

European Industrial Hemp Association's Novel Food Consortium

OBX is a member of the [European Industrial Hemp Association's \(EIHA\) Novel Food Consortium](#). The EIHA Novel Food Consortium, officially launched in June 2020, is the Association's project aimed at clearing the way for hemp foods and extracts – including CBD – in the UK and European Union member states.

By joining the Consortium established by the EIHA, OBX is joining forces with other companies to pursue the safety studies to provide safe and ready access to cannabinoid-based products throughout the UK and EU. The joint application for Novel Food approval requires, including all relevant toxicological studies, an estimated financial expenditure of up to € 3,500,000.

In May, the European Industrial Hemp Association's (EIHA) Novel Food Consortium [received confirmation from the UK Food Standards Agency \(FSA\)](#) that its novel foods application has been approved and its members' CBD products can remain on UK shelves. The approval applies to regular or full-spectrum and natural isolate CBD products produced by the consortium's members.

Official validation will be granted after the forthcoming results of toxicology studies on both CBD and THC, expected later in the year. By granting pre-validation, FSA is recognizing the ability of the EIHA consortium to evaluate and determine the safety levels of its CBD products. The THC study on human beings will be carried out by Chem-Safe in GLP laboratories in the beginning of the summer. The outcome of that study will allow FSA to determine and establish the safe consumption levels of naturally occurring traces of THC in hemp foods and supplements.

RAW INGREDIENTS:

The following products are approved through the EIHA Novel Foods Consortium Application:

- **COMPLIANT FULL SPECTRUM DISTILLATE** - The EIHA dossier number for CBD Regular (i.e., distillate):
Application Ref: RP438 (FULL SPECTRUM)
- **CBD ISOLATE** - The EIHA dossier number for CBD ISOLATE: Application Ref: RP427 (ISOLATE)

FINISHED GOODS:

- Any brand with a finished product that was on sale in the UK before Feb 13, 2020 that submitted their application before March 31, 2021 or has since sublicensed from an EIHA member, can continue selling that product in stores or online, and can switch CBD ingredient providers to any CBD ingredient provider that is part of EIHA's joint application or submitted their own application.
- Any brand with a new finished product that was NOT on sale prior to Feb 13, 2020 needs to go through the whole novel food process for the new product(s) that they want to introduce into stores, obtaining full authorization (inclusion on the FSA public list) prior to entering the market.

COSMETICS:

The EU Commission includes CANNABIDIOL (CBD) and CANNABIGEROL (CBG) to the CosIng database*. These ingredients are now allowed to be used in cosmetics without any restriction.

- CAS number(s): 13956-29-1, 25654-31-3

See Page 2 for further information on finished goods requirements for products in the UK and EU markets.



Product Formulations

Products covered by the EIHA's novel foods joint application

Parameter	Isolate	Gold	Regular	Raw
Refined Description	Pure Cannabidiol (CBD) in hemp seed oil	Extract/Distillate, honey-coloured, partial or complete decarboxylated, from Cannabis sativa L.-Extract, in hemp seed oil	Cannabis sativa L.-Extract, (nearly) complete decarboxylated, in hemp seed oil	Cannabis sativa L.-Extract, not thermally treated (non-decarboxylated), in hemp seed oil
Raw material (RM) 1 for the Formulation	Pure natural Cannabidiol (CBD, > 98.0 % assay, isolated after purification before formulation)	Distillate or extract (refined) from a Cannabis sativa L.-Extract	Cannabis sativa L.-Extract, (nearly) complete decarboxylated	Cannabis sativa L.-Extract, not thermally treated, contains mainly CBDA/CBD
Δ9-THC-content in RM1	< 0.2 %	Ca. 1% or max. 0.2 % (0.3 %) * may contain THCA in small amounts and ratios rel. THC	Ca. 1% or max. 0.2 % (0.3 %) * may contain THCA in small amounts and ratios rel. THC	Ca. 1% or max. 0.2 % (0.3 %) * may contain THCA in small amounts and ratios rel. THC
Raw material (RM) 2 for the Formulation	hemp seed oil	hemp seed oil	hemp seed oil	hemp seed oil
Production process for RM1	By solvent extraction (any solvent under Dir 2009/32/EC) of the aerial parts of Cannabis sativa L. (leaves and/or flowers)	By solvent extraction (any solvent under Dir 2009/32/EC) of the aerial parts of Cannabis sativa L. (leaves and/or flowers)	By solvent extraction (any solvent under Dir 2009/32/EC) of the aerial parts of Cannabis sativa L. (leaves and/or flowers)	By solvent extraction (any solvent under Dir 2009/32/EC) of the aerial parts of Cannabis sativa L. (leaves and/or flowers)
Production process for RM2	by cold pressing from hemp seeds of Cannabis sativa L., possibly filtration	by cold pressing from hemp seeds of Cannabis sativa L., possibly filtration	by cold pressing from hemp seeds of Cannabis sativa L., possibly filtration	by cold pressing from hemp seeds of Cannabis sativa L., possibly filtration
CoA with mass balance available for RM1	by certified lab	by certified lab	by certified lab	by certified lab
Production process for Formulation	by mixing RM1 into RM2 to give a homogeneous solution	by mixing RM1 into RM2 to give a homogeneous solution	by mixing RM1 into RM2 to give a homogeneous solution	by mixing RM1 into RM2 to give a homogeneous solution
CBD-content in Formulation	up to 10 %	up to 10 %	up to 10 %	up to 10 %
Δ9-THC-content in Formulation*	0.001 - 0.02 % (10 - 200 ppm)	up to 0.2 %	up to 0.2 %	up to 0.2 %

* Upper values for THC must be in accordance with THC-limits with narcotic regulations or guidance values for food given by national authorities and EFSA