

Initial Statement of Reason

SUMMARY OF THE PROPOSAL

The proposed regulations specify that intoxicating cannabinoids are 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). This proposed rulemaking action will make Section 23010 of the emergency regulations permanent. Please note that section 23010 “List of Intoxicating Cannabinoids” in the emergency regulations remains in effect for 18 months from September 23, 2024, pursuant to Health and Safety Code Section 111921.7(d).

FINDINGS

The Department may adopt regulations to include any other cannabinoid, in addition to those expressly listed in subdivision (l) of Section 111920, in the definition of “THC” if the Department determines that the cannabinoid causes intoxication, pursuant to Health and Safety Code Section 111921.7(b)-(d). Accordingly, the Department discusses its findings below.

The Department proposes to include additional cannabinoids in the definition of “THC”, or “THC or comparable cannabinoid” defined at Health and Safety Code Section 111920(l). The proposed additional cannabinoids cause intoxication at various levels, as supported by scientific and clinical research data. These cannabinoids have similar chemical structures to cannabinoids known to cause intoxication. Additionally, the proposed cannabinoids can cause serious side effects including seizures, organ damage, hallucinations, paranoia, vomiting, agitation, and in extreme cases even death, all of which are signs of intoxication that has led to an increase in hospitalization, poisoning, and increased emergency room visits across California and nationwide, highlighting the urgent need for regulation.

This finding is consistent with the Legislature’s finding, in Section 110065, subdivision (b), paragraph (3) of the Health and Safety Code, that “the initial adoption of emergency regulations and the readoption of emergency regulations authorized by this section shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.” Accordingly, the Department promulgated emergency regulations to include additional cannabinoids in the definition of “THC” or “THC or comparable cannabinoid”, and the Department is seeking in the proposed regulations to make these provisions permanent.

AUTHORITY AND REFERENCE

The Department is proposing 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.

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 the 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 (l) of Section 111920, in the definition of "THC."

Benefits:

List of intoxicating cannabinoids

AB 45 explicitly identifies only delta-8 THC, delta-9 THC, delta-10 THC, and THC acid (THCA) in the definition of "THC" or "THC or comparable cannabinoid." Currently, the Department's emergency regulations add additional intoxicating and potentially harmful cannabinoids to 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.

BACKGROUND

Existing state law

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 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. Industrial hemp inhalable products may be manufactured in California for the sole purpose of sale in other states. The sale of industrial hemp inhalable products 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 (l) 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 THC acid, delta-8 THC, delta-9 THC, and delta-10 THC and any intoxicating cannabinoid as defined by the Department to 0.3% of dry weight 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)). 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. Specifically, the Department proposes the following revisions to the emergency text:

- The list of intoxicating cannabinoids 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, to provide clarity 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 (l) of Section 111920, in the definition of “THC.” The proposed regulation works toward enhancing and protecting the public’s health.

Prior to the emergency regulations, anyone of any age could purchase industrial hemp products containing excessive concentrations of cannabinoids with limited safety data. Some manufacturers marketed their products to children with graphics and labels that mimicked brands of conventional candies and snacks.

Because industrial hemp food products are consumed and widely available, clear and effective regulations are needed to protect the public 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.

DETAILED DISCUSSION OF EACH REGULATION

The Department proposes to adopt the following section as follows:

Adopt Section 23010. List of Intoxicating Cannabinoids.

This section lists intoxicating cannabinoids included in the definition of “THC” or “THC or comparable cannabinoid” that must be included in the 0.3% total THC limit in industrial hemp extract.

Delta-8 THC, delta-9 THC, delta-10 THC, and THCA are defined as “THC” or “THC or comparable cannabinoids” in Section 111920(l) of the Health and Safety Code. This section lists cannabinoids added to the definition of “THC” or “THC or comparable cannabinoids.” The cannabinoids listed in this regulation were identified based on peer reviewed scientific literature demonstrating their psychoactive properties and potential to cause intoxication. This provision is needed because intoxicating cannabinoids, such as THC, forms of THC, and synthetic cannabinoids, can produce unpredictable and potentially dangerous side effects, including altered perception, loss of coordination, and increased heart rate. Unregulated use of these substances can lead to addiction, overdose, and long-term health consequences for all consumers. However, this is particularly important for vulnerable populations, such as individuals with pre-existing medical conditions and youth, who are more susceptible to the negative effects of intoxicating cannabinoids.

Regulators, retailers, and most importantly, consumers, can verify the content of intoxicating ingredients in industrial hemp products because manufacturers must provide lab testing results for extracts used in all industrial hemp products. Restricting the manufacture of intoxicating cannabinoids in industrial hemp products will reduce the adverse effects associated with consuming intoxicating cannabinoids. The Department has received complaints of injuries and illnesses within California caused by industrial hemp products with intoxicating cannabinoids. The Department is also aware of increasing numbers of emergency room visits in California, as well as cases where the use of intoxicating cannabinoids caused deaths outside of California.

