SAFETY STANDARDS SHOULD BE DRIVEN BY THE REGULATORS AND SCIENCE, NOT BY COMMERCIAL ENTITIES OR ASSOCIATIONS

YOU MAY CHOOSE YOUR OWN PATH, BUT TO DISMISS OUR ANALYSIS MAY BE UNWISE

Those who have been observing the CBD-Novel Food evolution over the last six months will be aware of some of the issues that we have covered which, you may feel, were all ahead of the curve and demonstrated our ability to read and predict the market through the depth of our knowledge and the breadth of our exposure across Stakeholders, some of which are:

- We authored **The Road to a Better Future** (October 2019) provided the blueprint for that which the FSA have implemented;

- **UN Vote on the WHO Proposals** (March 2020) will not be the end of the THC issue in the short-term;

- **Be Even More Careful Who You Listen To** (March 2020) stressed that individual Authorisation will be required for end products (including ADME work), in contrast to what was being peddled by some raw ingredient manufacturers – now confirmed by Paul Tossell and Frances Hill of the FSA in the 3-hour Webinar interview which we conducted with them **here**;

- **Beware the False Race for Validation** (May 2020) identified the opportunist claims as to having submitted full Dossiers and predicted the absence of quality and content therein – now confirmed by Paul Tossell and Frances Hill of the FSA in the 3-hour Webinar interview which we conducted with them **here**;

- **Is there a Sting in the Kanavape Tail** (July 2020) broke the news that no applications for naturally-derived CBD products will proceed to the Risk Assessment stage, later publicly confirmed by EFSA;

Reference to these market-pre-emptive publications is not for the purpose of chest-beating, but to place into context the remainder of this Position Paper.

COLLEGIATE NOVEL FOOD TOXICOLOGY BETWEEN COMMERCIAL COMPETITORS

We imagine that almost everyone involved in this marketplace has probably been approached directly by a Trade Association seeking to entice them into joining a "Collegiate" Novel Food application. If you haven't been approached directly you should not be offended, you avoided the waste of time - something not so easy when having to navigate the Social Media bombardment in respect of the same.

The draw of the Collegiate Novel Food application is the purportedly low cost – everyone contributes a "small" amount and everyone benefits from the results. We were not against the principle of the proposal, but when we scratched the surface and engaged in some Due Diligence, the folly of the union of otherwise commercially opposite entities became abundantly clear.

The Principle

The basic principle is that because Toxicology work is so expensive, if those costs are shared between interested parties then they all benefit. The problems arise when you seek to establish the criteria for the selection of the substance upon which the Toxicology work will be undertaken, in this example a CBD isolate:

- Would it be the highest purity CBD isolate?
- Would it be the CBD isolate with the lowest number of contaminants?
- Would it be the CBD isolate with the lowest relative strengths within its contaminants?

The Practice

The reality is that in order to engender the largest number of raw ingredients covered, the bar for the ingredient upon which the Toxicology work would actually be undertaken has to be set ever lower because there is no point setting it so high that only one manufacturer fulfils the criteria.

The Perversity

Thus, despite an assumed intention to promote the highest quality, the Collegiate application funded by commercially opposing market participants actually engenders lower standards than some of those participants already meet. Somewhat perversely, those who exceed the standard are assisting the commercial aims of those who do not and, even more perversely, are subsidising them in doing so!

The Guesswork

A further flaw in the aspiration is that it requires a "leap of faith" in respect of what we term Substantial Equivalence, by which we refer to an additional product which has either the same characteristics as a predicate product (here the CBD isolate upon which the Toxicology is undertaken), *or has different characteristics than the predicate product but where those differences can be demonstrated not to raise different questions of public health*.

In our experience it would be highly unlikely that two different manufacturers produced ***exactly*** the same product and, therefore, it is the second (*italicised*) limb of this "definition" that would be applicable. When we questioned Frances Hill of the FSA (to be found **here**), it is clear that the FSA had not (as at early July) considered defining criteria for Substantial Equivalence, indicating that all assessment would be on an ex post facto (after the event) basis.

