This document was provided to key Stakeholders in October 2019.

On 13th February 2020 the Food Standards Agency announced its intended approach to the issue of CBD and Novel Foods classification.

*We are pleased that the Agency has adopted the foundation structure that **The Canna Consultants** advocated.*

THE UK CANNABINOID INDUSTRY – THE ROAD TO A BETTER FUTURE

A MARKET IN IT'S INFANCY

The UK Cannabinoid industry is in its infancy, with competing participants advancing how it should move forward, and how it should be controlled and regulated.

Strong and effective leadership should be:

- Clear;
- Focussed;
- Recognise the needs of the market from the perspective both of participants and consumers - both now and in the future;
- Realistic;
- Represent the views of all market participants, not just those of the largest/loudest few; and,
- Compliant with the applicable law, even if the formulation of that law is perceived as incorrect or unnecessary.

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We at ***The Canna Consultants***, as observers and engagers in this fledgling market are uncomfortable with the approach towards regulation, being taken by certain "leaders" within the industry. The impact of this approach is detrimental to the short-term regulatory compliance within the market, and of the long-term existence of the industry within the UK as a whole, and in a wider global context.

Whatever opinions individuals or participant groups may hold as to the merits of the legal obligations and responsibilities incumbent upon them, the applicable law (as interpreted by the relevant regulatory authority), is the regime which should be complied with in order to remove market participant's exposure to regulatory breach.

The Canna Consultants believe that, in order to foster and secure the long-term prosperity of the whole Cannabinoid industry, the authority of the regulatory body should be respected until their interpretation of relevant matters is successfully overturned through judicial or other challenge.

Let us pose three questions:

1) Is there a need for regulation at all?

2) Do you agree with the regulatory structure, which is ***currently*** in force?

3) Will you abide with the regulatory requirements, which are ***currently*** in force?

THE CANNA CONSULTANTS **– CLEAR, FOCUSSED AND REALISTIC**

At ***The Canna Consultants*** we believe that the answers to the three questions posed above are:

1) Yes: One only has to look at some of the medical claims that are made, in breach of the clear prohibitions in respect of the making of such claims, to appreciate that were there no fetter on what an market participant could say about the benefits of their product, then the claims would be evermore outlandish in order to mislead the consumer into making a purchase.

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2) Yes: Why should a product containing CBD be regulated differently from any product of similar generic characteristics? Those organs of the State who are already involved in the protection of the public should continue to provide that supervision and protection:

a. Foodstuffs (Food Standards Authority);

b. The mis-selling of medicinal products (Medicine and Healthcare Regulatory Authority);

c. Consumer interaction (Trading Standards); and,

d. The restriction on access to prohibited substances (the Police).

3) Yes: The question is not "do you agree with the regulatory requirements that are currently in force" or "had you been asked to create a regulatory structure, would you have devised it in this way", but will you abide with the regulatory requirements as interpreted by the regulating authority?

YOU CHANGE THE LAW THROUGH CHALLENGE, NOT BREACH

Elements of the industry's "leadership" are currently positively informing market participants that they do not need to comply with the law in respect of Novel Food Applications, based upon a proposed (but as yet undisclosed), challenge to the conclusion of the EFSA (which has been adopted by the FSA) that Cannabinoids are "Novel Foods".

No company, body or industry is above the law – they are each perfectly entitled to lobby and challenge the need for the regulations that are in place, but for the duration that they are in place, they are applicable and we consider that it is wholly irresponsible for anyone to advocate their breach, especially in circumstances where the advocate of such breach would not be subject to any consequent penalty for breach - whereas the recipient of the advice would be.

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WHAT THE INDUSTRY NEEDS NOW

At ***The Canna Consultants*** we believe that what is required is for each of the organs of the state, whose role it is to ensure compliance with the regulations, to engage with those market participants whose approach is sufficiently credible, in order to ensure that there is open and realistic engagement between themselves and those credible market participants.

