REQUIRED

a) The Committee is asked whether the response from the applicant is sufficient to address the questions raised in November 2016.

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

Secretariat
January 2017

Annexes attached:

Annex A – Summary of responses from the public consultation

Annex B – Letter providing feedback to the applicant from the November meeting of the ACNFP

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