

**The Safe Drinking Water and Toxics Enforcement Act of 1986
Proposition 65**

Final Statement of Reasons

Title 27, California Code of Regulations

Adoption of Article 6, Sections 25607.38 – 25607.47

**Safe Harbor Warnings for Exposures to Cannabis (Marijuana)
Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC)**

June 2022



**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

Contents

General Information.....	3
Overview of New Sections 25607.38 – 25607.47	3
Process and Timeline	3
Update of Initial Statement of Reasons.....	4
Modifications to the Proposed Rulemaking	4
September 17, 2021 Modifications.....	4
May 20, 2022 Modifications	4
Summary of and Response to Comments Received on the March 2021 Proposed Regulations	5
General Comments.....	6
Need for Cannabis and THC Specific Safe Harbor Warnings	6
Requests to Delay Proposed Regulations.....	9
Potential Cost Impact of Proposed Regulations on Business	10
Warning Methods.....	12
Warning Language.....	14
Miscellaneous Comments.....	15
Comments Beyond the Scope of Proposed Regulations	16
Summary of and Response to Comments on September 2021 Modification of Proposed Regulations	18
Summary of and Response to Comments on May 2022 Modification of Proposed Regulations	19
Local Mandate Determination	20
Alternatives Determination	21

General Information

This is the Final Statement of Reasons for the adoption of Sections 25697.38 through 24607.47 into Title 27 of the California Code of Regulations¹. The new sections address exposures to listed cannabis (marijuana) smoke and Delta-9-THC.

Overview of New Sections 25607.38 – 25607.47

The new regulations provide non-mandatory, specific safe harbor exposure warning methods of transmission and content for retail products that can expose consumers to cannabis (marijuana) smoke or delta-9-THC via inhalation, ingestion, or dermal application, and for environmental exposures to cannabis smoke and delta-9-THC at businesses where smoking of cannabis or vaping or dabbing of delta-9-THC occurs. The safe harbor warning content for these regulations identifies the chemical, route of exposure and provides specific information to consumers about the risks of using cannabis products including cancer and, while pregnant, the impact exposures can have on the unborn child. Due to the importance of informing consumers of the risks posed to a pregnant woman's unborn child the safe harbor warning methods of transmission prohibit the use of the general short form warning in Section 25602(a)(4).

Process and Timeline

The Office of Environmental Health Hazard Assessment (OEHHA) published the Notice of Proposed Rulemaking and Initial Statement of Reasons (ISOR) for this action on March 19, 2021, initiating a public comment period that was to close on May 17, 2021. On March 26, 2021, OEHHA received a request for a public hearing. The public hearing was held on May 10, 2021, and the comment period was extended to May 24, 2021, to allow for comment submissions up to 14 days after the hearing date.

Following careful consideration of the relevant comments received during the initial comment period, OEHHA published a Notice of Modification to Proposed Text on September 17, 2021 and initiated a 15-day comment period on the proposed modifications, which closed on October 4, 2021. OEHHA received two public comments during the 15-day comment period.

After further consideration, OEHHA determined that a second modification to the text was necessary to provide further clarity regarding the one year phase-in period and sell-

¹ All further citations are to sections of Title 27 of the California Code of Regulations, unless otherwise stated.

through provisions introduced in the September 2021 modifications. OEHHA published a Notice of Second Modification to Proposed Text on May 20, 2022, and initiated a 15-day comment period that closed on June 6, 2022. OEHHA received three public comments.

The summary of and responses to the comments received during the comment periods on the original proposal and September 2021 and May 2022 modifications are incorporated in this Final Statement of Reasons (FSOR).

Some comments received during the regulatory process were not relevant because they were not specifically directed at the proposed action, or procedures followed in this rulemaking action². OEHHA has no obligation under the Administrative Procedure Act (APA) to respond to irrelevant comments received during the rulemaking process. The absence of responses to such comments should not be construed to mean that OEHHA in any way agrees or disagrees with them.

Update of Initial Statement of Reasons

As authorized by Government Code Section 11346.9(d), the Office of Environmental Health Hazard Assessment incorporates by reference the ISOR and second 15-day notice prepared for this rulemaking. Unless specifically discussed otherwise below, the ISOR's stated bases for the necessity of the proposed regulations continue to apply to the regulations as adopted. All modifications from the initial proposed text of the regulation are summarized below.

Modifications to the Proposed Rulemaking

September 17, 2021 Modifications

In the Notice of Modifications to Proposed Text published on September 17, 2021, OEHHA proposed amendments to the text of the proposed regulations. These amendments provided a one year phase-in period for the regulations and provided an unlimited sell-through provision for products manufactured and labeled with compliant warnings before the end of the one year phase-in period. Details and further descriptions of the changes are provided in the Notice of Modification of Text and the modified text.

