

Assessment of Pea and Rice Protein Fermented by Shiitake (*Lentinula edodes*) Mycelia as Novel Food for Use in Food (RP1437)

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FSA Research and Evidence

MycoTechnology, Inc., USA ("the applicant") submitted a novel food application for the authorisation of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelium as a novel food to each nation of Great Britain in February 2022.

The novel food is manufactured by fermenting pea and rice protein concentrates with Shiitake mushroom (*Lentinula edodes*) mycelium and consists of ≥ 75 % protein (dry weight) and < 0.1 % weight *Lentinula edodes* mycelium biomass.

This new application is seeking to use the novel food in the following food categories: baked goods; beverages; breakfast cereals; confectionary; dairy product analogues; salad dressings; processed meat and meat products; flavoured milk drinks; meal replacements; yogurt; pasta; meat alternatives; prepared soups and dry soup mixes.

In 2022, the European Food Safety Authority (EFSA) published a scientific opinion on the safety of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelium. The Food Standards Agency (FSA) and Food Standards Scotland (FSS) have reviewed the applicant's dossier and other the information available, including the EFSA opinion, and confirmed that the novel food is safe under the intended conditions of use. The anticipated intake levels and proposed use in food was not considered to be nutritionally disadvantageous.

Estimated intake levels for pea protein and rice protein from consumption of the novel food are expected to be much higher than from the background diet, which may increase the risk of sensitisation to pea and rice. Consumption of the novel food would be a risk to consumers who are allergic to pea or rice. As the proposed uses of the novel food include products where consumers would not normally expect to find pea protein or rice protein, risk managers may wish to consider labelling for these consumers.

This assessment represents the opinion of the FSA and FSS.

This is a joint FSA and FSS publication.



1. Introduction

In accordance with assimilated Regulation (EU) 2015/2283 on novel foods, the application RP1437 for the use of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia as a novel food, has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the risk assessments of the European Food Safety Authority (EFSA) in respect of authorisations for regulated food and feed products. Since the end of the transition period, FSA and FSS have adopted equivalent technical guidance and quality assurance processes to be able to undertake GB risk assessments for regulated product applications.

To ensure our regulatory systems are risk proportionate, and resources are used effectively, the FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to inform this assessment.

The FSA and FSS have evaluated the published EFSA risk assessment on the novel food and confirmed that this is appropriate for GB risk analysis. Consideration has been given to the processes undertaken to ensure the EFSA opinion is robust and whether there are any aspects that would require further review, such as specific issues for the countries of GB. The result of the assessment is that there is sufficient evidence of safety to conclude without requiring further risk assessment at this time.

This assessment represents the opinion of the FSA and FSS.

2. Details of other Regulators Opinions

The applicant, MycoTechnology, Inc. (USA), is seeking authorisation for the use of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia as novel food.

In February 2022, the safety of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia (MycoTechnology, Inc., USA), was assessed by EFSA and received a positive opinion (EFSA NDA Panel, 2022). This opinion has been reviewed by the FSA and FSS risk assessors.

Pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia is Generally Recognised as Safe (GRAS) in the USA as a food ingredient in baked goods and baking mixes, beverages and beverage bases, breakfast cereals, dairy product analogues, fats and oils, grain products and pastas, milk products, plant proteins and products, processed fruits and fruit juices, processed vegetable and vegetable juices, soups and soup mixes, non-baked goods (bars), and confectionary (FDA, 2020).

2.1. Methodology applied in the EFSA Opinion

EFSA conducted the assessment of the novel food in accordance with the procedure as outlined in the EFSA scientific opinion 'Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1)' (EFSA NDA Panel, 2021) and Commission Implementing Regulation (EU) 2017/2469.

2.1.1. Identity of the novel food

The novel food is a mixture of 65 % pea, and 35 % rice protein concentrates which are fermented by Shiitake (*Lentinula edodes*) mycelia. After heat treatment, the mixture is spray dried to yield a light cream powder containing ≥ 75 % protein (dry weight) and < 0.1 % weight *Lentinula edodes* mycelia biomass. The fermentation process improves the organoleptic profile of the pea and rice proteins (EFSA NDA Panel, 2022).

The fungus *Lentinula edodes*, commonly known by its Japanese name 'Shiitake', is listed in the Index fungorum as a member of the Omphalotaceae family. Under the aqueous culture conditions in the novel food production process, *Lentinula edodes* grows as the vegetative form.

The strain of *Lentinula edodes* used in the manufacture of the novel food was obtained from Pennsylvania State University (ID Number. WC 1008). A comparison of the highly conserved Internal Transcribed Spacer (ITS) region of *Lentinula edodes* to the genetic sequences in the NCBI public database (GenBank: AB366150.1) confirmed the fungus used to manufacture the novel food was 100 % identical to *Lentinula edodes*.

The FSA and FSS considered that no further assessment was necessary on the identity of the novel food.

2.1.2. Production Process

The novel food production process includes a number of steps. Initially, an inoculum of *Lentinula edodes* is made by successive fermentation steps under controlled conditions in liquid media.

