

Summary of the application: Powder of chitosan

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This is a novel food application for a powder of chitosan to be used for the preparation of pasta and bakery products in the context of Regulation (EU) 2015/2283.

Chitosan has a long history of use in food supplements, yet it was not used for human consumption to a significant degree within the European Union before 15 May 1997.

Chitosan is a linear cationic polysaccharide composed of randomly distributed (1-4)-linked D-glucosamine and N-acetyl-D-glucosamine produced commercially by the deacetylation of chitin, which is a component of the exoskeleton of crustaceans.

Chitosan is derived from the exoskeletons of crustaceans (crab shell, shrimp shell, squid pens, lobster shell), is mixed with ascorbic and tartaric acids and is simply added to regular flour with no other changes in the production process for regular pasta or bakery products.

The available literature shows previous human oral exposure to chitosan through food supplements and food additives, and exposure through medical devices, and cosmetic applications. For chitosan there is extensive documentation for use in humans as food supplement and as an excipient for pharmaceutical preparations. No adverse reactions have been reported for the dosage and timing of use for which the approval of this novel food is requested.

The powder of chitosan has been evaluated and characterised in terms of: presence of contaminants, degree of deacetylation, viscosity and protein content to exclude potential allergenicity, toxicological profile, and stability of the product after cooking.

In addition, chitosan was characterized by acute toxicity, subchronic and genotoxicity in rats and mice with LD50 of 1,500 and 16,000 mg / kg BW respectively. Available studies showed that chitosan has low oral toxicity. (Baldrick, 2010)

In conclusion: from the data collected in this dossier, it seems evident that the powder of chitosan used in pasta and baked products is safe, well tolerated, non-toxic and suitable to be included in a balanced diet instead of traditional pasta.