

Intoxicating Hemp and Synthetic Cannabinoids: Insights into Lab Testing



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Responses to registration and Q&A Questions.

When Things Go Wrong: Intoxicating Hemp and Synthetic Cannabinoids: Insights into Lab Testing

Registration questions:

1. Please discuss - the general lack of awareness among lawmakers about the intricacies of laboratory testing and the distinctions between natural and synthetic cannabinoids *as well as what the ISO/IEC 17025:2017 and 'passing PT' may require 4 'validation'

(Chris Hudalla) Many of the commercial products contain synthetic versions of cannabinoids that are found naturally. Because they are found in nature, these synthetics are often being marketed as natural products. For example, the THCP homolog of Delta-9-THC is found in trace amounts naturally, but not enough for commercial manufacturing. So the only way to produce this is through synthetic means. With a 7-carbon alkyl chain length, this cannot be converted from hemp-derived CBD, but rather can only be produce via pure synthetic routes. So commercially available THCP cannot even be considered semi-synthetic, nor can it be considered a hemp derivative, since it cannot be made from hemp.

It is fairly common for these products to be accompanied by a certificate of analysis (COA). However, typical testing laboratories are reporting for things they are looking for. So, if it is a Delta-8 product, they will report the Delta-concentration, but few labs will include any comment on the large number of unidentified contaminants signals that were observed during the analysis. Because these contaminants are mostly unknown in structure and toxicity, it is hard to include these on any COA. In an effort to convey this information to producers and consumers, certificates for these products that are issued from ProVerde Labs include the warning:

"In addition to compounds reported here, multiple cannabinoid isomers or byproducts, which do not occur naturally, were observed in this sample and cannot be identified. No toxicity data is available for these

unknown compounds, and as such would not be recommended for human consumption.”

Needless to say, we have few return customers for testing synthetics..... It is a similar issue with Proficiency Testing (PT) samples. Commercially available PT samples are based on pure reference standards, not real-life samples, so these samples do not contain the large number of synthetic byproducts and contaminants.

(Jeffrey Williams) Chris provided a great response to this discussion, which I agree with. As a reference standard manufacturer, we try to address the emergence of synthetic products by providing a pure reference standard for identification. It's webinar's such as this one where we have tried to outline the differences between testing for natural cannabinoids and synthetic ones, and we hope that can provide awareness to lawmakers about these issues.

- 2. ANECDOTE: While still an ER nurse, I cared for a 19 year old who ingested 1400mg D8 THC, thinking it was safely bought online. His aunt brought in the package which was rainbow tie dye and didn't even have a discernible brand name.**

(Chris Hudalla) We get a couple of calls a week with similar stories. Often times, parents will send us those products for testing, and unfortunately, we see so many contaminants in these products it is impossible to determine which contaminant caused the issue.

- 3. A few state supreme courts have refused to hear the concerns around intoxicating hemp products allowing them to remain on the shelves. What do you see as the pathway forward to intoxicating hemp products being held to the same standards as cannabis?**

(Chris Hudalla) Most producers and their lawyers have framed the issue for the courts as being about the legality of the target active ingredient, like Delta-8-THC. As a derivative of hemp, it is easy to make an argument for the legality of Delta-8-THC that was converted from CBD. Courts are often not given the information as to the true contaminated nature of these products, so are ruling based on an incomplete set of facts. Everyone would agree that unicorns should be treated humanely..... just don't bring up the fact that they don't exist.

As many states try to incorporate these synthetic compounds within their regulated cannabis programs, they will have to figure out how to have them tested for safety. Today, the standard instrumentation available at most cannabis labs cannot resolve all of the impurities, nor are there currently available reference standards for positive identification and quantitation of the contaminants.

(Jeffrey Williams) I'm somewhat optimistic that the recreational market is helping to establish methods for better testing for all cannabis derived products. There are many issues to address, but obviously we have some organizations that are setting the stage for better standard practices. Establishing these safety standards obviously isn't going to be as fast as we need them to be, but hopefully our continued efforts will have a positive impact.