For the main fermentation step, the starting materials, 65 % pea protein and 35 % rice protein concentrates, along with maltodextrin and carrot powder, which are nutrients for the *Lentinula edodes* mycelium, are transferred to the production mixer and sterilised. The inoculum of *Lentinula edodes* is then added and the fermentation process is conducted under controlled conditions whilst stirring slowly for up to 40 hours. The growth of the *Lentinula edodes* mycelium during the production process is monitored by visual inspection and by direct measurement of the pH of the fermentation media.

After the fermentation is complete, thermal processing sterilises the *Lentinula edodes* mycelia. The media containing the novel food is concentrated and then spray dried to a powder. The powder is packaged into poly-lined paper bags, heat-sealed and stored at ambient conditions.

A complete list of the fermentation media constituents and their respective certificates of analysis were provided. Information on the acceptance criteria for the raw materials and processing aids was also provided.

The novel food is produced following the principles of hazard analysis critical control points (HACCP).

EFSA concluded that the data provided on the novel food production process was sufficient and did not give rise to any safety concerns (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this conclusion and no further assessment on the production process was considered necessary.

2.1.3. Compositional information and Specification

The novel food specification is summarised in [Table 1](#).

Table 1. Specification of the novel food.

Parameter	Specification	Method of analysis
Protein	≥ 75 % DW	AOAC 990.03; 992.15 (Combustion-Dumas)
Moisture	≤ 7 % DW	AOAC 925.09; 985.14 (Gravimetric method)
Total fat	≤ 10 % DW	AOAC 996.06 internal adaption (GC-FID)
Ash	≤ 10 % DW	AOAC 942.05 (Gravimetric method)
Carbohydrates	≤ 15 % DW	By calculation
Aflatoxin B1	< 1 µg/kg	AOAC 999.07 mod. (UHPLC-MS/MS)
Aflatoxin B2	< 1 µg/kg	AOAC 999.07 mod. (UHPLC-MS/MS)

Parameter	Specification	Method of analysis
Aflatoxin G1	< 1 µg/kg	AOAC 999.07 mod. (UHPLC-MS/MS)
Aflatoxin G2	< 1 µg/kg	AOAC 999.07 mod. (UHPLC-MS/MS)
Total aflatoxins	< 3 µg/kg	AOAC 999.07 mod. (UHPLC-MS/MS)
Arsenic	< 0.1 mg/kg	J. AOAC (2007) v. 90: 844-856 mod. (ICP-MS)
Cadmium	< 0.1 mg/kg	J. AOAC (2007) v. 90: 844-856 mod. (ICP-MS)
Lead	< 0.3 mg/kg	J. AOAC (2007) v. 90: 844-856 mod. (ICP-MS)
Mercury	< 0.1 mg/kg	J. AOAC (2007) v. 90: 844-856 mod. (ICP-MS)
TAMC	< 1,000 CFU/g	AOAC 966.23
TYAM	< 100 CFU/g	FDA-BAM, Ch 18; AOAC 997.02
Coliforms	10 CFU/g	AOAC 991.14
<i>E. coli</i>	10 CFU/g	AOAC 991.14
<i>Salmonella spp.</i>	Absent in 25 g	AOAC 2016.01
<i>Listeria spp.</i>	Absent in 25 g	AOAC 2004.06; 2016.07

AOAC = Association of Official Analytical Chemists; CFU = colony forming unit; DW = dry weight; FDA-BAM = Food and Drug Administration – Bacteriological Manual; GC-FID = gas chromatography – flame ionisation detection; ICP-MS = Inductively coupled plasma – mass spectrometry; mod. = modified; TAMC = total aerobic microbial count; TYAM = total yeast and mould count; UHPLC-MS/MS = ultra-high pressure liquid chromatography – tandem mass spectrometry.

Batch to batch analysis confirmed that the protein content (78.11 – 79.71 % DW) complies with the specification limit. Ash (3.08 – 6.33 % DW), carbohydrates (7.46 – 13.13 % DW), fat (5.33 – 9.68 % DW) and moisture (1.80 – 3.00 % DW) also comply with their respective specification limits.

Aflatoxins were below the limit of quantification in four out five batches of the novel food. In one batch, aflatoxin B1 (0.619 µg/kg) and total aflatoxins (2.119 µg/kg) were present, but were within specification.

Arsenic (0.019 – 0.028 mg/kg), cadmium (0.020 – 0.035 mg/kg) and lead (0.023 – 0.046 mg/kg) were present at very low levels in all batches of the novel food, and mercury (0.01 mg/kg) was present in three out of five batches of the novel food (0.005 – 0.008 mg/kg), but at very low levels. All heavy metals were present in the starting materials – pea protein extract and rice protein. All values were below the specification level and complied with assimilated Regulation (EC) No 1881/2006 for setting maximum levels for certain contaminants in foodstuffs (cadmium and lead in vegetables at 0.05 mg/kg and 0.1 mg/kg, respectively; arsenic in non-parboiled milled rice at 0.2 mg/kg).

Pesticides residues were below the limit of detection. Glyphosate was reported at levels between 0.01 mg/kg and 0.05 mg/kg, which is under the lowest maximum residue limit (MRL) of 0.05 mg/kg.

EFSA considered that the information provided on the composition was sufficient for characterising the novel food (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this conclusion and no further assessment on the composition of the novel food was considered necessary.