The Gamble

Therefore, the collegiate approach between commercial competitors would (assuming that the Toxicology assessment produced no safety issues and omitting other non-Tox factors for the purpose of this analysis) guarantee the progress of the CBD isolate upon which it was undertaken, but may not be transferrable to any of the raw materials of the other companies who had subsidised and funded the work from which only one company would benefit – their competitor whose product was chosen to be the subject of the Toxicology work (and who knows how that would have been chosen?).

One is forced to ask the following question:

> ***What company would fund the assessment of the product of one of its direct competitors in circumstances where, if the funded work was successful, that competitor would certainly have a product which would benefit from the funded work but which those who funded it may not, such that the funded company could remain on the market and they could not?***

We venture that it would be a brave CEO who would gamble with the entire future of their company, to the direct benefit of their direct competitor.

Fanfare and Publicity to Silence: Where is it now?

We note that the promotion of the collegiate toxicology study by the organising entity has gone quiet. It may be that there is a lengthy period required to assess the products of all those who have subscribed prior to the selection of the one with the "Golden Ticket" (Willy Wonka-style). However, we understand that it wasn't a popular offering, that the vast numbers and low costs did not materialise and the organisers (and those raw material manufacturer(s) who believed that they were in the running for "the Ticket") and now back where they started.

IS THERE A PLACE FOR COLLEGIATE TOXICOLOGY?

The reader may be forgiven for concluding that we consider that there is no place for applications which utilise collegiate toxicology assessment. We believe that there is, however, it is not in a format organised by a Trade Association who seeks to benefit only those who are prepared to pay its fees. We believe that the criteria for a collegiate toxicology assessment should be set by the regulator and science, rather than a Trade Association or commercial market participants.

The Regulator and Science Must Come Together

It is perhaps clear from the way that we questioned Frances Hill of the FSA (to be found **here**), and our discussion about the implications of the FSA policies (which follows directly on from the Q&A with Frances) that we believe that the Regulator, in conjunction with scientists, has an obligation to define what Substantial Equivalence with a set of baseline default criteria would be for a CBD isolate.

If this were to be done, then market participants would know in advance of committing to a collegiate study whether their product would benefit from positive outcomes in an equal manner to the raw material which was directly assessed.

HOW ARE WE WORKING TOWARDS THIS?

A Science-Led Definition of Substantial Equivalence

We know from what Frances Hill told us that the FSA are awaiting the output of two Advisory Committees in the Autumn, from whom additional guidance will come. That output may permit the FSA greater engagement in respect of defining Substantial Equivalence from a benchmark in advance of toxicology work being undertaken.

At ***The Canna Consultants*** we are currently working with independent scientific institutions and experts to create the necessary framework of which market participants will be able to avail themselves in due course. We only work with the best and our scientific partners are truly involved with us at the very heart of the regulatory discussions on the intertwined issues of composition analysis and CBD toxicology.

The intention is, in combination with the regulators and their Advisory Committees, to produce a criteria for Substantial Equivalence as defined by the scientific community and not by commercial entities with their own inherent motivations.

Independently Funded Toxicology Purchasable After the Results Are Known

A further flaw that we saw in the "Trade Association sponsored" collegiate model was that all those who were willing to subscribe to the funding did so with an inherent risk of failure of the assessment. All market participants have diverse appetite for risk, some more than others, but there was risk nonetheless.

In order to remove the "gamble" of funding toxicology assessment which may not produce adequate results or be undertaken in a manner or to a level acceptable to the Regulator, at ***The Canna Consultants*** we are again working with parties on a structure under which the toxicology work on a product (which meets a defined benchmark criteria from which the Regulator will accept Substantial Equivalence), will be undertaken and funded entirely independently from any product manufacturer.

Once the results of the toxicology work are known, then market participants (who will then know whether they met the Substantial Equivalence criteria) will have the ability to purchase access to the data in order to support their individual applications. In this manner, the purchase would be made in circumstances where the results were known and the "gamble" removed.

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