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NOTICE OF PROPOSED RULEMAKING
Title 17, Chapter 5, Division 1, of the California Code of Regulations
Serving Size and Age for Industrial Hemp (DPH-24-005)

Notice Published June 13, 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 regulation 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: Dawn Basciano, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 558-1710, email to dawn.basciano@cdph.ca.gov or use the California Relay Service by dialing 711.

PUBLIC HEARING

The Department has scheduled public hearings to accept comments on the proposed action. Any person may present statements or arguments described in the Informative Digest. The Department requests, but does not require, that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Personal Information

California Department of Public Health

Office of Legal Services □ 1415 L Street, Suite 500, Sacramento, CA 95814

(916) 558-1710 □ (916) 440-5747 FAX

[Department Website \(www.cdph.ca.gov\)](http://www.cdph.ca.gov)



Date: Monday, July 28, 2025

Time: 10:00 A.M to 12:00 P.M.

Location: On-line (link below):

[Public Hearing: Serving Size and Age Industrial Hemp \(DPH-24-005\)](#)

Dial in by phone

[+1 916-306-8051..818135213#](#) United States, Sacramento

[Find a local number](#)

Phone conference ID: 818 135 213#

An agenda for the public hearing will be posted at the time and place of hearing location.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations on July 28, 2025, which is hereby 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:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-24-005" 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-24-005 Serving Size and Age Industrial Hemp, 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.

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 Regulations@cdph.ca.gov 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.

AUTHORITY AND REFERENCE

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

The Department is proposing to make permanent sections 23000, 23005, 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, 110390, 110395, 110398, 110400, 110660, 110680, 110760, 110765, 111920, 111921, 111921.3, 111922, 111925, 111925.2, 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 the (1) serving size limit for total tetrahydrocannabinol (THC), and package size limit, for industrial hemp final form food products intended for human consumption, and (2) age requirement for offering or sale of industrial hemp final form food products intended for human consumption. The proposed regulations will protect public health and safety by protecting consumers especially youth under 21 years of age 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 sections 23000, 23005, 23015, and 23100 of the emergency regulations permanent and also includes edits for consistency with the Department of Cannabis Control (DCC). 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). Thus, section 23010 is not included in this regulatory action.

BACKGROUND AND SUMMARY OF EXISTING LAWS AND REGULATIONS

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 THC acid). 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 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.”

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% 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 permanent sections 23000, 23005, 23015, and 23100 of the emergency regulations and include edits for consistency with DCC. Specifically, the Department proposes the following revisions to the emergency text:

- In proposed section 23000, the Department replaces the definition of limit of detection with a reference to DCC's related regulation at Title 4, California Code of Regulations, section 15700(jj) to clarify that the Department is aligned with DCC's definition. Additionally, the Department removes the letter and number hierarchy for ordering definitions.
- In proposed section 23100(b), the Department replaces specific methods with a reference to DCC's related regulation at Title 4, California Code of Regulations, section 15371 to clarify that the Department is aligned with DCC's regulations so that an independent testing laboratory must use DCC's method to calculate and establish the limit of detection (LOD).
- The proposed regulations are consistent with regulations of DCC. Testing laboratories servicing the industrial hemp industry are DCC approved or ISO/IEC 17025 accredited laboratories. Adherence to the exacting cannabis standards is necessary for industrial hemp products to protect consumers. Thus, the Department proposes to adopt DCC's definition of Limit of Detection (LOD) and to adopt DCC's three options for calculating the LOD for chemical method analyses. This ensures that testing laboratories follow a more standardized approach. This definition and these three options for LOD will produce valid testing results and avoid poor data quality and possible result fabrications.

Key policy elements of the proposed action

The Department's policy focus for the proposed regulations is on improving product safety and protecting consumers, especially protecting youth. The Department has explicit authority to establish regulations regarding age and serving size related to industrial hemp food products, and the proposed regulations all work toward enhancing and protecting the public's health.

