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UK CBD Pathway Clear As EU Decides

by David Ridley

The European Commission thinks that CBD might be a narcotic, after all. What should companies be doing while it decides? In this exclusive interview, regulatory expert Greer Deal – director at Global Regulatory Services – suggests that companies that haven't already done so should consider filing Novel Food (NF) applications with both the European Commission and the UK Food Standards Agency.

When it comes to cannabidiol in food supplements, the European Commission seems unable to make up its mind.

After deciding it should be classed as a novel food in the European Union at the beginning of last year, the EC is now considering whether CBD is, in fact, a narcotic, in line with the United Nations 1961 Single Convention on Narcotic Drugs. (Also see "*EU CBD Market Under Threat With Narcotic Classification Favored*" - HBW Insight, 22 Jul, 2020.)

Conversely in the UK – Europe's biggest market for CBD – the regulatory pathway has become relatively clear for CBD food supplements, as the country exits EU and moves out of the purview of the EC. (Also see "*UK Food Authority Clarifies CBD Compliance*" - HBW Insight, 5 Jun, 2020.)

In this exclusive interview, regulatory expert Greer Deal explains the background to the EC's *volte face* and offers sage advice to companies operating in or looking to enter Europe's CBD market.

GREER DEAL, DIRECTOR, GLOBAL REGULATORY SERVICES

Deal – who is director at Global Regulatory Services – suggests that companies that haven't already done so should consider filing Novel Food (NF) applications with both the EC and the UK

Food Standards Agency (FSA).

This way, they can benefit from free-of-cost feedback on NF dossiers from the FSA while waiting for the EC to decide whether CBD is a narcotic, while also joining the queue for NF approval if the EC decides that CBD is, after all, a Novel Food.

If, on the other hand, the EC decides CBD is a narcotic, Deal points out that these companies will then still have a dossier ready to go with the FSA for when it can formally accept NF applications in January, once the Brexit transition period is over.

Q **Why has the European Commission changed its mind about CBD. What's the context for this in your opinion?**

A The trouble is, there's a stigma attached with CBD and anything that's extracted from cannabis. CBD is known to be non-psychoactive but there are still people out there who have an issue with the strength that is being proposed to be put into food supplements. Meanwhile, decisions in Europe are made country by country and to be honest at the political level. Different countries have a different viewpoint on CBD. To find a way forward, it seems that the European Commission has now turned, or perhaps has been advised to turn, to the United Nation's 1961 Single Convention on Narcotic Drugs and to pause CBD Novel Food applications while it decides whether the ingredient is a narcotic or not.

Q **But isn't there also debate at the UN level as to whether CBD is a narcotic?**

A Yes, they are debating this. However, the decision deadline has been postponed again, and the meeting to discuss this issue is now supposed to take place in December. Interestingly the EC has said it's going to make a decision in September, so it's actually out of sync with the UN. I can't see how the EC can decide until the UN has made its own decision on CBD. Otherwise, the EC might have to change its opinion if it contradicted the UN.

Q **What do you think will happen at the UN meeting in December, if it takes place?**

A I would really like there to be some common sense. CBD, in my opinion, is not a narcotic and we need to find a way that makes it clear to the industry it's not a narcotic. I do think that politics will play a part because it's a massive industry and growing. Governments are going to get a lot of revenue from it. So they won't want to kill it overnight, which is what will happen if it's deemed to be a narcotic.

Q **What about synthetic CBD? My understanding is that synthetic CBD is completely separate from this discussion about CBD as a narcotic. Is that right?**

A Yes, we're talking about naturally derived CBD here not synthetic. If it's synthetic CBD then absolutely, that's novel food, that's black and white. There are no misunderstandings there, it's naturally derived CBD that's causing the issue at the moment. There is at least one synthetic CBD dossier that has been validated. Now it's going through the safety assessment phase so we don't know what the outcome of that will be but at least it's been validated but all the applications that have gone in for naturally derived CBD, they've all been paused. It all comes down to the wording of the UN Narcotics Convention. That CBD is a narcotic is not mentioned explicitly but is implied because it talks about cannabis extracts and tinctures. While synthetic CBD is chemically exactly the same, it is not extracted out of the cannabis plant. On the other hand, if CBD was just cold pressed oil – i.e. just squeezed out of the plant – then it would be classed as a traditional ingredient, and wouldn't come under EU Novel Food Regulation at all.

