

Application for consultation to determinate 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)

Name and description of the novel food concerned:

The food for which the opinion is requested is: **Encapsulated Quercetin-zein**

The components have been encapsulated with zein, which is a protein present in many foods, such as maize. Zein microparticles were prepared by a controlled disolvation procedure followed by a purification step by ultrafiltration and subsequent drying.

The product is intended to be consumed as Food supplement.

Status: Novel in foods.

Novel food category (where applicable): "Food resulting from a new production process not used for food production in the Union before 15 May 1997, resulting in significant changes in the composition or structure of the food affecting its nutritional value, metabolism or the level of undesirable substances" (article 2, a) vii)

Reasons Statement:

This production process increases the oral absorption and bioavailability of quercetin ,which, unlike free quercetin, is detected in the brain, what seems to be a significant change.If the ingredient passes the blood-brain barrier, it could also be considered as a medicine based on its function.

Despite the fact that the four ingredients are regularly consumed, it seems that the purposes of the encapsulation of quercetin in microparticles is to increase its oral absorption; use for which no information on human consumption before 1997 has been provided/demonstrated.

The possibility of nanoparticles should be further investigated.

Conclusion:

Encapsulated Quercetin-zein, has no history of consumption before 05/15/97 in the European Union in the food field, In addition, the production process leads to significant changes in the metabolism of the main ingredient, quercetin, falling within the scope of Regulation (UE) 2015/2283 on Novel foods, **unless it can be considered as a medicine.**