

# A Comprehensive Framework for Evaluating Cannabinoid Products

An Expert-Backed Checklist to Help Consumers and Healthcare Professionals Find High-Quality Hemp Products

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# Introduction

The hemp industry has been in a state of regulatory and legal limbo for six years now, ever since the passage of the 2018 Farm Bill. While the FDA was given the ability to regulate the industry, the agency has taken no substantial action to date and this has ultimately left the industry to "self-regulate." Unfortunately, self-regulation really means inconsistent regulation, with some companies going above and beyond to give customers high-quality products and others doing nextto-nothing while still collecting their profits. The current situation essentially leaves the consumer adrift, with little option other than to trust what companies tell them and put all their hopes into the reliability of Certificates of Analysis (COAs). If the lab reports are misleading and the companies lie, there isn't much the average consumer can do to confirm this. Simply put, self-regulation is not working.



# **Executive Summary**

The highest-quality hemp products meet the following criteria:



#### The Plant's Origin and Cultivation:

US-grown hemp, ideally cultivated organically, under natural sunlight in a good state for hemp like Colorado, California, Oregon, or Washington.



#### **Extraction:**

Using a clean extraction method and derived from flower, rich in terpenes, true fullspectrum, and ideally with no converted cannabinoids.



#### **Third-Party Lab Testing:**

Full-panel test results by batch from an ISOaccredited, reputable lab within the last year, showing accuracy in labeling, the terpene profile, free from contaminants, and consistency across batches.



#### **Quality Control:**

From a GMP-certified manufacturer in an FDA-registered facility, with a chain of custody document available, not "whitelabeled," and ideally USDA-certified organic and NSF-certified.



#### **Ingredients and Additives:**

Should list all active and inactive ingredients, without any added supplements, unlabeled cutting agents, dyes, colorings, vitamin E acetate, synthetic fragrances, or any other chemicals of concern.



#### **Packaging and Labeling:**

Packaged in a child-resistant container, with labels including an expiration date, accurate dosing instructions, batch number, health warnings, nutritional information (for edible products), and a QR code linked to the product's lab report.



### **Reputation**, **Transparency**, and **Marketing**:

The company should be transparent, provide clear information about their team, and ideally have been in business longer than three years. They should not make unapproved medical claims or market products in a way that appeals to youth.



### **Methodology:** How We Developed the Framework

To address these issues and give consumers a set of clear criteria to help them tell reliable products from unreliable ones, we have developed a set of criteria for the evaluation of cannabinoid products.

Our goal is to help consumers and the industry find and produce products that meet four key goals:



**Safety:** Have a low potential to cause harm.



**Reliability:** Offer consistent results every time.



**Efficacy:** Contribute positively to healing, or at least contain a potentially useful amount of specific cannabinoids.



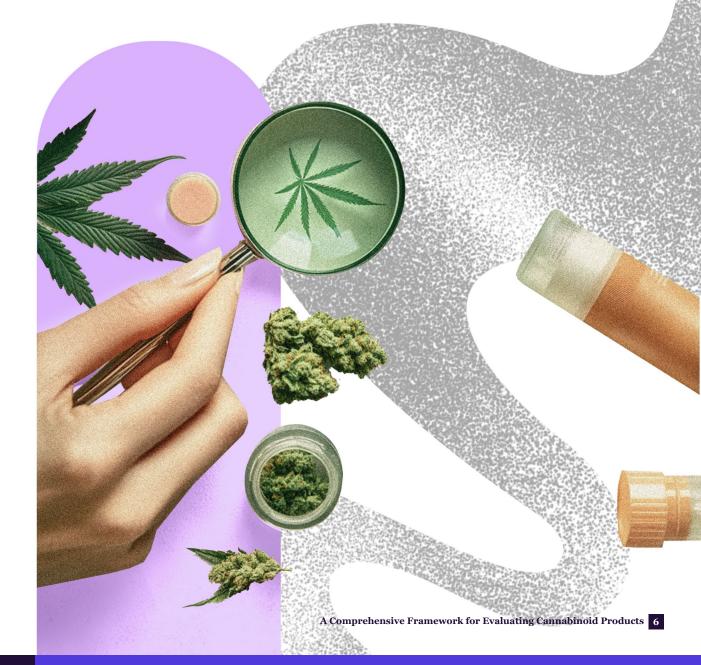
**Trust:** Made by a company that is transparent, responsible, and reputable.

We interviewed 22 experts from different fields, including industry insiders, lawyers, doctors, nurses, researchers, pharmacists, and analytical chemists, as well as the FDA and the California Department of Public Health. These interviews had a simple focus: we asked each expert how they would judge the options on the market if they were recommending products to a friend, family member, or (for doctors) a patient.

Based on their responses, along with existing frameworks (including <u>standards from the US Hemp</u> <u>Authority</u>, <u>ASTM's cannabis standards</u>, <u>FLOW Criteria</u>, <u>USP cannabis standards</u>, and <u>FDA Good</u> <u>Manufacturing Practices</u>), we established a set of criteria for evaluating cannabinoid products. In some cases, these are "bonuses," which are plus-points for the product but not requirements, but most of these are necessary for consumers to find products that are safe, effective, and reliable.



# CBD Oracle's Cannabinoid Product Evaluation Criteria





### 1. The Plant's Origin and Cultivation Method



### 1.1 The Crop Is Grown in the United States

Why? The U.S. has high standards for hemp crops and generally a great climate for hemp. While much of the world's hemp is grown in China, for instance, <u>their CBD content is lower</u> than plants grown in North America. While Canadian, French, or other nations' hemp crops are also high quality, if you're buying products in the U.S. there is no reason to source your hemp from anywhere else.

<u>Mike Sill</u>, CEO of Sunday Scaries, told us that if he was recommending a hemp product to a family member, he'd tell them, "They should make sure the cannabis is grown using organic methods and sourced preferably in the U.S.."

**How to check it:** Brands should ideally tell you where their hemp is grown on their website, but you can confirm their claims if you can get access to the right document.

Mike suggested getting a Chain of Custody document to show the origin of the hemp, and stressed that they have been to visit their farm personally:

"Yes, we've personally flown out to Greeley, Colorado to walk through the farms and meet the workers. We've also toured the facility that breaks down the raw materials into distillate and isolate. The facility we use is called KND. [...] Another document is called a Chain of Custody. This follows the record of the product's journey from seed to sale, tracking all steps in the production process."

Potential customers interested in checking the origin of the hemp can request the Chain of Custody document, or the brand should at least identify the farm that they use.

## **1.2** The Hemp Is Grown in States With Ideal Climates and Robust Hemp Programs

Why? Hemp grown in ideal climates will produce the best yield, and robust hemp programs are important to ensure that the crop and its products are high in quality.

<u>Hemp grows best</u> at a mean daily temperature of around 70 to 80 °F (21 to 26.4 °C), although

this can vary based on genotype characteristics. There is a fairly wide range of conditions where hemp can grow, and a good farmer can produce a high-quality crop outside of ideal conditions, but climate and soil still have a big role to play.



In terms of politics, the main thing is whether it's a well-regulated environment that supports hemp farmers. A <u>Hemp Industry</u> <u>Daily</u> document runs through the benefits and downsides of each state, combining geographical and political concerns. Overall, states like Colorado, Oregon, and California have the best combination of political approach and growing climate for hemp, with others like Washington having high-quality crops too.

How to check it: As above, companies should tell you where their hemp is grown, and the Chain of Custody document will have all of the information you need.

### **1.3 The Hemp Is Grown Outdoors Under Natural Sunlight**

Why? <u>Dave Baugh</u>, co-founder of R&R CBD explained the benefits of outdoor growing to us:

"We grow outdoor and keep it as natural as possible. Growing indoor is like putting your kid in daycare all day, they need sunlight and all the natural environmental factors (side note: Biosphere project). It's more efficient to grow indoor and you can grow all year but it's less environmental friendly because of all the lighting. It's like a cattle factory vs. free range pasture raised." In short, while indoor growing can certainly work, growing outdoors is more environmentally friendly and gives the plant everything it needs with minimal additional effort.

How to check it: Identifying the farm either through the Chain of Custody document or transparency from the company will tell you whether they grow outdoors or indoors, or a combination of both (e.g. starting plants indoors and moving them outdoors when they're stronger).

### **1.4 The Hemp Is Grown Using Organic Farming Methods**

Why? Organically grown hemp is the gold standard because organic farming practices generally lead to safer products than nonorganic farming. <u>Dr. Swathi Varanasi</u> explained it best:

"The product should ideally come from organically grown, non-GMO hemp to

minimize exposure to pesticides and heavy metals."

However, it's a common misconception that organic produce never contains pesticides, in fact, there are <u>pesticides approved for use in</u> <u>organic crops</u>. In many cases, organic farmers will use other techniques such as <u>companion</u>



planting and biological control agents (i.e. beneficial insects like ladybirds) to minimize pesticide use and produce a safer crop. Overall, while organic is not always synonymous with "pesticide free," it generally means fewer pesticides and a safer crop.

Passing third-party lab testing for pesticides is a requirement, but being certified organic is a highly-rated bonus for any hemp product.

How to check it: You can <u>check if a</u> <u>company is USDA organic certified directly</u>, but not all hemp grown with organic methods will be USDA certified. However, this is the only way to be completely sure that it was grown organically. The manufacturer's website should also give information about the farming methods used.

Arguably more important is to check the Certificate of Analysis (COA) for the product: if the product passes safety testing for pesticide residues, heavy metals, and other sources of risk, then the main benefits of organic farming have been met.

### 1.5 The Hemp Is Sourced From a Single Origin

Why? While this isn't a strict requirement – especially since this can be challenging for producers of ingestible products – products that use hemp from a single origin will likely have a higher-quality product at the end.

Dave Baugh from R&R CBD told us, "Many companies source from bulk distributors (who mass purchase biomass / mix strains from many different grows) or even low grade hemp (if making isolate, since most contaminants can be stripped out during refinement to isolate), which makes the biomass cheaper and more available."

Keeping it single origin makes it more likely that the extracts and products are of higher quality.

How to check it: See what information the company provides about their hemp. If there isn't enough to determine whether this is the case, the Chain of Custody document will enable you to identify the source.

## **1.6 The Product Is Extracted From a Single Strain**

Why? As above, this is a bonus rather than a strict requirement, and the reasons are basically the same. Of course, hemp products made from multiple strains can be safe and

effective for their intended purpose, but higher-quality products use a single strain from a single source.