Q **This must all be very confusing for industry!**

A I feel quite disappointed because there are some genuinely good companies out there that are doing their upmost to be compliant. Then suddenly there's this change and everything they have done could be a complete waste of time and money. Industry has spent millions of euros trying to comply with the Novel Food Regulation.

Q **What is happening with those companies that have submitted NF applications?**

A Because the EC is still deciding on the classification of CBD, all those dossiers have been paused. The EC is requesting a response from these companies to prove that CBD is not a narcotic and they have two months to respond. Essentially, the EC is pushing the issue back to industry and saying, "prove otherwise."

Q **So, what's next for industry?**

A I think that the industry as a whole has got to take an active stance especially whilst the EC is still deliberating. I believe it is important to bring together companies and put together a single document that goes to the Commission and gives a very robust scientific and legal response which represents the view of the CBD industry. That's what we're trying to encourage and progress at the moment on behalf of companies who, for whatever reason, are not members of a consortium etc. I'm hopeful that the consortia and associations are taking a similar approach on behalf of their members.

Q **GRS is playing an active role then?**

A We've decided to for the benefit of the industry. We believe there are very good products out there which should stay on the market. The whole point of the Novel Food Regulation is to confirm that a food is safe, that's what it's all about. If people want to start making claims you've got to first make sure that the product is safe, i.e. it complies with the Novel Food Regulation and then go down the health claim route. That adds another couple of years on but by running studies which can provide evidence of CBD's positive effect on health means that a company can make claims which are based on robust science. This is the next step after obtaining a Novel Food approval. To reiterate, a successful Novel Food application simply confirms the food product is safe to consume There are health benefits in taking CBD food products, but first of all we must prove that it's safe.

Q **In a recent article, you say that the "position for the UK and CBD as a novel food is now clear," could you explain why you think that is the case?**

A Fortunately, the UK Home Office has categorically stated that CBD is not a narcotic, and is therefore outside its remit. Meanwhile, the UK's Medicines and Healthcare products Regulatory Agency has categorically said that it is definitely not a medicine. All that's left is that it must be a food, and the UK Food Standards Agency has, until now, followed the EU in deciding it has to be a Novel Food. At the moment, the UK has left Europe but is in a transition period until the end of this year. This means that the FSA cannot, currently, formally accept Novel Food applications. But what it is doing is strongly encouraging companies to informally submit their NF dossiers to them so they can provide constructive feedback on the way the information is being presented. This then means that feedback can be acted upon and the quality and content of the dossier improved so that it's ready for UK submission from 1 January 2021.

Q **With the European Commission considering whether to regulate CBD as a narcotic, do you think we will see a lot of companies shifting their focus to the UK?**

A Most of the enquiries we get are about the UK or are from companies wanting to start in the UK and then expand across Europe. They see the UK, in terms of market share, being very attractive. Also, the approach of the UK FSA has made companies feel more comfortable about coming to the country – even more so now, because the regulatory pathway is clear. However, Germany is quite attractive as well.

Q **So, what's your message to CBD companies operating in or thinking about operating in Europe?**

A What I would say is put in a dossier with the EC while at the same time informally submitting your application to the UK FSA, to get their feedback. Then, unless you are part of a consortium already (for example, as part of the European Industrial Hemp Association), you could put together a robust legal and scientific response to the Commission showing that CBD is not a narcotic. If the Commission decides that CBD is not a narcotic, the clock will start again with regards to Novel Food applications and you will already be in the queue. If they decide that it is a narcotic,

then there will be many legal challenges, I'm sure, but in the meantime, you're still going down the route of entering the UK market. The other choice is that you start off with the UK, and not submit anything to the European Commission until they have decided what the classification of CBD should be.

Q **I think that's really good advice. Is there a cost to the informal process in the UK?**

A No, it's completely free. To be clear, it's for companies that already have products on the market and need to get their dossiers validated by the end of March next year, to conform to new FSA rules. For those companies that are not already on the UK market or are going to submit maybe some time next year there won't be quite the same level of input. Having said that, the FSA is extremely helpful, and will offer quite a bit of guidance. That's all free of charge.