Prior to the emergency regulations, anyone of any age could purchase these products containing excessive concentrations of cannabinoids with limited safety data. Some manufacturers marketed their products to children with graphics and labeling which 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.

Establishing a minimum age of 21 to purchase industrial hemp final form food products through this regulation helps the Department address consumption of cannabinoids by youth. This action protects them from the potential negative effects to their still developing bodies and brains.

Establishing a maximum of five servings per package helps the Department address accidental overconsumption by adults and consumers with little experience with cannabinoids.

Requiring each package of industrial hemp food products to contain no detectable amount of total THC helps protect purchasers of industrial hemp products who only want to consume non-intoxicating cannabinoids.

These actions combined allow the Department to protect consumers from accidental consumption of intoxicating cannabinoids and provide a clear regulatory framework for the industry to follow.

POLICY STATEMENT OVERVIEW

Problem Statement: Prior to the implementation of the emergency regulations, access to industrial hemp food products with excess levels of cannabinoids was unconstrained and underregulated. After AB 45 allowed for the lawful manufacturing and sale of some products, novel items began to appear in the marketplace that were not contemplated when the law was adopted. 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, and a death of a child occurred.

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 food 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 our youth and the public in general by setting the serving size limit for total THC, package size limit, and age requirement for industrial hemp final form food products intended for human consumption, including food, food additives, beverages, and dietary supplements.

Benefits:

Setting serving size limit for total THC and package size limit

AB 45 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 and no limits on servings per package. Currently, the Department's emergency regulations require that industrial hemp final form food products intended for human consumption must have no detectable amount of total THC per serving and require no more than five servings per package.

Prior to the emergency regulations, many hemp-derived food and beverage products were produced and sold with intoxicating levels of total THC, and some caused illness, injury, and death. Depending on the size of the product serving and how many servings are packaged together, an individual could receive significantly more THC in an industrial hemp food or beverage than in a cannabis product, which could impair a person, particularly youth. Many firms actively marketed their hemp products as having the same effect as cannabis, using statements such as a "full body buzz that'll have you feel like you're floating in zero gravity," "[t]he same potency edibles you'd find at a dispensary," "designed for the THC connoisseur craving that cosmic high without the hassle," "satisfy even the most experienced cannabis connoisseurs," and "[e]njoy a euphoric headspace."

The proposed regulations permanently clarify a serving size limit for total THC, and package size limit, for these products. These requirements mean the products are not psychoactive, significantly decreasing the risks associated with the products.

Age requirement for human food

AB 45 does not set an age requirement for the sale of industrial hemp products. Currently, the Department's emergency regulations require a minimum age of 21 for the sale of industrial hemp final form food products intended for human consumption. Prior to the emergency regulations, anyone could purchase these products with no restrictions. By permanently setting a minimum age requirement of 21 years, it will be clear that 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.

EFFECT OF REGULATORY ACTION

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 sections 23000, 23005, 23015, and 23100 of the emergency regulations permanent and also includes edits for consistency with the Department of Cannabis Control (DCC). 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). Thus, section 23010 is not included in this regulatory action.

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 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). This evaluation included a review of the Department's existing state regulations and those regulations specific to California Department of Public Health, Food and Drug Branch regulations. An internet search of other state agency regulations was also performed, and it was determined that no other state agency regulation addressed the same subject matter and that this proposal is not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that the regulations is not inconsistent or incompatible with existing state regulations.

DOCUMENTS INCORPORATION BY REFERENCE

The Department has made a determination these regulations are not proposing any incorporation by reference.

MANDATED BY FEDERAL LAW OR REGULATIONS

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

OTHER STATUTORY REQUIREMENTS

None

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 economic impact on California housing costs.

Disclosures Regarding the Proposed Actions

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

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPLETE

The Department has determined that the proposed regulatory action would have significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This regulation is considered a Major Regulation with a statewide impact of over \$50 million.

The Department has considered proposed alternatives that would lessen any adverse economic impact on business and invites you to submit proposals. Submissions may include the following considerations:

- (i) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses.
- (ii) Consolidation or simplification of compliance and reporting requirements for businesses.
- (iii) The use of performance standards rather than prescriptive standards.
- (iv) Exemption or partial exemption from the regulatory requirements for businesses.”

