Initial Statement of Reasons

SUMMARY OF THE 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.

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. Accordingly, the Department discusses its findings below.

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 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.” Accordingly, the Department promulgated emergency regulations for an age requirement and is seeking in the proposed regulations to make the age requirement permanent.

Additionally, there could be compounds not dangerous for adults, and not included in

the list of intoxicating cannabinoids at Health and Safety Code section 23010, that could harm youth. Therefore, because Health and Safety Code section 23010 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.

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.

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.

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 includes 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 provides a clear regulatory framework for the industry to follow.

DETAILED DISCUSSION OF EACH REGULATION

The Department proposes to adopt the following sections as permanent regulations as follows:

Adopt Article 1. Definitions.

Adopt Section 23000. Definitions. This section provides definitions for the terms used throughout the text.

The adoption of these definitions is reasonably necessary to provide for uniform interpretation of the text, consistency in the terminology used in the proposed regulations, and to provide clarity to the regulated industry to effectuate the purposes of the enabling statute.

Adopt the term “detectable.” The Department proposes defining “detectable” as any amount of analyte, subject to the limit of detection (LOD). This definition is needed to further clarify provisions in the proposed regulations. Requiring no detectable amount of total THC means that any trace amounts present are not significant enough to cause impairment. This provision maintains safety standards and compliance with regulations related to intoxicating and harmful substances.

The term "detectable" is appropriate since it provides the concept that an analyte's

presence can be sensed in analysis. According to this definition, an analyte must be above the LOD to be considered detectable to prevent the analyte presence from being mistaken with background interference and to show that the analyte in a sample can be consistently found. Distinguishing background interference in an analytical tool means distinguishing extraneous information (which makes it difficult to accurately detect an extremely low concentration of THC from the surrounding food matrix) from the amount of analyte present (a true signal). This is analogous to distinguishing background noise in a crowded room when wanting to hear one whisper.

Adopt the term "limit of detection." The Department proposes defining "limit of detection" (LOD) to mean the same as in Title 4, California Code of Regulations, Section 15700(jj). This definition states: "Limit of detection" (LOD) means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit. This definition is needed to further clarify provisions in the proposed regulations. The LOD provides a foundation for determining the presence or absence of intoxicating cannabinoids, like total THC. Further, this clarifies that the Department is aligned with DCC's definition for the cannabis industry, which is a well-established industry, and thus testing laboratories are knowledgeable about LOD when testing these kinds of products.

This definition is commonly used in the laboratory testing industry and provides the basis of detection in analytical chemistry. Reporting the LOD is a necessary component of method validation as well as quality control procedures when conducting sample analysis. Accurate analysis depends on being able to distinguish a true signal from background interference. Statistical characteristics of detection provide a confidence limit, ensuring that the findings are statistically significant.

Industrial hemp food products have different and distinct characteristics. The LOD definition allows testing labs to establish a LOD using the most suitable methods to account for those unique profiles. The LOD in chemical analysis is highly dependent on the matrix type and the sensitivity and specificity of detection methods, making it essential to determine the LOD for each specific matrix-analyte combination.

The manufacturing industry has added industrial hemp extracts to a wide variety of food matrices, each with the potential for a different LOD. For example, a matrix could be chocolate or a gummy candy, and the analyte would be THC. The LOD for THC in food products containing industrial hemp can vary depending on the type of food (matrix) that is used. Chocolate and gummies are different matrices and the LOD would be different for these. Chocolate contains fats and other lipids, which can enhance the solubility and stability of THC. This may cause slower release that could impact the LOD by potentially increasing its level. In contrast, gummy candies are water-based products with gelatin, which may allow cannabinoids to release faster. This could result in a lower LOD because the THC is more readily available for detection. Chocolate and gummy candy hemp products are common but are not the only matrices used in the industry.

Overall, the matrix containing industrial hemp impacts how cannabinoids are released,

absorbed, and detected, leading to differences in the LOD between different matrices. Accurate chemical analysis requires a matrix-specific LOD determination to ensure reliable detection of analytes, and the proposed regulations allow for such various methodology to account for the variety of products to be tested.

Adopt Article 2. General Provisions.

