







Dear Sir or Madam,

We are contacting you concerning a pressing matter that requires your urgent attention and engagement. We speak on behalf of four trade associations that together represent the vast majority of the UK hemp/CBD sector.

Specifically, following a round of apparent random testing at FERA, the FSA have deleted a number of CBD consumer products from the 'NF Public List' based on the '1 mg (THC) per container' recommendation (i.e., 'Regulation 2. limb c. of the MDR). We appreciate how the FSA may feel obliged to apply the MDR in this situation, but this is an incorrect use of the instrument and is already severely impacting several quality operators supplying safe products with considerable implications for the consumer and the UK industry as a whole.

We ask the Home Office to clarify with the FSA that random application of the MDR should cease whilst the ACMD review and associated discussions proceed. This will not only enable a more inclusive and informed decision-making process but also reinforce the principles of openness and accountability in government actions.

As you know, back in January 2021, Kit Malthouse, MP wrote to Professor Bowden-Jones reflecting on the lack of a legal framework specifically exempting CBD products from control under the Misuse of Drugs Regulation (MDR) and stating the Governments intention to "explore the possibility of creating a specific exemption". Clearly, the inference is that the MDR is not 'fit for purpose' in the context of CBD consumer products and should not be used for compliance activities on that basis.

The ACMD report published in December 2021 together with the considerable industry inputs from the sector provided a foundation for a review aimed at agreeing safe, practical and science-based levels of controlled cannabinoid in CBD products, assuring consumer safety, preserving consumer choice and supporting UK industry. It is understandable that the considerable changes in Westminster since the publication of the ACMD report will have contributed to the slow progress of the process, however this delay is now threatening the UK industry.









Whilst the ACMD report is being reviewed by the Home Office, we ask the British authorities to apply the Swiss values which are based on sound science and safety parameters. This would equate to a ARfD of 490 microgram/average adult or 0.49 mg THC per day<sup>1</sup>. These values have been confirmed as being safe by EIHA toxicological results<sup>2</sup>.

These values were established by the Swiss Federal Office of Public Health in 1995 and Switzerland has been successful in implementing regulations that balance public health concerns while allowing for the responsible consumption of food products containing traces of THC. Just to stress, after almost 30 years of this low/trace level of consumption of THC in food products no adverse effects have ever been reported.

As you may be aware, the EIHA Consortium is conducting the first comprehensive clinical study of THC toxicity involving 400 healthy consumers and this is widely predicted to support a TDI of at least that set by Switzerland.

We would also cite the "Kannavape" court case of 19 November 2020 during the Brexit transition period (<u>EUCJ ruling</u>), which defined hemp extracts not as drugs but rather as foods and recognizes that traces of controlled cannabinoids (as contaminants) will inevitably be present in the products. Just to stress, the companies we represent produce food and food supplements but not drugs.

We look forward to a positive response and available for further discussion at any time.

Mr. Daniel Kruse EIHA President

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<sup>&</sup>lt;sup>1</sup> The Swiss authority recognised a lowest observable physiological effect level of orally administered  $\Delta 9$ - THC of 5 mg per adult and applied an UF of 10. This means a provisional tolerable daily intake of 7 μg/kg b.w. (as reported by Zoller et al. 2000) <a href="https://pubmed.ncbi.nlm.nih.gov/10749491/">https://pubmed.ncbi.nlm.nih.gov/10749491/</a> **from page 101 to 110.** 

<sup>&</sup>lt;sup>2</sup> "Safe" means no effects have been recorded at these doses.