



May 24, 2021

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Sacramento, California 95812-4010

Via electronic submission to: <https://oehha.ca.gov/comments>

RE: Public Comments to Proposed Amendments to Article 6 Clear and Reasonable Warnings – Cannabis (Marijuana) Smoke and Delta-9-THC Exposure Warnings

Dear Ms. Vela,

The following comments are submitted by the American Herbal Products Association (AHPA), the national trade association and voice of the herbal products industry. AHPA is comprised of domestic and foreign companies doing business as growers, collectors, processors, manufacturers, marketers, importers, exporters and distributors of herbs and herbal products.

AHPA has prepared these comments in response to the March 19, 2021 OEHHA Notice of Proposed Rulemaking titled “Proposed Amendments to Article 6 Clear and Reasonable Warnings Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings New Sections 25607.38 – 25607.47.”¹ As OEHHA indicates in the proposed amendments, the intent of the rulemaking is to “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.” Marijuana smoke has been a Proposition 65 listed chemical as a carcinogen since March 2009. Marijuana smoke and delta-9-THC were added to the Proposition 65 list as developmental toxins on January 3, 2020.

AHPA’s membership includes companies that participate in California’s legal cannabis market and that produce products from hemp. AHPA’s members marketing products in California that may result in exposures to these chemicals may be directly impacted by the proposed safe harbor warnings issued by OEHHA, and these comments are offered on their behalf.

As explained in further detail below, AHPA acknowledges OEHHA’s recognition that non-quantifiable amounts of delta-9-THC do not require Proposition 65 warnings. However, AHPA does not agree with the proposal to establish unique safe harbor warnings for marijuana smoke

¹ Available at <https://oehha.ca.gov/media/downloads/cnrn/legalnoticeproposedrulemakingcannabisdelta9thc2021.pdf>.

and delta-9-THC in the absence of a demonstrable scientific need for such warnings, as well as the proposal to prohibit the use of short form warnings for these chemicals.

Clarification regarding unquantifiable levels of delta-9-THC

AHPA appreciates that OEHHA’s Initial Statement of Reasons (ISOR) document² includes a clear statement that “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 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.” This statement provides useful guidance to companies marketing products such as certain hemp extracts, which may contain trace levels of delta-9-THC, as to whether a Proposition 65 warning for delta-9-THC should be provided for their products.

While AHPA finds this statement to be a useful clarification, we are also aware that analytical methods continue to become increasingly sensitive, and a test result that is considered to be non-quantifiable today may be fully quantifiable in the near future. Multiple analytical methods are being utilized in the cannabis industry that may have varying limits of quantification as well. AHPA recommends that OEHHA consider specification of an analytical threshold for additional consistency. For example, both AHPA³ and the U.S. Hemp Authority⁴ define “broad spectrum hemp extracts” as those that contain no delta-9-THC at a limit of quantification of less than 0.01%. Also, pending legislation⁵ in California may impact whether the delta-9-THC in certain hemp products can be considered to be naturally occurring under the provisions of Proposition 65.

Justification is lacking for cannabis specific safe harbor warnings

OEHHA states that the issuance of these cannabis specific safe harbor warnings is intended to provide guidance to businesses impacted by the new listings of cannabis (marijuana) smoke and delta-9-THC as reproductive toxins, and to ensure that the public receives consistent and clear warnings about exposures to these chemicals. As justification for the need for unique safe harbor warnings for these chemicals, rather than using existing safe harbor warnings that have already

² Initial Statement of Reasons Title 27, California Code of Regulations Proposed Amendments to Article 6 Clear and Reasonable Warnings: Cannabis (Marijuana) Smoke and Delta-9-Tetrahydrocannabinol (Delta-9-THC) Exposure Warnings, February 2021, Accessible at <https://oehha.ca.gov/media/downloads/cnrn/legalisorcannabisdelta9thcwarnings2021.pdf>.

³ AHPA Hemp Lexicon (May 2021). Accessible at <http://www.ahpa.org/News/LatestNews/TabId/96/ArtMID/1179/ArticleID/1617/AHPA-publishes-Hemp-Lexicon.aspx>.

⁴ U.S. Hemp Authority Certification Program Standard 3.0. Accessible at <https://ushempauthority.org/assets/uploads/USHA-Standard-v3.0-final.pdf>.

⁵ California AB45 Industrial hemp. Accessible at https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=202120220AB45#:~:text=AB%2045%2C%20as%20amended%2C%20Aguiar,foods%2C%20beverages%2C%20or%20cosmetics.&text=Violation%20of%20the%20Sherman%20Food,Cosmetic%20Law%20is%20a%20misdemeanor.

been the subject of extensive public review, OEHHA cites evidence of the increasing sales of regulated cannabis products for all routes of consumption in California, information about increasing self-reported use of cannabis products by pregnant women in the U.S., and the availability of cannabis products of higher delta-9-THC content.