May 20, 2022 Modifications

² Government Code 11346.9 (a)(3).

In the Second Notice of Modifications to Proposed Text published on May 20, 2022, OEHHA proposed modifications that clarify language originally proposed in the first modification released for comment in September 2021. They restructure the September 2021 one year phase-in period and sell-through provisions to be clear that safe harbor warnings for consumer products are compliant for the first year after the regulations become effective so long as they are compliant with the general safe harbor warning method and content in the existing regulations, *or* the new tailored warning provisions. Products manufactured before the end of the one year phase-in period that are labeled with the general consumer warning (Sections 25602 and 25603) need not be relabeled. Additionally, these modifications provided clarification that warnings for environmental exposures to cannabis smoke and delta-9-THC in designated smoking, vaping and dabbing areas are compliant for one year after the effective date if they use the existing general safe harbor warning method and content (Sections 25604 and 25605) *or* the new tailored warning methods and content. Details and further descriptions of the changes are provided in the May 20, 2022, Second Notice of Modifications to Proposed Text and the Second Modified Regulation Text.

Summary of and Response to Comments Received on the March 2021 Proposed Regulations

The following organizations and individuals submitted oral comments at the May 10 public hearing or written comments during the March 17, 2021 to May 24, 2021 comment period on the proposed regulations:

American Herbal Products Association (AHPA)	Darren Story (DStory)
Leland Parachini Steinberg (LPS)	Gary Valasek (GValasek)
Shryne Group inc. (Shryne)	Getting it Right from the Start (GIRFS)
Anonymous	Joel Eberstein (JEberstein)
Brooklyn Branson (BBranson)	MVM Strategy Group for CMG/Caliva (CMG/Caliva)
California Cannabis Industry Association (CCIA)	Natura Life + Science and Body and Mind - Traci Stevens (TStevens)
CannDESCENT	Personal Care Products Council (PCPC)
CleanEarth4Kids.org (CE4K)	William Perno (WPerno)
Cresco California (Cresco)	Winters LLP (Winters)

The comments are summarized and responded to below.

General Comments

Need for Cannabis and THC Specific Safe Harbor Warnings

Comment 1 (BBranson, CE4K, GIRFS, and WPerno): These commenters support the proposed warnings for exposures caused by cannabis smoke and delta-9-THC. BBranson states a clear warning that includes the risk of cancer and developmental harm associated with smoking, vaping or dabbing cannabis should be required. CE4K supports the proposed warnings because multiple studies have shown cannabis use by pregnant women in California has increased and cannabis and delta-9-THC products are being marketed in a way that attracts youths. GIRFS and WPerno state they support the proposed warnings because research has shown pregnant women who live within a 15-minute drive of a cannabis dispensary are more likely to use cannabis than pregnant women who live more than a 15-minute drive from a dispensary.

Response: OEHHA acknowledges the commenters support of the proposed safe harbor warnings for cannabis (marijuana) smoke and delta-9-THC.

Comment 2 (AHPA and CannDESCENT): AHPA stated that OEHHA has not made clear why safe harbor warnings are being developed for cannabis (marijuana) smoke and delta-9-THC. There is no evidence that exposure to cannabis (marijuana) smoke or delta-9-THC causes greater risk of developmental or reproductive harm when compared to the many other listed developmental and female reproductive toxicants that do not have safe harbor warnings.

CannDESCENT stated that the proposed regulations constitute an arbitrary and capricious action because the proposed warnings only pertain to cannabis (marijuana) smoke and delta-9-THC, not other listed chemicals such as tobacco smoke or nicotine.

These commenters also stated that there is not sufficient evidence for OEHHA to determine that cannabis or delta-9-THC use among pregnant women has been increasing and the material relied upon by OEHHA for that conclusion does not prove use by pregnant women is increasing.

Response: OEHHA has adopted specific safe harbor warning regulations for a variety of chemicals, products, and places. To date, OEHHA has adopted 18 specific warnings, including one for environmental exposure to tobacco smoke. These regulations provide non-mandatory guidance on how to provide a “clear and reasonable” warning as required by Proposition 65.

The ISOR explained OEHHA's reasoning concerning this warning proposal stating:

“[m]arijuana (cannabis) smoke was added to the Proposition 65 list as a carcinogen on June 19, 2009, based on findings by the Carcinogen Identification Committee. On January 3, 2020, based on findings by the Developmental and Reproductive Toxicant Identification Committee, OEHHA added cannabis (marijuana) smoke and delta-9-tetrahydrocannabinol (delta-9-THC) to the Proposition 65 chemical list for developmental toxicity. In accordance with Proposition 65, the warning requirement for newly listed chemicals takes effect 12 months from its effective listing date.³¹ To assist businesses affected by this listing, OEHHA determined it is necessary to adopt safe harbor warning regulations that address exposures to cannabis products intended to be smoked, ingested, vaped, dabbed, or applied dermally containing delta-9-THC, and environmental exposures to cannabis (marijuana) smoke or delta-9-THC. The proposed amendments to the regulations would facilitate compliance for those businesses that choose to use the safe harbor tailored warnings for product and environmental exposures to cannabis smoke and delta-9-THC”. (ISOR, p. 4)

In addition to providing certainty to businesses, the warning

“also helps to ensure that the public receives consistent and clear warnings about the exposures that can occur through use of cannabis products and reduces the potential for warnings where there are no significant exposures. A business that knowingly and intentionally exposes individuals to these chemicals must provide a warning using those methods and content in order to claim safe harbor protection. Providing more specific warning methods and content will facilitate the public’s understanding of the warnings in the context in which they occur and ensure clarity and consistency.” (ISOR, p. 5)

A recent study published in 2021 by Young-Wolff et al.³ conducted in California using urine toxicology test data from a large integrated health care delivery system provides clear evidence that the rate of cannabis use by pregnant women in California is increasing. Specifically, this study reported that prenatal cannabis use increased by 25% during the COVID-19 pandemic (April –December 2020) compared with prenatal cannabis use during the 15 months prior to the pandemic (January 2019 – March 2020), increasing from 6.75% of pregnancies pre-pandemic to 8.14% of pregnancies during the

³ Young-Wolff KC, Ray GT, Alexeeff SE, Adams SR, Does MB, Ansley D, Avalos LA. 2021. Rates of Prenatal Cannabis Use among Pregnant Women Before and During the COVID-19 Pandemic. *JAMA*. Nov 2;326(17):1745-1747. doi: 10.1001/jama.2021.16328

pandemic⁴. This study adds to the evidence^{5,6} cited in the ISOR that “the prevalence and frequency of cannabis use in pregnant women has increased”.

No changes were made to the proposed regulations based on this comment.

Comment 3 (AHPA, Cannadescent, CCIA, Cresco, CMG/Caliva, LPS, Winters, and TStevens): These commenters stated that cannabis companies are already highly regulated and are required to provide detailed product information and multiple warnings. CCIA stated some required warnings currently provide the reproductive health and cancer warnings required under these proposed amendments. Winters and AHPA stated existing warnings are provided for pregnant and breastfeeding women. The commenters point to the required warning in Business and Professions Code Section 26120 and state that this warning requirement should be sufficient for Proposition 65 and that the Proposition 65 warning is redundant and provides consumers with no additional information related to cannabis exposures.

Response: The general warning language for cannabis in Business and Professions Code Section 26120 states:

“GOVERNMENT WARNING: THIS PACKAGE CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. **CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL**. CONSUMPTION OF CANNABIS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.” (Emphasis added.)

A similar warning is required in Section 26120 for cannabis products. The Business & Professions Code section 26120 warning does not meet the requirements for a Proposition 65 warning because it does not state that cannabis smoke can cause cancer and does not explain what “harmful” means in reference to pregnancy and breastfeeding. The statutory warning also does not include certain elements of the

⁴ Ibid

⁵ Volkow ND et al. (2019), Self-reported medical and nonmedical cannabis use among pregnant women in the United States, JAMA: 322(2): 167-168, available online at: <https://pubmed.ncbi.nlm.nih.gov/31211824/>.

⁶ Office of Environmental Health Hazard Assessment (OEHHA, 2019), Evidence on the Developmental Toxicity of Cannabis (Marijuana) Smoke and Δ^9 -THC, California Environmental Protection Agency, available online at <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/cannabisdarhid100419.pdf>, pp 17-18, hereafter “OEHHA (2019)”.

proposed safe harbor warning such as the warning symbol, endpoints of concern - cancer for cannabis smoke and the potential effects on the child from maternal exposure during pregnancy to cannabis smoke or products containing delta-9-THC.

Proposition 65 warnings for exposures to both cannabis (marijuana) smoke and delta-9-THC are currently required. Thus, adopting these proposed safe harbor warnings will help ensure the warnings include meaningful and accurate information for consumers, especially pregnant women, before exposure to cannabis smoke and delta-9-THC occurs. Businesses have the option to provide alternative warning language if they so choose, but the alternative language will not afford them safe harbor protection from enforcement actions.

No changes were made to the proposed regulations based on these comments.

