

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: **Aqueous extract of olive fruit (*Olea europaea* L.) containing at least 10% hydroxytyrosol**

It is an extract derived from a food (olive fruit). No organic solvent is used during the manufacturing process, only water is used as solvent during the extraction and concentration of the product. Extract in question is, after extraction, concentrated by an (unspecified) "physical chromatographic method" to achieve an enrichment of hydroxytyrosol to a level of 10 %.

The product contains a minimum of 10% hydroxytyrosol and other polyphenols, organic components and minerals present in the olive (tyrosol, oleuropein, etc.). The product is presented in a liquid format, soluble in water and hydroalcoholic solutions. Its color is dark brown with a characteristic taste and odor.

The product is intended to be used as an ingredient in milk-based drinks.

The status in food supplements was not part of the request and has not been evaluated.

Status –novel food.

Novel food category (where applicable): 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;

Reasons Statement:

The production process includes aqueous extraction and selective concentration of certain components (Hydroxytyrosol and other polyphenols).

These components from olive fruit do not have history of consumption prior to 15 may 1997 in food. The applicant is unaware of any product similar to this extract with a history of consumption in the EU prior to May 15, 1997.

Because *olea europaea* fruit has a history of consumption in the UE, the applicant believes that this concentrated source of select constituents should also be considered to have a history of consumption. To back this argument up, the applicant cites *COMMISSION REGULATION (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.*

With respect to the non-novelty of the ingredients when a declaration of healthy properties was approved, any decision on a declaration of healthy properties in accordance with Regulation (EC) No 1924/2006, as is the case with the incorporation of a declaration to the list of authorized

declarations referred to in Article 13 (3) does not constitute a marketing authorization for the substance to which the declaration concerns, nor a decision on the possibility of using the substance in foodstuffs or the classification of a certain product as food.

Conclusion:

The aqueous extract of olive fruit standardized in 10% hydroxytyrosol is a selective concentrate of constituents of the fruit of *Olea Europaea* tree with no history of consumption before 05/15/97 in the European Union in the food field, falling within the scope of Regulation (UE) 2015/2283 on Novel foods.