

CBD Novel Food Applications

FSA 24/12/07 - Report by Thomas Vincent and CBD Policy Team.

1. Summary

1.1 The FSA and Food Standards Scotland (FSS) have published the first safety assessments for Cannabidiol (CBD) novel food applications. They have now entered risk management, after which the FSA and FSS will make recommendations to Ministers across Great Britain (GB) on the authorisation of these applications.

1.2 Our current timetable is to make the first recommendations to Ministers in Spring/Summer 2025, following an eight-week public consultation launching in early 2025.

1.3 This paper sets out the key issues under consideration as we formulate these recommendations, and the principles upon which they will be based.

1.4 The Board is invited to:

- **agree** the principles that will underpin our risk management of CBD.
- **discuss** how these principles will be applied in practice for CBD novel food applications.

2. Progress to Date on CBD

2.1 Edible CBD products are novel foods, and therefore must go through our market authorisation service and receive authorisation from Ministers to be placed on the market in GB. The FSA is at the forefront of assessing CBD as a food, and other international regulators are following our work closely. We have sought to be pragmatic as a regulator, recognising that many CBD products were already on the market when the regulatory position became clear and that some consumers find these products beneficial. The FSA's Public List of CBD products (which applies in England and Wales) has allowed products linked to a valid market authorisation application to remain on the market whilst moving the industry towards compliance with novel food regulations.

2.2 Scientific assessment to date shows that CBD does not pose an acute safety risk at 10mg a day for a healthy adult. However, we have issued consumer advice that vulnerable groups, including children, those who are pregnant or breastfeeding, those trying to conceive, those taking regular medication and the immuno-suppressed, should avoid the consumption of CBD. The FSA published a provisional acceptable daily intake (ADI) of 10 mg/day of CBD for healthy adults in October 2023.

2.3 Three applications for CBD (>98% purity) isolated from Cannabis sativa have now received positive safety assessments – meaning that the FSA/FSS have concluded that the applicants have provided sufficient information to assure us they are safe under the proposed conditions of use. These applications are now undergoing risk management, the purpose of which is to consider any other legitimate factors that may affect a decision to authorise, before making a recommendation to Ministers about authorisation, including any conditions that may be

required such as labelling and consumer information. This paper seeks steers from the FSA Board to guide our overall approach.

Primary Objective

2.4 The primary objective of the FSA's work on CBD has been to ensure it is safe and bring the industry into compliance with food law as soon as possible. Working closely with FSS, we have been seeking to do this on a four-nation basis in line with the provisional Food and Feed Safety and Hygiene Common Framework, to ensure consumers across the UK have access to food that is safe and what it says it is

3. Principles for Risk Management

To guide the FSA's approach to the risk management of CBD applications in receipt of a positive safety assessment, the Board is asked to consider and agree the following principles:

- a) Consumer Safety - the FSA's core role is to protect public health, and therefore people must be given clear advice on the safe consumption of CBD.
- b) Proportionality - the FSA will ensure decisions taken on CBD protect public safety whilst not disproportionately limiting consumer choice or the CBD industry.
- c) Ensuring Compliance - CBD is no different to any other area of novel foods. Whilst we have adapted a pragmatic approach to allow certain products to stay on the market, only CBD that is an authorised novel food will be able to remain on the market once assessment of applications linked to products on the public list is complete.
- d) Supporting Enforcement - the FSA will ensure decisions made on the CBD public list, and recommendations made to Ministers on authorisation, will enable and support retailers and enforcement colleagues in preventing non-compliant products from remaining on the market.
- e) Maintaining Trust - the FSA's approach to CBD will maintain consumer trust in food safety and the FSA, including by managing the legal and reputational risks to the agency.

3.1 The principles above will guide the FSA's approach to the risk management of CBD applications in two key areas as we move towards making recommendations to Ministers: THC and protecting vulnerable groups, including under 18s.

4. THC

4.1 Tetrahydrocannabinol (THC) is a controlled cannabinoid found in CBD products. THC is classed as a controlled substance and subject to control under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001. Extracting pure CBD is almost impossible, therefore detectable levels of THC and other controlled cannabinoids CBD will be present. This is also the case with synthetically produced CBD, where THC and other controlled cannabinoids can remain present at trace levels.

4.2 Home Office guidance has confirmed that any level of THC present in a substance renders it a controlled substance under the Misuse of Drugs Act. However, where THC is present at very low levels and cannot be readily extracted in a quantity that is liable to be abused, it can be defined as an exempt product under drugs law and can be freely traded. Similarly, with the revised licencing conditions set out by the Home Office it will now be easier to obtain a licence to store or transport bulk materials containing low levels of THC. However, it still legally remains a drug despite the exemption above.

4.3 The FSA intends to make recommendations to Ministers on CBD food products containing THC under current food law, where they meet the Home Office exempt product definition. However, we will need to carefully consider the legal and operational implications of regulating a product that is considered both a food and a drug. To support enforcement, we will provide clear guidance on the respective responsibilities of Local Authorities and the police regarding CBD food products.

5. Vulnerable Groups - including Under 18s

5.1 The FSA's consumer advice suggests that CBD should not be consumed by vulnerable groups, including under 18s, and the safety assessments only cover healthy adults. We have some evidence that CBD poses a risk to certain groups, including those on medication and in pregnancy. We will therefore ensure clear labelling of CBD products to protect vulnerable groups, including warning labels for specific groups, and ensuring the ADI is clear on packaging.

5.2 In addition, there is limited data on the health risk posed to under 18s by CBD. It should also be noted the three applications currently being considered in risk management are only seeking authorisations for consumption by those over 18. The three applications currently being considered in risk management are requesting authorisations for food supplements (e.g. CBD oils), with one application also requesting for use in other food groups such as flavoured drinks and chocolate, which children might be more likely to purchase, depending on how the products are marketed and sold. In addition, it is reasonable to consider whether the under 18 population can be held responsible for making informed decisions about their consumption in the same way as an adult.

5.3 The FSA has therefore considered what options we have, within current legislation and proportionate to the safety risk, to ensure maximum protection for under 18s. Taking a precautionary approach given the lack of evidence on safety, the FSA proposes to mandate clear and unambiguous additional labelling for CBD products, including information about the ADI for healthy adults, and a warning that these products are not to be consumed by under 18s. In addition, we will introduce restrictions intended to restrict the marketing of these products to under 18s, and work closely with businesses, retailers and local authorities to inform consumers about the risk and ensure compliance with these conditions. This may include exploring voluntary schemes with industry to ensure under 18s cannot access these products.

6. Next Steps

6.1 The FSA is currently on track to make recommendations to Ministers on our first CBD applications in the Spring/Summer 2025, based on the principles and approach outlined above.

6.2 The FSA will make recommendations on CBD applications to Ministers in England and Wales, and FSS to Ministers in Scotland. Under the Windsor Framework arrangements, prepacked retail agri-food goods containing GB-authorized products would be permitted on the Northern Ireland market if moved via the Northern Ireland Retail Movement Scheme (NIRMS).

6.3 Should Ministers decide to authorise CBD applications, we will need to consider any impacts on the CBD Public List in England and Wales.

6.4 The Board is invited to:

- **agree** the principles that will underpin our risk management of CBD.

- **discuss** how these principles will be applied in practice for CBD novel food applications.