How to check it: Check the company's website and/or product pages for information about the source of the hemp. This may be

more difficult to confirm than single-origin hemp because a single farm may plant multiple strains.

### 2. Extraction



#### 2.1 The Extract Is Made Using a Clean Method That Removes Contaminants and Preserves Beneficial Compounds

Why? The extraction method used has a huge influence on the quality and safety of the resulting product, with the best extraction methods minimizing contaminants and preserving more of the natural compounds from the hemp plant.

Dr. Bob Miller, Chief Scientific Officer at ACT Lab told us, "There are three main approaches used to extract cannabinoids, butane, CO2 and ethanol. Each of the approaches has advantages and disadvantages. CO2 is reported to be the most efficient but tends to be more expensive. Both ethanol and butane tend to [be] less expensive and somewhat less efficient however, care must be taken for both to make sure there is no residual 'solvents' remaining in the product."

Overall, CO<sub>2</sub> extraction is preferred in most cases, but other methods are viable if they're handled carefully.

How to check it: The company should tell you which extraction method is used on their website. However, the best thing to check is the COA – if there are tests for residual solvents, minor cannabinoids, and terpenes, you can confirm that the method used was adequate. The product should pass the test for solvents, and should show minor cannabinoids and terpenes (unless it is an isolate product).



### **2.2** The Cannabinoids Are Naturally Extracted, Not Chemically Converted

Why? Cannabinoids created through chemical conversions (such as all commercially available delta-8 THC and a lot of hemp delta-9) are not expected to be dangerous in and of themselves. However, the production process invariably leads to unintended byproducts, as <u>Ryan Bellone and</u> <u>Dr. Richard Sams</u>, Chief Commercial and Scientific Officers, respectively, of KCA Labs explained:

"On the other hand, if the product contains materials like HHC or Delta-8-THC that are prepared by the conversion of CBD and its homologues, I want to see evidence that testing laboratory personnel use methods that are fit for purpose for correctly testing these substances. Conversion materials contain side products of the conversion process that are not present in plant materials or plant extracts."

<u>Dr. Chris Hudalla</u>, Chief Scientific Officer at ProVerde Labs stressed the challenges of testing for these byproducts:

"The synthetic byproducts are challenging to test for, most labs do not have appropriate instrumentation or staff to test accurately. Out of the 30+ synthetic byproduct signals we see, only two of them have certified reference standards available. Most labs are part of the game, and do not report the level of contamination in these samples, either out of ignorance or out of complicity."

These byproducts are generally not well known and their toxicity is also generally unknown. However, if the products are tested by a lab that is capable of detecting common byproducts (and is willing to report it) and they meet the other criteria, then they may be relatively safe. At the very least, customers can then make their own informed decisions about the product.

**How to check it:** This is difficult to check directly. However, there are some simple rules you can follow. First off, delta-8 THC, HHC, delta-10 THC, and other less common cannabinoids can only be produced in sufficient quantities using these methods. This means any delta-8 THC product, for example, uses converted cannabinoids.

For hemp-derived delta-9, the method from <u>CBD Oracle's study of the hemp delta-9</u> <u>market</u> may be enough to determine whether it is naturally derived. Naturally extracted hemp delta-9 THC products will not contain much (or any) delta-8 THC, because it is only present in small amounts in the plant. However, the conversion process leads to "miscyclization," with some of the CBD becoming delta-8 while the rest becomes delta-9. If the amount of delta-8 THC is more than 1% of the amount of delta-9, it's likely that the product was converted.

Similarly, since natural extractions also capture other cannabinoids, you can use CBG as a sign of a natural product. Hemp delta-9 THC with CBG at more than 1% of the delta-9 THC content is likely to be naturally extracted.

Two things are worth noting. Firstly, the study includes a third sign that the source of the THC is natural hemp – a trans:cis THC ratio of less than 8:1 – but this is usually not present in COAs. Secondly, it's best to have confirmation of both of the points above if you want to be confident about the source of the THC.



#### 2.3 The Product Contains a Full-Spectrum or Broad-Spectrum of Cannabinoids

Why? Full spectrum and broad spectrum products are preferred to isolates in most cases because of the "entourage effect." This is essentially the hypothesis that the positive effects of cannabinoids are enhanced by other cannabinoids – the whole is more than just the sum of its parts.

Dr. Ethan Russo, highly influential researcher, and founder/CEO of CReDO Science, told us, "In general, broad-spectrum cannabis extracts are favored over isolates, especially those solely composed of cannabidiol (CBD). CBD is a very versatile and safe agent, but when it is the sole ingredient, it most often requires high dosages to achieve therapeutic effects, making additionally quite expensive. I like to say, "There is nothing that CBD does that will not be enhanced by at least a small amount of THC." The availability of additional cannabinoid components, especially cannabigerol (CBG) will likely enhance the efficacy and safety of a given preparation."

How to check it: You can check this using the COA for the product, provided it has adequate information about the product. In particular, a terpene analysis is vital, as Dr. Chris Hudalla explained:

"A couple of years ago, it would have been sufficient to look for minor cannabinoids in a full- or broad spectrum product. For both, there should be low levels of minors like CBC, and CBG, maybe THCV or CBDV. For full spectrum, I would expect to see additional low levels of THC.

But as most of these isolate are readily available commercially, many producers take a CBD-isolate product, and throw in small amounts of isolate minors. To really tell if it is full/broad spectrum, I would say the COA should include terpene results. Still, if it is a low concentration CBD tincture, sometimes the minor cannabinoids and terpenes will be diluted by the bulk carrier (i.e. MCT oil), below the level of detection for standard sensitivity methods.

When we have a client, whose full/broad spectrum claim is crucial for their product, we will often recommend a higher sensitivity testing approach, relative to our standard testing methods. Most labs can offer this, so even if these trace level full/broad spectrum constituents are below normal detection limits, we can still detect them with the higher sensitivity instrumentation."

In short, if the product has a COA including terpene results, you can check that there is a realistic terpene profile (more than just one terpene) and that there are low levels of minor cannabinoids like CBC, CBG and possibly THCV and CBDV.



#### 2.4 If the Product Is an Isolate, It Contains 99% or Higher of a Single Cannabinoid

Why? Despite not benefiting from the entourage effect, isolates can also be useful if you're looking for the effects of one cannabinoid (such as CBD) without any other components interfering with it.

How to check it: Check the COA for the product. If it is a true isolate, there will only be

a single cannabinoid and any terpene testing will come back blank. If the brand shows the tests of the initial isolate, you should ideally see 99% purity or higher for the cannabinoid. If a product is made using an isolate, the cannabinoid isolated should ideally be 99% of the total cannabinoid content of the finished product.

### 2.5 The Extract Is Rich in Natural Terpenes

Why? Like the above, terpenes contribute to the entourage effect and also add the realistic aroma of cannabis. Dr. Russo also covered this:

"We like to see a generous terpenoid fraction that can similarly boost benefit: betacaryophyllene for anti-inflammatory and analgesic (painkilling) effects, alpha-pinene to reduce short-term memory impairment from THC, limonene to boost mood, and linalool to reduce anxiety from THC."

How to check it: As above, a COA with terpene results is the only reliable way to check that there are terpenes present in a product.

#### 2.6 The Extract Is Flower-Derived

Why? Flower has the highest concentration of cannabinoids, so products made from hemp flower are generally higher-quality than those derived from other parts of the plant.

Megan Mbengue, founder of Trusted Canna Nurse, explained to us that this is a key part of <u>FLOW Criteria</u>, "When recommending products to patients, we often use the FLOW criteria, which means the product is FlowerDerived, Lab-tested, Organic, and Whole plant. Products that meet flow criteria are evidence-based for optimal therapeutic outcomes."

How to check it: The company should describe where their hemp comes from on their website, particularly on pages that discuss the source of the hemp and how they handle the product from the farm.



### 3. Third-Party Lab Testing



#### 3.1 Full-Panel Lab Test Results Are Publicly Available for Both Raw Materials and Finished Products

Why? Lab testing is arguably the most crucial thing to look for when you're looking for a hemp product, and "full-panel" testing means that it includes safety tests as well as potency ones. <u>Eloise Theisen</u>, CEO of Radicle Health and expert cannabis nurse practitioner, explained to us that, "To find the best product, I start with a Certificate of Analysis (COA) which will show me test results for potency, cannabinoid content, terpene profile, pesticides, fungus, molds, and residual solvents for each batch."

Testing both the raw material and finished product is a good idea because there may be issues which only appear in the finished product. Dr. Chris Hudalla from ProVerde labs told us a story about just this issue:

"We have had clients make the highest quality tincture, then flavor it with orange flavor, bottle it and have it tested, only to find out it is contaminated with pesticides. Under investigation, we found that the orange flavoring they added (which they had not considered) was contaminated with pesticides. This is not uncommon. So they were left with hundreds of bottles of packaged tincture that they could not use."

Many brands won't share their raw material tests, but if they do, it's a bonus and a sure sign of a transparent company.

How to check it: COAs should be publicly available on the company's website, ideally linked to from each product page. Check these lab reports to see that there are tests for mycotoxins, microbials, heavy metals, residual solvents and pesticides, as well as the much more common tests for potency and cannabinoids. If these are difficult to access or the lab testing doesn't include safety tests, you shouldn't buy the product.

### **3.2 The Product Is Tested by an ISO/IEC 17025** Accredited Lab With a Credible Reputation

Why? Unfortunately, despite many good and reliable labs out there, there is a big problem with dishonesty in the space and a strong pressure to ignore potential issues for a product. <u>ISO/IEC 17025 accreditation</u> shows

that the lab is technically competent enough to perform the required analysis, and this is sufficiently important that was mentioned specifically by six of the experts we interviewed.



For example, KCA Labs' Ryan Bellone and Dr. Richard Sams commented, "I want the product to have a certificate of analysis from an ISO/IEC 17025 accredited laboratory with a reputation for excellence and commitment to high-quality testing."

And <u>Cynthia Cabrera</u>, Director of the Hemp Industries Association and Chief Strategy Officer at Hometown Hero, recommended that customers, "Look for companies that adhere to high standards in labeling, age restrictions and child-resistant packaging. Certifications such as ISO 17025 for testing labs or USDA organic certification can be strong indicators of a company's commitment to safety and quality."

