

**Initial Statement of Reasons
Title 27, California Code of Regulations**

**Proposed Amendments to Article 6:
Safe Harbor Clear and Reasonable Warnings for**

**Cannabis (Marijuana) Smoke and
Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings**

New Sections 25607.38 – 25607.47

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

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Summary

Proposition 65¹ requires businesses to provide a clear and reasonable warning before they knowingly and intentionally cause an exposure to a chemical listed as known to the state to cause cancer or reproductive toxicity.² The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65. OEHHA maintains the list of chemicals known to the state to cause cancer or reproductive toxicity and has the authority to promulgate and amend regulations to further the purposes of the Act.³ OEHHA added cannabis (marijuana) smoke and delta-9-tetrahydrocannabinol (delta-9-THC) to the Proposition 65 list for the developmental toxicity endpoint on January 3, 2020 based on findings of the Developmental and Reproductive Toxicant Identification Committee⁴. The listing became effective January 3, 2021. Marijuana (cannabis) smoke has been listed for the cancer endpoint since June 19, 2009.

This rulemaking would add specific tailored safe harbor exposure warning methods 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. These amendments would be added to OEHHA's regulations for safe harbor warnings in Title 27, California Code of Regs., section 25601 et seq.⁵, that provide warning methods and content deemed by OEHHA to be clear and reasonable for purposes of Proposition 65.

Background and Problem to be Addressed by the Proposed Rulemaking

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 list for developmental toxicity. Under Proposition 65, the warning requirement for newly

¹ Health and Safety Code section 25249.5 et seq., The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65". Hereafter referred to as "Proposition 65" or "the Act".

² Health and Safety Code section 25249.6.

³ Health and Safety Code section 25249.12(a).

⁴ Title 27, California Code of Regs., section 25305(b).

⁵ All further references are to Title 27 of the California Code of Regulations, unless otherwise indicated.

listed chemicals takes effect 12 months from the date it is listed.⁶ In this case, the warning requirement for the developmental endpoint for cannabis (marijuana) smoke and delta-9-THC took effect on January 3, 2021.

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 this new listing. Exposure-specific “tailored warning” methods of transmission and content provide certainty to businesses subject to the warning requirements of the Act. It 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.

The legalization of the recreational use of cannabis in California has resulted in an increase in cannabis smoking and in the number of marketed products that expose the consumer to delta-9-THC – by ingestion, vaping, dabbing, or dermal application.⁷ Further, the prevalence and frequency of cannabis use in pregnant women has increased,^{8,9} and the content of delta-9-THC in cannabis has been rising¹⁰. The listing of delta-9-THC and cannabis smoke as developmental toxicants under Proposition 65 requires that consumers be made aware of the potential harm they can cause a child when exposures occur during pregnancy.

While delta-9-THC is on the Proposition 65 list, cannabidiol (CBD) and other cannabinoids in cannabis are not. Products that are made with CBD or other cannabinoids or purified extracts of the cannabis plants - that do not cause exposures to delta-9-THC or other Proposition 65 listed chemicals within the meaning of Section 25249.10(c) of the Health and Safety Code - do not require a

⁶ Health and Safety Code section 25249.10(b).

⁷ Furnari C (2020), *California Cannabis Sales Grew 18% to Nearly \$3 Billion in 2019*, February 4. THC.net, available at <https://thcnet.com/news/california-cannabis-sales-grew-18-to-nearly-3-billion-in-2019> (last visited Jan. 21, 2021)

⁸ 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/>.

⁹ 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/cannabisdarthid100419.pdf>, pp 17-18, hereafter “OEHHA (2019)”.

¹⁰ OEHHA (2019) at page 14.

warning. For example, where products such as topical lotions made with CBD or other cannabinoids may have trace but unquantifiable levels of delta-9-THC, no warning is required. These proposed amendments providing safe harbor warning methods and content do not apply to those products. The scientific evidence on harm from exposures during pregnancy to CBD and other cannabinoids beside delta-9-THC has not been reviewed.

OEHHA is proposing safe harbor methods and warning content for exposures to cannabis smoke or delta-9-THC through products that are intended to be smoked, vaped, or dabbed, ingested, or applied dermally, or through environmental exposures in permitted smoking, vaping, or dabbing areas. These safe harbor warning methods and content can be used by retailers, cafés, or lounges where cannabis or delta-9-THC products are sold or used.

