

Application for consultation to determine the status of a novel food, pursuant to Article 4(2) of the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.

Recipient Member State: SPANISH AGENCY FOR FOOD SAFETY AND NUTRITION (AESAN)

***Ganoderma lucidum* dehydrated mycelium powder**

Name and description of the novel food concerned:

The food for which the opinion is requested is under the name ***Ganoderma lucidum* dehydrated mycelium powder**.

The product is intended to be used as food supplement and for smoothies.

Status – Novel Food

Novel food category (where applicable): food consisting of, isolated from or produced from microorganisms, fungi or algae; (Article 3.2.ii)

Reasons Statement:

Based on the evidence provided by the applicant, it cannot be justified that the *Ganoderma lucidum* dehydrated mycelium powder presents history of safe consumption in the European Union prior to May 15, 1997.

Although the carpophore (reproductive part) has a history of safe and significant consumption in the European Union before May 15, 1997, this consumption history is not valid for the mycelium (vegetative part), and a relationship of equivalence between both parties at the level of nutritional composition, metabolites and potentially active substances has not been established.

Also, after consulting other Member States, none of these has confirmed a history of consumption of ***Ganoderma lucidum* dehydrated mycelium powder** prior to May 15, 1997.

Conclusion:

***Ganoderma lucidum* dehydrated mycelium powder** is considered as **novel food** since it does not present history of safe and significant consumption in the European Union before May 15, 1997 and it is not possible to establish an equivalence relationship between the reproductive and vegetative part of the fungus in terms of nutritional composition, metabolites and potentially active substances, falling within the scope of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods.