



June 28, 2024

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

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 June 13, 2024 OEHHHA “Notice of 15-Day Modification: Amendments to Article 6, Clear and Reasonable Warnings Safe Harbor Methods and Content” (June 13th Notice).¹ In this Notice, OEHHHA summarizes modifications to past proposed amendments related to the short-form warning format. These modifications include the following:

- Increases the proposed implementation period for the revised short-form warning content from two years to three years;
- Introduces a new provision for a 60-day grace period for internet retailers from when they receive notice of an updated warning to change their short-form warnings online during the three-year implementation period; and
- Reverts to most of the original regulation text for internet and catalog short-form warning content.

AHPA’s members marketing products in California will be directly impacted by the proposed changes issued by OEHHHA, and these comments are offered on their behalf. AHPA has not offered comments to all elements in the June 13th 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/modification-proposed-amendments-regulations-clear-and-reasonable-warnings-safe>

Economic impact of labeling changes

The proposal represented in the June 13th Notice still requires that product marketers currently using the short-form warning 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 continues to find 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 prior Notices related to the short-form warning regulations, 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.

OEHHA concern about over-warning

In prior Notices related to revision of the short-form warning format, OEHHA has expressed its concern regarding the use of the short-form warning as a form of protection 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 chemical’s safe harbor level, 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 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

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 \(ca.gov\)](#)

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>

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

micrograms/day. Marketers may be providing a compliant short form warning 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.

Implementation period

AHPA appreciates that OEHHA incorporated prior comments submitted by AHPA and other stakeholders that the magnitude of the proposed change to the current short-form warnings to include a chemical name requires an extended implementation period. The three-year implementation period will help ensure that businesses can exhaust their inventory of any labeling materials already purchased by the effective date and that contain warnings compliant with the current short-form warning format. The extended implementation will assist businesses, especially small businesses, in making the proposed changes to labeling in today's challenging and complex supply chains and help to manage the overall financial impacts of this proposed change.

Concluding remarks

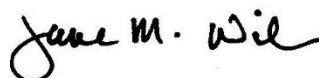
In summary, OEHHA's extension of the implementation period as proposed in the June 15th notice is a welcome change, however, AHPA maintains its opposition to the proposal to require the identification of a chemical name in the short-form warning format.

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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