

Summary of the application: Powder from lupine (*Lupinus angustifolius*) sprouted in iron solution

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The application submitted under the novel food Regulation (EU) 2015/2283 concerns a request to authorise use of "Powder from lupine sprouted in iron solution" as a novel food in a number of foodstuffs.

Powder from lupine sprouted in iron solution is produced by germinating disinfected seeds of *Lupinus angustifolius* in the presence of a solution of iron sulphate (FeSO_4) solution. Due to the high concentrations during the enrichment process, iron is bound in the sprouting plant as a ferritin, as well as other iron binding compounds naturally occurring in plants.

The semi-finished product (fresh sprouts) is crushed, heat treated and dried to ensure its stability and facilitate dosing processes. The presence of iron during the growth phase of the sprouts results in high ferritin and iron content in the product. The maximum iron concentration regardless of powder preparation method was 9400 mg Fe/1000 g dry weight.

The exhaustive studies and information on powder from lupine sprouted in iron solution proves the identity, composition, stability and safety for use and consumption in the European Union. Thorough analysis of five representative batches of the prepared sprouts confirmed the compliance with all requirements on microbial, organic and inorganic contaminations. The product is stable for at least 1 year, as supported by the microbial as well as organoleptic and physical stability at accelerated conditions. The *in vitro* studies did not show cytotoxic and genotoxic effects on cells isolated from the gastrointestinal tract and liver. The *in vitro* test confirmed the absence of hazards related to the Product's potential promutagenic and mutagenic effects. Subchronic toxicity studies also confirmed the safety of the Product.

Powder from lupine sprouted in iron solution shall be used in the production of many foodstuffs from a broad range of food categories and is not intended to replace other food.