Proposition 65 cancer warnings for marijuana (cannabis) smoke exposures have been required since its listing as “known to cause cancer” became effective in 2010. This proposed rulemaking provides guidance for businesses to combine the warnings for cancer and developmental toxicity caused by cannabis smoke and delta-9-THC into a single safe harbor warning and establishes safe harbor warnings for exposures to newly listed delta-9-THC.

Proposed Amendments

Exposures Covered

OEHHA is proposing to amend the warning regulations in Title 27, California Code of Regs., section 25607, by adding sections 25607.38 to 25607.47 to provide safe harbor warning methods and content for:

- Exposures from cannabis products that are smoked (Sections 25607.38 - 25607.39).
- Exposures to delta-9-THC from products that are ingested (Sections 25607.40 - 25607.41).
- Exposures to delta-9-THC from products that are vaped or dabbed (Sections 25607.42 - 25607.43).
- Exposures to delta-9-THC from products that are applied dermally (Sections 25607.44 – 25607.45).
- Environmental exposures to cannabis (marijuana) smoke or delta-9-THC vapor in establishments where such exposures can occur on the

premises of the business (Sections 25607.46 - 25607.47).

The amended regulations establish the requirements for clear and reasonable warnings. A business can claim safe harbor protection for exposures from its products if it uses the methods in Sections 25067.38, 25607.40, 25607.42, and 25607.44 and the warning content in Sections 25067.39, 25607.41, 25607.43, and 25607.45. Similarly, for environmental warnings, a business can do so if it uses methods in Section 25607.46 and the warning content in Section 25607.47.

Cannabis Smoke and Delta-9-THC Warning Content

Effects of Cannabis Smoke and Delta-9-THC in Warning Language

Smoking cannabis products exposes consumers to cannabis (marijuana) smoke. Marijuana smoke, which is synonymous with cannabis smoke, has been listed as a carcinogen under Proposition 65 since 2009. It was added to the list by the Carcinogen Identification Committee – the state’s qualified experts for carcinogenicity - who at its May 29, 2009, meeting, identified the substance as a carcinogen for the purposes of Proposition 65. The Developmental and Reproductive Toxicant Identification Committee (“DART Identification Committee” hereafter) – the state’s qualified experts in the male reproductive, female reproductive and developmental reproductive toxicity of chemicals – identified both cannabis smoke and delta-9-tetrahydrocannabinol, also known as “ Δ^9 -THC” (synonymous with delta-9-THC)¹¹, as known to cause reproductive toxicity based on developmental toxicity at its meeting on December 11, 2019.

The DART Identification Committee voted unanimously to identify cannabis smoke as causing developmental toxicity. In epidemiological studies cannabis smoking during pregnancy is observed to affect the birthweight of the child.^{12,13,14} Neurodevelopmental effects are also reported in numerous studies.¹⁵ As noted by the DART Identification Committee, smoking cannabis during pregnancy also

¹¹ “Delta-9-tetrahydrocannabinol”, also referred to as “delta-9-THC” and “ Δ^9 -THC”, as discussed in OEHHA (2019), at page12-14.

¹² OEHHA (2019), pp 4, 64-68, Appendix Table 1.1

¹³ Office of Environmental Health Hazard Assessment (OEHHA). Meeting Transcript. Developmental and Reproductive Toxicant Identification Committee, December 11, 2019, James Peters Certified Shorthand Reporter. Available at:

<https://oehha.ca.gov/media/downloads/cnrn/darticttranscript121119.pdf>

¹⁴ National Academies of Sciences, Engineering, and Medicine, “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research, 2017, National Academy Press, [available at http://nationalacademies.org/hmd/reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx](http://nationalacademies.org/hmd/reports/2017/health-effects-of-cannabis-and-cannabinoids.aspx)

¹⁵ OEHHA (2019), pp 7-11, 87-124; Appendix 2

results in fetal exposures to delta-9-THC.^{16,17} The DART Identification Committee also overwhelmingly voted to add delta-9-THC to the Proposition 65 list based on its neurodevelopmental toxicity. Fetal exposure to delta-9-THC due to maternal exposure during pregnancy has resulted in several neurodevelopmental outcomes, including effects on cognitive function and learning ability (including effects on memory and attention) and behavior (including emotionality and increased susceptibility to addiction).¹⁸ While there are multiple neurodevelopmental effects associated with delta-9-THC exposures, the warning language does not use the general term “neurodevelopmental effects” because it would be less well understood than terms used to describe the general types of neurobehavioral adverse effects caused by delta-9-THC, i.e., effects on learning ability and behavior. These terms will be more readily comprehended by the public and will focus the consumer on important specific effects of using the products during pregnancy.

