CBD in the UK: the industry responds

Recommendations for the FSA and the Home Office to expedite the Novel Foods authorisation process for ingestible CBD products

Association for the Cannabinoid Industry

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Foreword

Five years ago, the European Commission updated the Novel Food Catalogue to state that extracts of Cannabis sativa L. and derived products containing cannabinoids were to be considered as novel foods. As a result, all extracts of hemp and derived products containing cannabinoids (including CBD) were regarded by the European Commission as novel.

Contemporaneously, the Food Standards Agency (FSA) committed to implementing a process for accessing Novel Food applications. In February 2020, a policy for implementing this process was announced, and a deadline for applications to the FSA was set for 31 March, 2021.

In January 2021, the Home Office stated its intention to establish a legal framework for consumer CBD products in a commissioning letter to the Advisory Council on The Misuse of Drugs (ACMD). The ACMD response was published in December of that year.

In short, the process of implementation of both legal and regulatory frameworks for ingestible CBD products has been protracted, punctuated by U-turns and has been undertaken without any discernible coordination between the responsible authorities.

This whitepaper sets out the actions the respective authorities should implement in order to establish a full legal and regulatory framework for ingestible consumer cannabinoids in the UK.

In the final quarter of 2023, consecutive updates from the FSA and the Home Office provided some welcome clarity for the sector, while also raising challenges that this paper expressly addresses.

These updates included new precautionary advice for the consumer issued by the FSA on 12 October. It says, "based on the average lifetime exposure to food products containing CBD," healthy adults should limit their consumption of CBD (>98% purity) from food or beverages to 10 milligrams per day. That's equivalent to four or five drops of a 5% CBD oil.

The other key announcement was from the Home Office, made on 24 October. This broadly accepted the position of the ACMD in December 2021, which recommended that legislation be updated so that CBD ingestibles can legally contain up to 50 micrograms of controlled cannabinoids (including THC) per unit of consumption or serving.

This whitepaper outlines the impact of both announcements and the need for continued constructive engagement with the respective authorities. It also draws on a wide-ranging consultation across the CBD industry to establish a clear set of recommendations for the sector's next steps.

The result is a clear path to concluding the vital process of regulating CBD food and beverages in the UK, which when completed will create a clear and coherent legal and regulatory framework for consumer cannabinoids.

Steve Moore
Director, Association for the Cannabinoid Industry (ACI).

Section 1: Acceptable Daily Intake (ADI)

Given the relatively recent and increasingly common use of Cannabidiol (CBD) in food and beverages, it is understandable that guidance on their use has been tentative and evolving. Prior to the Food Standard Agency's latest precautionary advice for the consumer there had been a broad acceptance that healthy adult consumers should limit their CBD (<98% purity) intake to 70 milligrams per day. This acceptable daily intake (ADI) was previously supported by the FSA, and used by many brands and manufacturers as the basis for their novel foods applications.

As such, the FSA's October publication of new precautionary advice to the consumer which lowers the ADI for CBD from 70 milligrams to 10 milligrams – about four to five drops of 5% CBD oil – has caused widespread concern in the industry, including among brands, manufacturers and retailers.

In a joint position paper accompanying the advice, the FSA described the provisional ADI for CBD at >98% purity when used as a novel food ingredient:

> *"The scientific evidence from human studies and toxicological studies supports a provisional Acceptable Daily Intake (ADI) of 0.15 mg/kg bw/day (equivalent to 10 mg CBD/ day for a 70 kg adult) for pure form cannabidiol (CBD) (when used at ≥98% purity) as an ingredient in foods. It is expected that a healthy consumer will not come to harm with this level of intake of pure form CBD (≥98% purity)."*

This provisional ADI was based on data from material that was characterised as belonging to Group A.

This includes finished products incorporating ≥98% pure CBD only and no other cannabinoids (derived from either plant-based extraction or synthetic chemistry sources).

Group B includes products containing CBD and a mixture of other cannabinoids (derived from either plant-based extraction or synthetic chemistry sources).

Group C includes natural hemp or hemp-based extract ingredients containing a range of cannabinoids.

Group A includes human data and rodent toxicology studies. It is understood that three rodent toxicology studies were used in this analysis, and that No Observed Adverse Effect Levels (NOAELs) ranged from 25 to 72 mg/ kg b.wt/day of CBD. The rationale for deriving an ADI from this data is a conventional scientific approach with some clearly stated assumptions.

