

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: “**IBalance**”, a combination of 13 dead heat-treated microorganisms.

IBalance consists of a mixture of lysates from probiotic bacteria and yeasts, which are either purchased from specific suppliers or grown individually in fermenters. Each strain is processed individually and subsequently the lysates are mixed in the corresponding amount.

The food ingredient iBalance is obtained from a particular combination of microorganisms, lysed, sonicated and heat treated and mixed in specific proportions.

The product is intended to be used as an ingredient.

Status : Novel food

Novel food category (where applicable): Article 2.a.vi

Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

Reasons Statement:

Some of the microorganisms which are part of the composition of **IBalance** have already been used in the field of human nutrition as part of the production process in products for general population (baked and dairy products for example) , however the use as an ingredient is not established before 15/05/1997.

All the microorganisms belong to the qualified presumption of safety (QPS) list by EFSA, for *Bacillus sp.* QPS applies just for the production process not as food ingredient

The Competent authorities of the EU Member States and the European Commission were consulted.

Conclusion:

History of consumption before 15th may 1997 has not been established for the ingredient **IBalance** in the European Union in the food field, falling within the scope of Regulation (EU) 2015/2283 on Novel foods.