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## Guidance on regulations for food containing cannabidiol (CBD)

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Rules for marketing in Denmark of food, including food supplements, containing the active substance cannabidiol (CBD) from the hemp plant (*Cannabis sativa* L.) are described below.

Food products must generally comply with food legislation including [Regulation 2015/2283 on novel food](#), which says that food which have not been used for human consumption to a significant degree in the Union before 15 May 1997 shall be subject to risk assessment and authorisation prior to the placing on the market, and [Article 14 of the Food Regulation](#) according to which food must not be unsafe.

The following products of hemp are not considered novel food: Hemp seeds, seed flour, protein powder from seeds and seed oil from varieties of the hemp plant (*Cannabis sativa* L.), listed in the Community catalogue of varieties, which are free of or contain low levels of tetrahydrocannabinol (THC). There is no documented history of consumption in the EU to a significant degree as food before 15 May 1997 of other parts of the hemp plant, including extracts of hemp products. The Danish Veterinary and Food Administration (DVFA) therefore considers such products as novel food, and the placing on the market requires prior risk assessment and authorisation under the EU novel food regulation unless the operator can demonstrate a significant history of consumption according to the EU novel food regulation. Novel food status for hemp and cannabidiol can be found in the [EU Novel Food Catalogue](#). Current status is that pure cannabidiol as well as hemp products with high (concentrated) levels of CBD or other cannabinoids are covered by the novel food regulation.

There is an on-going process in the EU to identify whether other parts of the hemp plant (leaves, flowers, extracts of different plant parts, etc.) have been lawfully placed on the market as a food in the Community before 15 May 1997. The European Commission requested information from EU Member States in 2018.

If information is obtained from a Member State of the European Union that other parts of the hemp plant (leaves, flowers, extracts of different plant parts, etc.) have been lawfully placed on the market as food to a significant degree in the Community before 15 May 1997, the EU Novel Food Catalogue will be updated and clarified as to the parts of the hemp plant not considered as falling under the novel food regulation.

Information about how to initiate a consultation process with a competent authority in order to submit data on history of consumption of a food can be found

on the [European Commission website](#). Information about how to submit a consultation request to the DVFA can be found [here](#).

In Denmark, food supplements must be notified to the DVFA food supplement database. For more details on the placing on the market of food supplements, see the [Danish Veterinary and Food Administration's website](#).

The DVFA routinely asks the Danish Medicines Agency to evaluate all notified food supplements containing CBD. If the Medicines Agency considers that a product is a medicinal product, it cannot be placed on the market as a food supplement. The DVFA therefore recommends contacting the Danish Medicines Agency prior to notification of a food supplement containing CBD in order to clarify that the product is not a medicinal product.

Read the Danish Medicines Agency's advice on CBD products [here](#).

If the Danish Medicines Agency considers that a product is not a medicinal product, it may be a novel food, and an application for authorisation under the novel food regulation will have to be submitted. The examination of the application includes a risk assessment carried out by the European Food Safety Authority (EFSA) and a subsequent authorisation decision. The expected processing time is about 18 months from the submission of the application until a decision on possible approval has been taken. Find out about [the procedure for novel food authorisation](#) here.

The DVFA has set indicative guidance levels for THC content in hemp foods. You can read this on the [Danish Veterinary and Food Administration's website on Novel food](#) (under "Brug af hamp i fødevarer").