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# Cannabis and CBD Companies Subject to Increased Prop 65 Exposure

*Written by Ian A. Stewart – 6/25/20*

Cannabis and CBD companies must prepare for increased liability under California's notorious Proposition 65 statute. THC has been added to the list of chemicals for which Prop 65 warnings are required. The statute now identifies THC as a chemical that may cause reproductive harm and no "safe harbor" level has yet been identified, meaning that *any* detectable amount of THC in a product sold in California requires a compliant Prop 65 warning. This new rule for THC will become effective and enforceable as of January 3, 2021. Cannabis and CBD companies therefore should start planning now to mitigate this risk under Prop 65.

## **What Is Prop 65 and What Does It Require?**

California's Prop 65, also known as the Safe Drinking Water and Toxic Enforcement Act, requires a warning on all products that contain chemicals known to cause cancer or reproductive harm, even in amounts a fraction of what is deemed safe by federal standards. There are more than 900 such chemicals listed. Marijuana smoke has been included on the list since 2009, and THC was recently added. Businesses with nine or fewer employees are exempt from the statute.

Prop 65 has caused havoc within the dietary supplement and herbal product markets over the past decade, led by a cottage industry of "bounty hunter" attorneys who have weaponized the statute, ostensibly in the public interest but in reality as a lucrative for-profit business. These groups have increasingly focused their attention on new cannabis and CBD products.

Many businesses faced with the necessity of using a Prop 65 warning have no concern with the impact that a warning may have on sales or with consumer confidence in the product. After all, who would look twice at a Prop 65 warning on motor oil or insect repellent? Like the dietary supplement industry before them, however, many cannabis and CBD businesses resist including a warning that the product contains a chemical

known to cause reproductive harm or cancer. Many cannabis and CBD products rely on the consumers' belief that the product is harmless and even therapeutic. For many, this will be an important business decision that may give rise to expensive mistakes – a decision should be made with an understanding of the basis for Prop 65 liability and exposure.

### **Required Content of a THC Prop 65 Warning**

Legal advice should be sought before determining what Prop 65 warning to use for any particular product, which may require warnings in addition to the reproductive harm warning for THC. With that important caveat, an exemplar standard Prop 65 warning for THC looks like this:



**WARNING:** This product can expose you to  $\Delta$ 9-Tetrahydrocannabinol ( $\Delta$ 9-THC), which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

Alternatively, a *short form warning* may be provided on the product label using similar elements with a shortened written warning. An exemplar short-form Prop 65 warning for THC looks like this:



**WARNING:** Reproductive Harm – [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

A short-form warning on the product label is not required to include the name of a listed chemical within the text of the warning. The entire warning, however, must be in a type size no smaller than the largest type size used for other consumer information on the product, and the warning may not appear in a type size smaller than 6-point type.

### **Method of Transmitting the Warning**

The method of transmitting a Prop 65 warning meets the applicable requirements if it includes *one or more* of the following elements:

- A product-specific warning provided on a posted sign, shelf tag or shelf sign for the product at each point of display of the product.



- A product-specific warning provided via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the product without requiring the purchaser to seek out the warning.
- A warning on the label (or short-form warning on the label) that complies with the requirements set forth above.

For internet purchases, a warning (or short-form warning) that is compliant with the requirements above also must be provided by including either the warning or a clearly marked hyperlink using the word “**WARNING**” on the product display page, or by otherwise prominently displaying the warning to the purchaser prior to completing the purchase. A warning is not prominently displayed if the purchaser must search for it in the general content of the website.

### **Impact on CBD Products**

Companies that sell CBD products may erroneously believe that they are not subject to the new Prop 65 warnings for THC. Certainly any product that contains “full spectrum” hemp extract should carefully consider using a Prop 65 warning. A full spectrum product contains the full assortment of cannabinoids that are naturally present in the hemp plant, including THC (though at a level that should not exceed 0.3% concentration on a dry weight basis to be compliant with the requirements of the 2018 Farm Bill). Even “broad spectrum” products that contain the full assortment of cannabinoids *except* THC, which is extracted from the final product, must be handled carefully because *any* detectable level of THC will trigger Prop 65 obligations. Products that contain CBD isolate, manufactured through a process that separates the CBD molecule and strips out all remaining plant material, should fall in a lower risk category but must nevertheless be tested for any detectable THC.

