JUST BECAUSE THEY SAY IT, IT DOESN'T MAKE IT TRUE

THE ISSUE

The FSA refutes claims made by a prominent self-styled trade organisation that it has changed its toxicology policy.

On Monday 21st September 2020 we became aware of a 40-minute webinar video in which a commercial entity was promoting its commercial "toxicology safety study" and seeking to conscript market participants to the same. Within the promotion it was repeatedly asserted that the organisation had been informed privately by the FSA that, in order to be **Validated**, a CBD Novel Food application **MUST contain a completed OECD 408 Study.**

If true, this would have presented a monumental change in the regulator's policy and we were very surprised that the FSA would have chosen a private conversation with a self-styled trade organisation to "announce" such a seismic shift in Policy, rather than a public announcement to the market as a whole.

We contacted the FSA and were immediately informed that the assertions being made were inaccurate and that the FSA policy has not changed. The FSA has today (24th September) updated its website to confirm this position and seek to reverse the potential detrimental impact on the market, and confidence in the same.

SO, IS IN VIVO TOXICOLOGY REQUIRED AND WHEN?

At ***The Canna Consultants*** it is our opinion, and has always been our opinion, that an In Vivo OECD 408 toxicology study will be required on CBD as a raw ingredient and that such a study will have to be applicable to the raw ingredient which is utilised in an end product which seeks Novel Food Authorisation. The Committee on Toxicity (COT) are quite clear that there are gaps in the existing data available for CBD and these gaps can only be addressed through such a study.

However, this will not necessarily mean that every CBD raw ingredient will have to be the subject, itself, of an OECD 408 study – what will be required is that it will have to have a scientific link to such a study. In order to avoid the unethical impact of multiple in-rodent studies upon essentially the same ingredient we advocate, and have always advocated, the adoption of a "Substantial Equivalence" policy by the UK FSA.

You will see the manifestation of this approach in our 3-hour interview with Paul Tossell, Team Leader for Radiological, GM, Novel Foods and Feed Additives and Frances Hill, Team Leader for the Regulated Product Risk Assessment, recorded and aired in July 2002 when we questioned them in a free-to-all webinar for the benefit of all market participants (available from this link).

You will see a further manifestation of the consistency of our analysis in our Position Paper "Standards Need to be Driven by Science Not Commerce", published on 3rd August 2020.

WHAT IS SUBSTANTIAL EQUIVALENCE?

Substantial Equivalence in this context is a term which we use to refer to two (or more) individual ingredients which have such similar chemical properties and which react and behave in such a similar manner to each other, that the results of scientific testing upon one (the test subject) can be treated as applicable to the other without the need for the same testing to be undertaken on the other (the substantive equivalent).

From reading our Position Paper "Standards Need to be Driven by Science Not Commerce" you will appreciate that the first step to avoiding the duplication of testing (in this case In Vivo rodent testing which leads to the death of the test subjects), is defining the maximum acceptable divergence from a standard (the test subject) and for which Substantial Equivalence will still be held. It is through this definition that one knows whether two (or more) substances can share in the results of the study performed on one (the test subject) but intended to be used for the benefit of them all (the substantive equivalents).

Our approach is driven by regulatory science and not commerce. For us at ***The Canna Consultants***, once the parameters of Substantial Equivalence are defined, then companies are able to assess with whom they are compatible, and with whom they could engage to share costs – in the knowledge that the outcomes will be applicable to more than simply the test subject.

This is why at ***The Canna Consultants*** we are engaging with market participants to firstly understand - from the most exacting chemical analysis point of view - what their ingredient/product actually is and what it consist of, in order that they are positioned to be able to identify those other market participants with whom they are "compatible" from a Substantial Equivalence perspective.

In parallel with this engagement with market participants, we are engaged with regulatory scientists and the regulators themselves in order to define the parameters of Substantial Equivalence.

The end solution for sensible market participants, which can be provided through ***The Canna Consultants*** and our chemical analysis and toxicology partners, is:

- the marriage of market participants whose ingredients/products are aligned;
- who know that they are aligned in advance of being required to make long-term financial commitments to each other;
- leading to the achievement of the regulatory outcomes demanded by the regulatory scientists.

THE CANNA CONSULTANTS' SUCCESS AND PROGRESS WITH THE REGULATORS

One can see from the manner in which we questioned Frances Hill in July 2020 that we advocated this first step - the defining of Substantial Equivalence from a chemical composition viewpoint - to the UK FSA (see running time 27:00 to 32:00 on the Frances Hill Q&A).

