

Summary of the application: Broad Spectrum Hemp Extract 85%

Applicant: SPECTRUMS EUROPE, 1 rue de Stockholm, 75008 Paris, France.

This novel food application is related to a broad spectrum extract of hemp (*Cannabis sativa* L.), called PCR Broad Spectrum Hemp Extract 85%, containing 85% cannabinoids, almost exclusively CBD, and devoid of THC. 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, pregnant and lactating women, and people under anti-epileptic medications, are excluded from the target population.

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, Polycyclic aromatic Hydrocarbons (PAHs), polychlorinated Biphenyls (PCB), dioxins, residual solvents. In addition, a full analysis of cannabinoids, according to the Association of Analytical Chemists (AOAC) method, and of terpenes, has been performed on five independent batches to perfectly characterize the ingredient.

The safety of the novel food has been highlighted in accordance with the tiered approach proposed by EFSA, including two toxicity studies (Good Laboratory Practices (GLP) and Organisation for Economic Co-operation and Development (OECD) compliant studies): a bacterial reverse mutation test (OECD 471) and one in vitro micronucleus test (OECD 487).

The available scientific literature provide several animal toxicity studies and more than 130 human clinical trials showing the safety of CBD supplementations at daily intakes dramatically higher than the proposed uses. Regarding allergenicity, no safety concern can be highlighted due to the lack of protein in the product. Therefore, PCR Broad Spectrum Hemp Extract 85% 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.