

Safety Assessment of Mung Bean Protein as a Novel Food for Use in Food (RP32)

Food Standards Agency¹, Food Standards Scotland²

¹ Regulated Products Risk Assessment, Food Standards Agency, UK, ² Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application from Eat Just, Incorporated, USA (“the applicant”) for the authorisation of mung bean protein as a novel food in January 2021.

The novel food is mung bean protein which is intended to be used as a food ingredient. Mung bean protein is manufactured by the extraction, purification, and spray drying of the protein from mung bean (*Vigna radiata*) flour. The novel food is a white powder consisting of $\geq 84\%$ w/w protein.

This new application is seeking to use the novel food within the following food category: protein products (excluding dairy analogues, including beverage whiteners).

The FSA and FSS, in their evaluation of the application, reviewed the safety dossier and supplementary information provided by the applicant. The FSA and FSS did not consider any potential health benefits or claims arising from consuming the food, as the focus of the novel food assessment is to ensure the food is safe and not putting consumers at a nutritional disadvantage.

The FSA and FSS concluded that the applicant had provided sufficient information to assure that mung bean protein was safe under the intended conditions of use. The anticipated intake levels and the intended use in food was not considered to be nutritionally disadvantageous.

The safety assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.



1. Introduction

In January 2021, Eat Just, Incorporated, USA (“the applicant”) submitted a full novel food application for the authorisation of mung bean protein. The novel food is mung bean protein, which is manufactured by the extraction, purification, and spray drying of the protein from mung bean (*Vigna radiata*) flour. The novel food is a white powder consisting of $\geq 84\%$ w/w protein and is intended to be used as a food ingredient.

The FSA and FSS have undertaken a safety assessment for mung bean protein under the novel foods legislation, assimilated Regulation (EU) 2015/2283.

The evaluation by the FSA and FSS assessed the food safety risks of the novel food and its production, in line with Article 11 of assimilated Regulation (EU) 2015/2283 and Article 7 of assimilated Commission Implementing Regulation (EU) 2017/2469. The basis and structure of the assessment was conducted in accordance with the relevant technical guidance put in place by the European Food Safety Authority (EFSA) for full novel food applications (EFSA NDA Panel, 2016), which the FSA and FSS considers is relevant and should be applied to this novel food application owing to similarities in the regulatory regimes.

This safety assessment outlines the conclusions of the FSA and FSS on the safety of mung bean protein as a novel food.

The safety assessment represents the opinion of the FSA and FSS.

2. Assessment

2.1. Identity of the novel food

The novel food is sourced from the seeds (beans) of the plant *Vigna radiata*.

- Order: Fabales
- Family: Fabaceae/Leguminosae
- Genus: *Vigna*

- Species: *Vigna radiata* (L.) R. Wilczek
- Synonyms: Mung bean, *Phaseolus aureus*
- Parts Used: Semen/Seeds (beans)
- Geographical Origin: China, India and Tanzania

The identity of the novel food is verified by Sodium Dodecyl Sulphate – Polyacrylamide Gel Electrophoresis (SDS-PAGE) under reducing and non-reducing conditions. The main types of protein present in the novel food are 8S globulin (vicilin-type), 11S globulin (legumin-type) and albumin.

The novel food is a white powder consisting of $\geq 84\%$ w/w protein. The protein content is determined by Kjeldahl methodology.

Information to support the characterisation of the novel food is provided for six batches of mung bean protein.

2.2. Production process

The mung beans, which are the source of the novel food, are purchased from the world crop market. A surveillance programme is used to monitor the pesticide residues on the mung beans.

The dehulled mung beans are extracted using the same mechanical steps employed for other seeds such as soybean, pea, rapeseed or lupin. The beans are then heated to a high temperature for few minutes to a consistent moisture content and to reduce any undesirable volatile flavours.

