Food Safety
AUTHORITY OF IRELAND

MONITORING & SURVEILLANCE SERIES

Survey: Regulatory Issues with Hemp-based Food and Food Supplements on the Irish Market

February 2020

Table of Contents

Abbreviations 3

Relevant Food Law 3

Summary 4

Background 4

Regulatory Status of Hemp and Hemp-Based Foods in Ireland and the EU 5

Novel Food 5

Tetrahydrocannabinol (THC) In Food 6

Controlled Drugs in Ireland 6

Safety of Food From Animals Fed Hemp or Hemp-Derived Feed Materials Containing THC 6

General Food Labelling 7

Food Supplements 7

Nutrition and Health Claims 7

Objective of the Survey 8

Sampling and Analysis 8

Results 8

Conclusions 9

References 11

Abbreviations

CBD Cannabidiol

EFSA European Food Safety Authority

EHO Environmental Health Officers

EU European Union

FSAI Food Safety Authority of Ireland

NFC Novel food catalogue

THC Tetrahydrocannabinol

Relevant Food Law

- Novel Food: Regulation (EU) 2015/2283
- Provision of food information to consumers: Regulation (EU) No 1169/2011 (S.I. No 556 of 2014)
- General principles and requirements of food law: Regulation (EC) No 178/2002 (S.I. No 747 of 2007)
- Food Supplements: Directive 2002/46/EC (S.I. 506 of 2007)
- Nutrition and Health Claims: Regulation (EC) No 1924/2006 (S.I. No 11 of 2014)

Summary

The Food Safety Authority of Ireland (FSAI) coordinated a survey of foods and food supplements on the Irish market that consist of or contain hemp (*Cannabis sativa*) or hemp-derived material. Samples were collected by Environmental Health Officers (EHOs) of the Health Service Executive and analysed by the Public Analyst laboratory in Dublin for the presence of a number of cannabinoids found naturally in hemp.

Cannabidiol (CBD) is one of more than one hundred cannabinoids found naturally in the hemp plant (*Cannabis sativa*). Unlike the psychoactive cannabinoid Delta-9-Tetrahydrocannabinol (Δ^9-THC), CBD does not cause the euphoric "high" that is commonly associated with the consumption of narcotics. CBD is the predominant marketing feature associated with hemp-derived foods and food supplements placed on the EU market in recent years. As the market has expanded rapidly, so too have concerns about the safety, quality and integrity of many of the products on sale in Ireland, most of which originate outside of Ireland.

This FSAI survey has identified a considerable number of regulatory non-compliances with respect to EU and Irish food law. Many of the supplements had not been notified to the FSAI contrary to legal requirements and a substantial number are considered novel foods which require premarket authorisation under EU food law. The level of CBD content of all products determined by an accredited laboratory was found to vary considerably from that declared on associated packaging or online material.

Δ^9-THC was detected in 84% of the products tested. The level of Δ^9-THC in 37% of the products tested was such that consumption of the maximum stated dosages could result in a significant exceedance of the safety limit established by the European Food Safety Authority (EFSA) in 2015. In addition to the safety risk, the presence of THC in these products also poses a risk to consumers who could unwittingly record a positive drug test (THC), potentially jeopardising their athletic or professional careers.

Background

In 2016, the FSAI received two enquiries about the legal status of hemp-based foods and food supplements in Ireland and the EU. In 2017, the number of such queries was close to twenty and increased to over one hundred in both 2018 and 2019. This increase in the number of enquiries to the FSAI about hemp-derived foods and food supplements coincided with the rapid expansion in the market for such foods (predominantly food supplements) in Ireland, the EU and other parts of the world. While there are no reliable data available about the size of the Irish market for CBD products, industry group The Centre for Medicinal Cannabis expect it to reach almost £1 billion in the UK by 2025[1]. The hemp plant (*Cannabis sativa*) is perceived as relatively easy to cultivate, with growing interest in Ireland for the many feasible end uses and its environmental potential as an efficient carbon sink.

The public interest in food and food supplements containing CBD coincides with a relatively recent interest in the medicinal use of cannabis and cannabis derivatives for the treatment of certain medical conditions such as some severe forms of epilepsy. However, while there is some empirical and even scientific evidence supporting the medicinal use of cannabis-based products, any evidence of potential health benefits associated with the consumption of foods or food supplements containing CBD or hemp oil is largely anecdotal at this time.

