

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

NOVEL FOOD APPLICATION FOR MUNG BEAN PROTEIN – RP32 ADDITIONAL INFORMATION FOR REVIEW

Issue

1. The Committee has reviewed this application several time most recently considering the applicant's response to a request for further information at the September 2021 meeting. At the last meeting further information was requested on which to base the Committee's assessment of the novel food ingredient. Members are invited to consider the response from the applicant and whether it addresses the requests for information satisfactorily or if further information is required.

Background

2. On the 11th January 2021, the FSA (Food Standards Agency) received the submission for Mung Bean Protein (MBP) for Eat Just, Inc (JUST) by Analyse & Realize GmbH. The mung bean protein product made through extraction, purification and spray drying of protein from mung bean (*Vigna radiata*) flour. The MBP is intended to be used as a complement or substitute animal or vegetable proteins in a variety of conventional food and beverages. The product is intended for use in foodstuffs for the general population.
3. The Committee reviewed the mung bean dossier at a ACNFP meeting on 21st April 2021, where they identified several areas requiring further information to assess the safety of the novel food and its proposed use.
4. The Committee reviewed the applicant's response to these questions at a ACNFP meeting on 15th September 2021. They identified several areas where additional information was required to assess the safety of the novel food and its proposed use. Information was requested on the

- **Production Process**
- **Proposed Use and Intake Levels**
- **Nutritional Composition**
- **Toxicology**

- **Allergenicity**

The FSA's request for further information (**Annex A**) and the applicant's response is included as **Annex B**. The applicant has also provided a revised and consolidated version of their dossier and annexes in the light of the assessment by EFSA these are provided as **Annex C** and **Annex D** respectively.

EFSA consideration of novel food

5. In parallel to submitting the application to the UK for assessment the applicant has also submitted an application to EFSA. EFSA have completed their consideration and the EFSA opinion (**Annex E**) is provided to the Committee as further data to inform their assessment.

Applicant's response to request for further information

Production Process

6. The Committee sought clarification on the management of pesticide residues in the novel food. The applicant has responded by stating that the level of pesticides are monitored to ensure compliance with regulations periodically.
7. The Committee sought further assurance that legacy pesticides are not used during the cultivation of mung beans. The applicant has responded by stating that they ensure legacy pesticides are not used through the use of multi-residue pesticide screens. During pesticide screening, the analysis includes legacy pesticides DDT, chlordane and dieldrin, and these residues are below the limit of detection (less than 0.005ppm).

Proposed Use and Intake Levels

8. The Committee sought clarification on the intended use of the novel food given the proposed food categories could impact on the nutrition of consumers. The applicant has responded by explaining they had reviewed the requested uses and are now seeking a more restricted number of uses. The novel food is intended to be used in FAIM category 12.9 – protein analogues, such as meat, and especially non-animal egg replacers.
9. The Committee also sought clarification on the anticipated intake level of the novel food to assess the impact on the nutrition of consumers. The applicant has responded by stating that the maximum use level of novel food shall be 200g MBP per kg of food. Further the applicant has utilised the FAIM tool to calculate the anticipated daily intake of MBP per age class (Table 1) and the absolute daily intake of MBP per age class (Table 2). The applicant concludes

that the novel food does not pose a health risk to consumers because of the intended use, the calculated intake of MBP in foods is overly conservative, and MBP is not expected to be a major source of protein in a plant-based diet

10. They noted that the data on consumption of plant protein alternatives was limited as this is a relatively new dietary trend. As a result, the applicant comments on the limitations of the data and how this has been taken into account in the dossier.

Nutritional Composition

11. The Committee discussed the potential impact from the consumption of mung bean protein compared to other protein sources in the diet and sought further information from the applicant. The Committee acknowledged that this would be difficult for all food categories, but the applicant was asked to provide information on a few example products. The applicant has responded by explaining based on their revised requested uses, the intended use of the novel food will be in one food category only, which will substantially reduce the anticipated daily intake of MBP.

Toxicology

12. The Committee noted that the previous request for further information provided limited data, which was based primarily on mung beans. The Committee highlighted the expectation that the applicant should provide some evidence on the toxicology of their product and concluded that further information was needed to provide assurance for the safety of the novel food. The applicant has responded by providing further justification on why toxicological testing was not felt necessary. They referred to their previous response highlighting the following factors– the history of use of mung beans; the structural relationship between the MBP and legume proteins; that MBP is not chemically modified; and that the levels of anti-nutrients are not a cause for concern..

Allergenicity

13. The Committee were concerned by the potential for cross-reactivity with known legume allergens. The members requested information on IgE reactivity in patients with legume allergy, and if positive, human challenge tests to evaluate the potential allergenicity of the novel food in consumers. Queries were also raised on the digestibility of the protein from an allergenicity perspective. The applicant has responded justifying further why the next tier of studies is not needed in their view. They explain that allergic reactions to mung beans are

rare, the history of use of MBP in the USA has not recorded any allergic reactions, and reports of cross-allergenicity of MBP with legume proteins is uncommon.

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 information would be required.

ACNFP Secretariat November 2021

Annexes

Annex A – Request For Information

Annex B – Applicant's Response to Request For Information

Annex C – Revised Dossier and References

Annex D – Revised Annexes

Annex E – EFSA response for NF