QUESTIONS POSED TO THE F.S.A.

Question		
We have reproduced the questions as they have been submitted in order not to interfere with them. If you are unable to answer the question as drafted, we would encourage you to answer what you feel is the import of the question in order that market participant is not disadvantaged by potentially poor language selection in their phraseology		
EFSA APPROACH		
1. UK FSA must have known that EU Commission's position on legal status of derivatives of cannabis resin has not yet been established. Why was then UK FSA urging businesses to submit Novel Food applications via EU system? **2. Will UK FSA automatically inherit all pending and validated NF applications on Dec 31, 2020 with Risk Assessment status to that date?** 3. Will separate ADME studies be needed for all different dosage forms despite the fact Tox and ADME/PK data are available for the base ingredient? **4. Will UK further adopd a system of Union List of Authorized Novel Foods?**	Paul Tossell	
We need to ask the FSA whether this halt from EFSA is going to delay the application validation process for the UK? If EFSA have stopped the validation phase of the applications process, we need an extension on the March 2021 date. Can we add this question to the canna consultants q&a please?	Paul Tossell	
UNITED NATIONS VOTE		
How could the proposed UN vote on the rescheduling of hemp extracts affect CBD and Novel Foods?	Paul Tossell	
Do you think there's a chance to get Novel Food applications for CBD products approved before the December CND (Commission on Narcotics and Drugs) vote on the WHO cannabis recommendations (particularly the CBD recommendation)?	Paul Tossell	

QUESTIONS POSED TO THE F.S.A.

PRODUCTS NEW TO MARKET		
CBD products have been sold in contravention of UK law since January 2019. Company 1 brought a CBD product to the market on 31st March 2019, knowing that every product that it sold within the UK was sold unlawfully. Company 2 intended to bring a product to market in early 2019 but, following the classification of CBD as a Novel Food, decided not to do so - not wanting to act unlawfully. Following the FSA's announcement on 13th February 2020, Companies 1 and 2 each undertake the necessary scientific work to make Novel Food applications for their respective products. Both Companies submit their completed Dossiers for Novel Food Authorisation to the UK FSA on 1st January 2021. Having submitted its Dossier Company 2 brings its product to the UK market. On 1st March 2021 the two companies each have their Novel Food Authorisation applications Validated by the UK FSA. Thus, as at 31st March 2021 the two Companies each have products which meet the same regulatory requirements, with the same standard of regulatory data supplied to, and Validated by, the regulator. You say that Company 1 will be able to remain lawfully on the market, but Company 2 will be unlawful and must not sell its products until final Authorisation is granted. Company 1 only achieved this market advantage by acting unlawfully in the first place (through its unlawful conduct between March 2019 and February 2020). This approach would appear to be a breach of natural justice and contradictory to the observations in the publication "The Judge over your shoulder - a guide to good decision making" published by the Government Legal Department. What legal authority does the FSA assert that it has the autonomy to treat two otherwise indistinguishable companies in this manner?	Paul Tossell	
For new businesses that are preparing to enter the UK market prior to the March 2021 deadline, what requirements should product owners consider to ensure that they are not only approved before the closure date but also are prepared for the ongoing regulatory process to ensure that they can remain operating within the UK market?	Paul Tossell	
QUALITY CONTROL AND INDUSTRY REGULATION		
How do we stop outlandish claims re the benefits of CBD?	P.T.	
How does the industry stamp out products that are not what they say they are?	P.T.	
How can the industry be regulated without the regulations being too onerous?	P.T.	
Would a quality Kite Mark be of use ?	P.T.	
How do we ensure the industry is seen as 100% ethical?	P.T.	
Is there a code of conduct that participants are legally obliged to adhere to?	P.T.	
How do participants in the supply chain provide proof of provenance?	P.T.	
How do suppliers currently do recalls?	P.T.	

QUESTIONS POSED TO THE F.S.A.