Accreditation is crucial, but unfortunately not the whole picture. Cannabis testing labs have been <u>involved in a "THC inflation" crisis for</u> <u>many years</u> – where they systematically overreport THC content – and for hemp there is something of a culture of silence around unknown byproducts in converted cannabinoid products, as Dr. Hudalla explained:

"Most labs are part of the game, and do not report the level of contamination in these samples, either out of ignorance or out of complicity. If you report the contaminants, you lose that business... you get kicked out of the game." And unfortunately, there are likely many more similar issues we are not even aware of.

How to check it: Checking accreditation is easy enough. Go to the website of the lab (KCA Labs for example) and either look for an "About" page or something specifically about accreditation. On KCA's website, a link in the bottom right of the page takes you directly to their ISO/IEC 17025 accreditation certificate. You can also confirm this by going to the website of the accreditation body, for example, <u>Perry Johnson Laboratory</u> <u>Accreditation</u>. If you cannot find this certificate, then you should assume the lab is not accredited.

Having a "credible reputation" is more subjective and difficult to establish. However, there are some general steps you can take. Does the lab have a social media presence? How long have they been operating? Can you find external customer reviews on third-party platforms such as TrustPilot, the Better Business Bureau, Yelp, or Glassdoor? More reputable labs will have a social media presence, will have been in business for a longer period of time, and will be reviewed positively on third-party platforms.

Additionally, it is worth searching the lab's name specifically to see if they've been involved in any controversies. For example, if they're named in a suit about lab fraud, even if it hasn't been ruled on, this is certainly not a good sign.

## **3.3 A Certificate of Analysis Is Provided for Each Batch, Lot, and Product Variation**

Why? A COA is only useful if it actually corresponds to the product you're buying. As Dr. Hudalla's story about orange flavoring shows, even if the products use the same base extract, flavorings can change the results substantially. Additionally, there can be variation from batch to batch even if the specific product is exactly the same.



Dr. Adie Rae (Wilson-Poe), assistant scientist at Legacy Research Institute, was one of many experts to specifically mention testing by batch, "For cannabinoid products that are available online, I would only recommend cannabidiol (CBD), and only if the company proudly provides lab testing results for every single batch of their products. Lab tests should include not only the potency of CBD, but test for the presence of other cannabinoids like delta-9-THC, pesticides, and other toxins like residual solvents."

<u>Kelly Lombard</u>, Founder of Forge Hemp, also pointed out the risks of not having results for

the specific batch you're buying, "Another issue is bait-and-switch testing, where the test is performed on a sample that will meet specifications, but that's not what goes into mass production."

How to check it: This should all be available on the website of the company you're buying from. <u>Hometown Hero's lab results page</u> is a great example of what to look for. There are lab results for all of the products they carry and each test is coupled with a lot number, so you can check a report for the exact lot you're buying from.

# **3.4 Potency Test Results Are Within 10% of the Advertised Level, or 20% for Low-Dose Products**

Why? Inaccurate labeling is a very common problem in both the hemp and cannabis industries. This has been shown in studies of hemp (for example <u>here</u> and <u>here</u>) and cannabis (<u>here</u> and <u>here</u>).

For medical users, accuracy in labeling could be the difference between an effective and an ineffective dose. For recreational users, it could be the difference between a pleasant, manageable high or an uncomfortable, anxiety-inducing experience. Experts such as Dr. Swathi Varanasi mentioned this as one of her safety concerns with hemp products:

"Products often lack detailed labeling and sometimes misrepresent the concentration of cannabinoids which can be ineffective or potentially harmful." From a consumer perspective, users need accurate information to enable them to dose correctly and safely.

From a business perspective, it is also unwise to overlook the importance of accurate labels. <u>Shawn Hauser</u>, partner at Vicente, recommended that to comply with consumer protection regulations, companies should, "[Maintain] a strong testing program with a reputable testing lab to ensure the label accurately indicates the product contents and that the product is safe and free of contaminants or harmful byproducts."

Cannabis and hemp attorney <u>Rod Kight</u> explained:

"The days of off the cuff labeling in the hemp industry are over. In addition to federal



labeling requirements (i.e. for foods, dietary supplements, or cosmetics), many states have specific labeling regulations for hemp products. Unfortunately, this is currently a patchwork and it can be a challenge to stay on top of all of these regulations. It's important for a company to discuss its labeling plans with an attorney and to have an attorney review the labels."

It may be simple, but it is very important for both the well-being of customers and cannabis-based businesses overall that labels are an accurate reflection of the product.

How to check it: Companies should provide batch-specific COAs to make it possible to check the label claim against the product itself.

The criteria for "accurate" is ultimately a subjective decision, but in research (such as

the papers cited above) and in state regulations (for example <u>in California</u>), within 10% is a common benchmark. This isn't always appropriate for low-dose products (e.g. for a 5 mg product it would be between 4.5 and 5.5 mg), but 20% is also a commonly used standard which is more appropriate in these cases.

To get the figure, subtract the amount of the cannabinoid (e.g. CBD) in the COA from the amount advertised, and then divide the result by the advertised amount. Multiply by 100 to give the percentage.

For example: if we have 10 mg (label) vs. 8 mg (COA). The difference is 10 mg - 8 mg = 2 mg. This is a proportion of 2 mg / 10 mg = 0.2 of the original amount. This means the product is 0.2 × 100% = 20% away from the label value.

### **3.5 Lab Results Are Consistent Across All Batches**

Why? Dave Baugh, co-founder of R&R CBD, stressed the importance of batch testing and batch-to-batch consistency when he outlined what to look for in a lab test:

"Is it full-panel? [...] Is it tested by an ISOaccredited and credible lab with a good reputation? Do the results meet the industry requirements in their state? Is there a result for the 'mother' extract as well as the finished product? Is there a test for each batch? Are the results consistent across all batches?" Having consistent results across batches is a positive sign that the manufacturing processes are robust and reliable. While having any batch-to-batch testing enables consumers to know exactly what they'll be getting if they make a purchase, consistent results across this testing is the gold standard. Of course, there may be reformulations that result in substantial changes, but each test result after this reformulation should remain consistent.



How to check it: Any company with COAs per batch will have the results for at least a few batches available. Consistency can be checked by comparing the results across the most recent tests. The main thing to look for is the accuracy of the label claim, but of course any safety tests should also consistently come back clean. Small amounts of variation are expected for any naturally extracted product, but each result should remain within 10% of the label claim (or 20% for low-dose products).

#### **3.6 Lab Results Confirm the Product Is Free From Contaminants and Residual Solvents**

Why? It goes without saying that residual solvents, heavy metals, and other contaminants make a product more dangerous. This is why all hemp products should be safety tested, at the basic level. However, all testing is only conducted up to a certain sensitivity, and there are always cut-off levels, below which a product is considered to have "failed." If a product is under these standard cut-offs, there are no real safety concerns, as Dr. Chris Hudalla from ProVerde Labs explained:

"When results are reported against some safety limits, those limits most frequently used are USP limits. The USP limits are established for drug products, most often administered through oral or inhalation pathways. The limits are established with consideration of children to geriatrics, with the most frail or compromised health conditions, and consider the quantity of product that may be consumed in the worst cases, with regular and repeated dosing over time. If these limits are used for assessing safety of cannabis products, I think they are already taking into account the worst possible level of contamination, with the highest possible dosing regimen, relative to the toxicity concern for that particular contaminant."

Further adding that in cases where there is no established safety limit for a contaminant, "In that case, I would like to see the industry defer to either FDA or ICH guidelines for the limits on contaminants, which can be between 0.05 and 0.1%. Maybe even permit a 2x multiplier on that, establishing a limit of 0.1 to 0.2% for unknown impurities."

How to check it: The product's COA should include safety tests for residual solvents, pesticides, heavy metals, mycotoxins, and bacterial contaminants ("full panel" testing). You can easily see whether or not the product is graded as a "pass" on these.

In almost all cases, the detection limits and allowable limits used by labs will only grant a "pass" to products where any contaminants are well within safety limits. Most of the time, this is all you will have to check, particularly if you've followed the above advice about choosing an accredited and reputable lab.

However, it is possible (although not especially likely) that some labs will have not chosen an appropriate cutoff level for these contaminants. United States Pharmacopeia (USP) limits are the best guideline for what is an appropriate cutoff, for example, these documents describe <u>heavy metal</u>, <u>pesticide</u> (Table 4, p11), and <u>residual solvent</u> levels. <u>This</u> <u>article</u> published in the Journal of Natural Products (including Doctors Hudalla and Russo, among others, as authors) collects all of the information together and is explicitly focused on cannabis.

Generally speaking (and not exhaustively), the paper sets limits of:

- 0.01 parts per million (ppm) for hightoxicity pesticides
- 0.1 ppm for lower-toxicity pesticides
- Arsenic: 0.2 μg/g (equivalent to ppm)
- Cadmium: 0.2 µg/g
- Lead: 0.5 μg/g
- Mercury:  $0.1 \, \mu g/g$

- The total aerobic bacterial count:  $10^5$  cfu/g, or  $10^2$  cfu/g for inhalable
- The total combined molds and yeast count:  $10^4$  cfu/g, or  $10^1$  cfu/g for inhalable
- The total bile-tolerant Gram-negative bacteria: NMT 10<sup>3</sup> cfu/g
- Total of aflatoxins B1, B2, G1, and G2 combined: not more than 20 parts per billion (ppb)
- Aflatoxin B1: not more than 5 ppb

Noting that 10<sup>1</sup> cfu corresponds to a maximum acceptable count of 20, 10<sup>2</sup> cfu corresponds to 200, 10<sup>3</sup> cfu to 2,000, and so on (the superscript tells you the number of zeros).

#### 3.7 The Lab Results Confirm Multiple Cannabinoids and Terpenes If the Product Claims to Be Full-Spectrum or Broad-Spectrum

Why? Full-spectrum or broad-spectrum products are so called because they contain the "full spectrum" of cannabinoids and terpenes from the plant, with "broad spectrum" just omitting THC. This is desirable because of the entourage effect, but it is possible to fake this, as Dave Baugh, cofounder of R&R CBD, explained to us:

"We know some other companies out there use CBD isolate, then pepper in some other isolates like CBN/CBG, but this is not the same thing as a true whole-plant full spectrum extract - that omits many of the flavonoids, terpenes, antioxidants, and other phytonutrients that we include that many others don't."



