

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

MUNG BEAN PROTEIN ADDITIONAL INFORMATION – RP32

Issue

1. The Committee reviewed this application for the first time at the April 2021 meeting, and requested further information on which to base their assessment. 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 of January 2021, the FSA (Food Standards Agency) received the submission for Mung Bean Protein 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 raised several areas where further information is required to assess the safety of the novel food and its proposed use. Information was requested on the
 - **Production Process**
 - **Composition**
 - **Specification**
 - **History of use**
 - **Proposed use and intakes**
 - **Toxicology**
 - **Allergenicity**

The FSA's request for further information and the applicant's response are included as **Annexes A and B**, respectively.

Applicants' response to request for further information

Production Process

4. The Committee suggested that the applicant provided further detail on each of stages of processing in the production process to understand how this influenced

the final composition. The applicant responded by providing an updated version of the production process. Please note that this aspect of the response contains confidential information.

5. In reviewing the data, the Committee sought further reassurance of the quality control checks on the raw material of the mung bean flour and that these are effective in managing potential food safety risks. The applicant responded by providing a general description of the farming, training, dehulling, and milling of the mung bean crop (all that occurs before they receive the mung bean flour). The applicant also stated that they rely on quality controls which include visual testing of the beans, testing for aflatoxins, ochratoxins, microbes and basic compositional characteristics. The applicant states that they also complete comprehensive analysis on the final mung bean protein to check for impurities.
6. Queries were raised in the initial review on the evidence to support the applicants claim that the production process eliminates anti-nutritional factors and contaminants present in the flour. The applicant responded by conducting the analyses of the following compounds in 5 batches of mung bean protein and mung bean flour for a range of antinutritional factors including Phytic acid and Lectins. The applicant provides laboratory analysis of these compounds, including the analytical methods used.

Composition

7. The Committee noted a high sodium and potassium content present in the mung bean protein novel ingredient. Given the level of consumption proposed for the novel ingredient the Committee sought clarification on the uses of mung bean protein to understand the implications for consumers exposure to sodium and potassium. In their response, the applicant has analysed the mineral content in the mung bean protein and completed an exposure analysis for potassium and sodium. The tables for the calculations and exposure assessment are contained in the applicant's response as table 9, 10 and 11. The applicant concluded there was no safety risk relating to the exposure of sodium and potassium.
8. The Committee noted there are several potential anti-nutritional factors present in legumes that could be present in the final product that had not been considered. The applicant response highlights the additional analysis flagged in the answer to the query on the production process and antinutritional factors above.

Specifications

9. The Committee asked the applicant to update the specifications to account for the potential risks of the raw material. The applicant has provided a detailed

response justifying not including the parameters linked to the raw material in their specifications

History of Use

10. The Committee recommended that the systematic literature review on the safety of mung bean that had been provided be widened to be more comprehensive. This was felt to provide a stronger basis for informing the risk assessment. A particular concern was that little information from literature had been identified on the toxicology of mung bean.
11. The applicant has now produced a systematic literature review with respect to toxicology of mung bean protein. Details of the search strategy have been provided.
12. The Committee noted that history of use provided did not represent the product to be marketed. The focus of the review had been on the raw starting material, mung beans and alternative names in different cultures had not been included. The applicant notes that the wider systematic literature review described in Table 12 now provides a more comprehensive consideration of the available literature. They suggest that as green gram is a synonym for mung bean seeds and does not indicate mung bean flour this would not be appropriate to include.

Proposed Use and intake

13. The applicant was requested to provide clarification on the specific uses of the mung bean protein requested in the application. Specifically, what the level of substitution of mung bean protein for other proteins in various products may be.
14. The applicant responded by stating that the level of substitution could not be easily determined as reformulation is more complex than just replacing the protein source. It could be that the substitution or protein source with MBP could be 100%. The applicant also drew attention to the lack of recent food consumption data and used pancakes as an example to show that the consumption of mung bean protein may be overestimated using the FAIM model. The Committee had highlighted that the change in protein composition of some products using the novel ingredients could pose risks for those requiring a diet low in phenylalanine such as patients with Phenylketonuria (PKU). The applicant's view on this was sought. They have responded by stating that MBP contains 5.5% phenylalanine. The applicant stated that the difference between MBP and other proteins is only minor. PKU patients are educated to carefully select proteins. Since MBP will be indicated on the ingredient list of the product

labels, vulnerable consumer groups like PKU patients will be sufficiently informed to take educated purchasing decisions.

15. The Committee had also sought information on the wider nutritional implications of replacing other proteins with mung bean protein. A comparison of the proteins nutritional content were sought to inform the assessment of potential nutritional disadvantage. The applicant responded by stating that this data is not available for a comparison. They also highlight that replacing a protein by substitution is more complex than just switching the protein source, as the amount of mung bean protein needed to achieve the desired functionality may be different.

Toxicology

16. The applicant's view that toxicological data was not required as the literature supports the novel ingredients safety based on history of use was noted. The Committee considered that further information was needed to support this approach. They requested an expansion of the literature review to consider the components of the novel food potentially of concern such as antinutritional factors. The applicant completed an additional literature search, and states that their assessment demonstrates the safety of the mung bean protein.

Allergenicity

17. It was suggested by the Committee that the applicant provides further information on the potential for and severity of any cross reactivity with legumes for legume allergic consumers. The applicant responded by providing a range of information on the protein subunits of the mung bean protein and their cross homology to other protein in legumes. The applicant also reported on several studies that investigated the cross reactivity of sera with other legumes. They concluded that allergic reactions caused by mung bean protein is rare, even if there are structural similarities between the subunits in mung bean protein and legumes. The Committee requested that the assessment of the allergenicity potential of the novel food should also include assessment by the applicant of the impact of processing of the mung bean protein and thermal treatments applied. The applicant replied by stating that mung bean proteins are only moderately heated and avoid denaturation.

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.

Annexes

Annex A– Request for further information

Annex B – The applicants response

Annex C – Response Annexes