Two separate stability studies were conducted on two independently produced batches of novel food under accelerated conditions (40°C and 75 % relative humidity) for 168 days and 224 days, respectively. Both batches were assessed for the following parameters: pH, colour, moisture, protein and nitrogen. In addition, other macronutrients, amino acid profile, and microbiological contaminants were also assessed in the second study only. The novel food was found to be stable under these accelerated conditions for 168 – 224 days. From these results, a shelf-life of two years for the novel food at 25°C was proposed.

Further stability data was provided to support the proposed shelf-life of 2 years for the novel food. To simulate real-time storage of 3.5 years, a third batch of novel food, which was 659 days old, was used as a starting material and stored under accelerated conditions (40°C and 75 % relative humidity) for 24 weeks. The simulated age of the novel food was calculated by applying a factor of 3.25, which is derived from the Arrhenius equation to the duration of the accelerated stability study.

The following parameters were assessed: macronutrients, colour, pH, lipid oxidation (thiobarbituric acid, hexanal), microbiological parameters (aerobic plate count, mould, yeast, *E. coli*, coliforms, *S. aureus*, *B. cereus*), and sensorial analysis. The novel food was found to be stable under these accelerated conditions.

EFSA concluded that sufficient data had been provided to support the 2-year shelf-life for the novel food (EFSA NDA Panel, 2022).

The FSA and FSS agreed that the data supported the proposed shelf-life of two years and no further assessment on the stability of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia was considered necessary.

An assessment of the stability of the novel food in different food categories was conducted. A plant-based burger meat analogue and a plant-based whole milk analogue (unflavoured) were stored at 5°C for 10 and 14 days, respectively. A chocolate chip muffin was stored at 25°C and 60 % relative humidity for 10 days. Samples collected from each food category reported no changes in the visual appearance, acrylamide, macronutrients, heavy metals, and amino acid concentrations.

An increase in the microbiological parameters was reported for all food categories. This is consistent with the microbial growth observed during the storage of highly perishable food matrices. It was noted that the novel food itself has very low total microbial counts and low water activity.

Therefore, the reported microbiological levels in these food categories are related to the quality of the food matrices themselves rather than the novel food.

EFSA concluded that the stability data for the novel food as an ingredient did not raise any concerns provided the specification was met at the end of the shelf and the food products containing the novel food comply with the relevant legislation (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this conclusion and no further assessment on the stability of the novel as an ingredient in different food categories was considered necessary.

2.1.4. History of Use

The novel food is pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia.

Pea, rice and their protein concentrates have a long history of consumption in the UK.

Pea (*Pisum sativum*), which is rich in protein (23 – 31 %), is a legume from the Fabaceae plant family. Pea is grown from its edible seed and cultivated as food crop extensively around the world. Pea protein is currently used as an alternative protein source in different food products due to the beneficial nutritional and functional properties (Bessada et al., 2019).

Rice (*Oryza sativa*) is a grass from the Poaceae plant family. The grass seed is a cereal which is widely consumed in the UK, EU and around the world. The content of protein in rice is 6 – 10 % depending on cultivation conditions and rice variety.

Pea protein and rice protein concentrates, which are the raw materials used to manufacture the novel food, are Generally Regarded as Safe (GRAS) as food ingredients in the USA (FDA, 2016a, 2016b).

The mycelium of Shiitake (*Lentinula edodes*) which is used to manufacture the novel food has no history of use in the UK or the EU. There is a recognised history of consumption for the fruiting body of *Lentinula edodes* in Europe and the UK. *Lentinula edodes* is cultivated and consumed across Asia, where the dried and fresh forms are a feature in Chinese, Japanese, Korean and Thai cuisines (EFSA NDA Panel, 2010).

Pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia is GRAS as a food ingredient in the USA (FDA, 2020).

2.1.5. Proposed Use and Intake

The target population is the general population.

The intended food categories and maximum use levels are listed in [Table 2](#).

Table 2. Food Categories and Maximum Use Levels for the novel food.