Regulatory Status of Hemp and Hemp-Based Foods in Ireland and the EU

Novel food

A novel food is a food or ingredient that has not been available to a significant degree on the EU market prior to May 15, 1997. A novel food must be authorised in accordance with Regulation (EU) 2015/2283 before being placed on the EU market. The novel food catalogue[2] (NFC) is an informal, non-legally binding record of the conclusions of discussions that have taken place at EU level in relation to the novel food status of different foods. The information in the NFC is based on evidence provided to Member States or the Commission about a significant history of consumption of certain foods or food ingredients within the EU prior to May 15, 1997. The contents of the NFC are amended when new verifiable information becomes available.

The current novel food status of hemp (*Cannabis sativa*) outlined in the NFC stipulates that; "Some products derived from the *Cannabis sativa* plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel". It further clarifies that national legislation in place in some EU Member States may restrict the placing on the market of these foods.

A separate entry in the NFC under "Cannabinoids" stipulates that the hemp plant contains "a number of cannabinoids", including THC and CBD. It goes on to clarify that: "extracts of *Cannabis sativa* L. and derived products containing cannabinoids are considered novel foods as a history of consumption has not been demonstrated". This means that before being placed on the EU market, hemp-derived products that have been subjected to extraction with solvents like ethanol or CO_2 and used in or as foods and food supplements are considered novel and require authorisation in line with Regulation (EU) 2015/2283.

Tetrahydrocannabinol (THC) in food

Food is defined in "General Food Law" Regulation (EC) No 178/2002, (S.I. No 747 of 2007), which also requires that all food placed on the market is safe. THC is specifically designated as a psychotropic substance in accordance with Schedules I and II of the United Nations Convention on Psychotropic Substances, 1971. Unlike some residues and contaminants, there is no tolerance level set for THC in food under EU or Irish food law.

Controlled Drugs in Ireland

In Ireland, THC is a controlled drug in accordance with the Misuse of Drugs Act 1977, with no threshold or tolerance currently in place.

Regulation (EU) No 1307/2013 restricts the availability of direct EU farm payments for hemp cultivation to those hemp varieties in the Common Catalogue of Varieties of Agricultural Plant Species where the level of THC does not exceed 0.2%. Regulation (EU) No 1308/2013 allows for the import into the EU of hemp varieties where the level of THC does not exceed 0.2%. However, neither of these Regulations apply to food or food supplements and so the 0.2% THC tolerance does not apply.

Safety of Food from Animals Fed Hemp or Hemp-Derived Feed Materials Containing THC

The European Food Safety Authority (EFSA) published a scientific Opinion[3] in 2015 on the risks for human health related to the presence of the psychoactive Δ^9-THC in milk and other food of animal origin. EFSA concluded that exposure to Δ^9-THC in the diet through milk or dairy products from animals fed hemp seed is unlikely to pose a health concern. Since the available data was limited, EFSA had to estimate acute dietary exposure by combining different scenarios for the presence of Δ^9-THC in feed derived from hemp seed. Acute exposure to Δ^9-THC from the consumption of milk and dairy products ranged between 0.001 and 0.03 µg/kg bw/day in adults, and 0.006 and 0.13 µg/kg bw/day in toddlers. Accordingly, EFSA estimated an Acute Reference Dose for Δ^9-THC of 1µg/kg bw. This represents the highest dose of Δ^9-THC consumed in a sitting or a day that is unlikely to have an adverse effect.

General food labelling

A fundamental rule of food labelling in the EU relates to "Fair information practices" as set out in Article 7 of Regulation (EU) No 1169/2011 (S.I. No 556 of 2014). This stipulates that food information shall not be misleading. For example, it is not permitted to suggest that a food possesses special characteristics when in fact all similar foods possess such characteristics, particularly emphasising the presence or absence of certain ingredients or nutrients.

Food supplements

The placing on the EU market of food supplements is governed by Directive 2002/46/EC as amended (S.I. 506 of 2007). As well as a number of labelling requirements, food supplements being placed on the Irish market for the first time must be notified using the online notification system. Notification is not an authorisation nor is it a confirmation that a food supplement complies with EU or Irish food law.

Nutrition and health claims

Nutrition or health claims may only be associated with foods where they have been authorised in accordance with Regulation (EC) No 1924/2006 (S.I. No 11 of 2014).

