

CHEAC Summary CDPH Cannabis Regulations

[Manufacturing](#)

The California Department of Public Health (CDPH) has released proposed regulations focused on the manufacturing of cannabis products throughout California. These regulations are only slightly modified from the April 2018 emergency regulations package. We encourage members to read the entire proposed regulations document released by CDPH; however, a summary of the most relevant revisions is provided below.

Key Revisions Made in Regulations

- Clarifies which products are classified as edibles and which are classified as concentrates.
- Specifies that orally-dissolving cannabis products (such as lozenges) are classified as edibles.
- Defines “tablets” as concentrates intended to be swallowed whole and that contain no added flavorings or sweeteners.
- Allows orally-dissolving tablets sold in the medicinal market to contain up to 500 milligrams of THC per package as long as these products contain no more than 10mg THC per serving.
- Allows statutory requirements for child-resistant packaging to be fulfilled using exit packaging at the retail level rather than by individual product packaging.
- Clarifies that temporary licenses will not be issued or extended beyond December 31, 2018.
- Allows the Bureau to issue an emergency decision to avoid the immediate danger to public health, safety, or welfare.

Subchapter 1. General Provisions and Definitions

Definitions (Pages 1-6)

- Clarifies that “edible cannabis product” includes cannabis products that resemble conventional food or beverages and cannabis products that dissolve or disintegrate in the mouth.
- Defines “infused pre-roll” to mean a pre-roll into which cannabis concentrate (other than kief) or other ingredients have been incorporated.
- Defines “kief” to mean the resinous trichomes of cannabis that have been separated from the cannabis plant.
- Defines “orally-consumed concentrate” to mean a cannabis concentrate that is intended to be consumed by mouth and is not otherwise an edible

- product. Orally-consumed concentrate includes tinctures, capsules, and tablets.
- Defines “pre-roll” to mean any combination of the following rolled in paper: flower, shake, leaf, or kief that is obtained from accumulation in containers or sifted from loose, dry cannabis flower or leaf with a mesh screen or sieve.
 - Defines “tablet” to mean a solid preparation containing a single serving of THC or other cannabinoid that is intended to be swallowed whole, and that is not formulated to be chewable, dispersible, effervescent, orally disintegrating, used as a suspension, or consumed in a manner other than swallowed whole, and that does not contain any added natural or artificial flavor or sweetener.

Premises Diagram (Pages 8-9)

- Requires a premises diagram to be specific enough to enable ready determination of the bounds of the property and the proposed premises to be licensed, the diagram must be to scale, and if the premises consists of only a portion of a property, the diagram must be labeled to indicate which part of the property is the proposed premises and identify what the remaining property is used for.
- Premises diagrams must also include all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, windows and doorways.
- All areas in which all commercial cannabis activities will be conducted must be included in the diagram including infusion activities, extraction activities, packaging activities, labeling activities, and transportation activities.
- Premises diagrams must also include all limited-access areas and cannabis waste disposal areas.

Subchapter 2. Manufacturing Licenses

Temporary Licenses (Pages 13-14)

- Temporary licenses or extensions will not be issued after December 31, 2018. Any temporary license issued or extended with an expiration date after December 31, 2018, will be valid until it expires.

License Constraints (Page 31)

- Manufacturer licensees can only use cannabinoid concentrates and extracts that are manufactured or processed from cannabis obtained from a licensed cannabis cultivator.

- Manufacturer licensees are prohibited from manufacturing, preparing, packaging, or labeling cannabis products in a location that is operating as a retail food establishment or as a processed food registrant.
- Manufacturer licensees are prohibited from manufacturing, preparing, packaging, or labeling cannabis products in a location that is licensed by the Department of Alcoholic Beverage Control.

Notification of Criminal Acts, Civil Judgments, and Revocation of a Local License, Permit, or Other Authorization after Licensure (Pages 36-37)

- Licensees are required to notify CDPH in writing of a criminal conviction of any owner within 48 hours of conviction.
- Licensees are required to notify CDPH in writing of a civil penalty or judgment rendered against the licensee or any owner in their individual capacity within 48 hours of delivery of the verdict or entry of judgment.
- Licensees are required to notify CDPH in writing of a local license, permit, or other authorization within 48 hours of receiving notice of the revocation.

Preventive Controls (Pages 67-69)

- Requires manufacturers to establish critical limits for each critical control point in order to prevent, eliminate, or reduce to an acceptable level the occurrence of an identified hazard.
- Requires manufacturers to identify controls, other than critical control points, that are appropriate for ensuring cannabis product quality such as cleaning, sanitizing, and maintenance of the premises, equipment, and machinery; supervisor, manager, and employee quality control and hygiene training; an environmental monitoring program for the premises to verify the effectiveness of pathogen controls in processes where a cannabis product is exposed to a possible contaminant; a food allergen control program to prevent allergen cross-contact.