Adopt Section 23005. Age Requirement for Human Food.
This section requires that a person cannot offer or sell industrial hemp final form food products intended for human 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. Further, other states also prohibit sale to those under 21 years of age, including Washington, New York, Alaska, and Rhode Island. 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 to the Department and also emergency visits to hospitals nationwide regarding the use of industrial hemp products by children and other youth under 21, with associated illness, injury, and death.

As stated above, 21 years of age is consistent with other restricted use products such as tobacco, cannabis, and alcohol products. Establishing the same standard for industrial hemp food products enables retailers to implement similar prohibition steps and more effective staff training. The age requirement applies only to final form food products and does not affect lawfully manufactured drugs, such as Epidiolex, which contains CBD. Such products are not considered foods, are manufactured under a different regulatory structure, and would still be available by prescription from a medical professional.

Industrial hemp food manufacturers often package and market their products with cartoons, images, and phrases used by youth under 21 years of age. Some have also used similar brand names and logos as other well-known, non-industrial hemp products leading to potential confusion in the marketplace. On July 15, 2024, the FDA and U.S. Federal Trade Commission issued a warning letter to an industrial hemp food product manufacturer in Florida employing such practices. The age limit is reasonably necessary to prevent youth access to such products.

Though these proposed regulations require no detectable amount of total THC in final form food products, these products could contain significant amounts of cannabinoids still under study and not prohibited by these regulations. Additionally, the no detectable amount of total THC standard does not eliminate all THC from products, due to the limit of detection; thus, consumption of large quantities of legal hemp food products could result in a person consuming enough THC to cause an adverse health effect. In light of there being no safe levels of THC for children, the no detectable amount of total THC standard along with the age restriction serve to more fully protect this vulnerable population.

The aim of the age restriction is to prevent access and reduce health risks associated with early exposure. The brain under the age of 21 is still developing, making it more susceptible to harmful substances. Early exposure to industrial hemp cannabinoids could have long-lasting impacts on cognitive development and mental health, such as influencing neural changes. Other negative effects may include drowsiness, fatigue, changes in appetite, diarrhea, and dry mouth. Fatal overdose can occur depending on the dosage and individual sensitivity.

The Department considered an age requirement of 18 years of age instead of the proposed 21 years of age. However, because the brain continues to develop past 18 years of age, it is susceptible to impacts from consumption of cannabinoids. The human brain, particularly regions responsible for decision-making, impulse control, and reward processing, continues to mature well into the early 20s (Johnson et al., 2009; National Institute of Mental Health, 2023; Squeglia et al., 2009). Limiting access to consumption of cannabinoids until 21 years of age reduces the likelihood of negative public health outcomes.

Early exposure to substances such as cannabinoids, could have long-lasting effects on cognitive development and mental health during the prenatal and childhood period (Hamidullah et al., 2020; Wanner et al., 2021; Winters & Arria, 2011). Further, a study about toxicity in children shows that ingested THC can lead to severe toxic effects in children under six years old, with very low doses being predictive of severe outcomes (Pepin et al. 2023). Another study shows THC exposure during adolescence can lead to long-term cognitive deficits, including impaired memory and learning, and long-term THC exposure during adolescence can disrupt neurodevelopmental processes, leading to synaptic pruning and altered emotional reactivity (Testai et al., 2022).

Thus, the scientific evidence, with these and other studies, suggests that a 21-year-old age limit for hemp-based products is a prudent measure to protect public health, particularly among young adults. Accordingly, the Department rejected the 18-year-old alternative. By delaying access to these substances until brain development is more complete, the potential long-term negative consequences can be mitigated.

Adopt Section 23015. Severability.
This section provides that should a part of the regulations 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.

The Department proposes to adopt this section to include a severability clause. This ensures that the group of regulations are in effect to protect public health and safety. Severability in regulatory language is necessary to ensure that any portion of the regulations affected by a successful and final legal challenge does not affect the validity of the remaining regulations. The benefit of severability language is to avoid this type of problem in advance. The related emergency regulations have already been subject to legal challenges making severability language important and relevant.

Therefore, this provision is necessary to make clear that if one or more provisions of these regulations are invalidated the remaining provisions shall continue in full force and effect. Courts generally presume that statutes and regulations are severable, and the severability statement here is intended to resolve any doubt as to the drafters' intent in this regard.

