FOOD STANDARD AGENCY CHIEF EXECUTIVE'S REPORT TO THE BOARD

(8TH DECEMBER 2021)

The FSA Chief Executive has updated the FSA Board on:

- **their progress with the assessment of CBD Novel Food applications;**
- **how they intend to proceed with their further assessment of those applications;**
- **their intention to maintain two "lists" (one for already Validated and one for what appears to be "heading in the direction of Validation";**
- **their intention to target "stakeholder retailers" (i.e. national and larger regional chains) retailers and advise them of the status of products which they say (by reference to the above lists); and,**
- **their intention to advise Trading Standards to direct enforcement against rejected products (rather than products on either of the above two lists).**

The full text of the Report is reproduced here (emphasis added by ourselves):

> *I wanted to give an update on the CBD applications in particular. As the Board know, the FSA has been concerned for some time about CBD food products which are on sale but have been concerned for some time about CBD food products which are on sale but have not yet been through the formal novel foods market authorisation process. CBD products are unusual, in food regulatory terms, for three reasons:*
>
> - ***Confirmed as a 'novel food' after many on sale**. After some time discussing the novel food status of CBD extracts, in January 2019, the European Commission confirmed that CBD is a novel food (i.e., with no significant history of consumption before May 1997). By that time, however, a substantial number of products had already been placed on the market. Our consumer research in 2020 told us that of the 60% who said they had heard of CBD, 13% said they had used it in the past year.*

MAST CONSULTING LTD
20 Old Bailey
London EC4M 7AN
Co. No. 12191810
VAT Reg. No. 334 8110 23

www.thecannaconsultants.co.uk
info@thecannaconsultants.co.uk
0203 468 1520

- ***A food but could be a drug or a medicine****. CBD is in the nexus of regulatory regimes between drugs, medicines and food. Some CBD products are classed as medicines and are therefore regulated by the MHRA (Medicines and Healthcare products Regulatory Agency). CBD is widely associated with general health benefits; these claims have not been substantiated by the relevant bodies. Further, if there is THC (tetrahydrocannabinol, the psychoactive compound in cannabis) in the product – which is a risk as it is derived from the Cannabis plant - it becomes an illegal drug. A product cannot, legally, be both a food and an illegal drug.*

- ***A dearth of existing research****. There is little existing scientific evidence about the safety or effect of CBD on the body. The Committee on Toxicity (COT) identified in July 2019 that CBD can have a number of adverse side effects and that there were numerous data gaps and uncertainties. Further data are needed to fully assess its safety. It is a basic principle of food law that the food business which sells the product is responsible for making sure it is safe for the consumer.*

Since 2020, the FSA has been taking a proactive and phased approach to bringing this part of the food industry into compliance with the law. The approach balances legal compliance, consumer safety, the interests of consumers who take CBD products, and the desire to support innovation in the food industry*.*

In the interests of consumer safety, in February 2020 we offered consumer advice, highlighting that none of the products currently for sale had been formally safety assessed. Further, if consumers were going to eat them, they should limit themselves to a maximum of 70mg a day, and we advised vulnerable consumers not to eat CBD products on a precautionary basis. We understand we were the first food regulatory agency in the world to do this.

To encourage the industry to become compliant, at the same time we set a deadline of 31 March 2021 for applications to be registered with the FSA so that CBD products could be taken through the usual novel foods assessment process. The responsibility for novel foods market authorisation assessments transferred from the EU to the FSA on 1 January 2021.

MAST CONSULTING LTD
20 Old Bailey
London EC4M 7AN
Co. No. 12191810
VAT Reg. No. 334 8110 23

www.thecannaconsultants.co.uk
info@thecannaconsultants.co.uk
0203 468 1520

We received a large number of enquiries and applications by our deadline but after filtering only around 210 applications were viable for further consideration, connected to several thousands of products.

Since April 2021 we have therefore been working progressively to give more clarity to the market, local authorities and to consumers about the likelihood of those applications getting market authorisation. ***So far, we have looked at almost all of the applications to see if they have provided enough scientific data to enable us to do a scientific risk assessment for safety. The quality of applications was lower than we anticipated, so this work has taken longer than we thought it would.*** *Where necessary, we have had to ask for additional scientific information from applicants. Once we are confident we have sufficient information, we 'validate' the application and it then goes formally into the scientific assessment process.* ***Currently, four applications have passed through the validation stage.*** *We have made this list public.*

Over the next few months, we expect to:

- ***reject some further applications which have insufficient information to be validated and no prospect of that information being provided;***

- ***add further applications to the published validation list*** *and commence formal scientific assessment on them;*

- ***publish a list of the applications where work on studies was in train before our March 2021 deadline but where we are awaiting information and where there is a reasonable expectation that such scientific information will be provided in a timely manner in order that the application will be validated****.*

We will shortly have triaged all applications into the three categories above. After this time, only those products on the two lists should remain on the market. At that point we will remind stakeholders including retailers of this and will offer guidance to local authorities on the enforcement of novel food legislation.

MAST CONSULTING LTD
20 Old Bailey
London EC4M 7AN
Co. No. 12191810
VAT Reg. No. 334 8110 23

www.thecannaconsultants.co.uk
info@thecannaconsultants.co.uk
0203 468 1520

For the products that are on the two lists *we need to be clear that these products are still not formally authorised for sale and neither have they yet been assessed for safety. But* ***[there] are credible applications, and we are therefore proposing that products connected to them that are on sale should not be prioritised for enforcement action****.* ***Obviously this would change if they were subsequently rejected from the authorisation process,*** *for example because information came to light about their safety, or about their status as a drug rather than a food. In the meantime, we continue to advise consumers to take account of our messaging, which is based on current knowledge.*

Over the next 1-2 years we will then conclude our scientific assessments*, our consultations with the public over the authorisation of these products and ultimately offer advice to ministers on which products should be formally authorised. This may seem slow, but I should note that the novel foods authorisation process is one guided by statutory timescales, and where the 'clock' can be stopped when additional information is awaited.*

The CBD industry continues to grow. We hope that in taking this phased approach, ***we are acting in a reasonable way to support innovation while also protecting consumers and creating a level playing field for the CBD industry****. Retailers and producers need to be responsible when marketing and selling these products, in relation to health claims and other aspects of food law. We will continue to work closely with the Advertising Standards Authority and DHSC where we become aware of unsubstantiated health claims being made on CBD food products. We continue to monitor the situation closely and will take other steps if we consider that consumer safety is at risk.*

MAST CONSULTING LTD
20 Old Bailey
London EC4M 7AN
Co. No. 12191810
VAT Reg. No. 334 8110 23

www.thecannaconsultants.co.uk
info@thecannaconsultants.co.uk
0203 468 1520