THE FSA SAFETY ASSESSMENT OF RP 427

IF YOU ARE A BRAND WHO FUNDED APPLICATION RP 427, THEN DEPENDING UPON YOUR PRODUCT TYPES AND THEIR STRENGTHS, THE OUTCOMES OF THE SAFETY ASSESSMENT MIGHT BE "SWEET", "BITTERSWEET" OR JUST DOWNRIGHT "BITTER"

A (very) qualified congratulations is in order to those who run EIHA, their application RP427 is to be recommended for Authorisation in due course and they will no doubt give themselves a congratulatory pat on the back for what they have achieved. Whether the Brands that paid for the application would contribute to the patting or would prefer their hands to be swapped for knives is up to them.

Why do we suggest that any congratulations are qualified? An analysis of the assessment distills the following:

(a) EIHA supplied toxicology data which asserted that CBD could only be demonstrated as being safe at doses of up to 10mg per day* (*see later note*);

(b) EIHA charged all members of the consortium a fee, but only applied for Authorisation as a Novel Food for a very small, binary section of them; and,

(c) EIHA furthermore excluded most of those who fell within the already very selected application type to a single product.

Thus, despite the hundreds and hundreds of thousands of pounds which has been extracted from the members of the consortium, EIHA have succeed in securing a recommendation for CBD tinctures and liquid capsules made solely with Hempseed Oil (i.e. no other oil and no other product format) and only to a maximum daily intake of 10mg.

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THE SAFETY ASSESSMENT – IN THE FSA'S OWN WORDS

The following extracts are taken directly from the Assessment Report itself (emphasis has been added by ourselves to aid the reader):

EXECUTIUVE SUMMARY

***"An application was submitted**… from EIHA Projects GmbH ("the applicant") for the authorisation of isolated cannabidiol (CBD) as described in RP427, as a novel food. This is a joint application from EIHA associated product partners pertaining to a novel food **which is to be prepared and used according to the specification set out within this document**. **It must be noted that any authorisation subsequent to this application pertains solely to the novel food and not to any proposed uses as an ingredient in any other products**."*

***"The novel food is** a >98% pure, hemp-derived CBD isolate which is intended **to be used in hemp oil** as a food supplement for adults."*

2.1: IDENTITY

***"The novel food is** a hemp-derived CBD isolate of ≥98% purity, presented as a colourless-to-yellow crystalline powder. This is dissolved and standardised to **between 2.5% and 10% CBD concentration in hemp seed oil**."*

2.2: PRODUCTION PROCESS

*"Final formulation and **dilution in hemp seed oil**."*

2.4. STABILITY

*"The stability of five batches of the novel food, and five batches of **the novel food in hemp oil**."*

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2.7: PROPOSED USED AND ANTICIPATED INTAKE

*"**The proposed use for the novel food** is as a food supplement in the form of **an oil sold as capsules and drops at the dose of 10 mg per day** of CBD (Table 7)."*

"Concerns were raised by the Committee and noted in the FSA and FSS assessment regarding any further uses there may be for the novel food. It must be noted that the reformulation of the novel food, or incorporation of the novel food into other food products, would not be permitted under this authorisation."

***"The only permitted use of the novel food is within hempseed oil** as a food supplement up to a maximum daily intake of 10mg."*

Table 7. Proposed uses for the novel food application RP427

Food Category	*Maximum intake level from product use*
***Food Supplements** (for adults) as defined in the Food Supplements (England) Regulations 2003 **as capsules, liquid or drops** in dose form intended for those 18 years of age or over.*	*10 mg per day*

1.12: DISCUSSION

"A safety concern was raised regarding the potential future uses of the novel food as an ingredient in other foods. Further uses are not specified within this application and would therefore not be permitted under this authorisation."

"The evidence presented is consistent with evidence presented to support the development of a provision ADI of 10 mg/day for CBD of 98% purity or above. As such the provisional ADI should be applied to this novel food."