How to check it: Checking this used to be simpler, as Dr. Hudalla explained to us:

"A couple of years ago, it would have been sufficient to look for minor cannabinoids in a full- or broad spectrum product. For both, there should be low levels of minors like CBC, and CBG, maybe THCV or CBDV. For full spectrum, I would expect to see additional low levels of THC."

However, Dr. Hudalla echoed Dave Baugh's comment about producers combining specific cannabinoid isolates to mimic a full-spectrum or broad-spectrum product. So to be sure, he suggests:

"To really tell if it is full/broad spectrum, I would say the COA should include terpene results. Still, if it is a low concentration CBD tincture, sometimes the minor cannabinoids and terpenes will be diluted by the bulk carrier (i.e. MCT oil), below the level of detection for standard sensitivity methods. When we have a client, whose full/broad spectrum claim is crucial for their product, we will often recommend a higher sensitivity testing approach, relative to our standard testing methods."

In summary, to check that a product is truly full spectrum, you should check the COA for the presence of minor cannabinoids (CBC and CBG, for example), and for a spectrum of terpenes (with the top 4 terpenes generally making up about 70% of the total). If the COA does not include terpene results, you cannot be sure it is truly full or broad spectrum.

It is possible that a genuinely full or broad spectrum product will not show terpene or minor cannabinoid results (as Dr. Hudalla said), but unfortunately in these cases, it cannot be confirmed by a third party. Manufacturers in this situation should consider higher-sensitivity testing.

### **3.8** The Lab Result Includes the Terpene Profile of the Product

Why? Terpenes impact the effects of hemp and cannabis, so having terpene results helps ensure customers are fully informed. However, the most important reason this should be included is if the product claims to be full or broad spectrum. As detailed above, this is required to reliably evaluate this claim. How to check it: Check the COA. Terpene results are a common element of testing, and many COAs will explicitly say whether or not they were tested. If you can't find it, assume it has not been tested.

### 3.9 The Lab Report Is Less Than 12 Months Old

Why? Each batch of a product should be lab tested, and most companies will make a new batch of each product much more frequently than each year. Jan Brandrup, CEO of Neurogan, told us:

"Make sure the lab report is no more than 12 months old—ideally, between 3 to 12 months. If the lab report is older than a year, it's a major red flag."

While it is certainly true that hemp products generally have a shelf life of over a year, this is only the case if they have been stored in ideal conditions. It is possible that older COAs are still broadly descriptive of the product, but crucially, customers have no way of knowing whether products have been stored in ideal conditions. Therefore, a COA from over a year ago is a warning sign – a red flag, as Jan Brandrup put it – and it's better to choose another product.

Additionally, even when stored in ideal conditions, the levels of cannabinoids do change within a year. In <u>one study</u>, CBD levels decreased by 10 to 11%, THC levels decreased by 22% and CBN levels increased by 222 to 244% after one year, stored in darkness at refrigerator temperature (4°C / 39.2 °F).

How to check it: All COAs state the date the test was performed. Simply identify the date and confirm it was within the past year.

### **3.10** The Lab Report Includes a QR Code for Easy Verification of Results

Why? Fake lab reports are unfortunately common in the hemp industry. CBD Oracle's investigations of <u>delta-8 THC products</u> and <u>THCA flower</u> have identified faked COAs, and interviews with lab employees for these and other investigations have also touched on this as an issue. ProVerde labs' Dr. Hudalla mentioned it specifically when we spoke to him for this project:

"Unfortunately, the consumer has to be their own advocate. The consumer has to verify any lab results that they are given with a product. We put QR codes on every COA so consumers can verify the authenticity of those results. We had to do that because we had so many fraudulent COAs circulating with our name on them."

It's difficult to know how likely this is – since many fakes are likely not caught – but it happens often enough that consumers should always be on guard for this. A QR code leading to the same report on the lab's website is the simplest and most effective way to guard against this.

How to check it: Check the lab report for a QR code, and if it has one, scan it. Compare the two reports closely, because it's possible that minor edits were made which are not immediately obvious.



#### 3.11 The Lab Report Includes a Chromatogram to Confirm Accurate Product Analysis

Why? This criterion is not a requirement, since most people couldn't read a chromatogram even if they wanted to, but it is a valuable bonus for those who can. Dr. Richard Sams and Ryan Bellone from KCA Labs commented to us:

"I want to see a certificate of analysis that includes a chromatogram from the analysis of the cannabinoids. I want to review the chromatogram for evidence of appropriate product analysis. Finally, I want to see a certificate of analysis that is easy to read and interpret."

As they said, the chromatogram can be used to verify that the analysis was likely performed properly. Broadly speaking, chromatograms show a series of peaks for each compound detected, with the size of the peak corresponding to the concentration of the compound (<u>simple explanation here</u>). In the case of delta-8 THC products, for example, <u>coeluting signals</u> (peaks that appear very close to one another) are often ignored by the labs and reported as a single compound, but this may be noticeable from the chromatograph.

Even if you can't read them, though, the presence of a chromatograph on a lab report is a sign of transparency from the lab which is generally a very good sign.

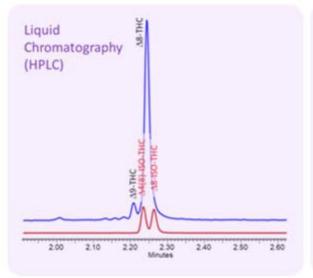
How to check it: You will be able to see the graph on the COA if it is presented. This doesn't appear to be especially common, though.

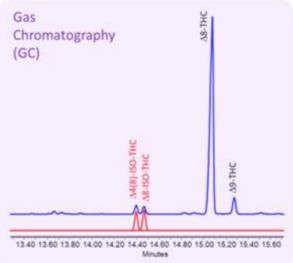
### 3.12 Lab Testing for Converted Cannabinoids Distinguishes Between Delta-8 THC and Common Byproducts

Why? Widely used high-performance liquid chromatography (HPLC) methods are not ideal for distinguishing between delta-8 THC

and iso-THCs, because of co-eluting signals (as mentioned above).







Dr. Richard Sams and Ryan Bellone explained:

"If the product contains materials like HHC or Delta-8-THC that are prepared by the conversion of CBD and its homologues, I want to see evidence that testing laboratory personnel use methods that are fit for purpose for correctly testing these substances. Conversion materials contain side products of the conversion process that are not present in plant materials or plant extracts. Therefore, test procedures that are used for plant materials may not be and often are not appropriate to determine cannabinoids, conversion materials, and side products in these consumer products. I want to see evidence that the laboratory knows the additional challenges of testing these materials."

Generally speaking, high-performance liquid chromatography (HPLC) <u>has trouble</u> <u>differentiating</u> between iso-THC and delta-8 THC, while gas chromatography is more effective. If the lab is aware of the issue they can likely perform tests that can distinguish between the two, as the comment from KCA Labs suggests. How to check it: This is more challenging to check, since most labs use HPLC-UV for their standard potency panels. However, checking the website of the lab for information about their testing methods is the best first step. For instance, on <u>KCA Labs' testing page</u>, under "Cannabinoids by GC-MS/MS," they explicitly list that they can test for iso-THC.

If there is no helpful information on the website, contacting them directly about this issue is the best way to determine whether they can detect common byproducts.



### 4. Quality Control



### 4.1 The Hemp Is USDA-Certified Organic

Why? USDA certification is the easiest way for consumers to verify that any hemp has been grown organically. While non-organic hemp can also be high-quality, and non-USDA organic certified hemp can also be grown using organic methods, certification remains the most convenient and easily verifiable way to confirm this to consumers.

This was mentioned by many of the experts we spoke to, including worldwide cannabis coach <u>Dr. Abraham Benavides</u>, who said, "I'd be further reassured by a domestic brand that achieves distinctions like being USDAcertified organic, good agriculture and manufacturing processes (e.g., GAP and GMP, and the current versions), or cannabis safety and quality (CSQ) certification."

How to check it: This can be checked most easily using the <u>USDA Organic Integrity</u> <u>database</u> – if a company is on there, they're certified organic.

However, it's important to note that it's possible to be USDA-certified without being in the publicly accessible USDA database. In these cases, you can contact the company directly to find out. CBD Oracle will be doing this over time and will maintain an additional list customers can check.

### 4.2 The Manufacturer Is Certified for Good Manufacturing Practices (GMP)

Why? Good Manufacturing Practices certification was mentioned specifically by eight of the experts we spoke to, including the <u>California Department of Public Health</u> (CDPH), who simply stated:

"Manufacturers of industrial hemp food products must follow all applicable California statutes as well as the current federal good manufacturing practices for food and dietary supplements."

Jan Brandrup of Neurogan also offered very

similar advice to other brands:

"As for standards in the industry, certifications like cGMP, AB45/CDPH certification, and FDA Facility Registration are essential, along with up-to-date training in areas such as foreign supply verification, HACCP, and others. These certifications need to be renewed regularly-usually every year or two-so make sure everything is current. Spend the time to do your research; it will help you avoid disappointment."



<u>Good manufacturing practices</u> are just what they sound like – sensible practices that ensure that manufacturers produce highquality and safe products. For example, they include personal hygiene and facility sanitation, and process controls for things like cooking foods. Having a cGMP-certified facility is an assurance that the product has been made with precision and with safety in mind. How to check it: Check the company's website to see if they are GMP certified. For external confirmation, you can search the FDA Firm Database for the company, or look for GMP inspections on the Inspections dashboard.

### **4.3 The Product Is Made in an FDA-Registered** Facility

Why? This goes hand-in-hand with cGMP certification. For example, Shawn Hauser, partner at Vicente, mentioned this specifically:

"I also review a company's website to confirm they are cGMP compliant, use safe ingredients, clear testing results, are registered with the FDA, have professional marketing, and have a qualified team."

How to check it: As above, checking the company's website or the <u>FDA Firm Database</u> is the best way to check this.

## 4.4 The Product Has NSF Certification, If Applicable

Why? NSF certification for hemp products can take a few different forms, but most notably they have a GMP certification equivalent and NSF Certified for Sport. NSF Certified for Sport can be particularly useful in some cases because CBD products with small quantities of THC can cause you to fail a drug test, particularly if you use them every day. This certification basically sets strict limits on THC and checks that the product is free from over 280 banned substances in sports.

If a company already has cGMP certification

and you are not participating in sports where you may be drug tested, NSF certification is not necessary for a hemp product.