Comment 4 (Cresco): This commenter states that proposed warnings will not achieve greater consumer and patient understanding of the risks of exposure to cannabis products and that the proposed warnings will not result in more consumers visiting the Proposition 65 Warnings Website.

Response: Proposition 65 requires businesses to warn individuals about exposures to carcinogens and reproductive and developmental toxicants prior to exposure. The proposed warnings further the purposes of the Act because they provide consumers with more specific and relevant information about these exposures, while also directing them to the website for more detailed information. The regulation was not proposed specifically to increase visits to the warnings website. Instead, the URL is included in the warning for those consumers who wish to obtain additional information about the exposures.

No changes were made to the proposed regulations based on this comment.

Requests to Delay Proposed Regulations

Comment 5 (LPS): This commenter requested that the phase-in period of the regulations be for two years to allow businesses time to come into compliance with the safe harbor warnings.

Response: Based on this and other comments, OEHHA amended the proposed regulations to provide an unlimited sell-through period for products manufactured before the end of the one year phase-in period, so long as the warning complies with the general safe harbor requirements in Sections 25602 and 25603. Further, OEHHA provided the one year phase-in period for the regulations to facilitate compliance.

Comment 6 (AHPA, CCIA, Cresco, and LPS): These commenters oppose the proposed amendments at least until the cannabis industry is guaranteed a sure date as to when the many other expected regulatory changes, particularly those related to packaging and labeling, must be implemented. These commenters point to the recent consolidation of California's three cannabis licensing programs into a single Department of Cannabis Control. It is uncertain how this consolidation will affect warning requirements. These commenters recommend that OEHHA withdraw the current proposal in the absence of a demonstrable scientific need for such warnings.

Response: OEHHA is aware that there are many existing and proposed legal requirements related to the sale of cannabis products. To assist businesses, the regulations have been modified to provide a one year phase-in period. This will allow businesses that choose to provide the safe harbor warnings time to make the necessary changes. Further, all products that are manufactured before the end of the one year phase-in period that are labeled in accordance with Section 25602 and 25603, do not have to be changed when the one year phase-in period ends because the regulations provide an unlimited sell-through period for these products.

Cannabis (marijuana) smoke and delta-9-THC are listed under Proposition 65 as causing reproductive toxicity (developmental endpoint). As discussed in the ISOR and in the response to comment 2 above, cannabis use by pregnant women in California is increasing. The listing of delta-9-THC and cannabis smoke as developmental toxicants under Proposition 65 requires that consumers be warned about the potential harm they can cause a child when exposures occur during pregnancy (e.g., exposure during pregnancy can affect the child's birthweight, behavior and learning ability). Thus, OEHHA determined it would be beneficial to adopt safe harbor warning regulations for exposures to cannabis smoke and delta-9-THC to provide guidance to the businesses affected by these listings.

No changes were made to the proposed regulations based on these comments.

Potential Cost Impact of Proposed Regulations on Business

Comment 7 (Canndescent, CCIA, CMG/Caliva, Cresco, LPS, Shryne, and Winters): These commenters stated that businesses will bear the costs associated with the proposed warnings creating an unnecessary hardship, especially for small businesses. These commenters stated that the costs of designing, ordering, and implementing new packaging are significant up and down the supply chain and will place significant pressures on an already overburdened industry. These commenters further stated that

these costs and unnecessary hardships will not benefit the health and safety of California consumers.

Response: Based on these and other comments, OEHHA has determined that allowing additional time for businesses to implement these regulations will benefit businesses who choose to use the safe harbor warnings. Therefore, a one year phase-in period was provided. This will allow businesses time to make the necessary changes to their warnings to comply with the new safe harbor warning provisions, to the extent they choose to use the warning methods and content provided in the regulations.

Additionally, based on these and other comments, OEHHA amended the proposed regulations to state that a warning provided on a product manufactured during the year after the effective date of the regulations is deemed to be clear and reasonable if it complies with the methods of transmission in Section 25602 and content set out in Section 25603. Thus, businesses do not have to replace the warnings on products manufactured and labeled before the end of the one-year phase-in period. The regulations therefore provide sufficient time for businesses to transition to the new warning provisions if they choose to do so. The proposed safe harbor methods and content for cannabis products are not mandatory. Businesses can give any warning they feel is clear and reasonable as required by Proposition 65. However, compliance with the safe harbor regulations provides a defense in an enforcement action. Further, the specificity about the effects of the products on children resulting from the mothers' exposures during pregnancy will help to ensure pregnant women are aware of the effects so they are much better informed in making decisions about avoiding exposure, which is clearly a benefit to California consumers and their children.

