

# Health and Human Services Agency California Department of Public Health



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## NOTICE OF PROPOSED RULEMAKING

Title 17, Chapter 5, Division 1 California Code of Regulations Industrial Hemp Cannabinoids (DPH-24-005B)

Notice Published: November 14, 2025

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

#### **PUBLIC PROCEEDINGS**

The Department is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Coordinator Dawn Basciano, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 558-1710, email to <a href="mailto:dawn.basciano@cdph.ca.gov">dawn.basciano@cdph.ca.gov</a> or use the California Relay Service by dialing 711.

## **PUBLIC HEARING**

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a public hearing if a written request for a public hearing is received from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.



#### **Assistive Services:**

For individuals with disabilities, the Department will provide assistive services such as conversion of written materials into Braille, large print, audio format, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takers, reading, or writing assistance. To request these assistive services, please call (916) 558-1710 or (California Relay at 711 or 1-800-735-2929), email <a href="mailto:Regulations@cdph.ca.gov">Regulations@cdph.ca.gov</a> or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are received less than 10 business days prior to public hearing.

#### WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations on December 29, 2025, which hereby is designated as the close of the 45-day written comment period. Comments received after this date will not be considered timely.

Written Comments must be submitted as follows:

- By email to: <a href="regulations@cdph.ca.gov">regulations@cdph.ca.gov</a>. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-24-005B" in the subject line; to facilitate timely identification and review of the comment.
- 2. By fax transmission to: (916) 636-6220;
- 3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-24-005B "Industrial Hemp Cannabinoids", along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

## **AUTHORITY AND REFERENCE**

The Department proposes to adopt the proposed rulemaking under the authority provided in sections 100275, 110065, 111921.7, and 131200 of the Health and Safety Code.

The Department is proposing to make permanent Section 23010 to Subchapter 2.6 of Chapter 5 of Division 1 of Title 17, California Code of Regulations in order to implement, interpret, or make specific sections 110045, 110085, 110095, 110100, 110390, 110395,

110398, 110400, 110660, 110680, 110760, 110765, 111920, 111921, 111921.7, 111926, 111926.2, 131095, and 131100 of the Health and Safety Code; Section 15731, Title 4 California Code of Regulations; and Part 101, Title 21 Code of Federal Regulations.

## **INFORMATIVE DIGEST**

## **SUMMARY OF PROPOSAL**

The proposed regulations specify intoxicating cannabinoids included in the definition of THC or "THC or comparable cannabinoid." The proposed regulations will protect public health and safety by protecting consumers and reducing risk of illness, injury, or death.

Currently, the California Department of Public Health (Department) is enforcing emergency regulations (DPH-24-005E), which became effective on September 23, 2024, under statutory authority of Assembly Bill (AB) 45 (Chapter 576, Statutes of 2021).

## BACKGROUND AND SUMMARY OF EXISTING LAWS AND REGULATIONS

**Background:** AB 45 requires the Department to implement statutory requirements, codified in Health and Safety Code sections 111920 et seq., to regulate industrial hemp in extracts, food, beverages, dietary supplements, processed pet food, cosmetics, and inhalable products. AB 45 established the Industrial Hemp Enrollment and Oversight Fund for the collection of fees to pay for the new regulatory work, including establishing and maintaining an industrial hemp enrollment and authorization, registration, and inspection program for industrial hemp manufacturers who produce raw hemp extract or who produce industrial hemp final form products.

AB 45 requires that all industrial hemp products that are sold or distributed in California shall conform with all applicable state laws and regulations. AB 45 also requires that industrial hemp products cannot include more than 0.3% total THC (delta-8 THC, delta-9 THC, delta-10 THC, and THC acid (THCA)). Industrial hemp products cannot include THC isolate as an added ingredient; cannabinoids produced through chemical synthesis are also prohibited. Manufacturers must include a certificate of analysis to confirm allowable total THC concentration and product content, and they must provide proof that the industrial hemp product in its final form or extract was from an approved industrial hemp growing program.

The Department conducts licensure and compliance activities statewide to ensure these facilities, and their products meet state and federal laws. To implement AB 45, the Department added industrial hemp firms into its existing registration structure, including licensing, inspecting, and conducting enforcement. The Department must separately license and evaluate the operations of firms that manufacture industrial hemp extracts

out-of-state for import into California, as well as California firms that manufacture industrial hemp inhalable products for sales out-of-state. Industrial hemp inhalable products may be manufactured in California for the sole purpose of sale in other states; sale in California is prohibited until the Legislature establishes a tax on industrial hemp inhalable products.

