COMMITTEE PAPER FOR DISCUSSION **ACNFP/147/01**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

MUNG BEAN PROTEIN – RP32

Issue

1. A notification has been received under the novel food authorisation process (regulation 2015/2283) for mung bean protein.

2. The Committee is asked whether there are safety concerns with the proposed use of this novel food in the UK market. The information from the Committee will provide the basis for any safety objections raised at national level.

Background

3. On the 11th of January 2021, the FSA received the submission for Mung Bean Protein for Eat Just, Inc (JUST) by analyse & realize GmbH.

4. 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.

5. The FSA completed the validation of mung bean protein on 22nd February 2021. The Committee have 9-months to submit reasoned safety objections to the application. If authorised, the authorisation will be open to any company subject to the specification and the condition of use detailed in the dossier.

Identification

6. The identity of the mung bean protein – scientific name: *Vigna radiata,* Order: Fabales, Family: Leguminosae and Fabacea, Genus: *Vigna,* Species: Vigna radiata, Synonyms: Mung bean and Phaseolous aureus, parts used: Semen/Seeds, Geographical Origins: China, India, Tanzania

7. The flour used for mung bean protein is produced from the seeds of the mung bean plant which are selected for their high protein content (20-25% protein content) which was shown to mainly consist of the major seed storage protein of mung bean, vicilin-like 8S-globulin. The product itself contains more than 85% protein, with the remining part being water, fat and minerals (SDS-phage analysis on pages 8,9 of the application).

Production Process

8. The protein extraction from the seeds of mung bean (Vigna radiata) involves the same sequence of mechanical or physical steps that are commonly used for the protein extraction from seeds of dicotyledonous plants such as soy, pea, rapeseed, lupin or hemp.

9. The flow of the production is as follows 1) Mung bean Dispersed in water 2) Slurry 3) Protein and fibre/Start Separation 4) Protein precipitation 5) Protein Separation 6) Protein Washing 7) Pasteurisation (CCP 1) 8) Spray Drying 9) Sifting (CCP 2) 10) Protein Powder 11)Packaging.

Composition

10. Composition is provided on 6 samples. The sample plan is on pages 20, 21 of the application.

11. The Physiochemical properties: The appearance should be an off-white powder, with a neutral to grassy smell, with a natural clean taste, that is dispersible in water in a pH. range of 6.00 – 6.20.

12. The Composition: The applicant submitted analysis on 5 batches of product of the production line and these 5 products had an average moisture content of 4.2%, an average water activity of 0.15, an average ash content of 3.8%, an average protein content of 89.2%, an average fat content of 3.2% and the fibre was not detected.

13. The Minerals and Trace Elements: The applicant submitted analysis on 5 batches of product of the production line and these 5 products had an average calcium content of 232.5 mg/kg, Chromium 0.1 mg/kg, Copper 6.6 mg/kg, iron 79.8mg/kg, Magnesium 872.8mg/kg, Manganese 9.9mg/kg, Molybdenum 5.6mg/kg, Phosphorous 5595.0 mg/kg, Potassium 5816.7 mg/kg, selenium not detected, sodium 8921.7 mg/kg, zin 17.7mg/kg.

14. Impurities: For the impurity's assessment on the 5 representative samples, the average amount of arsenic came out as 0.018 mg/kg and Cadmium 0.002 mg/kg. Lead and Mercury were not detected. With regards to the microbiological assessment CFU/g (colony forming units per gram) of coliforms, e. coli, mesophilic aerobic spores, genus listeria and salmonella, all values where less than <10 or negligible. For Aerobic plate count counts range from less than 10 to 2800, and for Moulds counts range from 50-70.

Composition - Stability

15. Stability Study: The applicant completes a stability study over one year on 6 batches of mung bean protein over a one-year period. All samples tested for Aerobic plate count, Coliform Petrifilm, E.coli Petrifilm, Mesophiphilic Aerobic Spores, Mould and yeast remained in specification.

