

From Rebecca Sudworth Director of Policy

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By e-mail: cc:

20 March 2025

Dear Marika,

Thank you for your letter of 11th March 2025, also copied to Susan Jebb and Robin May. Once again, apologies for not having sent our reply to your letter of December 2024. I will address both letters here.

I welcome the positive comments on the ADI for isolates and synthetics. You'll be aware our consumer advice relates to all CBD products. Our scientific advisory committees are looking at other forms of CBD products including full spectrum products and we will review any further advice they issue on CBD levels. This work is being done in parallel to the progression of specific applications, including those with published risk assessments and others earlier in the assessment process.

Our risk managers across GB are addressing several points to be ready for consultation, with the launch date dependent on their resolution. As our Chair, Susan Jebb, has explained, because CBD applications are more complex, the consultation period will be12 weeks. We will outline the timetable for this process in due course.

Our independent scientific advisory committees have been considering potential food safety implications of THC and are due to publish their findings, expected April/May. This advice will include a safe upper limit for THC. This advice does not require agreement with the Home Office to be published as it relates to food safety where the FSA has independent responsibilities. We are familiar with the issues relating to detection and will factor this into decisions on how we proceed with applications and any wider advice on THC. Just as we do for any authorised product where other substances may be present in the final product, limits for THC will be included in the Terms of Authorisation (ToA) for each application, based on evidence provided by the applicant and the FSA's decision about how the presence of THC should be managed to ensure consumer safety.

Your letter from December made some suggestions for the forthcoming consultation. I'd like to clarify that the upcoming consultation will be covering the specific proposed ToA for the first three CBD application currently being considered in the Risk Management stage of the process. The proposed ToAs will include the specifications for the product, labelling requirements and the conditions of use.

Following consultation, we will make recommendations to health ministers in England and Wales, and Food Standards Scotland will do the same in Scotland. If and until Ministers decide to authorize these applications, all CBD food products remain non-compliant unless authorised. Our primary goals are to ensure that food is safe, it is what it says it is, to move the CBD market into a compliance with food law. This will require compliance with drugs law as well. We are aware of the need for bulk suppliers to have licenses. This is a Home Office requirement so we cannot comment further.

Sequencing and process

The Market Authorisation service processes applications in sequence based on when they were received and when applications are ready for risk assessment. CBD applications are handled in this manner too. The recommendations and possible authorisation decisions from Ministers will also match this sequence. Delays have been caused by the volume of applications received, with a high number of these being of poor-quality adding time to the process for validation or removal. It was not appropriate to single out just bulk suppliers to be favoured in the sequencing. Applications progress on merit, more quickly with better quality data. We recognise the time already taken on the application process, which is partly due to the effect of applications being retrospective rather than pre-market as the law requires. The approach of tolerating some products on the market through the Public List has added extra complications but the desire to get all applications processed remains a priority for the FSA. As you may be aware we have issued a further five safety assessment with more due out soon. We remain committed to progressing these through risk management as a priority and for more safety assessments to be progressed as soon as possible.

CBD Public List

I note your concerns over the operation of the CBD Public List. This list was designed as an interim decision aiding tool to help local authorities, retailers and consumers identify products already on the market, linked to credible applications. The list will therefore remain closed to new products, and we do not allow further white labelling. If a food business does introduce a new product to the market, it will not get the tolerance offered to products on the list. If new products are added to the market, the relevant local authority can consider taking enforcement action.

The decision to authorise CBD products rests with Ministers. Subject to this decision, we will issue further advice on how the list will operate once the first authorisations come into force. This is because the context in which the list operates will have changed. We will engage with key stakeholders when we intend to issue these updates. Of course, the CTA will be part of these discussions.

THC and the EPD

The Home Office is advised by the Advisory Committee on Misuse Drugs on the status of THC in consumer CBD products from a drugs perspective. Following the current law, we are required to use the Exempt Product Definition (EPD).

The EPD is a Home Office policy which is a part of Home Office legislation (the Misuse of Drugs Regulations). It would be inappropriate for the FSA to consult on another department's legislation and policy.

The FSA can consider compliance with wider legislation as an "Other Legitimate Factor" when setting the ToA and making recommendations to Ministers. Products using CBD as an ingredient must comply with their ToA to remain an authorised novel food.

Post-authorisation

We do not authorise individual product lines, and the FSA cannot be seen to endorse specific products offered on the market. We will, in line with the Novel Foods regulations, update the <u>list of authorised novel food applications</u> if they become approved. It is therefore not necessary to create a separate list of authorised CBD products. Food businesses can however point to the novel foods list to show their products are legal, assuming these products comply with the conditions set in the approval.

Thank you once again for your continued engagement with the FSA on these matters and I trust that this letter has addressed your most pressing points. I look forward to continuing dialogue with the CBD industry as we work together to bring the market into compliance.

Yours sincerely,

Rebecca Sudworth Director of Policy

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