Meeting

Dried Miracle Berry (DMB®) Further Information Discussion Paper

Committee Paper for Discussion - ACNFP/168/05

Advisory Committee For Novel Foods and Processes

Application for Authorisation of Dried Miracle Berry (DMB®) as a Novel Food

Application Number RP1351

Issue

The Committee last reviewed this application at the September 2023 meeting where members requested further information. The Committee is invited to consider the response from the applicant and whether it addresses the request for clarification satisfactorily or if further information is required. To support the evaluation, a draft Committee Advice Document (CAD) has also been prepared.

Background

1. In November 2021, the FSA received the submission for Dried Miracle Berry (DMB) from Baïa Food Co (Spain). The novel food consists of dried pitted fruits of *Synsepalum dulcificum*. It is often consumed for the presence of the substance miraculin. It serves as a functional food, food supplement taken before consumption of sour foods for palatability (taste modifier). This food has not previously been commercialised in Europe but is eaten in other regions of the world. This application has a positive EFSA opinion (2021).

2. The Committee reviewed this dossier in September 2023 where further information was sought from the applicant in the following areas: production process, composition and specification.

3. The Committee is asked whether the applicant’s response addresses the outstanding questions providing a basis to reach conclusions on the safety of the novel food. To inform the discussion, the draft CAD is in Annex A, the requested further information and the applicant’s response is in Annex B and the supporting data is in Annex C.

Applicant’s response to request for further information

Production Process

4. Members noted that the flowchart in the updated HACCP plan did not highlight the CCPs mentioned in the previous response. They requested this is updated and resubmitted. The applicant has provided a summarised HACCP and a revised flowchart (Annex C).

5. To note, any authorisation will eventually be generic for food producers to use. On this basis, Members are asked if there are any points from the assessment of the production process that need to be highlighted to risk managers for consideration in development of the conditions of authorisation.

Composition and Specification

6. The Committee requested the applicant to provide further information on the classes of polyphenols representing 4% of the novel foods composition in order to appropriately characterise the novel food. Clarification was sought on whether the information provided previously on polyphenol content was for the leaves or the fruit.

7. The applicant has clarified that their previous response highlighted the information from literature, was from the pulp and skin of the fruit and represents the novel food seeking authorisation. Additionally, they have provided analysis of the content of phenolic compounds in the novel food (the pulp and skin of *Synsepalum dulcificum* berries) which can be found in Annex C: Annex 2. The applicant argues that the data suggests the polyphenol content is unlikely to have harmful antinutritional properties. This is because the phenolic compounds in this product are very low compared to other similar foods rich in phenolic compounds that are consumed without any adverse health effects.

8. The Committee noted a discrepancy with the miraculin levels in the novel food with 2 different figures provided. They requested clarity on miraculin and protein content of the food so as to appropriately characterise the food.

9. The applicant clarifies that where miraculin is described to be 17%-47% of the fruit powder, this refers to concentration of miraculin in relation to the total protein content. They further explain that based on their previous response, they do not assert that miraculin content is 2.5%-13.5%. They propose the total miraculin content of the novel food is maintained between 1.5%-2.5% as per H^1 -NMR analysis. The total protein and miraculin certificate of analysis is attached in Annex C: Annex 3.

10. The applicant was also requested to explain their reasoning for using H^1-NMR as their choice of analysis considering this is not a commonly used method of quantification of miraculin. The applicant was requested to consider any limitations in using this method for quantification of molecules with disulphide bonds.

11. The applicant explains that different techniques were considered with the H^1-NMR method chosen since despite the limitations identified as this method has been demonstrated to be reproduceable for the quantification of miraculin (Annex B).

12. In order to address the inconsistency in the data, the Committee requested a detailed specification of the product. The applicant has provided this (Annex C:Annex 4). They note that since the novel food might be influenced by extrinsic factors such as climate, concentration ranges were assigned for macromolecules based on historical data. This calculation in addition to the compositional data which characterises different batches over 6 years, suggests the proposed specification captures the variability in the novel food and is consistent with that applied by other regulators.

13. Members advice is sought on whether from the information in the dossier and the additional information provide, the novel food has been appropriately characterised.

Further points for consideration

14. The applicant agrees to have the data on SDS-PAGE method retained as supplementary information as was requested by the Committee. They also note and accept the advice given by the Members that the approach used in the

toxicological study to evaluate one dose and deviate from the standard protocols prevented consideration of dose related responses.

Committee Action Required

- The Committee is asked whether the response from the applicant is sufficient to clarify the outstanding questions in the assessment.
- Members are asked if a conclusion can be reached on the safety of the novel food. If so, comments are sought on the draft Committee Advice Document and the conclusions that can be reached.
- If not, the Committee is asked to indicate what further data is required and the feedback that should be given to the applicant.

ACNFP Secretariat

September 2024

Annexes

Annex A – Draft Committee Advice Document

Annex B - The applicant's response to request for further information

Annex C – Supporting documents