### **Is there Exposure to Chemicals other than THC?**

**When identifying liability under Prop 65, it is important for companies that sell marijuana and CBD products in California to broaden their focus beyond just the potential exposure to THC and marijuana smoke.** Although there is no safe-harbor level for THC, many chemicals with safe-harbor levels include additives or ingredients in pesticides, food, drugs and common household products. Most food and many dietary supplements contain at least some level of one or more of these substances. Prop 65 safe-harbor levels, however, are in many cases around 1,000 times lower than levels set by the Food and Drug Administration (FDA), Environmental Protection Agency (EPA) and

World Health Organization (WHO). The exposure levels established by Prop 65 are often lower than what occurs naturally in fruits, vegetables, grains and even drinking water.

#### *Lead as an Example*

The Prop 65 limit for lead is 0.5 micrograms per day, which is below the amount of lead naturally found in many fruits, vegetables and herbs grown in non-contaminated soil. By comparison, the FDA allows 75 mcg/day and the European Union allows 250 mcg/day for lead. The European Food Safety Authority estimates the average adult consumes lead at around 50 mcg/day, which is *100 times* the Prop 65 limit. It is nearly impossible to manufacture herbal products, including cannabis products, without trace amounts of lead. Although there is a Prop 65 exemption involving chemicals that occur naturally in food, the burden is on the company to prove the exemption, which often is expensive and unsuccessful. It is therefore dangerous to simply assume that a cannabis or CBD product complies with safe-harbor levels.

#### **Determining the Exposure Level**

Determination of the “exposure level” also is an important consideration. Prop 65 focuses on the level of a chemical to which the consumer is actually exposed. Although a product may have a very low amount of a chemical on the Prop 65 schedule that is below the safe-harbor level, liability under the statute may nevertheless be triggered based on the recommended serving size. It is advisable for companies to work with a laboratory that specializes in Prop 65 testing to determine the cumulative exposure level in order to verify the recommended serving size.

#### *Chemicals without a Safe Harbor Level*

Only about 300 of the more than 900 Prop 65 chemicals have specific safe-harbor levels. For those chemicals without a safe-harbor limit, the burden will be on the cannabis business to establish that the subject chemical is within a safe range. This typically requires expensive testing, the results of which may be open to multiple interpretations as to whether a warning is required.

Because THC currently has no safe-harbor level under Prop 65, any detectable amount will trigger potential liability under the statute. It remains unclear whether California’s Department of Toxic Substances Control (DTSC) will eventually set a Prop 65 safe harbor level for THC. Regardless, any future safe harbor level set by DTSC will likely be far lower than the naturally occurring level of THC found in essentially all hemp varieties.

### **Enforcement of Prop 65**

Prop 65 is enforced through litigation brought by the government or by private attorneys that “act in the public interest.” It is the threat of these private lawsuits that causes such consternation by those targeted with Prop 65 liability. After a 60-day notice period, the attorney may file a civil suit against the offending company. Typically, the plaintiff will demand that the defendant provide warnings compliant with Prop 65, pay a penalty and either recall products already sold or attempt to provide health hazard warnings to those who purchased the products.

Though ostensibly brought in the public interest, it is the collection of penalties and attorneys’ fees that in reality drives this litigation. Prop 65 allows individuals who bring suit to recover 25 percent of the penalties awarded, which by statute is calculated at up to \$2,500 per violation per day. Certain voluntary actions by the defendant – reformulation of the product, for example – may preclude penalties. The threat of paying the plaintiff’s attorney’s fees makes litigating Prop 65 cases potentially very expensive. The attorney is incentivized to drag out the litigation, and the longer the case goes on, the more difficult it becomes to resolve because of the mounting fees.

According to the California Attorney General, 829 Prop 65 settlements were reported in 2018 (the most recent year reported) with total settlement payments of more than \$35 million. Attorneys’ fees accounted for 77 percent of that amount.

### **Best Protection for Cannabis and CBD Companies**

Until a safe-harbor limit is set for THC, all marijuana products and many CBD products sold in California are at risk of Prop 65 violations without compliant product warnings. A compliant Prop 65 warning should be placed on any “full spectrum” CBD product and on some “broad spectrum” products. CBD isolate products should fall in a lower risk category, but rigorous testing with a low detection threshold for THC should be used.

It is important for all cannabis and CBD companies to take a broad approach to their Prop 65 risk analysis. Because additional warning language may be necessary as a result of exposure to listed chemicals in addition to THC, Prop 65 testing should be performed on all ingestible consumer products sold within the state of California, and the inclusion of any additional warning language should be determined based on those tests.

Prop 65 litigation continues to burden many industries in California, now including the

cannabis and CBD industries. For any company that has not yet evaluated how to respond to the changes to Prop 65 that become effective and enforceable on January 3, 2021, the time to do so is now.



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