The mung beans are milled and then extracted in aqueous solution at a slightly alkaline pH and low concentration of sodium chloride. The fibre and starch are removed by decantation. The protein is recovered from the extract as a precipitate by lowering the pH with citric acid. The precipitate is recovered from the supernatant by decantation. The protein fractions that are discarded and retained during these steps were identified.

The precipitate is redispersed in water. This mixture is neutralised and then undergoes pasteurisation. Finally, the novel food is spray dried to a white powder which consists of $\geq 84\%$ w/w protein.

The certificates of analysis for the raw materials and the processing aids used in the manufacture of the novel food were provided.

The novel food is produced in line with Hazard Analysis and Critical Control Point (HACCP) principles.

The production process has characterised the potential hazards and the corresponding control measures are appropriate.

2.3. Compositional information

Results from six batches of the mung bean protein appropriately characterise the proximate composition ([Table 1](#)), the microbiological quality ([Table 2](#)) and the mineral content ([Table 3](#)) of the novel food.

The most abundant elements in the novel food are phosphorus, potassium, and sodium ([Table 3](#)). The mean content for each of these elements is 5595.0 mg/kg, 5816.7 mg/kg and 8921.7 mg/kg, respectively.

A multi-residue pesticide screen of six batches of mung bean protein reported that all screened compounds were below the limit of detection of 0.005 mg/kg (method EN15662/CFIA PMR-006).

Certification was provided to demonstrate that the contract laboratories were accredited to perform these analytical studies. Where in-house analysis was utilised, full methodology and supporting validation documentation was provided.

The data presented indicate the novel food and any hazards present were appropriately characterised.

2.4. Stability

The microbiological stability of novel food was assessed with the five independent batches of mung bean protein divided into three sub-lots for each batch. Samples were stored at the manufacturing site at 20°C in a dry environment. Analytical data were reported for two time points: time zero and time 11 to 13 months, depending on the batch. The results confirmed that all batches of the mung bean protein met the specification limits ([Table 4](#)) after 11 to 13 months in storage.

The data provided supports the stability of the novel food for up to 12 months.

2.5. Specification

The specification for the novel food ([Table 4](#)) was assessed using internationally recognised methods or determined using internally developed and validated methods.

Table 1. The proximate composition of six independent batches of the novel food

Parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6
Moisture (%)	≤ 6%	5.5	4.3	4.7	4.0	3.7	3.0
Water activity		0.231	0.144	0.175	0.139	0.116	0.093
Ash (%)	≤ 6%	3.8	3.7	3.8	3.7	3.7	4.2
Protein (N x 6.25) (%)	≥ 84%	88.2	89.3	89.6	90.6	90.5	88.6
Fat (%)	≤ 5.5%	3.0	3.6	2.9	3.9	2.8	3.2
Total dietary fibre (%)		< 0.45	< 0.45	< 0.45	< 0.45	< 0.45	0.51

AOAC = Association of Official Agricultural Chemists; N = nitrogen

Moisture – AOAC 925.09 Vacuum oven method; Water activity – AOAC 978.18 Electrical conductivity change; Ash – AOAC 923.03 Ashing method; Protein – AOAC 992.23 (N* 6.25) Generic combustion method; Fat – AOAC 933.05 Acid hydrolysis method; Dietary fibre – AOAC 991.43 (modified) Enzymatic-gravimetric method

Table 2. Microbiological quality of six independent batches of novel food

Parameter	Specification	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6
Aerobic plate count (CFU/g)	≤ 5,000	50	< 10	90	20	2,800	< 10
Coliforms (CFU/g)	≤ 100	< 10	< 10	< 10	< 10	< 10	< 10
<i>E. coli</i> (CFU/g)	≤ 10	< 10	< 10	< 10	< 10	< 10	< 10
Mesophilic aerobic spores (CFU/g)		8	1	6	1	10	3
Yeast (CFU/g)	≤ 100	< 10	< 10	< 10	< 10	< 10	< 10
Mould (CFU/g)	≤ 100	50	10	70	10	20	< 10
<i>Listeria</i>	Absent in 25g	Absent in 125g	Absent in 125g	Absent in 125g	Absent in 125g	Absent in 125g	Absent in 125g
<i>Salmonella</i>	Absent in 25g	Absent in 375g	Absent in 375g	Absent in 375g	Absent in 375g	Absent in 375g	Absent in 375g

AOAC = Association of Official Agricultural Chemists; CFU = colony forming unit; CMMEF = compendium of methods for the microbiological examination of foods; FDA-BAM = U.S. Food and drug administration – Bacteriological analytical manual.