4. How can we streamline testing of Hemp derived intoxicants (ignoring synthetics) to demonstrate to good actors that they can participate in regulated markets and be profitable

(Chris Hudalla) In most cases, analytical testing can distinguish between natural and synthetic cannabinoids. There are many high quality products on the market which contain natural, rather than synthetic, Delta-9-THC that was extracted and recovered from hemp. If these products are regulated, to ensure consumer safety, and inaccessibility to minors, these products could easily be included in a regulated market.

5. What is your opinion on how to address Delta 8 related issues? What should be done to reduce instances when Delta 8 is added in CBD products to increase the effects and bi-passing regulatory requirements for THC?

(Chris Hudalla) Delta-8-THC is not the problem. It is the contaminants in the Delta-8 products that are the problem. There are ways to remove the contaminants from these products, but when I discuss this with producers, they reply "why would I? Nobody makes us remove those contaminants"

It is true, that removing the contaminants would increase production costs. But these contaminants have not been studied for toxicity or long term health impacts, so it is nothing but irresponsible to continue to distribute on such a massive scale, just because producers want to maintain their healthy profit margins.

(Jeffrey Williams) Ultimately it may come down to removing the scheduling of Cannabis at the federal level and determining what type of regulatory framework for product safety can be established to protect consumers. Delta-8 and other synthetics may start to disappear from the market once that happens.

6. For each panelist: do you feel / believe / think that intoxicating cannabinoids (whether derived via synthetic conversion or otherwise) should be made available in the stream of commerce exclusively through adult use and/or medical cannabis dispensaries?

(Chris Hudalla) Today, we can find intoxicating THC beverages in our liquor and convenience store, outside of the regulated cannabis market. I would not be

opposed to this, but it still needs to include some level of regulatory oversight, which is absent today.

(Jeffrey Williams) I agree with Chris, there needs to be a regulatory element for product safety that isn't currently in place. Availability of these products should be subject to making sure the consumers can assume the known risk, not the unknown ones that are currently being overlooked.

7. How do you think policymakers should decide which cannabinoids should be allowed and which should be prohibited?

(Chris Hudalla) It would be difficult to prohibit cannabinoids which are found naturally in cannabis.

Many synthetic cannabinoids have potential as therapeutic compounds, even as potential recreational, adult-use products. I would hope that policymakers adopt strict regulations for production and distribution of these products, and include requirements to ensure consumer safety.

8. What is the biggest challenge when testing these new cannabinoids?

(Chris Hudalla) Most of the synthetic byproducts and contaminants have not been characterized for toxicity. Typical LC and GC instrumentation found in most cannabis labs may not be sufficient to resolve all of the contaminants present. More advanced instrumentation would do a better job, but is typically cost prohibitive for most labs. In addition, there are few certified reference standards available to confirm the identity and quantity of observed signals.

(Jeffrey Williams) Identifying these new cannabinoids, and their potential side-products is the most difficult in providing reference standards to testing labs. We don't see any real-world samples (hemp or cannabis). Instead, we rely on people like Chris in the testing community to alert us to the presence of new cannabinoids. Then we must determine if we can make a standard for other labs to identify and quantify them as well.

9. Do consumers need to stay away from D8? My understanding was yes but now I'm hearing that there are people creating it in a way that's safe for consumption, I'm not sure how but it's what I keep hearing. Delta is pretty much it in TX.

(Chris Hudalla) These synthetic products are a bit like Russian Roulette. There is a good chance that these will not harm you. But there is also a definitive risk factor associated with these products, so you just never know.

(Jeffrey Williams) I agree with Chris. You may find a product that is safe for consumption but it's not always clear if that product is sourcing their material from the same place for each batch.

10. How far out is this country from the first man-made cannabis related health epidemic, or, at the least, a health related class action lawsuit?

