

Summary of the application: Refined industrial hemp extract from *Cannabis sativa* L.

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This novel food dossier contains the application for the novel food status of refined industrial hemp extract from *Cannabis sativa* L. needed for authorized use in the EU ingredient market according to the Regulation (EU) No 2015/2283. Refined industrial hemp extract falls under the novel food class 'Food consisting of, isolated from, or produced from plants or their parts' as set in Article 3(2)(a)(iv) of Regulation (EU) 2015/2283.

The novel food Refined industrial hemp extract is an extract obtained from leaves and tops from *Cannabis sativa* L. by CO₂ extraction. Only varieties are used that are registered in EU's Common Catalogue of Varieties of Agricultural Plant Species and do not contain more than 0.2% total Tetrahydrocannabinol (THC, i.e. Δ 9-THC + Δ 9-THCA). These low-THC (<0.2%) varieties of industrial hemp are cultivated and harvested. The leaves and tops are dried, pelletized and subsequently CO₂-extracted to obtain hemp extract. The hemp extract is refined to obtain a refined hemp extract.

Refined industrial hemp extract is specified to contain a maximum level of 12% total CBD. The main components are fat and small amounts of dietary fibre and protein. Specific plant components are a spectrum of cannabinoids. The processing is performed according to ISO22000 and complies with the general food safety principles, food contaminants and microbiological requirements laid in Regulation (EC) No 178/2002, Regulation (EC) No 1881/2006, Regulation (EU) No 1307/2013, Regulation (EC) No 396/2005 and Regulation (EC) No 1441/2007.

Refined industrial hemp extract is targeted towards the general, healthy population. It will be used as an ingredient for CBD oil and consequently sold as a food supplement. The novel food is not intended for infants, pregnant and lactating women, and people on medication. The conditions of use are maximum of 100% refined hemp extract with the restriction that Δ 9-THC concentrations in CBD oil never exceed 0.05%. Analyses show no safety concerns for heavy metals, mycotoxins, dioxins, polychlorinated biphenyls (PCBs), polycyclic aromatic hydrocarbons (PAHs), pesticides, THC, antinutritional factors and microorganisms in refined industrial hemp extract. Genotoxicity and subchronic toxicity studies, human data and post-marketing evaluation of comparable hemp extracts showed no safety concerns for consumers.