

# Safety Assessment of Pea Protein Fermented by Shiitake (*Lentinula Edodes*) Mushroom Mycelia as a Novel Food (RP1759)

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## FSA Research and Evidence

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The Food Standards Agency (FSA) and Food Standards Scotland (FSS) received an application in October 2022 from MycoTechnology, Inc. ("the applicant") for authorisation of pea protein fermented by Shiitake mycelia as a novel food.

The novel food is manufactured by fermentation of pea protein concentrate with Shiitake mycelia. The resulting biomass is concentrated and spray dried to a powder.

The novel food is intended for use by the general population in the following food categories: dairy analogues; margarine; nut butters; breakfast cereals; baked goods; meat products; soups; protein products, excluding products covered in category 1.8; iced coffee; ready-to-eat snacks; and foods intended for total diet replacement for weight control, as defined in assimilated Regulation (EU) 609/2013.

Potential de novo sensitisation to pea protein and cross-reactivity in legume allergic consumers due to consumption of the novel food, which contains higher levels of pea protein compared to the traditional diet, cannot be disregarded.

Consumption of the novel food would likely be a risk to pea-allergic consumers; risk managers may wish to consider labelling as some proposed food categories are not generally recognised as sources of pea protein.

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 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 the novel food was safe under the proposed conditions of use. The anticipated intake levels and the proposed use in food and beverages 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 October 2022, MycoTechnology, Inc (“the applicant”) submitted a full novel food application for the authorisation of pea protein fermented by Shiitake mycelia. The novel food, pea protein fermented by shiitake mycelia, is intended to be used as a protein source in a range of foods and beverages, such as dairy analogues, fats and oil emulsions including spreads, breakfast cereals and baked goods, protein products and meals for weight control.

FSA and FSS have undertaken a safety assessment for pea protein fermented in Shiitake mycelia under the novel foods legislation, in line with Article 11 of 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 regulatory framework and the technical guidance put in place by the European Food Safety Agency (EFSA) for full novel food applications is retained as the basis and structure for the assessment (EFSA NDA Panel, 2016).

This assessment outlines the conclusions of the FSA and FSS on the safety of pea protein fermented by Shiitake mycelia as a novel food.

## 2. Assessment

### 2.1. Identity of the novel food

The novel food is pea protein fermented by Shiitake mycelia. Both the pea and Shiitake proteins are present in the final novel food. The novel food provides a total of  $\geq 75\%$  protein on dry weight basis. The estimated level of Shiitake mycelia biomass in the final product is  $< 0.1\%$  by weight.

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 – Shiitake mycelia. (Aminuddin et al., 2007, 2013; Tsivileva et al., 2005).

The strain of *Lentinula edodes* (Shiitake mushroom mycelia) used to produce the novel food was originally obtained from Pennsylvania State University, ID No. WC 1008 (<https://plantpath.psu.edu/facilities/mushroom/cultures/spawn>). 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*.

### 2.2. 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, pea protein concentrate, along with maltodextrin and carrot powder, which are nutrients for the *Lentinula edodes* mycelia, 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 forty hours. The growth of the *Lentinula edodes* mycelia 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.

The absence of viable Shiitake mycelia was investigated in four independent batches of the novel food, with each batch tested in triplicate. The results showed that there was no fungal mycelia growth in any of

sample plates at the end of the 7-day incubation period. Fungal mycelia growth was observed in the positive control plates that contained untreated Shiitake mycelia. The temperature used to inactivate the Shiitake mycelia was also considered adequate to manage the microbial content of the novel food.

The conditions utilised in the concentration and spray-drying steps of the novel food manufacturing process are consistent with those which denature and deactivate enzymes. The absence of fungal enzymes in the novel food was confirmed by testing for residual laccase enzyme activity and tyrosinase activity after termination of fermentation. The results confirmed that the enzymes secreted by the Shiitake mycelia during the manufacturing process were inactivated.

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).

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

## 2.3 Compositional information

Results from the nutrient profile analysis for five independent batches of novel food is reported in [Table 1](#).

Table 1. Analysis of the macronutrient profile for five independent batches of novel food

| Parameter                         | Specification | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|-----------------------------------|---------------|---------|---------|---------|---------|---------|
| Protein (N x 6.25) (% dry weight) | ≥ 75          | 76.25   | 75.44   | 75.19   | 73.94   | 77.75   |
| Moisture (%)                      | ≤ 7           | 2.6     | 3.0     | 3.5     | 2.3     | 1.8     |
| Ash (%)                           | ≤ 10          | 4.31    | 4.16    | 6.06    | 3.68    | 5.95    |
| Total fat (%)                     | ≤ 10          | 8.99    | 8.89    | 8.61    | 9.18    | 7.72    |
| PUFA (%)                          |               | 3.72    | 3.76    | 3.5     | 4.14    | 3.49    |
| MUFA (%)                          |               | 2.90    | 2.84    | 2.81    | 2.42    | 2.06    |
| SFA (%)                           |               | 1.92    | 1.85    | 1.87    | 2.16    | 1.79    |
| Total TFA (%)                     |               | 0.05    | 0.05    | 0.05    | 0.05    | 0.04    |
| Cholesterol (mg/100 g)            |               | 0.8     | 0.8     | 0.8     | < 0.8   | < 0.8   |
| Carbohydrates (%)                 | ≤ 15          | 7.85    | 8.51    | 6.64    | 10.9    | 6.78    |
| TDF (%)                           |               | 3.21    | 5.00    | 3.90    | 5.37    | 5.7     |

| Parameter        | Specification | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|------------------|---------------|---------|---------|---------|---------|---------|
| Total sugars (%) |               | 0.81    | 1.03    | 1.03    | 1.03    | < 0.35  |