Thus, where the product results in exposure to cannabis smoke, the safe harbor language warns about 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.

Simplified Warning Language and Other Content

OEHHA is modeling the safe harbor warning content for cannabis smoke and delta-9-THC exposures on that adopted for consumer product warnings in section 25603. Thus, the warning includes:

- the warning symbol (black exclamation point in a yellow equilateral triangle with a bold black outline)
- the word “WARNING:” in all capital letters and bold print
- the name of the listed chemical(s) for which the warning is being given (e.g., cannabis smoke, delta-9-THC)
- the nature of effect from the exposure (e.g., cancer, specific developmental outcomes)

¹⁶ OEHHA (2019), pp 23-26.

¹⁷ Office of Environmental Health Hazard Assessment (OEHHA). Meeting Transcript. Developmental and Reproductive Toxicant Identification Committee, December 11, 2019, James Peters Certified Shorthand Reporter. Available at: <https://oehha.ca.gov/media/downloads/cnrn/darticttranscript121119.pdf>

¹⁸ OEHHA (2019) at pages 8-11.

- the URL for the OEHHA website where the consumer can access more information about the cannabis related exposures:
www.P65Warnings.ca.gov/cannabis

However, for these tailored warnings for cannabis-related exposures OEHHA is proposing simplified warning language that more directly and concisely conveys the nature of risks of exposure. Thus, the proposed warning includes more specific information about the potential risks the exposure can cause to unborn children exposed in utero. The more general warning statement used for consumer product exposures to chemicals listed under Proposition 65 warns that the named chemical is

“known to the State of California to cause birth defects or other reproductive harm”¹⁹.

Instead, in the proposed regulations, the developmental effects specific to cannabis smoke and delta-9-THC exposures (discussed in the preceding section) will be included. Thus, for example, the consumer will be warned that delta-9-THC exposure during pregnancy can affect the child’s behavior and learning ability. In addition, the phrase “known to the State of California to cause” will not be used in the proposed warnings to reduce the length of the warnings and focus the consumer on the specific chemicals and the adverse effects that can result from the exposure.

Cannabis smoke is also a carcinogen and exposures during pregnancy also affect development, as discussed above. For example, the warning language for cannabis smoke includes:

“Smoking cannabis increases your cancer risk and during pregnancy exposes your child to delta-9-THC and other chemicals that can affect your child’s birthweight, behavior and learning ability.”

The above discussion pertains to safe harbor language for consumer products that result in cannabis smoke or delta-9-THC exposures. At some establishments in California cannabis is legally consumed on-site. Therefore, OEHHA is also providing regulatory safe harbor guidance for business establishments that have on-site consumption. The content of the environmental exposure warning, in proposed section 25607.47, covers exposures to cannabis (marijuana) smoke or delta-9-THC vapor in establishments where vaping, dabbing or cannabis smoking occurs. It is modeled after the safe harbor regulation for environmental exposures (Section 25605), but similarly proposes

¹⁹ Section 25603 (a)(2)

the simple and direct language proposed for consumer products.

While combusted cannabis products create cannabis smoke, which is a Proposition 65 carcinogen, some delta-9-THC products that do not involve combustion may also contain or release carcinogens. For example, carcinogens may be introduced during manufacture, they may be intentionally added, or they may be formed when the product is used. If levels are sufficiently high – that is they expose the consumer to significant risk within the meaning of Section 25249.10(c) of the Health and Safety Code – a warning for carcinogen exposures may also be required. Under Proposition 65

“the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level.”²⁰

Thus, exposures need to be sufficiently high to require an additional warning. Should carcinogen exposures in non-combusted delta-9-THC products require a warning the proposed regulation provides the language for doing so.

This and other aspects of the proposed content for cannabis smoke and delta-9-THC warnings are covered below in the discussions of Sections 25067.39, 25607.41, 25607.43, 25607.45, and, 25607.47.

Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures

OEHHA is also conforming the methods of transmission for cannabis-related consumer products to that adopted for consumer products in Section 25602, with one exception. In this way the proposed regulations provide methods of transmission for use: on the product (e.g., product labels), off-product (e.g., shelf tags), via electronic device, via the internet, and via catalog purchases.

The exception to the use of methods of transmission for consumer products is that the use short-form warning provided in Section 25602(a)(4) is excluded from use for cannabis smoke and delta-9-THC. This is so that consumers receive the full safe harbor warning language so they can be made aware of the specific effects the exposures can cause to unborn children. The short-form warning method in Section 25602(a)(4), does not provide for this level of specificity. The full warning language clearly conveys the adverse developmental effects delta-

²⁰ Section 25703(b)

9-THC and cannabis smoke can cause. Also, as noted above with respect to content (Section 25603), OEHHA removed the “known to the State of California to cause” language in part to reduce the length of the warning. If the product packaging is too small to accommodate the proposed warning, other warning methods, such as posted signs and shelf tags, are available.

Consistent with Sections 25602 and 25604, as well as tailored warnings in Subarticle 2, the proposed regulations for cannabis smoke and delta-9-THC exposures require that when material used to provide a warning includes consumer information about a product in a language other than English, the warning must also be provided in that other language.

Under subsection (b) in product exposure warnings (Sections 25607.38, 25607.40, 25607.42, 25607.44) the warning must be provided in the same language or languages used for providing consumer information for a safe harbor. OEHHA does not intend for this to apply where only the name of the product is provided in a language other than English. This was determined to be the most feasible method to ensure that a warning is likely to be understood by non-English speaking members of the public without burdening a business with language requirements beyond those already provided with a product. Similarly, for the environmental exposure warning in Section 25607.46, the warning must be provided in English and in any other language used in signage in the affected area.

These provisions will allow people to read and understand the warning and should not create a significant hardship for businesses, since it only applies where the business is already providing consumer information in an alternate language. Given California’s linguistic diversity, OEHHA believes this safe harbor requirement in the proposed regulation will further the purposes of the statute by expanding the number of individuals who can understand the warning, thus ensuring it is “clear and reasonable”. Further, more than 25 percent of those individuals who participated in a UC Davis Extension Collaboration Center Study reported speaking a language other than English at home and over 15 percent chose to complete the survey in Spanish, thus reflecting a need for the information to be provided in alternative languages in some situations.²¹

²¹ UC Davis Extension Collaboration Center (2015), Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 9

Some specific aspects of the proposed method of transmission for cannabis smoke and delta-9-THC warnings are covered below in the discussions of Sections 25607.38, 25607.40, 25607.42, 25607.44, and, 25607.46.

§ 25607.38. Cannabis (Marijuana) Smoke from Consumer Products Exposure Warnings – Methods of Transmission

Proposed Section 25607.38 provides methods for businesses to give warnings for exposure to cannabis (marijuana) smoke²² and delta-9-THC from consumer products made from cannabis that are used for smoking. This covers products made from the cannabis plant that are burned or combusted, and inhaled. Vaped or dabbed products that are inhaled but whose use does not involve combustion of plant material are covered by separate sections (25607.42 and 25607.43). The warning meets the safe harbor requirements (Subarticle 2) if it uses one or more of the methods provided in Section 25602 – but not the short-form warning (Section 25602 subsection (a)(4)) as discussed above - and it uses the content requirements in proposed Section 25607.39 discussed below.

Consistent with Section 25602 and other provisions of the safe harbor warning regulations, proposed Section 25607.38 subsection (b) requires that when a sign, label or shelf tag used to provide the warning includes consumer information about a product in a language other than English, the warning must also be provided in that other language.

For further discussion, see section above “Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures”.

§ 25607.39. Cannabis (Marijuana) Smoke from Consumer Products Exposure Warnings – Content.

Proposed Section 25607.39 provides the safe harbor content for cannabis (marijuana) smoke exposures. Specifically, the warning must contain the symbol required in Section 25603(a)(1), namely, a black exclamation point in a yellow equilateral triangle with a bold black outline, the word “WARNING:” in all capital letters and bold print and the words,

²² For purposes of proposed Sections 25607.38 and 25607.39, “cannabis products” are products made from parts of the cannabis plant that are smoked, such as flowers, buds, leaves, stems, seeds, or resins of plants in the genus Cannabis (OEHHA 2019). It does not include purified CBD and other purified extracts so long as they do not have measurable levels of delta-9-THC.

