

Vitamin D2 Mushroom Powder - Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/165/05

Advisory Committee for Novel Foods and Processes

Application for Authorisation of Vitamin D2 Mushroom Powder as a Novel Food, applicant response.

Application number RP1550

Issue

The Committee reviewed this application for the second time at the February 2024 meeting where members advised further information was needed on the production process to complete the assessment. The Committee is invited to consider the response from the applicant and whether it addresses the request satisfactorily or if further information is required.

A Draft Committee Advice Document had been previously reviewed and has been updated in light of members comments and the additional information from the applicant. Members are asked to review the document with a view to finalising the assessment.

Background

1. In April 2022, the FSA received the submission for vitamin D2 mushroom powder from Monterey Mushrooms, LLC. The novel food consists of *Agaricus bisporus* mushrooms that have been exposed to UV light to catalyse the conversion of endogenous ergosterol within the mushrooms to vitamin D2, then ground to a powder.

2. Following the review of this dossier at the last meeting, the Committee identified areas requiring further information to assess the safety of the novel food and its proposed use. Information was requested on the; production process and composition. The Request for information sent to the applicant is provided in Annex A, the applicants response in Annex B (confidential) and is also summarised below.

3. The draft for the Committee Advice Document for Committee input is attached in Annex C.

Applicant's response to request for further information

Production Process and Composition

4. Queries had been raised on the blending of the product to understand the reliability of the data on vitamin D content and moisture levels that had been provided in the composition data. To reassure that the blending process was producing a homogenous output, queries were raised with the applicant on the blending technology used and how the effectiveness of the process has been validated.

5. The applicant has explained that they use double-cone blenders. The design of the cones excludes moving blades or sharp edges which enables homogenous mixing, while minimising risk of contamination. They have outlined the design and operation of the blender in mixing, loading and discharge of materials and the sanitary design. Information on their sampling plan and how this informs the samples routinely analysed for the product was provided. Validation testing to underpin their approach was not provided.

6. The members also queried how the packing stage was managed to minimise moisture content in the novel food and control microbial hazards especially the potential of fungal growth. The applicant was requested for details of studies to validate and verify that the moisture is uniform before and after packaging, conditions under which packaging takes place, and data proving that ambient temperatures do not fall below dew point during storage and transportation.

7. The applicant has explained that packaging and storage is carried out under ambient temperature (18°C-24°C), and with these temperatures, hot filling does not occur. There is also negligible heat produced by the blender. They cite their

stability studies as presented in the dossier as evidence that product moisture levels and packaging barrier prevents microbial activity for a minimum of 3 years.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the data gaps identified at the last meeting.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.
- The Committee is also asked to review and comment on the draft output for the assessment of this novel food.

ACNFP Secretariat

April 2024

Annexes

Annex A – Request for further information

Annex B – The applicant’s response to the request for further information

Annex C – Committee Advice Document