Objective of the Survey

The objective of this survey was to determine the regulatory compliance of food and food supplements, predominantly in liquid form that claim to contain CBD in Ireland. Compliance was checked against the requirements set out in legislation governing novel food, general food law, food supplements, general food labelling and health claims legislation.

Sampling and Analysis

Hemp derived foods on the Irish market are predominantly in the form of food supplements in liquid form, although the number of general foods claiming to contain CBD is increasing. It is difficult to estimate the number of different hemp-based products on the Irish market. However, for the purpose of this survey, the number of food samples selected (38) was considered representative of the Irish market.

Samples were collected by Environmental Health Officers across Ireland and sent for analysis to the Public Analyst Laboratory in Dublin (PALD). Analysis was based on a method published in 2018 by the Shimadzu Corporation[4]. The Shimadzu method concerned the determination of CBD and general cannabinoid content in hemp oils using HPLC with UV detection but was substituted by PALD with UPLC chromatographic separation and LC-MS/MS detection.
In the method adapted by PALD, cannabinoids were extracted from the samples using acetone, followed where necessary by centrifugation and dilution. The individual cannabinoids were chromatographically separated using a Waters I-Class Ultra-Performance liquid chromatography (UPLC) system and detected via a Waters TQ-XS Mass Spectrometry instrument.
The identification of the analytes was performed using both qualification and quantification ions. Quality control was performed on every analytical run through the analysis of a Certified Reference Material as well as in-house spiked samples. The laboratory regularly participates in international external quality assurance and proficiency testing schemes. The method was approved for accreditation by INAB in 2019.

Results

Analytical data presented refers only to the product batches tested.

- 84% (32/38) of products tested were found to contain the psychotropic substance THC. If consumed at the maximum stated dosage, 37% (14/38) of products tested could deliver levels of Δ^9-THC that would significantly exceed the EFSA acute reference dose of 1µg/kg body weight.
- 34% (13/38) of the samples are considered to be novel foods and require novel food authorisation before being placed on the EU market.
- 41% (15/37) of the products tested contained CBD levels which differed from the declared content by ≥50%, (one product did not declare CBD levels). 92% of products differed from the declared CBD content by ≥10%. Some products contained trace levels of CBD, despite the fact that significant levels were declared on the label.
- 36% (13/36) of samples that were classed as food supplements had not been notified to the FSAI, as required under S.I. No 506 of 2007.
- 50% (19/38) of the products sampled made various claims either on the packaging or on associated online material. These claims included unauthorised nutrition or health claims, possible medicinal claims and misleading lactose free, gluten free and non-GMO claims.

Information provided on two products was not in the English language as required under S.I. No 556 of 2014.

Conclusions

Some of the results of this national survey are similar to those reported in 2019 by the Centre for Medicinal Cannabis in the UK[1] in terms of the presence of THC and the declared levels of CBD. The difference between this survey of the Irish market and other recent reports from different countries is the level of detail examined and the fact that the results of this survey form the basis for corrective action to be coordinated by the FSAI and the Health Service Executive in Ireland.

All of the food products analysed in this survey were found to have one or a number of regulatory issues that need to be addressed with the responsible food businesses. Novel foods must be authorised before being placed on the market and the authorisation process along with relevant legislation and guidance is available on the EU Commission website[12]. Irish food law clearly requires that food supplements destined for the Irish market must be notified to the FSAI. Unauthorised nutrition and health claims, medicinal claims and misleading labelling claims are not permitted in line with the relevant pieces of EU and Irish legislation. The discrepancies between declared and analytical levels of CBD in foods has been highlighted previously[1]. In this survey, sample analysis was carried out by an Irish official control laboratory using an accredited method. Natural variation as well as the type and timing of cultivation, harvesting and processing can all influence the level of the various cannabinoids in *Cannabis sativa*. A slight variation between the analytical and declared CBD content of a sample could be attributed to deviations in laboratory handling and analytical methods used. However, some of the discrepancies identified in this survey suggest a significant problem with the general quality control of these products.

The results of this survey revealed that 32 out of the 38 samples tested (84%) contained detectable levels of Δ^9-THC. Using the maximum stated dosage provided by the manufacturer, it was estimated that 14 of those 38 products (37%) could result in the acute reference dose set by EFSA[3] being significantly exceeded.

