

FSA CBD NOVEL FOOD UPDATE

The FSA recently engaged with CBD market Stakeholders (of which TCC were one) to set out their intentions in respect of proposed changes to the manner in which the market will be regulated – particularly in respect of:

- the (forceful) encouragement for the reformulation or change to products so as to comply with what the FSA's now terms its “**safety reasons**”, i.e.:
 - **ADI of 10mg/day for CBD**; and,
 - **ADI 0.07mg/day for THC**;
- any consequential amendments necessary to the Public List due to reformulation or changes to the products on the List; and,
- the (forceful) encouragement for labelling to identify the two maximum intakes above, as well as the age and breast-feeding declarations which all responsible Brands will already have been doing.

MAXIMUM THC LIMITS

1. The maximum ingestion limit will be set at a **ceiling of 0.07mg/day** in respect of the **aggregate levels of Δ-9 THC and Δ-9 THCA**.

REFORMULATION FOR “SAFETY REASONS”

2. A Brand can reformulate a product to achieve the CBD 10mg/day **and** THC 0.07mg/day levels, which the FSA will refer to as a reformulation for “**safety reasons**”.
3. If the reformulation for “*safety reasons*” does not impact the description of the product as it currently appears on the Public List, then the FSA do not require to be consulted (because there would be nothing within the Public List to change).

Note that, given that the Public List is likely to contain reference to one or more of the following, the instances where no changes are required are likely to be minimal:

- *the overall CBD content of the retail unit;*
- *the % strength or mg content of the retail unit;*
- *the CBD content of a single dose;*
- *the definition of a single dose;*
- *the CBD content of a daily dose; and,*
- *the definition of a daily dose.*

REFORMULATION IS ENCOURAGED BUT IS NOT MANDATORY

4. Reformulation for “*safety reasons*” is not mandatory, but is encouraged and “**expected**” by the FSA because they want businesses “**to do the right thing**”.

LABEL CHANGES RESULTING FROM REFORMULATION WILL BE PERMITTED

5. The FSA are encouraging all products to contain:
 - “the amount (or size) of CBD per serving”;
 - “the 10mg/day CBD maximum ADI” and;
 - “warnings for vulnerable groups.”
6. If the reformulation means that changes are required to the Public List then an application can be made to the FSA to amend the Public List accordingly.
7. If a reformulation is required for “*safety reasons*” then the FSA will permit a change in the source of the CBD ingredient, but the new CBD ingredient must continue to meet the “*composition, production process and specification*” of the CBD ingredient which is associated with the Novel Food Application to which the Brand is associated.
8. If a reformulation is required for “*safety reasons*” the FSA will not automatically require an analytical demonstration which justifies the asserted requirement for safety reasons and indicate that they will accept “*a statement that the changes are required for safety purposes.*”

With the embargo on publication of these changes having been removed today, we thought that we'd give you the *TCC View* as to some of the options available to Brands who might be affected by the new forcefully-encouraged, non-requirements (i.e. everyone).

CAN A BRAND CHANGE TO A NEW CBD SUPPLIER WHO IS YET TO MAKE THEIR OWN NOVEL FOOD APPLICATION?

While they have not stated a position (they may not have yet thought that far ahead), but the answer should be “No” because in order to be self-certify the substantial equivalence of the two ingredients the applicant is going to have to name the new-comer – at which point it will be drawn to their attention that the newcomer is not an ingredient that they have had any exposure to whatsoever.

If the FSA are feeling open-minded, at the very least the request should produce a response for the provision of the evidence necessary for them to make an assessment of substantial equivalence, i.e. for the provision of evidence to demonstrate that the “*composition, production process and specification*” of the two ingredients are the same. For the reasons already outlined, the applicant is unlikely to be able to produce the same.

However, if the FSA don't check their database then who knows – they might simply say yes and grant the applicant (and their new supplier) a pyrrhic victory - because when the application to which the Brand is currently associated is Authorised (assuming that it is) then:

- product will be removed from the Public List (and so will not be protected from Trading Standards action); and,
- nor will the Brand be made with an authorised ingredient and will be unlawful (and unprotected from Trading Standards action).

CAN A BRAND CHANGE TO A NEW CBD SUPPLIER WHO HAS THEIR OWN NOVEL FOOD APPLICATION?

On the face of it, a change of CBD supplier is now permitted if it is accompanied by a **self-certification statement** that the change is required for “*safety purposes*”.

That said, the policy position does leave open the potential for the FSA to demand:

- a demonstration of the need for the change by reference to the “unsafe” nature of the previous ingredient; or,
- for the provision of evidence to demonstrate that the “*composition, production process and specification*” of the two ingredients are the same.

If the FSA were to demand the evidence in the latter situation, then it may be that the Brand would not be able to provide it to demonstrate the substantial equivalence between the two CBD Ingredients (the soon-to-be-ex supplier would have no motivation to provide them with the necessary data), however, over the course of 5 years we have not seen the FSA demand that which they have previously stated is unnecessary – they tend not to create work for themselves.

WHAT IF I BELIEVE THAT THE APPLICATION TO WHICH I AM ASSOCIATED TO NOT GOING TO BE AUTHORISED?

If you are one of the many who hitched their trailer to a particular cart because you thought that it was your best (or only) option in 2020, but are now regretting having done so or are fearing that those who promised so much in those cash-grab days do not have the commitment (or continuing fees) to see the application through – then July may be Christmas come early and the FSA may be wearing a red suit, a full white beard and carrying a sack full of joy.

If you want to fully understand your options, then you know who to listen to...