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FINDING OF EMERGENCY
Regulations for Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp
DPH-24-005E

The director of the California Department of Public Health (Department) finds that an emergency exists and that the proposed emergency regulations are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, and general welfare of Californians.

NOTICE AND INTRODUCTION

Notice is hereby given that the Department proposes to adopt the regulations described below. Government Code section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law (OAL), the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the OAL, the OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

DEEMED EMERGENCY

The Department has statutory authority to adopt emergency regulations to implement the industrial hemp program, and such emergency regulations are deemed to be an emergency and necessary for the immediate preservation of the public health and safety. Section 110065, subdivision (b), paragraph (3) of the Health and Safety Code states 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.”

FINDINGS

The Department may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health, pursuant to Health and Safety Code section 111921.3. Additionally, the Department may 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.

Age requirement

The Department proposes to impose an age requirement for the sale of certain industrial hemp products, as defined in Health and Safety Code section 111920. The proposed age requirement of 21 years of age for industrial hemp extract in its final form and industrial hemp final form food products intended for human consumption, including food, food additives, beverages, and dietary supplements, is necessary due to ongoing brain development in adolescents and young adults. Studies show that use of these products can negatively impact cognitive functions, memory, and decision-making abilities in developing brains. In California and nationwide, there have been significant reports of hospitalizations among teenagers and young adults, highlighting the health risks for these age groups. The proposed age requirement protects vulnerable populations from adverse effects on still-maturing brains and reduces associated public health threats. 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.”

Additionally, there could be compounds not dangerous for adults, and not included in the list of intoxicating cannabinoids, that could harm youth. For example, for CBD, despite being a more widely studied compound, health effects on youth continue to be uncertain.

Therefore, because the Department’s proposed list of intoxicating cannabinoids does not include all compounds, and because research on effects on youth are ongoing, the Department determined an age requirement serves to protect youth from what could be permanent and irreparable adverse health impacts.

List of intoxicating cannabinoids

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 department visits across California and nationwide, highlighting the urgent need for regulation.

AUTHORITY AND REFERENCES

The Department is proposing to adopt the proposed rulemaking under the authority provided in sections 100275, 110065, 111921.3, 111921.7, 111922, 111925, and 131200 of the Health and Safety Code.

The Department is proposing to add sections 23000, 23005, 23010, 23015, and 23100 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, 111920, 111921.3, 111921.7, 111921, 111922, 111925, 111925.2, 111926, 111926.2, 131095, and 131100 of the Health and Safety Code; and Part 101, Title 21 Code of Federal Regulations.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Purpose

These proposed regulations will specify the (1) serving and package size limits for total THC for industrial hemp final form food products intended for human consumption, (2) age requirement for offering or sale of industrial hemp extract in its final form or industrial hemp final form food products, and (3) intoxicating cannabinoids included in the definition of THC or “THC or comparable cannabinoid.” The proposed regulations will protect public health and safety by protecting youth and reducing risk of illness, injury, or death.

Background

Existing state law

Assembly Bill (AB) 45 (Chapter 576, Statutes of 2021) was signed by the Governor on October 6, 2021. 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. In current law, industrial hemp products cannot include total tetrahydrocannabinol (THC) of more than 0.3% (delta-8 THC, delta-9 THC, delta-10 THC) and THC acid. Industrial hemp products cannot include THC isolate as an added ingredient and cannabinoids produced through chemical synthesis. 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 inhalable products for sales out-of-state. Inhalable products may be manufactured in California for the sole purpose of sale in other states; sale of inhalable products in California is prohibited until the Legislature establishes a tax on 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. Enforcement may include:

- Regulatory warnings

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

Health and Safety Code sections 111922(a) and 111925(b) state that the Department “may determine maximum serving sizes for hemp-derived cannabinoids, hemp extract, and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements for foods and beverages,” and may “regulate and restrict the cap on extract and may cap the amount of total THC concentration at the product level based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed.”

Health and Safety Code section 111921.3 states that the Department “may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health.”

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.”

Federal law

Under the federal 2018 Farm Bill, industrial hemp is defined as the *Cannabis sativa* *Linnaeus* plant with a delta-9 tetrahydrocannabinol (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 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.

Current U.S. Food and Drug Administration (FDA) law is that cannabidiol (CBD) is an unapproved food additive, regardless of the source, and CBD in human food, dietary supplements and pet food are unapproved. Federally unapproved products are illegal to enter interstate commerce.