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WHAT QUESTIONS ARE BRANDS LIKELY TO BE ASKING THEMSELVES AT THIS STAGE – ASSUMING THAT EIHA HAS PROVIDED THEM WITH THE FULL ASSESSMENT DOCUMENT?

Please note that all of the responses to these not-so hypothetical questions are posited on the basis that the organisation responding to them did so in a fully frank "fully informed" manner. While this might be expected to be a given, experience within this industry demonstrates that that such an expectation might be rather naïve.

Q1: I BELIEVE THAT CBD IS SAFE AT MUCH HIGHER LEVELS THAN 10mg, I WANT EIHA TO CHALLENGE THAT DECISION AND APPEAL IT, DEMANDING A HIGHER DAILY INTAKE

The toxicology data submitted as part of the application was only able to demonstrate safety at 10mg. Why that is, is not clear to ourselves (although we have our opinion), but possible explanations are:

- an anomaly in the results which could not be explained by the scientists; or,
- an anomaly in the rats which were used – resulting in them being biologically different to all of the other Wistar rats used in toxicology studies which produced evidence of safety at much higher levels; or,
- a poorly designed study which (potentially to save costs?) did not include sufficient graduated dose levels such that when the parachute principle was enacted at "Dose X", the next dose down was that which equated to 10mg/day in humans.

However, on any basis you are not able to challenge a level which you yourselves advocated because the Committee has not disagreed with you – quite the contrary, it has used your data to impose a 10mg/day level on all other market participants, irrespective of what the data from their respective studies established.

To that end it could be said that you have managed a comparative benefit from the results because everyone in the industry has been pulled down to your level, rather than just those who paid for the EIHA application.

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Q2: THE ONLY PRODUCTS THAT I HAVE ARE GUMMIES, DRINKS, CHOCOLATES AND COMPRESSED PODWER CAPSULES, BUT THE ASSESSMENT SAYS THAT THESE ARE NOT TO BE INCLUDED IN THE AUTHORISATION – I WANT EIHA TO CHALLENGE THAT DECISION AND APPEAL IT

You cannot challenge or appeal a decision which has given you exactly what you have asked for. The EIHA application requested Authorisation for only two very specific products:

- >98% CBD isolate tincture in a Hempseed oil carrier with a maximum intake of 10mg/day; and,

- >98% CBD isolate in a Hempseed oil carrier within a capsule, with a maximum intake of 10mg/day.

The Assessment did not consider any other products, such as the Gummies, Drinks, Chocolate and Compressed Powder Capsules that you sell because no application was made in respect of any other then the two products identified above.

The Members of the Committee were clearly very aware of the likelihood that there were market participants which believed that the application was for products far in excess of the two which were applied for – a look at the Public List and the plethora of different product types which are said to be associated with RP 427 (and reliant upon it for their continued presence on the Public list) would have alerted them to that reality.

In consequence, it would appear that they wanted to make it very clear that they have considered exactly the specification and product types that are within the application, but **only** those product types. Consequently, many Brands who erroneously believed that they were within the specification defined by EIHA are mistaken.

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Q3: THE ONLY PRODUCTS THAT I HAVE ARE GUMMIES, DRINKS, CHOCOLATES AND COMPRESSED PODWER CAPSULES - WHY WAS I CHARGED CONSORTIUM FEES IN RESPECT OF AN APPLICATION WHICH I COULD NEVER BENEFIT FROM BECAUSE THOSE IN CHARGE OF THE CONSORTIUM (AND THOSE WHO WERE CHARGING ME THOSE SAME FEES) DID NOT INCLUDE MY PRODUCTS WITHIN THEIR APPLICATION?

One would have thought it obvious that either:

- Brands whose money was funding the application should have had their product types included within the specifications sought as part of the application in order that they could benefit from that which they were paying for; and,

- Brands whose product types were not intended to be included within the application specification should not have been charged fees to fund the very application from which they could not benefit.

