Statements

Joint Advisory Committee on Novel Foods and Processes (ACNFP) & Committee on Toxicity (COT) Position paper on establishing a provisional acceptable daily intake (ADI) for pure form ≥ 98% CBD in foods based on new evidence: Lay Summary

Lay Summary

In response to a call by the Foods Standards Agency (FSA) for applications to use cannabidiol (CBD) as a novel food ingredient, applicants submitted fresh evidence on the safety of CBD in food products. The FSA had not previously considered this evidence in its consumer advice.

A joint ACNFP and COT Subgroup was formed in 2022 to perform a review of existing and new CBD evidence that was received to support the novel food applications.

The CBD products will be considered in three distinct groups; Group A, products using ≥98% pure CBD only; Group B, products using CBD and a mixture of cannabinoids; and Group C, natural hemp or hemp-based extract products. The sub-group has completed its work on Group A products.

Sufficient evidence from toxicological and human studies is now available for >98% purity CBD products to perform a human health risk assessment seeking to establish a provisional acceptable daily intake (ADI) below which no harm is expected for the general consumer population.

A provisional ADI is established of 0.15 mg/kg bw/day i.e., 10 mg CBD/day for a 70 kg healthy adult, which is approximately equivalent to 4-5 drops of an oil-based supplement product containing 5% CBD of ≥98% purity. Currently, somnolence (excessive tiredness) and adverse effects on the liver are the main concerns if one were to consume levels higher than the provisional ADI.

This ADI is provisional as it might be possible to refine it with new scientific information in the years ahead. The sub-group also concluded that due to data gaps, CBD-containing foods should be avoided by potentially vulnerable consumers including pregnant/breastfeeding women, prospective parents trying for a baby, those who are immunosuppressed, children, and people on prescription medication, without the advice of a medical professional.

This is the first time a provisional ADI has been established as a daily intake value for CBD in the UK or anywhere in the world. An intake value of 10 mg/day (for an average adult weighing 70kg) can now be applied to the safety assessments of the hundreds of novel food products containing >98% pure CBD for which dossiers have been submitted under the novel food regulation. The CBD intake levels from novel foods relative to the provisional ADI can be considered by the FSA in their risk management and risk communication to the public for > 98% purity CBD ingredients in food.

Group B and Group C novel food products, as described above, are more challenging and require further technical evaluation of the existing evidence and data gaps by the FSA, with further advice from the ACNFP/COT joint sub-group.

Dependent upon the nature of the food type, further considerations and information on how CBD is absorbed across the gut in humans in different food matrices may also need to be factored into product specific risk assessments by the ACNFP.

The statement from the ACNFP and COT reads: Joint position paper from ACNFP & COT on establishing provisional ADI for pure form CBD in foods

The subgroup was of the view that the available evidence was sufficient to perform a risk assessment of ingredients containing >98% pure form CBD, in Group A product types, with the caveats for potentially vulnerable consumers. The commissioning of any further 90-day animal toxicology studies on >98% pure form CBD ingredients was strongly discouraged. Human evidence in the form of bioavailability data and adverse events data should be considered by applicants in providing further information in support of their specific novel food products.