Comment 8 (Canndescent, CCIA, CMG/Caliva, Cresco, LPS, and Winters): These commenters state that the proposed warnings will incentivize consumers to purchase lower-cost cannabis from the illicit market due to the costs associated with compliance. The commenters also stated that the redundant warnings from multiple agencies without coordination on language or requirements sets back efforts to eradicate the black-market for cannabis products and discourages illicit operators from becoming legal by creating higher barriers for entry.

Response: OEHHA does not anticipate any business will incur significant cost related to these proposed regulations. They are not mandatory, and further, to assist businesses OEHHA amended the proposed regulations to provide an unlimited sell-through period for products manufactured before the end of the one year phase-in period if the warning on the product complies with the general consumer product warning in Sections 25602 and 25603. Thus, businesses do not have to replace compliant warnings on products manufactured and labeled before the end of the one

year phase-in period. The one year phase-in period should provide sufficient time for businesses to transition to the new warning provisions if they choose to do so.

No changes were made to the proposed regulations based on these comments.

Warning Methods

Comment 9 (BBranson, CE4K, GIRFS, and WPerno): These commenters support the proposed regulations, and offered ways to strengthen the warning methods, including making the safe harbor warning mandatory, requiring larger signage, signage in more locations, illumination of signage in dimly lit areas, and additional warnings with specific requirements for cannabis deliveries.

Response: OEHHA acknowledges the commenters support of the proposed safe harbor warnings for cannabis (marijuana) smoke and delta-9-THC. Given that the existing Proposition 65 regulations define “sign” in Section 25600.1(m) as “a physical presentation of written, printed, graphic, or electronically provided communication, including shelf signs, other than a label or labeling, posted in a conspicuous manner that is associated with the exposure for which the warning is being provided under the Act and is *clearly visible under all lighting conditions normally encountered during business hours and under such conditions as to make it likely to be seen, read, and understood by an ordinary person.*” (Emphasis added). Additional requirements for signage are unnecessary. OEHHA declines to make the warning regulations mandatory. They are offered as compliance assistance the businesses can use to ensure the warnings they provide are “clear and reasonable” as required by Proposition 65.

OEHHA has incorporated the consumer products warning methods in Sections 25602 and 25604 into this regulation to ensure consistency. Section 25602 provides methods of transmission for consumer product warnings which can include “a posted sign, shelf tag, or shelf sign, for the consumer product at each point of display of the product.” Section 25604 provides the requirements for environmental exposure warnings and requires warning signs be posted at all public entrances to the affected area in no smaller than 72-point font and be provided “in a conspicuous manner and under such conditions as to make it likely to be seen, read, and understood by an ordinary individual in the course of normal daily activity.” The additional suggested requirements are unnecessary.

Cannabis delivery businesses must provide Proposition 65 warnings before exposures occur to comply with the Act. Most of these purchases are likely to be transacted online. Section 25602(b) of the existing regulations states that warnings for internet purchases must be provided using one of the methods in Section 25602(a) and “... by including

either the warning or a clearly marked hyperlink using the word “WARNING” on the product display page, or by otherwise prominently displaying the warning to the purchaser prior to completing the purchase.” Thus, consumers will receive a warning at the time of purchase via the internet and when the product is delivered by one of the methods described in Section 25602(a).

No changes were made to the proposed regulations based on these comments.

Comment 10 (AHPA, CCIA, Cresco, LPS, and Shryne): These commenters stated that the short-form warning is sufficient and provides businesses with needed flexibility by allowing for a shorter warning that does not take up as much space. The commenters also stated the justification for prohibiting the use of the short-form warning on cannabis products is not scientifically justified because OEHHA has not established the risk of exposure from cannabis products are greater than other exposures for which the short-form warning is not prohibited. The commenters further stated that the cannabis industry has used the short form warning in good faith and have not abused the use of the warning by using it on large packaging.

Response: OEHHA disagrees with the commenters that the short form warning is a sufficient warning for cannabis and delta-9-THC products. As explained in the ISOR for these proposed regulations, OEHHA determined that the short-form warning method in Section 25602(a)(4) does not provide the level of specificity needed for cannabis (marijuana) smoke and delta-9-THC exposures. This is because the warning language in the proposed regulations clearly conveys the adverse developmental effects cannabis smoke and delta-9-THC can cause when used by pregnant women. The adoption of safe harbor warning methods and content are provided as non-mandatory compliance assistance for businesses. OEHHA has adopted many other safe harbor warnings for products, places, and chemicals. Further, there is no requirement that the warning be placed on the product label. There are other methods such as signs or shelf tags for providing the warning if it is too large to fit on a label.

No changes were made to the proposed regulations based on these comments.