The relatively high levels of Δ^9-THC in some products tested in this survey gives rise to immediate concern in relation to the EFSA-derived safety value. However, it is of more general concern when considering consumers who purchase these products for their CBD content, but who may subsequently encounter the physical and physiological effects associated with ingestion of the psychoactive Δ^9-THC.

Concern was expressed in a 2020 EFSA Opinion[5] that the acute reference dose for THC could be exceeded by foods containing or consisting of hemp in the EU. This concern had already been highlighted in a 2018 report[6] by the German Federal Institute for Risk Assessment (BfR)

which concluded that THC levels were too high in many hemp-containing foods and that physical and health impairments were possible. The BfR report went on to explain:
"Moreover, it also appears possible that the consumption of foods containing hemp might result in the intake of Δ9-THC doses in the range of the pharmaceutically administered doses of ≥ 2.5 mg per person and day. In this case, the occurrence of pharmacological effects must be expected. As psychomotor effects must also be expected in this dose range, consumption of hemp containing foods may also result in restrictions in a person's ability to drive or operate a dangerous piece of machinery. The psychomotor effects can also be intensified by the consumption of alcohol and certain other drugs."

A number of products in this survey of the Irish market had the potential to deliver approximately 2.5mg of Δ^9-THC in a day. According to the German report, this level of Δ^9-THC could affect the motor skills of people driving or operating certain pieces of machinery. In the USA[7,8,9] there have been reports of professional drivers losing their jobs following positive drug tests which they claim were due to the consumption of THC-contaminated CBD products.

Sport Ireland has published an advisory notice on social media[10] warning athletes of the possible risk of failing drug tests due to the consumption of CBD products which may contain varying levels of Δ^9-THC and other cannabinoids. World Anti-Doping Agency (WADA) rules[11] stipulate that "All natural and synthetic cannabinoids are prohibited, except for Cannabidiol". A considerable number of potential regulatory breaches have been identified from this survey of the Irish market. Accordingly, the FSAI is working with official agencies and the relevant food businesses to rectify all issues identified, with priority given to products that could pose a safety risk to consumers. Further work in examining this expanding range of Cannabis-based foods and food supplements for regulatory compliance is planned by the FSAI.

References

1. CBD in the UK. Centre for Medicinal Cannabis (2019): https://irp-cdn.multiscreensite.com/51b75a3b/files/uploaded/Report%20%7C%20CBD%20in%20the%20UK%20-%20Exec%20Summary.pdf

2. EU Novel food catalogue: http://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm

3. Scientific Opinion Scientific Opinion on the risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin. EFSA (2015): https://www.efsa.europa.eu/en/efsajournal/pub/4141

4. The determination of CBD and general cannabinoid content in hemp oils using HPLC with UV detection, *Application News No. HPLC-018*, Shimadzu Corporation, First Edition, Feb. (2018): https://www.shimadzu.eu/sites/shimadzu.seg/files/018_cbd_hemp_oil_b.pdf

5. Acute human exposure assessment to tetrahydrocannabinol (Δ9-THC). EFSA (2020): https://www.efsa.europa.eu/en/efsajournal/pub/5953

6. Tetrahydrocannabinol levels are too high in many hemp-containing foods - health impairments are possible. BfR (2018): https://www.bfr.bund.de/cm/349/tetrahydrocannabinol-levels-are-too-high-in-many-hemp-containing-foods-health-impairments-are-possible.pdf

7. Testing Positive for THC from CBD, New Food (2019): https://www.newfoodmagazine.com/article/99602/testing-positive-for-thc-from-cbd/

8. Class Action Complaint (2019): https://www.courtlistener.com/docket/16391145/1/darrow-v-just-brands-usa-inc/

9. US School bus driver suspended (2019): https://abc7chicago.com/health/suburban-bus-driver-warns-of-cbd-use-after-failing-drug-test-losing-job/5568430/

10. Sport Ireland Anti-doping Advisory Notes (2020): https://www.sportireland.ie/anti-doping/athlete-zone/advisory-notes

11. World Anti-Doping Agency (2020): https://www.wada-ama.org/en/content/what-is-prohibited

12. European Commission website on novel food (2020): https://ec.europa.eu/food/safety/novel_food_en

Food Safety Authority of Ireland

The Exchange, George's Dock, IFSC,

Dublin 1, D01 P2V6

T +353 1 817 1300

E info@fsai.ie

Join us on LinkedIn

Follow us on Twitter @FSAIinfo

Say hi on Facebook

www.fsai.ie