AOAC = Association of Official Analytical Chemists; GC-FID = gas chromatography – flame ionisation detector; MUFA = monounsaturated fatty acid; N = nitrogen; PUFA = polyunsaturated fatty acid; SFA = saturated fatty acid; TDF = total dietary fibre; TFA = total trans fatty acid isomers

Ash (gravimetric) – AOAC 942.05; cholesterol – AOAC 994.10; moisture and volatiles (gravimetric) – AOAC 925.09; protein (Dumas method) – AOAC 990.03, 992.15; TDF – AOAC 991.43 modified; total fat, MUFA, PUFA, SFA and total TFA (GC-FID) – AOAC 996.06 modified; total sugars – AOAC 982.14 modified

The novel food primarily consists of protein (73.94 – 77.75 %) with smaller quantities of fat (7.72 – 9.18 %) and carbohydrates (6.64 – 10.9 %). Ash (3.68 – 6.06 %) and moisture (1.8 – 3.5 %) are also present.

Results from the heavy analysis for five independent batches of novel food is reported in [Table 2](#).

Table 2. Analysis of the heavy metal content for five independent batches of novel food

| Parameter       | Specification | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|-----------------|---------------|---------|---------|---------|---------|---------|
| Arsenic (mg/kg) | < 0.1         | 0.0131  | 0.0137  | < 0.010 | 0.0149  | 0.0135  |
| Cadmium (mg/kg) | < 0.1         | 0.0356  | 0.0376  | 0.0369  | 0.0304  | 0.0324  |
| Lead (mg/kg)    | < 0.3         | 0.0145  | 0.0115  | 0.0127  | 0.0094  | 0.0108  |
| Mercury (mg/kg) | < 0.1         | < 0.005 | < 0.005 | < 0.005 | < 0.005 | < 0.005 |

AOAC = Association of Official Analytical Chemists; ICP-MS = inductively couple plasma – mass spectrometry  
Heavy metals (ICP-MS) – AOAC 2011.49 and 993.14 (modified)

Mercury was below the limit of quantification for all batches of the novel food. Arsenic, cadmium and lead were present at very low levels, but within their respective specification limits. There are no specific limits for arsenic and mercury in fungi, according to assimilated Commission Regulation (EC) No. 1881/2006, setting maximum levels for certain contaminants in foodstuffs. Specific levels for cadmium (0.20 mg/kg) and lead (0.30 mg/kg) are defined in this assimilated regulation for *Lentinula edodes*. Based on this information, the levels of heavy metals in the novel food are not a cause for concern.

Five independent batches of the novel food were screened for pesticide residues (AOAC 2007.01 – GC-MS/MS and LC-MS/MS). Glyphosate was below the limit of detection (< 0.01 mg/kg) for three batches of novel food, but present in two batches at 0.01 mg/kg and 0.05 mg/kg, respectively. There is no maximum residue limit (MRL) for glyphosate in the novel food; however, the MRL for peas is 10 mg/kg (assimilated Regulation (EU) 293/2013). All other screened pesticide residues were below the limit of detection. On this basis, pesticide residues in the novel food were not considered to be a cause for concern.

Results from the microbiological analysis for five independent batches of novel food is reported in [Table 3](#).

Table 3. Analysis of the microbiological quality for five independent batches of the novel food

| Parameter                                 | Specification | Batch 1 | Batch 2   | Batch 3 | Batch 4 | Batch 5   |
|-------------------------------------------|---------------|---------|-----------|---------|---------|-----------|
| APC (CFU/g)                               | < 5,000       | < 10    | < 10      | < 10    | 1,100   | 20 (est.) |
| Yeast (CFU/g)                             | < 100         | < 10    | 60 (est.) | < 10    | < 10    | < 10      |
| Moulds (CFU/g)                            | < 100         | < 10    | < 10      | < 10    | < 10    | < 10      |
| Coliforms (CFU/g)                         | < 10          | < 10    | < 10      | < 10    | < 10    | <10       |
| <i>Escherichia coli</i> (CFU/g)           | < 10          | < 10    | < 10      | < 10    | < 10    | < 10      |
| <i>Staphylococcus aureus</i> (CFU/g)      |               | < 10    | < 10      | < 10    | < 10    | < 10      |
| <i>Bacillus cereus</i> (CFU/g)            |               | < 10    | < 10      | < 10    | < 10    | < 10      |
| <i>Salmonella</i> spp. (ND in 25g)        | ND in 25 g    | ND      | ND        | ND      | ND      | ND        |
| <i>Listeria monocytogenes</i> (ND in 25g) | ND in 25 g    | ND      | ND        | ND      | ND      | ND        |
| Water activity at 25°C                    |               | 0.102   | 0.124     | 0.211   | 0.103   | 0.089     |

