Summary of the application: Chitin-glucan from Aspergillus niger

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The novel food application requests for an extension of use of the authorization of Chitin glucan from Aspergillus niger. The authorization we are referring to is the following: 2011/76/EU: Commission Decision of 2 February 2011 authorising the placing on the market of a chitin-glucan from Aspergillus niger as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. The novel food 'chitin-glucan from Aspergillus niger' named 'Chitin-glucan' in the dossier falls under the category defined in article 3.2 (a) (ii) of Regulation (EU) 2015/2283: food consisting of, isolated from or produced from microorganisms, fungi or algae; Chitin-glucan from Aspergillus niger is a purified ingredient, presented in the form of a powder, which is composed largely of two polysaccharides: chitin, composed of repeating units of Nacetyl-D glucosamine and beta(1,3)-glucan, composed of repeating units of D-glucose.

Regarding the manufacturing process, chitin-glucan is extracted from the mycelium of Aspergillus niger, purified and dried, before being packed and stored. The manufacturing process is performed accordance with HACCP based principles, including quality control checks. The final ingredient is safe and respects high quality standards in compliance with EU legislation.

The specifications of Chitin-glucan from Aspergillus niger are detailed in the dossier and are in compliance with European legislations, in particular: microbiological aspects and contaminants (including heavy metals).

The targeted group is the general population. The present submission seeks approval for a new intended use as an ingredient in the Food for Special Medical Purposes (FSMP) category (category 13.2 excluding infants and young children) in addition to the food supplement category (category 17).

The new intended use with the current request for extension is the Food for Special Medical Purposes (FSMP) category (13.2) excluding infants and young children. The condition of use is a maximum daily intake of chitin glucan up to 4.5 g in FSMP. In combination with the diet, the intended use in FSMP satisfies the recommended daily intake for fibre without presenting a risk of overdose for the target population. In this context of use under medical supervision mandatory for FSMP as stated in regulation EC n°609/2013 and delegate regulation EC n°128/2016, a population with specific disease-related dietary requirements will be followed and supervised by health care practitioners, dieticians and specialists according to their disease and nutritional needs. No other source of chitin glucan will be expected in this specific population consuming Chitin-glucan as a FSMP.

Fibre-rich diets such as cereals, nuts, fruits, and vegetables have a positive effect on human health. Recommendation for fibre ranges from 25 to 45g/day depending on EU countries. However, the actual intake in all countries extracted from epidemiological studies suggests an insufficient global intake in fibre ranging from 17 to 22g/day for most countries.

Results from human and animal studies have indicated that beta-glucan is not expected to be absorbed in the upper gastrointestinal tract and as it passes through the colon, where it undergoes microbial fermentation. There is no risk of systemic toxicity and no safety concern regarding the metabolism of beta-glucan is anticipated, as this substance cannot be absorbed. Similarly, chitin is not expected to raise any

safety concern as it is demonstrated by its metabolism, that it is expected to be excreted intact in the feces. Therefore, as chitin-glucan comprises beta-glucan and chitin, there is no risk of systemic toxicity, and no safety concern is expected from the metabolic products from either polysaccharide. Moreover, the allergenicity risk of Chitin-glucan is expected to be low.

Chitin-glucan from Aspergillus niger is safe for the consumption by the European population at the proposed conditions of use and no adverse nutritional effects are expected at the anticipated intake level.