Meeting

Vitamin D2 Mushroom Powder Additional Information Discussion Paper

Committee Paper for Discussion - ACNFP/164/03

Advisory Committee for Novel Foods and Processes

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

Application number RP1550

Issue

The Committee reviewed this application for the first time at the September 2023 meeting where members requested further information from the applicant. The Committee is invited to consider the response from the applicant and whether it addresses the request satisfactorily or if further information is required.

In parallel, the Committee requested that the Secretariat draft an assessment output for this novel food for consideration, subject to the applicant’s response to the request for information addressing outstanding questions. Comments are sought on the draft Committee Advice Document.

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, 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, composition, specification, stability and allergenicity.

3. The draft for the Committee Advice Document is attached in Annex A, the request for further information and the applicant's response is attached as Annex B, and all supporting data in Annex C. All annexes contain confidential information.

Applicant's response to request for further information

Production Process

4. Further to reviewing the production process, members suggested that information on the production process be revisited to better explain the production steps, any hazards generated, how these are managed and whether the controls are effective. This was specifically in relation to how blending between batches was done and on what parameters. This was to help better understand variability of vitamin D2 content in the specification and the management of any non-compliance with the specification.

5. The applicant has clarified that even though the vitamin D2 content varies naturally between batches, it is always stated in the finished product, within the food specification level of 125-462.5 µg/g and that customers can also request to have specific amounts of the vitamin. They also explained this as the link to the flowchart step where, if the vitamin content is unsatisfactory based on the customer's request, this is not shipped but re-blended with another batch to achieve the customers desired levels of vitamin D2. This is done under food production conditions.

6. Members of the Committee noted the applicant's choice in the testing kit used for *Listeria* and *Salmonella* and that this was not a method widely used in the UK. Further to this, it was unclear how the method used would ensure safety and evidence of its effectiveness in comparison to existing standards was requested.

7. The applicant explained they use internally recognised methods (AOAC 2004.03 and AOAC 2004.06) and that these methods both mention use of VITEK® Immuno Diagnostic Assay System (VIDAS) kits. They also highlight this is

according to the EFSA novel food guidance which states analysis should be conducted using nationally or internationally recognised methods and are therefore within the remit of guidance.

8. The Committee also queried how the powder is packaged and stored as they were concerned that the plastic bags used had the potential risk of condensation which could lead to pathogen growth.

9. The applicant clarified that the final product packaging is thermally sealed. The moisture content of ≤7% is low enough to stop pathogen growth for 3-4 years based on their stability studies (dossier 2.c.3), with the storage conditions described in the dossier (2.c.3.1) and the microbial stability of the product in the bags and within the storage conditions detailed (dossier 2.c.3.2), with no pathogen growth observed over 4 years.

Composition and Specification

10. The Committee queried the variation in the levels of vitamin D2 within the compositional analysis of the 5 batches. An explanation was sought on the applicant’s batch selection, the source of variation, as well as how the compositional data generated supports the specification identified for the product.

11. The applicant explained that in comparison to a similar product authorised as a novel food and on the UK market containing vitamin D2 content of 1,000-1,300 µg/g, their product specification has a much lower range of 151.5-182.6 µg/g (dossier Table 2.c.1-1) hence a maximum vitamin D2 specification of 462.5µg/g is considered safe as this does not exceed the tolerable upper limits for vitamin D (dossier section 2.f).

They also highlight the source of the natural variation in vitamin D2 content of different batches is explained in the production process (dossier 2.b.1.2). To manage the variability there is adjustment of the targeted exposure informed by radiometers that give UV band specific readings in joules of energy based on the types of bulbs used, exposure time and speed of the conveyor belt.

12. Members noted that aflatoxins as group were tested for but not specific common aflatoxins such as Ochratoxin A and further explanation was sought on whether this or other mycotoxins not tested were likely to be a risk for the novel food. The basis for their testing strategy was sought.

13. The applicant explained that the analysis, and that of only aflatoxins was conducted due to a request made by EFSA during risk assessment of this product within EU hence why this data was also included in this application. The limit of detection was 0.6 µg/kg (w/w) for the individual aflatoxins and 0.7 µg/kg (w/w) for total aflatoxins (sum of B1, B2, G1 and G2) with analysis done using internationally recognised methods. Modifications to this method are outlined in Annex B and do not affect the analytical results. They further explain inclusion of specification for aflatoxins is the same as that of another application that is similar and was concluded to be safe by the ACNFP (FSA) and EFSA.

Stability

14. Members requested the applicant to explain why the stability results showed a decrease then increase of vitamin D levels over time, how this impacts interpretation of the results.

15. The stability of the novel food was explored in composite foods such as the fruit juice and cereal bars and deem them acceptable as per their third-party testing lab. The variability was expected to be a result of variation in mixing methods used in production and during laboratory analysis, and from multiple factors such as lack of homogeneity from bar to bar for the cereal bar and also due to sizes of ingredient such as nuts, raisins etc.

Allergenicity

16. Members noted that the novel food would be added as an ingredient into a range of products that don’t usually contain mushrooms. An explanation was sought from the applicant on how they would manage accidental consumption of UV treated mushrooms for those with a potential mushroom allergy.

17. The applicant commented that mushrooms are not one of the 14 identified major allergens for the purposes of labelling. They highlighted that there was a similar product concluded to be safe by the FSA and EFSA, and as such the allergic risk was considered to be the same.

18. The secretariat raised the question of the current risk management for these products with risk managers. They explained that the potential for reactions in mushroom allergies is not subject to additional risk management for the authorised product beyond the requirement to accurately label the ingredient in line with labelling rules. It is required to be labelled as UV-treated mushrooms (

Agaricus bisporus)’.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the concerns discussed 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

January 2023

Annexes

Annex A – Committee Advice Document

Annex B – Request for further information

Annex C – Supporting documents