How to check it: This can be <u>checked on the</u> <u>NSF website</u>, either by searching for the company specifically or by identifying the appropriate certification guideline (e.g. NSF Certification Guideline 306 for sport certification, under "Nutritional Products"). Companies will also list NSF Certification on their website, but it is best to confirm elsewhere if possible.



## **4.5** The Company Can Provide a Chain of Custody Document for the Hemp

Why? As mentioned in section 1.1, the Chain of Custody document traces the hemp plant, as Sunday Scaries' Mike Sill explained:

"Another document is called a Chain of Custody. This follows the record of the product's journey from seed to sale, tracking all steps in the production process."

This provides crucial accountability - you

know exactly where the hemp came from and where it went from seed to sale. This is required as part of many states' hemp programs (for example <u>New York</u>, <u>Colorado</u>, and <u>Missouri</u>).

How to check it: This document is generally not made freely available but can be requested directly from manufacturers.

### 4.6 The Company Oversees the Entire Production Process (Seed-to-Sale) and Is Not a White-Label Brand

Why? "White label" brands are basically those that don't make the product themselves, instead buying it from another company (for example) and simply adding their own branding to the result. While there is nothing intrinsically wrong with white-labeling, if you're looking for quality hemp products, there is no reason to buy from a brand that can't personally vouch for the manufacturing quality.

Dave Baugh from R&R CBD commented:

"Is it white label or do they actually control the entire process? Most companies white label. In 2019, there were 10,000 hemp brands; a lot of get rich quick schemes. Now it's been consolidated down to about a 1,000. If you don't own the farm and can't touch the plant, how do you know what's going on? I avoid white label. It's like Whole Foods vs. Kroger. There's no way to really verify if a company is white label vs. owned; if you ask specific questions you'll be able to know how much they actually understand about the process."

**How to check it:** This is very difficult to verify, but a Chain of Custody document would make it possible to check. Otherwise, as Dave suggested, asking specific questions about the product – for example, is it flowerderived? What were the growing conditions? – is a good way to determine if the brand understands the manufacturing process.



### **5. Ingredients and Additives**

5.1 The Product Is Made With Clean Ingredients and Contains No Harmful Additives or Synthetic Compounds

Why? Ideally, hemp products shouldn't contain any ingredients that expose users to unnecessary risks. For example, vitamin E acetate was <u>likely the main cause</u> of the <u>EVALI</u> <u>outbreak of 2019</u>. Likewise, synthetic cannabinoids (i.e. compounds in "spice" or "K2") are associated with a <u>wide range of negative health effects</u>.

Here is a list of harmful (and/or totally unnecessary) ingredients that must be avoided:

- Vitamin E acetate
- Synthetic cannabinoids
- Synthetic terpenes
- Synthetic fragrance
- PEGs
- Dyes or artificial coloring

These compounds are potentially harmful (and/or not strictly needed) and should be avoided if possible:

- High amounts of cane sugar
- High fructose corn syrup
- Mineral oil

- Seed oils
- Sulfates
- Parabens
- Silicones

Dr. Swathi Varanasi commented to us that additives were one of her main safety concerns about products available on the market today:

"Products often have unnecessary additives, artificial colors, or flavorings, which can potentially cause adverse reactions."

A key part of this quote is the word "unnecessary." The goal isn't to remove all risks from products – this is generally not realistic – but to limit them where possible and to not increase risks by adding an ingredient unless it is absolutely needed.

How to check it: Unfortunately, many of these components are not included in typical COAs. While they will often mention vitamin E acetate as a result of EVALI, for other components, the only way to check is to look at the ingredients listed by the company. This leaves open the possibility of undeclared ingredients (covered below), but unfortunately, there is no other way to know what has been added.



#### **5.2 The Product Avoids Unregulated Supplements Like Melatonin or Valerian Root**

Why? As in the previous point, there is an element of unnecessary risk here. Adding a component that is not strictly needed opens another avenue for potential risk. However, a more important reason was expressed by many of the medical professionals we spoke to.

This was best summarized by Dr. Abraham Benavides, who said:

"Beyond that, when you venture into the world of combining cannabinoids with nutraceuticals - it becomes more difficult for us to keep track of what is actually working for you, and you tend to lose control over the dosing. If you keep the products separate, you can try one thing at a time to see if it works for you and at what doses."

He also importantly pointed out that these components also make products more likely to interfere with any prescription drugs you might be taking.

**How to check it:** Again, these are unfortunately less likely to be listed on a COA, so you should look at the ingredients listing for the product. In these cases, since they're "active" ingredients, they are likely to be listed – if anything, outwardly advertised – by the manufacturer.

#### 5.3 Vape Products Are Free From Unlabeled Cutting Agents and Heavy Metals, and Use a Base of Propylene Glycol and/or Vegetable Glycerin

Why? Aside from smoking, vape pens are likely the highest-risk way to consume hemp. This is simply because they involve inhalation, and thus open your lungs up to potential dangers. Vitamin E acetate was likely the cause of the <u>EVALI outbreak of 2019</u>, and it should go without saying that it is a dangerous component.

However, there are risks to inhaling other ingredients too. Generally speaking, inhaling oils and fats may cause lipoid pneumonia and other lung issues. This has been <u>observed as a</u> <u>result of "oil pulling"</u> (swishing edible oil around in your mouth before spitting it out) and was <u>identified as an issue with nasogastric</u> <u>lipid feedings</u>.

Most MCT oil is coconut oil, and this has been implicated in lipoid pneumonia cases in the past. One study compared the effects of CBD dissolved in MCT oil with a more traditional nicotine vape and noted:



"The presence of lipid laden intra-alveolar macrophages observed in cells recovered from the BAL of mice after CBD aerosol-inhalation in our study corroborates with a previous report that showed the onset of exogenous lipoid pneumonia in a patient who vaped cannabis oils and had lipid laden lung macrophages. As exogenous lipoid pneumonia with lipid-laden lung macrophages is a hallmark of EVALI, it thus suggests that inhalation of CBD vape oil might not be riskfree and could lead to lung injury in cannabis vapers."

Unfortunately, lipoid pneumonia <u>has been</u> <u>observed in people vaping pure cannabis oil</u> <u>too</u>. There have been many cases of this (<u>here</u>, <u>here</u>, <u>here</u>, and <u>here</u>), and the authors from the first citation commented:

"As two out of our three cases that underwent bronchoalveolar lavage (BAL) revealed lipidladen macrophages, this may suggest that this injury is a form of lipoid-pneumonia from aerosolized cannabinoid oils."

Ultimately, the risk appears to come with the vaping of oils in general, and this has largely been ignored by the industry to date, with some suggestions that cannabis oil is safe to vape supported by apparently no evidence.

On the contrary, the liquid ingredients used in nicotine vaping, vegetable glycerin/VG (aka glycerol), and propylene glycol/PG, are not lipids. In general, these are likely safer to inhale than cannabis oils or MCT oil.

There have been cases of lipoid pneumonia which <u>were suspected to relate to VG</u>, with the authors pointing out the possibility that the lipids were endogenously released (i.e. from the body) as a result of VG inhalation rather than directly inhaled from an external source. However, they note that, "The homogeneous distribution in this case means that the lipid has been inhaled as a vapour," and so it was likely not endogenous. In these cases, there are other possibilities. While VG is not a lipid, it is derived from lipids (including from coconut oil), and so low-quality VG may still contain lipids. Additionally, it's possible that flavoring agents in the vape liquid were oil-based (the authors did not check this). In any case, it does not appear that VG in and of itself is a substantial cause of lipoid pneumonia.

However, with this possibility in mind, PGbased vapes are likely the safest option, with VG adding a small amount of risk but likely still not much if it is high quality. The fact that nicotine vaping with VG is <u>very common</u> <u>around the world</u> and there are not many potential cases adds weight to this conclusion.

MCT oil, vitamin E acetate, and unspecified "cannabis oil" should generally be avoided. Dry herb vaping is likely a much safer solution than any liquid-based vaping.

How to check it: Check the manufacturer's website to see what their vaping products contain. Vaping liquids and pens should have no unlabeled cutting agents such as acetates (especially vitamin E acetate), MCT, olivetol, triethyl citrate, or any heavy metals leached from hardware. Ideally, they use a base of propylene glycol and/or vegetable glycerin.

Keep in mind that vape pens that claim to just contain CBD and terpenes, for instance, will either be suspended in an oil or PG or VG. Check the COA for the product to see if it was tested for vitamin E acetate and heavy metals.



### 6. Packaging and Labeling

## 6

### 6.1 The Product Is Packaged in a Child-Resistant Container

Why? Accidental consumption of hemp products can be dangerous to children. Poison control center calls related to CBD <u>increased</u> <u>after the Farm Bill was passed</u>, and CBD isn't even particularly risky – delta-8 THC exposures <u>are also a major concern</u> for poison control.

While child-resistant packaging <u>is not a</u> <u>guarantee of safety</u> – it just means it's significantly difficult to open for children aged under 5 – it is a vital last line of defense against disaster.

Dr. Adie Rae (Wilson-Poe) was clear about this requirement:

"'Quality' products are always lab tested, always accurately labeled, always have suggested serving sizes, always come in childproof packaging, and are age-restricted to adults 21 and over."

There is a competing concern here that's worth mentioning: child-resistant packaging is also more difficult for seniors to open and <u>this remains an issue</u> even after initial attempts to strike a balance. However, if we consider other consumer products, like bleach or prescription medications, it's obvious that this difficulty does not justify removing child protection on all products.

Unfortunately, some seniors will need assistance with child-resistant hemp products, just as they may need assistance opening prescription medication. There are potential solutions for this, such as having someone transfer the product to an easier package to open after it is purchased, provided the individual does not have children around in their home.

How to check it: The manufacturer or seller should list that they use child-resistant packaging on the product page. If it is not there, it should be mentioned elsewhere on the website, for example in the FAQs.



#### 6.2 The Label Includes a QR Code to Verify Lab Results

Why? All products should be lab tested by batch, and as well as listing this on the product page, a QR code on the product itself makes it easy for customers to check the COA.

This is required by law in some places, as the California Department of Public Health told us:

"Additionally, California law provides that industrial hemp food products sold at retail must include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the product."