GENERAL NOVEL FOOD ISSUES		
Can you confirm that because traditional olive oil infussion (immersion of industrial hemp into olive oil with no further manipulation, concentration, distillation or isolation of any kind whatsoever) falls outside of novel food qualification and therefore does not require authorisation, how does the FSA, can or will the FSA be providing a 'not requiring authorisation' certificates or statements of such traditional and totally natural infusions?	Paul Tossell	
Please describe the most likely path, including a general timeline, of how a NF application that is submitted to the EU Commission will be processed post-Brexit?	Paul Tossell	
What jurisdiction does an approved Novel application give the license holder and what cost would be expected to receive a license, if I have a ready to go product, complying with legislation, including lawyer fees and registration fees? What time table could a client expect?	Paul Tossell	
In your view, should the CBD industry be spending more time learning from other food ingredients that have obtained novel food approval, rather than "reinventing the wheel"? After all, the novel food framework has existed for many years and there should be plenty of other ingredients we could draw experiences from.	Paul Tossell	
Can you define what a 'Selective CBD Extract' is, as this phrase has been used in regards to novel food applications.	Paul Tossell	
Is the likelihood of a Novel Foods Application being accepted affected by the number of end products that are applied for? For example, is a CBD Isolate that is intended only for use in Oil Drops more likely to be approved than the same CBD Isolate for 4 or 5 end uses?	Paul Tossell	
THE TIMING OF DOSSIER SUBMISSIONS		
Do you have an update on the UK submission portal		Frances Hill
Your announcement on 13th February 2020 requires market participants to achieve a Validated application by 31st March 2021. This obviously requires you to receive the application in sufficient time for you to Validate it by that date. In order for a market participant to know by what date they need to submit their Dossiers in order to achieve the "backstop" deadline, they need to know how long will you take to Valiate an application. How long will it take you? What happens on 31st March 2021 to applications which have been submitted, but which you have not Validated? Would the publication of a "Submitted By" date not be more helpful to market participants?	Paul Tossell	

QUESTIONS POSED TO THE F.S.A.

FUTURE ENFORCEMENT		
The FSA has clarified requirements for Novel Foods over the past 5 months. Given the abundance of products currently out in the market, what does enforcement look like post March 2021?	Paul Tossell	
The FSA say, 'it's up to the company to determine whether their products are novel', whilst saying in the same breath that they will start enforcing next year. If an enforcement officer challenges my opinion that my products are not novel, what would the process be from there?	Paul Tossell	
WHO NEEDS TO MAKE AN APPLICATION AND THE TRANSFER BETWEEN CANNABINOID INGREDIENT SUPPLIERS		
Most of our members buy extracts or finished products and are not involved in the extraction or manufacture of raw materials. Is it enough for these business to use a supplier that has a validated novel food application or do they need to be named and have their product data (stability, formulation matrix) on their suppliers novel food dossier?	Yes	
I am a manufacturer of end products. If we proceed on the basis that (1) the supplier of my CBD isolate has submitted their application for NF authorisation on their CBD isolate and it has been validated by the UK FSA and (2) I have submitted my application for NF authorisation of my end-product, utilising their data for the underlying ingredient. If I want to switch to another supplier of CBD isolate, who also has a validated application for the same (and the chemical composition of whose CBD islate is the same as my current supplier), will I be required to submit a new application for my own product despite my "recipe and production" being consistent?	Paul Tossell	
If the answer to Q48 is "yes", then please relate it to the following analysis: EFSA have Validated a synthetic CBD. If a CBD isolate derived from a natural source possesses the same chemical characteristics/the same biological fingerprint as a synthetically-derived one, why is information concerning (a) the origins of the biomass from which originated or (b) the extraction and/or processing techniques by which it is obtained a key driver to the Novel Food application because, by the time that it is CBD isolate it is a chemical ingredient no different to the synthetic?		Frances Hill
Once there have been some successful applications, how will the process work when a company brings a new product to market and wants to say it should it should fall under its existing novel food approval?	Paul Tossell	

QUESTIONS POSED TO THE F.S.A.

IS THERE TO BE A HARMONIOUS APPROACH TO DATA BETWEEN THE UK FSA AND EFSA?		
Does the FSA intend to apply the same criteria as EFSA in respect of the data required, and criteria to be applied thereto, as EFSA? If so, will Validation and/or Authorisation by one body lead to automatic treatment by the other body?		Frances Hill
A CONSORTIUM APPROACH TO TOXICOLOGY		
If Company 1 undertakes rodent in vivo toxicology studies on its CBD isolate in an MCT oil, will a second company (Company 2) be able to utilise that same toxicology data of Company 1 (with the permission of Company 1) in a separate Novel Food application for its own CBD isolate in an MCT oil, on the premise that Company 2 can demonstrate, by reference to its production batch samples, that its own isolate is substantially equivalent?		Frances Hill
If the answer to Q39 is "yes", what would be the criteria necessary to demonstrate that "substantial equivalence" between the isolate from Companies 1 and 2?		Frances Hill
Company 1 manufactures a CBD isolate of a quality which is 99.2% CBD and 0.8% other compounds (which are consistent in thier respective ratios batch to batch). Company 2 manufacturers a CBD isolate of a quality which is 99.2% CBD and 0.8% other compounds (which are consistent in their respective ratios batch to batch), but where the ratio of the "Other Compounds and/or Cannabinoids" are different to that of Company 1. Can the two manufacturers undertake rodent in vivo toxicology studies on the isolate of Company 1, but from which they can both rely on the results in support of their individual applications?		Frances Hill
How proximate in composition (+/- % of the various comounds) would the two products have to be in order for the answer to the above question to be/remain "yes"?		Frances Hill
How long will cbd remain novel. How can collab with other companies to reduce costs. Do you think many brands will survive?	Paul Tossell	
TOXICOLOGY AND ADME: WHAT IS A RISK-BASED APPROACH?		
What's the FSA's thinking on using a 'risk' based approach for NF testing?	P.T.	
The FSA has previously indicated that a Novel Food application will not be necessary unless the "new" end product presents a "different risk profile" to those products which have already received authorisation. What issues are to be taken into account when seeking to assess whether the risk factors are sufficiently disparate that the new end products falls outside of the qualifying criteria of the existing product?		Frances Hill

