

Summary of the application: Polyphenol extract from water olive mill by-product

Applicant: Extractos y Derivados S.L. C/Juncarillo, 64 18130 Escúzar Granada, Spain

Extractos y Derivados S.L. request the commercialisation in Europe of Polyphenol extract from water olive mill by-product (PEWOMP) obtained from the olive mill wastewater (OMW), which is the liquid extract fraction resulting of the oil mechanic extraction of olives, the fruit of *Olea europea L.* The liquid phase after decantation and evaporation process produces an organic liquid concentrate (composed by pulp, phenols and olive water), which is the raw material used as the source of the present novel food.

The novel food, rich in polyphenols (mainly Hydroxytyrosol (HT) and Tyrosol (Tyr)), may serve as a food ingredient to be included in different matrices, in the context of Regulation (EU) 2015/2283. The proposed matrices or food categories are: fats and oils and fat and oil emulsions, fruit juices based drinks, milk based drinks and food supplements.

This application falls under the Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods and specifically it corresponds to the category or type covered in Article 2(iv) “food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by traditional propagating practices which have been used for food production within the Union before 15 May 1997”.

A characterization of the composition provided for the novel food by Extractos y Derivados S.L. supports the safety of the product, in terms of potentially toxic components, potential contamination by pesticides, mycotoxins, microbes, etc. Moreover, extensive analytical studies of its composition, critical nutrients have been provided. The analyses were conducted using external certified laboratories.

Systematic assessment of all toxicological and allergenicity information, as well as the performed genotoxicity, and acute and subchronic toxicological studies of this novel food support the safety of the product. As expected, all the studies did not reveal any safety outcomes, being HT the main characteristic component of the novel food; in this line, a chemically synthesised HT has been previously evaluated as a NF and considered safe by the EFSA under specific conditions of use.