The following businesses will be affected:

- Retailers, including alternative or herbal medicine stores, smoke shops, grocery and food stores, wine stores, liquor stores, supermarkets, convenience stores, and superstores.
- Hemp growers, distributors and wholesalers.
- Hemp manufacturers.
- Restaurants, bars, and cafés.
- Licensed cannabis retailers.

STATEMENTS OF THE RESULTS OF THE STANDARDIZED REGULATORY IMPACT ASSESSMENT (SRIA)

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

The Department prepared a Standardized Regulatory Impact Analysis (SRIA), which is required for major regulations by the California Administrative Procedure Act. Due to its extensive length and in the interest of ease-of-reading, the SRIA is available as Attachment 1 of this document.

The Department has determined that the regulations affect the following as described:

- A. **The creation or elimination of jobs within the State of California.** The proposed regulations will create some jobs but eliminate others in California. See Attachment 1, SRIA, for further details.
- B. **The creation of new businesses or the elimination of existing businesses within the State of California.** The proposed regulations will eliminate some existing businesses in California. See Attachment 1, SRIA, for further details.
- C. **The competitive advantages or disadvantages of businesses currently doing business within the State of California.** The proposed regulations will create competitive advantages for some businesses and competitive disadvantages for other businesses currently doing business in California. See Attachment 1, SRIA, for further details.
- D. **The increase or decrease of investment in the state.** The proposed regulations are likely to decrease investment in California. See Attachment 1, SRIA, for further details.
- E. **The incentive for innovation in products, materials, and processes.** The proposed regulations could induce innovation. See Attachment 1, SRIA, for further details.
- F. **The benefits of the regulations, including but not limited to, benefits to the**

health, safety, and wellbeing of California's residents, worker safety, and the state's environment and quality of life. The proposed regulations will benefit public health and safety of California residents. See Attachment 1, SRIA, for further details

SUMMARY OF DEPARTMENT OF FINANCE REVIEW OF SRIA AND DEPARTMENT RESPONSE

Department of Finance comment #1: "[T]he SRIA estimates that total economic impacts would result in a loss of \$173 million in hemp market revenues in the first 12-month period following full implementation in 2025 for manufacturers, wholesalers, retail stores and delivery services, and decrease by \$897 million in the five-year period following full implementation (2025-2029)."

Department response: The numbers referenced do not reflect the actual estimates of decreases in California hemp market revenues. Below, for clarity, we state the correct numbers for estimates of decreases in revenues collected by all California businesses in the 12-month and five-year time period following implementation of the Proposed Regulations, compared with the AB 45 baseline:

Estimates (as shown in SRIA Table A2.0, p. 108), are as follows:

- Total revenue decrease of \$602 million in the first 12 months.
- Total revenue decrease of \$3.14 billion in the first five years.

Estimated direct revenue impacts on different categories of California businesses due to the Proposed Regulations, compared with the AB 45 baseline (see SRIA Table A2.0, p. 108):

- Manufacturers: Revenue decrease of \$120 million in the first 12 months and decrease of \$615 million in the first five years.
- Wholesalers: Revenue decrease of \$42 million in the first 12 months and decrease of \$227 million in the first five years.
- Carry-out retailers: Revenue decrease of \$392 million in the first 12 months and decrease of \$2.02 billion in the first five years.
- Food service retailers: Revenue decrease of \$47 million in the first 12 months and decrease of \$268 million in the first five years.
- All California businesses (sum of four categories): Total revenue decrease of \$602 million in the first 12 months and decrease of \$3.14 billion in the first five years. (These numbers correspond to the total revenue impacts stated above.)

To clarify further, \$173 million and \$897 million referenced in the comment are not

estimated revenue impacts or total market impacts, but rather Type II (induced) impacts on economy-wide *earnings* (corresponding roughly to corporate profits or net income), one of the estimates estimated by RIMS II models whose results (including impacts on value added and jobs as well as earnings) are shown in SRIA Table 4.2, p. 88.