The doctrine of severability holds that upon finding a component of a regulation, statute, or provision to be unenforceable, inapplicable, or unconstitutional, a court may, in appropriate circumstances, excise the unenforceable, inapplicable, or unconstitutional part rather than declare the entire regulation, statute, or provisional framework invalid. One rationale for severance is that it can minimize judicial interference with administrative regulation making and thus honoring the administrative intent.

The doctrine is relevant given the legal challenge to these regulations that began when they were filed as emergency regulations. Any potential ruling that these regulations are partially invalid will give rise to questions concerning what to do with the valid remainder, making the severability clause highly relevant.

Adopt Article 3. Manufacture

Adopt Section 23100. Serving and Package Requirements.
Subsection (a). This subsection requires that an industrial hemp final form food product intended for human consumption including food, food additives, beverages, and dietary supplements shall have the following: non-detectable total THC per serving, each package shall have no more than five servings, and serving and package sizes shall be determined using the same federal standards for non-industrial hemp food products. A detailed discussion for each requirement is listed in (a)(1) through (a)(3).

Subsection (a)(1). The Department proposes that each serving in a package has 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. Additionally, similar to California, two other states (Washington and Alaska) have established requirements of no detectable THC in 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.

THC is the primary psychoactive component in cannabis, responsible for the "high" sensation. Non-detectable total THC in a food demonstrates that total THC either is

absent or is present in such minimal quantities that it cannot be measured with current standard testing methods. Products with non-detectable total THC levels are safer for a number of reasons described below.

Protect children from injury and death. Non-detectable total THC will enhance protection against accidental harm in children. Data corroborating public health harm was published by the American Academy of Pediatrics in 2023, showing that from 2017 to 2021 there were 7,043 reported cases of pediatric exposures to edible cannabis products nationwide, with 22.7% requiring hospitalization.

Pertinent data also exists from the California Overdose Surveillance Dashboard, maintained by the Department's Substance and Addiction Prevention Branch, which collects and analyzes data on fatal drug-related overdoses and risk factors, non-fatal drug-related overdoses, and more. Data from the California Overdose Surveillance Dashboard shows that although the overall emergency room visits caused by non-fatal acute poisonings from cannabis products decreased from 2019 to 2023 for the population as a whole, emergency room visits increased overall for children ranging from less than 5 years old up to 14-year-olds. For 10- to 14-year-olds, emergency room visits increased approximately 74% in 2022 and 2023 after AB 45 became effective in October 2021.

Also, the National Center for Complementary and Integrative Health, one of the 27 institutes of the National Institutes of Health, which conducts and supports research and provides information about health practices including information on cannabis and cannabinoids, identified concerns about the safety of cannabinoids. Concerns include that adolescents using cannabis are four to seven times more likely than adults to develop cannabis use disorder, and that among a group of people who became ill after accidental exposure to candies containing THC, the children generally had more severe symptoms than the adults and needed to stay in the hospital longer.

Protect adults from injury and death. Non-detectable total THC will enhance protection against accidental harm in adults. The Department's investigations found many products that exceeded the limit in legal cannabis products in California, including a gummy product containing 50 milligrams of THC per gummy, which far exceeds the legal limit for licensed cannabis.

According to the Centers for Disease Control and Prevention (CDC), from 2010 to 2015, three deaths were recorded where synthetic cannabinoids were involved, either as the sole agent or with multiple agents.

Protect against dependency and side effects. Non-detectable total THC avoids the psychoactive effects that can impair judgment and motor skills and also reduces the risk of dependency. THC can lead to dependency and has side effects like short-term memory impairment and anxiety. THC can impair judgment and motor skills, increasing the risk of accidents, particularly in people who need to stay alert like those driving vehicles or operating machinery. THC also negatively interacts with some enzymes in

the human body.

Non-detectable total THC also helps to protect against unfavorable drug interactions. THC can alter the effects of medication, thus increasing the risk of adverse events or reducing medication effectiveness. For example, THC can alter the effectiveness of various medications, including anticoagulants (blood thinners) and immunosuppressants (drugs to treat autoimmune diseases and used after organ transplants). THC affects the body in that the body cannot effectively break down some medications and may cause high levels of medication in the bloodstream.