On Friday 18th September 2020 we were able to indicate that our efforts on behalf of the market were having success: the UK FSA's advisory Committee, the Advisory Committee on Novel Foods and Processes (ACNFP) (the Committee and the meeting referred to by Frances Hill in our July 2020 interview with her), held its meeting on 10th September 2020 and published its Discussion Paper (143/03).

It will be noted that the ACNFP identified the "Actions Required" by them as:

- Members are asked whether it is possible to establish acceptable ranges of CBD and other components in the product to account for company batch variability in joint applications;
- If so, members are asked whether it is possible to provide a numerical range, in absolutes or percentage; and,
- Members are asked whether they are willing to accept evidence from relevant toxicology studies and evidence of safe use across different producers in joint applications.

At ***The Canna Consultants*** we will continue to liaise with the regulatory scientists between now and then to discuss what the practical manifestations of Substantial Equivalence will be.

THE INHERENT PROBLEM WITH COMMITING TO A TOXICOLOGY STUDY BEFORE SUBSTANTIAL EQUIVALENCE IS DEFINED BY THE REGULATORS

The fundamental problem the currently touted consortium proposition, is now and has always been since it first emerged is that the regulatory scientists and ACNFP have not confirmed that:

(a) Substantial Equivalence will be afforded to CBD ingredients/products; or,

(b) what such definition will mean in terms of chemical composition.

Until such time as the ACNFP provides its advice to the FSA (and the regulatory scientists have translated such advice into workable parameters), no-one knows which disparate ingredient manufacturers have "compatible" products that would fall within the (as yet undefined) criteria of Substantial Equivalence to each other.

The upshot is that market participants are being engendered to join a consortium for which there is absolutely no knowledge or certainty that the toxicology testing which it is being proposed to undertake on the ingredient (let us say supplied by Manufacturer A), will be applicable and usable by Manufacturers B, C and D (or thereafter the products manufactured by Brands utilizing Manufacturer B, C and D's CBD ingredients), despite the results having been paid for by Manufacturers B, C and D.

Again, we invite recourse to the Q&A which we conducted with Frances Hill Q&A and which exposes the commercial risks being taken by signatories to the A.C.I. proposal:

- Five manufacturers (A, B, C, D and E) of CBD isolate each pay the A.C.I. £100,000 (the figure is representative of nothing other than its use in the example);
- The ingredient of one of those five manufacturers - Manufacturer A which, according to a promotional Webinar that we viewed in June 2020 , would be the "worst" one (whatever that means?), would be the subject material for toxicology testing, at a cost of £500,000 and paid for through the contributions of Manufacturers A, B, C, D and E;
- Manufacturer A would include the toxicology data from the study in its Novel Food Dossier;
- Manufacturers B, C, D and E would include the toxicology data from the study in their respective Novel Food Dossier, asserting that they were part of the "safety consortium";

- In January next year the FSA may indicate that the four non-subject ingredients (those of Manufacturers B, C, D and E) cannot benefit from the study results of the ingredient which was the subject of the test because, based upon the advice provided to them from the ACNFP, they are too disparate - too chemically dissimilar.

In such circumstances, Manufacturers B, C, D and E will have just subsidised the Novel Food toxicology costs of their direct rival by 80% and received absolutely no benefit for it.

Ignoring for these purposes the inaccuracy of the assertions propagated in the video of Monday 21st September - if the assertion were true then Manufacturers B, C, D and E would have to remove their products from the market because they would not have recognized toxicology studies applicable to their ingredients completed prior to Validation - they would be back at the drawing-board as if they had never embarked upon any testing.

THE RESPONSE OF MARKET PARTICIPANTS TO THE INACCURATE "RECRUITMENT DRIVE"

At ***The Canna Consultants*** we don't know whether the response to the Association was as they implored and begged within the video: *"pick up the phone and call us before it is too late"* (to save yourself), but market participants certainly picked up the phone and called us.

