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FSA Should Review 10mg CBD Daily Guideline Based On Latest Toxicology Data

by David Ridley

The UK Food Standards Agency should review its recently published guidance recommending an acceptable daily intake (ADI) of 10mg cannabidiol for consumers, says food law expert Mark Tallon. Data in the public domain, such as that published by Tallon and colleague Robert Child shows that short-term consumption of CBD isolate is safe for adults at circa 100mg per day if applying the FSA's assessment approach, he explains.

Recent toxicology data may show the UK Food Standards Agency's recently published 10mg CBD acceptable daily intake (ADI) level to be set too low, says food law expert Mark Tallon.

"There should be an obligation on the risk assessor to review the data, as new science is produced," insisted Tallon, who is managing director of UK-based regulatory affairs firm Legal Foods Ltd.

Co-author of one of two recently published scientific papers which conclude significantly higher CBD intakes are safe, Tallon thinks the FSA may not have taken such data into account when setting its "provisional" 10mg level. (Also see "*10mg CBD Per Day – UK Food Regulator Sets 'Provisional' Acceptable Daily Limit*" - HBW Insight, 13 Oct, 2023.)

Significantly lower than the FSA's previous "pragmatic upper level" of 70mg a day, the new ADI, Tallon claimed, is based on only three toxicological datasets out of the "hundreds" of CBD novel food applications submitted to the FSA, and assessed by the agency's scientific committees, the Advisory Committee on Novel Foods and Processes (ACNFP) and Committee on Toxicity (COT).

Data in the public domain, however, such as that *published by Tallon and Legal Foods chief science*

officer Robert Child, shows that short-term consumption of CBD isolate is safe for adults with a body weight of 70 kg at circa 100mg per day if applying the assessment approach of the FSA's science committees, Tallon explained. Similar studies by Rayetta Henderson and colleagues *found similar high levels in their data*.

"Such data seems to have been ignored by the ACNFP and COT," Tallon commented. "Ultimately, ACNFP and COT assesses the data that's put before them. However, it's up for the FSA to say, 'okay, we think now this new data should be looked at.'"

Industry Dialogue

It may have been the case that the FSA didn't even realize that there was new data that should have been included, Tallon suggested. Which is why, he said, the regulator should have spoken to industry stakeholders before publishing the consumer facing 10mg guidance.

"The jobs and the lives of the FSA are not hanging on what the CBD opinions are," he pointed out. "Businesses, on the other hand, are economically damaged by any adverse publications, whether from the regulator or in the scientific literature."

This was certainly the case when UK health food chain Holland & Barrett took over 30 CBD products from its shelves following the FSA's 10mg per day announcement. (Also see "*UK Health Food Chain Reinstates CBD Products After FSA-Related Review*" - HBW Insight, 31 Oct, 2023.)

Despite the FSA noting that the guidance was only advisory, and that there was no expectation for manufacturers to reformulate or retailers to remove products, Holland & Barrett felt that "as a responsible retailer" it had to temporarily remove products from sale while its science, legal and independent advisors assessed the new guidance from the FSA.

While Holland & Barrett was the only retailer to respond in such a way, one of the companies affected, CBD drinks manufacturer TRIP, was nevertheless relieved when products were restored.

Given the material impact of FSA guidelines on companies, the regulator "could at least give industry a right to reply," Tallon argued.

Industry's sensitivity to new publications, whether they be regulatory or science-based, also means that it is a resource for the FSA. "The FSA would have done well to ask companies if there was any new data, which may be in pre-publication or have been funded by them," Tallon suggested.

New Research

Tallon and Child's CBDmd-funded study investigated the toxicology of a CBD isolate.

Under the conditions of the study and based on the toxicological endpoints evaluated, the lowest-observed-effect-level (LOEL) for the oral administration of the CBD isolate in MCT oil was 30 mg/kg bw/d for males and females.

“The no observed adverse effect level (NOAEL) for the oral administration of this CBD isolate was 460.5 mg/kg bw/d for male Sprague-Dawley rats and 230.25 mg/kg bw/d for female Sprague-Dawley rats when delivered in a MCT oil vehicle,” Tallon explained.

“Using an uncertainty factor of 100 (10 (between species) x 10 (within species)) this indicates subchronic intake of the CBD isolate in this trial is safe for reference adult humans (70 kg) at a dose of 161 mg per day,” he continued. “Using the uncertainty factors COT and ACNFP used this gives a value of 100 mg.”

The results of Tallon and Child’s study are in line with the findings of a previous study by Rayetta Henderson et al, which found a NOAEL level for oral isolate CBD at concentrations up to 150 and 140 mg/kg-bw/d for men and women respectively.

Peer Review

“Surely, you would look at data that's been through peer review and assessed by toxicologists, and consider this more independent than the raw data submitted by applicants, which hasn’t been scrutinized other than by the regulator?” Tallon asked.

Particularly the Henderson paper, Tallon insisted, which was published online on the 25 August, “at least eight weeks before the FSA issued its consumer facing 10mg ADI press release.”

“So, I do think that the FSA should go back and reassess the data,” he concluded. “But it’s now the job of individual businesses and trade associations to push and lobby the FSA on this issue.”