CBD Novel Food Applications: Recommendations to Ministers on First Authorisations

1 Purpose of the paper

1.1 This paper discusses recommendations for the authorisation of three cannabidiol (CBD) novel food applications. The recommendations include proposed conditions of authorisation, designed to protect consumers and vulnerable groups, support compliance and enable proportionate enforcement.

1.2 As this is the first time FSS will recommend the market authorisation of CBD applications, we are seeking confirmation of the Board's support for the risk management approach. This is as per the agreed approach that where applications are considered to be non-routine, they will come to FSS Board to provide additional scrutiny ahead of providing advice to Ministers. Final decisions on authorisations will be made by Scottish Ministers.

1.3 The Board is asked to:

- **Discuss** the outcomes of consultation on the first high-purity CBD novel food applications and the risk management recommendations formed in response.
- **Note** the wider SPS Agreement context on recommendations to Ministers.
- **Agree** that the recommendations on the three applications are suitable for presentation to Scottish Ministers.

2 Strategic priorities

2.1 This paper and the work on market authorisation of CBD supports delivery of all three strategic priorities with a focus on ensuring public health protection and providing an effective public service for the people of Scotland.

3 Background

3.1 The first three CBD novel food applications are RP 7 synthetic CBD, RP 350 CBD isolate and RP 427 CBD isolate. These are ≥98% pure CBD foods and are intended for adults at a maximum dose of 10 mg/day. They were found to be safe under their proposed conditions of use, based on advice from the Advisory Committee on Novel Foods and Processes (ACNFP).

3.2 Subsequently, FSS and FSA risk managers have worked together on how to adequately protect consumers and advise then on safe consumption of CBD novel foods, as discussed with FSS Board in December 2024.

3.3 FSS consulted on these risk management proposals for twelve weeks from 24 March 2026 to 16 June 2026. The proposals set out that products must be labelled

with the provisional acceptable daily intake (ADI) of CBD of 10 mg/day and warnings for under-18s; people who are pregnant, breastfeeding or trying to conceive; and those taking medication or who are immunosuppressed. We proposed that authorisation should only be granted with strict specifications, including low limits for delta-9-tetrahydrocannabinol (Δ^9-THC) and other controlled cannabinoids.

3.4 FSS received six consultation responses from consumers, trade associations and local authorities alongside the forty-six responses received in respect of the FSA consultation. Responses overall indicated support for the risk management approach, while identifying areas where minor changes or clearer explanations were needed. Our proposals include some targeted changes and confirm our recommended approach on the key issues set out below. Our Summary of Responses can be accessed here.

3.5 The progress made on these CBD applications represents a major milestone in the regulation of the CBD food sector. There are approximately 3000 individual CBD products linked to these first three applications. These recommendations therefore represent a significant step towards moving the CBD market into regulatory compliance, supporting consumer confidence under the novel food's framework.

4 Discussion

Key aspects of risk management

THC and other controlled cannabinoids

4.1 We maintain our recommendation that authorised products are subject to strict specifications for Δ^9-THC and other controlled cannabinoids, reflecting the need to protect consumers, support enforcement and ensure consistency with wider legal requirements.

4.2 The Board should note that we propose a more feasible Δ^9-THC specification for application RP 427 following consideration of additional evidence submitted by the applicant during consultation. This revision reflects a higher Δ^9-THC level that can be consistently achieved and verified across production and is in line with our principle for contaminant levels to be as low as reasonably achievable (ALARA). It continues to provide very strong protection for consumers while ensuring that the specification is proportionate, enforceable and achievable in practice.

4.3 Consultation responses also highlighted the need for further guidance to support enforcement authorities, particularly in relation to Δ^9-THC controls and the interaction between food and drugs legislation. Throughout 2026, we have worked across Government and with local authorities to identify the key issues that FSS and FSA guidance will need to address. We plan to provide comprehensive CBD enforcement guidance to local authorities in the coming months and will continue to work closely with enforcement partners to ensure it is practical and fit for purpose.

Food supplements

4.4 We maintain our recommendation to authorise the novel foods for use in food supplements for all three applications, reflecting the categories of use requested and assessed for each application. For RP 350, we also maintain the recommendation to authorise for use in additional categories of beverages and confectionery requested by the applicant. Authorisation under the Novel Foods Regulation would permit the placing on the market of the specified novel food only where it meets the relevant terms of authorisation, including the stated conditions of use.

4.5 We set out in our consultation that any wider requirements in food law, such as those for food supplements, must be considered by the applicant and complied with prior to placing the authorised product on the market. We intend to maintain that recommendation. In Scotland, food supplements sold as food and presented as such must also comply with the Food Supplements (Scotland) Regulations 2003.

4.6 Existing prohibitions on health and medicinal claims for CBD foods will continue to apply. Only authorised nutrition and health claims that are included in the GB Nutrition and Health Claims Register can be used on foods and there are no authorised claims for CBD products.

Labelling

4.7 We have revised our recommendation on labelling requirements in the terms of authorisation in order to provide clearer and more concise wording on the ADI. We recommend that this is presented alongside warnings for under-18s and other vulnerable groups to mitigate against consumption by these groups. Consultation responses broadly supported the principle of mandatory safety information but identified concerns regarding the proposed statement. The revised wording (provided in the Summary of Responses) is intended to improve consumer understanding of how much CBD they can safely consume. All products linked to the applications will need to comply with the conditions of use imposed by Ministers as part of an authorisation: failure to do so is an offence.