(Chris Hudalla) I certainly expect to see something down the road, maybe 5 to 10 years from now. I often hear some of these synthetic processes (like for HHC) being compared to hydrogenation of food oils, so if it is OK for food oils, then how can it be bad for these cannabinoids? Trans fats from hydrogenated oils have been in our diet for over 100 years, but it is only fairly recent that it has been identified as a health concern. The WHO estimates that diets high in trans fats contribute to more than 500,000 deaths a year from cardiovascular disease.

Class action lawsuit? I am shocked it has not happened yet. Consumers are buying contaminated products. Producers of final consumer products are buying contaminated distillates, and are unaware of the contaminated nature of their raw ingredients. Violation of label claim would be the easiest suit to bring, as very few of these products are accurately labeled. I would guess it's only a matter of time.

(Jeffrey Williams) We may already be in an epidemic. Because everyone is trying to find the profits they were promised were in this market we are starting to see riskier behavior. For example, we have seen a new product appear in Japan marketed as CB9 or CBG9. It's claimed to have a "natural five-carbon tail" has "similarities to CBD and H4CBD." The name, molecular formula and molecular weight are ambiguous, and no one has provided a possible structure to identify it. Is it new, is it safe, is it just more Delta-8, who knows? It likely isn't the last time someone will try to sell products as being new or novel but not revealing what they really are.

Webinar Q&A questions:

11. While we've been using cannabis and "hash" for thousands of years, how can we predict and be sure that isolated converted cannabinoids in high concentrations (and possible chirality difference) are not possibly causing long-term harm?

(Chris Hudalla) We can't. This type of information comes from extensive research, which takes a great deal of time and money. But these are exactly our concerns. Rarely do we hear about chirality.... There are four possible isomers of Delta-9-THC, but only one observed naturally in any significant quantity. There are over 30 isomers of THC possible, only two of which are observed naturally. Which isomers are being created during synthesis? What is the toxicity of those isomers? These are all unanswered questions....

(Jeffrey Williams) Consumers assume some risk when using any type of cannabis or products from cannabis. Long-term use of any drug, natural or synthetic also poses some risk that a consumer should be aware of. However, they shouldn't have to accept the unknown risk from products that are marketed as being safe because they are from hemp.

- 12. Isn't it true that the "post-decarboxylation" requirement under the 2018 Farm Bill and USDA rule solely applies to hemp production? There are only two statutory provisions that use the term "post-decarboxylation". The first is 7 USC § 1639p(a)(2)(A)(ii), in which Congress sets forth the criteria that states and Indian tribes must comply with in order to "have primary regulatory authority over the production of hemp" within their jurisdictions. The second statutory provision, 7 USC § 1639q(a)(2)(B), is similar in that it sets forth the criteria that the USDA shall use to "monitor and regulate [hemp] production" in states that do not have an approved hemp plan and thus do not have primary authority over hemp production within their jurisdictions. The key term is "production", which is defined in the CFR as "growing hemp". In other words, this post-decarboxylation does not apply to post-harvested hemp that has satisfied the pre-harvest test. In other words, harvested cannabis material with D9 levels that do not exceed 0.3% are lawful "hemp" under the plain language of the Farm Bill, without respect to their THCa concentrations.**

(Chris Hudalla) The assessment of hemp compliance, which includes the evaluation of post-decarboxylation Delta-9-THC, is done pre-harvest. However, the increase in total THC between pre-harvest testing and the final harvest material would only be minimal. A plant that tests compliant at 0.28% Total THC pre-harvest, might be 0.39% post-harvest, but it could not go from 0.28% pre-harvest to 32.5% post-harvest. Most of the "THCA Hemp" on the market is over 15% total THC, so could never have passed pre-harvest hemp compliance testing, with Total THC \leq 0.3%. THCA hemp is just black market marijuana.

(Jeffrey Williams) I agree with Chris, the differences pre- and post-harvest for total THC (THCA + Delta-9) shouldn't significantly increase.