Policy Statement Overview

The proposed regulations focus on protecting our youth and public in general by identifying the serving size and package limits for total THC in final form food products intended for human consumption, setting age requirements, and prohibiting intoxicating cannabinoids in industrial hemp products.

The objective of these proposed regulations is to 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, and

to protect the public health and safety through regulation of industrial hemp products that may pose a threat and to prevent injury, illness, or death.

Serving and package size limits

Since AB 45 was signed in late 2021, many food and beverage products are produced with intoxicating levels of total THC, and some have caused illness, injury, and death. The current law allows for up to 0.3% of total THC for extracts in industrial hemp final form products with no limits on the serving size of total THC. Depending on the size of the product, an individual could receive significantly more THC in an industrial hemp product compared to a cannabis product. The proposed regulations clarify that there shall be no detectable amount of total THC in each serving size and package of industrial hemp final form food products intended for human consumption including food, food additives, beverages, and dietary supplements. Such an amount is not psychoactive and significantly decreases the risks associated with the products.

Age requirement for extract and human food

At present, there is no minimum age requirement for the sale of industrial hemp products, which could contain high amounts of total THC. Thus, anyone can purchase with no restrictions. By setting a minimum age requirement of 21 years, it will be clear that industrial hemp extract in its final form and industrial hemp final form food products intended for human consumption, including food, food additives, beverages, and dietary supplements, are not intended for sale to youth and may not be safe for youth to consume.

List of intoxicating cannabinoids

Under AB 45, only delta-8 THC, delta-9 THC, delta-10 THC, and THC acid (THCA) are explicitly identified in the definition of THC or “THC or comparable cannabinoid.” Adding additional intoxicating and potentially harmful cannabinoids to the definition of THC or “THC or comparable cannabinoid” will ensure that the presence of these cannabinoids in industrial hemp products is restricted to the limits of AB 45 and this regulation to ensure the safety of industrial hemp products.

EFFECT OF REGULATORY ACTION

This proposed action will add sections 23000, 23005, 23010, 23015, and 23100 to Subchapter 2.6 of Chapter 5 of Division 1 of Title 17 of the California Code of Regulations, as follows:

Add §23000. Definitions.

This section establishes definitions for Subchapter 2.6 as follows:

“Detectable” is defined as any amount of analyte, subject to the limit of detection. This definition is needed to further clarify provisions in the proposed regulations. By requiring no detectable amount of total THC, we establish a standard for what constitutes a level of THC or comparable cannabinoids that is below the threshold of detection, ensuring that any trace amounts present are not significant enough to cause impairment. This precision is crucial in maintaining safety standards and compliance with regulations related to intoxicating and harmful substances.

“Limit of detection” is defined as the lowest quantity of a substance or an analyte that can be reliably distinguished from the absence of that substance within a specified confidence limit. This definition is needed to further clarify provisions in the proposed regulations. The limit of detection provides a foundation for determining the presence or absence of the intoxicating cannabinoids.

Add §23005. Age Requirement for Extract and Human Food.

This section requires that a person cannot offer or sell industrial hemp extract in its final form or industrial hemp final form food products intended for human food consumption including food, food additives, beverages, and dietary supplements, to a person under 21 years of age. The age aligns with other restricted use products in California, such as tobacco, cannabis, and alcohol products. This provision is necessary to ensure individuals with developing biological systems are protected from potential acute reactions and long-term impacts which have not been fully studied. There have been complaints regarding the use of industrial hemp products by children, with associated illness, injury, and deaths.

Add §23010. List of Intoxicating Cannabinoids.

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

Delta-8 tetrahydrocannabinol (THC), delta-9 tetrahydrocannabinol (THC), delta-10 tetrahydrocannabinol (THC), and tetrahydrocannabinolic acid (THCA) are defined as THC or “THC or comparable cannabinoids” in the statutory definition at 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 named cannabinoids were selected based upon scientific literature that the cannabinoids are intoxicating. 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. This is particularly important for vulnerable populations, such as youth and individuals with pre-existing medical conditions, who may be 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 documented cases of injuries and illnesses within California caused by industrial hemp products with intoxicating cannabinoids, and there are known cases of the use of intoxicating cannabinoids causing death to persons located outside of California.

Add §23015. Severability.

This section provides that should a part of the regulation be challenged the Department's intent is that the remaining parts will remain in effect. This provision is needed to preserve the remaining, valid parts of the regulations to ensure the protection of public health and safety.

