IS THE FSA's POLICY THAT ANY C.B.D. "NEW TO MARKET" PRODUCTS WILL BE TREATED DIFFERENTLY THAN THOSE "ALREADY ON THE MARKET" JUSTIFIED DESPITE THERE BEING NO DIFFERENCE IN THEIR POTENTIAL RISKS?

PERHAPS THE MORE TELLING QUESTION IS WHETHER THE POLICY WILL BE SUSTAINED IN THE FACE OF AN INEVITABLE LEGAL CHALLENGE?

NOVEL FOODS

1. Before a "Novel Food" can be legally marketed in the UK, it is required to have a pre-market safety assessment and authorisation.

2. This applies to any food and food ingredient that hadn't been used in the UK or EU for human consumption to a significant degree before May 1997.

3. All novel foods that are Authorised are included in the Union List of Novel Foods.

CBD AS A NOVEL FOOD

4. The novel food status of CBD extracts was confirmed in January 2019.

5. On 17th January 2019 a new entry was added to the Union List for generic "Cannabinoids" and the entry for CBD was then linked to a new entry stating "Products containing Cannabinoids are considered Novel Foods as a history of consumption has not been demonstrated."

6. The result of this change was that CBD changed from being a permitted food in Europe to being considered an Unauthorised Novel Food.

THE LEGAL POSITION OF C.B.D. PRODUCTS IN THE UNITED KINGDOM

7. It is for Member states to decide on the legality of CBD within their jurisdictions. In the United Kingdom the Food Standards Agency decided to follow the analysis which had led to the change in the Union List and decree that it did not consider that there was the necessary evidence of a history of CBD consumption prior to the 1997 date.

8. The consequence of the FSA's decision is that, since January 2019:

   a. ***ALL*** CBD products marketed within the United Kingdom have been marketed unlawfully and illegally; and,

   b. ***ALL*** CBD products sold within the United Kingdom have sold unlawfully and illegally.

9. In marketing and selling CBD products since January 2019 all of those market participants have (applying the FSA Policy):

   a. broken Trading Standards laws;

   b. broken Consumer Protection laws; and,

   c. broken the Criminal Law.

10. Given the amount of internal industry publicity that there has been on the subject then, were there to have been any prosecutions, it is hard to see an English Court deciding anything other than the individuals and companies who have done so, did so knowingly, did so intentionally and did so flagrantly – with the increased penalties that would inevitably flow from such intentional breaches.

11. Thankfully, we are unaware of any criminal prosecution which resulted from continued marketing and selling in the face of service of repeated Prohibition Notices having been served.

THE F.S.A.'s POSITION AS AT 13TH FEBRUARY 2020

12. On 13th February 2020 the Food Standards Agency announced a Policy intended to transition the UK CBD industry from its non-compliant position in which all products were unlawful and all manufacturers, suppliers and retailers acting in contravention of UK Food Law (which continues to be the case today), to a compliant position by 31st `March 2021, when all participants will have to be compliant.

13. Its announcement (which remains on its website[1]) was:

> *"**After 31st March next year, only products which have submitted a valid application will** be allowed to **remain on the market**. The authorisation process ensures novel foods meet legal standards, including on safety and content."*
>
> *"Local authorities enforce the novel food legislation. They have been advised that **businesses should be able to sell their existing CBD products during this time** provided they are not incorrectly labelled, are not unsafe to eat and do not contain substances that fall under drugs legislation."*
>
> *[Emphasis added]*

14. The FSA's position was clear:

    a. They had taken a pragmatic and proportionate approach to achieve the transition from a non-compliant market (with non-compliant participants) to a compliant one (with compliant participants);

    b. Their aim, through the requirement for the achievement of Validation, was to ensure that a minimum standard had been met in respect of data provision by every product;

    c. That those products which achieved Validation, and had therefore met the minimum standard, were to be permitted to remain on the market after 31st March 2021;

    d. The reference to "remaining" on the market within a sentence in which the only other date was 31st March 2021 can only be interpreted as applying to a product which was on the market as at 31st March 2021 – the "backstop" (our word) for the achievement of the minimum standard, as signified and demonstrated by the award of Validation;

    e. The FSA had advised Local Authority Trading Standard Departments that companies should be able to continue selling their existing (i.e. Un-validated) CBD products;

[1]As at 15/7/20 the original version was still published by the FSA: https://www.food.gov.uk/news-alerts/news/food-standards-agency-sets-deadline-for-the-cbd-industry-and-provides-safety-advice-to-consumers

f. The "existing CBD products" referred to, in the context of what was being outlined, refers to products which are Un-validated CBD products right up until midnight on 31st March 2021, after which a lack of Validation would terminate the non-enforcement "exemption" (our word).