Food Category Name	Maximum Use Level (%)
Gluten-free bread, extruded, pressed or puffed bread, unleavened or flat bread and similar, leavened bread and similar, breadcrumbs, croutons ^(a) , bread stuffing(a), doner kebab ^(a) , pizza with cheese/fish/processed meat or meat/mushroom/vegetable ^(a) filling/topping, sandwich with cheese/fish or seafood/processed meat or meat/vegetable filling/topping ^(a)	5
Cereal bars, plain or mixed	33
Fruit nectars (minimum 25–50% fruit as defined in EU legislation), fruit juices (100% from named source)	1.04
Fruit juice concentrates ^(b) , dehydrated/powdered fruit juice ^(b)	5.2
Vegetable juice concentrate ^(c) , vegetable juices, fruit smoothies	20
Mixed fruit and vegetable juices ^(d) , multivitamin juices ^(d) , other (mixed) fruit and vegetable juices or nectars	10.5
Powdered drink bases	93.3
Muesli and similar mixed breakfast cereals, processed and mixed breakfast cereals	33
Chocolate-coated confectionery	7
Ice cream, milk-imitate based, imitation cream, non-dairy coffee creamer, imitation cheese, coconut milk (<i>Cocos nucifera</i>) liquid, milk imitates	11
Single meal replacement for weight reduction (non-milk based)	11
Mushroom salad ^(a) , mixed green salad ^(a) , mixed vegetable salad ^(a) , Caesar salad ^(a) , Greek salad ^(a) , prepared legume (beans) salad, prepared rice salad ^(a) , prepared nut salad ^(a) , prepared meat salad ^(a) , prepared mixed egg/meat/fish/vegetable salad ^(a)	26
Canned-tinned meat, sausages, meat specialties, meat in aspic, meat loaf, meat burger (no sandwich), meat balls, meat terrine, omelette with bacon ^(a) , sausage roll ^(a) , meat-based canapé ^(a) , processed whole meat products, hot dog with bread ^(a) , hamburger with bread ^(a)	14
Flavoured milks	1.04
Single meal replacement for weight reduction	1.04
Yoghurt, yoghurt drinks, including sweetened and/or flavoured variants, soya yoghurt, imitation yoghurt, non-soya	5
Pasta, plain (not stuffed), uncooked, pasta-based dishes, uncooked(a), pasta, gluten free, Gnocchi, prepared pasta salad(a), pasta, filled, cooked(a), pasta, plain (not stuffed), cooked, filled (stuffed) pastas(a)	15
Meat imitates	40
Soups (ready-to-eat), soups (dry mixture, uncooked)	3.3

^(a) Recipe – only the proportion of food reflecting the amount of the target food is to be considered in the intake assessment.

^(b) Use level for fruit juice (1,040 mg/100 g) multiplied by 5 to account for it being a concentrate, which brings it to the volume as consumed.

^(c) Use level for vegetable juice (20,000 mg/100 g) multiplied by 5 to account for it being a concentrate, which brings it to the volume as consumed.

^(d) Assumed that half of the beverage was fruit juice and half was vegetable juice. Fruit juice: 1040 mg/100 g use level 50%, vegetable juice: 20,000 mg/100 g use level 50%.

^(e) 93,300 mg of novel food (NF) per 100 g powder – assumes 32.67 g NF per 35 g powder per serving.

The intended uses of the novel food include food categories that are not generally recognised as sources of protein.

EFSA conducted an intake assessment using the summary statistics of consumption from the dietary surveys in the EFSA Comprehensive European Food Consumption Database by matching the proposed conditions of use with the FoodEx2 categories (EFSA NDA Panel, 2022).

The estimated mean and 95th percentile intake levels of the novel food from the intended conditions of use for each population group on an absolute and a body weight basis are presented in [Table 3](#).

Table 3. The estimated daily intake of the novel food on an absolute basis and a body weight basis from the intended food uses and maximum use levels.

Population Group	Mean Intake of the NF (g/day)	P95 intake of the NF (g/day)	Mean Intake of the NF (g/kg BW/day)	P95 intake of the NF (g/kg BW/day)
Infants	0.9 – 7.8	4.3 – 29.4	0.1 – 1.0	0.5 – 3.7
Young children	6.5 – 26.0	17.4 – 35.6	0.6 – 1.9	1.7 – 3.1
Other children	13.4 – 34.2	26.6 – 67.0	0.7 – 1.2	1.4 – 2.4
Adolescents	13.8 – 35.0	26.9 – 75.2	0.3 – 0.8	0.5 – 1.7
Adults	20.3 – 41.9	40.9 – 86.7	0.3 – 0.6	0.8 – 1.2

BW = body weight; NF = novel food; P95 = 95th percentile.

Infants < 1 year; young children 1 to < 3 years; other children 3 to < 10 years; adolescents 10 to < 18 years; adults ≥ 18 years.

The highest mean and 95th percentile intake levels on an absolute basis were reported in the adolescent population group at 35.0 g/day and the adult population group at 86.7 g/day, respectively. On a body weight basis, young children reported the highest mean intake at 1.9 g/kg BW/day, and infants reported the highest 95th percentile intake at 3.7 g/kg BW/day.

The FSA and FSS considered that no further assessment on the proposed uses and estimated intake levels for the novel food using the EFSA Comprehensive European Food Consumption Database was necessary.

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

No ADME studies were conducted on the novel food, which is mainly composed of protein (≥ 75 % dry weight).

EFSA considered that no ADME studies were necessary for the safety assessment of the novel food (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this decision and considered that no further assessment was required given the nature of the novel food.

3.1.7. Nutritional Information

The novel food is mainly composed of protein (≥ 75 % dry weight).

An assessment of the protein quality of the novel food was conducted by calculating the Protein Digestibility Corrected Amino Acid Scores (PDCAAS) and the Digestibility Indispensable Amino Acid Scores (DIAAS). These parameters were calculated for an 'unfermented blend' of pea and rice protein and the fermented pea and rice blend.

The amino acid profile, from five independent batches of the novel food, was provided to support the derivation of PDCAAS and DIAAS ([Table 4](#)).

The impact of the fermentation process on the pea and rice protein was investigated. The crude protein content in the 'unfermented blend' of pea and rice protein and the novel food was similar. The content of indispensable amino acids was also comparable in both samples; however, the lysine content was 25 % higher in the 'unfermented blend' of pea and rice protein compared to the novel food.

