



January 3, 2024

Ms. Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
P. O. Box 4010
Sacramento, California 95812-4010

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

RE: Public comments to amendments to Article 6 Clear and reasonable warnings – short-form 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 October 27, 2023 OEHHA “Notice of Proposed Rulemaking and Announcement of Public Hearing: Amendments to Article 6, Clear and Reasonable Warnings Safe Harbor Methods and Content” (October 27th Notice).¹ In this Notice, OEHHA summarizes new proposed amendments related to the short form warning format. These proposed amendments include, but are not limited to the following:

- Identification of a specific chemical for which a warning is being given, when using the short form warning format;
- Provide clarity to businesses regarding other aspects of the short form warning; and
- Provide clarity to businesses regarding provision of safe harbor warnings for internet and catalog purchases.

AHPA’s members marketing products in California will be directly impacted by the proposed changes issued by OEHHA, and these comments are offered on their behalf. AHPA has not offered comments to all elements in the October 27th Notice; the absence of comments on any element or section of the Notice and the accompanying regulatory text should not be taken to mean that AHPA agrees with such element or section, unless such agreement is specifically stated.

¹ Available at <https://oehha.ca.gov/proposition-65/crn/public-hearing-information-proposed-amendments-regulations-clear-and-reasonable>

Economic impact of labeling changes

According to the October 27th Notice, product marketers currently using the short form warning would be required to make changes to their Proposition 65 labeling practices to revise the short form warning content to identify a chemical name, along with a phrase such as “can expose you to <chemical name>” or “risk from exposure to <chemical name>.” AHPA finds that OEHHA’s proposal does not reflect a realistic assessment of the financial impact of this change on product marketers across various industries that are currently providing compliant safe harbor warnings using this option. In the October 27th Notice, OEHHA states that it has calculated an approximate cost to businesses of \$14,700,000 for the proposed safe harbor warning changes. For the dietary supplement industry alone, AHPA estimates the cost of updating labels to be in the millions of dollars based on information obtained from a cross-section of our membership that utilize the short-form warning.

AHPA notes that the proposal provides a two-year sell through period from the effective date of the proposed amendments for any product manufactured and labeled using the current short form warning format. In consideration of the magnitude of this change to add a chemical name, AHPA requests that this transition period be increased to three years, and provisions be added to ensure that businesses can exhaust the inventory of any labeling materials already purchased by the effective date and that contain warnings compliant with the current short form warning format. These additional provisions will assist businesses, especially small businesses, in making changes to labeling in today’s challenging and complex supply chains and help to limit the financial impacts of this proposed change.

OEHHA concern about over-warning

In the October 27th Notice, OEHHA states that “many businesses are using the short-form warning prophylactically because it protects from potential litigation,” with the result that consumers may be receiving warnings when none is required. It is AHPA’s position that the overall framework of Proposition 65 results in systemic over-warning, and OEHHA’s concern about over-warning is unlikely to be addressed in a significant way by changing the provisions of the current short-form warning in the manner proposed.

When marketers are unsure whether their product may sometimes result in a consumer exposure above a safe harbor, it stands to reason they may provide a compliant warning as a means of legal protection. Private plaintiffs do not always respect certain provisions of the Proposition 65 regulations or OEHHA’s findings regarding certain listed chemicals. This is evidenced by the March 16, 2021 filing of a 60-day notice² for failure to warn for exposure to β -myrcene in thyme leaves, even though the β -myrcene is clearly a naturally occurring chemical in this food product.³ This action was followed on March 17, 2021 by the filing of two 60-day notices⁴ for failure to

² Accessible at <https://oag.ca.gov/system/files/prop65/notices/2021-00643.pdf>

³ Notice of Intent to List: Beta-Myrcene, February 7, 2014. Accessible at [Notice of Intent to List: Beta-Myrcene | OEHHA \(ca.gov\)](https://oehha.ca.gov/notice-of-intent-to-list-beta-myrcene)

⁴ Accessible at <https://oag.ca.gov/system/files/prop65/notices/2021-00650.pdf> and <https://oag.ca.gov/system/files/prop65/notices/2021-00648.pdf>

warn for exposure to pulegone in two peppermint oil products, which again ignores the fact that pulegone is a known naturally occurring constituent in various plants and their essential oils.⁵ These three filings represent aggressive private plaintiff actions in which companies must defend their products even in situations where a Proposition 65 warning is clearly not warranted.

The Proposition 65 listed chemical lead is ubiquitous in the environment and is a chemical for which many of AHPA's members provide a warning, given the safe harbor MADL for lead is 0.5 micrograms/day. Marketers may be providing a compliant short form warning to avoid testing every lot of product to confirm that it does not exceed the lead safe harbor where testing history shows that individual lots of product may fall above or below the MADL threshold. AHPA notes that the provisions of Proposition 65 do not preclude providing a warning for an exposure that may sometimes fall below a safe harbor threshold.

Concluding remarks

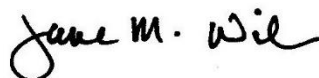
In summary, AHPA strongly recommends that OEHHA withdraw the proposal to require the identification of a chemical name in the short-form warning format and instead work with industries currently using short-form warnings to formulate solutions that will be meaningful to California consumers and more effectively address OEHHA's concerns regarding over-warning.

AHPA greatly appreciates the opportunity to present comments during this public comment process. We welcome any questions that may arise from AHPA's comments.

Respectfully submitted,



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⁵ Notice of Intent to List: Pulegone, February 7, 2014. Accessible at [Notice of Intent to List Pulegone by the Labor Code Mechanism | OEHHA \(ca.gov\)](#).