“Smoking cannabis increases your cancer risk and during pregnancy exposes your child to delta-9-THC and other chemicals that can affect your child’s birthweight, behavior and learning ability. For more information go to www.P65Warnings.ca.gov/cannabis.”

As discussed in OEHHA (2019)²³ and OEHHA (2009)²⁴, cannabis (marijuana) smoke contains many other Proposition 65 listed chemicals that can be formed when cannabis is burned. Some products may also contain other chemicals that have been intentionally or unintentionally added such as carcinogenic pesticide residues associated with cannabis production processes²⁵. Consistent with the content required for other safe harbor warnings, businesses are not required to include the name of all listed carcinogens or developmental toxicants in the warning and may instead use the content provided in the proposed regulation.

For further discussion, see section above “Cannabis Smoke and Delta-9-THC Warning Content”.

§ 25607.40. Delta-9-THC from Ingested Products Exposure Warnings - Methods of Transmission.

Proposed subsection (a) refers to “a cannabis or other consumer product that is intended to be ingested” which can include products that can be eaten, drunk or otherwise taken into the body orally such as hard candy products, chocolate products, gummy products, chewing gum, oral sprays or extracts containing measurable delta-9-THC. The product does not have to be one that is swallowed to take advantage of this safe harbor method.

The proposed regulation incorporates by reference the existing methods for providing warnings in Section 25602, except for short-form warning described in subsection (a)(4). As discussed above, this method cannot be used.

Consistent with Section 25602 and other provisions of the safe harbor warning regulations proposed subsection (b) requires that when a sign, label or shelf tag used to provide warning includes consumer information about a product in a

²³ OEHHA (2019) pages 13-16.

²⁴ OEHHA (2009). Evidence on the Carcinogenicity of Marijuana Smoke, OEHHA, California Environmental Protection Agency, August. Available at:

<https://oehha.ca.gov/media/downloads/proposition-65/chemicals/finalmjsmokehid.pdf>

²⁵ Bureau of Cannabis Control (BCC, 2020), *Required Testing Chart*, California Department of Consumer Affairs, September 8, 2020, available at https://bcc.ca.gov/about_us/documents/17-261_required_testing_chart.pdf (last visited Jan. 23, 2021); Title 16, California Code of Regs., Section 5714(b)(7) (requires laboratory testing of cannabis for residual pesticides).

language other than English, the warning must also be provided in English and that other language.

For further discussion, see section above “Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures”.

§ 25607.41. Delta-9-THC from Ingested Products Exposure Warnings - Content

Proposed Section 25607.41 provides the safe harbor content for exposures to delta-9-THC from products intended to be ingested. Specifically, the warning must contain the symbol required in Section 25603(a)(1), namely, a black exclamation point in a yellow equilateral triangle with a bold black outline, the word “WARNING:” in all capital letters and bold print and the words,

“Consuming 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.”

If the product will also expose consumers – within the meaning of Section 25249.10(c) of the Health and Safety Code - to a listed carcinogen by ingestion then, in addition to the warning for exposure for the developmental effects of delta-9-THC, a warning must be given for the carcinogen. The safe harbor warning must include the words,

“Consuming this product exposes you to carcinogens including [name one or more listed carcinogens], and 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.”

Where the product only exposes the consumer to one listed carcinogen, consistent with Section 25603(a)(2)(E), the business may use the phrase “the carcinogen” rather than “carcinogens including” in the warning.

As discussed above, OEHHA is proposing this simplified warning language because it concisely conveys the developmental risks of exposure to delta-9-THC while still including the basic elements of a safe harbor warning.

For further discussion, see section above “Cannabis Smoke and Delta-9-THC Warning Content”.

§ 25607.42. Delta-9-THC from Vaping or Dabbing Products Exposure Warnings – Methods of Transmission

A safe harbor warning for delta-9-THC exposures from products intended to be vaped or dabbed can be transmitted using one or more of the methods required in Section 25602, with one exception: Short-form warnings described in subsection (a)(4) are not being permitted as a safe harbor warning method for delta-9-THC exposures, as discussed above.