AOAC = Association of Official Analytical Chemists; APC = aerobic plate count; est. = estimated; FDA-BAM = Food and Drug Administration – Bacteriological Analytical Manual; ND = not detected

APC – AOAC 966.23; total coliforms – AOAC 991.14; *Bacillus cereus* – FDA BAM Chapter 14; *Listeria monocytogenes* – AOAC-RI 061703; moulds and yeasts – FDA BAM Chapter 18; *Salmonella* spp. – AOAC-RI 121501; *Staphylococcus aureus* – FDA BAM Chapter 12; water activity – AOAC 978.18 modified

APC, yeasts, moulds, coliforms and *Escherichia coli* were below their respective specification limits in all five batches of the novel food tested. *Listeria monocytogenes* and *Salmonella* were absent in 25 g for all batches of novel food.

Solid state cultivation of Shiitake mycelia is a well-known process for producing Shiitake mushrooms as a food (Van der Molen et al., 2017). Neither Shiitake mushrooms or Shiitake mycelia are known to produce mycotoxins during the growth of the mycelia or during the fruiting phase (Han et al., 2014) using solid state cultivation conditions. Reports also indicate that mycotoxins are not produced when Shiitake mycelia is grown under aqueous culture conditions (Van der Molen et al., 2017).

A literature search failed to identify any reports for which *Lentinula edodes* or closely related fungal species (*Schizophyllum commune*; *Gymnopus luxurians*) have been associated with the production of mycotoxins or other toxic compounds.

Analysis of the *Lentinula edodes* genome identified a total of 32 metabolite gene clusters; however, none are involved in the production of known fungal toxins (Chen et al., 2016).

Results from the mycotoxin analysis for five independent batches of novel food is reported in [Table 4](#).

Table 4. Analysis of the mycotoxin content for five independent batches of the novel food

| Parameter              | Specification | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|------------------------|---------------|---------|---------|---------|---------|---------|
| Aflatoxin B1 (µg/kg)   | < 1           | < 0.500 | < 0.500 | < 0.500 | < 0.500 | < 0.500 |
| Aflatoxin B2 (µg/kg)   | < 1           | < 0.500 | < 0.500 | < 0.500 | < 0.500 | < 0.500 |
| Aflatoxin G1 (µg/kg)   | < 1           | < 0.500 | < 0.500 | < 0.500 | < 0.500 | < 0.500 |
| Aflatoxin G2 (µg/kg)   | < 1           | < 0.500 | < 0.500 | < 0.500 | < 0.500 | < 0.500 |
| Aflatoxin M1 (µg/kg)   |               | < 0.500 | < 0.500 | <0.500  | < 0.500 | < 0.500 |
| Aflatoxin M2 (µg/kg)   |               | < 0.500 | < 0.500 | <0.500  | < 0.500 | < 0.500 |
| Deoxynivalenol (µg/kg) |               | < 100   | < 100   | < 100   | < 100   | < 100   |
| Fumonisin B1 (µg/kg)   |               | < 25.0  | < 25.0  | < 25.0  | < 25.0  | < 25.0  |
| Fumonisin B2 (µg/kg)   |               | < 25.0  | < 25.0  | < 25.0  | < 25.0  | < 25.0  |
| HT-2 Toxin (µg/kg)     |               | < 100   | < 100   | < 100   | < 100   | < 100   |
| Ochratoxin A (µg/kg)   |               | < 1.00  | < 1.00  | < 1.00  | < 1.00  | < 1.00  |
| T-2 Toxin (µg/kg)      |               | < 10.0  | < 10.0  | < 10.0  | < 10.0  | < 10.0  |
| Zearalenone (µg/kg)    |               | < 30.0  | < 30.0  | < 30.0  | < 30.0  | < 30.0  |

UHPLC-MS/MS = ultra high-performance liquid chromatography – tandem mass spectrometry

Mycotoxins analysis (UHPLC-MS/MS) – Analytical and Bioanalytical Chemistry (2012), 402 pp 2675-2686

The results confirmed that the mycotoxins were below the limit of quantification for all batches of the novel food and therefore not considered to be a cause for concern.

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

The data presented indicate the novel food can be consistently produced within the proposed specification and any hazards present were appropriately characterised.

