

Summary of the application: Dry biomass of *Paecilomyces variotii* KCL-24

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The novel food application concerns the authorisation of a dry biomass of *Paecilomyces variotii* KCL-24.

The strain *Paecilomyces variotii* KCL-24 has been unambiguously taxonomically identified based on the whole genome sequencing data. The novel food fermentation product consists of non-viable, non-genetically modified fungal cells that have been dried and milled. The production process of the novel food is carefully monitored, and quality assurance programs have been established to ensure the compliance with HACCP (Hazard Analysis and Critical Control points) principles and the release specification. The composition of the novel food has been comprehensively characterised and is consistent in the representative, independent batches of the novel food. The novel food is mainly composed of protein and dietary fibre. Furthermore, the chemical and microbiological contaminants raise no safety concerns, and the final product is compliant with the European legislation of foodstuffs (e.g. in microbiological quality, mycotoxins, pesticides and heavy metals). The studies performed both for the novel food ingredient and the food products made of the novel food ingredient show the safety and long-term stability similar to the corresponding traditional ingredients and foods. The long history of safe use of *Paecilomyces variotii* KCL-24 as a feed ingredient and the results obtained from numerous feeding trials provide substantial evidence on the safety of the novel food. The novel food is intended to be used as an ingredient in a range of foods in the EU, including baked goods, cereals and cereal bars, dairy substitutes, and meat and fish imitates. The targeted population group is the general population. The dry biomass of *Paecilomyces variotii* KCL-24 is considered not nutritionally disadvantageous for consumers under the proposed conditions of use. There are no concerns that it would cause an excess intake of nutrients. The product does not contain types or amounts of antinutritional factors that would adversely impact consumers' nutritional status, and there are no concerns about the novel food replacing other foods. Furthermore, its characteristics are in line within the specific considerations for a novel protein source. In vitro genotoxicity studies (Ames test, mammalian cell micronucleus test) on the novel food gave no indication of genotoxicity. The long history of safe use as a feed ingredient, the results of numerous feeding trials and a three-generation study on pigs support the safety of the *Paecilomyces variotii* KCL-24. The allergenicity of the novel food and its source organisms *Paecilomyces variotii* was assessed based on the literature review and the analysis of whole genome sequence data, indicating no major risks for the allergenicity of the novel food.

The novel food, dry biomass of *Paecilomyces variotii* KCL-24, is considered safe by the applicant under the proposed use and use levels and conforming the proposed specification, based on the data presented for the identity of the novel food, manufacturing process, compositional data, history of use of the source and the novel food, intake assessment, nutritional composition, toxicological data and allergenicity assessment.