Specifications

16. The provided specifications which are – **Description:** Protein isolate extracted from mung bean flour, **Appearance**: White to off white powder, free flowing, Odour: Clean, neutral to slightly grassy, Taste: Clean, Bland, mild flavour, Moisture: Maximum 6% moisture content, Protein: Minimum 85% protein content, Fat: Maximum 5% protein content, Ash: Maximum 6% ash content, pH: pH of 6.00+/-0.20**. Microbiology** – Aerobic Plate count less than 10,000 cfu/g, Listeria: Must return negative in 125g, Salmonella spp.: must be negative in 375g, E.coli: must be less than or equal to10 cfu/g, Coliforms: Must be less than or equal to 10 cfu/g, Yeast: Must be less than or equal to 100 cfu/g, Mould: must be less than or equal to 100 colony forming units. Shelf-life: one-year, Strange conditions: Keep in a dry environment at ambient temperatures.

History of Use

17. History of the source: The applicant states that the seeds and the mung beans are a common food and that its safety in the diet is well established. They go on to describe its history (4500 years of use), its number of uses in foods (dhals, sweets, snacks etc) and give consumption data for the US (20 million pounds), and that the UK stated that mung bean has a significant history of consumption before 1997.

18. History of the novel food: the applicant states that there is no history of safe use for mung bean protein, but highlights it use outside of the EU/UK including use as a liquid egg substitute.

19. The applicant included in their application a systematic review on request by EFSA on the safety on Mung Bean protein from the known scientific literature and reported that no result on human studies have been published that provide data on the safety of mung bean protein.

Proposed Use and Intake

20. Mung bean protein is intended for use for the general public and **NOT** for use in infant and follow-on formula.

21. Mung bean protein is intended to complement or partially substitute animal or vegetable proteins in a variety of food and beverages. MBP is intended to be used as part of a varied and mixed diet. MBP shall not entirely replace other plant proteins or other food that already exists on the EU market.

22. Propose max use level in foods of grams of mung bean protein per kilogram of food. Dairy analogues 50g, Edible ices 30g, Breakfast cereals 30g, Pasta 40g, fine bakery wares 100g, sauces 30g, salads and savour based sandwich spread 50g, Protein products 200g, Dietary foods for weight control 30g, Potato, cereal, flour or starch based snacks 50g, desserts 30g.

23. Anticipated intake of the Novel Food: The applicant completed an intake assessment using the FAIM tool. The worked at expected intake in a range of age groups for mung bean protein, in infants, toddlers, other children, adolescents, adults and elderly. The intake calculation revealed that the application of MBP in the proposed categories and at the proposed use levels results in up to 220 mg/kg bw/day for adults in the total population (max. average intake on consuming and non-consuming days). On consuming days, high consumers (adult consumers in the highest 95th percentile) ingest up to 593 mg MBP/kg bw/day. These values correspond to an absolute daily intake of 16 g and 44 g, respectively.

24. Combined intake from the novel food and other sources: The applicant concludes that as mung bean protein powder is not authorised the only other source is mung bean itself (sprout, and beans). They concluded that in the EU there is not enough data to draw conclusion on the consumption of the beans. For the sprouts, the intake data shows, in the adult population, the mean intake of mung bean sprouts on consuming days ranges from 5.6 g/day to 10.7 g/day, or 0.08-0.14 g/kg bw/day. In the 95th percentile, the intake may rise to 28.9 g/day or 0.34 g/kg bw/day.

25. Combined intake from the novel food and other sources: regarding the comparison the applicant concludes that the comparison of mung bean protein with the mung bean sprout is not an effective comparison as the protein in is used for the growth and development of the plant. Instead, the applicant draws a comparison with other structurally related storage proteins from other legumes seeds. They concluded that the adult population in the 95th percentile may be 200 g/day and higher. If a protein content of dry legumes of 20 % is considered, consumers would ingest at least 40 g of legume protein in the natural matrix. Adult consumers in NF 2020/1651 Novel Food application for mung bean protein Page 34 of 60 the lower-bound 95th percentile would still ingest 2-12 g of legume seed proteins from various legumes. The corresponding data in [g/kg bw/day] are included in Annex A5.8.