## 2.4. Stability

No stability data for the novel food was provided. Instead, data from a stability study conducted using a similar product, pea and rice protein fermented by Shiitake mycelia (EFSA NDA Panel, 2022), was used to support the proposed shelf-life for the novel food for the following

reasons: both products are manufactured by the same fermentation process; they both utilise the same thermal treatment and spray drying methods; and the final products are stored in the same packaging under ambient conditions. The only difference between these two products is the lack of rice protein in the novel food and this is not expected to impact on the stability of pea protein fermented by Shiitake mycelia.

Two separate stability studies were conducted on two independently produced batches of pea and rice protein fermented by Shiitake mycelia 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. Pea and rice protein fermented by Shiitake mycelia food was found to be stable under these accelerated conditions for 168 – 224 days. From these results, a shelf-life of two years for pea and rice protein fermented by Shiitake mycelia at 25°C was proposed.

Further stability data was provided to support the proposed shelf-life of 2 years for the pea and rice protein fermented by Shiitake mycelia. To simulate real-time storage of 3.5 years, a third batch of pea and rice protein fermented by Shiitake mycelia, 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 pea and rice protein fermented by Shiitake mycelia 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, *Escherichia coli*, coliforms, *Staphylococcus aureus*, *Bacillus cereus*), and sensorial analysis. Pea and rice protein fermented by Shiitake mycelia was found to be stable under these accelerated conditions.

An assessment of the stability of pea and rice protein fermented by Shiitake mycelia 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 pea and rice protein fermented by Shiitake mycelia 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.

No areas of concern with the stability of the pea and rice protein were identified. It is reasonable that the stability of the novel food without the rice protein present is likely to be very similar. As such, the evidence did not suggest further examination of the stability of the novel food in this safety assessment was required.

## 2.5. Specification

The specification for the novel food ([Table 5](#)) was assessed using internationally recognised methods or determined using internally developed and validated methods.

Table 5. Specification for the novel food

| Parameter                           | Specification | Method                                     |
|-------------------------------------|---------------|--------------------------------------------|
| Protein                             | ≥ 75.0 % DW   | AOAC 990.03; AOAC 992.15                   |
| Moisture                            | ≤ 7 %         | AOAC 925.09                                |
| Ash                                 | ≤ 10 %        | AOAC 942.05                                |
| Total fat                           | ≤ 10 %        | AOAC 996.06 modified                       |
| Carbohydrates                       | ≤ 15 %        | FDA CFR 21 – calculated                    |
| Aerobic Plate Count                 | < 5,000 CFU/g | AOAC 966.23                                |
| Coliforms                           | < 10 CFU/g    | AOAC 991.14                                |
| Yeast and Mould                     | < 100 CFU/g   | FDA-BAM Chapter 18                         |
| <i>Escherichia coli</i>             | < 10 CFU/g    | AOAC 991.14                                |
| <i>Salmonella spp.</i>              | ND in 25 g    | AOAC-RI 121501                             |
| <i>Listeria monocytogenes</i>       | ND in 25 g    | AOAC-RI 061703                             |
| Aflatoxin B1                        | < 1 µg/kg     | Anal. Bioanal. Chem (2012) 402 pp2675-2686 |
| Aflatoxin B2                        | < 1 µg/kg     | Anal. Bioanal. Chem (2012) 402 pp2675-2686 |
| Aflatoxin G1                        | < 1 µg/kg     | Anal. Bioanal. Chem (2012) 402 pp2675-2686 |
| Aflatoxin G2                        | < 1 µg/kg     | Anal. Bioanal. Chem (2012) 402 pp2675-2686 |
| Sum of Aflatoxins B1 + B2 + G1 + G2 | < 3 µg/kg     | Anal. Bioanal. Chem (2012) 402 pp2675-2686 |
| Arsenic                             | < 0.1 mg/kg   | AOAC 2011.19 and 993.14 (modified)         |
| Cadmium                             | < 0.1 mg/kg   | AOAC 2011.19 and 993.14 (modified)         |
| Lead                                | < 0.3 mg/kg   | AOAC 2011.19 and 993.14 (modified)         |

| Parameter | Specification | Method                             |
|-----------|---------------|------------------------------------|
| Mercury   | < 0.1 mg/kg   | AOAC 2011.19 and 993.14 (modified) |

AOAC = Association of Official Analytical Chemists; DW = dry weight; 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.

Pea and pea protein concentrate 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).

Pea protein concentrate, which is the raw material used to manufacture the novel food, are Generally Recognised as Safe (GRAS) as food ingredients in the USA (FDA, 2016).

The mycelia 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 protein fermented by Shiitake (*Lentinula edodes*) mycelia is GRAS as a food ingredient in the USA (FDA, 2024).

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

## 2.7. Proposed use and intake

Foods containing the novel food are intended for the general population.

The proposed use and maximum use level for the novel food in each food category is shown in [Table 6](#).