It should be noted and emphasised that:

1. The reported advice for ADI is "precautionary advice" aimed at the consumer and is provisional, which means that the ADI is likely to be revised as more novel food applications are assessed.
2. The Point of Departure (POD)/ NOAEL approach to deriving an ADI is widely accepted in the scientific safety evaluation community.
3. The joint subgroup will have made their evaluations on the data that was available to them at the time of their deliberations.
4. The subgroup's primary objective is science-based consumer safety.

The Association for the Cannabinoid Industry's View

The ACI recommends that further data underpinning consumption recommendations be evaluated urgently and regular updates regarding ADI to be published online even if this is to reiterate the current precautionary advice to the consumer of up to 10 milligrams per day for long-term use still applies.

The ACI is aware of rodent toxicology data submitted to the FSA that brings additional analysis and opinion on NOAELs. There is also a case for incorporating data from Group B and Group C into the wider understanding of CBD safety.

The FSA should explain the reasoning of the joint subgroup's conclusions and publish any non-confidential information that supports the safety margins applied – notably to clarify the recommendations relating to short-term versus long-term CBD use.

The FSA should be mindful of the potential economic harm caused by such ad-hoc announcements which, on this occasion, caused widespread panic within the British CBD industry and retailers withdrawing product from sale. Not only is there potential economic harm but also reputational damage and withdrawal of funds by investors. We recommend that the FSA provides regular bi-monthly or quarterly updates on their website because it is very feasible that, as more applications move through the assessment phase of the Novel Food process, new data will be available to support the safety of higher ADI levels.

Bearing in mind the FSA's role regarding safety and the consumer, we urge the FSA to focus on the Novel Food applications linked to Group A Products (i.e. >98% purity) so that these are in the first tranche of authorisations to be issued. General consensus is that CBD ingestibles including CBD at >98% purity, are the 'safer' consumer products and it is anticipated that the scientific data presented in these applications will provide robust evidence to support ADI in excess of the current precautionary advice to the consumer.

Section 2: Upper limit for THC and other controlled cannabinoids

On 24 October 2023, the government published a long-awaited plan to update legislation on controlled cannabinoid content in CBD products, based on recommendations from a working group under the Advisory Council on the Misuse of Drugs (ACMD) published in December 2021.

The government statement accepted in principle all of the ACMD recommendations, the most important of which was Recommendation 1:

> That the total dose of Δ9-THC (including Δ9-THCA, as calculated using Equation 1 in the report) and all other controlled phytocannabinoids in consumer CBD products be controlled. The dose of each controlled phytocannabinoid should not exceed 50 micrograms (µg) per unit of consumption.

This conclusion was based on the working group's review of scientific literature, consultations with industry and analytical laboratories, a public call for evidence, information from the Government Chemist's Team and Defence Science and Technology Laboratory, and other sources.

The wider ACMD report also explored:

- The dose at which cannabinoids have no detectable psychoactive effect on humans
- The analytical capabilities to test for these cannabinoids
- The feasibility of production of consumer CBD products with low levels of controlled cannabinoids

The government intends to bring forward legislation to implement Recommendation 1, subject to parliamentary approval. To do this, however, the ACMD statement that the "unit of consumption or 'single serving' is the typical quantity of a CBD product consumed on one occasion" must be revisited. This is because there is ambiguity on what is meant by a "typical quantity of a CBD product consumed on one occasion". As the government noted in its response to the ACMD recommendations, typical quantities' will "differ between different products" and "require further careful consideration".

It is understood that the Home Office has now defined what a 'unit of consumption' or 'single serving' is for a CBD ingestible, although this information does not appear to be in the public domain yet.

The Association for the Cannabinoid Industry's View

Both the ACI and CBD food and beverage industry representatives believe that the ACMD working group report has made a justifiable recommendation for the 50 microgram limit per unit of consumption as proposed, and is an advance on the current legislative limit of zero. There is no data currently that would challenge this limit.

For many CBD ingestibles, product labelling indicates a variety of daily doses such as once, twice, three or four times a day. It is our collective view that rather than attempting to clarify what is meant by a "unit of consumption" or "single serving" based on a "typical quantity of a CBD product consumed on one occasion," reference should be made to a permitted ADI.

Therefore, we propose that a permitted level of 50 micrograms must be the maximum total daily intake of controlled cannabinoids (including THC) and to remove any reference to a "unit of consumption" or "single serving".