The Department may investigate misbranding, adulteration, food manufacturing safety, unapproved drug products, and other issues to determine compliance with AB 45 or other laws, pursuant to authority in AB 45 and under the Sherman Food, Drug, and Cosmetic Law (Sherman law). Enforcement may include:

- Regulatory warnings
- Public health advisories or warnings
- Administrative and civil penalties
- Criminal penalties including imprisonment
- Recall of products
- Seizure and embargo of products
- Condemnation of embargoed products

Health and Safety Code Section 111921.7(b) states that the Department "may include any other cannabinoid, in addition to those expressly listed in subdivision (I) of Section 111920, in the definition of THC or 'THC or comparable cannabinoid' if the department determines, consistent with subdivisions (c) and (d), that the cannabinoid causes intoxication.

Additionally, the Department promulgated emergency regulations to specify the serving size for total THC, and package size limit, for industrial hemp final form food products intended for human consumption; an age requirement for offering or sale of industrial hemp industrial hemp final form food products intended for human consumption; and intoxicating cannabinoids included in the definition of "THC" or "THC or comparable cannabinoid."

#### Federal law

Under the federal 2018 Farm Bill, industrial hemp is defined as the Cannabis sativa Linnaeus plant with a delta-9 THC concentration of not more than 0.3% (United States Code, Title 7, Section 5940(b)(2)). Industrial hemp regulation under AB 45 is stricter than federal law by limiting THCA, delta-8 THC, delta-9 THC, and delta-10 THC and any intoxicating cannabinoid as defined by the Department to 0.3% or less. In addition, industrial hemp cannot be synthetically derived or contain any THC isolates.

The Food and Drug Administration (FDA), whose authority was not affected by the 2018 Farm Bill, has deemed hemp in food as prohibited in interstate commerce (other than

FDA-recognized hemp ingredients Generally Recognized As Safe (GRAS), which are hulled hemp seed, hemp seed protein powder, and hemp seed oil). When hemp other than GRAS is found in food, the hemp is considered an unapproved additive, regardless of the source. Federally unapproved products are illegal to enter interstate commerce.

## Establishment of permanent regulations

This proposed rulemaking action will make Section 23010 of the emergency regulations permanent. Additionally, the Department proposes the following minor edits to the emergency text:

The list of intoxicating cannabinoids in this proposed rulemaking is the same as
in the emergency regulations. However, the Department uses formulas from the
International Union of Pure and Applied Chemistry to accompany common
names for items 9 through 16 and items 25 through 30 on the list of intoxicating
cannabinoids, instead of the chemical formulas used in the emergency
regulations. This edit provides clarity and consistency for the industry.

## Key policy elements of the proposed action

The Department's policy focuses on improving product safety and protecting consumers. The Department has explicit authority to establish regulations to include any other cannabinoid, in addition to those expressly listed in subdivision (I) of Section 111920, in the definition of "THC." The proposed regulation works toward enhancing and protecting the public's health.

Adding additional cannabinoids to the definition of THC helps protect consumers of industrial hemp products from cannabinoids with potentially dangerous side effects and long-term health consequences. This action, combined with previous regulatory actions, allows the Department to protect consumers from accidental consumption of intoxicating cannabinoids and provides a clear regulatory framework for the industry to follow.

## **POLICY STATEMENT OVERVIEW**

**Problem Statement**: California's AB 45 legalized and regulated many industrial hemp products in California. AB 45's framework allowed consumer exposure to some intoxicating industrial hemp food products as the law identified only a fraction of the total cannabinoids known to cause intoxication and did not represent what the industry was adding to products. Manufacturers exploited this to market and distribute intoxicating products. Specifically, food products with intoxicating and synthetic cannabinoids were being marketed to youth. As a result, youth and the public in general experienced illness and injury from these products, including a report of one death. The proposed regulation explicitly identifies 30 cannabinoids and adds them to the list of compounds which must not be present above a limit of detection in industrial hemp final form food products.

Identifying and restricting these cannabinoids helps to protect consumers from accidental consumption and provides industry unambiguous guidance.

**Objectives**: The broad objective of this proposed regulatory action is to protect public health and safety from injury, illness, or death through regulation of industrial hemp products. The regulatory action will assure consumers that products sold as industrial hemp meet a consistent standard and that extractors, manufacturers, and retailers are following standards to ensure the quality and safety of their products.

The proposed regulations focus on protecting the public by including other cannabinoids, in addition to those expressly listed in subdivision (I) of Section 111920, in the definition of "THC."

## Benefits: List of intoxicating cannabinoids

AB 45 explicitly identifies delta-8 THC, delta-9 THC, delta-10 THC, and THCA in the definition of "THC" or "THC or comparable cannabinoid." Currently, the Department's emergency regulations include additional intoxicating and potentially harmful cannabinoids in the definition of "THC" or "THC or comparable cannabinoid." Permanently adding these cannabinoids to the definition ensures that the presence of these intoxicating cannabinoids in industrial hemp products is restricted, provides clarity to the industry and consumers regarding cannabinoid content, and helps to ensure the safety of industrial hemp products.