Subchapter 4. Products

Prohibited Products (Pages 83-84)

- Allows for commercially available candy or snack food items to be used as ingredients in a cannabis product, provided that they are used in a way that renders them unrecognizable as the commercially available items and the label, including the ingredient list, does not note that the final cannabis product contains the commercially available item.

THC Concentration Limits (Page 86)

- Edible cannabis products cannot contain more than 10 milligrams THC per serving and 100 milligrams THC per package.

- A package containing an edible product that is an orally-dissolving product, such as sublingual lozenges or mouth strips, may contain up to 500 milligrams THC per package if the product consists of discrete servings of no more than 10 milligrams per piece, the product is labeled “FOR MEDICAL USE ONLY”, and the product is only available for sale to a medicinal-use customer.
- Topical cannabis products or cannabis concentrates shall not contain more than 1,000 milligrams THC per package. A topical cannabis product or a cannabis concentrate may contain more than 1,000 milligrams THC per package, but not more than 2,000 milligrams THC per package, if the product is labeled “FOR MEDICAL USE ONLY” and is only available for sale to a medicinal-use customer.

Failed Product Batches (Pages 86-88)

- Any finished cannabis product that fails any laboratory testing requirement established by the Bureau must be destroyed unless the cannabis batch can be remediated or relabeled or a corrective action plan for remediation or reprocessing has been approved by CDPH.
- Edible cannabis products that fail lab testing requirements may not be remediated or reprocessed and must be destroyed. If any edible cannabis product that has failed lab testing is remediated, reprocessed, or otherwise mixed with another batch of cannabis product, such an action renders the final cannabis product adulterated, regardless of the defect level of the final cannabis product.

Subchapter 5. Labeling and Packaging Requirements

General Provisions (Page 90)

- If a cannabis product container is separable from the outer-most packaging, the product container held within that outer packaging must include all primary paneling labeling requirements and all additional primary panel labeling requirements pertaining to edible cannabis products, topical cannabis products, suppositories, or orally-consumed concentrates, and the universal cannabis product symbol.

Labeling Requirements: Pre-Rolls and Packaged Flower (Pages 90-91)

- Prescribes label requirements for packages of pre-rolls or packaged flower to include the identity of the product, the net weight of the cannabis in the package, the universal symbol for cannabis, and the cannabinoid content.
- Packaging must also include the following warning statement in bold print: “GOVERNMENT WARNING: THIS PACKAGE CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS MAY ONLY BE POSSESSED

OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER
UNLESS THE PERSON IS A QUALIFIED PATIENT. CANNABIS USE
WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL.
CONSUMPTION OF CANNABIS IMPAIRS YOUR ABILITY TO DRIVE
AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.”

Cannabinoid Content Labeling (Pages 94-95)

- All cannabis product packages must be labeled with the following pharmacologically active ingredients:
 - THC content: For an edible product, and a cannabis concentrate for which the manufacturer has established serving designations, THC content must be expressed in milligrams per serving and milligrams per package. For topical cannabis products and a cannabis concentrate without serving designations, THC content shall be expressed in milligrams per package.
 - CBD content: For an edible product, and a cannabis concentrate for which the manufacturer has established serving designations, CBD content shall be expressed in milligrams per serving and milligrams per package.
- Packages of pre-rolls or cannabis flower that do not include cannabinoids other than those naturally occurring in the plant material are not required to list cannabinoid content in milligrams. Instead, such packages may be labeled with the cannabinoid content expressed as a percentage.
- Infused pre-rolls must be labeled with either the cannabinoid content in milligrams or the cannabinoid content of the dried flower expressed as a percentage and the added cannabinoid content in milligrams.

Labeling Restrictions (Pages 95-96)

- Prohibits the use of variants in the spelling of candy or candies such as “kandy” or “kandeez.”
- Edible products may not include a picture of the product contained within the package.

Subchapter 6. Compliance

Emergency Decision and Order (Pages 108-111)

- Allows CDPH to issue an emergency decision and order for temporary, interim relief to prevent or avoid immediate danger to the public health, safety, or welfare. Causes can include:
 - Cannabis products manufactured, processed, packed, or held at the licensee’s premises has a reasonable probability of causing serious adverse health consequences or death.

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- Unsanitary or other conditions at the licensee's premises exist that could lead to the adulteration of finished cannabis products and has a reasonable probability of affecting the safety of finished cannabis products.
- Conditions occur at the licensee's premises that present an immediate risk to worker or public health and safety.
- The prevention of illegal diversion of cannabis or cannabis products, or other criminal activity at the licensee's premises
- The prevention of the destruction of evidence related to illegal activity or violations of the Act