This permitted limit should be more straightforward to implement and enforce especially when considering the wide variety of daily doses of consumption. The onus will be on manufacturers and brand owners to provide finished product which complies with this ADI and there will need to be clear labelling to the consumer not to exceed the daily dose of the finished product.

Section 3: Testing methodology and standards

It is important that before CBD food and beverages are issued for sale that they are analysed by validated analytical methods, ensuring product quality and reproducibility. It is also key to evaluate product stability to confirm shelf life.

A variety of analytical methods have been reported for use in the quality control and assurance of consumer CBD products. These include Gas Chromatography Mass Spectrometry (GC-MS), high-performance liquid chromatography (HPLC) plus colorimetric tests.

When an active ingredient such as CBD or an extract containing CBD has been analysed by a fully validated procedure the product in which it is included may be quality controlled and assured using simpler methods. If the active ingredient does not have a certificate of analysis, the more sophisticated analytical methodology should be employed prior to its inclusion in the final product.

The Association for the Cannabinoid Industry's View

The ACI suggests that a small working group of experts from public organisations and relevant industry members be consulted urgently to review and to propose specific analytical methodology that the FSA can rely on in evaluating the acceptability of the quality of products on their review list, including for CBD and Δ9-THC.

Given the amount of published literature, studies such as the Ring Study, and the discussions relating to analytical methodology to be included in a Pharmacopoeial monograph for CBD, we propose that experts from public bodies must include representatives from the Laboratory of the Government Chemist (LGC Group).

Section 4: Register of CBD products linked to novel food applications

As the centrepiece of the novel foods application process, in April 2022 the FSA published a register – often called the 'public list' – of products linked to active novel food applications. Initially it comprised 3,000 products, but with subsequent updates, the list of products is currently in excess of 11,000.

The register was created to incentivise companies to engage in the novel foods process. Any CBD ingestible that appears on the list is allowed to remain on sale in Great Britain pending full Novel Food authorisation, while products not on the list face enforcement action from Trading Standards officers.

This setup has sustained the British CBD market, but at some cost. Although the register was presented as comprehensive when it was first published in April 2022, it quickly became apparent that products had been mistakenly left off the list. The FSA also extended the deadline for applicants to submit information.

Delays have continued to characterise management of the list. Brands and manufacturers had expected the FSA to authorise the first CBD ingestibles at the start of 2023, in line with messaging from the agency.

As novel food applications are authorised, the current thinking of the FSA is to remove linked products from the CBD novel foods register and add them to the FSA's register of regulated food and feed products for Great Britain. If a novel food application is declined, the CBD products linked to that application are removed from the Register, and subsequently, from sale.

Uncertainty around when the process will be completed has also increased with the publication of the FSA's precautionary advice lowering the ADI for long-term consumption of CBD to 10 milligrams per day, as well as the Home Office announcement that it would legislate to allow up to 50 micrograms of controlled cannabinoids per unit of consumption for CBD ingestibles.

CBD brands and manufacturers are understandably concerned about the timeline for completing the novel foods application process, and the prospect of some applications being given priority over others.

The Novel Foods Regulatory Framework Review conducted by Deloitte and published in June 2023 suggested that the FSA adopt a triage-based approach for sifting through applications:

> *"The FSA could retain the current approach to how the safety of novel foods is established, but would change* ***how the pipeline of novel foods applications is processed****. This* ***could include triaging and grouping similar applications into high/medium/low risk cases*** *and tailoring the framework to provide a clear route for different emerging technologies. It could also* ***include prioritisation of applications based on specific criteria****."*

It has also been suggested that the FSA might prioritise applications where CBD content is below the new provisional ADI of 10 milligrams per day. Applicants are understandably concerned that having engaged in the novel foods application process in good faith, some may claim an unfair advantage of early authorisations should the FSA adopt a triage-based approach, as suggested by Deloitte.

The Association for the Cannabinoid Industry's View

While the ACI advocates that the novel foods application process be completed as quickly as possible, this should not be at the cost of yielding an unfair market advantage to applicants or compromising the interests of consumers.

We note that the new provisional ADI of 10 milligrams per day is based on a partial reading of available data. As the FSA noted in its precautionary advice, higher amounts do not present an acute risk, and may be proven safe from a fuller reading of available data.