Absorption, Distribution, Metabolism and Excretion (ADME)

26. The applicant did not complete their own ADME studies but instead completed a systematic literature review. From this review they concluded that all information on mung bean protein relates to the nutrition concluding that it contains 85%+ protein. From this they decided to complete protein analysis and the contents of this is shared in the Nutritional information sections.

Nutritional Information

27. The applicant completed analysis based of the 6 samples of tested substance. The analysis per 100g of Mung bean protein is Energy 1613 kJ or 386kcal, 3.2g of fat, 0g of carbohydrate, 89.2g of protein and 2.2.g of salt.

28. The applicant completed an amino acid profile on four batches of mung bean powder and provided several protein quality scores. These demonstrated that although isolated Mung Bean Protein is readily digestible, the nutritional quality of mung bean protein, expressed as PDCAAS, is limited because the levels of the sulphur containing amino acids methionine and cysteine are below the amino acid requirements.The PDCASS of mung bean protein was 0.638% which is less when comperes with soybean, dairy and pea protein.

29. The applicant supplies DIAAS scores (a measure of protein quality) of mung beans at 86% for mung bean protein and 62% for mung beans. The applicant compares to other protein sources noting that the DIAAS is lower for pea, field beans, jack beans and kidney beans protein. They also reference a further study (page 57) stating the true ileal digestibility of mung bean protein is 57.7-63.4%.

30. Anti-nutritional factors: The anti-nutritional factors reported in mung bean include tannins, phytic acid, hemagglutinins (lectins), polyphenols, trypsin and other protease inhibitors, and alpha-amylase inhibitors. The applicant analysed phytic acid and lectin in three representative (pilot) batches of MBP (analyses by Eurofins). As indicated in the certificates of analyses, the batch codes assigned by Eurofins correspond to the codes by the applicant as listed in Table 27. Levels of phytic acid ranged from 1.2 to 1.3 %. Lectin concentrations were below the LOQ.

Toxicological Information

31. The applicant has not completed a study and asserts that:

    a. A history of safe use exists for mung beans. The FSA and the EU member states acknowledged that mung beans were consumed as food in the EU prior to May 15, 1997 (FSA, 2019).

    b. Mung bean protein was only mechanically extracted from the beans. The protein is not chemically modified.

    c. Mung bean protein is structurally closely related to the predominant seed storage proteins in other legume seeds, e.g., in soy, lupin, and pea. None of these proteins is known to be toxic to humans or animals.

32. The applicant did complete a systematic review on mung protein and did not find any information that it is toxic.

Allergenicity

33. The applicant notes that the cross-reactivity potential of mature mung bean with other legumes or major allergens.

34. The applicant notes the data is limited, but there has been one report indicating cross-reactivity between peanut and mung bean seeds and sprouted mung beans.

35. The applicant notes that clinically relevant allergens in crude mung bean protein extracts that showed pepsin resistance and IgE-binding capability with sensitized human and mice sera.

36. Cross-reactivity between mung bean seedlings and birch pollen as a result of common antigenic determinants has been reported.

37. The applicant concludes that mung bean protein has the potential to cause allergic reactions in sensitive individuals but so far, reports on such reactions, or on cross-reactivity with other legume allergens are very rare.

Dietary Exposure

38. N/A

Conclusions

39. The applicant summates the main conclusion in their report.

Committee Action Required

- Members are asked whether there are safety concerns that need to be managed with this novel food.
- The Committee's advice will form the basis for the UK's formal response to the application and whether reasoned safety objections are submitted.

Secretariat
March 2021

Annexes

ACNFP-141-01-01 – Mung Bean Protein Dossier

ACNFP-141-01-02 – Annexes