Aerobic plate count – AOAC 966.23; Coliforms (Petrifilm) – AOAC 991.14; *E. coli* (Petrifilm) – AOAC 991.14; Mesophilic aerobic spores – CMMEF, 5th edition; yeasts and moulds – FDA-BAM, 7th edition; *Listeria* – AOAC 2004.06; *Salmonella* – AOAC 2004.03

Table 3. Heavy metal and mineral content of six independent batches of novel food

Parameter	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5	Batch 6	Maximum level of contaminants in foodstuffs
Arsenic (mg/kg)	0.02	0.01	0.02	0.02	0.02	0.02	
Cadmium (mg/kg)	0.001	0.002	0.002	0.002	0.002	0.002	0.05 *
Lead (mg/kg)	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	< 0.01	0.10 **
Mercury (mg/kg)	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005	< 0.005	
Calcium (mg/kg)	243	183	218	309	229	213	
Chromium (mg/kg)	0.03	0.04	0.05	0.02	0.31	0.04	
Copper (mg/kg)	5.70	7.23	6.40	7.04	5.34	7.94	
Iron (mg/kg)	82.0	68.6	78.3	70.8	88.0	91.3	
Magnesium (mg/kg)	836	880	875	847	822	977	
Manganese (mg/kg)	9.24	10.5	10.1	9.35	9.59	10.7	
Molybdenum (mg/kg)	3.84	5.04	4.97	7.00	5.59	7.07	
Phosphorus (mg/kg)	5350	5700	5500	5260	5490	6270	
Potassium (mg/kg)	5720	6110	6170	5270	4980	6650	
Selenium (mg/kg)	< 0.1	0.1	< 0.1	0.1	< 0.1	< 0.1	
Sodium (mg/kg)	12200	7610	8490	7320	8190	9720	
Zinc (mg/kg)	17.9	20.2	16.8	17.6	16.3	17.1	

AOAC = Association of Official Agricultural Chemists; ICP-MS = Inductively Coupled Plasma - Mass Spectrometry

Heavy metal and mineral – AOAC 2015.01 (modified) ICP-MS

* Maximum permitted limit in vegetables and fruit, excluding root and tuber vegetables, leaf vegetables, fresh herbs, leafy brassica, stem vegetables, fungi and seaweed [assimilated Commission Regulation (EC) No 1881/2006]

** Maximum permitted limit in vegetables excluding leafy brassica, salsify, leaf vegetables & fresh herbs, fungi, seaweed and fruiting vegetables

Table 4. Specification for the novel food

Parameter	Specification	Method
Moisture	≤ 6%	AOAC 925.09
Protein	≥ 84% w/w	AOAC 992.23
Ash	≤ 6% w/w	AOAC 923.03
Fat	≤ 5.5% w/w	AOAC 933.05
Carbohydrate	≤ 5.0%	By calculation
Aerobic plate count	≤ 5,000 CFU/g	AOAC 966.23
Coliforms (Petri film)	≤ 100 CFU/g	AOAC 991.14
<i>E. coli</i> (Petri film)	≤ 10 CFU/g	AOAC 991.14
Yeast	≤ 100 CFU/g	FDA-BAM, 7th ed.
Mould	≤ 100 CFU/g	FDA-BAM, 7th ed.
<i>Listeria monocytogenes</i>	Negative in 25g	AOAC 2004.06
<i>Salmonella spp.</i>	Negative in 25g	AOAC 2004.03

CFU = colony forming units; AOAC = Association of Official Analytical Chemists; FDA-BAM = Food and Drug Administration – Bacteriological Analytical Manual

The information provided is sufficient for the specification of the novel food and appropriately characterises the novel food seeking authorisation.

