

Summary of the application: Phytocomplex of *Melissa officinalis* L., leaves, from standardized cultures

Applicant: AETHERA BIOTECH SRL, Via dell'Innovazione n.1, 36043 Camisano Vicentino VI, Italy.

This novel food application consists in *Melissa officinalis* L. phytocomplex from cell culture called MeliBrainTech-PC phytocomplex (*Melissa officinalis* L., leaves) from standardized cultures. The applicant requests the possibility to use the novel food in food supplements (category 17) at the maximum dose of 1 g per day. The novel food 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.

The similarity of the novel food phytochemical profile with commercialized *Melissa officinalis* L. extracts has been demonstrated using LCMS, GCMS and NMR analytical techniques. Therefore, it is estimated that the novel food is safe for human consumption under the same conditions of use as the various *Melissa officinalis* L. preparations available on the market.

The safety of *Melissa officinalis* L. extracts has been previously evaluated by EFSA in the context of feed additives (EFSA, 2020 [6016]; EFSA, 2021 [6904]). In addition, the applicant provided all requested information on the standardized production process, analytical data revealing absence of contaminant and available toxicological data on *Melissa officinalis* L. supporting the safety of the novel food.

Thus, this application requests the possibility to use the novel food in food supplements (category 17).