An *in vivo* study (Bailey & Stein, unpublished; Clark et al., 2022) was conducted to investigate the ileal digestibility of the novel food and the 'unfermented blend' of pea and rice protein. The results from this study were used to derive the standardised total tract digestibility (STTD) of the indispensable amino acids and crude protein, and the standardised ileal digestibility (SID) of crude protein. These two values are used to calculate the PDCAAS and DIAAS, respectively.

The PDCAAS and DIAAS were compared to the FAO recommended amino acid scoring patterns (FAO, 2013) for the age groups 'child 6 months to 3 years' and for 'older child, adolescent, adult' (> 3 years).

PDCAAS values for the 'unfermented blend' of pea and rice protein and the novel food were similar for both age groups. For children aged 6 months to 3 years, PDCAAS values for the unfermented protein blend and the novel food were 86 and 91, respectively. For older children, adolescents and adults, the values were 101 and 108, respectively. The first limiting amino acids are the sulphur amino acids for the 'unfermented blend' of pea and rice protein and lysine for the novel food.

Table 4. The amino acid profile from five independent batches of novel food.

Amino acid	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Alanine (%)	3.71	3.66	3.75	3.67	3.77
Arginine (%)	6.25	6.30	6.35	6.51	6.38
Aspartic Acid (%)	8.16	8.04	8.25	8.19	8.29
Glutamic Acid (%)	13.35	13.36	13.56	13.74	13.57
Glycine (%)	3.20	3.17	3.24	3.20	3.26

Amino acid	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
Histidine (%)	1.77	1.81	1.83	1.89	1.84
Isoleucine (%)	3.61	3.61	3.71	3.67	3.71
Leucine (%)	6.48	6.42	6.60	6.54	6.65
Phenylalanine (%)	4.23	4.17	4.30	4.23	4.32
Proline (%)	3.47	3.48	3.54	3.49	3.58
Serine (%)	3.86	3.74	3.87	3.82	3.90
Threonine (%)	2.81	2.73	2.82	2.76	2.84
Total lysine (%)	4.39	4.37	4.52	4.61	4.52
Tyrosine (%)	3.15	3.17	3.26	3.23	3.29
Valine (%)	4.29	4.32	4.41	4.36	4.42
Cysteine (%)	0.81	0.90	0.89	0.92	0.87
Methionine (%)	1.26	1.32	1.36	1.32	1.41
Tryptophan (%)	0.78	0.83	0.82	0.84	0.83

The calculated DIAAS scores for both age groups were greater ($p < 0.05$) for the novel food than for the 'unfermented blend' of pea and rice protein. The DIAAS values for the 'unfermented blend' of pea and rice protein were 70 for children aged 6 months to 3 years, and 82 for older children, adolescents and adults, respectively. For the novel food, the DIAAS values for the novel food were 86 for children aged 6 months to 3 years, and 102 for older children, adolescents and adults. The first limiting amino acids are the sulphur amino acids for the 'unfermented blend' of pea and rice protein and lysine for the novel food.

Based on the Food and Agriculture Organisation (FAO) guidelines (FAO, 2013), the DIAAS values for the novel food meet the criteria to be classified as a 'good' quality protein (DIAAS 75 – 99).

The estimated 95th percentile protein intakes from consumption of the novel food by different population groups (Table 5) were derived from the lowest specification limit for protein (75 % dry weight) and the 95th percentile estimated intakes of the novel food on a body weight basis (Table 3).

Table 5. Estimated high level protein intake from consumption of the novel food (75 % protein dry weight) from the intended food categories and maximum use levels.

Population Group	Highest P95 intake of NF (g/kg BW/day)	Highest P95 protein intake from NF (g/kg BW/day)	Population reference intake for protein (g/kg BW/day)
Infants	3.7	2.8	1.31 *
Young children	3.1	2.3	0.97 – 1.14 **
Other children	2.4	1.8	0.85 – 0.92
Adolescents	1.7	1.3	0.83 – 0.91

Population Group	Highest P95 intake of NF (g/kg BW/day)	Highest P95 protein intake from NF (g/kg BW/day)	Population reference intake for protein (g/kg BW/day)
Adults	1.2	0.9	0.83

BW = body weight; NF = novel food; P95 = 95th percentile.

Infants < 1 year; young children 1 to < 3 years; other children 3 to < 10 years; adolescents 10 to < 18 years; adults ≥ 18 years.

* 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 highest estimated 95th percentile protein intake for consumers from all population groups exceeds the population reference intake value (EFSA NDA Panel, 2012). In the infants and young children population groups, the estimated protein intakes are 2.5 and 2.4 times higher, respectively. No tolerable upper intake level has been derived for protein. In addition, the estimated intake of the novel food is based on high consumption of a large number of food categories. This conservative scenario could result in an overestimation of the protein intake in consumers of the novel food.

Analytical data for vitamin D, sodium, potassium, calcium and iron from five independent batches of novel food was provided. Except for the iron content, the contribution of these other nutrients to the diet was not considered a concern.

