Public summary of the dossier: *Antrodia camphorata* mycelia powder

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The novel food application concerns request for authorisation of *Antrodia camphorata* (syn. *Taiwanofungus camphoratus*) freeze dried mycelia as a novel food in food supplements in the European Union (EU) intended for the general population.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods. It is also in line with 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.

The safety of the novel food ingredient *Antrodia camphorata* is substantiated by the history of safe consumption in Taiwan, human data as well as by publically available safety and toxicological information and toxicity reviews, which include acute and long terms toxicity, genotoxicity and teratogenicity studies in animals.

An overall NOAEL of 3,300 mg/kg bw in rats was established, based on the highest dose tested with repeated administration. No toxic effect at all was observed, *Antrodia camphorata* is not genotoxic and not carcinogenic. The NOAEL of 3,300 mg/kg bw obtained in rats corresponds to a human equivalent dose of 532 mg/kg body weight. For a human with a standard bodyweight of 50 kg, this human equivalent dose will correspond to a daily intake of 26.60 g.

The intended maximum daily dose of the novel food applied for is 1000 mg powder containing 990 mg dried *Antrodia camphorata* mycelium. Hence, there is a high Margin of Safety to the theoretical 'NOAEL' value.