NOVEL FOODS UPDATE

Food Standards Agency confirm CBD products can continue to be sold and will be exempt from enforcement.

Note: This advice is given by the BRITISH CANNABIS® and the Cannabis Trades Association. It does not constitute legal advice.

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BRITISH CANNABIS® today welcomes the clarity that has been provided by the <u>Food Standards</u> <u>Agency</u> (FSA). We are of the opinion that it provides a route towards protecting CBD companies from enforcement and steering a direction for a compliant industry moving forwards.

Today's update by the FSA will provide great assurance to consumers, the industry and retailers, as for the first time, it provides clarification of an exemption from enforcement.

So, what will this mean for your CBD business?

While there is some legal clarification required around a couple of points, read on to find out exactly how this change will impact your business and how to take advantage of the opportunity that has been handed to us.

Legally Questionable

Firstly, this is not a clear statement. There is certainly further clarification needed and we are in communication with the FSA to provide clarity on this.

- What forms the basis of a valid application?
- What is the definition of a new product?
- What are the specifics around the UK authorisation process?
- How is this exemption legally binding or what provisions are anticipated in the UK authorisation process that allow for the exemption?

While these are all technical questions, it is very encouraging that now there is a route to compliance and protection from enforcement being presented by the FSA. On the basis that this is now a matter of process, we welcome this route and the assurances it will give our customers moving forwards.

What is the media's take on this?

While the media seems to be scaremongering and concentrating on safety concerns and the possibility that products will be removed from sale in a year's time, the story right here right now is that the FSA have provided us with a route to legally continue to sell CBD without enforcement. This is the best news we have had in a long time. We can continue to operate; our customers can continue to use our products and they are being offered protection from enforcement.

Exemption from enforcement moving forwards

The statement from the FSA is clearly stating that there will be protection from enforcement and a green light will be given to all products currently on the market.

So essentially you can be protected from enforcement if you submit and have validated your novel food authorisation applications before 31st March 2021.

After 31st March 2021, only products which have a fully validated application will be allowed to remain on the market.

Now this is great news, but currently there is no provision for an exemption in law. We will address that later with regards the UK authorisation process that will need implementing in law.

So, while we need further clarification on what is defined as a new product, our current legal opinion is that if an ingredient is covered by the exemption, so too will any products made from that ingredient.

This is great positive news for the majority of the industry. Providing your supplier is exempt, your products will also be exempt. The worst-case scenario will be that you just need to change your supplier to one that is covered by the exemption.

BRITISH CANNABIS® and its clients will be covered from enforcement moving forwards

BRITISH CANNABIS® can today confirm that all its products and ingredients will be covered by the exemption. So, any of our current clients will benefit from the protection of enforcement. The required process is already underway that will afford all

How long will this exemption last?

Currently and for the foreseeable future the exemption would, on the face of it, cover products until the food has been evaluated and authorised as a novel food. As we have seen with the first CBD application, in its 6th year of processing, this exemption could last some considerable time. This is dependent on what is set out in the UK authorisation process.

However, ultimately there will be no action for over a year and following this it is the intention to only remove products that are not undergoing assessment. So, we have a clear route to protect our customers for the foreseeable future.

What is the authorisation process and how will it work?

We have seen the first indication that a new UK authorisation process will be in place in 2021.

From this we can assume that post-Brexit there will be a "UK authorisation process" passed into law that will legally allow for the exemption. With no details on this at present, we can only assume that it will be substantially similar to the current novel food process but specifically allows for this legal exemption.

Current Novel Foods Regulations do not allow for any exemptions for CBD, so it is our opinion that the new regulations will likely mimic many of the current Novel Food regulations. The FSA are also asking that submissions are made to them.

"As well as submitting them to the European Commission website as usual, we also strongly recommend businesses also send them to us."

"This will allow us to give businesses guidance and answer any queries we may have, in order to ensure they progress at pace through our UK authorisation process from 1st January 2021."

Further indicating that as of January 2021 the UK will have a process to assess Novel Foods.

What about the 70mg maximum daily dosage?

The Regulator based its recommendations on advice from the government's Committee on Toxicity (COT), which has found evidence of "*potential adverse health effects*" from CBD. However, COT said it *"still does not know enough to be sure about such a risk".*

So, this is just advisory and only targeted as medical guidance if taking other medications or pregnant.

There is still no clear evidence and there is certainly no new limit on products. They still do not know if there is any risk. We are confident that there is no risk posed at up to 200mg daily, as was agreed as an upper limit with The Medicines and Healthcare products Regulatory Agency (MHRA) in 2016.

How about Scotland?

The FSA's advice will apply in England, Wales and Northern Ireland but not Scotland which is covered by a separate regulator. We would expect a similar position to be adopted by the Scottish regulator.

What does this all mean?

The industry can breathe a sigh of relief that the Novel Foods issues is drawing to a conclusion. If the FSA statement can be taken on face value, the industry can move forwards with no risk of enforcement. The technical aspect of the actual novel food application will happen in the background but is unlikely to have any impact on the majority of the industry.

The requirements for authorisation will fall to companies in the industry, like British Cannabis who as the largest supplier of CBD ingredients in the UK, will protect its customers and those using CBD as an ingredient in their products. We will be working to secure an exemption for all our clients and take the worry out of the whole process. You can carry on with business as normal with the assurance from us that you will be fully protected and free to sell based on the FSA's proposal.

We can now see some further investment in the industry as risk has been greatly reduced and returns on investment are looking much more favourable. This is good news for all and we will be further updating our clients as we receive further information.

2020 looks set to be the year we solidified the CBD industry moving forwards and as long as you are buying CBD products from a compliant company, that offers you protection, like British Cannabis, you have nothing to worry about.