Protect against mislabeling and inconsistent potency. Non-detectable total THC helps to protect against mislabeling and inconsistent potency. The Department is aware of many mislabeled products sold or offered for sale to consumers. All consumers, and especially youth, could be exposed unknowingly to products that contain more cannabinoids than what the labels show, thus leading to potentially serious adverse effects. The National Center for Complementary and Integrative Health, maintained by the National Institutes of Health, identified a concern that some products contain amounts of cannabinoids that differ substantially from what is stated on the label.

The Department considered and rejected three alternatives, in favor of the proposed no detectable amount of total THC. The Cannabis Economics Group of the University of California Davis, who wrote the Department's Standardized Regulatory Impact Assessment (SRIA), selected the following alternatives: Alternative 1 sets the maximum allowable total THC limit per package of hemp at 50 milligrams, Alternative 2 sets the maximum at 10 milligrams per package, and Alternative 3 sets the maximum at 5 milligrams per package. These three alternatives are within the limits set by some states, though Alaska and Washington are similar to California in requiring no detectable amount. Despite some states allowing up to 50 milligrams per package, the Department rejected the alternatives for two primary reasons.

First, the Department rejected the alternatives because the alternatives do not align with federal standards. As discussed in more detail above, industrial hemp THC is an unapproved food additive and prohibited in food products pursuant to federal law. Specifically, the FDA prohibits industrial hemp derived unapproved food additives like THC in food, beverages, and dietary supplements. In contrast to the alternatives, the proposed no detectable amount of total THC aligns with federal standards.

Second, the Department rejected the alternatives because they do not provide the same public health and safety benefits compared to the proposed regulation. The alternatives allow 5, 10, and 50 milligrams per package. Five milligrams is a psychoactive or "intoxicating" dose of THC sufficient to feel mind-altering effects. As discussed above in more detail, because the alternatives allow for consumption of total THC in food and beverage products, consumers purchasing intoxicating items would be exposed to psychoactive effects that can impair judgment and motor skills, and expose consumers to risks of dependency, side effects, illness, and injury. The Department has received complaints of injury, illness, and one death of a child associated with the consumption of

hemp-derived THC in food, and data and studies corroborate public health harm. Thus, the alternatives do not provide the same public health and safety benefits compared to the proposed regulation.

As a result, for the reasons above, the Department rejected the alternatives in favor of the proposed no detectable amount of total THC per serving.

Subsection (a)(2). The Department proposes that each package has no more than five servings. This is needed to ensure industrial hemp products are not packaged in a manner to provide excessive amounts of cannabinoids to the consumer in a single package.

Five servings per package is necessary because it will protect against unintentional over-consumption of cannabinoids. The products subject to the emergency regulations are often marketed and packaged similarly to conventional, non-industrial hemp containing food products. Five servings per package keeps consumer intake within safe levels for an average adult's body weight.

Current research is inconclusive and not exhaustive regarding the impacts of all cannabinoids in a food product. For example, prescription drugs Marinol and Syndros contain synthetic delta-9 THC to treat loss of appetite causing weight loss in people with AIDS and to treat severe nausea and vomiting in those undergoing cancer chemotherapy. Marinol comes with a warning that it may cause new or worsening psychosis, while a common side effect of Syndros is acute cognitive impairment. Marinol and Syndros, as prescriptions drugs, are regulated by the FDA drug approval process and dispensed by licensed healthcare professionals, all of which offer many consumer protections while industrial hemp final form food products, regulated as food, do not. Thus, a package size limit for industrial hemp food products is reasonable to protect public health.

Many other cannabinoids with similar impacts may be present in industrial hemp extracts added to food with much less conclusive data demonstrating safety. Limiting the number of servings in a package may be an effective way to reduce the likelihood of accidental overconsumption of the myriad of under-researched cannabinoids.

Additionally, relying exclusively on label instructions to limit the amount of industrial hemp final form food products consumed per eating occasion may be ineffective. Consumer response to food labeling information varies based on a number of factors, including, but not limited to the consumer's background, the specific nutrient, as well as general consumer awareness of the issue. To promote healthy eating, the FDA has promoted several initiatives including updating consumer-facing labeling and educational campaigns. Limiting the number of servings in a package of industrial hemp food products is consistent with these initiatives and protective of public health.