Type II induced earnings estimates are one of several impacts and indirect economic “ripple effects” reported in the SRIA. Earnings impacts are not typically used as a primary indicator of economic impacts, and are not one of the central results of the SRIA.

Department of Finance comment #2: The Department of Finance requests “a fiscal impact analysis on how the proposed regulation impacts state and/or local government funding and enforcement and compliance costs,” and asks to “quantify any possible state revenue impacts, such as losses in sales tax revenue that may result from the business revenue losses.”

Department response: The primary fiscal impacts of the Proposed Regulations are losses in tax revenue resulting from revenue losses at businesses in California. These include impacts on sales and use tax revenue, cannabis excise tax revenue, and corporate income tax revenue.

Estimates of retail revenue impacts under the Proposed Regulations, as shown in SRIA Table 3.7, and economy-wide earnings impacts, as shown in SRIA table 4.2, are used to generate estimates of the impacts on state tax revenue.

Tax revenue impacts are calculated assuming a statewide average sales and use tax rate of 8.375% (including the 7.25% state sales tax plus a statewide average local sales tax rate of 1.125%), the current California cannabis excise tax of 19%, and the current California corporate income tax of 8.84%.

Retail revenue estimates are as follows: In the first 12 months after implementation, California retail revenue from hemp food and beverage products decreases by \$445 million, and revenue from licensed cannabis increases by \$6 million, for a net retail revenue decrease of \$439 million. In the first five years after implementation, retail revenue from hemp food and beverage products decreases by \$2.37 billion, and retail revenue from licensed cannabis increases by \$78 million, for a net retail revenue decrease of \$2.29 billion.

Earnings impact estimates are as follows: In the first 12 months after implementation, earnings decrease by \$173 million. In the first five years after implementation, earnings decrease by \$897 million.

Estimates of tax impacts of the Proposed Regulations, using the above estimates and tax rates as inputs, are as follows:

- Sales and use tax impacts

- o Decrease of $(\$439 \text{ million} \times 8.375\%) = \37 million in the first 12 months.
- o Decrease of $(\$2.29 \text{ billion} \times 8.375\%) = \192 million in the first five years.
- Cannabis excise tax impacts
 - o Increase of $(\$6 \text{ million} \times 19\%) = \1 million in the first 12 months.
 - o Increase of $(\$78 \text{ million} \times 19\%) = \15 million in the first five years.
- Corporate income tax impacts
 - o Decrease of $(\$173 \text{ million} \times 8.84\%) = \15 million in the first 12 months.
 - o Decrease of $(\$897 \text{ million} \times 8.84\%) = \79 million in the first five years.
- Total state tax impacts
 - o Decrease of \$51 million in the first 12 months.
 - o Decrease of \$256 million in the first five years.

The other fiscal impacts of the Proposed Regulations are limited to Department costs of administration, enforcement and other aspects of ensuring compliance with the Proposed Regulations. Given the limited consumer demand for hemp products with no detectable total THC, costs to State enforcement and compliance of enforcing the minimum age of 21 or no-detectable-total-THC standard are negligible.

- Total State Enforcement and Compliance Costs
 - o \$758,000 per year.

Department of Finance comment #3: “The SRIA states that 100 of the 115 manufacturers are assumed to be eliminated, while it also states that 50 businesses are estimated to need to comply with packaging redesign. The SRIA should clarify the number of manufacturers that would remain active in California and would be required to comply with the proposed regulations.”

Department response: The group of 50 businesses that must comply with packaging redesign (at an average cost of about \$20,000 per business, and an aggregate cost of \$1 million) is not the same group of businesses as the 15 manufacturers (of 115 current manufacturers) that would remain active with the Proposed Regulations in place.

