BE CAREFUL WHO YOU LISTEN TO

Following the FSA's announcement last week on the Novel Foods position, we observed that many so-called experts were coming out of the woodwork and positing questions that, if they held the expertise that they assert, they would know the answer to. We pointed out where the law could be found, and what it meant – you can see our document "***What is a Valid Application?***" **here**.

A week on we see that those same "experts" are back professing a detailed knowledge of the subject and suggesting that market participants rely upon what they have to say. At ***The Canna Consultants*** we caution reliance on such individuals and law firms, and suggest that participants undertake significant due diligence prior to taking a decision based upon their advice.

The individual who we quoted last week has overcome their inexperience and is able to pronounce:

> *"Producers of the active ingredients (CBD isolates, etc...)* ***[See Note 1 below]*** *must submit a valid marketing authorisation application to the FSA by this date [31/3/21]* ***[See Note 2 below]****."*
>
> *"What constitutes a valid application? There are a number of categories that have to be satisfied in order for your submission dossier to be considered complete. Provided you make submissions in all categories then your application should be deemed valid* ***[See Note 3 below].***
>
> *"If you are buying in your CBD extract and then creating your own range of finished products, will you have to submit your own novel food application? The answer is no, but with several caveats. "The issue here is whether your finished product has been cited in your supplier's application and has the necessary data been submitted by your supplier accordingly. If your finished product has been included in your supplier's application then you will not require your own marketing authorisation… Ensure that data in respect of your product range is submitted as part of your supplier's dossier.* ***[See Note 4 below****]"*

We suggest that any reader of those statements would be left with the understanding that:

That "active ingredients" were limited to CBD isolates and other such;

That you only need to have your documents with the FSA by 31/3/21 to secure the continued marketing exemption; and,

That as long as you said something in respect of each required category, then your application should be deemed valid.

At ***The Canna Consultants*** we believe that if you are to openly pronounce your knowledge on a public forum, then you have an obligation to be accurate and responsible, rather than misleading and cavalier.

Why do we believe that their statements are inaccurate and misleading?

Note 1 The Novel Foods application process addresses ***all*** ingredients in a product because the assessment takes into consideration not simply the "active ingredient" (*which is a definition to nothing*), but the whole of the end-product. It does so because it is the potential effect on the consumer of the end-product which is being assessed, not individual elements of it.

For example, the core ingredients of a product may be perfectly safe, but if another element/compound is added to that product, then there is the potential for an adverse reaction between, or in consequence of, the added compound and some of the elements of the original product.

The Novel Food assessment process must have the opportunity to asses ***exactly*** what the consumer is to ingest into their body in order that any potential detrimental effect has been considered, assessed and discounted. Therefore, this applies to all ingredients, not just those which are "active" – whatever the original author meant by that.

Note 2

The author gives the impression that the applicant just needs to get their Novel Foods application/dossier to the FSA by 31/3/21, which could not be further from the truth - the application will need to have submitted their application ***and have had it validated by the FSA by that date***.

Until the FSA has validated the application, it is not a "valid application". Therefore, any applicant will need to engage with the FSA once they have begun their data collection/collation process in order to establish what the 'then' timescale will be between placing the application in the hands of the FSA and the FSA completing their validation of it.

To take the most extreme example, if an applicant submitted an application on 30/3/21, it would not be validated by 31/3/21 and the applicant will have no ability to continue to market their product after 31/3/21 because there will be in existence no valid (i.e. validated) application at the expiry of the exemption period.

The expiry of the exemption period on 31/3/21 is an absolute backstop, not simply a submission date to aim for.

Note 3

The data subsets required are not a "box ticking" exercise where, as long as you say something, then the application will be "valid". The data and information provided must be (a) in the correct format and (b) contain the required data, across all of the required spectrums. If at the point of assessment, the FSA are unhappy with either the format or content of the data, then the application will not be validated.

Perhaps now one can see why 31/3/21 is not a date to fixate upon, save for it being a complete backstop. Were an applicant to submit their application on 1/1/21 (some three months prior to the expiry date), and the FSA were to revert back to them on 1/3/21, informing them that the data submitted was not in the required format, then the applicant would then have only one month to obtain and/or prepare their data in the required format, re-submit the application and have it validated by the FSA. Subject to any re-submission short-cuts which the FSA introduced, it is unlikely that those three sequences would be completed within the one-month window, leading to the result that there would be no ability to market after the expiry of the exemption period on 31/3/21.

Note 4

If the product which the Brand sells is a "pure" White Label product, by which we mean that the Brand does nothing to the product which it purchases, then it is probably the case that the Brand will not need to make a separate application, other than registering the name of the product with the FSA as being unchanged from the product which has de-facto authorization through their approval of the White Label producer.

However, where the Brand adds ingredients to the product or does anything to it which changes it, then it will be a different product than that for which the White Label supplier has achieved authorization and the Brand will need to submit a Novel Food application for their product.

This does not necessarily mean that the Brand will be required to undertake all of the scientific testing which has been undertaken by their White Label supplier, but the Brand will need to supply that data with their application (assuming that their White Label supplier is willing to permit them access to and use of it), plus the Brand's own data in respect of the product that they have created.

Building upon the answer that we have outlined in Note 1 above, we believe it highly unlikely that bulk manufacturers of cannabinoids will be willing to submit applications which cover the products of every one of their purchasers where the Brands have changed the constituent elements of the base product.

At ***The Canna Consultants*** we believe that it is more likely that White Label providers will permit their customers to utilize the non-intellectually protected datasets which they have themselves submitted, but that the customer Brands which have amended the chemical composition of the base product will be expected to make their own application. We come to this conclusion because *with responsibility comes liability* and we do not believe that White Label providers will assume the potential commercial exposure to their customers, who would potentially number in the hundreds.