Vaping is a method that uses non-combusting heat to heat the product to a point where delta-9-THC is released in an aerosol and inhaled^{26,27}. Dabbing refers to a process that enables the user to inhale a high concentration of delta-9-THC by aerosolizing a concentrated product that has been placed on a hot surface²⁸, or by otherwise heating a highly concentrated product to form a vapor that can be inhaled,²⁹ such as when using delta-9-THC concentrates in a dab pen or vaporizer.³⁰ Thus vaping and dapping products are used to deliver delta-9-THC exposures by inhalation.

Consistent with Section 25602 and other provisions of the safe harbor warning regulations, proposed subsection (b) requires that when a sign, label or shelf tag used to provide a warning includes consumer information about a product in a language other than English, the warning must also be provided in that other language.

For further discussion, see section above “Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures”.

§ 25607.43. Delta-9-THC from Vaping or Dabbing Products Exposure Warnings – Content.

Proposed Section 25607.43 provides the safe harbor content for delta-9-THC vaping or dabbing exposures. Specifically, the warning must contain the symbol required in Section 25603(a)(1), namely, a black exclamation point in a yellow

²⁶ OEHHA, 2019, p. 17

²⁷ Center for Disease Control and Prevention, *E-Cigarette, or Vaping, Products Visual Dictionary*, U.S. Department of Health and Human Services, at page 14, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf (hereinafter “CDC Visual Dictionary”).

²⁸ CDC Visual Dictionary, at page 19.

²⁹ OEHHA, 2019, p. 17

³⁰ CDC Visual Dictionary, at page 19.

equilateral triangle with a bold black outline, the word “WARNING:” in all capital letters and bold print and the words,

“Vaping or dabbing 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.”

If the product will expose consumers – within the meaning of Section 25249.10(c) of the Health and Safety Code (i.e., at sufficiently high levels, see discussion above “Simplified Warning Language and Other Content”) - to a listed carcinogen in addition to delta-9-THC, then the warning must include the words,

“Vaping or dabbing this product exposes you to carcinogens including [name one or more listed carcinogens], and 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.”

Thus a warning about cancer exposure must be given, in addition to the warning for developmental effects from delta-9-THC, and the name of one or more listed carcinogens that the consumer will be exposed to must be included. This is consistent with the approach for other safe harbor warnings for consumer products (Section 25603(a)(2)(C)).

Where the product only exposes the consumer to one listed carcinogen, consistent with Section 25603(a)(2)(E), the business may use the phrase “the carcinogen” rather than “carcinogens including” in the warning.

As previously discussed, OEHHA is proposing this simplified warning language because it concisely conveys the developmental risks of exposure to delta 9-THC while still including the basic elements of a safe harbor warning.

For further discussion, see section above “Cannabis Smoke and Delta-9-THC Warning Content”.

§ 25607.44. Delta-9-THC in Dermally Applied Products Exposure Warnings - Methods of Transmission.

Proposed Sections 25607.44 provides safe harbor methods for delta-9-THC exposures from products intended to be applied to the skin. Consistent with the previous provisions, the proposed amendments incorporate by reference the provisions of Section 25602, except for short-form warnings (Section 25602 subsection (a)(4)) which are excluded from the methods of transmission for safe harbor warnings for delta-9-THC exposures for the reasons discussed above.

As noted above, CBD is not on the Proposition 65 list and lotions made with CBD, other cannabinoids, or other purified extracts of the cannabis plants - that do not cause exposures to delta-9-THC or other Proposition 65 listed chemicals within the meaning of Section 25249.10(c) of the Health and Safety Code - do not require a warning. Added CBD may have trace but unquantifiable levels of delta-9-THC, and its presence in products should not trigger a warning. These proposed amendments providing safe harbor warning methods and content do not apply to products that have not been identified as posing risk of reproductive harm for the purposes of Proposition 65.

Consistent with Section 25602 and other provisions of the safe harbor warning regulations, proposed subsection (b) requires that when a sign, label or shelf tag used to provide a warning includes consumer information about a product in a language other than English, the warning must also be provided in that other language in addition to English.

For further discussion, see section above “Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures”.

§25607.45. Delta-9-THC in Dermally Applied Products Exposure Warnings - Content.

Proposed Section 25607.45 provides the safe harbor content for delta-9-THC dermal exposures. The warning must contain the symbol, the word “WARNING:” and the words,

“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.”

