USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

Voluntary Report – Voluntary - Public Distribution **Date:** December 04,2020

Report Number: E42020-0092

Report Name: The Status of Hemp Plant Extracts and Cannabinoids in the European Union

Country: European Union

Post: Brussels USEU

Report Category: Agriculture in the News

Prepared By: Sophie Bolla

Approved By: Lisa Allen

Report Highlights:

In January 2019, the European Commission decided to classify extracts of the hemp plant Cannabis sativa L. and derived products containing cannabinoids, such as cannabidiol (CBD) oil, as “novel foods.” Several companies have started the authorization process for CBD oil to be used as a food ingredient. A final decision is expected in 2021.

General Information

In January 2019, the European Commission decided to classify extracts of the hemp plant *Cannabis sativa L*. and derived products containing cannabinoids as "novel foods."[1] The hemp plant contains a number of cannabinoids and the most common ones are delta-9-tetrahydrocannabinol (Δ9-THC), delta-9-tetrahydrocannabinolic acid A (Δ9-THCA-A), delta-9-tetrahydrocannabinolic acid B (Δ9-THCA-B), delta-8 tetrahydrocannabinol (Δ8-THC), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabigerol (CBG), cannabinol (CBN), cannabichromene (CBC), and delta-9-tetrahydrocannabivarin (Δ9-THCV).

The novel food classification applies to:

- the extract themselves
- any products to which the extracts are added as an ingredient
- extracts of other plants containing cannabinoids
- synthetically obtained cannabinoids

In the EU, the classification of a food as "novel" triggers the application of the Novel Foods Regulation[2]. The Regulation requires a pre-market authorization for novel foods. Applications for authorization must be submitted to the European Commission via an e-submission system. The Commission may request the European Food Safety Authority (EFSA) to carry out a risk assessment. Authorizations are generic and not applicant-linked. The novel food approval process generally takes between nine months to a year. However, the European food Safety Authority (EFSA) has the right to ask for additional information and the procedure can take more time if necessary.

Several companies have started the authorization process for cannabidiol (CBD) as a novel food ingredient[3]. These are still currently under consideration with EFSA.

A Delayed Authorization Process

In July 2020, due to an internal review, the Commission decided to suspend the applications for CBD to be authorized under the Novel Foods Regulation. The Commission wrote to companies who had started an authorization procedure to let them know that an internal preliminary ruling found that cannabidiol products are not included in the scope of the EU's General Food Law, and therefore not in the scope of the Novel Foods Regulation. The Commission found that CBD and other extracts from hemp flowers would be better regulated as narcotics under the United Nations Single Convention on Narcotics of 1961.

However, on November 19, 2020, the European Court of Justice (ECJ) ruled that CBD oil is not a narcotic drug. The case was brought to the ECJ in 2018 when the French government opposed a Czech company that sold CBD extracted from the whole cannabis plant to use in electronic cigarette

[1] See EU Novel Food Catalogue's entry for "Cannabinoids": https://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm#
[2] For more information about the Novel Food Regulation, please see GAIN Report 'New EU Novel Food Regulation Applicable as of January 1, 2018'
[3] https://ec.europa.eu/food/safety/novel_food/authorisations/summary-applications-and-notifications_en

cartridges. As part of the judgement, the ECJ stated that to define the terms “drug” or “narcotic drug”, EU law references the UN Convention on Psychotropic Substances and the UN Single Convention on Narcotic Drugs. These two conventions do not specifically mention CBD, although they do mention “cannabis extracts.” The Court wrote that CBD “does not appear to have any psychotropic effect or any harmful effect on human health.”

On December 3, 2020, the European Commission announced that it had reconsidered its position after the ECJ’s ruling and concluded that cannabidiol should not be considered as drug within the meaning of the UN Single Convention on Narcotic Drugs. Commission Spokesman, Stefan De Keersmaecker, confirmed that “this means that CBD can indeed be qualified as food” and that the authorization process for cannabidiol as a novel food ingredient can now resume. EFSA is expected to finalized its review of the existing applications for authorization in 2021.

Attachments:

No Attachments.