

Extension of use of Schizochytrium SP. Oil Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/162/01

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

This application was reviewed for the first time by the Committee in April 2023, where a number of questions were raised. A subsequent request for additional information (RFI) was sent to the applicant in order to address these questions. Members are now invited to consider the applicant's responses and provide comments on whether the outstanding questions on the additional proposed uses and use levels have been addressed.

Background

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 a 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 extensions of use applications to extend the uses of the novel ingredient have since been submitted and approved.

4. In the previous meeting, the Committee highlighted several areas where further information is required to complete the assessment of the safety of the novel ingredient under two newly proposed uses. Further information has been requested on the following sections:

- Specification
- Stability
- Proposed uses and anticipated intake

5. The Secretariat's request for information can be found in Annex A and the applicant's response can be found attached as Annex B. At the previous meeting it was indicated that subject to suitable answers being provided by the applicant a draft Committee Advice Document should be produced. This is attached as Annex C for Committee review and comment.

Applicant's response to request for further information

Specification

6. Further information was sought within the specification section, where context was needed for how the product seeking authorisation fits within previous authorisations.

7. It was noted that there are four oils derived from *Schizochytrium* species authorised for use in GB. These are defined based on the strain and composition of the oils. These are *Schizochytrium sp.* oil rich in DHA and EPA with a minimum

DHA content of 22% and minimum EPA content of 10%, *Schizochytrium sp.* (ATCC PTA 9695) oil with a minimum DHA content of 35%, *Schizochytrium sp.* oil with a minimum DHA content of 32% and *Schizochytrium sp.* (T18) oil with a minimum DHA content of 35%. The novel food in this application was confirmed as *Schizochytrium sp.* oil rich in DHA and EPA also known as DHA-O.

8. The applicant has provided specifications for the DHA and EPA content of the *Schizochytrium sp.* oil and has referenced this to the previous authorisations (July 2012 - NFU 786). The DHA and EPA content of the novel ingredient is specified as $\geq 22.5\%$ and $\geq 10\%$, respectively. All information regarding the specifications can be found in the applicant's response to the RFI attached as Annex H. This is unchanged from the specifications approved for the novel food previously.

Stability

9. The Secretariat requested further information on how the stability of the novel ingredient may be affected by the newly proposed food matrices, with an emphasis on whether changes to the fatty acid composition is likely. The applicant provided details of shelf-life testing of the novel ingredient in examples of the newly proposed food categories, where the composition of DHA and EPA are monitored. Sensory characteristics have also been analysed as a means of monitoring any potential oxidation of the fatty acids within the food matrices. Details of the methodology and results provided by the applicant can be found attached in Annex H. This indicates the novel food remains stable in the new matrices under normal storage conditions.

Proposed uses, use levels, and anticipated intake

10. Clarity was sought by the Secretariat on the nomenclature used to define the newly proposed food categories. The terms 'meat analogues' and 'fish analogues' were considered to be broad and further information and examples of such food categories was requested. The applicant provided an explanation of the terms and has provided a table of example food products which fall within the proposed food categories. This information can be found in Table 2 of Annex H.

Committee Action Required

- The committee is asked whether the response from the applicant is sufficient to complete the risk assessment.
- If not, The Committee is asked to indicate what additional data would be required.
- The Committee are also asked to review and provide comments on the draft Committee Advice Document attached as Annex C

ACNFP Secretariat

September 2023

Annexes

Annex A - Secretariat request for further information

Annex B - Applicants response to request for further information

Annex C - Draft Committee Advice Document