Many manufacturers we spoke to mentioned this specifically too, including Hometown

Hero, Bloom Hemp, and +PlusCBD. <u>Jesse</u> <u>Karagianes</u> from +PlusCBD said:

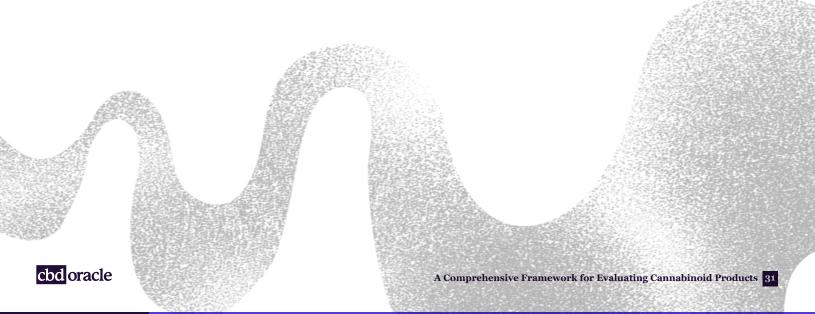
"Customers can scan the QR code on the labels to check the reports themselves even before buying the products at the store. By choosing brands with clear ingredient lists, transparent practices, and positive consumer reviews, buyers can avoid products from companies that cut corners."

**How to check it:** This should be visible on the product packaging. In many cases, images of the product on the company's website will show the QR code on the packaging.

## **6.3** The Label Displays the Packaging and Expiration Date

Why? Customers need some indication of whether a product can be safely consumed on the current date. This is required on all perishable products.

How to check it: This should be clearly visible on the product packaging.



### **6.4 The Label Provides Accurate Dosing Instructions**

Why? If there is no clear listing of how much of a product to take, it may not be clear to all consumers what an effective dose is. In the case of CBD or another non-intoxicating cannabinoid, a lack of accurate dosing information could reduce any positive medical effects the customer was looking for, possibly making it totally ineffective. For THC and intoxicating cannabinoids, a lack of dosing could lead to an overwhelming experience, or feeling no effects at all.

Additionally, from a more practical standpoint, the lack of accurate dosing has been mentioned by the FDA in many warning letters related to hemp (examples <u>here</u> and <u>here</u>). This is generally because the product has (unwittingly) made itself an "unapproved new drug" in the eyes of the agency, but that is not relevant for our purposes. Even if a product makes no medical claims, CBD sellers

(for example) know full well that people are using their products for medical issues, and so it is morally imperative to provide accurate dosing information for those people.

Shawn Hauser, partner at Vicente, also stressed the importance of clear serving sizes on labels, "To evaluate quality and effectiveness, I look for companies who have clear, truthful labels that do not make unsubstantiated claims and have compliant labels (consistent with food and dietary supplement regulation) that clearly indicate the product's serving size, cannabinoid and THC limit."

How to check it: This should be shown clearly on the label and should be described on the product page too.

### **6.5 The Product Complies With Existing Labeling Regulations**

Why? Labeling rules are the law, but more importantly, they make sure consumers are accurately informed about the product they've bought or are considering. While offending products may not see legal consequences, it is always bad for the consumer to not adequately inform them.

State-level labeling rules are crucial to follow, but Vicente's Shawn Hauser explained that there are relevant federal rules too: "Yes, the labeling rules under the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and certain FTC regulations apply to consumable hemp products. Since the 2014 Farm Bill's legalization of some commercial hemp activity, the FDA and FTC have enforced federal laws against hemp companies, but have generally limited enforcement to products that make unlawful drug claims or raise material public safety concerns."



And Rod Kight also commented that:

"In addition to federal labeling requirements (i.e. for foods, dietary supplements, or cosmetics), many states have specific labeling regulations for hemp products. Unfortunately, this is currently a patchwork and it can be a challenge to stay on top of all of these regulations. [...] For hemp-specific labeling rules, about 30 states have them."

How to check it: In addition to the requirements of the Fair Packaging and Labeling Act, there are many labeling requirements for foods specifically in the FD&C Act. Unless you're a manufacturer (or a federal regulator), you don't really need to make sure a product meets all of these, but you can look for some of the basic requirements as a way to quickly judge compliance.

- Is the product identified on the label? (i.e. "CBD Gummies")
- Does the package tell you the net quantity of the contents in both metric and US customary units (or a numerical count)?

- Does it contain the name and address of the manufacturer, packer, or distributor?
- If it is a food, does it have the Nutrition Facts panel?
- Does it contain an ingredients listing?

There are many other requirements, but if all of these are met, for most purposes you can assume it meets its legal obligations.

For businesses looking to remain compliant, we want to emphasize this comment from Rod Kight:

"It's important for a company to discuss its labeling plans with an attorney and to have an attorney review the labels."

Customers, product reviewers, and other people on the consumer side don't need to be exact; you as a business *must be absolutely certain you are compliant*. As Shawn Hauser said, enforcement so far has been focused on companies making drug claims or where there are public safety concerns. However, this doesn't mean that it will remain that way, and it's better to be safe than sorry.

## 6.6 The Label Includes a Batch and Lot Number for Traceability

Why? This ties in with the need for batch testing mentioned in section 3.3. Without a batch or lot number, problems with one batch cannot be identified and those with affected products cannot be notified.

How to check it: It should be shown on the label. While product pages may not show

specific batch numbers, it should be clear from investigation that there are batch numbers for the product. For example, it's not immediately clear that <u>this product</u> has a batch number, but going to "Lab Reports" takes you to a list of reports by batch which clearly identifies the latest batch.



### 6.7 The Label Includes Appropriate Health Warnings

Why? Again, it is crucial both legally and morally to inform consumers of any relevant facts about your products, especially so in cases where there may be risks to the consumer. Rod Kight, in his comment on labeling quoted above, explained:

"Also, it's important to provide warnings about restricting access to minors, not passing a drug test after use, intoxication, and for pregnant, nursing, and people with health conditions." As always, it's important to check the requirements for specific states, but this covers the most important warnings you'll have to include. For intoxicating products, some variation of the <u>universal cannabis</u> <u>symbol</u> is a very clear way to inform consumers.

How to check it: This can only really be checked on the product itself, but it should be visible on product images on the seller's website and should also be verbally conveyed in the product description.

## **6.8 The Label Lists Nutritional and Content Information**

Why? As discussed in section 6.5, consumers should be informed about the product's contents and all applicable laws should be followed. For edible products, this includes a nutritional facts label. How to check it: This should be visible on product packaging and on online product listings.

### **6.9 The Product Label Clearly Lists All Active and Inactive Ingredients**

Why? This is simple: you should be explicitly informed of what you are consuming whenever you buy any product. This is far from limited to hemp but is particularly important in the hemp industry because regulations tend to be unclear and loose.

How to check it: By the nature of this

problem, it is hard to check. However, in a case where a product lists very few ingredients, you should think about the implications of this. If you're buying a liquid vape pen, but it only lists CBD and terpenes, there must be some kind of solvent or carrier to make it possible to vape.



### 7. Reputation, Transparency, and Marketing



### 7.1 The Company Avoids Making Unapproved Medical Claims on Its Website or Labels

Why? This is an issue for both moral and legal reasons. While you may be of the viewpoint that CBD (or another cannabinoid) has a medical benefit in specific cases, the rules in place are there to prevent manufacturers from making claims not backed up by medical science. If you're a manufacturer, you may feel as though you are accurately representing the science, but it's important to remember that not everybody is honest, and the only fair way to tackle this is to make everybody meet the same bar in terms of evidence.

In short, there are rules about permissible and impermissible claims, and these rules are incredibly important. We spoke to the FDA about these requirements and they were very clear:

"The FDA continues to be concerned about the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. The FDA will continue to work to safeguard the health and safety of U.S. consumers by monitoring the marketplace and taking action when companies sell products that present a threat to public health."

They also stressed the moral aspect of this issue:

"Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases."

Even speaking purely practically, this is an area where the FDA does send out warning letters and takes enforcement actions, so this is not a place where it is even reasonable to take a risk. If you <u>review the warning letters</u> for cannabis-derived products, you will notice that in many cases, the medical claims are not only on product pages but also from social media posts (even discussing the results of scientific research) or even testimonials.

Shawn Hauser also made this point when we spoke to her, "Companies can also ensure their social media, blogs, and other marketing content does not include unsubstantiated or false or misleading claims. This includes citing to articles or posting certain comments/reviews."

It is simply not worth the risk. If your product does have medical benefits, the scientific evidence will show this eventually, and



customers may even independently come to this conclusion before you're allowed to put it on your labels.

How to check it: This is challenging to check fully, including social media posts, blogs, and other potential sources of medical

claims. However, simply reviewing the product pages gives an idea of whether medical claims are made. The FDA's <u>guidance on structure/function claims</u> is very informative and the 10 criteria should be kept in mind as you review the manufacturer's website.

#### 7.2 The Company Avoids Marketing That Appeals to Teens, Such as Cartoon Images or Candy-Like Designs

Why? ? There is a great deal of concern about hemp products that are marketed in a way that may appeal to youth, with <u>FDA and FTC</u> <u>warning letters</u> addressing this issue recently. There are two levels to this issue.

Firstly, and most importantly for companies, you should not do anything that may be interpreted as appealing to youth. From FDA warning letters from the past few years, we noted a few key quotes that show how the agency is interpreting rules surrounding this:

- "Imitating non-THC-containing food products often consumed by children through the use of advertising or labeling is misleading."
- "The brightly colored packaging includes depictions of the gummy products in fruity and sour flavors that enhance their appeal to children and increases the likelihood that children will ingest these products as candies."
- "...in forms that would be attractive to children and could easily be mistaken for traditional foods that are commonly

consumed by children."

From a business perspective, it is unwise to package your products in a way that might look like something intended to be consumed by children. It may be interpreted as appealing to youth and could land you in trouble.

Secondly, and more relevant to "responsible marketing" in theory than in practice, you should not do anything that will actually make your product appeal to children because it is wrong. We do not agree with the FDA's implicit assertion that "brightly colored packaging" and "fruity and sour flavors" for hemp products are inherently bad because they may enhance the product's appeal to children.

Products for adults do not need to be packaged in beige with a plain-text description and boring flavors. This is simply not a realistic way to think about products intended for adults vs. those intended for children. Likewise, just because describing a pleasant flavor will increase appeal to children does not mean that the intent of doing so is to appeal to



children, nor that you shouldn't do so.