The highest estimated 95th percentile intake for iron from consumption of the novel food in infants, young children, other children, adolescents, and adults is 5.7, 6.9, 12.9, 14.5 and 16 mg/day, respectively. EFSA recently reviewed the tolerable upper intake level (UL) iron but were unable to establish a value due to insufficient data. Instead, a safe level of 40 mg/day for adults was derived. For all other population groups, allometric scaling was used to derive their respective safe levels (EFSA NDA Panel, 2024). The highest estimated 95th percentile intake for iron from the novel food for all population groups, except for infants, is lower than the corresponding safe levels for iron.

The highest estimated 95th percentile intake for iron in infants is 5.7 mg/day and the corresponding EFSA safe level is 5 mg/day. When the novel food intake assessment was conducted using the dietary surveys in the EFSA Comprehensive Food Consumption Database, the UK was still a Union Member State. Based on the UK Diet and Nutrition Survey of Infants and Young Children (DNSIYC, 2011) survey, the estimated 95th percentile intake for iron in the UK infant population groups was reported as 2.99 mg/day. Therefore, the exposure levels for iron in all population groups are not a cause for concern.

Lentinula edodes mycelia are present in the novel food (< 0.1 % w/w). Although the fungal mycelia consist primarily of carbohydrates, with low amounts of fibre and protein, and a small quantity of fat, these

macronutrients are not nutritionally relevant given the small quantities of *Lentinula edodes* present in the novel food. The other raw materials, carrot powder and maltodextrin, are not expected to have any adverse or anti-nutritional effects on consumers.

The levels of anti-nutrients in the starting materials, pea protein and rice protein concentrates, the unfermented blend of pea and rice protein, and the novel food were reported.

The average phytic acid content in the novel food was 0.95 %. EFSA noted that this value is within the range of the anti-nutrients in the human diet.

Lectin analysis could not be performed on the novel food due to the proteinaceous matrix. Therefore, the presence of this anti-nutrient in the novel food could not be quantified. EFSA noted that the novel food undergoes thermal processing during the production process which should be sufficient to destroy lectin activity. For this reason, lectin is not expected to be present in the novel food.

EFSA concluded that consumption of the novel food is not expected to be nutritionally disadvantageous considering the composition of the novel food and the intended conditions of use (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this conclusion and no further assessment on the nutritional information of the novel food was considered necessary.

2.1.8. Toxicological Information

No toxicological information was provided.

EFSA considered that no toxicological studies were required for the novel food given the nature of the novel food and the history of safe use of the raw materials, pea protein concentrate and rice protein concentrate (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this decision and considered that no further toxicological studies on the novel food were necessary.

2.1.8.1. Human trials

No human trials were conducted with the novel food.

EFSA considered that no human studies were required for the novel food given the nature of the novel food and the history of safe use of the raw materials (EFSA NDA Panel, 2022).

The FSA and FSS agreed with this decision and considered that no further human studies on the novel food were necessary.

2.1.9. Allergenicity

Analytical data was provided to confirm that the food allergens listed in Annex II of assimilated Regulation (EU) 1169/2011 were absent in the novel food.

A literature review confirmed that allergic reactions to pea (Sanchez-Monge et al., 2004), rice (Jeon et al., 2011) and *Lentinula edodes* mushrooms (Nguyen et al., 2017) have been reported.

EFSA concluded that allergic reactions could potentially occur due to consumption of the novel food in individuals with allergy to pea, rice and/or *Lentinula edodes* mushroom (EFSA NDA Panel, 2022). However, according to EFSA, this risk is not expected to be any higher compared to normal consumption of pea, rice, or the fruiting body of the *Lentinula edodes* mushroom (EFSA GMO Panel, 2021).

To provide information on the extent of clinically relevant allergy in the UK adult population, the FSA and FSS interrogated the Patterns and Prevalence of Adult Food Allergy (PAFA) study (University of Manchester, 2024) for information on the prevalence of allergy to pea, rice and shiitake mushroom.

While confirmed diagnostic data are lacking, self-reported symptoms suggest that adverse reactions to pea and rice occur in the UK adult population, with rice showing a slightly higher estimated prevalence than pea. These prevalence levels are broadly comparable to other legumes and grains that are not listed in UK food allergen legislation. Data on the prevalence of allergy to shiitake mushrooms in UK adults, or to pea, rice or shiitake mushroom in UK children, was not available.

There is also anecdotal evidence from clinicians and allergy support organisations of allergic reactions to pea proteins in the GB population.

Data for adults in the UK suggest that a crude estimate of prevalence of self-reported possible immunoglobulin E (IgE)-mediated food allergy to pea is 0.82 %. Self-reported allergies to other legumes, such as peanut (3.40 %) and soya (1.58 %), are higher in the UK adult population (University of Manchester, 2024).

Only pea and rice were explored further in this assessment as data on those with food hypersensitivity to Shiitake mushrooms was not available.

Pea, and peanut (listed in UK food allergen legislation), are both legumes which belong to the Fabaceae plant subfamily. Cross-reactivity between pea and peanut (Wensing et al., 2003), as well as pea with lentil and chickpea, has been reported (Martínez San Ireneo et al., 2008). Therefore,

the potential risk of IgE-mediated allergic reactions due to cross-reactivity of pea protein in consumers with a clinically recognised legume allergy was reviewed.