The number of products which appear on the Public List and which do not fall into either of the two products in respect of which the application was made is huge and, we would suggest, it is highly unlikely to be the case that they all, independent of one another, knew that they would not benefit from the outcome of the application but nonetheless chose to pay the fees to EIHA and seek inclusion on the Public List pursuant to the payment of those fees to EIHA.

Rather, common sense would suggest that someone had led them to believe that authorisation was being sought for their products and that their products would be authorised as part of the application.

Therefore, perhaps the real questions are:

- Who caused them to have that belief?

- How much did they pay to EIHA to be part of an application which EIHA knew that they could not benefit from?

- Why did EIHA never “come clean” and tell them that their products were not part of the application that EIHA had made (using the money that they had paid)?

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Q4: I PARTLY FALL WITHIN THE PRODUCTS FOR WHICH AUTHORISATION WILL BE GRANTED – I ONLY HAVE OIL TINCTURE PRODUCTS, BUT I USE M.C.T. OIL AND NOT HEMPSEED OIL – WHERE DO I STAND?

We're afraid that your products will not be covered by the Authorisation because the Assessment Committee repeatedly referred to being limited to the specification defined within the application and ***only*** the specification defined within the application – and the specification (which was not imposed on anyone but was defined by EIHA itself) was limited only to >98% CBD isolate in **Hempseed Oil**.

Had EIHA drafted the application to include >98% CBD isolate in MCT oil then we have no doubt that it would have been authorised at the same 10mg/day maximum, just as it is being for Hempseed oil (there could be no other conclusion because they have agreed the safety - albeit at that low level - of CBD in a carrier oil which might have its own cannabinoid contaminants which would add to the CBD content within the product).

However, the fact of the matter is that, according to the Assessment Committee, EIHA did not widen the specification beyond Hempseed oil and the consequence of their failure in that regard is that only Hempseed oil products will be included within the Authorisation – and then only in the two product types discussed previously: tinctures and liquid capsules.

Q5: HAPPILY, I AM ONE OF THE VERY, VERY, VERY, VERY FEW BUSINESESS WHO FUNDED THE EIHA APPLICATION THAT ONLY SELLS HEMPSEED TINCTURES. WHEN THE FSA INTRODUCED THE 10mg/DAY RECOMMENDATION THEY TOLD US NOT TO CHANGE OUR PACKAGING FROM THE 70mg/DAY. CAN I CONTINUE TO USE THE 70mg LIMIT?

Unfortunately, not. One of the aspects of the Assessment Report that we did not extract above informs the reader that, in order to come within the ambit of the Authorisation, the products to which the authorisation applies "*are to be labelled… as follows: Do not exceed the safe limit of 10 mg/day for a 70 kg healthy adult.*" Therefore, in order to be compliant with the Authorisation you will be required to change to the "maximum 10mg" position.

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Q6: HOW COME I AM ONLY LEARNING NOW, RIGHT AT THE END OF THE PROCESS, THAT NONE OF MY PRODUCTS ARE GOING TO BE COVERED BY THE AUTHORISATION – OR COULD EVER HAVE BEEN COVERED, GIVEN THAT EIHA NEVER EVEN APPLIED FOR THEM TO BE COVERED?

Clearly, at **The Canna Consultants** we cannot answer for EIHA – we can't even think how they spin this, but they have been spinning it for years and so they are probably very skilled at it. What we can say is that this is not the first time that we have told the whole of the market what our assessment of the position was, given what EIHA themselves had published about their application:

Q7: I'M NOT A CLIENT OF THE CANNA CONSULTANTS AND I APPRECIATE THAT YOU HAD NO OBLIGATION TO TELL ME THIS BEFORE, BUT IF THERE WAS AN OBVIOUS PROBLEM THAT YOU WERE AWARE OF, WHY DID YOU NOT MAKE YOUR VIEWS PUBLIC?

The answer is that we have done so, and have done so repeatedly, but the Associations obviously don't want to hear it, even if it is not their specific Association that you are holding to account at that point in time – they clearly like to stick together. No doubt we will now be accused of scare mongering, negative news and only looking after our own clients.