We believe it is in the public interest that the FSA should make no significant changes to the CBD register based only on the current precautionary advice of ADI of 10 milligrams of CBD per day. We recommend that the joint subgroup of the Committee on Toxicity (COT) and the Advisory Committee on Novel Foods and Processes (ACNFP) complete their review of safety evidence submitted by the industry (as part of their novel foods applications) and release updates to the precautionary advice re ADI on completion of each Group of applications (i.e. Groups A, B and C).

We propose that once the daily intake limits for CBD and controlled cannabinoids (including THC) have been defined, the FSA should announce a timetable for the completion of its review of the novel food applications which have products listed on the Public List. We recommend that these applications should be assessed as per the previously defined groups and in priority order of Group A, B and C. It would be preferable for the FSA to confirm a timetable for completing the reviews for each Group.

The ACI does acknowledge that the FSA is unable to progress to authorisations until the Home Office has ministerial support to incorporate agreed recommendations into UK law with respect to the permitted level of controlled cannabinoids. This is critical to support the progress of the CBD Novel Food Authorisations but if legislation is not in place then these authorisations will be further delayed. We are encouraged that the FSA is working closely with the Home Office to ensure that future legislation is aligned with the UK Novel Food Regulation and as a result that much needed clarity is provided to the industry and consumers.

We recommend that the CBD Public List remains available online until the very last application has been assessed and authorisation provided or denied. Currently there are three 'status' fields: "awaiting evidence," "removed," and "validated." A fourth 'status' field should be included – "authorised."

By retaining the CBD Public List online with these four different status fields until the last application has gone through the assessment process, will provide clear messaging to the industry, trading standards, border control and the consumer. Naturally all **authorised applications** will also be listed on the Novel Foods Register within the Regulated Products area of the FSA website.

The CBD Public List, however, will list products which are linked to the authorised applications and therefore, will be listed on the Public List as "authorised." Explanatory text should be included at the top of the first web page of the Public List to explain the meaning of each status field. In addition, other than those products which have the status of "removed," there should be a clear statement that only products on the Public List can be legally sold in Britain.

Section 5: Labelling

Clause 33 of the EU Regulation 2015/2283 on Novel Foods has been retained in UK law. It states:

> *"Novel foods are subject to the general labelling requirements laid down in Retained Regulation (EU) No 1169/2011 – the Food Information to Consumers (FIC) Regulation and other relevant labelling requirements in Union food law.* ***In certain cases it may be necessary to provide for additional labelling information, in particular regarding*** *the description of the food, its source, its composition or* ***its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population****."*

The text in bold is of particular relevance to CBD Novel Foods and explains why the FSA issued the precautionary advice with regards to the ADI of CBD, as well as including "parents trying to conceive" as an additional "vulnerable group".

The FSA's current precautionary advice is consumer advice highlighting a **possible** safety issue if consumers decide to ingest more than 10mg of CBD per day, over their lifetime. If a consumer chooses to ingest higher levels of CBD over a short period of time, the FSA has determined that there is **no acute safety risk**. The FSA encourages consumers to monitor their daily consumption of CBD and to make an informed decision on how much CBD they are willing to ingest when considering possible long-term side effects.

Chapter II, Article 6 of Regulation (EU) 2015/2283 retained in UK law states that:

> *"Only novel foods authorised and included in the [Regulated Products] List may be placed on the market within the United Kingdom … in accordance with the* ***conditions of use*** *and the labelling requirements specified in the list."*

And in Article 6, paragraph 2(a), it goes on to state:

> *"The conditions under which the novel food may be used, including in particular* ***any requirements necessary to avoid possible adverse effects*** *on particular groups of the population, the* ***exceeding of maximum intake levels and risks in case of excessive consumption****."*

These 'conditions' will be included with a novel food's authorisation specification on the Register of Regulated Food and Feed Products for Great Britain (the Official Register).

It is a requirement that labels "do not mislead the consumer" and that labels include "conditions of use" and "instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions." (Retained Regulation (EU) No 1169/2011 Chapter IV, Article 9 - List of Mandatory Particulars).

The granting of approval for a novel food may also include specific labelling requirements to ensure that consumers are appropriately informed.

Labelling requirements also apply to the websites of retailers, where mandatory labelling information must be made available to the consumer before a purchase is finalised. This ensures that the consumer can make an informed choice. (Article 14 Distance Selling (Retained Regulation (EU) No 1169/2011).