2.6. History of use

There is no history of use for the novel food in the UK; however, the novel food has been available in Asia and the USA as a liquid egg substitute since November 2017. No adverse reports have been reported by US consumers.

There is history of use for mung beans, the source of the novel food, in the EU and the UK. However, they are usually consumed in the form of mung bean sprouts rather than mung beans. Powdered mung beans and mung bean flour have also been used in the EU prior to 1997.

There is a long history of safe use in Asia for the consumption of mung bean seeds and sprouts as a food (Fuller & Harvey, 2006; Shanmugasundaram et al., 2010; Tang et al., 2014). The highest annual per capita consumption of mung beans is reported to be in China and India at 0.5 kg/person/year and 0.8 – 2.1 kg/person/year, respectively (Shanmugasundaram et al., 2010; Vijayalakshmi et al., 2003).

Mung bean protein has been authorised in the EU (assimilated Regulation (EU) 2017/2470) for use as a food ingredient in 'protein products, excluding products covered in category 1.8 (includes dairy analogues, including beverage whiteners').

The history of use does not indicate any further areas for concern.

2.7. Proposed use and intake

The target population is the general population.

Mung bean protein is intended to be used as a food ingredient but is not intended to be used in infant formulae and follow-on formulae.

The intended food categories and maximum use levels are listed in [Table 5](#).

Table 5. Food Categories and Maximum Use Levels for the Novel Food

Food Category	Maximum Use Level (g/kg)
12.9 Protein products, excluding products covered in category 1.8 *	200

* Category 12.9 includes protein analogues or substitutes for standard products, such as meat, fish or milk, including gelatine and unflavoured soy drinks. Category 1.8 includes dairy analogues, including beverage whiteners.

The estimated mean and 95th percentile intakes of mung bean protein in the proposed food category for all population groups on a body weight basis ([Table 6](#)) were derived using the EFSA Food Additives Intake Model 2.0 (FAIM) tool. The use of the FAIM tool is appropriate because the intended use of the novel food matches the food category used in this tool.

The EFSA FAIM 2.0 tool uses the summary statistics from the EFSA Comprehensive European Food Consumption Database, including the UK National Dietary and Nutrition Survey (NDNS).

Table 6. Estimated daily intake for the novel food on a body weight basis from the intended food category based on EU and UK [in brackets] dietary surveys in the EFSA FAIM 2.0 tool

Population Group	Mean intakes of the novel food (mg/kg bw/day) *	95 th percentile intakes of the novel food (mg/kg bw/day) *
Young children	0.0 – 581 [65.9]	0.0 – 64.3
Other children	0.0 – 177 [42.6]	0.0 – 758
Adolescents	0.0 – 16.8 [4.55]	0.0 – 71.3
Adults	0.4 – 31.7 [13.0]	0.0 – 260 [60.0]
Elderly	0.1 – 19.7 [19.7]	0.0 – 66.7

bw = body weight

Infants < 1 year; young children 1 to < 3 years; other children 3 to < 10 years Adolescents 10 to < 18 years; adults 18 to < 65 years; elderly > 65 years

* Values in square brackets are estimated intakes for UK consumers only – where there is no square bracket, the intake of the novel food by UK consumers could not be determined because survey data is not statistically valid (n < 60).

The highest estimated mean intake for mung bean protein consumption is 581 mg/kg BW/day in young children, and the highest estimated 95th percentile intake is reported in other children at 758 mg/kg BW/day.

When the UK NDNS survey data is considered alone (see [Table 6](#) – UK intake data in square brackets), the highest estimated mean intake for mung bean protein consumption is 65.9 mg/kg BW/day in young children, and the highest estimated 95th percentile intake is reported in adults at 60.0 mg/kg BW/day.

2.8. Absorption, Distribution, Metabolism and Excretion (ADME)

No ADME studies were conducted on the novel food.