## <u>Evaluation As To Whether The Regulations Are Inconsistent Or Incompatible With</u> Existing State And Federal Regulations

The Department has determined these regulations are not inconsistent or incompatible with existing state regulations. As the oversight of industrial hemp activity is a newly created state responsibility, no other state regulations are already in existence that address the same topics. In addition, the Department must ensure that its regulations must not conflict with the Food and Agriculture Code, Alcoholic Beverage Control Act, and division 9 (commencing with Section 23000) of the Business and Professions Code (see Health and Safety Code section 110040).

## <u>Substantial Difference From Federal Regulation Or Statute</u>

The Department has determined these regulations are not substantially different from either a federal regulation or statute.

## **Documents Incorporation By Reference**

The Department has determined these regulations are not proposing any incorporation by reference.

## **CONSIDERATION OF REASONABLE ALTERNATIVES**

The Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposed action, or more cost-effective to affected private persons and equally effective in implementing the statutory policies or other provisions of law.

## **ECONOMIC IMPACT ASSESSMENT**

The Department determined the proposed regulations will affect the following as described:

- 1. The creation or elimination of jobs within the state: The proposed regulations will have a negligible direct impact on job creation or elimination in California. The current consumer market for products containing cannabinoids on the list is very small. Because consumers primarily seek other cannabinoids included in the calculation of total tetrahydrocannabinol (THC), such as delta-8, delta-9, and delta-10 THC when purchasing industrial hemp food products, the regulation will have a negligible impact. Additionally, cannabinoids on the list are prohibited when produced through chemical synthesis and added to food pursuant to existing California law. This regulation does not establish a prohibition against those specific cannabinoids, rather it clarifies the existing prohibition for both industry and consumers.
- 2. The creation of new businesses or the elimination of existing businesses within the state: The proposed regulations will not create any new businesses or eliminate any existing businesses in California due to the limited current consumer market for and existing prohibitions on the cannabinoids included in the list.
- 3. The expansion of businesses currently doing business within the state: The proposed regulations will not cause the expansion of businesses in the California hemp market due to the limited current consumer market for and existing prohibitions on the cannabinoids included in the list.
- 4. The benefits of the regulation to the health and welfare of California residents, worker safety, and the environment: The proposed regulations will benefit public health and safety of California residents by clearly identifying cannabinoids which must not be present above a limit of detection in industrial hemp final form food products. The proposed regulations will not impact worker

safety, the state's environment, or quality of life.

## SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

The proposed regulations will not have any significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Mandated Use of Specific Technologies, Equipment, Actions, or Procedures
The Department has determined the proposed regulations will have no mandated use of
specific technologies, equipment, actions, or procedures.

## LOCAL MANDATE DETERMINATION

The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

## **HOUSING COSTS**

The Department has determined that the proposed regulations would not have a significant impact on California housing costs.

#### FISCAL IMPACT ASSESSMENT

- A. Cost to Any Local Agency or School District: None.
- B. Cost or Savings to Any State Agency: None.
- C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.
- D. Cost or Savings in Federal Funding to the State: None.

#### **BUSINESS REPORTING REQUIREMENTS**

The proposed regulations do not impose a new reporting or recordkeeping requirement, as there already is an existing process. Currently, absent the proposed regulations, manufacturers are required to show a product is compliant with the industrial hemp program by submitting a Certificate of Analysis (COA) to the Department. The COA must include analytical results for multiple cannabinoids and other analytes. The proposed regulations would require analysis for more compounds but does not establish a new record keeping requirement.

## MANDATED BY FEDERAL LAW OR REGULATIONS

The Department has made the determination these regulations are not mandated by federal law or regulations.

<u>COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS</u> The Proposed Regulations are expected to have a negligible effect on a representative person or businesses (small or large).

**EFFECT ON SMALL BUSINESS** The Proposed Regulations are expected to have a negligible effect on small businesses. The Department has determined that that there is almost no viable consumer market for products with non-detectable levels of the 34 named cannabinoids.

## SPECIFIC TECHNOLOGIES OR EQUIPMENT

The Department has determined the proposed regulations will have no mandated use of specific technologies, equipment, actions, or procedures.

## **CONTACT PERSON**

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Kim Scrivner, Food and Drug Branch at: <a href="mailto:kim.woodscrivner@cdph.ca.gov">kim.woodscrivner@cdph.ca.gov</a>

All other inquiries concerning the action described in this notice may be directed to Dawn Basciano, Office of Regulations, at (916) 558-1710 or the designated backup contact person, Michael Boutros at (279) 217-0866.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-24-005B.

## **AVAILABILITY STATEMENTS**

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please

call (916) 558-1710 (or the California Relay Service at 711), send an email to <a href="mailto:regulations@cdph.ca.gov">regulations@cdph.ca.gov</a>, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audio format, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

## **FINAL STATEMENT OF REASONS**

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

## **INTERNET ACCESS**

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at <a href="www.cdph.ca.gov">www.cdph.ca.gov</a> by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.