What we can say is that we are not a Trade Association, we are not members of any of the ACI, EIHA, CTA, CIC, APPG (or any other acronym that one can think of) because we feel that to be so would compromise our integrity and hinder our ability to challenge them and hold them to account when it is appropriate to do so. Furthermore, we do not covet their members or their self-proclaimed positions as "Leaders of the Industry". Unlike one Association, we never funnelled people to the EIHA Consortium, but we told anyone who listened that they should be very clear about the terms upon which they were entering a collegiate application.

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What we do is seek to inform market participants whom we have never met and whom we never expect to meet, and we do so in an effort to ensure that they have the opportunity to hear an independent voice, rather than the echo-chamber of the Associations. One gets the impression that the each of the Associations would rather that people do not have the ability to hear an independent voice – perhaps to protect themselves from ever being held to account by their own members?

POSITION PAPERS PUBLISHED BY THE CANNA CONSULTANTS

Almost two years ago, on 8th November 2022 we published – freely available to the whole of the market – our Position Paper EIHA's RUDE AWAKENING in which, amongst other observations, we stated (underlining added):

BAD NEWS WAS ALWAYS COMING FOR EIHA CONSORTIUM MEMBERS

For many, many months now we at The Canna Consultants have we have repeatedly informed market participants that those who had subscribed to the EIHA Toxicology Consortium were going to get a Rude Awakening – ever since we saw that the products which would be covered by the toxicology submission would be limited to a CBD strength of 10% and would only be Hemp Oil tinctures.

We were repeatedly told by Brands who had happily handed over their cash to ensure their longer-term advancement that that wasn't the case and that it couldn't have been the case because, were it to have been the case, then it would undoubtedly have been a ***material disclosure*** *required to be made before EIHA banked the cheque for the Brand's entry to the consortium, or accepted the Direct Debit instruction for the Subscription.*

We make no comment about whether it was a required ***material disclosure*** *(although we expect that there will be a few law firms who will be agreeing that it was, and that the failure to mention it gives a cause of action to the aggrieved party), but we would certainly consider it to be an* ***expected disclosure*** *– how could it not be you may ask in unison with us?*

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A GOOD DAY TO BURY BAD NEWS

There is an art in Public Relations in which the publisher seeks to hide their own bad news on a day when people's attention is directed elsewhere. Members of the EIHA Toxicology Consortium will be forgiven if their attention is diverted away from the bad news that we have identified above, however, it only gets worse for them because the more fundamental news is not unconnected, but at the heart of the CBD industry – and the likely futures of their respective businesses.

That is because EIHA has dropped the even bigger bombshell to the members of its Toxicology Consortium that their toxicology submission will only support the case for safety to a maximum daily ingestible amount of 17.5mg CBD. The EIHA document of which we have had sight asserts that this is not "new information" but a matter which has been raised repeatedly with members since June of this year, however, given the exposure that we have to those members – they appear to have a different recollection of what was said over that time, and they are somewhat shocked.*

* 2024 Update While it was certainly being asserted by EIHA in 2022 that they could justify a maximum intake of 17.5mg/day, **in contrast**, that is not what they were telling the FSA because (as we now know from the Assessment Report), the EIHA application was actually made on the basis of 10mg/day (not 17.5mg/day).

THE SUITABLILITY FOR SALE OF PRODUCTS RELYING ON THE EIHA TOXICOLOGY DATA AND THEIR CONTINUED PRESENCE ON THE UK FSA "PUBLIC LIST OF CBD PRODUCTS"

The change in EIHA's advised maximum daily intake for which safety can be established from 70mg to 17.5mg CBD represents a 400% reduction in that presently quoted by the UK Food Standards Agency.*

As the regulator in the UK, the FSA has thus far been in a position that it did not know what the maximum safe level of CBD ingestion was, but recommended 70mg per adult per day. Now however, it is overtly aware that the Applicant in respect of the RP 427 Dossier itself asserts that ***safety for the CBD which is the subject of application RP 427*** *cannot be established above 17.5mg* per day – it is an open declaration to the regulator which the regulator, in our opinion, cannot ignore.*

