

Consultation request for the determination of the novel food status ARTICLE 4 of Regulation (EU) 2015/2283

Consultation request to determine the novel food status of CBD isolate and CBD extract

Recipient Member State: Czech Republic, Ministry of Agriculture, Food Safety Department

Date: 30/11/2023

Name and description of the novel food:

The request concerns CBD isolate/extract, which is intended to be used in food supplements (hemp oil with CBD and capsules with CBD).

Cannabidiol edible oils and capsules, which are produced from European industrial hemp (Leaves, Flowers, Seeds, Whole plant). The hemp material is crushed and subsequently associated with the solvent, which is alcohol. This creates a tincture containing a cannabinoid (CBD), flavonoids, terpenoids, and other substances, removing the rest of the solvent. Molecular distillation separates flavonoids, terpenoids, and other substances, removing the rest of the solvent. The result is a THC-free Broad Spectrum CBD oil with concentration 2% to 20% of CBD/hemp tincture in the oil, or is filled into capsules.

Novel food status:

Novel food

Novel food category:

Category: Art. 3(2) (a)(iv)

Reason statements:

Competent authorities of the EU Member States and the European Commission were consulted. A history of consumption to a significant degree prior May 1997 has not been demonstrated for the CBD distillate and CBD extract. Therefore, cannabidiol extract and/or cannabidiol isolate and food or food supplement consists of cannabidiol extract and/or cannabidiol isolate are considered novel foods.