Summary of the application: Fungi protein from *Fusarium* strain *flavolapis*

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This is an application for the approval of Fungi Protein from *Fusarium* strain *flavolapis*, marketed under the trade name Fy Protein™, as a novel food ingredient in the European Union. Fungi Protein from *Fusarium* strain *flavolapis* is derived from liquid surface fermentation of *Fusarium* str. *flavolapis* and can be used as an ingredient or macronutrient. The fungal microorganism, *Fusarium* str. *flavolapis*, was discovered in Yellowstone National Park in the United States. Under appropriate cultivation conditions, a filamentous mat of mycelial biomass, termed a "biomat", with a texture profile similar to that of muscle fibres, is formed. Fungi Protein falls under "Foods consisting of, isolated from or produced from microorganisms, fungi or algae" as per Article 3(2)(a)(ii) of Regulation (EU) 2015/2283.

Fungi Protein from *Fusarium* strain *flavolapis* is intended for use as a macronutrient ingredient in a variety of products, including meat and dairy analogues. Fungi Protein from *Fusarium* strain *flavolapis* is manufactured in a controlled process that does not involve the introduction of microbial or chemical hazards. The ingredient is comprised of protein, carbohydrates and fats. The production process is compliant with cGMP and the principles of HACCP. Analytical results for 5 production batches of Fungi Protein from *Fusarium* strain *flavolapis* demonstrate that the manufacturing process produces a consistent product that conforms to the established product specifications, and is free of microbial, chemical and environmental hazards that, if present, would not pose a safety concern. The results of analysis for a number of regulated mycotoxins demonstrated that there are no safety concerns with respect to exposure to *Fusarium* mycotoxins. The culture supernatants and Fungi Protein from *Fusarium* strain *flavolapis* did not display any antimicrobial activity when tested against various reference strains known to be susceptible to a range of antibiotics.

Toxicology studies (including in-vitro genotoxicity studies and a subchronic 90-day rat study) have been conducted to support the safety of Fungi Protein from *Fusarium* strain *flavolapis*. There was no evidence of genotoxicity in the in vitro tests, and the highest dose tested in the 90-day study was established as the no-observed adverse-effect-level. A multi-pronged assessment for potential allergenicity of *Fusarium* strain *flavolapis* has been conducted using bioinformatics analysis and comparison of genetic sequence information using scientific principles, in vitro digestibility studies, and an evaluation of published literature. Based upon its extensive analysis, it was concluded that food produced from *Fusarium* strain *flavolapis* is unlikely to represent any additional risk of food allergy beyond what is currently available in the human food supply. Foods containing Fungi Protein from *Fusarium* strain *flavolapis* will be clearly labelled in their ingredient list as containing fungi, to inform consumers that may be sensitive to fungi. The safety of Fungi Protein from *Fusarium* strain *flavolapis* for human consumption was further corroborated by a large body of scientific literature available on a compositionally similar product. Together, the available evidence on Fungi Protein from *Fusarium* strain *flavolapis* supports the safe use of the ingredient under the proposed conditions of use.

This dossier 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, supported by 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 (EFSA NDA Panel, 2021) and the EFSA Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283 (EFSA, 2021).