The Department considered 10 servings per package, instead of the proposed 5

servings per package. Industrial hemp food products come in a variety of forms including, but not limited to beverages, candy, powders, and pills. Since each product has a different reference amount customarily consumed (RACC) per eating occasion established in federal regulation and, consequently a different serving size, the Department sought a limit per package which could be implemented by the industry and prevent accidental over-consumption of cannabinoids. It was determined that 10 servings per package was not a practical limit for some product categories, such as beverages, and thus the Department rejected the 10 servings per package alternative. The proposed 5 servings per package is preferred because it is a more conservative approach to protecting public health from cannabinoids that are not well-studied.

Subsection (a)(3). The Department proposes 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.

The Department proposes that the serving and package sizes be determined using the same federal standards as non-industrial hemp food products unless specified in Subchapter 2.6 (Industrial Hemp) or Part 5 of Division 104 of the Health and Safety Code. The FDA has standardized the overarching requirements for food labels in Title 21 Code of Federal Regulations, Part 101, including provisions for serving sizes of food products based on the size of the package of food and the reference amounts customarily consumed per eating occasion. These standards are widely known and required to be implemented by non-industrial hemp food manufacturers to provide consistent nutrition information and enable consumers to make informed buying decisions in the marketplace. Industrial hemp food manufacturers must comply with California law on food manufacturing by obtaining a Processed Food Registration (PFR) per Health and Safety Code section 111923.3. Having a PFR means the industrial hemp food manufacturer must follow Sherman law, which incorporates the FDA standards for serving and package sizes.

Subsection (b). This subsection requires that an independent testing laboratory must calculate and establish the LOD for chemical method analyses according to Title 4, California Code of Regulations, Section 15371. Section 15371 lists three methods: (1) Signal-to-noise ratio of between 3:1 and 2:1; (2) Standard deviation of the response and the slope of calibration curve using a minimum of 7 spiked blank samples calculated as follows; LOD = (3.3 x standard deviation of the response) / slope of the calibration curve; or (3) A method published by the United States Food and Drug Administration (FDA) or the United States Environmental Protection Agency (EPA). 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.

The use of an independent testing laboratory for verification and analysis of samples is

important to ensure process integrity and prevent potential conflicts of interests. Use of an independent testing laboratory is required pursuant to HSC section 111925 and is defined pursuant to HSC section 111920(e).

This provision means that the independent testing laboratory is responsible to calculate and establish its own LOD for the test following one of the three methods that are well-established requirements in the cannabis industry. Testing laboratories servicing the industrial hemp industry are Department of Cannabis Control approved or ISO/IEC 17025 accredited laboratories familiar with the widely used options. Adherence to the exacting cannabis standards is necessary for industrial hemp products to protect consumers.

Proposed subsection (b) specifies that the laboratory is responsible for calculating and establishing its own LOD for the test following one of the options in Title 4, California Code of Regulations, Section 15371. There are several methods and approaches from various sources, such as the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Association of Official Analytical Chemists (AOAC), and the American Chemical Society (ACS) to determine LOD for analytical quantitation in different matrices and using different instruments. LOD is the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit. LOD is one of the important performance characteristics in method validation and helps to make decisions based on the uncertainties and limitations associated with these reporting limits.

To ensure the testing laboratories follow a more standardized approach, the Department's proposed regulations require that the three options in Title 4, California Code of Regulations, Section 15371 guide testing laboratories in the calculation of LOD.

These three options for LOD will produce valid testing results and avoid poor data quality and possible result fabrications.

In the first option, the Department proposes that an independent laboratory may calculate and establish the LOD for THC by using a signal-to-noise ratio of between 3:1 and 2:1. This method guides the LOD calculation based on signal-to-noise ratio. The determination of the signal-to-noise ratio is performed by comparing measure signals from samples with known low concentrations of analytes with those of method blank samples and establishing the minimum concentration at which the analyte can be reliably detected. A signal-to-noise ratio of between 3:1 and 2:1 is acceptable for estimating the LOD. This proposed approach is described by the FDA's guideline.