- 13. There are companies that specialize in hemp derived D9 THC emulsions. Are there companies with bad reputations? Also how can I find out if they do things correctly? Or is the conversion of CBD to THC inherently dangerous?**

(Chris Hudalla) Because of marketing ambiguity, "hemp derived D9-THC" can mean one of two things; the D9-THC is synthetic, converted from hemp-derived CBD, or it is natural, recovered from hemp extracts. It is fairly easy for an analytical chemist to tell these apart, based on the fingerprint of chemical signals observed during the analysis. There are several companies that produce high

quality emulsions, beverages, and edibles from natural hemp-derived D9-THC. But from a consumer standpoint, it will be difficult to distinguish, because both products may come with a COA that looks identical, due to many labs not reporting the observed contaminants.

(Jeffrey Williams) The conversion of CBD to THC doesn't have the same testing requirements for consumer safety that Delta-9 has in states with a recreational market. Some states are trying to establish additional requirements for testing but to date there isn't a regulatory standard for product safety applying to these converted products.

14. Which federal law says that THC is calculated post-decarboxylation?

(Chris Hudalla) The 2018 Farm Bill defines hemp as cannabis not having more than 0.3% Delta-9-THC as measured by a post-decarboxylation or similarly reliable method.

15. What can be done about cases like that of Jeeter, where brands push their own testing "formulations" on labs to boost results in their favor?

(Chris Hudalla) Inflation of cannabinoid concentrations is a nationwide problem, but outside the scope of this webinar.

16. Does the Federal Analog Act provide any useful guidance in this discussion of synthetic cannabinoids?

(Chris Hudalla) It should... Many of the synthetic products in the market place today are analogs of D9-THC. One could argue that Delta-8-THC and HHC, and even THCO can be derivatives of hemp, and exempted from the CSA by the Farm Bill. But many of these other synthetic analogs, like THCB, THCH, THCP, THCjd, HHCP, cannot be made from hemp starting materials, and therefore would not be included in the Farm Bill's exemption from the CSA.

(Jeffrey Williams) We still see the DEA step in on some products. For example, THCO (THC acetate) has been designated by the DEA as still being schedule 1 under the CSA because it is synthetic and not found in the plant. It applied drug code 7370 for tetrahydrocannabinols to establish this product as still schedule 1. While we haven't heard the end result of this finding, I'm sure it will be litigated for years to come.

17. There are other "medicines" sold at gas stations that appear to have a limited market. A. What is the approx size of the delta 8 market? 2. In your opinions, what can be done to educate consumers about the inherent risks of these delta 8 products?

(Chris Hudalla) The market for synthetic cannabinoids was estimated at \$4 Billion for 2023, expected to grow to \$16 Billion by 2031.

It's hard to educate people on the hazards associated with these products. Many organizations that are focused on science as it relates to consumer safety including the FDA, CDC, USP, FOCUS, AHPA have come out with warning or position statements about these products. Most newspapers and news programs have had headline stories with fatalities or adverse events associated with these products. We can shout from the roof tops, but many people still will not listen. In my opinion, it is a simple two-step solution:

1) Deschedule marijuana

Then much of this goes away

2) Make it illegal to produce and distribute contaminated products, then enforce this.

One would think this would be obvious, but apparently not.

18. Over 40 million people have consumed delta 8.

(Chris Hudalla) Most of those consumers probably had no issue. But for the parent of the child that died from a Delta-8 product, or the person who is now in a long term care facility due to a Delta-8 vape, that number of 40 million is of little comfort.

(Jeffrey Williams) Consumption by 40 million people doesn't mean that there are not product safety issues. Chris provided a graph showing just the reported issues that arise, you must imagine there are other incidents that go unreported. The last 10-15 years we have started to make progress on establishing a regulatory space and market for recreational cannabis products. However, that progress could be stunted by the introduction of products with unknown safety issues or synthetic derivatives like those seen for synthetic cannabinoids ("spice") or opioids like fentanyl.

For further inquiries, please contact [The GMP Collective](#).