QUESTIONS POSED TO THE F.S.A.

TOXICOLOGY AND ADME: GENERAL		
How will the FSA ensure there will be no unethical use of animals in replicated toxicology studies as a result of these regulations?		Frances Hill
Please expand on the specific ADME/Tox requirements for a submission to the FSA. How much can be inferred from existing data on the active ingredient in question?		Frances Hill
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The Home Officer is the entity which holds the authority to issue licences for the cvonduct of rodent in vivo toxicity trials within the UK. Is it the FSA's position that each CBD isolate manufactured by different companies (unless manufactured with the same input ingredients and utilising the very same techniques, to identical tolerances) must undergo individual toxicity testing?		Frances Hill
With regard to the testing of Cannabinoid products do you expect to see a full methodology for the analytical processes adopted in a dossier or simply evidence of accrediitation with UKAS		Frances Hill
TOXICOLOGY AND ADME: THE SPECIFICS OF THE WORK REQUIRED		
The published data concerning Epidyolex recognises certain safety concerns regarding CBD, but which are only seen at much higher levels than 1mg/kg/day. In the FSA's current opinion, would it be likley that you could be satisfied that there was no toxicological safety issue from CBD on a review of the available and published data?		Frances Hill
If the answer to Q33 is "no", then in the opinion of the FSA, what would be the minimum toxicology work required: in vitro studies or rodent in vivo toxicology work?		Frances Hill
Are the FSA willing to validate applications which have ongoing/planned toxicology (incomplete) at the time of submission.		Frances Hill

QUESTIONS POSED TO THE F.S.A.

TOXICOLOGY AND ADME: APPLICATION OF ONE SET OF DATA TO DIFFERENT CARRIERS/DELIVERTY MECHANISMS		
If I undertake rodent in vivo toxicology safety studies for CBD in an MCT oil, what other oil carriers would the FSA consider substantially equivalent, such that it was not necessary to undertake the same studies in a different carrier/delivery mechanism? For example would hemp oil, oilve oil, almond oil and coconut oil be considered substanially equivalent?		Frances Hill
If I undertake rodent in vivo toxicology safety studies for CBD in an MCT oil, what other non-oil delivery mechaninisms would the FSA consider substantially equivalent, such that it was not necessary to undertake the same studies in a different carrier/delivery mechanism?		Frances Hill
If I undertake rodent in vivo toxicology safety studies for CBD in an MCT oil, can I utilise published data demonstrating the difference in bioavailability between CBD in MCT oil and CBD in another delivery mechansim, such that it was not necessary to undertake the same studies in a different carrier/delivery mechanism?		Frances Hill
If my Isolate supplier has submitted a dossier using for their CBD isolate and has conducted toxicology on the isolate in a carrier oil, can I use that ingerient to produce a carbonated drink? Am I required to conduct rodent In Vivo ADME tests on my end product because of the ingestion method?		Frances Hill
Given the wide variation in bioavailability between products within different carriers/delivery mechanisms, will ADME testing be required on all individual products? If so, will in vitro testing be acceptable, or will rodent in vivo tests be required?		Frances Hill
Do you think that the industry need to consider the accumulative effect of multiple products for the consumer. For example usage of ingestibles along side topicals.		Frances Hill
STABILITY		
How many months of stability and/or safety data will be required?		Frances Hill
DOSAGE		
Given the wide variation in bioavailability between products within different carriers/delivery mechanisms, how is it proposed to reflect those disparities within the dosage limitations/recommendations?		Frances Hill

QUESTIONS POSED TO THE F.S.A.