In the California hemp market, as in the national hemp market, many manufacturers and distributors that package hemp products (e.g. gummies or beverages) are out of state and not required to be licensed with the Department. The majority of the 50 businesses facing relabeling costs due to the Proposed Regulations, at an average of \$20,000 per business, are out of state distributors/manufacturers rather than Department-licensed manufacturers.

Therefore, while there is some overlap between the 15 remaining Department-licensed hemp manufacturers and the 50 businesses that must comply with packaging redesign, these are two different and only partially overlapping groups, as some hemp manufacturers produce packaged products that are ready to sell at retail, whereas

others do not. In some cases, distributors or retailers package the products, and thus are the businesses that would incur repackaging costs. Of the 15 Department-licensed manufacturers remaining in the market, approximately 10 are expected to incur relabeling costs.

These estimates come with a particularly high degree of uncertainty, as the Department did not have access to information about the internal strategies, product assortments, or future contingency plans of hemp manufacturers.

Department of Finance comment #4: “Currently, the SRIA quantifies the total cost as equal to the revenue losses from the elimination of manufacturers, however, the SRIA should also include the total compliance costs for the manufacturers that will need to comply with the proposed regulation (separate from the revenue losses, but as part of the total economic cost analysis, without netting).”

Department response: Neither the age limit of 21 nor the no-detectable-total-THC standard in the Proposed Regulations imposes any costs on businesses manufacturing, distributing, or retailing, aside from the \$1 million (\$20,000 x 50 businesses, as described in SRIA Section 2.5 and clarified in Section 2 above) in aggregate costs of designing and manufacturing compliant packaging, and phasing out non-compliant packaging.

A small number of non-psychoactive CBD products will likely remain on the California market with the Proposed Regulations in place, resulting in the need for manufacturers of those products to reduce total THC content from current total THC levels (less than 0.3%) to a non-detectable level of total THC.

As discussed in the SRIA, CBD isolate and other cannabinoid isolates that contain no detectable total THC are costly. It is estimated that there were not any pre-existing hemp products in the California market, prior to the Emergency Regulations, that would have reliably complied with the no-detectable-total-THC standard. Many products previously available that were marketed as “CBD” had very low levels of total THC, but would still have been non-compliant with the Proposed Regulations due to trace amounts of total THC that would still be detectable at some level.

To comply with the Proposed Regulations (and Emergency Regulations), manufacturers need to use a purified CBD isolate that eliminates traces of total THC. Given that consumers who buy CBD products do not demand that they have no detectable total THC, producers had no reason to use the purified CBD isolate prior to the Emergency Regulations. Products that would be able to reliably comply with the Proposed Regulations would thus be newly designed products.

The need to use more costly ingredients to comply with the no-detectable-total-THC standard will not result in any direct economic costs to manufacturers, distributors, or sellers. The large majority of producers, distributors, and retailers will not enter the market for such products. In cases where businesses alter existing products to create

new no-detectable-total-THC products, it is estimated that such products will be offered at correspondingly higher prices to consumers at the wholesale and retail level; thus economic costs will not be imposed on hemp manufacturers, distributors, or sellers. Products, if any, that may have had non-detectable total THC levels prior to the regulations would not need to change their manufacturing processes and thus would not be expected to change their prices.

At this time, limited consumer demand exists for these new products at the higher price points that would be necessary for businesses (manufacturers, distributors, or retailers) to break even on manufacturing these products. Some businesses may nonetheless choose to manufacture, distribute, or retail no-detectable-total-THC products.

An estimated 100 of 115 businesses in the manufacturing segment will exit the California hemp manufacturing market, either by shutting down their businesses or by moving their businesses to another state. This is where some costs will arise.

Businesses incur certain costs (including legal costs, lease obligations, employee severance, service fees, moving and transportation costs, etc.) when they shut down or leave the California market for another state. In many cases, businesses that close must sell off their assets below market value, resulting in additional economic losses or take their assets out of state. Shut-down and dissolution costs are not currently covered in the SRIA, so estimates are added below.

It is estimated that no retail businesses will shut down as a direct result of the Proposed Regulations because hemp products are not the primary source of income for legal retail businesses in California.