The novel food contains greater than 84% protein with the remaining fraction as water, fat and minerals. The protein is expected to undergo hydrolysis in the intestinal tract where the amino acids are resorbed and enter the regular amino acid metabolic pathways.

The ADME of the components in the novel food is well understood and the information does not indicate any further areas of concern.

2.9. Nutritional information

The nutritional analysis confirms that the novel food is high in protein and low in carbohydrates and fats. The nutrient profile of the novel food is shown in [Table 7](#).

Table 7. Nutritional profile of the novel food.

Nutritional information	Per 100g of novel food
Energy *	1,690 kJ 406 kcal
Fat	5.5 g
Carbohydrates	5.0 g
Protein	84.0 g
Salt **	2.2 g

* Calculated according to Regulation (EU) No 1169/2011: fat 9 kcal/g; carbohydrates 4 kcal/g, dietary fibre 2 kcal/g, protein 4 kcal/g.

** Salt content calculated as NaCl according to Regulation (EU) No 1169/2011: 2.5 × sodium content.

The amino acid profile based on four batches of the novel food was provided. This data was used to derive the amino acid score, an indicator of the nutritional value of mung bean protein (see [Table 8](#)).

The results confirmed that the novel food provides optimal amounts of the essential amino acids, except for the sulphur-containing amino acids, cysteine and methionine (amino acid score reported as 0.65). This is attributed to the main protein fraction of the novel food, 8S vicilin-like globulin, which does not contain cysteine.

Table 8. The calculated amino acid scores (AAS) for mung bean protein.

Essential Amino Acid	Mean amino acid in mung bean protein (mg/g protein) *	Amino acid requirements for children aged 3 – 10 years old (mg/g protein) **	Calculated AAS using amino acid requirements for children aged 3 – 10 years old
Histidine	28.7	16	1.79
Isoleucine	48.6	31	1.57
Leucine	85.8	61	1.41
Lysine	70.7	48	1.47
Cysteine and methionine	16.7	24	0.68
Tyrosine and Phenylalanine	101.5	41	2.48
Threonine	28.1	25	1.12
Tryptophan	9.5	6.6	1.44
Valine	54.7	40	1.37

* Amino acid content in mg/g protein – mean value calculated based on the analytical results from four batches of novel food.

** Reference requirements for amino acids as described by EFSA NDA Panel (2012) and WHO (2007) for children aged 3 to 10 years old.

The digestibility and quality of the novel food was assessed by determining the Protein Digestibility Corrected Amino Acid Score (PDCAAS). Relevant data was obtained from an *in vivo* faecal digestibility study in rats. Using the reference scoring pattern (WHO, 2007), the PDCAAS was 0.635 and 0.638 for uncooked novel food, and 0.580 and 0.598 for cooked novel food. These results confirmed that the nutritional quality of the novel food was limited due to low levels of sulphur-containing amino acids.

The highest estimated daily protein intake from the novel food was derived from the estimated intake for the novel food in all population groups ([Table 5](#)) and the highest reported protein content in the novel food (90.6% – [Table 1](#)). These values were compared to their respective population reference intake (PRI) values ([Table 9](#)).

Based on all EU dietary surveys used in the EFSA FAIM 2.0 tool, the percentage contribution of protein from consumption of the novel food is expected to be highest in the other children and young children population groups: 75 – 81% and 46 – 55%, respectively. However, the percentage contribution of protein from consumption of the novel food for all population groups is significantly lower when these values are derived using data from the UK dietary survey only ([Table 8](#) – values in square brackets).

Table 9. Percentage contribution of novel food to the PRI for protein in all population groups based on EU and UK [in brackets] dietary surveys.