If the product will also expose consumers – within the meaning of Section 25249.10(c) of the Health and Safety Code (i.e., at sufficiently high levels, see discussion above “Simplified Warning Language and Other Content”) - to a listed carcinogen in addition to delta-9-THC when applied to the skin, then the safe harbor warning must contain the words,

“Using this product exposes you to carcinogens including [name one or more listed carcinogens], and 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.”

Where the product only exposes the consumer to one listed carcinogen, consistent with Section 25603(a)(2)(E), the business may use the phrase “the carcinogen” rather than “carcinogens including” in the warning.

As previously discussed, OEHHA is proposing this simplified warning language because it concisely conveys the developmental risks of exposure to delta 9-THC while still including the basic elements of a safe harbor warning.

For further discussion, see section above “Cannabis Smoke and Delta-9-THC Warning Content”.

§ 25607.46. Cannabis (Marijuana) Smoke or Delta-9-THC Inhalation Exposure Warnings (Environmental Exposures) - Method of Transmission.

OEHHA is aware that currently there are few locations licensed for on-site use of cannabis products for smoking, vaping, or dabbing. However, it is important to make an environmental exposure warning available to those businesses that allow on-site use. The environmental exposure warning is to be used for second-hand exposures to cannabis or delta-9-THC. Primary or direct exposures through individual use of the products are covered by proposed Sections 25607.38 and 25607.45 above.

Consistent with Section 25604 and other provisions of the safe harbor regulations for environmental exposures, there are various methods for providing an environmental exposure warning that businesses can use. These include signs posted at all entrances to and within the area where the exposure may occur. The proposed requirements for environmental exposure warnings for cannabis (marijuana) smoke or delta-9-THC are similar to those required for environmental exposures to tobacco smoke in Section 25607.28 because the two types of exposures are similar.

Proposed subsection (a) provides that a warning for environmental exposures to cannabis smoke or delta-9-THC meets the requirement of Subarticle 2 if it complies with the content requirement in Section 25607.47 and is provided on an 8 1/2 by 11-inch sign printed in no smaller than 22-point type and enclosed in a box posted both at the entrance to and within the area in which the exposure occurs.

Consistent with Section 25604, proposed subsection (b) requires that if other signage in the smoking, vaping or dabbing area is provided for the public in any

language other than English the warning must be provided in both English and that language.

For further discussion, see section above “Methods of Transmission and Exclusion of Short Form Warnings for Cannabis Smoke and delta-9-THC Exposures”.

§ 25607.47. Cannabis (Marijuana) Smoke or Delta-9-THC Inhalation Exposure Warnings (Environmental Exposures) - Content.

Proposed subsection (a) addresses the warning content for environmental exposures to cannabis (marijuana) smoke or delta-9-THC. Warnings for cannabis smoke or delta-9-THC exposures must include the symbol described in Section 25603(a)(1), namely, a black exclamation point in a yellow equilateral triangle with a bold black outline and the word, “WARNING:” in all capital letters and in bold print. For exposures to cannabis (marijuana) smoke or both cannabis (marijuana) smoke and delta-9-THC the warning must include the words,

“Breathing the air in this area exposes you to cannabis smoke, which increases your cancer risk and, during pregnancy, exposes your child to delta-9-THC and other chemicals that can affect your child’s birthweight, behavior and learning ability. For more information go to www.P65Warnings.ca.gov/cannabis.”

For exposures in designated areas where vaping or dabbing of delta-9-THC occurs, but cannabis smoking does not, the words,

“Breathing the air in this area 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.”

For exposures in designated areas where vaping or dabbing of delta-9-THC occurs, but cannabis smoking does not, and where consumers can be exposed to one or more listed carcinogens in ambient air the words,

“Breathing the air in this area exposes you to carcinogens including [name one or more listed carcinogens] and 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.”

Where the product only exposes the consumer to one listed carcinogen, consistent with Section 25603 (a)(E), the business may use the phrase “the carcinogen” rather than “carcinogens including” in the warning.

The warning content is different for exposures to cannabis smoke versus delta-9-THC because while both are Proposition 65 listed developmental toxicants, cannabis smoke is also listed for cancer. Differentiating between these two types of exposures will allow businesses to provide the appropriate safe harbor warning language for the type of exposure occurring at their business.

Recognizing that exposures to other carcinogens may occur in areas where only delta-9-THC exposure occurs, OEHHA is proposing specific language for these types of exposures.