Hemp manufacturing businesses in California vary widely by size, and financial information is not available for private companies (all businesses in the sector are currently private), so these estimates come with an unusually high degree of uncertainty. Closing and shut-down costs are estimated to range between \$5,000 and \$1 million per business, with an average of about \$75,000 per business, for a total of \$7.5 million in total costs for the 100 manufacturing businesses that will exit the market due to the Proposed Regulations.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

1. Compliance costs to businesses in California

As detailed in the SRIA, costs of re-labeling new compliant products are estimated at an average of \$20,000 per business for 50 businesses that will re-label such products, a total of \$1 million in costs in the first 12 months.

Closing and shut-down costs are estimated to average \$75,000 per business for 100 businesses that close, for a total of \$7.5 million in costs for the 100 manufacturing businesses that will exit the market due to the Proposed Regulations.

2. Compliance costs to private individuals in California

Consumers of certain hemp products with THC will substitute a significant portion of their in-state hemp purchases (e.g. purchases of hemp beverages) with purchases by mail order from out-of-state providers (prohibited products within California). Market prices are not significantly different for such products in other states, so it is estimated that there is no additional direct cost of purchasing hemp. However, such consumers will incur additional shipping costs from ordering out-of-state.

About 70,000 California residents (1% of California's 7 million regular cannabis users) who regularly consume hemp products would be likely to order hemp products by mail order, and would receive shipments about once per month (6 times per year), at an average shipping cost of \$7.50 per order, for a total cost of \$45 per year per hemp consumer, or \$3.15 million per year.

3. Enforcement compliance costs

The Department will incur costs of administration and enforcement, in compliance with the Proposed Regulations. The Department estimates these costs at \$758,000 per year.

4. Costs of revenue, earnings, and tax losses

As detailed in the SRIA, in addition to the direct out-of-pocket costs listed above, compliance and enforcement of the Proposed Regulations results in losses that are not direct "costs" in the sense of being necessary out-of-pocket *spending* of dollars on compliance or enforcement by businesses or individuals in California, but rather are direct, indirect, and induced costs incurred by businesses, individual, and the state.

The Proposed Regulations are estimated to result in first-year revenue losses of \$602 million to California businesses (\$120 million in losses to manufacturers, \$42 million in losses to wholesalers, and \$439 in losses to retailers) resulting the Proposed Regulations in the first 12 months; losses of \$173 million in earnings, which transfer from businesses to private individuals holding shares in California businesses; and losses of \$51 million in state and local tax collections.

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. THC is one of multiple cannabinoids on the COA that already is required. The proposed regulations now require a certain amount of total THC, which is a nondetectable amount, on the COA. Thus, the proposed regulation requires a certain result on the COA and is not a new reporting or recordkeeping requirement.

EFFECT ON SMALL BUSINESS

The Department has determined that the proposed regulatory action may affect small businesses.

The proposed regulations, compared with the AB 45 baseline, affects the following categories of small businesses as follows:

- Independent general-purpose small retailers (alternative or herbal medicine stores, smoke shops, grocery and food stores, wine shops, liquor stores, convenience store franchisees): Will lose an aggregate of \$1.9 billion in revenue and 5,567 jobs over 5 years.
- Small hemp growers, distributors and wholesalers: Will lose an aggregate of \$204 million in revenue and 112 jobs over 5 years. Ninety percent are small businesses.
- Small hemp manufacturers (About 111 of 115 industrial hemp businesses licensed by CDPH): Will lose an aggregate of \$586 million in wholesale revenue and 1,049 jobs over 5 years.
- Small restaurants, bars, and cafes: Will lose an aggregate of \$242 million in wholesale revenue and 2,449 jobs over 5 years.
- Licensed cannabis retailers: Will gain an aggregate of \$69.8 million in revenue and 232 jobs over 5 years. These numbers are comparatively low to retail sales lost in other sectors because demand for THC beverages are low through the licensed cannabis channel (1% of all licensed cannabis retail sales).