Population	Highest protein intake from NF (g/kg bw/day) *	PRI for protein (g/kg bw/day)	% of PRI for protein from NF consumption
Infants	0.029 [0.020]	1.31 **	2.2 [1.5]
Young children	0.530 [0.060]	0.97 – 1.14 ***	46 – 55 [5.2 – 6.2]
Other children	0.690 [0.039]	0.85 – 0.92	75 – 81 [4.2 – 4.6]
Adolescents	0.065 [0.004]	0.83 – 0.91	7.1 – 7.8 [0.4 – 0.5]
Adults	0.235 [0.054]	0.83	28 [6.5]
Elderly	0.060 [0.018]	0.83	7.2 [2.1]

bw = body weight; PRI = population reference intake; NF = novel food.

* For EU survey, highest NF intake in infants and young children are mean consumers; all other population groups are 95th percentile consumers. UK survey only [in brackets]: highest NF intake in all population groups are mean consumers, except adult population group (Table 6).

** Average requirement value for protein quoted for infants 7 – 11 months.

*** Average requirement value for protein quoted for young children 12 – 17 months, 18 – 23 months and 2 years.

The novel food is high in potassium (mean – 5,817 mg/kg) and sodium (mean – 8,922 mg/kg). An exposure assessment of these minerals in 95th percentile consumers reported that the highest estimated intake levels were 5.00 mg/day for potassium and 6.76 mg/day for sodium, both in the other children sub-population. The values are not a cause for concern because the potassium and sodium content from the consumption of the novel food only makes a small contribution to the overall intake to the diet.

The presence of anti-nutritional factors in mung beans has been reported in the literature (Dahiya et al., 2014; Hou et al., 2019). Analytical data was provided to assess the impact of the production process on the level of anti-nutrients in five independent batches of the novel food and mung bean flour (Table 10).

Table 10. Summary of mean anti-nutrient content in the novel food and mung bean flour

Anti-nutrient	Mean content in mung bean flour	Mean content in novel food	Comments
Lectins	< 120 HAU/g	120 HAU/g	Jain <i>et al.</i> (2009) report that mung bean lectins are non-toxic.
Phytic acid	6.55 mg/g	12.64 mg/g	Phytic acid within range reported for a broad variety of plant foods (EFSA, 2013).
Trypsin inhibitors	4.42 U/mg	4.42 U/mg	TIA levels for legume seeds range from ~ 1 U/mg for black gram to ~ 90 U/mg for soybean (Aviles-Gaxiola et al., 2018)
Total phenolic	1.27 mg/g	1.12 mg/g	Intake for phenolics in Mediterranean diet at 2 – 3 g/day (EFSA, 2013).

Anti-nutrient	Mean content in mung bean flour	Mean content in novel food	Comments
content			
Tannins (condensed)	12.12 µg/g	6.91 µg/g	
Cyanogenic glycosides	< 3 µg/g	< 6 µg/g	Not a cause for concern – below the limit of detection

HAU = Haemagglutination Units; U/mg = enzyme unit/mg; TIA = Trypsin Inhibitor Activity; LOD = limit of detection; LOQ = limit of quantification.

Lectin testing by haemagglutination; phytic acid LOQ = 1.25 mg/g; trypsin inhibitor assay LOQ = 0.50 TIU/mg; total phenolic content by Folin–Ciocalteu spectrophotometric assay as gallic acid equivalents; condensed tannins by dimethylaminocinnamaldehyde (DMAC) spectrophotometric assay as procyanidin A2 equivalents – LOD = 5 ppb; cyanogenic glycosides by liquid chromatography with tandem mass spectrometry.

Consumption of the novel food at the proposed use levels is not expected to be nutritionally disadvantageous for consumers.

2.10. Toxicological information

No toxicological studies were conducted on the novel food. This decision was considered appropriate given the recognised history of use of mung beans as a food in the EU prior to 1997, the fact that the novel food is mechanically extracted from mung beans and not subject to chemical modification, and mung bean protein is structurally similar to seed storage proteins found in other legume seeds (soy, lupin, pea) which are not harmful to humans.