The list of intoxicating cannabinoids 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 a 25 through 30 on the list of intoxicating cannabinoids, instead of the chemical formulas used in the emergency regulations, to provide clarity for the industry.

Though some of the listed cannabinoids occur naturally in extremely small amounts, when found in quantities in a product, the cannabinoids are produced through chemical synthesis. Cannabinoids produced through chemical synthesis are prohibited (Health and Safety Code Section 111920(f)) and the Department includes them here for clarity for the industry.

The Department has expressed authority to include any other cannabinoid to the definition of “THC” or “THC or comparable cannabinoid” if the cannabinoid causes intoxication (Health and Safety Code Section 111921.7). There is much scientific literature that supports THC and structurally similar cannabinoids as being intoxicating. For example, studies show THC and structurally similar cannabinoids impair cognitive functions such as attention, memory, and executive functioning. These effects vary with the method of consumption and dosage. Users report heightened drug effects, including elation and paranoia, which peak shortly after consumption. Common physiological symptoms include tachycardia, bradycardia, hypertension, and hypoxemia.

These and other studies underscore the complexity of intoxication due to the variability in individual responses to THC and other structurally similar cannabinoids.

The presence of non-detectable levels of intoxicating cannabinoids in a substance demonstrates that these compounds are either absent or present in such minimal quantities that they cannot be measured with current standard testing methods. Listing cannabinoids involves recognizing all potential intoxicating agents, including those that might be present at even lower than non-detectable levels.

The Department considered two alternatives: (1) a longer list of cannabinoids, and (2) no list of cannabinoids.

For alternative 1 (longer list of cannabinoids), the Department considered adding another 20 intoxicating cannabinoids, based on current scientific research, to the 30 intoxicating cannabinoids in the proposed regulation. This would mean the definition of “THC” and “THC or comparable cannabinoid” would include delta-8 THC, delta-9 THC, delta-10 THC, and THCA (as specified in statute); the 30 chemical compounds included in the proposed regulation; and 20 additional compounds. Alternative 1 would not have any clear current public health and safety benefits. The proposed regulations already constitute a substantially thorough current list of known intoxicating cannabinoids. Adding 20 more would represent a negligible increase of the share of hemp or cannabis derived products in the current U.S. market.

For alternative 2 (no list of cannabinoids) the Department considered eliminating

Section 23010, promulgated as an emergency regulation, by not following up with a permanent regulation. Thus, the definition of “THC” and “THC or comparable cannabinoid” would return to what AB 45 specifies in statute (delta-8 THC, delta-9 THC, delta-10 THC, and THCA). In other words, removing the list of 30 intoxicating cannabinoids would return the definition of THC to what is outlined in Health and Safety Code Section 111920 which provides, in part, “...any tetrahydrocannabinol, including but not limited to...”. Alternative 2 would result in confusion in the industrial hemp food market. Although this broad definition captures some of the 30 identified cannabinoids, they would no longer be explicitly stated in regulation. Additionally, removal of the list would imply those cannabinoids are allowable in industrial hemp food products. In fact, they would still be prohibited if produced through chemical synthesis. Alternative 2 would reduce clarity for stakeholders regarding which cannabinoids are included in the calculation of total THC and consequently could lead to the introduction of violative products in the market. Accordingly, the Department rejected both of these alternatives.

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CONSIDERATION OF REASONABLE ALTERNATIVES

The Department considered reasonable alternatives as addressed in Section 23010. The Department determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulatory action or would be more cost-effective to affected private persons.

ECONOMIC IMPACT ASSESSMENT

The Department made an initial determination these regulations would not have a significant statewide adverse economic impact directly affecting businesses, and/or individual consumers, including the ability of California businesses to compete with companies in other states. 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 or the ability of California businesses to compete with businesses in other states.

Determination of Local Mandate

The Department has further determined that the proposed regulations 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.

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.

Housing Costs

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

Determination of Significant Statewide Adverse Impact Directly Affecting Private Persons or Businesses, Including Ability to Compete

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

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 the analysis for more compounds but does not establish a new record keeping requirement.

Involvement with Affected Parties

The proposed regulations do not involve complex proposals or a large number of proposals that cannot easily be reviewed during the comment period. Instead, the proposed regulations are limited to only one subject.

The Department sought public input on the Emergency Regulations. As part of the emergency rulemaking process, a 5-day public comment period was provided for the first emergency promulgation and for the readoption, during which the Department received public feedback from stakeholders, industry representatives, and the general public. Additionally, the Department engaged in informal stakeholder outreach in September 2025 and later held a 45-day public comment period in which the public submitted comments regarding the regulations.