

Summary of the dossier: Pea and rice protein fermented by Shiitake mycelia

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This is a novel food application for authorisation of pea and rice protein fermented by Shiitake mycelia for use in baked goods, beverages, breakfast cereals, confectionary, dairy product analogues, fats and oils, processed meat and poultry products, milk products, pasta, plant protein products, soups and soup mixes, at levels ranging from 1% to 40%.

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Food Safety Authority (EFSA) Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.

The pea and rice protein fermented by Shiitake mycelia is intended to be used as a substitute for, and/or in conjunction with, pea protein, rice protein and other protein sources in conventional food products. Target product categories include food products needing protein-source properties such as promotion of ease of dry flow, masking of off-flavours, texturing of meat analogues, increasing water holding capacity and gelation, and increase of water-solubility.

In an Opinion letter issued by the Federal Public Service of Belgium (Health, Food Chain Safety and Environment), it was concluded that the pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia must be regarded as a novel food as defined in Article 3(2) of Regulation (EU) 2015/2283.

The novel food, is prepared from commonly consumed, nutritional raw materials (pea and rice protein), manufactured with fermentation technology using *Lentinula edodes* (Shiitake mushroom) mycelia. The pea and rice protein fermented by Shiitake mycelia is primarily comprised of pea and rice protein, with only a small remainder of heat-killed Shiitake mycelia present in the novel food in an amount of less than 0.1% by dry weight.

The applicant estimates that the maximum exposure level per person per day (i.e., 95th to 98th percentile) to the heat-killed Shiitake mycelia contained in the novel food is only in milligram amounts, specifically, up to 86.3 mg/person/day. This exposure level is well within safe limits as shown by literature review and discussed extensively in the application. Accordingly, after an appropriate literature review and quality testing, the applicant has concluded the safety of the use of pea and rice protein fermented by Shiitake mycelia as a novel food.

The applicant's safety conclusion is based on an extensive analysis which has determined that the Shiitake mycelia used to ferment the input raw protein materials are 98% similar in composition to commonly consumed culinary Shiitake mushrooms.

In addition, historical consumption of fermented vegetables and grains (including peas and rice) as part of the human diet is well documented. Both pea and rice proteins, the main constituents of the novel food, have been consumed for centuries through the consumption of peas and rice and through the consumption of the protein products affirmed as Generally Regarded As Safe (GRAS) for use as food ingredients by the United States of America Food and Drug Agency.

The fermentation organism used to produce the novel food, *Lentinula edodes* (Shiitake mushroom), is commonly consumed as food and the Shiitake mushroom fruiting body is substantially equivalent to the Shiitake mycelia used in the fermentation of the pea and rice protein. There are no identified hazards associated with the use of Shiitake mycelia described herein. Following fermentation, there is no live Shiitake mycelia or fungal enzymes in the final novel food preparation as a result of multiple heat treatment steps and thermal deactivation. The weight-of-evidence from reliable published toxicological and human clinical studies using the same or closely-related (e.g. Shiitake mycelial extracts, reconstituted powdered Shiitake mushroom) test materials as those components included in the novel food, support a conclusion that no adverse health effects are expected at dietary intake levels of the heat-killed Shiitake mycelia which are estimated based on food uses proposed for the pea and rice protein fermented by Shiitake mycelia.

Consumption data and information pertaining to the individual proposed food uses of pea protein and rice protein were used to estimate the all-person and all-user intakes of the novel food for the U.S. population. In summary, the mean and high level (95th to 98th percentile) intake of the pea and rice protein fermented by Shiitake mycelia for adults is estimated to be 29.3 g/person/day and 86.3 g /person/day, respectively. Correspondingly, the mean and high level (95th to 98th percentile) intake of the heat-killed Shiitake mycelia present in the novel food for adults is estimated to be 29.3 mg/person/day and 86.3 mg/person/day, respectively. These mean intake estimates for the pea and rice protein fermented by Shiitake mycelia are similar to or less than the U.S. Institute of Medicine (IOM), the World Health Organisation (WHO), and the European Food Safety Authority (EFSA), recommended intake levels of protein in the diet, supporting a conclusion of safety.

The pea and rice protein fermented by Shiitake mycelia will substitute for other protein sources in the diet, and thus will not increase the overall consumption of protein in the diet. The novel food is manufactured within a BRC (Brand Reputation through Compliance) inspected facility under current Good Manufacturing Practices (cGMPs) and meets appropriate food grade specifications.

The identity of the pea and rice protein fermented by Shiitake mycelia has been clearly defined and confirmed through scientific data and information. All ingredients included in the novel food, including Shiitake mycelia, are concluded to be safe for use in food at inclusion levels and food categories proposed for the pea and rice protein fermented by Shiitake mycelia. No pea and rice protein fermented by Shiitake mycelia raw materials are listed as major allergens in the Food Allergen Labelling and Consumer Protection Act of 2004.