The Association for the Cannabinoid Industry's View

Considering that:

1. The mandatory requirements for the labelling of food;
2. The FSA's remit to ensure all food products are safe to be consumed;
3. The role of the Home Office to control the amount of controlled drugs in circulation on the British market,

The ACI acknowledges that clear labelling of CBD Novel Foods is of paramount importance to mitigate any risk to the consumer when ingesting such products.

The 'precautionary advice' recently issued by the FSA, however, caused a major panic within the industry with many retailers withdrawing all CBD products from their shelves and websites. This had an immediate and detrimental impact on the CBD sector. Fortunately, some of the major retailers, with direction from the FSA, compiled explanatory guidance for CBD product websites and information at 'shelf edge' so that consumers could make an informed choice when purchasing a product. As a result, CBD products were reinstated.

While current CBD novel food applications are being assessed, the ACI urges the FSA and the Home Office to work together to compile clear messaging which can be used by the CBD industry, for their online presence and at 'shelf edge'. This will help to avoid any confusion and panic in the future (as dosage levels are revised) and at the same time will ensure consumer safety. The ACI recognises that this is only an interim measure until novel food authorisations are issued. The 'Regulated List' for authorised novel foods will then specify any "additional specific labelling requirements" for the approved CBD novel food.

To reiterate earlier recommendations, it is critical that the Home Office clarifies what the permitted level of controlled cannabinoids in CBD consumer products will be. Specifically for CBD novel foods, the ACI's recommendation should be implemented in that a "permitted level of 50 micrograms must be the maximum total daily intake of controlled cannabinoids (including THC)", and not the ACMD's ambiguous recommendation that the 'permitted level' is 50 micrograms per serving or unit of consumption "based on a typical quantity of a CBD product consumed on one occasion."

Once the Home Office provides this much needed clarification, the FSA can proceed with the issuing of Novel Food authorisations. Until the Home Office acts on this, and obtains Ministerial approval, the novel food application process for CBD is 'paused', making the British market an increasingly unattractive and high risk investment.

Section 6: Conclusion and proposed timeline

This white paper represents the considered, settled view of the ACI and wider CBD industry regarding the completion of the novel foods authorisation process.

As outlined herein, the ACI makes the following recommendations for completing the novel foods process in a timely and fair fashion:

1. The COT and ACNFP should evaluate further data underpinning the new provisional ADI for CBD with a view to potential revision of the precautionary advice.
2. The Home Office should relate the 50 microgram limit to a maximum total daily intake for controlled cannabinoids, as opposed to per serving or per unit of consumption.
3. After addressing existing ambiguities, as highlighted above, the Home Office must obtain Ministerial approval to implement the ACMD recommendations into law by April 2024. Any significant deviation from these recommendations will cause further extensive delays and investors will continue to withdraw from the British market (Note: there is concern that the 2024 General Election will cause even further delay and therefore, time is very much of the essence).
4. The ACI recommends that a small working group of experts convene to urgently review and propose specific analytical methodology that the FSA can rely on in evaluating the acceptability of CBD product quality and safety.
5. The FSA should retain the Public List online until the last application has been assessed and to include a fourth 'status' field – "Authorised".
6. Once the daily intake limits for CBD and controlled cannabinoids (inc. THC) are defined, the FSA should announce a timetable to complete their review of Novel Food Applications and in priority of the previously defined Groups - A, B and C.

Appendix: The use of CBD in food and beverage products on the British market

Background information including definitions:

The FSA has a statutory responsibility, as a regulator, to ensure that food and beverages on sale to the public are safe for consumption and that they contain what the label claims. Their focus is on safety only and therefore, they do not provide approvals for health, nutritional or medicinal claims. These come within the scope of other regulations, while medicinal claims are governed by the Medicines and Healthcare products Regulatory Agency (MHRA).

The Home Office (otherwise known as "The Department") is the "lead government department for crime, the police, drugs policy, immigration and passports, and counter terrorism." Since they are responsible for 'drugs policy', they are responsible for the amount of controlled drugs which are on the British Market. CBD novel foods (as finished products) may contain controlled cannabinoids, such as THC, and therefore, companies are required to hold a Home Office licence. The current view by the Home Office, however, is to allow a 'permitted level' of controlled cannabinoids (inc. THC) in CBD novel food finished products and they have already presented to government ministers the recommendations made by the ACMD with the aim of incorporating the recommended 'permitted level' in UK legislation by April 2024.

