

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

Receiving Member State: SPANISH FOOD SAFETY AND NUTRITION AGENCY O.A (AESAN O.A)

Name and description of the food:

The food for which the opinion is sought is ***Sus scrofa domestica -brain- lyophilized*** -dried consisting of the fine powder resulting from freezing, grinding, and sifting the whole pork brain (without meninges).

How the food is intended to be used:

The intended use of ***Sus scrofa domestica – brain – lyophilized*** in the European Union is as a food supplement.

Status: Not novel food

Category (When applicable): NA

Justification:

The ingredient for consultation ***Sus scrofa domestica -brain- lyophilized***, consists in the brain of the species *Sus scrofa domestica* with a proven history of safe and significant consumption in the European Union before 15 May 1997, which is subsequently lyophilized, and then undergoes a grinding and sifting process. The resulting powder is brown/beige, unctuous, with a characteristic smell and taste.

Lyophilization consists of dehydrating the product through the process in which the liquid solvent (water naturally present in the food) is sublimated directly from the solid phase (freezing state) to the gaseous phase, without passing through the liquid state.

Grinding consists of obtaining powder from the resulting lyophilized product (identical to the source food, but without the presence of moisture -dehydrated-).

Sifting consists of the passage of this powder through a mesh with particle diameter of less than 700 microns, in this case.

It is considered that the process of obtaining the ingredient is not novel and does not lead to significant changes in the composition or structure of the food that affect its nutritional value, metabolism, or the level of undesirable substances.

In addition, this ingredient is obtained from animals obtained through traditional selection practices used for food production in the Union prior to 15 May 1997 and whose derivatives (including brains) have a history of safe food use in the Union.

Conclusion:

Sus scrofa domestica -brain- lyophilized, is not a novel food and therefore not fall within the scope of Regulation (EU) 2015/2283 on novel foods.