On this more "common sense" level of the issue, manufacturers should avoid mimicking snacks intended for children (especially if the packaging looks very similar) and should not use cartoon mascots or other clearly childassociated marketing tactics. For more vague issues, such as "bright colors," the product should be judged as a whole. You can use bright colors on a package but if it is clearly labeled as a THC-containing product for adults, does not use sound-alike names or look-alike logos, and has child-resistant packaging, there is no realistic cause for concern.

Fundamentally, this is an issue because youth should not consume hemp products, particularly intoxicating ones. This can be effectively managed with robust laws and responsible parenting. If your THC gummies are kept in a locked container out of your child's reach, who cares whether they have a cartoon tiger on them?

In summary: if you're a manufacturer, you

should take care not to do anything that the FDA would likely take issue with. If you're a consumer, you should judge products based on your own standards of what constitutes "youth appeal" and not by the standard of public statements on the topic.

How to check it: Look at the product's packaging and marketing.

If you would have to genuinely examine it to determine whether it was a hemp product or a conventional candy/foodstuff, this is a sign the company is not acting responsibly. It shouldn't be the case that you could be fooled into thinking this was ordinary candy if you weren't paying enough attention.

If it is clearly a hemp product and does not externally look like candy or other treats intended for children, there is no real issue. This doesn't mean that you should produce such a product as a company (because the FDA may not agree with our assessment), but it does mean that from a consumer perspective, there is no major problem.

#### 7.3 The Company Requires Age Verification and Delivery Signatures for Intoxicating Products

Why? Intoxicating products should not be sold to youth. This is true by law in many places, and even where it isn't in the statute books, the industry should (and generally has) make this a norm.

However, in order to guarantee this with online sales, companies need to do more than simply asking customers to enter their age, which <u>does not prevent purchases</u>. On-site age verification (for example through <u>AgeChecker</u> or <u>Bluecheck</u>) and signature on delivery are effective, and the bare minimum that should be expected in the industry. <u>CBD Oracle's</u> <u>study of hemp delta-9 THC products</u> found that 85% of products did not do this.

How to check it: This can only be fully checked by going through the process of making a purchase. However, if you look at FAQ pages for the company or elsewhere on their website, you should be able to confirm that they use age verification.



#### 7.4 The Company Shares Clear Information About Its Founders and Team

Why? Kelly Lombard, founder of Forge Hemp, put this perfectly: "I tell friends and family to shop for hemp companies, not just products. Reputable hemp companies want to build a relationship with you."

And a key part of this is knowing exactly who you're dealing with. A company simply being transparent and showing you a little about the people involved goes a long way to building trust.

Jan Brandrup from Neurogan put it this way,

"Another key factor is the company itself—are they reputable, or are they just in it for the short term? While well-known companies like Charlotte's Web are trusted, there are many smaller players that might be questionable. I prefer brands that make me feel comfortable and have websites that are informative, with real people you can reach out to if needed."

How to check it: Check the company's website. Is their "About Us" page informative and personal, or is it generic and without an introduction to the owners/staff?

### 7.5 The Company Provides Transparent Details About Sourcing, Production, and Lab Testing

**Why?** Transparency. We need to know all of these things, so if you don't tell us, the natural question is: why not? What is there to hide? It should not be difficult to find this information.

How to check it: Browse the website to try to answer key questions (from elsewhere in the criteria) about how the product was sourced, made, and tested.

## 7.6 The Company Collaborates With Experts in Medical, Scientific, and Legal Fields

Why? Producing safe and high-quality hemp products requires expertise, and so any reliable company should have experts on staff. As Dave Baugh from R&R CBD put it:

"Are the personals professionally educated? We work with a doctor and two chemists. Do they have expertise about the strains, planting, harvest, biomass, extraction? Are they able to answer technical questions? Many companies use a distributor who gets the hemp from 10 different small farms. The plants are grown at different locations and may not be consistent."

How to check it: Check the company's "About Us" page and see who they work with.



#### 7.7 The Company Does Not Remove Negative Customer Reviews From Its Website

Why? Customer reviews are a crucial tool for consumers to make the best purchasing decisions for their needs, and many experts mentioned this as an important factor for them.

For instance, Jesse Karagianes from +PlusCBD said, "Consumer reviews and personal experience with the product would also play a major role in me feeling confident in a product's effectiveness and reliability."

However, when these reviews are hosted on their own website, it is entirely possible that they will hide negative reviews. This is deceptive to consumers and a very bad sign about the company overall.

The <u>FTC recently addressed this issue</u> in a final rule that explicitly prohibits review suppression. The agency explained the rule in an accompanying press release:

"The final rule also bars a business from misrepresenting that the reviews on a review portion of its website represent all or most of the reviews submitted when reviews have been suppressed based upon their ratings or negative sentiment."

How to check it: There are two important things to check. Firstly, any product, essentially however good, will have some negative reviews. If every single review of a product is positive, this is a very clear hint that something isn't quite right. Secondly, look at third-party review sites, as Mike Sill from Sunday Scaries explained:

"I'd have them search for the brand on Google and see what type of credible publications have written about them. These articles will not say 'Sponsored' at the top, they are considered earned media and unbiased. They should also ensure the brand is using a review tool, like Okendo, which only allows reviews from verified buyers."

#### 7.8 The Company Has Positive Reviews on Third-Party Platforms and Actively Engages With Customers

Why? This ties in with the previous point and Mike Sill's comment. As well as not hiding negative reviews, it's also a good sign if they have positive reviews on third-party sites. Engaging with customers and responding to reviews indicates that they take feedback seriously. How to check it: Search for the company on third-party platforms such as the Better Business Bureau, Yelp, Trustpilot, Reddit, and Google. The overall score is the easiest thing to look at, but be sure to check a sample of the actual reviews to see the nature of any criticism.



#### 7.9 The Company Is a Member of Industry Organizations and Supports Advocacy Efforts

Why? The industry is in a very precarious position right now. It's likely that the 2025 update to the Farm Bill <u>will ban any THC from</u> <u>hemp products</u>, which would ban any delta-8 THC or hemp delta-9 THC products, but also any full spectrum CBD oil and many other non-intoxicating products. Even the current system gives manufacturers a patchwork of regulations to navigate, with new changes coming pretty much continuously as states make adjustments to their existing rules.

This is also likely to continue in the future. We asked Shawn Hauser about the main legal challenges for the hemp industry on the horizon, and she commented that since the FDA has failed to establish regulations for 5 years, hemp businesses are in a "legal gray area" federally.

She said, "For the hemp industry, this means 50 different state rules as to whether hemp products can be manufactured and sold, licensing, product potency, serving and container size, packaging/labeling, marketing, testing, and points of sale. Until we have a uniform federal regulatory framework, federal FDCA legality and the 50 state patchwork, and the extreme frequency in which the state laws change will remain the fundamental legal challenge."

If the company actually cares about the industry, consumers, and hemp in general, being involved in industry organizations and advocacy is a must.

How to check it: Checking this is pretty easy, just look at the member lists of hemp organizations such as:

- U.S. Hemp Roundtable
- <u>National Hemp Association</u>
- <u>Hemp Industries Association</u>
- National Cannabis Industry Association
- Hemp Beverage Alliance

You can also check the manufacturer's website to see if they are members of any relevant organizations and check their blog and/or social media to see if they engage in advocacy.

#### 7.10 The Company Offers a Money-Back Guarantee

Why? This is just good for customers. If you're not happy, any respectable company will offer you a money-back guarantee.

How to check it: Check out the company's website, particularly their returns policy (or FAQ page).



### 7.11 The Company Has Not Received FDA or FTC Warnings in the Past 12 Months

Why? The FDA and FTC don't really take much action against hemp companies. In fact, if a company has received a warning, it is likely because they've either:

- Made an unapproved medical claim
- Sold a product that looks suspiciously like an existing product, particularly ones targeted at youth
- Made any type of claim about COVID-19

While many letters mention the illegality of adding CBD or THC to food, this does not tend to be the sole reason for sending a warning letter.

It's technically possible that a company that did one of these things has made a highquality product, but it's not really possible that they are a responsible company.

How to check it: The FDA lists <u>all warning</u> <u>letters sent out about cannabinoid products</u>. You can search this list for the company's name.

#### 7.12 The Company Has Been in Business for Over Three Years

Why? It's not a perfect indicator, but generally, if a company has been in business for a longer period of time, they're probably more reliable. With so many companies cropping up as short-term, white-labeling operations, it's better to stick with older, more established brands in general.

Neurogan's CEO Jan Brandrup made this point, "First, I always check how long the company has been in business. Too many 'Wild West' companies come and go without doing things properly."

If they've been in business for over two years, it's less likely they're just in it for a quick buck, and if they've been around for over three years, you can be pretty confident. How to check it: The company's "About" page should have this information, and if not, you should be able to find it with a simple web search. You can also search the company name within a custom date range (on Google, search, then go to "Tools" and the drop-down menu where it says "Any time") to see the earliest mention of the company online. If this information is not available, take it as a bad sign.



### 7.13 The Company Provides Prompt and Knowledgeable Customer Service

Why? Any company that cares about you and your business will respond to customer queries. If they don't offer good customer service, they don't care about their customers. And if they can't answer technical questions, they may not even know much about their product, making it more likely that they're just in it for a quick buck.

<u>Elizabeth Mack</u>, CEO of Bloom Hemp CBD, identified this as one of the biggest shortcuts brands take: "Many shortcuts people take is to mislead customers, to not have customer service, and to overcharge for crap." How to check it: The best way to check this is to simply ask a technical question about a product. For example, you might ask, "Does this CBD oil contain terpenes?" or "Is this gummy suitable for vegans?" or basically anything relating to these criteria.

Any reliable company that knows their products and cares about their customers will answer this quickly and confidently.



# Conclusion

Safe, effective, and reliable products are good for consumers, but they are also good for the industry. Every governmental crackdown on the products that help Americans every day is driven by stories of unsafe, unreliable, or inappropriately marketed products. Violations of these criteria are fuel for the fire of prohibition and news reports that scare off would-be customers.

It is in all of our interest to make sure hemp is as good as it can be, and to make that a reality, we must push the industry to do better. This means rewarding companies that do things right and calling out those that fail consumers, mislead, and cut corners. While the upcoming changes to the Farm Bill put a tight clock on any meaningful internal reform, every day that the industry strives to do better is another signal to lawmakers to let it continue to flourish.