15. Thus, other than the date of the press release being 13th February 2020, that date played absolutely no part in:

    a. defining of the Policy;

    b. in any exemption (our word) from the applicability of UK law and the enforcement thereof; or,

    c. defining any criteria in respect of products to which the exemption (our word) from the applicability of UK law and the enforcement thereof would apply and those to which it would not apply (the references to labelling, general consumption and drugs legislation being irrelevant for these purposes).

16. The message to the market was clear: commit to becoming a regulated supplier of CBD products by achieving Validation in respect of them by 31st March 2021 and (in contravention of UK law), they can remain on the market after that date.

17. In essence the FSA had decided to abandon the "letter of the law" in order to bring back to compliance a market which it had permitted, through the lack of enforcement action having been taken in the previous year (for very understandable reasons), to get out of control. At ***The Canna Consultants*** we had advocated just this Policy from early Autumn 2019 in our Position Paper, "***The Road To a Better Future***", which was provided to Stakeholders (including the FSA) in October 2019 (it is viewable **here**).

THE F.S.A.'s POSITION AS AT 19TH MARCH 2020

18. By 19th March 2020 the FSA re-stated its position, but with a new additional caveat[2]:

> *"Businesses need to submit, and have fully validated, novel food authorisation applications by 31 March 2021. After this date, only products for which the FSA has a valid application will be allowed to remain on the market."*

[2] As at 15/7/20 the original version was still published by the FSA: https://www.food.gov.uk/business-guidance/cannabidiol-cbd

"We have advised local authorities that businesses can continue to sell their existing CBD products during this time, provided they are not incorrectly labelled, are not unsafe and do not contain substances that fall under drugs legislation. ***However, no new CBD extracts or isolates should be sold until they have the necessary authorisation****."*

[Emphasis added]

19. It is to be noted that the additional rider refers only to "CBD extracts or isolates" and nowhere does it refer to end-products. This was perhaps an early indication of how ill-thought-out this additional element of the Policy, presumably dreamed up between 13th February 2020 and 19th March 2020, actually is.

20. It appears that the FSA were then seeking to suggest:

    a. That no new manufacturer of base CBD ingredient could supply to any market participant;

    b. That no existing manufacturer of base CBD ingredient could supply a new base ingredient to a market participant;

    c. That no existing manufacturer of base CBD ingredient could supply a base CBD ingredient manufactured through a different process to a market participant; or,

    d. That no new manufacturer of an end product could utilise a base CBD ingredient not as at that date (19th March 2020) on the market within another product;

21. However, it would appear from an analysis of the additional rider, that an existing manufacturer of end products can utilise any supplier of base CBD ingredient, as long as the base CBD ingredient was being supplied to someone in the market as at 19th March 2019.

22. This latter point is a matter which the FSA have sought to address more recently in assertions that a change of supplier leads to a "new" product, but one struggles to keep up with the "on the hoof" evolution of Policy and the apparent lack of foresight in respect of that Policy which the FSA has sought to define.

23. At ***The Canna Consultants*** it has always been our view that the additional rider was (and still is) ill-defined, was (and still is) ill-considered and was (and still is) unlawful – but more of that later.

THE FSA's POSITION AS AT 13th JULY 2020

24. The FSA's position as at 13th July 2020 was:

    a. Any product which was unlawfully on the market as at 13th February 2020 can remain on the market after 31st March 2021 if it has a Validated Application for Novel Food Authorisation at that date;

    b. Any product which was not on the market at the date of their announcement on 13th February 2020 cannot be brought to the market until it has achieved full Novel Food Authorisation following the completion of the Validation Stage, Risk Assessment Stage and it has been added to the undefined equivalent of the Union List which the FSA and/or another Government body or Department will administer after the EU Transition Period; and,

    c. Any changing of the CBD ingredient within such a product, irrespective of the reason why, constitutes a "new" product and it cannot be brought to market until the criteria identified in (b) have been met.

