

Summary of the dossier: Olive fruit dry extract standardized in hydroxytyrosol (10 or 20%)

Applicant: NATAC BIOTECH S.L., C/ Electrónica 7, 28923 Alcorcón, Madrid, SPAIN

This novel food application is related to an olive fruit dry extract standardized in either 10 or 20% hydroxytyrosol. Approval is sought under Regulation (EC) No 2283/2015 of the European Parliament and of the Council of 25th November 2015 concerning novel foods. The ingredient falls under the following category: "Food consisting of, isolated from or produced from plants and their parts". The applicant request the authorization to use of the novel food in food supplements. Children under 18 years, as pregnant and lactating women are excluded from the target population. The novel food is not intended to replace any food. It does not mislead the consumer.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.

All the specifications of the novel food are in accordance with European standard and regulations. Analyses have demonstrated the lack of various contaminants, including notably heavy metals, microbiological contaminants, pesticides, PAH, PCB/dioxins, mycotoxins. In addition, stability of the novel food has been demonstrated with tests in accelerated conditions and intermediate conditions.

The safety of the novel is based on the data available in the scientific literature substantiating the lack of toxicity of olive fruit and of hydroxytyrosol. Moreover, the application has performed two genotoxicity studies in order to clearly demonstrate the lack of genotoxicity of the novel food. Regarding allergenicity, olive fruit is not a major allergen, and the lack of protein in the product substantiates the lack of allergenic risk.

Therefore, the olive fruit dry extract (10 or 20% hydroxytyrosol) is well-characterized and compliant with European regulations. The product is safe and devoid of significant allergic potential. The novel food does not present consequently any potential hazard to the European population in the conditions proposed by the applicant.