

APPLICATION TO AMEND THE UNION LIST ENTRY FOR “PROTEIN EXTRACT FROM PIG KIDNEYS” FOR THE INCLUSION OF A DIFFERENT SPECIFICATION DUE TO A DIFFERENT MANUFACTURING PROCESS.

Applicant: BIOIBERICA, S.A.U. c/Antic Camí de Tordera, 109-119, Palafolls (Barcelona, Spain).

Protein Extract from pig kidneys is a novel food ingredient included in the Union list of Novel foods established under Commission Regulation (EU) 2017/2470 of 20 December 2017.

The first authorization as a novel food of this porcine kidney extract was requested in 2012 based on the mutual recognition procedure to porcine kidneys, as established in article 5 of the old novel foods Regulation (EC) 258/97.

BIOIBERICA, S.A.U. also manufactures a Protein Extract from pig kidneys through its own manufacturing method, thus leading to a slightly different specification than the already approved.

Basically, our manufacturing process consists in defatting and dehydrating the starting material (minced porcine kidneys). Defatted kidneys, through solvent washes, will be then drained, dried, milled and sieved in subsequent stages, resulting in a protein extract with naturally occurring enzyme diamine oxidase (DAO).

The specification proposed for BIOIBERICA’s kidney extract with respect to the specification of the already approved novel food basically differs in the appearance of the product. The limits of the microbiological parameters are even stricter in our specification than those included in the already approved specification.

Information provided in this application sufficiently demonstrates that our proposed specifications derived from a different manufacturing process are not expected to entail any risk to human health or any food safety concerns to consumers.

This application is not pretending changes on the conditions of use of the kidney extract neither on the maximum levels already authorized.