In the second option, the Department proposes that an independent laboratory may calculate and establish the LOD for THC by using the standard deviation of the response and the slope of calibration curve using a minimum of 7 spiked blank samples calculated as follows: LOD = (3.3 x standard deviation of the response) / slope of the calibration curve. This method guides the LOD calculation based on the standard

deviation of the response and the slope of calibration curve. Standard deviation of the response can be determined using minimum 7 spiked blank samples or the standard error of the calibration curve can be used instead of the standard deviation. The LOD may be calculated as follows:
LOD = 3.3 x standard deviation of the response / slope of the calibration curve

This proposed approach is also described in the FDA's guideline. According to the FDA guideline, as a part of the analytical procedure control strategy, analytical procedure parameters is needed for the system suitability test (SST).

In the third option, the Department proposes that an independent laboratory may calculate and establish the LOD for THC by using a guideline or method published by the FDA or the EPA. Because in some situations there may be some technical difficulties with using the FDA calculations or not available to get the baseline noise data, the Department offers more options as other methods published by the FDA or the EPA such as method detection limit (MDL) using blanks and spike samples. Another reason for this third option is that some laboratories may already have procedures to determine LOD based on reliable published methods.

Subsection (c). This subsection requires that manufacturers of final form food products must prove their products do not exceed the total THC per serving size limits established in Subchapter 2.6 (Industrial Hemp). This provision is necessary to prevent products with total 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 total THC as specified 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 of total THC.

More specifically, the Department proposes that a manufacturer of industrial hemp final form food product must provide documentation that includes a certificate of analysis from an independent testing laboratory to confirm the amount of total THC in the final form food product does not exceed the total THC per serving size limits as set forth in Subchapter 2.6 (Industrial Hemp). Food manufacturers already must provide inspection records that have a bearing on whether the product is adulterated, misbranded, or falsely advertised, pursuant to Health and Safety Code section 110140. A certificate of analysis from a laboratory is a widely used document in food manufacturing and frequently provided by reputable laboratories for a variety of analytes.

An industrial hemp food product that has a Certificate of Analysis showing no detectable total THC, using a LOD established by one of the acceptable methods listed in section 23100 subdivision (b), would be sufficient to show compliance with no detectable total THC standard.

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

Subsection (d). This subsection requires 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 LOD for total THC per serving. This provision is necessary to prevent the inclusion of total THC as specified 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 of total THC.

This provision addresses the physical movement of products throughout the supply chain, as well as advertising and marketing. First, regarding the supply chain, this provision establishes the restriction of total THC from the initial steps of formulating and manufacturing, through distribution and sale of final form food products throughout the supply chain using terms common to the food industry.

Second, this provision not only applies to moving of product in the physical supply chain but also to advertising and marketing. Industrial hemp products have been advertised with claims typically used in the cannabis edible marketplace, including language that is suggestive of the product having an intoxicating effect. To protect the public health, this provision prohibits advertising and marketing of industrial hemp human food products that are above the limit of detection for total THC per serving. This provision also prohibits any advertising and marketing that falsely claims that a product is intoxicating, which is consistent with existing Sherman law prohibiting false advertisement and misbranding at Health and Safety Code section 110390, 110395, 110398, 110400, 110660, 110680, 110760, and 110765. This provision ensures that people engaged in advertising and marketing comply with the limit of detection for total THC per serving, thereby further protecting the public health.

This provision is necessary to make clear that all aspects of the supply chain as well as advertising and marketing must align with the LOD for total THC per serving, which is set at no detectable amount of total THC. This provision also makes clear the distinction between industrial hemp final form food products and products in the cannabis edible market.

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CONSIDERATION OF REASONABLE ALTERNATIVES

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). 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.

STATEMENTS OF DETERMINATIONS and STANDARDIZED REGULATORY IMPACT ASSESSMENT (SRIA)

In addition to the following determinations, 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.

Determination of Local Mandate

The Department has determined that the proposed regulations will 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 will 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 regulations will have a significant economic impact on California business enterprises and individuals. The proposed regulations are considered a Major Regulation with a statewide impact of over $50 million. The required SRIA is included as Attachment 1 to this document.

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.