A systematic review of the published literature for mung bean protein identified two published papers. The first paper was not considered relevant as specific parameters on the potential toxicity of mung bean protein isolate were not investigated (Watanabe et al., 2016). The results from the second paper could not be readily correlated to the novel food, as this study evaluated the toxicity of bruchid-resistant mung beans (Yao et al., 2015).

Considering the nature of the novel food and the history of use of the source of the novel food, no toxicological concerns were raised.

2.11. Allergenicity

The novel food is sourced from mung bean, which is a legume, like the important allergenic legume, peanut. However, mung bean belongs to a different group (clade) of legumes to peanut, and is more closely related to several edible legumes, such as navy (haricot) or pinto beans. There is a single study concerning the allergy of mung bean which was undertaken in

a small number of mung bean allergic subjects in India. Two types of seed protein in mung bean, Vig r 2 and Vig r 4, were identified as allergens (Misra et al., 2011).

The mung bean allergens, Vig r 2 and Vig r 4, have sequence homology with the cognate allergens from soybean (Gly m 5: 66 – 69%), lupin (Lup an 1: 54 – 57%) and peanut (Ara h 1: 50 – 51%). From a phylogenetic perspective, soybean is more closely related to mung bean. These *in silico* data indicate that the mung bean proteins have the potential to be cross-reactive with immunoglobulin E (IgE) from patients with allergies to legumes, such as peanut and soybean.

The level of sequence homology that is a prerequisite for cross-reactive allergies remains uncertain. Much higher levels of homology are associated with clinical cross reactivity, such as walnut and pecan (Brough et al., 2020; Nesbit et al., 2020) where the 7S seed storage globulin allergens for walnut (Jug r 1) and pecan (Car i 1) have sequence identities of 92.7 % (Mills et al., 2024).

IgE-immunoblotting using human sera from six patients indicated cross-reactivity between the novel food with soybean and green pea (Calcinai et al., 2023). However, the clinical characteristics of the patients were poorly described in this study, so the reported cross-reactivity may simply be due to legume sensitisation. Another larger study in well characterised patients with legume allergies, has established that clinical co-reactivity is much lower than *in vitro* IgE cross-reactivity (Smits et al., 2023).

The FSA and FSS recommended that the applicant conduct further allergenicity testing following the results from the sequence homology analysis of the novel food. The EFSA technical guidance indicates that this should be targeted serum screening (*in vitro* IgE-binding data). However, no further information was provided by the applicant, and this remains a data gap in the allergenicity assessment of mung bean protein.

Vig r 1 is another mung bean protein allergen and a homologue of the major birch pollen allergen, Bet v 1. The Vig r 1 protein, which is found in mung bean sprouts, is reported to cause allergenic reactions in individuals with birch pollen allergy (Guhsl et al., 2014; Mittag et al., 2005).

Both Vig r 1 and Bet v 1 are members of the PR10 protein family, which also includes seed proteins. The food allergies associated with sensitisation to PR10 proteins are generally considered to be mild. However, there are cases of severe reactions reported in peanut or soybean allergic subjects following consumption of large quantities of peanut (Turner & Weinburger, 2020). There is also evidence that food processing can affect the PR10 allergies to soybean by reducing levels of PR10 homologues, such as Gly m 4 (Mittag et al., 2004).

The applicant did not provide any data regarding the levels of Bet v 1 homologues in the novel food. Nor did they provide information concerning the potential for clinical reactivity in consumers of mung bean protein. This remains a data gap in the allergenicity assessment of the novel food.

Therefore, based on the levels of sequence homology and the known patterns of clinical reactivity between legumes, the novel food represents a low risk of causing clinically relevant reactions in individuals with allergies to other legumes, such as peanuts. Such allergic reactions could range from mild skin reactions to life-threatening anaphylactic shock.

Depending on the exposure to the novel food (use levels of mung bean in food products; extent of consumption), mung bean protein may emerge as a new allergen in a manner similar to pea protein isolate. Pea protein isolate, which is used in both meat and dairy imitates, has been documented as causing severe allergic reactions in paediatric patients (Abi-Melhem & Hassoun, 2023; Lavine & Ben-Shoshan, 2019). Factors such as poorer digestibility, the use level and the type of food categories, such as dairy and meat imitates, will likely increase the risk of new allergies developing in the UK population.

