



HEMP FEDERATION IRELAND

April 29th 2021

REF: Hemp Industry Regulation and Enforcement Practices in Ireland

Dear Minister Donnelly,

We sincerely hope that you and your loved ones are healthy and safe in these uncertain times.

Hemp Federation Ireland (HFI) represents the common interests of hemp farmers, producers and traders working with hemp fibres, shives, seeds, leaves and cannabinoids. Our main task is to serve, protect and represent the Irish hemp sector. Through the work of our EU industry body in Brussels; the European Industrial Hemp Association (EIHA), we also constantly monitor the EU policy environment.

On behalf of our members, most of which are food business operators trading hemp and its derived products in Ireland and Europe, we would like to address our concerns regarding the Food Safety Authority of Ireland's inaccurate and misleading interpretation of EU regulations governing the operation of our industry.

Hemp Federation Ireland members' produce and sell CBD food products which are extracted by various approved methods, including the use of [Carbon dioxide \(CO2\)](#) and [Ethanol](#) solvents, both of which are permitted without prior authorisation in Europe under the provisions of Novel Food **Regulation (EU) 2015/2283**. This same regulation also permits cold-pressed, aqueous and food-based extraction processes without prior Novel Food (NF) authorisation.

Following a recent meeting with the Food Safety Authority of Ireland (FSAI), the Irish Pharmacists Union (IPU), whose members are significant retailers of our products, last week issued a wholesale ban on CBD on the basis of extraction solvents which FSAI advises are prohibited but which are clearly permitted under Regulation (EU) 2015/2283 which is directly applicable to Ireland.

As you are aware, regulations are legal acts defined by Article 228 of the Treaty on the Functioning of the European Union (TFEU). They have general application and are binding in their entirety and directly applicable to all Member States (MS). As such, EU regulations must be complied with fully by all to whom they apply - including Ireland.

**Regulation (EU) 2015/2283** clearly states that "*extraction solvents falling within the scope of Directive 2009/32/EC of the European Parliament and of the Council should be excluded from the scope of Novel Food Regulation*". **Directive 2009/32/EC** (Part 1 of Annex 1) then provides a positive list of (six) extraction solvents which are permitted without prior authorisation for use in foods in Europe. These are *Propane; Butane, Ethyl acetate; Ethanol; Carbon dioxide (CO<sub>2</sub>) ; and Acetone.*

The Directive is also clear that "*Member States may not prohibit, restrict or obstruct the marketing of foodstuffs or food ingredients on grounds relating to the extraction solvents used or their residues if these comply with the provisions of this Directive.*"

While FSAI advice (copied below) interprets **Regulation (EU) 2015/2283** and **Directive 2009/32/EC** correctly for cold pressed and aqueous extraction methods, their advice prohibits the use of our most used extraction processes which are equally permitted under the same regulation:

- *Hemp/CBD products produced using non-aqueous extraction methods such as CO<sub>2</sub> or ethanol extraction have always been considered to fall within the scope of the novel food Regulation.*
- *"Generally speaking, hemp oil obtained by cold-pressing the seeds or other parts of the hemp plant does not require authorisation.*

This situation is extremely serious for all Irish and EU operators as FSAI's new enforcement measures, "on grounds related to the extraction methods", are inconsistent with the European regulation and would have the effect of removing 95% of all EU and Irish products from the market. Ireland's hemp industry is one of the oldest in the European Union and, as elsewhere in Europe, hemp foods have been available in Ireland for many decades and CBD products of all descriptions have been widely sold on the Irish market for many years.

Previously, FSAI had offered NF authorisation pathways locally, however, the Irish regulation was rescinded in December 2017 following the introduction (in 2015) of centralised EU Novel Food regulation and procedures. A main reason for the introduction of EU centralised provisions was to align and harmonise divergent and often contradictory NF regulations and requirements across EU Member States. While we acknowledge that FSAI, under the previously applicable national regulation, had required Novel Food authorisation for certain extraction processes, this is no longer a requirement under the EU regulation which now applies.

Similarly, FSAI has never required NF authorisation for CBD oils if they are extracted by aqueous and cold pressed extraction methods because the resulting products are considered traditional foods by Irish authorities. Therefore, while the FSAI website informs hemp industry operators of EU measures which would permit CBD products to remain on the market pending EU Novel Food authorisation, their misapplication of the EU regulation regarding solvents then excludes all of the CBD products to which this provision could possibly apply in Ireland.

EU Novel Foods authorisations are processed under a centralised administrative pathway overseen by the European Commission. Novel Food authorisation was not previously a requirement for these products in Europe, however, Irish operators are fully compliant with the new procedures and have submitted *the required* applications for assessment by the European Food Safety Authority (EFSA). The EU

assessment relates to cannabinoids (including THC) which are a natural, integral constituent of hemp and hemp-derived CBD products.

Our EIHA Consortium novel food applications are highly scientific in nature and include extensive toxicology studies as well as the largest ever clinical study of the effects on the human body of trace amounts of THC. Hemp Federation Ireland has no control over the timeframe of EFSA procedures and FSAI provides no separate pathway or provision to authorise products according to special criteria or rules being applied in Ireland.

Nevertheless, on the advice of the FSAI, Irish operators have invested significant money and resources in complying with (very costly) EU NF application requirements. The verification and validation of all EU hemp-derived CBD applications is still ongoing and no authorisation has yet been awarded by EFSA for any CBD product in Europe. Therefore, FSAI's further instruction to IPU retailers, that only CBD products which have already been awarded Novel Food authorisation by EFSA can legally be sold in Ireland, is equally misleading and contradictory as no such product exists.