Table 6. Proposed uses and maximum use level for the extension of use of the novel food

| Food Category Name                                                                  | Maximum Use Level (%) |
|-------------------------------------------------------------------------------------|-----------------------|
| Milk imitates, imitation cream, non-dairy coffee creamer, sour cream <sup>(a)</sup> | 10                    |
| Ice cream (milk-imitate based), water-based ice creams                              | 10                    |

| Food Category Name                                                                               | Maximum Use Level (%) |
|--------------------------------------------------------------------------------------------------|-----------------------|
| Cream cheese <sup>(a)</sup>                                                                      | 12                    |
| Imitation cheese, imitation yogurt (non-soy)                                                     | 25                    |
| Margarines and similar                                                                           | 12                    |
| Nut/seeds paste/emulsion/mass                                                                    | 10                    |
| Muesli and similar mixed breakfast cereals, breakfast cereals (plain), cereal flakes and similar | 15                    |
| Crackers and breadsticks, tortilla                                                               | 5                     |
| Biscuits, pancakes, waffles                                                                      | 10                    |
| Bread and rolls with special ingredients <sup>(b)</sup>                                          | 15                    |
| Cereal bars                                                                                      | 20                    |
| Meat based dishes                                                                                | 25                    |
| Soups (ready-to-eat), soups (dry mixture uncooked)                                               | 5                     |
| Whey powder <sup>(c)</sup> , milkshakes <sup>(c)</sup>                                           | 25.3                  |
| Meat imitates                                                                                    | 30                    |
| Single meal replacement for weight reduction <sup>(c)</sup>                                      | 25.3                  |
| Iced coffee <sup>(d)</sup>                                                                       | 10                    |
| Popcorn (maize, popped), fried and extruded cereal, seed or root-based products, pretzel         | 4                     |

<sup>(a)</sup> FoodEx2 codes were not available for “imitation sour cream” or “imitation cream cheese”; therefore, food codes for the conventional product were used as surrogates.

<sup>(b)</sup> FoodEx2 codes were not available for “high protein bread”; therefore, “bread and rolls with special ingredients” was used as surrogates.

<sup>(c)</sup> FoodEx2 codes were not available for plant-based protein (powder or ready-to-drink beverages); therefore, the codes for whey powder and milk shakes were selected as surrogates

<sup>(d)</sup> FoodEx2 codes were not available for high protein ready-to-drink coffee beverages; therefore, food codes for the conventional product were used as surrogates.

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

An intake assessment was conducted using the EFSA Dietary Exposure (DietEx) Tool, which is based on individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The intended conditions of use were matched with the FoodEx2 categories. The estimated mean and 95<sup>th</sup> percentile intakes of the novel food from the proposed conditions of use for each population group are presented in [Table 7](#).

Table 7. Estimated mean and 95<sup>th</sup> percentile intake levels for the novel food using the EFSA Comprehensive European Food Consumption on a body weight basis

| Population Group | Mean NF intake (g/kg BW/day) | P95 NF intake * (g/kg BW/day) |
|------------------|------------------------------|-------------------------------|
| Infants          | 0.02 to 0.78                 | 0.12 to 3.43                  |
| Young children   | 0.24 to 0.88                 | 0.62 to 3.02                  |
| Other children   | 0.11 to 0.63                 | 0.32 to 2.22                  |
| Adolescents      | 0.07 to 0.24                 | 0.20 to 0.94                  |

| Population Group             | Mean NF intake (g/kg BW/day) | P95 NF intake * (g/kg BW/day) |
|------------------------------|------------------------------|-------------------------------|
| Adults                       | 0.03 to 0.28                 | 0.11 to 0.89                  |
| Pregnant and lactating women | 0.07 to 0.19                 | 0.20 to 0.50                  |
| Elderly                      | 0.03 to 0.31                 | 0.11 to 0.83                  |
| Very elderly                 | 0.03 to 0.28                 | 0.09 to 0.84                  |

BW = body weight; NF = novel food; P95 = 95<sup>th</sup> percentile

Infants (< 11 months); young children (12 – 35 months); other children (3 – 9 years); adolescents (10 – 17 years); adults (18 – 64 years); elderly (65 – 74 years); very elderly (75+ years)

The highest mean and 95<sup>th</sup> percentile intakes of the novel food on a body weight basis are reported in the young children and infant population groups, 0.88 g/kg BW/day and 3.43 g/kg BW/day, respectively. On an absolute basis, the highest mean and 95<sup>th</sup> percentile intakes are reported in the elderly (23.7 g/day) and adult (63.2 g/day) population groups.

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

No ADME studies were conducted on the novel food, which is mainly composed of protein ( $\geq 75$  % dry weight), with smaller quantities of carbohydrates ( $\leq 15$  %) and fats ( $\leq 10$  %). Metabolites formed during the consumption of pea protein fermented by Shiitake mycelia and the common food ingredients used to manufacture the novel food are expected to be similar.

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

## 2.9. Nutritional information

The novel food is mainly composed of protein ( $\geq 75$  % dry weight).

The amino acid profile from five independent batches of the novel food ([Table 8](#)) was provided to support the derivation of the Protein Digestibility Corrected Amino Acid Scores (PDCAAS).