Comment 11 (CannDESCENT, CMG/CALIVA, LPS, and Shryne): These commenters stated that the amount of space on cannabis products for Proposition 65 warnings is limited due to the other warnings required by law. The commenters state that some non-retail cannabis businesses will not be able to fit the warning on their products and as such will have to enter into agreements with retailers for signage to be posted which will put non-retail businesses in a situation where they are reliant on the retailer to post the provided warning signage to ensure compliance with the Act. These commenters further state that businesses are frequently unable to have segregated shelves for each

product type and as a result the space available for shelf signs with warnings is limited, making shelf signs difficult for businesses to use. The commenters also stated that the overabundance of warnings on cannabis products creates the visual effect of “white noise” and that the warnings are printed so small and condensed so they fit on the packaging that they are meaningless to consumers.

Response: As the commenters’ note, warnings do not have to be provided on the product. Other warning methods may be used, including shelf signs and shelf tags. These can be used near the associated products. The methods also include providing warnings via any electronic device or process that automatically provides the warning to the purchaser prior to or during the purchase of the consumer product (Section 25602(a)(2)). This could include providing a warning on a cash register receipt or invoice, so long as the consumer sees the warning prior to exposure and knows what product(s) it is referring to.

Businesses can choose which warning method is appropriate for their products and situation. Section 25600.2 of the warning regulations sets out the relative responsibility for providing warnings and allows businesses to enter into an agreement to allocate warning responsibilities that is different from those in the regulation, so long as the warning is provided to the consumer prior to exposure.

No changes were made to the proposed regulations based on these comments.

Comment 12 (LPS): This commenter stated that the safe harbor warning will require more space on packaging resulting in more single use plastics being produced to accommodate the size of the warning. Specifically, the commenter stated that approximately 2 million single use plastic tubes for cannabis products end up in landfills each year.

Response: Warnings do not have to be provided on the product. Businesses can comply with the requirements of Proposition 65 by providing the warning on a shelf sign or shelf tag near the product. The proposed safe harbor methods and content for cannabis products are not mandatory. No changes were made to the proposed regulations based on this comment.

Warning Language

Comment 13 (Shryne): This commenter stated that that the warning language for cannabis products should be uniform instead of having unique warnings for each exposure type. The commenter suggested amending the warnings to state “using this product during pregnancy exposes your child to delta-9-THC, which can affect your

child's behavior and learning ability. For more information go to www.P65Warnings.ca.gov/cannabis" because it will allow businesses more flexibility with packaging. The commenter also stated that "using this product" is sufficient information for consumers to understand the risks of the product whether it is applied topically, inhaled, or consumed.

Response: OEHHA disagrees that there should be a uniform warning for all types of cannabis products. The different language used in the safe harbor warnings in these regulations is necessary because it identifies the specific route of exposure and relevant exposure endpoints. The warning proposed by the commenter does not meet the requirements of Proposition 65 because it does not include the specific endpoints/effects (cancer, effects on developing child) of exposure to the chemicals for various products. As explained in the ISOR, where the product results in exposure to cannabis smoke, the safe harbor language includes increased cancer risk, effects on birthweight, and two broad categories of neurodevelopmental effects - behavior and learning ability. Where use of the product causes delta-9-THC exposures, but not cannabis smoke exposure, the warning for exposures during pregnancy is for behavior and learning ability but there is no cancer warning required for delta-9-THC since it is not listed as a carcinogen.

No changes were made to the proposed regulations based on this comment.

Miscellaneous Comments

Comment 14 (AHPA and Winters): These commenters stated that the proposed warnings may result in an increase of Proposition 65 litigation related to cannabis products because the warnings will incentivize private plaintiffs to target companies who do not use the safe harbor warning language or smaller operators that have more difficulty complying with changes to warning requirements.

Response: There is no indication that businesses using the existing general consumer safe harbor warning have encountered additional litigation and OEHHA does not anticipate such an increase will occur with the proposed regulations. Further, the proposed safe harbor warnings are not mandatory. Adopting safe harbor warnings that are specific to cannabis and delta-9-THC exposures will give businesses an optional way to comply with Proposition 65 and provide a defense against enforcement actions. Further, the amended proposal includes a one year phase-in period, as well as an unlimited sell through period for products manufactured before the end of the one year phase-in period that are labeled in accordance with existing Sections 25602 and 25603. Both provisions will help reduce costs for businesses to comply with the new safe harbor warning regulations.

No changes were made to the proposed regulations based on these comments.

Comment 15 (JEberstein): This commenter provided a copy of a fact sheet from the San Diego County Center for Community Research Marijuana Prevention Initiative about whether marijuana helps alleviate various medical conditions but provided no written or oral comments.