The actions of Irish regulators also run counter to positive developments in Europe following the recent ruling of the Court of Justice of the European Union (CJEU). In response to the Court Judgement, the EU Commission issued immediate clarifications regarding the regulation of hemp and CBD products in Europe. The Commission is also currently working to integrate the Court's main findings within the *acquis communautaire*; the overarching set of laws governing the smooth and harmonious functioning of the European Union. This process, which will result in further clarifications and adjustments, is also ongoing and is expected to be finalised soon.

In addressing the scientific safety and the legality of CBD products made from any part of the hemp plant, the recent judgement of the [CJEU in Case C-663/18](#) reached three important findings:

- i.) The CBD at issue in the main proceedings does not appear to have any psychotropic effect or any harmful effect on human health on the basis of available scientific data.
- ii.) The CBD at issue in the main proceedings is not a drug within the meaning of the Single Convention."
- iii.) A Member State may not prohibit the marketing of cannabidiol (CBD) legally produced in another MS when it is extracted from the cannabis sativa plant in its entirety [including the flowers and fruiting tops] and not only from its fibres and seeds.

In respect of the above ruling the EU Commission advised EU operators:

- CBD derived from any part of the EU hemp crop is not a drug within the meaning of the UN Single Convention, as it does not have psychotropic effect, and that CBD is regulated by EU authorities in accordance with EU food law (**Regulation (EC) 178/2002**).

FSAI's advice to Irish operators is completely at variance with the Commission's advice:

- *"Certain parts of the hemp plant can be considered food (e.g. seed), but certain parts cannot as they are considered narcotic drugs (e.g. "flowering or fruiting tops etc."). In addition, food parts of the hemp plant can be considered novel food depending on the processing they may undergo. "*

- *"EU food law was not mentioned in the ECJ ruling and as such is not superseded by this ECJ ruling. In essence, THC specifically does not fall within the EU definition of "food" on the basis of it being recognised internationally as a psychotropic substance. "*

Indeed, DG SANTE has recently confirmed to Hemp Federation Ireland that it has already begun the process of establishing authorised limits for THC in hemp foods in Europe.

Following the CJEU ruling, (which was announced on November 19th 2020) **COUNCIL DECISION (EU) 2021/3 of 23 November 2020**, was formally ratified and signed in Brussels. The Council Decision establishes the EU position on the World Health Organisation's recommendations to the UN regarding the control of cannabis within the Single Convention. Paragraph (28) of the Council Decision clarifies that the European Union would *"welcome further consultation with all relevant stakeholders in respect of cannabis preparations with a low delta-9-tetrahydrocannabinol [THC] content."*

Paragraph (35) specifically notes that *"Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision."*

Whereas the UN Single convention of course applies to Narcotic Drugs, consultations with the WHO in advance of the UN vote also considered and confirmed the scientific safety of CBD food and other products derived from hemp, therefore EU hemp industry operators are 'relevant stakeholders' in this instance.

As previously stated, the EU Commission is currently integrating the findings of the CJEU more fully into the *acquis communautaire*. As part of this alignment, in February of 2021, the Commission lifted its ban on Cannabidiol (previously restricted under Annex II/306 of Cosmetics [Regulation \(EC\) No. 1223/2009](#)) thus allowing this ingredient (which had been restricted with reference to the Single Convention) to be used in cosmetic products in Europe.

Ireland's approach is out of step with regulations and positive developments and indications at EU level, and with the obligation of EU Member States to ensure the smooth and harmonised functioning of the European Single Market. It is very disappointing that newly restrictive and contradictory enforcement measures continue to be introduced by Irish competent authorities. Ireland is weakening ONLY Irish farmers and operators who are already prevented, by Ireland's current framework of unworkable and contradictory rules, from engaging on an equal footing with our EU industry colleagues and fellow pioneers across the European Union.

Ireland requires immediate, appropriately clarified and workable rules that are consistent with EU legislation and regulations. If the necessary steps to set up a transparent and consistent regulatory environment continue to be delayed, Ireland and its operators will lose an economic advantage that will be very hard to recover. Hemp Federation Ireland therefore asks you, as Ireland's Minister for Health, to put on hold any actions taken by Irish authorities concerning CBD products until the revision of the *acquis communautaire* is completed by the European Commission.

Hemp Federation Ireland represents some of Europe's most highly regarded hemp industry experts and we would very much welcome an opportunity to discuss the regulation of our industry with appropriate Department of Health officials. Stakeholder engagement is a core principle of EU democratic procedure which has been entirely denied to Irish hemp industry operators since 2018. In an emerging sector with so

much to offer in terms of EU economic, social and environmental policy objectives, such an engagement could only be beneficial.

For Europe's 500 million consumers, the EU's Single Market is one of the Union's greatest achievements in terms of increased choice of goods and services and better value for money. Europe's hemp consumers and industry operators are entitled to expect that their right as EU citizens to take full advantage of the Single Market will be upheld through the correct interpretation and application of EU legislation and regulation across *all* Member States, including Ireland.

We appreciate the many competing demands on your Ministerial and Departmental resources at present and I thank you in advance, on behalf of the board and members of HFI, for your time and attention in considering these important matters.

Yours sincerely,

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