Risk managers may wish to consider the need for consumer information given the potential for a risk to legume allergic consumers.

3. Discussion

The novel food is mung bean protein, which is a white powder containing $\geq 84\%$ protein, $\leq 5\%$ carbohydrates, $\leq 5.5\%$ fat and moisture $\leq 6\%$.

Mung bean protein is manufactured by the extraction, purification, and spray drying of the protein from mung bean (*Vigna radiata*) flour.

Mung bean protein is intended to be used as a food ingredient in protein products, excluding dairy analogues (including beverage whiteners). The general population is identified as the target population of the novel food, but MBP is not intended to be used in infant formulae and follow-on formulae.

Based on the proposed use of the novel food, the results from the EFSA FAIM 2.0 tool report the highest estimated mean intake for mung bean protein is 581 mg/kg BW/day in the young children population group, and the highest estimated 95th percentile intake is 758 mg/kg BW/day in the other children population group.

The EFSA FAIM 2.0 tool uses the summary statistics from the EFSA Comprehensive European Food Consumption Database, including the UK National Dietary and Nutrition Survey (NDNS). When the UK NDNS survey

data is considered alone, the estimated intake levels are for the novel food are lower for most UK population groups. The highest estimated mean intake for mung bean protein consumption is 65.9 mg/kg BW/day in young children, and the highest estimated 95th percentile intake is reported in adults at 60.0 mg/kg BW/day.

The novel food contains most of the essential amino acids in sufficient amounts, but sulphur-containing amino acids are limited. Although the novel food is high in potassium and sodium, these levels are not a cause for concern. Anti-nutritional factors are present in the novel food, but the levels are comparable to other foods.

No toxicological studies were provided given the (i) recognised history of use of mung beans as a food in the EU prior to 1997; (ii) the fact that the novel food is mechanically extracted from mung beans and not subject to chemical modification; and (iii) mung bean protein is structurally similar to seed storage proteins found in other legume seeds (soy, lupin, peanut) which are not toxic to humans.

Based on the levels of sequence homology and the known patterns of clinical reactivity between legumes, the novel food presents a low risk of causing allergenic reactions in individuals with clinically relevant allergies to other legumes, such as peanuts.

4. Conclusions

The FSA and FSS have undertaken the assessment of the novel food and concluded that the novel food is safe under the proposed conditions of use and does not pose a safety risk to human health. The anticipated intake level and the proposed use in food and food supplements was not considered to be nutritionally disadvantageous.

Based on the levels of sequence homology and the known patterns of clinical reactivity between legumes, the novel food presents a low risk of causing allergenic reactions in individuals with clinically relevant allergies to other legumes, such as peanuts.

These conclusions were based on the information in the novel food dossier submitted by the applicant, plus the supplementary information, and could not have been reached without the following data claimed as proprietary by the applicant

- annexes to the dossier which relate to the production process and the composition.

Abbreviations

Abbreviation	Definition
AAS	Amino acid score
ADME	Absorption, Distribution, Metabolism and Excretion
AOAC	Association of Official Agricultural Chemists
BW	Body weight
CFU	Colony forming unit
CMMEF	Compendium of methods for the microbiological examination of foods
EC	European Commission
EFSA	European Food Safety Agency
EU	European Union
FDA-BAM	U.S. Food and Drug Administration – Bacteriological analytical manual
FAIM	Food Additives Intake Model
HACCP	Hazards Analysis and Critical Control Points
ICP-MS	Inductively coupled plasma – mass spectrometry
LOD	Limit of detection
LOQ	Limit of quantification
NDNS	National Dietary and Nutrition Survey
PDCAAS	Protein Digestibility Corrected Amino Acid Score
SDS-PAGE	Sodium dodecyl sulphate – polyacrylamide gel electrophoresis

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