6. *Public summary of mycelium from oyster mushroom*

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The application is submitted pursuant to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, for the authorisation of mycelium from oyster mushroom. Mycelium from oyster mushroom is produced via solid-state fermentation of *Pleurotus ostreatus*, producing a slab of aerial mycelium. Mycelium from oyster mushroom is intended to be sold to food manufacturers for further food- and heat-processing and incorporation into alternatives (i.e. imitate products) for meat, fish, seafood, poultry, or fungi and mushroom- and vegetable-based dishes. The cultivation process is broadly similar to the cultivation process of conventional *Pleurotus ostreatus* that has been traditionally consumed in the EU prior to 15 May 1997 (OECD, 2013).

Whereas, the fruiting body of the fungus has a history of safe use and has been consumed and cultivated in Europe since the First World War, the mycelium of *Pleurotus ostreatus* has not been used for food production within the European Union prior to 15 May 1997 and is therefore classified as a novel food, belonging to the novel food category of "*food consisting of, isolated from, or produced from microorganisms, fungi or algae*" (Article 3(2)(ii) Regulation (EU) 2015/2283).

Literature data and analytical data of the novel food revealed that the composition and nutrient profile of mycelium of oyster mushroom is comparable to the composition and nutrient profile of the fruiting body of the fungus.

Nutrients in mycelium from oyster mushroom are expected to be absorbed, digested, metabolised and excreted identically to conventionally grown oyster mushroom. Based on the nature, source, and production process of mycelium from oyster mushroom, the product shows no toxicological concern. Moreover, considering the comparable composition of the mycelium and the fruiting body and the history of safe use of the fruiting body of the fungus, mycelium of oyster mushroom is expected to be safe for consumption. Literature data revealed that the fruiting body of oyster mushroom is not expected to be mutagenic or clastogenic. Acute and subacute toxicology testing reported that *P. ostreatus* has a high margin of safety. *Pleurotus ostreatus* is known to be antigenic and can cause adverse effects after inhalation or after skin contact. Genotoxic potential of the novel food was investigated through an in vitro bacterial reverse mutation test and an in vitro mammalian cell micronucleus test. Both studies showed negative results.

Based on this evidence, the applicant considers mycelium from oyster mushroom to be safe for human consumption.