25. There has even been some suggestion to market participants that a change of product name and/or packaging would define it as a "new" product for which the same criteria would have to be met.

THE VIEW OF THE CANNA CONSULTANTS

26. Our position at ***The Canna Consultants*** is that the Policy as first announced (and as contended for in our Position Paper, "***The Road to a Better Future***" (viewable **here**), is that any product for which there is a Validated Application for Novel Food Authorisation as at 31st March 2021 should be permitted to remain on the market until the full Risk Assessment has been undertaken in respect of that product.

27. In this way there should be no differentiation between products which were on the market at the (randomly selected) date of the announcement of the FSA's "exemption" (our word) and those which were not, provided that they have each been Validated.

28. We believe that this is the only justifiable and lawful position because:

    a. It treats all market participants uniformly - in the circumstances that we have defined, all Validated products are equally compliant (with what we suggest should be the FSA Policy) and non-compliant (with UK Law) as each other;

    b. The threat/danger profile to consumers presented by each of the Validated products is the same – they have all achieved a standard which the FSA believes is deserving of further consideration, such that none of the Validated products are any "better" or "worse" than each other; and,

    c. Thereafter, resources should be targeted at those products which are being presented to the consumer which have not achieved those standards.

WHY DO WE HOLD THIS VIEW?

29. The reason that we come to this conclusion is that it is fundamental that a Regulator is obliged to treat all market participants who are subject to its authority equally, and this fundamental principle is wholly ignored when a Regulator decides to make one rule for one participant and one rule for another.

30. The Regulator's Policy is even more absurd when the rule which the Regulator seeks to advance positively benefits those market participants who have broken the law for the longest period and penalises those who had sought to comply with it.

31. In making its Policy announcement on 13th February 2020 and creating the "exemption for Validated products after 31st March 2021", the FSA decided that it was not going to follow or apply UK law – this is undoubtedly the case because UK law requires that no Novel Food product is brought to market until it has been acknowledged as being safe following a full Risk Assessment by the competent authority and designated as permissible for lawful sale following inclusion in a register created and retained for the purposes of identifying those (previously) unlawful Novel Foods which are then permitted for sale.

32. In advising Local Authority Trading Standards that, pursuant to its Policy, they should not take enforcement action against unlawful products, it probably exceeded its authority.

33. Let there be no thought that we believe that there should have been a blanket enforcement against all CBD products, we absolutely do not – we argued against it and for a transition to regulation in "***The Road to a Better Future***". On the contrary, we believe that the FSA's Policy as originally announced is:

a. good for the consumer;

b. good for those market participants within the industry who want to be compliant;

c. good for those market participants within the industry who want to be Regulated;

d. good for the Regulator;

e. good for employment;

f. good for enterprise; and,

g. good for the Exchequer.

34. However:

a. positive discrimination to the benefit of those who were unlawfully on the market at the random date of the announcement in February 2020;

b. to the detriment of those who had acted lawfully;

c. where they each have Validated products;

d. in circumstances where there is no impact upon the consumer by them being treated equally;

is a bad and unlawful Policy because it fails to treat them equally and is a breach of the principle of "Natural Justice".

THE CANNA CONSULTANTS INTERVIEW THE FSA

35. In a three-hour recorded Q&A session with the Food Standard Agency's *Paul Tossell* (Head of Radiological, GM, Novel Foods and Feed Additives Team) and *Frances Hill* (Team Leader for the Regulated Product Risk Assessment Team), we questioned and probed with our own questions, plus others provided by market participants.

36. At the Canna Consultants we had grown sick of interest-group organisations and quasi-associations representing that they had some form of access to the Regulator that could not be achieved unless you paid their membership fee. Our experience of Regulators is that they are willing to engage with market participants, but that it can be difficult for them to do so on an individual basis given the disparity between their resource levels and the number of individual market participants.