The need to restrict the engagement to those market participants who are sufficiently credible may necessitate the exclusion of self-proclaimed "leaders" who, through their conduct and statements, have demonstrated an inability or unwillingness to engage with the regulatory regime which is currently in force, and which the regulatory authorities are required to police.

This approach is necessary to define the future of the cannabinoid industry for the benefit of all current market participants, current consumers, future market participants and future consumers: ***for now, for the future, for all.***

THE JOURNEY STARTS WITH ONE STEP

The inevitable question is: how do we move from the infant industry that we currently witness - divisive, disjointed, fractious and fragmented – to a future structured, unified, transparent and stable industry that benefits all market participants and all potential consumers?

What is required is a mechanism through which the industry can engage with the Food Standards Agency and make such Novel Food applications as are necessary, whilst continuing to trade in the interim period. There is little point in making a lengthy and costly Novel Food application if a product is to be starved out of existence during the period that the application is being considered.

None of this proposed structure impacts, in any way, on the continued need for compliance with all other food-based regulations, it simply addresses the impact of the recent requirement for a successful Novel Food application.

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We at ***The Canna Consultants*** would propose the following structure:

The following is only applicable to market participants to the extent that they are selling their products within an applicable jurisdiction.

1) The Foods Standards Authority announces the suspension of any enforcement action emanating from a breach of the Novel Food requirements:

a. Until after a Specified Date: (Date 1)	As against the manufacturer of a "base Cannabinoid material" (MBCM) if that manufacturer is able to demonstrate that they have submitted a Novel Food application by that specified date (Date 1).
b. Until after a Specified Date: (Date 2)	As against the manufacturer of an end-product (MEP) if that manufacturer (the MEP) is able to demonstrate that the "manufacturer of the base Cannabinoid material" (MBCM) utilised in the manufacture of their end-product has, by Date 1, submitted a Novel Food application in respect of that "base Cannabinoid material" in the ratio that it is incorporated within the end-product.
c. Until after a Specified date: (Date 3)	As against a retailer of an end-product if that retailer is able to demonstrate that the "manufacturer of the base Cannabinoid material" (MBCM) utilised in the manufacture of their end-products has submitted, by Date 1, a Novel Food application in respect of that "base Cannabinoid material" in the ratio that it is incorporated within the end-product.

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2) The suspension of any enforcement action until specified dates (Dates 4, 5 and 6 shown below), following the outcome of any Novel Food application by a "manufacturer of base Cannabinoid material" (MBCM).

3) The six dates referred to (Dates 1-6) are to be set to ensure that:

   a. Novel Food applications are made by the "manufacturers of base Cannabinoid material" (MBCM) within an identified timescale, ensuring that they have certainty and stability, which will then flow down through the supply-chain;

   b. The manufacturers of end-products are able have sufficient "reaction time" in which to make any supply-chain decisions and still maintain compliance with the structure, reflecting that some matters (such as the making of a Novel Food application for a base ingredient) are entirely beyond their control.

   c. The retailers of end-products are able have sufficient "reaction time" in which to make any supply-chain decisions and still maintain compliance with the structure, reflecting that some matters (such as the making of a Novel Food application for a base ingredient) are entirely beyond their control.

AN EXAMPLE

DATE 1	1/1/21	A "manufacturer of base Cannabinoid material" (MBCM) which makes a Novel Food application on or before 1/1/21 will not be the subject of enforcement action by the FSA in the intervening period or whilst a decision in respect of their application is pending.
DATE 2	1/3/21	A manufacturer of an end-product whose supplier of "base Cannabinoid material" makes a Novel Food application on or before 1/1/21, in the ratio that it is incorporated within the end-product, will not be the subject of enforcement action from the FSA before 1/3/21.

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The two month time delay between 1/1/21 and 1/3/21 is to ensure that a manufacturer of end-products is not exposed to enforcement action should their current supplier of "base Cannabinoid material" fail to make a Novel Foods application and they are holding a stock of otherwise now non-compliant base material. They will have sufficient time to use their otherwise non-compliant stock and secure a source of compliant base material.