Table 8. The amino acid profile for five independent batches of novel food

| Parameter         | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|-------------------|---------|---------|---------|---------|---------|
| Alanine (%)       | 3.27    | 3.20    | 3.23    | 3.30    | 3.40    |
| Arginine (%)      | 6.49    | 6.39    | 6.56    | 6.46    | 6.61    |
| Aspartic Acid (%) | 8.95    | 8.79    | 8.91    | 8.98    | 9.19    |
| Glutamic Acid (%) | 13.4    | 13.15   | 13.48   | 13.19   | 13.49   |
| Glycine (%)       | 3.16    | 3.09    | 3.13    | 3.16    | 3.24    |
| Histidine (%)     | 1.93    | 1.9     | 1.96    | 1.92    | 1.98    |
| Isoleucine (%)    | 3.83    | 3.76    | 3.82    | 3.83    | 3.93    |

| Parameter            | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|----------------------|---------|---------|---------|---------|---------|
| Leucine (%)          | 6.66    | 6.52    | 6.59    | 6.67    | 6.75    |
| Phenylalanine (%)    | 4.15    | 4.07    | 4.11    | 4.20    | 4.29    |
| Proline (%)          | 3.26    | 3.34    | 3.35    | 3.48    | 3.45    |
| Serine (%)           | 3.97    | 3.90    | 3.95    | 4.00    | 4.04    |
| Threonine (%)        | 2.8     | 2.76    | 2.77    | 2.84    | 2.89    |
| Lysine (%)           | 5.77    | 5.68    | 5.73    | 5.73    | 5.88    |
| Tyrosine (%)         | 2.83    | 2.77    | 2.8     | 2.87    | 2.94    |
| Valine (%)           | 4.06    | 3.97    | 4.01    | 4.07    | 4.17    |
| Cystine (%)          | 0.68    | 0.67    | 0.68    | 0.72    | 0.74    |
| Methionine %         | 0.89    | 0.89    | 0.85    | 0.91    | 0.97    |
| Tryptophan (%)       | 0.70    | 0.68    | 0.70    | 0.70    | 0.72    |
| Total Amino Acid (%) | 76.8    | 75.53   | 76.63   | 77.03   | 78.68   |

AOAC = Association of Official Analytical Chemists

Amino acid analysis: all amino acids except cysteine, methionine and tryptophan – AOAC 982.30 modified; cysteine and methionine – 994.12 modified; tryptophan – 988.15 modified

An *in vivo* study (Durando, 2021 [unpublished]) was conducted to investigate the digestibility of the novel food and the pea protein raw material. The results from this study reported the digestibility for the novel food and the pea protein raw material were 94 % and 92 %, respectively.

The results from this study along with the amino acid profile of the novel food were used to derive the PDCAAS for each batch of novel food ([Table 9](#)). The PDCAAS was 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).

Table 9. The PDCAAS values for five independent batches of novel food

| Parameter               | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|-------------------------|---------|---------|---------|---------|---------|
| 6 months to 3 years old | 72      | 72      | 71      | 77      | 76      |
| > 3 years old           | 84      | 84      | 83      | 90      | 90      |

For children, aged 6 months to 3 years, the PDCAAS for the pea protein raw material and novel food were 0.65 and 0.78, respectively. For older children, adolescents and adults, the PDCAAS for the pea protein raw material and novel food were 0.76 and 0.84, respectively. The first limiting amino acids were the sulphur amino acids (SAA) for both the pea protein raw material and the novel food for both age groups.

The estimated 95<sup>th</sup> percentile protein intakes from consumption of the novel food by different population groups ([Table 7](#)) were derived from the lowest specification limit for protein (75 % dry weight) and the 95<sup>th</sup> percentile estimated intakes of the novel food on a body weight basis ([Table 10](#)).

Table 10. 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          | 3.43                                   | 2.6                                              | 1.31 *                                                |
| Young children   | 3.02                                   | 2.3                                              | 0.97 – 1.14 **                                        |
| Other children   | 2.22                                   | 1.7                                              | 0.85 – 0.92                                           |
| Adolescents      | 0.94                                   | 0.7                                              | 0.83 – 0.91                                           |
| Adults           | 0.89                                   | 0.7                                              | 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 95<sup>th</sup> percentile protein intake for consumers from the infant, young children, and other children 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 and up to 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.

Results from the mineral and vitamin analysis for five independent batches of novel food is reported in [Table 11](#).

