

Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25th November 2015 on novel food, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327 11.12.2015, p. 1).

Recipient Member State:

Główny Inspektorat Sanitarny (The Chief Sanitary Inspectorate) – Poland.

Name and description of the novel food:

The request concerns lupin sprouts (powdered) enriched with iron. It is produced by germinating disinfected seeds of *Lupinus angustifolius* in the presence of a solution of iron sulphate (FeSO₄) solution. Due to the high concentrations during the enrichment process, iron is bound in the germ as a ferritin, as well as citrate complexes, phytates, complexes with polyphenolic compounds, Fe–S clusters and other prosthetic groups of proteins. The semi-finished product (fresh sprouts) is crushed, heat treated and dried to ensure its stability and facilitate dosing processes. The enrichment process 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.

Status: Novel food

Novel food category:

Article 3(2)(a)(vii) *“food resulting from a production process not used for food production within the Union before 15th May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.”*

Reasons statement

The production process includes not in common used production practices/process technologies used before 15th May 1997 and gives rise to significant changes in the food, affecting its nutritional value. On the basis of scientific data at the moment it is not possible to state that the process of lupin sprout enrichment with iron was in common use in the European Union before 15th May 1997.

Conclusion

The production process of lupin sprouts (powdered) enriched with iron is new and results in significant changes in the composition, affecting its nutritional value.