Meeting

Extension of use of Schizochytrium SP. Oil Discussion Paper

Committee Paper for Discussion - ACNFP/157/08

Advisory Committee for Novel Foods and Processes

Application for an extension of use of Schizochytrium SP. Oil - Rich in DPA and EPA, from DSM Nutritional Products

Application number RP1411

Issue

An application has been received under the novel food authorisation process (regulation 2015/2283 as repatriated) for an extension of use for Schizochytrium sp.
oil rich in DPA and EPA, from DSM Nutritional Products.
The Committee is asked to advise on whether the available data provides an adequate
basis for a risk assessment, and whether the novel food as changed by the extension
of use application is safe and not nutritionally disadvantageous under the additional
proposed uses and use levels. Members are asked to focus on the changes sought to
the current authorisation and the additional evidence available in their review.

Introduction

1. On the 17th January 2022, the FSA and FSS received a request for the extension of use for Schizochytrium sp. oil rich in DPA and EPA as an authorised novel food, from DSM Nutritional Products. The application is seeking to extend the permitted uses of the ingredient to meat and fish analogues.

2. DHA-rich oil is produced by heterotrophic fermentation of wild-type micro-alga Schizochytrium sp. T18. It is predominantly comprised of triglycerides, with docosahexaenoic acid (DHA) being the principle fatty acid.

3. An application was originally submitted to the Food Standards Agency in 2001 and subsequently received a positive opinion from the ACNFP in 2003, under the novel foods regulation 258/97 EC and was subject to authorisation by the EU. Since the original authorisation, a number of extension of use applications to extend the uses of the novel ingredient have since been submitted and approved.

4. The original technical dossier submission, for DHA-Rich Oil from Schizochytrium sp. by DSM Nutritional Products is attached as Annex A. The initial ACNFP opinion has been attached as Annex B. The Commission Implementing Decision is attached as Annex C.

5. The paper outlines the changes proposed as compared to the original application, pertinent to the extension of use request. Unless otherwise stated
below, the information provided in the original application remains applicable here. The dossier provided by the applicant to support the extension of use can be found in Annexes D, E and F and contains confidential information.

This application

6. The applicant has justified not providing information for the identification; production process; composition; Absorption, Distribution, Metabolism, and Excretion (ADME); toxicology; nutrition; and allergenicity sections on the basis that the details remain the same as in the original application supplied.

History of Use

7. The food supplement, Schizochytrium sp. oil, is currently authorised for use within the UK as demonstrated in Annex A, Annex B, and Annex C. The applicant provides a consideration of its history of use in the UK, which is attached as Annex D.

8. The applicant also brings forward a previous extension of use request, submitted in 2012, for use of the Schizochytrium sp. oil in food supplements intended for the normal population. The application for the extension of use was

successful and is demonstrated in Table 1 of Annex D. The table contains the food categories in which the ingredient is currently authorised for use, along with the current extent and limits of use within those categories.

Specifications

9. The applicant states that the product specifications have not changed and the ingredient complies with the specifications as set out in Annex II of the Union List. The specification table is also reported below in Table 1.

Authorised Novel Food	**Specification**	
Schizochytrium sp. oil rich in DHA and EPA		
	Acid Value	≤ 0.5 mg KOH/g
	Peroxide value (PV)	≤ 5.0 meq/kg oil
	Oxidative stability	All food products containing *Schizochytrium sp.* oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC).
	Moisture and volatiles	≤ 0.05%
	Unsaponifiables	≤ 4.5%

Trans-fatty acids	≤ 1%
DHA content	≥ 22.5%
EPA content	≥ 10%

Proposed Uses, Use Levels, and Anticipated Intake

10. The applicant proposes two new food categories in which *Schizochytrium sp.* oil is to be used as an ingredient. The oil is to be added to both meat and fish analogues up to a maximum concentration of 300 mg/100g.

11. The reasoning provided for use within these particular food categories is to allow manufacturers to deliver doses of DHA and EPA similar to what is found naturally in meat and fish, to ensure certain requirements for nutritional claims are met. The applicant also states that addition of the oil to these foods would allow population groups who do not eat meat and fish to maintain a balanced diet and allow for adequate consumption of omega-3 fatty acids.

12. A list of currently permitted uses and use levels, along with the newly proposed uses and use levels, can be found in Annex F. The information is also presented in Table 2 below.

Specified Food Category Name	**Maximum Use Level of DHA and EPA Combined**
Authorised Uses	
Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	3,000 mg/day

Food Supplements as defined in Directive 2002/46/EC for pregnant and lactating women	450 mg/day
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Milk-based drinks and similar products intended for young children	200 mg/100g
Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100g
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	200 mg/100g
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	200 mg/100g
Bakery Products (Breads, Rolls and Sweet Biscuits)	200 mg/100 g
Breakfast Cereals	500 mg/100 g

Cooking Fats	360 mg/100 g
Dairy Analogues except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)
Dairy Products except milk-based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)
Non-alcoholic Beverages (including analogue and milk-based drinks)	80 mg/100 g
Cereal/Nutrition Bars	500 mg/100 g
Spreadable Fats and Dressings	600 mg/100 g
Proposed Uses	
Fish Analogues	300 mg/100g
Meat Analogues	300 mg/100g

13. An estimate of the anticipated intake of *Schizochytrium sp.* oil has been provided by the applicant; the full study report and summary of results can be found attached as Annex E.

14. Two dietary exposure assessments have been conducted with reference to the European Food Safety Authority Comprehensive Database. The two studies estimate and assess: exposure through currently authorised uses, and exposure through currently authorised uses combined with the proposed uses. Total combined exposure was estimated at both mean and high-level intake for each consumer population group.

15. The results of the intake assessment, for combined authorised and proposed uses of *Schizochytrium* sp. oil, are summarised in section 4.1.2 of Annex E. Tables 4.1.1-1 and 4.1.2-1 display the estimated intakes for authorised uses alone and authorised uses combined with proposed uses, respectively. A summary of the original 90-day study in rats by DSM Nutritional Products can be found attached in Annex A, section XIII.C.3 – pg.61.

16. The applicant concludes from the data that the impact of the newly proposed uses on both mean and high-level intake is minimal; estimated high-level intake for all groups falls within the safe intake level when compared to the 'No Observed Effect Levels' (NOELs) for this product. It is concluded that the addition of the two proposed use categories will not pose any additional risk to consumers.

17. Additionally, the applicant also provides an uncertainty assessment within the study report and additional considerations of exposure to their product in vulnerable population groups - such as children and the elderly. The results also show that additional exposure is negligible and maximum daily intake is predicted to remain far below the NOAEL.

Committee Action Required

- The committee is asked whether the available data provide a satisfactory basis for evaluating the safety of this novel food.
- If so, The Committee is asked whether it is content to recommend approval of Au+ as a food supplement.
- If not, The Committee is asked to indicate what additional data would be required.

ACNFP Secretariat

January 2023

Annexes

Annex A – Technical Dossier for DHA-Rich *Schizochytrium* sp. Oil from DSM Nutritional Products

Annex B – Initial ACNFP opinion on *Schizochytrium* sp. oil from DSM Nutritional Products

Annex C – Commission implementing decision

Annex D – History of use - technical dossier section

Annex E – Exposure assessment and intake report

Annex F – Proposed uses - technical dossier section