AHPA notes that none of this information provides direct evidence of any documented increase in the female reproductive and developmental toxicity associated with cannabis use that correlates with these parameters cited by OEHHA. Almost 300 chemicals have been classified by OEHHA as Proposition 65 developmental toxins and 58 as female reproductive toxins. Numerous of these are common chemicals to which pregnant women may have ongoing exposures from consumer products, including acrylamide, heavy metals, phthalates, pesticides, and pharmaceuticals. It is not clear why OEHHA has determined that unique, detailed warnings are indicated to achieve consistent messaging to consumers for cannabis (marijuana) smoke or delta-9-THC, and not for the multitude of chemicals that have been previously been identified as reproductive and developmental toxins by the State of California. AHPA is not aware of evidence that suggests the risk of reproductive or developmental harm is any greater with cannabis products compared to the numerous other ubiquitous chemicals also associated with these hazards, and therefore questions the need for such detailed safe harbor warnings.

AHPA is concerned that the codification of such unique safe harbor warnings, particularly when it is optional for companies to utilize the warning language, may incentivize private plaintiffs to target companies who do not adopt the suggested warning language and allege that they are not providing an adequate or compliant warning.

Coordination needed with other warnings required by the State of California

Manufactured cannabis products marketed in California are required by the Manufactured Cannabis Safety Branch (MCSB) to bear the following warning in their labeling⁶ (in emphasis added):

GOVERNMENT WARNING: THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE I CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY ONLY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOXICATING EFFECTS OF CANNABIS PRODUCTS MAY BE DELAYED UP TO TWO HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.

Many cannabis industry products have relatively small labels presented on packages and containers of edibles and dosage form products such as tinctures, tablets, capsules, soft gels, and gummies. In a highly regulated cannabis market such as that in California, companies must

⁶ California Code of Regulations, Title 17 Division 1 Chapter 13. Manufactured Cannabis Safety, §40404. Labeling Requirements: Pre-Rolls and Packaged Flower and §40408. Informational Panel Labeling Requirements.

comply with numerous other regulations that mandate specific labeling content and how that content is presented, such as the warning cited above. This particular warning already identifies the potential risk of using delta-9-THC containing products while pregnant or breastfeeding.

AHPA suggests that coordination of warnings amongst California agencies with jurisdiction over cannabis product would be beneficial to the industry, which will reduce potential redundancy among product warnings and provide greater overall clarity to consumers.

Prohibition on the use of the short-form warning format

OEHHA proposes to prohibit the use of short-form warning format for cannabis products, but does not provide any specific criteria or scientific basis for this restriction.

The option to use the current short-form warning format provides needed flexibility that allows marketers to comply with Proposition 65 as well as other regulatory labeling obligations. As previously noted, numerous other Proposition 65 listed chemicals have been identified as reproductive and developmental toxins, and OEHHA has not presented a scientific basis that establishes why the risk of reproductive or developmental harm from cannabis products is significantly greater than the numerous other common chemicals also associated with these hazards. Therefore, AHPA questions the technical justification for this proposed restriction, given that no other chemicals that have been identified as reproductive or developmental toxins are similarly restricted.

AHPA also notes that OEHHA has proposed significant changes to the use of the short-form warning in a separate proposed rulemaking.⁷ Those changes include limitations to the size of label that can use the short-form warning and changes to the content of the short form warning. That proposal does not also establish limitations as to whether it is appropriate to use a short form warning for specific Proposition 65 listed chemicals, as is proposed in the present rulemaking for cannabis (marijuana) smoke or delta-9-THC. If OEHHA believes that such restrictions are needed, the agency should first undertake rulemaking to establish specific criteria for identifying listed chemicals for which use of the short-form warning should be prohibited. This will allow such restrictions to be applied consistently and in a transparent manner.

Conclusions

In summary, AHPA strongly recommends that OEHHA withdraw the current proposal to establish unique safe harbor warnings for cannabis products in the absence of a demonstrable scientific need for such warnings and recommends that OEHHA maintain access to the short form warning as an option for the cannabis industry.

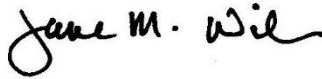
AHPA greatly appreciates the opportunity to present comments during this public comment process. We welcome any questions that may arise from AHPA's comments and look forward to working with OEHHA and other stakeholders on this significant topic.

⁷ January 8, 2021 OEHHA Notice of Proposed Rulemaking titled "Proposed Amendments to Article 6 Clear and Reasonable Warnings." Accessible at <https://oehha.ca.gov/media/downloads/cmr/p65noticeshortformold2021.pdf>.

Respectfully submitted,



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