Small businesses, compared with larger businesses, are more sensitive (especially in terms of the risk of closing) to the types of revenue impacts above as well as the overall revenue impacts for the following reasons: (1) they are typically operating with less working capital reserves than larger businesses, (2) have a higher proportion of fixed to variable costs, and (3) thus face more direct threats of having to shut down due to a change in revenue.

Of all categories mentioned above, it is estimated--with the caveat that individual businesses vary widely in each of their financial stability--that retail businesses, particularly restaurants, bars, and small food stores, are the most sensitive to short-term changes in monthly revenue. Impacts to these businesses would be reflected in impacts estimated for revenue, jobs, and value added, but not in income.

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.

DETERMINATION OF SIGNIFICANT STATEWIDE ADVERSE IMPACT DIRECTLY AFFECTING PRIVATE PERSONS OR BUSINESSES, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that the proposed regulations would have a significant economic impact on California business enterprises and individuals. This regulation is considered a Major Regulation with a statewide impact of over \$50 million. The required SRIA is included as Attachment 1 to this document.

There are significant statewide adverse economic impacts directly affecting private persons and businesses in California, including ability to compete.

Statewide adverse economic impact directly affecting private persons or businesses

- The estimate is a total of \$3.14 billion in lost revenue to California businesses; \$1.19 billion in lost value added, \$666 million in lost earnings, and 13,522 jobs from Type 1 indirect impacts; and \$1.64 billion in lost value added, \$897 million in lost earnings, and 17,875 jobs from Type 2 induced impacts, in the 5 years after implementation.
- It is estimated a total of 115 businesses will close and 18,478 jobs will be lost in the 5 years after implementation.
- Impacts on revenue affect the ability of businesses to remain financially stable and economically viable, and to have sufficient monthly cash flow to cover overhead and operating costs. These impacts disproportionately affect small businesses.
- Impacts on value added directly affect businesses and represent the economic value in the supply chain that is eliminated by the proposed regulations.
- Impacts on earnings directly affect individuals in California, including owners and investors in businesses, and people with investment or savings accounts.

- Economic “ripple effects” estimated by Type 1 and Type 2 impacts, as discussed above, have financial impacts on a wide variety of private persons, across all regions of California, who work in a wide variety of industries.
- Businesses affected by Type 1 and Type 2 impacts are not limited to the categories mentioned above, but include a wide variety of businesses across industries in California.

Ability to compete

- All the businesses affected will experience a decrease in competitiveness, and manufacturing and processing of hemp products will move out of state.
- Out-of-state businesses and the illegal market will supply the California THC hemp market.
- About 100 CDPH-licensed hemp businesses will close or exit the California hemp manufacturing market.

Types of businesses affected

- Retailers, including alternative or herbal medicine stores, smoke shops, grocery and food stores, wine stores, liquor stores, supermarkets, convenience stores, and superstores.
- Hemp growers, distributors and wholesalers.
- Hemp manufacturers.
- Restaurants, bars, and cafés.
- Licensed cannabis retailers.

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 four subjects, one of which is a severability provision.

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.

The Department later conducted informal stakeholder engagement between April 4, 2025, and April 18, 2025, and received approximately 20 comments. The Department also will hold a 45-day public comment period during which the public may submit comments regarding the proposed regulations.

SUBSTANTIAL DIFFERENCE FROM FEDERAL REGULATION OR STATUTE

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

CONSIDERATION OF 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, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Department considered reasonable alternatives as addressed in related sections, specifically in section 23005 (Age Requirement for Human Food) and section 23100 (Serving and Package Requirements).

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Ashley Mills, Food and Drug Branch at: Ashley.mills3@cdph.ca.gov.

All other inquiries concerning the action described in this notice may be directed to Dawn Basciano, Office of Regulations, at (916) 558-1710 or to the designated backup contact person, Michael Boutros at (916) 949-3514.

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

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 regulations@cdph.ca.gov, 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: [DPH-24-005E Emergency Regulations for Serving Size, Age, and Intoxicating Cannabinoids for Industrial Hemp](#)