Table 11. Analysis of the mineral and vitamin content for five independent batches of novel food

| Parameter                      | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|--------------------------------|---------|---------|---------|---------|---------|
| Potassium (%)                  | 0.071   | 0.07    | 0.067   | 0.075   | 0.065   |
| Sodium (%)                     | 1.14    | 1.11    | 1       | 0.889   | 0.914   |
| Calcium (%)                    | 0.033   | 0.033   | 0.033   | 0.042   | 0.038   |
| Iron (%)                       | 0.017   | 0.0168  | 0.0173  | 0.0154  | 0.0161  |
| Total Vitamin D2 + 3 (µg/100g) | < 0.1   | < 0.1   | < 0.1   | < 0.1   | < 0.1   |
| Vitamin D2 (µg/100g) *         | < 0.1   | < 0.1   | < 0.1   | < 0.1   | < 0.1   |
| Vitamin D3 (µg/100g) *         | < 0.1   | < 0.1   | < 0.1   | < 0.1   | < 0.1   |

AOAC = Association of Official Analytical Chemists; ICP-MS = inductively couple plasma – mass spectrometry; LC-MS/MS = liquid chromatography – tandem mass spectrometry

Calcium, iron, potassium and sodium (ICP-MS) – AOAC 984.27 modified, 927.02 modified, 985.01 modified, 965.17 modified; Vitamin D (LC-MS/MS) – Huang et al. (2014). Rapid Communications in Mass Spectrometry p28

\* < 4 IU/100 g Converted from International Units (IU) using the conversion factor of 0.025 µg = 1 IU stated in the European Food Safety Authority Technical Report on Dietary Reference Values for nutrients (EFSA, 2017)

Based on this analytical data, the contribution of calcium, potassium and sodium to the diet was not considered a concern.

The highest estimated 95<sup>th</sup> percentile intake for iron from consumption of the novel food in infants, young children, other children, adolescents, and adults is 5.3, 5.9, 9.5, 6.9 and 11 mg/day, respectively. These values are close to or slightly exceed the population reference intake values for iron in these population groups (EFSA NDA Panel, 2017). This was not considered to be a concern because the exposure assessment is conservative and there is no tolerable upper intake level for iron.

Raffinose and stachyose, phytic acid, and trypsin are recognised anti-nutrients that are present in peas. Since the novel food is produced from pea protein concentrate, five independent batches of novel food were analysed for these anti-nutrients ([Table 12](#)).

Table 12. The content of raffinose and stachyose, phytic acid, and trypsin in five independent batches of novel food

| Parameter                  | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|----------------------------|---------|---------|---------|---------|---------|
| Phytic acid (%)            | 2.05    | 2.06    | 1.89    | 1.36    | 1.46    |
| Trypsin inhibitors (TIU/g) | > 3,700 | 3,500   | 2,300   | 3,000   | 2,900   |
| Stachyose (%)              | < 0.05  | < 0.05  | < 0.05  | < 0.05  | < 0.05  |
| Raffinose (%)              | < 0.05  | < 0.05  | < 0.05  | < 0.05  | < 0.05  |

AOCS = American Oil Chemists' Society; TIU = trypsin inhibitor unit

Phytic acid – Analytical Biochemistry (1977), 77 pp 536-539; raffinose and stachyose – Journal of the American Oil Chemists' Society (1980), p143; trypsin inhibitor – AOCS Ba 12-75

The levels of phytic acid in the novel food ranged from 1.36 to 2.06 %. These levels are comparable to those reported in dried cowpeas (*Pisum sativum*) and in pea protein concentrates, 0.3 to 2.9% (Schlemmer et al., 2009) and 2.0 – 2.5% (Naczek et al., 1986), respectively, both of which are consumed in the diet

Trypsin is a protease involved in the digestion of protein in the diet. Trypsin inhibitors block this enzyme and decrease protein digestibility. The levels of trypsin inhibitor in the novel food ranged from 2,300 to > 3,700 TIU/g. By comparison, published values for trypsin inhibitors for cowpeas range from 2,900 and 10,800 TIU/g (Valdebouze et al., 1980). This information indicates that trypsin inhibitors in the novel food are not a cause for concern.

Lectins are heat sensitive proteins that have the potential to bind to soluble carbohydrate (Petroski & Minich, 2020). These anti-nutrients are present in legumes, including peas. 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. Heat treatment

of the novel food includes post-processing pasteurisation and flash-heat spray-drying. These steps are likely to reduce the levels of lectins present given they are heat labile (Pusztai & Grant, 1998). The FSA and FSS also note that in the EFSA safety assessment for pea and rice protein fermented with Shiitake mycelia (EFSA NDA, 2022), the thermal processing steps in the novel food production process were considered sufficient to destroy lectin activity. On this basis, lectin is not expected to be present in the novel food.

The consumption of the novel food is not expected to be nutritionally disadvantageous under the proposed conditions of use and maximum use levels.

## 2.10. Toxicological information

No toxicological information was provided

The novel food, pea protein fermented with Shiitake mycelia is mainly composed of protein ( $\geq 75$  % dry weight), with smaller quantities of carbohydrates ( $\leq 15$  %) and fats ( $\leq 10$  %). There is a history of safe use for the raw material, pea protein concentrate. The novel food also contains  $< 0.1$  % by weight of Shiitake mycelia. Shiitake mushroom (*Lentinula edodes*) is an edible and widely cultivated mushroom.

A literature search did not identify any studies that were relevant for toxicological assessment of pea protein and Shiitake mycelia. In addition, a recent published report indicated that there were no substantial differences (98% similarity) in the composition of Shiitake fruiting body compared to the mycelia (Van der Molen et al., 2017).