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In our view, this now means that every product which is included within the UK FSA Public List of CBD Products and which is linked to Dossier RP 427 must now be reconsidered for the suitability of its continued inclusion in that list because the toxicology data and Dossier as submitted:

- *will not support safe usage at anything above 17.5mg CBD per day;*
- *will not support any product other than a Hemp Oil Tincture; and,*
- *will not support that Hemp Oil Tincture which is at a strength greater than 10%.*

We suggest that to do anything else risks the regulator being complicit in the exposure of the population to product which are unlawful per se and which the applicant openly acknowledges that it cannot establish a safety case for usage in excess of 17.5mg per day.

THIS HAS FAR WIDER IMPACT THAN SIMPLY THE EIHA APPLICATIONS

While it may be the case that EIHA has stared this "Hare running", it will not simply be their own applications which are impacted by it – the repercussions will spread to every single application that has been made, both to the UK FSA and the EU Commission.

The reality is that most of the CBD Isolate applications that we have seen are for ingredients which have a CBD purity in excess of 98% and, while it is for every applicant to establish the case for safety of their own ingredient at their individual discrete level, the regulatory scientists cannot fail but be influenced by the knowledge gained from one Dossier when considering the next – because the science is universal.

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In the same week, the same two years ago, on 11th November 2022 we published – freely available to the whole of the market – our Position Paper THE CONSEQUENCES OF EIHA's ISOLATE TOXICOLOGY SUBMISSION FOR MEMBER BRANDS IN THE UK in which, amongst other observations, we stated (underlining added):

> *This week alerted the wider CBD market to some old issues which we had been repeatedly raising with participants who were either already subscribed to the EIHA application or were the recipients of invitations to join the application, plus a considerable new issue around the EIHA Toxicology Consortium results.*
>
> *THE END PRODUCTS TO BE COVERED BY THE EIHA APPLICATION WERE ALWAYS INCREDIBLY LIMITED*
>
> *The old issue was that a procession of EIHA members and potential members who had received various "talks" from key stakeholders within EIHA sought our opinion of their applications likely future progress and appeared to be completely surprised when we told them that the EIHA CBD Isolate (RP 427) and full spectrum/distillate applications (RP 438) were only ever going to cover an incredibly limited number of products.*
>
> *Many months ago we saw EIHA documentation which indicated that* ***the only products to be covered by the EIHA applications (and the respective toxicology submissions which would support each of them) were Hemp Oil Tinctures at a strength no greater than 10%****, but in discussions with a large number of market participants (many of whom are full fee-paying members of EIHA and the Toxicology Consortium), it appeared that they were completely unaware of these significant restrictions, many believing that they had been told by EIHA and its lead members that there were no restrictions at all.*
>
> *This got us thinking: how could all of these separate, independent and unconnected companies, comprising of multiple people within each, all be wrong and be making the exact same mistake as each other in failing to comprehend that which we expect EIHA would have been explaining to them in very clear terms? We came to two potential conclusions:*

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(a) *each group were individually and collectively failing to understand what EIHA had been explaining to them before taking their money (and they just happened to be independently misinterpreting, in the same way as other similar groups, who were misunderstanding the same information in exactly the same way); or,*

(b) *each group were not misunderstanding at all and no-one had bothered to explain to them the constraints with which they were choosing to voluntarily handcuff themselves in the run-up to being asked to part with their money for their EIHA membership fees and Toxicology Consortium subscriptions.*

<u>WHAT ARE THE CONSEQUENCES FOR THE PRODUCTS WHICH ARE THE SUBJECT OF APPLICATION RP 427, MANY OF WHICH ARE ON THE PUBLIC LIST?</u>

We have taken some time to review the public information about RP 427 as gleaned from the UK FSA Public List: for the Brands involved there are some chilling consequences.