Throughout all of Monday we were deluged with calls from market participants who had registered and viewed our free-to-all July interview with the FSA. There was an absolute core consistency to their questions:

- *How could the FSA change from their July indication that they (the FSA) would be prepared to Validate an CBD Novel Food Application in circumstances where the applicant had not completed their toxicology study, but where the FSA was satisfied that there was a process in place by which the toxicology will be made available in due course when completed (i.e. post-Validation but pre-Authorisation)?*

Our response to those who contacted us was as follows:

- to inform them that we did not believe that there would be any circumstances where the FSA would engage in such a radical change of policy (which had been published to the market for months and upon which people– if the reports as to policy change were accurate – would have acted to their detriment) without a public pronouncement to that effect;

- that such an announcement, if there had actually been such change in policy, would be to the whole of the market, and not in a private one-to-one meeting with a so-called trade association which purports to represent the whole industry (although actually represents no more than a handful of participants); and,

- that the assertion itself, and further assertion that an immediate subscription to a collegiate approach was the only way in which the new "Validation pre-requisite" could be achieved, flew in the direct face of the ACNFP's decision only last week that it would consider its acceptance of the principle of Substantive Equivalence for the purpose of toxicology studies on and individual but cross-applicable ingredient and report to the FSA and market participants who follow the issue in due course.

Having decided to ignore it for the misinformation that we considered it to be, our hand was forced when we started receiving calls from White Label and Contract Manufacture clients, who themselves had been fielding calls from their own client Brands for whom they manufactured.

CONTACTING THE UK F.S.A.

We acknowledge that we have a relationship with the regulator and that many in the market do not and we also acknowledged that the potential seismic change on policy was a change from that which the FSA had publicly announced within the Q&A that we had conducted with them.

Recognising those factors, we decided that we would formally write to the FSA in order that we could ascertain their position for the market participants who had viewed the FSA Q&A webinar with ourselves – clearly many had contacted us in various states of panic about what they were hearing, but we also reasoned that many would have not done so and would be labouring under the potential misapprehension that the A.C.I.'s announcement was indeed the UK FSA's new regulatory policy.

Late in the afternoon of 21st September 2020 we wrote to the FSA. Immediately upon their receipt of the emailed letter we received a telephone call from Paul Tossell, Team Leader for Radiological, GM, Novel Foods and Feed Additives who indicated that:

- the assertion as to the FSA's "new Poicy" was not correct and was not something which they had been told in a meeting (which had taken place) on 14th September 2020;

- the UK FSA's position had not changed: while an application could not be Authorised without the completion of an OECD 408 Study (with which agree, and have always agreed), the UK FSA maintained the stance that it did in the July interviews - that an application can be **Validated** without such a study having been completed, in the circumstances as described by Frances Hill.

The necessity for FSA output to pass through numerous departments before leaving the organisation means that, like many government and quasi-government organisations, the FSA is not the swiftest in formal responses.

Today (24th September) we have received a response to our letter confirming what we always expected and what has been outlined above. The FSA has re-stated its original position and it is available on its website (emphasis added by ourselves):

> **Novel Food Application Guidance**
>
> The content of any application for CBD products should follow the usual application process for all novel foods. The guidance is available on the EFSA's website (Opens in a new window) and we will continue to use this when assessing applications into 2021.
>
> An important part of any application will be a consideration of the product's safety. **Applicants will need to include details of the toxicological studies they** have undertaken, or **propose to undertake** with clear details of the reasoning for these particular tests. **Where all information isn't available at the time of submission**, a justification for the delay and when results will be available must also be included. Without such information it is unlikely we will be able to validate an application.
>
> Meeting the validation standard does not mean the product will necessarily be authorised. Each application will be considered on its own merits, but with so little publicly available information on the safety of CBD we anticipate that directly relevant studies will be needed. Only by including this directly relevant safety information will applications be able to progress and potentially be authorised.

CONCLUDING THOUGHTS

The "prudence" of awaiting the policy guidance of the ACNFP before embarking upon any OECD 408 In Vivo rodent study was stated by Frances Hill when we interviewed her and Paul Tossell in July. As invited to do so by ***The Canna Consultants***, the ACNFP is considering the issue of Substantive Equivalence and will report back to the FSA and market participants. We would suggest that a delay in the commencement of any Study until the ACNFP guidance is available is exactly the "justification" that is referred to by the FSA.

At The Canna Consultants, in conjunction with our scientific partners, we have a toxicology solution:

- no-one is required to subscribe to it;
- no-one is required to subscribe to it in circumstances where they have no idea whether they will be able to benefit from it; and,
- no-one is required to subscribe to it in circumstances where doing so effectively subsidises one of their greatest rivals.

If you would like to discuss CBD Novel Food issues with those who know about them, without any pressure, then get in touch.

Remember what we always say: Be Careful Who You Listen To.