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# 10mg CBD Per Day – UK Food Regulator Sets 'Provisional' Acceptable Daily Limit

by David Ridley

The UK Food Standards Agency has issued new advice aimed at consumers warning them not to take more than 10mg CBD per day, an acceptable daily intake level significantly lower than the agency's previous ADI of 70mg per day. However, CBD brand owners should not reformulate their products, Canna Consultants warns, as this would be a breach of FSA's conditions for remaining on the market.

"A healthy adult should not consume more than 10mg of CBD per day," says the UK Food Standards Agency.

This "provisional" acceptable daily intake (ADI), which translates to about four or five drops of 5% CBD oil, is significantly lower than FSA's previous recommended upper limit of 70mg a day, equivalent to 28 drops of 5% CBD a day. (Also see "*UK CBD Firms Given Deadline For EU Compliance*" - HBW Insight, 13 Feb, 2020.)

FSA continues to advise that CBD is not taken by people in vulnerable groups, including children, people taking medication (who have not consulted a medical professional) and those who are pregnant or breastfeeding and those trying to conceive.

"The more CBD you consume over your lifetime, the more likely you are to develop long-term adverse effects, like liver damage or thyroid issues," commented the FSA's chief scientific advisor Robin May.

"The level of risk is related to how much you take, in the same way it is with some other potentially harmful products such as alcoholic drinks," May added.

FSA's new advice of 10mg per day is based on an assessment of data received from hundreds of

novel food applications by a joint subgroup of the Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT).

The scientific evidence from human studies and toxicological studies submitted as part of these applications supports a provisional Acceptable Daily Intake (ADI) of 0.15mg/kg bw/day, the subgroup recommends in a *position paper*, which is equivalent to 10mg CBD/day for a 70kg adult.

While the assessment looked specifically at data from "pure form CBD," which is CBD as an ingredient in food – not as an inhalant or cosmetic – that is at least 98% pure, FSA has aimed its guidance at all CBD products currently on the UK market, including so called "full spectrum" CBD.

## Only Advice

CBD industry expert and Canna Consultants co-founder Stephen Oliver is keen to stress that the advice is "advisory and not mandatory" for the 11,652 CBD food products currently legally marketed in England and Wales, some of which contain more than 10mg of CBD in a single serving.

Having spoken to FSA's head of regulated products, Oliver reassured companies marketing CBD-containing foods – all listed on FSA's "Register of CBD products linked to novel food applications" and designated as "validated" or "awaiting evidence" – that the advice "does not have to be followed."

"No products will be removed from the public list simply because they are single consumption units at a dosage of greater than 10mg," Oliver told HBW Insight. "Manufacturers should not immediately react and change the formulation or packaging of their products."

FSA confirmed to HBW Insight this guidance was correct. "We are not removing products from the market based on the new consumer advice, and we will continue to work with industry and retailers to move CBD products into compliance with our novel foods regime," the agency said.

"This will include engaging with industry and retailers about how this updated advice needs to be reflected in their products," it added.

## Don't Reformulate

Reformulating products now to meet FSA's 10mg limit would in principle breach one of the the regulator's own conditions for allowing as yet unauthorized products to remain on sale: that they "were on the market at the time of our announcement on CBD (13 February 2020)," Oliver's colleague and Canna co-founder Matthew Lawson pointed out.

"FSA recognizes the anomaly that were you to seek to follow their safety guidance and change a

product's formulation, you would be voluntarily removing yourself from the public list via their existing policy," Lawson noted.

As to what FSA might mean by "engaging with industry and retailers about how this updated advice needs to be reflected in their products," Lawson suggested that FSA intends to "conduct a review of how the public list will operate."

This was also confirmed by FSA. "We are reviewing our approach to managing the public list," the agency clarified. "Any changes will be made following discussion with representatives from the CBD food industry."

## ADI Could Change

Both FSA and the ACNFP/COT subgroup also suggest that the 10mg ADI could change if new, compelling evidence comes to light. "We continue to review our advice based on the evidence we gather from industry," FSA noted.

The ADI is deemed "provisional," the subgroup said, because the studies used in risk assessment were "sub-chronic in design and relatively short-term in relation to the potential for chronic lifetime exposure, particularly given possible accumulation of CBD in the body."

"If further data were to become available that could impact on the provisional ADI, then it could be revisited in the future."

However, because the existing toxicology data is sufficient to establish an adequate hazard characterization for sub-chronic oral exposure to pure-form CBD, the subgroup warned that further sub-chronic toxicity studies "would be an unnecessary use of animals."

"Applicants are encouraged to find alternative means of providing new evidence," it advised. "The data gap on the consequences of chronic exposure to CBD on a daily basis might, for example, best be addressed by post-marketing surveillance," it suggested.

Where animal studies are deemed unavoidable, the subgroup encouraged applicants to "act collaboratively where scientifically appropriate, to generate robust evidence while minimizing the use of animal testing."