The closely related product, pea and rice protein fermented with Shiitake mycelia, utilises the same production process and pea protein concentrate as a raw material as the novel food. The only difference concerns the use of rice protein as an additional raw ingredient. Pea and rice protein fermented with Shiitake mycelia is currently authorised in the EU under assimilated Regulation 2017/2470.

Based on this information, there is no evidence to suggest a toxicological concern arising from consumption of the novel food; therefore, no toxicological studies were required for the novel food.

### 2.10.1. Human studies

No human trials were conducted with the novel food.

The FSA and FSS considered that no human studies were required for pea protein fermented with Shiitake mycelia given the nature of the novel food and the history of safe use of the raw materials.

## 2.11. 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.

The novel food provides a total of  $\geq 75\%$  protein on a dry weight basis.

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

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 and Shiitake mushroom.

While confirmed diagnostic data are lacking, self-reported symptoms suggest that adverse reactions to pea occur in the UK adult population. These prevalence levels are broadly comparable to other legumes that are not listed in UK food allergen legislation. Data on the prevalence of allergy to Shiitake mushrooms in UK adults, or to pea 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 was considered further 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 Vicieae tribe, whilst chickpea (*Cicer arietinum*), is a member of the close relatedly Cicereae tribe. Peanut (*Arachis hypogaea*) 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).

To understand the potential for the novel food to sensitise or elicit clinical allergic reactions, the FSA and 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 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, three to five times higher than typical consumption of pea. In some scenarios, pea protein intake was up to nine 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 in the UK population.

No established threshold of protein intake has been identified as a trigger for allergic reactions to pea. 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.

There is uncertainty regarding the degree to which the higher doses of pea 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 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 of 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. 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 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. Risk managers are advised to consider whether consumer-facing information is needed to ensure that those with an existing food allergy to pea in GB can avoid the novel food, particularly as there is potential for elevated pea 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 protein.

### 3. Discussion

The novel food is pea protein fermented by Shiitake (*Lentinula edodes*) mycelia with a protein content  $\geq 75$  % (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 95<sup>th</sup> percentile intake of the novel food using the EFSA Comprehensive European Food Consumption Database is 3.43 g/kg BW/day in the infant population group.

The estimated 95<sup>th</sup> 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 95<sup>th</sup> percentile protein intake levels are 2- 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 raw 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 of the raw materials, toxicological studies were not considered necessary.

Risk managers are advised to consider whether labelling is required to ensure that those with an existing food allergy to pea in GB can avoid the novel food, particularly as there is potential for elevated pea 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 protein.

## 4. Conclusions

The FSA and FSS have undertaken the assessment of pea protein fermented by Shiitake mycelia 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.

The novel food contains pea and *Lentinula edodes*, which are reported to trigger allergic reactions in sensitised individuals. FSA/FSS also noted the potential for *de novo* sensitisation to pea protein and for cross-reactivity to pea protein in GB consumers with clinically relevant legume allergies, given the estimated high intake levels of pea proteins from the novel food compared to the traditional diet.

Risk managers are advised to consider whether labelling is required to ensure that those with an existing food allergy to pea in GB can avoid the novel food, particularly as there is potential for elevated pea 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 protein.

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 identity of the novel food, production process, composition, and stability.
- Protein Digestibility Corrected Amino Acid Score (Durando, 2021 [unpublished])

# Abbreviations

|             |                                                                      |
|-------------|----------------------------------------------------------------------|
| ACNFP       | Advisory Committee on Novel Foods and Processes                      |
| AOAC        | Association of Official Analytical Chemists                          |
| APC         | Aerobic plate count                                                  |
| BW          | Body weight                                                          |
| CONTAM      | Panel on Contaminants in the Food Chain                              |
| CFU         | Colony Forming Unit                                                  |
| 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                      |
| GC-MS/MS    | Gas chromatography – tandem mass spectrometry                        |
| HACCP       | Hazard Analysis and Critical Control Point                           |
| ICP-MS      | Inductively coupled plasma – mass spectrometry                       |
| IgE         | Immunoglobulin E                                                     |
| ITS         | Internal Transcribed Spacer                                          |
| IU          | International units                                                  |
| LC-MS/MS    | LC-MS/MS liquid chromatography – tandem mass spectrometry            |
| Mod.        | Modified                                                             |
| MRL         | Maximum residue limit                                                |
| MUFA        | Monounsaturated fatty acid                                           |
| N           | Nitrogen                                                             |
| NCBI        | National Centre for Biotechnology Information                        |
| ND          | Not detected                                                         |
| 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                                          |
| PUFA        | Polyunsaturated fatty acid                                           |
| SCF         | Scientific Committee on Food                                         |
| SFA         | Saturated fatty acid                                                 |
| TDF         | Total dietary fibre                                                  |
| TFA         | Total trans fatty acid isomers                                       |
| TIU         | Trypsin inhibitor unit                                               |
| UHPLC-MS/MS | Ultra-high pressure liquid chromatography – tandem mass spectrometry |

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