For further discussion, see section above “Cannabis Smoke and Delta-9-THC Warning Content”.

Necessity

Marijuana (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.

Benefits of the Proposed Regulation

Regulated businesses that choose to follow the safe harbor provisions of the clear and reasonable warning regulations will likely benefit from the proposed amendments because the amendments provide safe harbor protection for businesses causing exposures to listed chemicals from cannabis products intended to be smoked, ingested, vaped, dabbed, or applied dermally containing

³¹ Health and Safety Code section 25249.10(b)

delta-9-THC, and environmental exposures to cannabis (marijuana) smoke or delta-9-THC. The health and welfare of California residents will likely benefit by increasing the public's ability to understand the warnings they receive for these products.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Bureau of Cannabis Control (BCC, 2020). *Required Testing Chart*, California Department of Consumer Affairs, September 8, 2020, available at https://bcc.ca.gov/about_us/documents/17-261_required_testing_chart.pdf.

Center for Disease Control and Prevention (CDC, 2019). *E-Cigarette, or Vaping, Products Visual Dictionary*, U.S. Department of Health and Human Services, at page 14, available at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf (hereinafter "CDC Visual Dictionary").

Furnari C (2020). *California Cannabis Sales Grew 18% to Nearly \$3 Billion in 2019*, THC.net, February 4, 2020, available at <https://thcnet.com/news/california-cannabis-sales-grew-18-to-nearly-3-billion-in-2019> (last visited Jan. 21, 2021).

Office of Environmental Health Hazard Assessment (OEHHA, 2019). Evidence on the Developmental Toxicity of Cannabis (Marijuana) Smoke and Δ^9 -THC, OEHHA, California Environmental Protection Agency, October 2019, available online at <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/cannabisdartheid100419.pdf>.

Office of Environmental Health Hazard Assessment (OEHHA, 2009). Evidence on the Carcinogenicity of Marijuana Smoke, OEHHA, California Environmental Protection Agency, August. Available at: <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/finalmjsmokehid.pdf>

Volkow ND, Han B, Compton WM, McCance-Katz EF (2019). Self-reported medical and nonmedical cannabis use among pregnant women in the United States, *JAMA*: 322(2): 167-168, 2019, available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6582258/>

UC Davis Extension Collaboration Center (2015). Proposition 65 Clear and Reasonable Warning Regulations Study: Survey results assessing the effectiveness of existing and proposed Proposition 65 warning signs, p. 9,

available online at:

<https://oehha.ca.gov/media/downloads/cnr/112715isorappendixa.pdf>

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The action provides non-mandatory safe harbor warning methods and content for these chemical exposures.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business, would be as effective or less burdensome on small business. In addition, OEHHA has determined that the proposed regulatory action will not impose any significant requirements on small businesses that already must comply with the warning requirements in the Act. Further, Proposition 65 expressly exempts businesses with less than 10 employees³² from the requirements of the Act.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

The proposed regulatory action will not have a significant adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The action does not impose any new requirements upon private persons or businesses. It simply clarifies the warning provisions of the regulations as they relate to cannabis and other consumer products that when used result in exposure to cannabis smoke and delta-9-THC, and to businesses that have environmental exposures to cannabis smoke or delta-9-THC.

³² Health and Safety Code section 25249.11(b).

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulatory action does not duplicate and will not conflict with federal regulations.

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

Creation or Elimination of Jobs within the State of California

The proposed regulatory action will not impact the creation or elimination of jobs within California. The action provides clarification and specificity to the regulations concerning how safe harbor warnings should be provided for exposures to cannabis smoke and delta-9-THC from cannabis and other products, and environmental exposures to cannabis smoke or delta-9-THC.

Creation of New Businesses or Elimination or Expansion of Existing Businesses within the State of California

The proposed regulatory action will not impact the creation of new businesses or the elimination or expansion of existing businesses within California. The action provides clarification and specificity to the regulations concerning how safe harbor warnings should be provided for exposures cannabis smoke and delta-9-THC to cannabis and other products, and environmental exposures to cannabis smoke or delta-9-THC.

Benefits of the Proposed Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The proposed regulatory action will benefit California residents by enabling businesses to understand how to comply with the warning requirements such that warnings considered to be clear and reasonable are provided to Californians using consistent and uniform content and methods. The action furthers the right-to-know purposes of the statute and therefore promotes public and worker health and safety.