### **Supplementary Material**

<u>This document</u> includes the full responses from all the experts interviewed for this project.

Additionally, a <u>self-evaluation scorecard</u> has been developed to assist consumers and healthcare professionals in evaluating the quality of cannabinoid products.



### References

Andrews, H., & Rose, M. A. (2018, December 28). Understanding pesticides in organic and conventional crop production systems. Ohio State University. <u>https://ohioline.osu.edu/factsheet/anr-69</u>

Atienza, M. I. M., Afable, G. E. R., & Concepcion, N. D. P. (2022). Three cases of virgin coconut oil-induced lipoid pneumonia in infants. Journal of Case Reports and Images in Pediatrics, 2. <u>https://www.ijcripediatrics.com/archive/article-full-text/100008Z19MA2020</u>

Bhat, T. A., Kalathil, S. G., Goniewicz, M. L., Hutson, A., & Thanavala, Y. (2023). Not all vaping is the same: Differential pulmonary effects of vaping cannabidiol versus nicotine. Thorax, thoraxjnl—2022–218743. <u>https://doi.org/10.1136/thorax-2022-218743</u>

Bix, L., de la Fuente, J., Pimple, K. D., & Kou, E. (2009). Is the test of senior friendly/child resistant packaging ethical? Health Expectations, 12(4), 430–437. https://doi.org/10.1111/j.1369-7625.2009.00534.x

Blount, B. C., Karwowski, M. P., Shields, P. G., Morel-Espinosa, M., Valentin-Blasini, L., Gardner, M., Braselton, M., Brosius, C. R., Caron, K. T., Chambers, D., Corstvet, J., Cowan, E., De Jesús, V. R., Espinosa, P., Fernandez, C., Holder, C., Kuklenyik, Z., Kusovschi, J. D., Newman, C., . . . Pirkle, J. L. (2020). Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI. New England Journal of Medicine, 382(8), 697–705. <u>https://doi.org/10.1056/nejmoa1916433</u>

Champagne, J. (2021, February 10). FLOW™ criteria for assuring cannabis is optimal therapeutic quality. Cannabis Nurse Approved. <u>https://www.cannabisnurseapproved.com/post/four-criteria-for-assuring-cannabis-is-medical-quality</u>

Conuel, E. J., Chieng, H. C., Fantauzzi, J., Pokhrel, K., Goldman, C., Smith, T. C., Tiwari, A., Chopra, A., & Judson, M. A. (2020). Cannabinoid oil vaping-associated lung injury and its radiographic appearance. The American Journal of Medicine, 133(7), 865–867. https://doi.org/10.1016/j.amjmed.2019.10.032

Dicpinigaitis, P. V., Trachuk, P., Fakier, F., Teka, M., & Suhrland, M. J. (2019). Vaping-Associated acute respiratory failure due to acute lipoid pneumonia. Lung, 198(1), 31–33. <u>https://doi.org/10.1007/s00408-019-00277-6</u>

Drotleff, L. (2020). 2020 US hemp harvest outlook: Top hemp-producing states. Hemp Industry Daily. https://hempindustrydaily.com/wp-content/uploads/2020/08/hemp-harvest-2020 FINAL.pdf

Small entity compliance guide on structure/function claims. (2017, November 10). U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims

Gay, B., Field, Z., Patel, S., Alvarez, R. M., Nasser, W., Madruga, M., & Carlan, S. J. (2020). Vaping-Induced lung injury: A case of lipoid pneumonia associated with e-cigarettes containing cannabis. Case Reports in Pulmonology, 2020, 1–4. https://doi.org/10.1155/2020/7151834

Geweda, M. M., Majumdar, C. G., Moore, M. N., Elhendawy, M. A., Radwan, M. M., Chandra, S., & ElSohly, M. A. (2024). Evaluation of dispensaries' cannabis flowers for accuracy of labeling of cannabinoids content. Journal of Cannabis Research, 6(1). <u>https://doi.org/10.1186/s42238-024-00220-4</u>

He, T., Oks, M., Esposito, M., Steinberg, H., & Makaryus, M. (2017). "Tree-in-Bloom": Severe acute lung injury induced by vaping cannabis oil. Annals of the American Thoracic Society, 14(3), 468–470. <u>https://doi.org/10.1513/annalsats.201612-974le</u>

Jerzyński, T., & Stimson, G. V. (2023). Estimation of the global number of vapers: 82 million worldwide in 2021. Drugs, Habits and Social Policy. <u>https://doi.org/10.1108/dhs-07-2022-0028</u>

Johnson, E., Kilgore, M., & Babalonis, S. (2022). Label accuracy of unregulated cannabidiol (CBD) products: Measured concentration vs. label claim. Journal of Cannabis Research, 4(1). <u>https://doi.org/10.1186/s42238-022-00140-1</u>



Johnson, L., Malone, M., Paulson, E., Swider, J., Marelius, D., Anderson, S., & Black, D. (2023). Potency and safety analysis of hemp delta-9 products: The hemp vs. cannabis demarcation problem. Journal of Cannabis Research, 5(1). https://doi.org/10.1186/s42238-023-00197-6

Kuroyama, M., Kagawa, H., Kitada, S., Maekura, R., Mori, M., & Hirano, H. (2015). Exogenous lipoid pneumonia caused by repeated sesame oil pulling: A report of two cases. BMC Pulmonary Medicine, 15(1). <u>https://doi.org/10.1186/s12890-015-0134-8</u>

McGrath, C. (2020). 2019 hemp annual report. United States Department of Agriculture. https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=2019%20Hemp%20Annual%20R eport\_Beijing\_China%20-%20Peoples%20Republic%20of\_02-21-2020

Meehan-Atrash, J., & Rahman, I. (2021). Novel 88-tetrahydrocannabinol vaporizers contain unlabeled adulterants, unintended byproducts of chemical synthesis, and heavy metals. Chemical Research in Toxicology, 35(1), 73–76. https://doi.org/10.1021/acs.chemrestox.1c00388

Outbreak of lung injury associated with the use of e-cigarette, or vaping, products. (2020, February 25). Centers for Disease Control and Prevention. <u>https://archive.cdc.gov/www\_cdc\_gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html</u>

Paulson, E., Swider, J., & Eisenberg, Z. (2022, July 28). The inflated THC crisis plaguing california cannabis. Cannabis Industry Journal. <u>https://cannabisindustryjournal.com/feature\_article/the-inflated-thc-crisis-plaguing-california-cannabis/</u>

Sarma, N. D., Waye, A., ElSohly, M. A., Brown, P. N., Elzinga, S., Johnson, H. E., Marles, R. J., Melanson, J. E., Russo, E., Deyton, L., Hudalla, C., Vrdoljak, G. A., Wurzer, J. H., Khan, I. A., Kim, N.-C., & Giancaspro, G. I. (2020). Cannabis inflorescence for medical purposes: USP considerations for quality attributes. Journal of Natural Products, 83(4), 1334–1351. https://doi.org/10.1021/acs.jnatprod.9b01200

Schwabe, A. L., Johnson, V., Harrelson, J., & McGlaughlin, M. E. (2023). Uncomfortably high: Testing reveals inflated THC potency on retail Cannabis labels. Plos One, 18(4), Article e0282396. <u>https://doi.org/10.1371/journal.pone.0282396</u>

Smith, T. (2020). The ultimate guide to growing hemp. In Organic grain production resource book 2020 (pp. 175–181). OGRAIN. https://ograin.cals.wisc.edu/wp-content/uploads/sites/65/2020/04/Ultimate-guide-to-growing-hemp.pdf

Spindle, T. R., Sholler, D. J., Cone, E. J., Murphy, T. P., ElSohly, M., Winecker, R. E., Flegel, R. R., Bonn-Miller, M. O., & Vandrey, R. (2022). Cannabinoid content and label accuracy of hemp-derived topical products available online and at national retail stores. JAMA Network Open, 5(7), Article e2223019. <u>https://doi.org/10.1001/jamanetworkopen.2022.23019</u>

Trofin, I.G., Dabija, G., & Filipescu, L. (2012). Long - term Storage and Cannabis Oil Stability. https://www.researchgate.net/publication/236170001 Long - term Storage and Cannabis Oil Stability

Vethanayagam, D., Pugsley, S., Dunn, E., Russell, D., Kay, J. M., & Allen, C. (2000). Exogenous lipid pneumonia related to smoking weed oil following cadaveric renal transplantation. Canadian Respiratory Journal, 7(4), 338–342. https://doi.org/10.1155/2000/248915

Viswam, D., Trotter, S., Burge, P. S., & Walters, G. I. (2018). Respiratory failure caused by lipoid pneumonia from vaping ecigarettes. BMJ Case Reports, bcr–2018–224350. <u>https://doi.org/10.1136/bcr-2018-224350</u>

Williams, R. S., Phillips-Weiner, K. J., & Vincus, A. A. (2020). Age verification and online sales of little cigars and cigarillos to minors. Tobacco Regulatory Science, 6(2), 152–163. <u>https://doi.org/10.18001/trs.6.2.6</u>

Wolfson, B. J., Allen, J. L., Panitch, H. B., & Karmazin, N. (1989). Lipid aspiration pneumonia due to gastroesophageal reflux. Pediatric Radiology, 19(8), 545–547. <u>https://doi.org/10.1007/bf02389570</u>

Žydelis, R., Herbst, M., Weihermüller, L., Ruzgas, R., Volungevičius, J., Barčauskaitė, K., & Tilvikienė, V. (2022). Yield potential and factor influencing yield gap in industrial hemp cultivation under nemoral climate conditions. European Journal of Agronomy, 139, 126576. <u>https://doi.org/10.1016/j.eja.2022.126576</u>



### Acknowledgments

We would like to thank Dave Baugh, Elisabeth Mack, Mike Sill, Chris Fontes, Chris Hudalla, Sibyl Swift, Ryan Bellone, Richard Sams, Eloise Theisen, Jesse Karagianes, Jan Brandrup, JJ Coombs, Kelly Lombard, Abraham Benavides, Rod Kight, Ethan Russo, Cynthia Cabrera, Megan Mbengue, Swathi Varanasi, Erica Stark, Adie Rae (Wilson-Poe), Shawn Hauser, Bob Miller, the FDA and the California Department of Public Health for their insight and suggestions, without which this project would not have been possible.



### Funding

This project was funded by CBD Oracle, an independent consumer research organization dedicated to improving the safety and transparency of cannabis products.

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