Pea (*Pisum sativa*) and lentil (*Lens Culinaris*) are members of the Viciae tribe, whilst chickpea (*Cicer arietinum*), is a member of the close relatedly Cicereae tribe. Peanut (*Arachis hypogea*) belongs to the phylogenetically more distant Dalbergieae tribe. A comparison of the amino acid sequences for the 7S and 11S globulins in pea and peanut reports 53.1 % and 50.9% sequence homology, respectively (Smits et al., 2023). The potential for cross-reactivity between allergenic proteins is reported to be indicated where the sequence homology > 50% (McClain, 2017).

Whilst high co-sensitisation (where IgE antibodies bind but do not necessarily target common structural features in proteins) rates with other legumes have been reported in pea allergic patients, this is not always clinically relevant. However, IgE-mediated allergic reactions due to cross-reactivity in a legume allergic population cannot be excluded because co-sensitisation and co-allergy (presence of clinical allergic reactions for two or more sources) have been observed in multiple legume-allergic patient groups (Smits et al., 2023).

Similarly, crude data on possible self-reported IgE-mediated reactions to foods suggests the prevalence of rice allergy in the UK adult population is 1.46%. (University of Manchester, 2024). Lisiecka (2025) reports the prevalence of rice allergy in Europe is less than 1 %; however, this includes both IgE- and non-IgE-mediated allergic reactions.

The applicant provided chronic exposure data which is required as part of the novel food assessment. To understand the potential for the novel food to sensitise or elicit clinical allergic reactions, the FSA/FSS calculated the protein exposure levels based on the proposed conditions of use of the novel food. These exposure levels were then compared to the estimated protein intake levels from pea and rice consumption in the UK diet. Shiitake mushroom was not included in the comparative protein consumption analysis due to the absence of specific consumption data for this mushroom within the UK population.

Pea protein intake from consumption of the novel food was found to be, on average, four to eight times higher than typical consumption of pea. For rice, estimates of protein exposure suggest that consumers would be exposed to five times more rice protein from the novel food compared to exposures from the normal consumption of rice. In some scenarios, pea protein intake was up to eleven times greater. While not unexpected from a concentrated protein source, this does raise questions on whether consumption of pea or rice protein at levels exceeding those typically

observed in the UK diet may increase the likelihood of sensitisation and whether this could lead to an increase in the prevalence of allergy to pea or rice in the UK population.

No established threshold of protein intake has been identified as a trigger for allergic reactions to pea or rice. Consequently, we are unable to estimate the extent to which the higher doses that may be consumed when eating these novel foods could lead to an increase in the number of reactions in people who are already allergic to pea or rice.

There is uncertainty regarding the degree to which the higher doses of pea and rice allergens due to consumption of the novel food may increase reaction severity.

There remain uncertainties on whether the fermentation process used in the production process impacts the allergenicity of pea or rice proteins present in the novel food. One published report suggests fermentation may reduce allergenicity of pea (Barkholt et al., 1998). However, the information required to assess the impact of fermentation on the allergenic potential or proteins in food is not currently available.

The data reviewed highlight the potential for allergic reactions from the novel food in consumers who are allergic to pea and rice. Although the estimated prevalence of self-reported possible IgE-mediated allergy to pea in the UK adult population is only 0.82%, and comparable to other legumes not listed in UK allergen legislation, risk managers may wish to consider the potential for increased exposure to pea protein via consumption of the novel food.

The FSA and FSS have reviewed and accept the EFSA opinion. However, the potential for *de novo* sensitisation and for cross-reactivity in GB consumers with clinically relevant legume allergies, given the estimated high intake levels of pea protein from the novel food compared to the traditional diet is noted.

Consumption of the novel food may be a risk to GB consumers who are allergic to pea or rice. Risk managers are advised to consider whether consumer-facing information is needed to ensure that those with an existing food allergy to pea and or rice in GB can avoid the novel food, particularly as there is potential for elevated pea and rice protein exposure through use of this novel food and because it is intended for use in products consumers would not normally expect to contain pea or rice protein.

3. Other Regulators Opinions and Conclusions

The novel food is pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia with a protein content ≥ 75 % (dry weight) and < 0.1 % weight *Lentinula edodes* mycelia biomass.

The novel food is intended to be used by the general population in a number of food categories. This includes food products that are not normally considered as sources of protein.

The estimated highest 95th percentile intake of the novel food using the EFSA Comprehensive European Food Consumption Database is 3.7 g/kg BW/day in the infant population group.

The novel food is a source of good quality protein and provides sufficient amounts of essential amino acids. The estimated 95th percentile protein intakes from chronic consumption of the novel food exceeds the PRI for protein for all population groups. For the infant and young children population groups, the estimated 95th percentile protein intake levels are 2.5- and 2.4-fold above the PRI values, respectively.

Although there is no tolerable upper intake level for protein, the consumption of the novel food may contribute to the existing high protein intake in the European diet (EFSA NDA Panel, 2012). However, the intake estimates are conservative and may overestimate the protein intake from the novel food.

The different starting materials present in the novel food are not considered to have any adverse or antinutritional effect on consumers under the intended conditions of use.

No toxicological studies were provided. Given the nature of the novel food and the history of safe use, toxicological studies were not considered necessary.

