



March 29, 2021

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 January 8, 2021 OEHHA Notice of Proposed Rulemaking titled “Proposed Amendments to Article 6 Clear and Reasonable Warnings.”¹ In this notice, OEHHA states that “there has been widespread use of short-form warnings in ways that were not intended and do not further the purposes of Proposition 65,” and that numerous businesses have sought clarification regarding use of the short-form warnings for food products.

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.

Restriction to labels of a total of 5 square inches or less

OEHHA’s proposal would limit the use of short-form warnings to product labels for which the “surface area of the product label available for consumer information is 5 square inches or less,” and that cannot accommodate a full size warning. OEHHA provides no basis for the 5 square inches or less limitation. In examining other definitions of small labels, AHPA notes that FDA² defines small food packages as those with less than 12 square inches of total surface area available to bear labeling.

¹ Available at <https://oehha.ca.gov/media/downloads/crn/p65noticeshortformald2021.pdf>.

² US FDA. Guidance for industry: A food labeling guide. January 2013.

The current short-form warning format is useful to AHPA's members since many of the products our members market have relatively small labels presented on packages and containers of dietary supplement dosage forms such as tablets, capsules, soft gels, and gummies. Marketers of these products must comply with numerous other regulations that mandate specific labeling content and how that content is presented - such as the federal labeling regulations for dietary supplements.³ 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.

AHPA finds the proposed limitation to less than 5 square inches of labeling to be arbitrary, in the absence of specific information about how this size limitation was determined, and the proposal lacks an 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. For many products in the supplement industry, a typical label would easily exceed 5 square inches and would require the unnecessary expense of revising currently compliant labeling, only a few short years after OEHHA introduced the short-form option in the last revision of the Proposition 65 warning regulations. For the dietary supplement industry alone, AHPA estimates this cost 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 regarding over-warning

In the Initial Statement of Reasons (ISOR)⁴ document for the proposed changes, OEHHA states that use of the short-form warning is resulting in “over-warning” as it provides businesses with “safe harbor protection from enforcement actions without requiring the business to provide sufficient information to consumers.”

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 don't preclude providing a warning for an exposure that may sometimes fall below a safe harbor threshold.

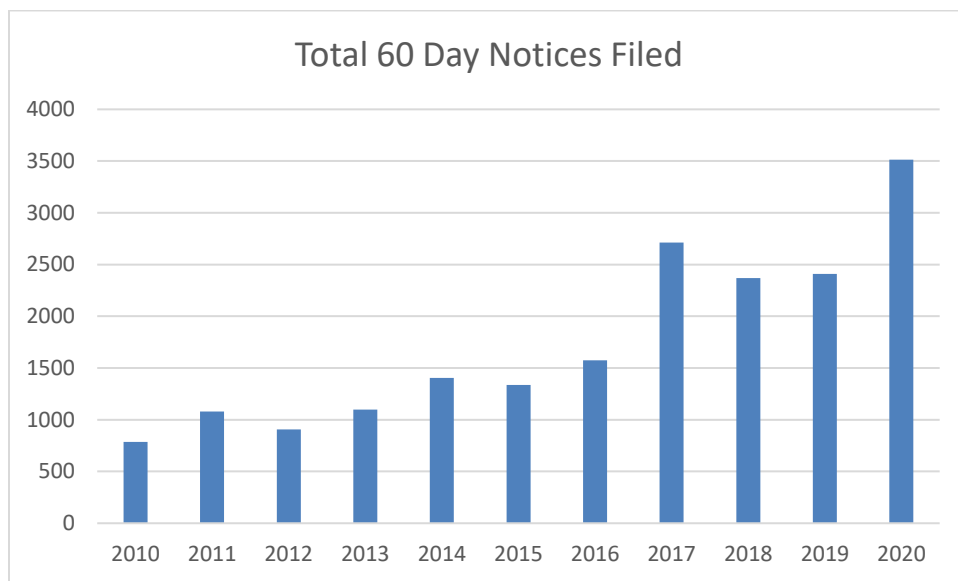
The overall framework of Proposition 65 results in systemic over-warning, and OEHHA's concern about over-warning as expressed in the ISOR is unlikely to be addressed in a significant way by changing the provisions of the current short-form warning in the manner proposed. If marketers are unsure whether their product may 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.

³ 21 CFR Part 101.36 Nutrition labeling of dietary supplements, available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101>

⁴ Initial Statement of Reasons Title 27, California Code of Regulations Proposed Amendments to Article 6 Clear and Reasonable Warnings: Short-Form Warnings for Consumer Product Exposure, January 8, 2021, Accessible at <https://oehha.ca.gov/media/downloads/crn/p65noticeshortformald2021.pdf>

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 notice⁵ 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.⁶ This action was followed on March 17, 2021 by the filing of two 60-day notices⁷ 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.⁸ 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 following chart demonstrates the steady rise in 60-day notices filed over the last 10-year period.



As of the date of these comments, 799 60-day notices have been filed in 2021, which already surpasses the total number filed in 2010.

In summary, AHPA strongly recommends that OEHHA withdraw the current proposal to amend the short-form warning provisions and work with industries currently using short-form warnings

⁵ Accessible at <https://oag.ca.gov/system/files/prop65/notices/2021-00643.pdf>

⁶ Notice of Intent to List: Beta-Myrcene, February 7, 2014. Accessible at [Notice of Intent to List: Beta-Myrcene | OEHHA \(ca.gov\)](#)

⁷ 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>

⁸ Notice of Intent to List: Pulegone, February 7, 2014. Accessible at [Notice of Intent to List Pulegone by the Labor Code Mechanism | OEHHA \(ca.gov\)](#).

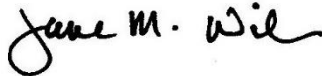
to formulate solutions that will maintain reasonable access to this important warning option and be meaningful to California consumers.

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.

Respectfully submitted,



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