Add §23100. Serving and Package Size Limits.

Subsection (a): requires that an industrial hemp final form food product intended for human consumption including food, food additives, beverages, and dietary supplements shall have no detectable amount of total THC. This is needed to ensure products do not contain a scientifically detectable amount of total THC because of intoxicating effects and side effects on users. The Department has documented cases where high levels of total THC were found in food products that caused illness, injury, or death. Limiting the total THC in the serving sizes of products to a non-detectable amount reduces the risk of illness, injury, and death especially in children who may consume these products.

- Paragraph (1): requires each serving in a package to have no detectable amount of total THC. This is needed to ensure intoxicating cannabinoids are not included in final form food products. The identification of servings per package is a standard and common way of communicating to consumers the content in foods, beverages, and dietary supplements. Connecting total THC levels to this practice is necessary to further clarify provisions in the proposed regulations.
- Paragraph (2): requires each package to have no more than five servings. This is needed to ensure industrial hemp products are not packaged in a manner to provide high quantities of intoxicating cannabinoids to the consumer in a single package.
- Paragraph (3): requires that serving and package sizes must be determined using the same federal standards as non-industrial hemp food products. This is needed to clarify that industrial hemp food products must follow current established statutes for serving and package sizes for food, food additives, beverages, and dietary supplements. Using non-standardized serving and package sizes increases the potential for consumers to be exposed to high levels of total THC.

Subsection (b): provides that an independent testing laboratory must calculate and establish the limit of detection for all analytes in accordance with section 15731 of Title 4 of the California Code of Regulation as part of the chemical method verification or analysis. This provision is necessary to ensure testing results are accurate and in accordance with current scientific methods. Variations in methodology may yield inaccurate testing results and could lead to unintended cannabinoid exposure to consumers.

Subsection (c): provides that manufacturers of final form food products must prove their products do not exceed the serving size limits established in this subchapter. This provision is necessary to prevent products with THC above the limits which produce intoxicating effects when consumed. Otherwise, it may not be clear that manufacturers must show their process to ensure their products meet the law. This provision is necessary to prevent the inclusion of intoxicating cannabinoids in products for human

use so the Department can fulfill its mandate to oversee food manufacturing activities and protect public health from the adverse effects, including injury, illness, or death of the use of THC or other intoxicating cannabinoids.

Subsection (d): provides that a person cannot manufacture, warehouse, distribute, offer, advertise, market, or sell industrial hemp final form food products intended for human consumption including food, food additives, beverages, and dietary supplements that are above the limit of detection for total THC per serving. This provision is necessary to prevent the inclusion of intoxicating cannabinoids in products for human consumption so the Department can fulfill its mandate to oversee food manufacturing activities and protect public health from the adverse effects, including injury, illness, or death of the use THC or other intoxicating cannabinoids.

STATEMENTS OF DETERMINATIONS AND ECONOMIC IMPACT ASSESSMENT

The Department has determined that the proposed regulatory action would have a significant economic impact on California business enterprises and individuals.

EVALUATION AS TO WHETHER THE REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department has made a determination that 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 has determined that its regulations do 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).

MANDATED BY FEDERAL LAW OR REGULATIONS

The Department has made a determination that this proposal is not mandated by federal law or regulations.

LOCAL MANDATE

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.

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.

DOCUMENTS RELIED UPON

- A. Adams, T. K., Masondo, N. A., Malatsi, P., & Makunga, N. P. (2021). Cannabis sativa: From Therapeutic Uses to Micropropagation and Beyond. *Plants (Basel)*, 10(10). doi:10.3390/plants10102078

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- I. López-Olmos, C., García-Valverde, M. T., Hidalgo, J., Ferrerio-Vera, C., & Sánchez de Medina, V. (2022). Comprehensive comparison of industrial cannabinoid extraction techniques: Evaluation of the most relevant patents and studies at pilot scale. *Frontiers in Natural Products*, 1. doi:10.3389/fntpr.2022.1043147
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- M. Ohtsuki, T., Friesen, J. B., Chen, S. N., McAlpine, J. B., & Pauli, G. F. (2022). Selective Preparation and High Dynamic-Range Analysis of Cannabinoids in "CBD Oil" and Other Cannabis sativa Preparations. *J Nat Prod*, 85(3), 634-646. doi:10.1021/acs.jnatprod.1c00976
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CONTACT PERSON

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