Response: OEHHA appreciates the commenter sharing this fact sheet with us. OEHHA has also developed fact sheets concerning these exposures that are specific to Proposition 65. These can be found at <https://www.p65warnings.ca.gov/fact-sheets/cannabis-marijuana-smoke> for cannabis (marijuana) smoke and <https://www.p65warnings.ca.gov/fact-sheets/thc> for delta-9-THC.

No changes were made to the proposed regulations based on this comment.

Comment 16 (Anonymous and WPerno): These commenters state that delta-9-THC should not be singled out and that all isomers of THC, including delta-8-THC and delta-10-THC, should require a warning.

Response: Delta-9-THC is the only THC isomer listed individually under Proposition 65. The listing was based on the opinion of the DARTIC that it was clearly shown to cause developmental toxicity. Therefore, the safe harbor warnings are only being adopted for delta-9-THC and not for any of the other THC isomers. A considerable number of studies of the developmental toxicity of delta-9-THC were available for review and consideration by the DARTIC. In contrast, the developmental effects of other isomers of THC have not been well studied, thus delta-9-THC was the only individual isomer of THC considered for listing in 2019 by the DARTIC. It should be noted that cannabis smoke was also considered and listed by the DARTIC in 2019 as causing reproductive toxicity (developmental endpoint). Cannabis smoke is a complex chemical mixture that contains many different chemicals including delta-9-THC, other isomers of THC, as well as other cannabinoids.

No changes were made to the proposed regulations based on these comments.

Comments Beyond the Scope of Proposed Regulations

Comment 17 (AHPA): This commenter stated that the changes to the short-form warning regulation that OEHHA has proposed in a separate rulemaking should set limitations on when a short-form warning is appropriate by proposing a new rulemaking process to establish specific criteria for identifying listed chemicals for which use of the short-form warning should be prohibited.

Response: This comment is beyond the scope of the proposed rulemaking.

As stated previously, OEHHA has determined that a warning containing more specific information about the effects of exposure to cannabis smoke and THC are needed to focus pregnant women on these concerns. The warnings are not mandatory. A business can provide any warning they determine is “clear and reasonable” as required by Proposition 65.

No changes were made to the proposed regulations based on this comment.

Comment 18 (AHPA and PCPC): These commenters requested that OEHHA clarify the term “unquantifiable” used in the ISOR to identify situations where cannabidiol (CBD) products that contain small amounts of delta-9-THC do not require a warning. AHPA stated OEHHA should consider adopting an analytical threshold for delta-9-THC in CBD products for consistency, and PCPC stated that OEHHA should change “unquantifiable” to “trace” and adopt the federal level of 0.3 percent for delta-9-THC in industrial hemp products. AHPA also referred to State legislation (AB 45 Industrial Hemp) stating that it may impact whether delta-9-THC in certain hemp products can be considered naturally occurring under Proposition 65.

Response: The request to establish an analytical threshold for delta-9-THC and determine that the THC in hemp products is naturally occurring is beyond the scope of this rulemaking.

The proposed regulations do not specify when a warning is required, instead they provide safe harbor methods and language for warnings where a business determines one is needed. OEHHA has determined that the term “unquantifiable” is the most appropriate term to use to indicate when a CBD product containing delta-9-THC may not require a warning.

The Proposition 65 regulations include Section 25501, which applies to naturally occurring chemicals in foods. To the extent hemp products are classified as foods that regulation could apply. The State legislation (AB 45, concerning Industrial Hemp) referred to by the commenters does not establish that delta-9-THC in certain hemp products is naturally occurring for purposes of Proposition 65. The business relying on Section 25501 would have the burden of showing the product is a food or derived from a food and that the THC in that product is naturally occurring and thus would not require a warning.

In the future, OEHHA may consider other regulatory or compliance assistance to address delta-9-THC in hemp products.

No changes were made to the proposed regulations based on these comments.

Comment 19 (DStory): This commenter states that differentiating between cannabis grown in accordance with Organic Farming practices and other cannabis not grown in accordance with such practices should be investigated because broad classification of cannabis is outdated. The commenter states that cultivators are now allowed to apply regenerative organic practices at a commercial scale. Thus, prior studies misled the public because they were conducted under poor conditions due to the illegality of cannabis.

Response: This comment is beyond the scope of the proposed rulemaking. No changes were made to the proposed regulations based on this comment.

Comment 20 (GValasek): This commenter stated that the similarity between the health consequences of cannabis smoke and tobacco smoke should be disclosed to the public. The commenter provided several references to publications that discuss the health consequences of smoking and the detrimental emissions coming from the burning or smoking of any agricultural vegetation.

Response: This comment is beyond the scope of the proposed rulemaking.