We have analysed the products and categorised them as follows:

1. *Oils/Tinctures;*
2. *Gummies;*
3. *Capsules;*
4. *Chocolates;*
5. *Edibles other than 2-4;*
6. *Coffee;*
7. *Tea; and,*
8. *Cold Drinks.*

<u>THE OVERALL NUMBER OF PRODUCTS AND THE REDUNDANCY/FAILURE RATE</u>

There are 3,224 products on the Public List, but when one removes the 54 which relate to raw ingredients and are not consumer-facing End Products, this falls to 3,170 separate entries.

- *Of those 3,170 products, the only category of products which is capable of being covered by the EIHA's application are oils/tinctures, which number 1,878 in total.*

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- *However:*

    - *616 of the 1,878 are at a strength exceeding 10% and 4 are unquantified and so the eligibility figure is reduced to 1,262;*

    - *12 of the 1,262 contain other ingredients which are Novel Foods in themselves and will not be considered as part of the EIHA submission, bringing the figure down to 1,250;*

    - *the 1,250 includes 93 products which are bound to failure because they are Full Spectrum products (not Isolate-based), reducing the figure to 1,157 (62%);*

Therefore, of the 3,224 products on the list, the EIHA application is only suitable (and was only <u>ever</u> suitable) for 1,157 of them - a 36% eligibility rate and a redundancy/ failure rate of 64%. This means that the toxicology and Dossiers costs of the eligible products have been subsidized 2 to 1 by the two-thirds of products who could never have benefitted in any way.

The first question that arises in our mind is just how much money the owners of those 2,009 products have paid to EIHA:

*(a) from the outset for the 1,292 products which were <u>**never**</u> suitable for inclusion in the EIHA application?*

(b) since the date upon which EIHA knew that the results of the isolate toxicology study required a 400% reduction in the daily ingestion level and were not as they publicly represented to the market in April 2022 (and ever since)?

It is important to stress that what follows is a theoretical assessment of the non-oil products. It is theoretical because no product other than a Hemp Oil product with a maximum 10% CBD isolate content has been applied for under the EIHA application RP 427.

*<u>IF ONE IGNORES THE "ONLY OILS NEED APPLY" LIMITATION IMPOSED BY EIHA AND SEEKS TO INCLUDE PRODUCTS OTHER THAN OILS BUT SUBSEQURNTLY APPLIES THE 17.5mg</u>** *<u>MAXIMUM DAILY INTAKE, WHAT IS THE REDUNDANCY/FAILURE RATE?</u>*

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GUMMIES

There are 689 Gummy products on the Public List, all of which are bound to failure because only oils are covered by the Dossier.

If Gummies were within the submission, then 555 of the 689 Gummy products would fail because they would not be within the safety assessment criteria because a single Gummy would exceed the 17.5mg maximum intake, with a further 4 of unquantified potency. This is an eligibility rate of only 19% (130 products) and a failure/redundancy rate of a whopping 81%.

CAPSULES

There are 293 Capsule products on the Public List, all of which are bound to failure because only oils are covered by the Dossier (notwithstanding that these capsules may contain oil-based CBD, they will inevitably metabolize differently within the body and will therefore require different toxicological and ADME assessments).

If Capsules were within the submission, then 200 of the products would fail because they would not be within the safety assessment criteria because a single Gummy would exceed the 17.5mg maximum intake, with a further 3 of unquantified potency. In addition, of those 90 products which are in principle eligible, another 10 must be removed because they are made with Full Spectrum CBD rather than isolated CBD. This creates an eligibility figure of 80 products from the original 203, an eligibility rate of only 27% and a failure/redundancy rate of a not inconsiderable 72%.

CHOCOLATE

There are 88 Chocolate products on the Public List, all of which are bound to failure because only oils are covered by the Dossier (notwithstanding that these capsules may contain oil-based CBD, they will inevitably metabolize differently within the body and will therefore require different toxicological and ADME assessments).

If Chocolate was within the submission, then 46 of the 88 Chocolate products would fail because they would not be within the safety assessment criteria because a unit of the Chocolate would exceed the 17.5mg maximum intake, with an additional 2 having an unquantified strength. This is an eligibility rate of only 45% (40 products) and a failure/redundancy rate of over half at 55%.