The novel food contains pea, rice and *Lentinula edodes*, which are reported to trigger allergenic reactions in sensitised individuals. However, this risk is not expected to be any higher compared to normal consumption of pea, rice, or the fruiting body of the *Lentinula edodes* mushroom.

The novel food, pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia, is safe under the intended conditions of use.

4. Uncertainties and Limitations

No specific uncertainties were flagged in the assessment by EFSA.

The FSA and FSS noted that the following additional uncertainties in the allergenicity assessment of the novel food:

- The PAFA study (University of Manchester, 2024) reports the crude estimate of prevalence of self-reported possible IgE-mediated food allergy in UK adults to pea and rice is 0.82 % and 1.46 %, respectively. However, confirmed diagnostic data for UK adults are lacking, and no current data are available for UK children. The prevalence of clinically confirmed allergy to rice and pea in GB consumers is therefore not known.
- Cross-reactivity between pea and other legumes has been reported (Martínez San Ireneo et al., 2008; Wensing et al., 2003). Therefore, IgE-mediated allergenic reactions due to cross-reactivity in a legume allergic population cannot be excluded, although the extent to which this might happen is uncertain.
- Estimates for the consumption of pea protein and rice protein from the novel food exceed those typically found in the background diet. This may potentially lead to an increase in the likelihood of sensitisation and prevalence of allergy to pea protein and rice protein in GB consumers, although the extent to which this might happen is uncertain.
- There is no established threshold for pea protein or rice protein to trigger allergic reactions. Therefore, the extent to which higher doses could result in an increase in the number of reactions and/or increase the severity of the allergic reaction in consumers with a clinically relevant allergy to these foods cannot be estimated.
- There remain uncertainties regarding whether the fermentation process used in the production process impacts on the allergenicity of pea proteins present in the novel food.

5. FSA-FSS conclusion for GB assessment

The application has been evaluated in line with 'Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of assimilated Regulation (EU) 2015/2283 (EFSA NDA Panel, 2016), and assimilated Commission Implementing Regulation (EU) 2017/2469, for purposes of the GB assessment.

The conclusions of the EFSA opinion (EFSA NDA Panel, 2022), which have been reviewed in detail by the FSA and FSS for the purposes of the GB assessment, are considered appropriate and consistent within the uncertainties and limitations identified by EFSA.

6. Outcome of the assessment

The FSA and FSS has reviewed the applicant's dossier, supporting documentation, and most notably the EFSA opinion (EFSA NDA Panel, 2022), and consider that there is sufficient evidence to conclude the assessment of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia without obtaining further information or conducting a further risk assessment.

The FSA and FSS conclude that pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia is safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food is not considered to be nutritionally disadvantageous.

In making this assessment, the FSA and FSS were able to rely on sufficient scientific evidence to make a conclusion on safety with no further questions to the applicant, and therefore no further risk assessment activities are necessary.

Sufficient evidence was available in the literature to give the FSA and FSS confidence about the safety of this novel food, for example, where other national food safety authorities had positively assessed the application using the same risk assessment guidance and core legal requirements which apply in GB.

Applicants provided sufficient relevant information as requested by the FSA and FSS.

The FSA and FSS review did not find any issues of divergence from the EFSA guidance (EFSA NDA Panel, 2021) or mutual approaches or new scientific issues for consideration.

There was additional consideration of the allergenicity of the novel food; however, the review did not consider this altered the conclusion on the safety of the novel food.

Risk managers are advised to consider whether labelling is required to ensure that those with an existing food allergy to pea or rice in GB can avoid the novel food, particularly as there is potential for elevated pea and rice protein exposure through use of this novel food and because it is intended for use in products consumers would not normally expect to contain pea or rice protein.

There were no other specific issues that would require an assessment for the UK or the nations of the UK.

The FSA and FSS could not have completed the assessment of the novel food under the proposed conditions of use without the following data claimed as proprietary by the applicant:

- i. the detailed novel production process
- ii. data concerning the composition and analysis of the novel food

Abbreviations

ACNFP	Advisory Committee on Novel Foods and Processes
AOAC	Association of Official Analytical Chemists
BW	Body weight
CFU	Colony Forming Unit
DIAAS	Digestibility Indispensable Amino Acid Scores
DW	dry weight
EFSA	European Food Safety Agency
EU	European Union
FAO	Food and Agriculture Organisation
FDA-BAM	Food and Drug Administration – Bacteriological Manual
FSA	Food Standards Agency
FSS	Food Standards Scotland
GB	Great Britain
GC-FID	Gas chromatography – flame ionisation detection
HACCP	Hazard Analysis and Critical Control Point
ICP-MS	Inductively coupled plasma – mass spectrometry
ITS	Internal Transcribed Spacer
Mod.	Modified
MRL	Maximum residue limit
NF	Novel food
P95	95th percentile
PAFA	Patterns and Prevalence of Adult Food Allergy
PDCAAS	Protein Digestibility Corrected Amino Acid Scores
PRI	Population reference intake
SCF	Scientific Committee on Food
SID	standardised ileal digestibility
STID	standardised total tract digestibility
TAMC	total aerobic microbial count
TYAM	total yeast and mould count
UHPLC-MS/MS	Ultra-high pressure liquid chromatography – tandem mass spectrometry

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