DATE 3	1/5/21	A retailer of an end-product in respect of which the manufacturer of the "base Cannabinoid material" makes a Novel Food application on or before 1/1/21 will not be the subject of enforcement action from the FSA before 1/5/21.

This is to ensure that a retailer of end-product is not exposed to enforcement action should the supplier of "base Cannabinoid material" fail to make a Novel Foods application and they are holding stock of otherwise now non-compliant product. They will have sufficient time to sell their otherwise non-compliant stock and secure another compliant product.

DATE 4	Variable	A "manufacturer of base Cannabinoid material" will not be the subject of enforcement action by the FSA until the expiry of two months following the rejection of their Novel Foods application.

This is to allow them to amend their business practices so as to minimise the impact of the loss of revenue-stream due to the future absence of "base Cannabinoid material" from their product range, with the consequent impact on revenue. We considered whether there should be a further period of grace in which re-submission could be made (and exemption continue), but rejected the princple because it would be open to a repeated cycle of rejections/ exemption from the manufacturer and consequent similar exemptions for the remainder of the supply-chain, potentially leading to permanent non-compliance.

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DATE 5	Variable	A manufacturer of an end-product will not be the subject of enforcement action by the FSA until the expiry of three months following the rejection of the Novel Foods application submitted by the relevant "manufacturer of base Cannabinoid material". *This is to allow them to use the otherwise non-compliant stock being held and secure a compliant source of "base Cannabinoid material".*
DATE 6	Variable	A retailer of an end-product will not be the subject of enforcement action by the FSA until the expiry of four months following the rejection of the Novel Foods application submitted by the "manufacturer of the base Cannabinoid material" included in their retail product. *This is to allow them to sell the stock being held and maintain the same supply-chain relationship with their current end-product supplier, assuming that that supplier achieves compliance within the three-month period that they are afforded (see Date 5).*

Again, none of this proposed structure impacts, in any way, on the continued need for compliance with all other food-based regulations, it simply addresses the impact of the recent requirement for a successful Novel Food application.

It is acknowledged that:

- This structure will create different applicable dates for enforcement against individual industry participants, but that is a product of the inevitable variable timescales over which the Food Standards Agency/European Food Standards Agency will respond to the Novel Food applications that are made, which is wholly outside of the control of the market participants. What would be clear is that each market participant would be fully aware of the dates, which were applicable to themselves, such that there would be no breach of natural justice.

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- It is possible, following the rejection of a novel food application by their current supplier, the manufacturers or retailers of end-products changed so as to source their material from a supplier who is at that stage awaiting a decision in respect of their own novel food application. In principle, this could be done any number of times, but not indefinitely because there would come a point at which the last of the applications submitted prior to Date 1 was decided.

- Were the early recipients of Novel Food exemptions to increase their prices comparative to those manufacturers whose application were still pending (for example in order to seek to recoup the costs of the application), there is the possibility of a drive from the manufacturers of end-products towards the cheaper suppliers whose Novel Food applications were still pending, thus elongating Date 5 (and by consequence Date 6). However, we believe that the grant of a Novel Foods application is likely to lead to a drive towards those suppliers rather than away from them, even at the expense of slightly higher unit input costs, because it will ensure certainty of compliance for the manufacturer of end-product and their retail customer.

DISEMINATION OF INFORMATION TO MARKET PARTICIPANTS AND CONSUMERS

In order to make **all** market participants aware of the actions and status of the supply chain, we would suggest that the Food Standards Agency maintains, and publishes, two Registers:

1. Of those Manufacturers of Base Cannabinoid Material (MBCM) who have submitted Novel Food applications, and the dates upon which they did so.

2. Of end products retailed within the UK in respect of which applications have been made by the Manufacturers of Base Cannabinoid Material (MBCM) in the ratio applicable to the retailed end product.

These would mean that all within the market would be aware of:

- Who had made Novel Food applications within the required timescale so as to benefit from the abeyance of enforcement; and,

- Which products are currently exempt from enforcement action because of the application having been submitted by their manufacturer of base cannabinoid material and which, subject to positive approval of that application, would not be the subject of enforcement action.

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