It is important to understand the different definitions for each food type. CBD food products are classified as 'novel' and therefore, they must comply with the Novel Food Regulation.

1. Different food types as defined by the applicable regulation

a) Food or foodstuff: means "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes drinking water after the point of compliance."

"Food" does not include:

Narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971.

Foods must comply with relevant legislation covering hygiene, labelling, nutritional labelling, additives, contaminants, weights and measures and advertising.

b) Food supplement: foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in "measured small unit quantities".

Applicable Regulations:

The EU Food Supplements Directive 2002/46/EC came into force on 1 August 2005 and is implemented in the UK by the Food Supplements (England) Regulations 2003 (as amended) and equivalent regulations in Scotland, Wales and Northern Ireland.

- The Food Supplements (England) Regulations 2003 SI 2003 No. 1387
- The Food Supplements (Scotland) Regulations 2003 SSI 2003 No. 278
- The Food Supplements (Wales) Regulations 2003 WSI 2003 No. 1719 (W186)
- The Food Supplements (Northern Ireland) Regulations 2003 Statutory Rule 2003 No. 273

c) Novel food: a food or food ingredient that does not have a significant history of consumption within the UK or the EU prior to 15 May 1997. An application for a pre-market authorisation is assessed by the FSA covering England and Wales. Scotland comes within the scope of the Food Standards Scotland (FSS) and Northern Ireland must comply fully with the EU Novel Food authorisation process.

A dossier to prove safety of foods and ingredients must include full characterisation of the material, potential exposure and significant toxicity data. The review process itself is likely to take at least two years, during which time the product cannot be marketed. The exception to this are CBD novel foods for which the FSA has developed a mechanism to retain CBD novel foods on the market in England and Wales whilst applications are being assessed.

All CBD novel foods listed on the CBD Public Register (the 'public list') are allowed to remain on the market until the appropriate application is either authorised, or not authorised. (See: https://data.food.gov.uk/cbd-products/products-list)

There are two types of novel food submission:

1. A full application to prove safety of a food or ingredient with no history of use before May 1997
2. A traditional food notification – this is a simplified route to authorise products that have 25 years' continuous use by a significant number of people in a country outside the UK or EU.

Important note:
The FSA website states:

> *"The law includes deadlines for key steps in the process. In a full novel food application made under Article 10, one month is allowed for the validation process, then up to nine months (on a start stop the clock basis if further information is needed) for the risk assessment element, with up to a further seven months for any subsequent risk management considerations and authorisation decision. These add up to a total of seventeen months as the overall legislative timeline for authorisation, noting this can be extended if the clock is stopped and restarted."*

(See: https://www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance#how-long-will-my-application-take)

Best case scenario for achieving novel food authorisation is 17 months from submission of the application.

Remember, however, that invariably, questions will be raised by the FSA in which case the clock is stopped and can only restart when a response has been provided by the applicant. It is known that some non-CBD novel food applications submitted in Europe have taken five years, and some cases remain unresolved having not been authorised or refused.

Applicable Regulations

- EU Regulations 2015/2283 (retained in Great Britain)
- Regulation (EC) 2017/2469 (retained in EU law)*

*This guidance was previously developed by the European Food Safety Authority (EFSA). This guidance is still relevant for applications submitted to the FSA as their approach is based on EU processes which apply to the development of dossiers. Post-Brexit, the process for submitting applications is different between EFSA and the FSA.

2. Additional requirements for food products

a) Legal requirements for food packaging and labelling

All food types must comply with the legal requirements for providing food information to consumers on the product packaging and labelling.

The Food Information to Consumers (FIC) Regulation 1169/2011 on the provision of food information to consumers, combines the EU rules on general food labelling and nutrition labelling in one piece of legislation. The retained version of Regulation 1169/2011 applies to food businesses in Great Britain. Northern Ireland follows the EU regulation No. 1169/2011 – see comment re: Windsor Framework below.

b) The Windsor Framework and the Agrifood Green Lane

"From Autumn 2023, the Windsor Framework will allow UK public health standards to apply for retail goods moved via the agrifood green lane and placed on the NI market. Therefore, goods moving via this route containing GB authorised novel foods will be able to be placed on the NI market."

(See: https://www.food.gov.uk/our-work/statement-on-the-publication-of-the-novel-foods-regulatory-framework-review-executive-summary (Updated 7 June 2023)).