37. The underlying strength of The Canna Consultants is as a bridge between the commerciality of the market participant and the legal requirements of the Regulator. We decided to utilise that strength to the benefit of the whole market, whether those participants are clients or businesses who we have never met, and will never meet.

38. To that end, one of the questions that we posed to the FSA was on the issue of "New to Market" – it's necessarily long so please bear with it:

> *"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.

The FSA's position is that Company 1 will be able to remain lawfully on the market [**Our note: it is not lawfully on the market, it is unlawfully on the market, but there is a Policy position that the law will not be enforced***], but Company 2 will be unlawful and must not sell its products until final Authorisation is granted* [**Our note: the sale of its product is unlawful, but no more so than the unlawful sale of the product by Company 1**].

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?"

THE FSA's RESPONSE

39. What follows here are ***notes*** of the answer of Paul Tossell. You are all encouraged to watch the answers that he gave to the questions and discussions on this topic, which flowed for 10 minutes while we probed him in respect of the Policy and its effects [*we will update this document with the counter times of this discussion when the footage is back from the edit*].

40. A summary of the points that Paul made in defence of the Policy are:

    a. The products of both Companies 1 and 2 would technically be unlawful because they should both have a prior authorisation before being placed on the market;

b. Company 2 is not being disadvantaged, it is doing it in the correct manner, like every other Novel Food on the market [Our note: every other non-CBD food on the market];

c. Company 1 has taken an illegal step to gain undue advantage;

d. We [the FSA] couldn't allow a new product on the market because it would be against the spirit of the Novel Food authorisation process.

e. A lot of companies have gone out there and made a lot of money.

f. We had a decision to make on how we brought the industry into compliance. We had choices. It was well within our rights to remove all products from the market. We wanted to respond in a proportionate manner.

g. We treated all those on the market as a lump. In theory they should have come off the market because they weren't authorised.

h. It would have been a nonsense for us to have permitted new products to market [prior to 31/3/21].

i. We said to those on the market they can continue to sell, but we said to others that there can be no new products on the market without prior authorisation.

41. We summarised the position at the end of the discussion:

"The company that broke the law for the longest, receives a state-sponsored exemption to continue breaking the law, to the commercial and financial detriment of a competitor who acted lawfully."

42. The FSA's answer was:

"We thought that this was the best balance overall for bringing the industry into compliance."

WHERE DO MATTERS GO FROM HERE?

43. We have every sympathy for the FSA and those, such as Paul and Frances, who are tasked with making Policy with limited resources internally, and with Advisory Committees who meet on limited occasions and for limited durations. However, if the current manifestation of the Policy is maintained, then all those companies who were not on the UK market on 13th February 2020, but who are making significant long-term resource and financial investments into CBD products for the UK market, are liable to have their products removed from the market at any time, irrespective of whether they achieve a Validation Application by 31st March 2021.

44. They face that jeopardy because the Regulator has acted outwith its powers in deciding to ignore the law in respect of one sub-set of market participants (those who were breaking the law on 13th February 2020), but actually apply the law to another sub-set (whose products pose no greater detriment to the consumer than those in the former group) who were not breaking it on that date.

45. For the reasons outlined within this document and within the discussion that we conducted with the FSA, we do not believe that this Policy is either acceptable or lawful and that a Judicial challenge is, if it maintained, inevitable by those companies who are penalised by it. The challenge would be by way of Judicial Review and can be taken by an individual market participant or a collection of participants who are affected by the same issue.

46. Each participant who would be adversely affected by the Policy could wait and hope that neither they nor any of their commercial, wholesale or retail customers suffer any enforcement action from Local Trading Standards pursuant to the Policy. We would Counsel against such optimism because when the action stuck it would remain in place until the conclusion of the legal challenge – which would likely be many months.

47. At ***The Canna Consultants*** we will continue to engage with the Regulator in order to pursue the effective dialogue that we have with them, in an effort to have the "New to Market" rider removed from their Policy.

48. If we are successful in that regard, we will bring the information to the market. If we are unsuccessful and they confirm their position as final, then we will notify the market and invite approaches from those participants who would wish to be involved in a challenge to the Policy in advance of 31st March 2021.

Remember what we say: Be Careful Who You Listen To…