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OTHER EDIBLES

There are 40 Other Edible products on the Public List, all of which are bound to failure because only oils are covered by the Dossier (notwithstanding that these capsules may contain oil-based CBD, they will inevitably metabolize differently within the body and will therefore require different toxicological and ADME assessments).

If Other Edible were within the submission, then 14 of the 40 Other Edible products would fail because they would not be within the safety assessment criteria because a single unit of the Other Edible would exceed the 17.5mg maximum intake. The data provided in respect of 18 products is insufficient to ascertain the minimum delivery dosage, leaving only 8 products which are within the required 17.5mg tolerance. This is an eligibility rate of only 20% (8 products) and a failure/redundancy rate of over half, at 80% (potentially skewed because of the inadequate information).

COFFEE

There are 52 Coffee products on the Public List, all of which are bound to failure because only oils are covered by the Dossier.

If Coffee was within the submission then 1 of the 52 Coffee products would fail because it would not be within the safety assessment criteria because a unit of the Coffee would exceed the 17.5mg maximum intake. The data provided in respect of 3 products (6%) is insufficient to ascertain the minimum delivery dosage. This is an eligibility rate of 92% (48 products) and a failure/redundancy rate of only 8%.

TEA

There are 35 Tea products on the Public List, all of which are bound to failure because only oils are covered by the Dossier.

If Tea was within the submission then 28 of the Tea products would be within the safety assessment criteria of 17.5mg maximum intake. The data provided in respect of 7 products (20%) is insufficient to ascertain the minimum delivery dosage. This is an eligibility rate of 80% (28 products) and a failure/redundancy rate of zero.

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OTHER DRINKS

There are 95 Other Drink products on the Public List, all of which are bound to failure because only oils are covered by the Dossier.

If these Other Drinks were within the submission then 48 of the 95 products would fail because they would not be within the safety assessment criteria because a serving unit would exceed the 17.5mg maximum intake. The data provided in respect of 20 products (21%) is insufficient to ascertain the minimum delivery dosage. This is an eligibility rate of 28% (27 products) and a failure/redundancy rate of just over half at 51%.

BACK TO 2024 AND OUR CONCLUSIONS

The Assessment Committee could not have been clearer in its Report:

- only tinctures and liquid capsules have been applied for, and it is only those two product types which will be authorized as part of RP 427;
- in order to qualify those tinctures and liquid capsules must fulfill two additional criteria:
    - they must use Hempseed Oil as their carrier; and,
    - they must not have a strength which exceeds 10% CBD.

If you are a Brand which has products on the Public List because you are part of the EIHA application (i.e. you paid for it) and your products do not fit into these criteria, then as and when the FSA gets around to updating the Public List, then we are afraid that such products as do not fit the criteria will be removed from the List.

Historically it has been our experience that the FSA have not been overly motivated to actively manage the Public List on a Brand by Brand basis and have instead undertaken a periodic update – it makes sense in terms of its use of man hours.

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However, there are a few of factors which might engender a quicker manifestation of the "RP 427 wastage" from the List than otherwise might have been the case:

- there are large number of products affected and so it would give the appearance of significant progress;

- there is a new government in town and nothing shouts "We're making progress" than significant movement in government decisions, but this is tempered by the new kids on the block not wanting to be the wielders of bad news (NB: We appreciate that the FSA is not formally a government department, but it is in all but name); and,

- there is a new Chief Executive of the FSA on the horizon and this represents "significant progress in regulating the CBD market" (how one might expect them to position it), an early win for the incoming Chief.

What the Assessment does mean is that it is another blow for CBD Brands and, more galling for them, it is a kick in their teeth delivered by one of the very bodies which they were told (admittedly by this body itself) was meant to be leading them and they had to pay for the privilege of being kicked – perhaps EIHA's management will also try to charge them for the damage to their shoes (which the Brands paid for in the first place - along with their suits, cars, travel, accommodation etc.).

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

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