Data protection

4.8 All three applicants have requested data protection of proprietary data provided in support of their applications. We will provide advice to Ministers confirming whether FSS considers the conditions for data protection to be sufficiently met. Where they are met, the novel food authorisation would include market exclusivity for the applicant for a five-year period, unless a subsequent applicant obtained authorisation for the novel food without reference to the proprietary data or with the agreement of the applicant.

Future risk management considerations

4.9 Since concluding and publishing safety assessments on these three applications, FSS and the FSA have continued to assess additional CBD novel food applications. To date, we have published fourteen positive safety assessments for >97% pure CBD novel foods. Future applications will continue to be assessed on a

case-by-case basis, with any previous risk management conclusions applied when supported by the evidence and appropriate in the circumstances.

Discussion of wider considerations

Four-country working

4.10 FSS will provide advice to Scottish Ministers. FSA will similarly provide advice to Ministers in England and Wales, with the Minister for Health in Northern Ireland kept informed.

4.11 Board Members should note that under Windsor Framework arrangements, businesses must apply to the EU to place regulated products on the market in Northern Ireland. CBD novel foods authorised in GB may also be placed on the NI market as retail goods, provided they are eligible for, and are moved through, the Northern Ireland Retail Movement Scheme (NIRMS).

4.12 FSS and the FSA continue to work towards a consistent approach across GB.While authorisation decisions are a matter for Ministers in each administration, established arrangements under the Food and Feed Safety and Hygiene Common Framework provide mechanisms for managing any divergence, should it arise.

SPS Agreement

4.13 Detailed negotiations with the EU on a UK-EU SPS Agreement are underway. The proposal for dynamic alignment would mean that (subject to any exceptions that may be negotiated), once an SPS Agreement is in place, an EU market authorisation would be required to market novel foods, including CBD, in GB. In the absence of any exception, businesses would no longer apply to FSS/FSA for novel food authorisations and would have to apply to the EU instead. The scope of EU authorisations would in future include the whole of the UK and GB authorisations would cease to apply. We remain committed to supporting the CBD industry in moving towards regulatory compliance and to keeping applicants and wider stakeholders informed and engaged as plans for an SPS Agreement take shape.

4.14 The European Food Safety Authority (EFSA) has not yet published any positive safety assessments of CBD novel foods. In February 2026, EFSA published an updated statement on the safety of CBD, which sets a safe CBD dose of 0.0275 mg per kg of body weight per day (approximately 2 mg/day for a 70 kg adult). The provisional safe level applies solely to food supplement formulations containing CBD with a purity of at least 98%, without nanoparticles, and for which the production process is deemed safe and genotoxicity has been excluded. For individuals under 25 years old, pregnant and lactating women, and those on medication, EFSA's scientists concluded that the safety of CBD has not been established.

4.15 Whilst EFSA's and FSS/FSA's provisional safe levels differ and are based on different datasets; they involved considerations of the same adverse effects and safety data gaps. We remain confident in FSS/FSA's provisional ADI of 10 mg/day,

which has been produced in line with established risk assessment principles and with the use of independent expert judgement.

4.16 In March 2026, the European Chemicals Agency (ECHA) Risk Assessment Committee adopted an opinion recommending that CBD be classified as a Category 1B reproductive toxicant and lactation toxicant ("may damage fertility or the unborn child and may cause harm to breast-fed children") under the EU Classification, Labelling and Packaging (CLP) Regulation, following a proposal by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES). The recommendation remains subject to a decision by the European Commission and does not itself determine whether CBD food products may be authorised. The FSS/FSA previously reviewed the evidence underpinning the ANSES proposal and concluded that it did not present new data requiring revision of FSS/FSA's provisional ADI for CBD. However, our advice remains that people who are pregnant, breastfeeding or trying to conceive should not consume CBD. We will continue to monitor developments and consider any new evidence as part of our ongoing work to ensure consumer protection.

5 Identification of risks and issues

5.1 The proposals are in line with the Board's very low risk appetite in relation to regulatory impacts and will lead to compliance with delivery of our statutory duties in respect of the market authorisation of regulated products.

5.2 A similar paper is being brought to FSA Board in line with the four-country approach and common frameworks.

6 Equality Impact Assessment and Fairer Scotland Duty

6.1 The need to consider an Equality Impact Assessment (EQIA) and the Fairer Scotland Duty will be completed at a more appropriate stage.

7 Consumer Duty

7.1 Not applicable

8 Conclusion/Recommendations

8.1 We recommend that FSS now advises Scottish Ministers to authorise the three high-purity CBD novel foods, subject to the proposed conditions of authorisation. The applications have been assessed as safe under their proposed conditions of use, and the recommended risk management approach is designed to follow our agreed principles for CBD. Thorough consideration of the risk management approach for these novel foods has led us to conclude the authorisation would be the most effective way to improve consumer safety and start bringing the CBD market into compliance.

8.2 Subject to the Board's agreement, officials will finalise the ministerial advice package for submission to Scottish Ministers as soon as possible. The final decision on whether to authorise the novel foods, and on any associated conditions of authorisation, rests with Ministers following consideration of FSS advice.

8.3 The Board is asked to:

- **Discuss** the outcomes of consultation on the first high-purity CBD novel food applications and the risk management recommendations formed in response.
- **Note** the wider SPS Agreement context on recommendations to Ministers.
- **Agree** that the recommendations on the three applications are suitable for presentation to Scottish Ministers.

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