

## **GUIDANCE DOCUMENT -**

### **NEW REQUIREMENTS FOR INHALED CANNABIS PRODUCTS**

The Department of Cannabis Control (DCC) has adopted new regulations that clarify what can be included in inhaled cannabis products. These regulatory provisions became effective on November 7, 2022.

This guidance is a tool to assist licensees with understanding the new regulations, but it does not impose additional requirements or change the regulations. This guidance explains:

- Inhaled Cannabis Products
  - What changed in regulation
  - Answers to common questions
  - Expectations for compliance

The complete text can be found in California Code of Regulations, Title 4, Division 19, and on the <https://cannabis.ca.gov/cannabis-laws/dcc-regulations>.

## **Cannabis Products**

### **What Changed in Regulation**

#### Additional Requirements for Inhaled Cannabis Products

DCC has adopted section 17303.1, which limits the components that may be included in cannabis products intended for inhalation. Cannabis products intended for inhalation may contain only cannabis; cannabis concentrate; terpenes; rolling paper leaf; pre-roll filter tips; and ingredients permitted by the United States Food and Drug Administration as an “inactive ingredient” for inhalation, as specified in the United States Food and Drug Administration Inactive Ingredients Database.

#### Definitions

“Terpenes” is defined in section 15000(ppp), which defines “terpenes” as “terpenes, terpenoids, flavonoids, polyphenols, and other naturally occurring phytochemicals and secondary metabolites contributing to the aroma or flavor of cannabis.

#### What is the purpose of the new inhaled products regulations?

The new regulations limit the substances that can be used to add flavor to inhaled products, including flavors that are attractive to children, by masking the natural flavor and aroma of cannabis.

The regulation limits ingredients in inhalable cannabis products in accordance with the United States Food and Drug Administration (FDA) *Inactive Ingredients Database* for inhalation.

## Answers to Common Questions About Cannabis Products Intended for Inhalation

### Are there limits on flavors that can be included in cannabis products intended for inhalation?

Yes. Section 17303.1 imposes limitations on the components that may be included in cannabis products intended for inhalation. In particular, the regulation limits the terpenes that can be included in inhaled products by defining terpenes.

“Terpenes” is defined to mean “terpenes, terpenoids, flavonoids, polyphenols, and other naturally occurring phytochemicals and secondary metabolites contributing to the aroma or flavor of cannabis” in section 15000(ppp). Through this definition, DCC has specifically limited the terpenes that may be added to inhaled products to those that are naturally occurring and contribute to the flavor or aroma of cannabis. As such, artificial, synthetic, and natural flavorings or terpenes that do not contribute to the natural flavor or aroma of cannabis are not permitted. This means that added terpenes do not need to be cannabis derived but they must be consistent with the terpenes that naturally exist in cannabis. Flavors that would be prohibited under this definition include, but are not limited to, menthol, mint, mango, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, popcorn, and bubblegum.

### Are artificial, synthetic or non-cannabis terpenes, permitted in cannabis products intended for inhalation?

Artificial or synthetic terpenes are not permitted. Through the definition of “terpenes” in section 15000(ppp), DCC has specifically limited the terpenes that may be added to inhaled products to those that are naturally occurring and contribute to the natural flavor and aroma of cannabis. Terpenes that are not derived from cannabis may be added if they are naturally occurring, consistent with the terpenes that naturally occur in the cannabis they are being added to, and contribute to the natural flavor and aroma of cannabis.

### What other limitations are placed on cannabis products intended for inhalation?

Section 17303.1 limits the components that can be included in cannabis products intended for inhalation to the following: cannabis; cannabis concentrate; terpenes; rolling paper leaf; pre-roll filter tips; or ingredients permitted by the United States Food and Drug Administration as an “inactive ingredient” for inhalation, as specified in the United States Food and Drug Administration *Inactive Ingredients Database*. The DCC believes that prohibiting inactive ingredients that have not been approved for inhalation by the Food and Drug Administration is necessary to protect the consumer. The FDA database is available at <https://www.fda.gov/drugs/drug-approvals-and-databases/inactive-ingredients-database-download>.

### Are there labeling or marketing restrictions for cannabis products intended for inhalation?

Cannabis products intended for inhalation must comply with all labeling and advertising requirements in the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), which begins at Business and Professions Code (BPC) section 26000, and the DCC's regulations. This includes ensuring that all ingredients are listed on the label and that any labeling, advertising and marketing comply with restrictions on content that is attractive to minors under the age of 21. (BPC §§26120 and 26152; CCR §§15040, 17300, 17406, and 17408). Cannabis products that are labeled or designed in a manner that is attractive to minors under the age of 21 are prohibited. Licensees should exercise particular caution when labeling, advertising or marketing cannabis products with flavor-like names (for example, "bubblegum" or "cherry kola") to ensure that such products are not attractive to minors.

### **Expectations for Compliance**

#### What must licensees do to comply with the new regulations?

All licensees in possession of cannabis products intended for inhalation that do not meet the requirements of the new regulation should move the existing product through and out of the supply chain as quickly as possible. DCC recognizes that licensees may need to transition their business operations to come into compliance. DCC plans to initially prioritize education over discipline and assist licensees with coming into compliance.

Licensees that manufacture cannabis products intended for inhalation should immediately stop producing products that are not compliant with the new regulations. All cannabis products intended for inhalation manufactured on and after November 7, 2022, are subject to the regulatory requirements. Cannabis products intended for inhalation that do not meet the new requirements may be considered adulterated pursuant to Business and Professions Code section 26039.6(a)(4).

#### What is the timeframe for complying with the new regulations regarding the additional requirements for inhaled cannabis products?

The new regulations became effective on November 7, 2022. This means that cannabis products intended for inhalation manufactured on and after November 7, 2022 are subject to the new regulatory requirements. Licensees that manufacture these products should immediately stop producing cannabis products intended for inhalation that are not compliant with the new regulations. All licensees with existing cannabis products intended for inhalation that do not meet the requirements of the new regulation should move the existing product through and out of the supply chain as quickly as possible.

DCC recognizes that licensees may experience compliance issues as they transition their operations. DCC plans to initially prioritize education over discipline and assist licensees with coming into compliance.