Separate regulations address exposures to tobacco smoke for purposes of Proposition 65 (see Title 27, Cal Code of Regs., sections 25607.28-25607.29). No changes were made to the proposed regulations based on this comment.

Commenter 21 (PCPC) requested that OEHHA “change any references from ‘topical lotions’ to ‘topical cosmetics’ ... to avoid any implication that dermally applied products are limited to just ‘lotion’ forms.”

Response: The regulations makes no reference to topical lotions themselves. The regulation applies to any dermally applied products containing delta-9-THC.

Summary of and Response to Comments on September 2021 Modification of Proposed Regulations

As explained above, the September 17, 2021 modification provided a one year phase-in period for the regulations and provided an unlimited sell-through period for products manufactured and labeled with compliant warnings before the end of the one year phase-in period. Two organizations submitted written comments on the proposed modification:

Harvest Health & Recreation Inc. (Harvest)

Southern California Coalition (SCC)

The comments received are summarized and responses to them are provided below.

Comment 22 (Harvest and SCC): The commenters stated that the proposed modifications do not address the potential expenses businesses may incur to comply with the proposed safe harbor warning, the inadequate scientific basis for the warning, the impact the changes will have on small businesses and social equity businesses, the allocation of warning responsibilities between manufacturers and retailer and other required warnings.

Response: The comments concerning the alleged inadequate scientific basis for the proposed warning are not directed toward the modifications to the regulations provided in the 15-day Notice of Modification and require no response. OEHHA responded to similar concerns during the initial comment period. OEHHA disagrees that the changes did not address cost concerns. To alleviate the potential cost burden to cannabis businesses, OEHHA amended the regulations to provide a one year phase-in period and an unlimited sell-through period for products manufactured before the end of the one year phase-in period that are labeled in accordance with existing Sections 25602 and 25603. These amendments will allow more time for businesses to comply if they choose to do so, and avoid the need to relabel products, thus reducing potential costs (see Comments 1, 3, 7, and 11).

No changes were made to the proposed regulations based on these comments.

Summary of and Response to Comments on May 2022 Modification of Proposed Regulations

As explained in greater detail above, the May 20, 2022, modifications restructured and provided further details on the phase-in and sell through provisions introduced in the September 2017 modifications. Four individuals or organizations submitted comments:

California Cannabis Industry Association (CCIA)

California Cannabis Manufacturers Association (CCMA)

Cannabis Distribution Association (CDA)

Darren Story (DStory)

The comments received are summarized and responses to them are provided below.

Comment 22 (CCIA, CCMA, CDA): CCIA commented that the proposed warnings will add significant costs and workload pressures to an overburdened industry that is highly regulated and that the impact would be high to all cannabis businesses, especially small businesses and could result in being a barrier to entry to the legal market. CCIA, CCMA, and CDA commented that the cannabis industry already provides several legally required warnings, including Proposition 65 warnings and that the amount of space the proposed warning language will require on labels is too much for many cannabis products, especially if the warning cannot be provided using the short-form warning method. Further, the text of the warnings will be small and hard for consumers to read. CCMA also commented that the packaging will have to be larger to accommodate the longer warning requiring the use of more material which produces more waste. CCMA also proposed amendments to the content for the warning language for inhalable and ingestible cannabis products based on existing legally required warning on cannabis products.

Response: These comments are not directed toward the modifications to the regulations provided in the 15-day Notice of Modification and require no response. This FSOR responds to similar comments received during the initial comment period (see Comments 3, 7, 8, 10, 12, and 13).

Comment 23 (DStory): This commenter stated that the evidence on which OEHHA relies is “faulty and inconclusive” and that there were insufficient controls for things such as florescent lighting which does not simulate a natural environment. The commenter also stated that there is no control for the “method to grow and cultivate the cannabis samples from which the smoke was created” and that there were no controls for other carcinogens or reproductive toxicants.

Response: This comment is not directed toward the modifications to the regulations provided in the 15-day Notice of Modification and requires no response.

No changes were made to the proposed regulations based on these comments.

Local Mandate Determination

OEHHA has determined this regulatory action will not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. Local agencies and school districts are exempt from Proposition 65.

OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

Alternatives Determination

In accordance with Government Code Section 11346.9(a)(4), OEHHA has determined 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 regulations are proposed, would be as effective as, 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.

OEHHA considered and responded to alternatives suggested by the public commenters in this FSOR. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected private persons, than the proposed action.

OEHHA considered withdrawing the proposal and taking no action but finds that taking no action is inconsistent with the intent of the Act and that the general safe harbor warning would not provide sufficient specificity about the anticipated effects of use of these products by pregnant women. Therefore, OEHHA has determined that no alternative considered would be more cost-effective, or as effective in implementing the statutory policy or other provision of law.