THE FSA DECLINED TO ANSWER THE FOLLOWING QUESTIONS

Hi guys. .what is it going to cost> We have company's like Canabidiol spreading miss-information that the application is free however, the cost for completing this will be north of £250k, I'm sure this is not accurate coming from the CTA board members however, it would be nice to have some type of clarification on costs for a completed application.

Do suppliers have visibility of their products from field to shelf?

1) Where a supplier of CBD has submitted a novel food application for use of their CBD in specified food product uses, does it follow that every finished food product containing that supplier's CBD will require a separate novel food application?

2) If yes to (1), if there are different strengths of CBD within a finished product range, does every strength require a separate novel food application?

3) If yes to (1), if there are different flavours within a finished product range, does every flavour variant require a separate novel food application?

4) If yes to (1), (2), & (3), is it acceptable to create a single, universal "master" application which combines all the ingredients, and flavours at maximum CBD strength, which would cover all variations within the range?

5) When marketing a CBD-containing food product, is it permitted to change supplier of CBD, provided the new supplier also has submitted a novel food application covering the usage in the final product?

6) Is it permitted to change certain formulation details during the lifecycle of the food-containing product, (such as flavour, carrier oil, and other minor excipient factors) without re-submitting an application?

7) As part of the application, technical data is required. When considering all the non-CBD ingredients of a finished product:

i) For the toxicological information required, is sufficient to limit the content to the data that is freely available via the ECHA website? If no, then what information is required?

ii) For stability data, does every variation covered in (2) and (3) require a separate stability study?

iii) Do stability studies have to be carried out strictly in accordance with ICH guidelines? If not then what are the guidelines we should follow?

iv) Is accelerated stability acceptable to support the shelf life claim?

v) Will different primary packs require separate data submissions, e.g. glass bottles with a glass dropper, as well as glass bottles with plastic spray cap?

8) Are the timelines the same for the finished product novel food application as the API novel food application?

9) Will sections of the API application need to be approved before the finished product application

10) Will there be a portal where all API applicants / finished product applications are listed?

11) Will the FSA be releasing detailed guidelines / protocols on exactly what should be contained in the risk assessment and stability study sections of the finished product dossier.

If the answer to the above is "yes", then in the opinion of the FSA, at what daily ingestion levels of CBD do you believe that would be the case?

If you believe that there will be a difference, in what areas and to what extent will there be differences in approach?

Using the above example where I add other compex ingredients to my drink or end product am I required to conduct in vivo ADME or will in vitro suffice.

If the answer to the above is "no", can the FSA identify the required tolerances between that CBD isolate which does undergo rodent in vivo toxicity testing and that which does not in order for the latter to be able to "passport" the results of the former to its own Novel Food application?

QUESTIONS POSED TO THE F.S.A.

Under EU Regulation 178/2002 Article 2(g) a "food" shall not include "narcotic or psychotropic substances within the meaning of the United Nations Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971". The United Kingdom is a signatory to both Conventions. Please confirm that the FSA considers CBD in its isolated form to be a food.
What is the FSA position on Controlled Cannabinoids in 'food' and are the FSA looking to follow any decision eminating form the EU.
Are the UK and EU in conversation regarding any passporting of maret authorisation or are the withdrawal negotiations preventing dilogue.
Are the FSA looking towards partnering with other UK/EU enforcement agencies to prevent unlawful products entering the market post April 2021
What effect will/could the votes regarding the 1961 UN Single Convention on Narcotic Drugs have for the industry
Does the FSA have any advice on safe dosage for the industry
THE FOLLOWING QUESTIONS WERE SUBMITTED AFTER THE DEADLINE BY WHICH THE FSA REQUESTED NOTIFICATION OF THE QUESTIONS AND WERE THEREFORE NOT ANSWRED
There is sufficient evidence to show that hemp has been consumed by humans for thousands of years. Would the FSA consider taking an independent approach from the EU, since Brexit, and recognise the importance of hemp in British History and now. In a post-Covid-19 landscape, UK farmers and small businesses could benefit from an estimated £300 milllion a year CBD domestic market, and keep the circular, green and local economies buoyant. Allow the UK market to harvest and use the whole plant, and make isolates Novel Food, which, by definition, it is.
Where are applications most likely to fail and how can this be avoided? Please could you explain how dossiers need to differ for extracts in isolate and distillate form ? When registering broad spectrum CBD Distillate what information are you suppose to provide in regard to other cannabinoids such as CBN and CBG for example ?
Does the new Novel Food Authorisation regulation affecting CBD products risk little or no enforcement? Practicaly, how can it be enforced widely?
Do hemp animal products which are ingestible governed by the FSA as well?