



For immediate release

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ACI novel food applications validated

The Association for the Cannabinoid Industry's novel foods applications (RP126 and RP127) have been validated by the Food Standards Agency (FSA).

The ACI received formal notification from the FSA that both its applications for the authorisation of CBD isolate and distillate 'fall within the scope of the novel foods regime' as set out in Regulation (EU) 2015/2283 (as retained) and fulfil the requirements set out in Article 10(2) of that Regulation.

These applications are now regarded as valid, and will now move on to the risk assessment stage to be assessed further.

ACI member applications account for 30% of the products currently permitted to remain on the market under the novel foods authorisation process.

These applications relate to 320 brands on sale in Britain.

In 2022, the ACI submitted a complete toxicological package and related bioavailability data to the FSA to support the consortium of member applications.

This included the dose range finding study and the OECD408 rodent toxicity study to determine a No Observable Adverse Effect Level (NOAEL), to cover the safety implications of not only CBD, but also the minor cannabinoids and other plant matrices present in these plant-derived products.

Two years on from the novel food application submission deadline, this week's FSA update comes a year after the food safety body published its first public list of ingestible CBD products deemed temporarily compliant, pending the submission of toxicology data, its risk assessment and acceptance to progress to the validation stage.

Steve Moore, ACI co-founder and strategic counsel, said:

"This is a key milestone for the sector and the ACI. The new consumer cannabinoid sector has been set as an important regulatory challenge. Today's outcome suggests that by collaborating, they are both progressing towards market authorisation for thousands of products but also delivering the safety data the authorities have been crying out for."

Paul Birch, ACI co-founder, said:

"This outcome was only achievable due to the expertise of our regulatory and scientific team led by Dr Parveen Bhatarah and Dr Paul Duffy who have provided exemplary insight and advice throughout this process."

Notes to editor

In 2019, the FSA assigned ingestible CBD products with novel food classification under the Novel Food Directive. For a product to be legally available for sale, it must be present on the FSA's public register, which is updated when the status of an application changes.

Ingestible CBD products include CBD oil drops, tinctures, and any infused food or beverage. The directive does not apply to CBD vape products, cosmetics or topicals.

Ends

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