



1773 T St, N.W. Washington, D.C. 20009
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

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Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
1001 I Street
Sacramento, California 95812-4010
Via Email: P65Public.Comments@oehha.ca.gov

RE: Pre-Regulatory Draft: Proposed Amendments to Article 6 Clear and Reasonable Warnings

Dear Ms. Vela:

The Natural Products Association (NPA) is submitting this letter as general comments to the California Office of Environmental Health Hazard Assessment (OEHHA) regarding a pre-regulatory draft proposing amendments to Proposition 65 (Prop 65) Article 6, Clear and Reasonable Warnings. The NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. The NPA is a non-profit 501(c)(6) association whose mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,900 members accounting for almost 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. Most NPA member companies do business in California and are therefore impacted by Prop 65. Thus, the pre-regulatory draft regarding Article 6 Clear and Reasonable Warnings is of great interest and importance to our members. Thank you for the opportunity to comment.

Background – NPA was heartened by Governor Brown’s May 7, 2013, press release promising reforms to “revamp Proposition 65 by ending frivolous ‘shake-down’ lawsuits, improving how the public

is warned about dangerous chemicals and strengthening the scientific basis for warning levels.”¹ Following the Governor’s announcement, OEHHA held a public meeting and developed a pre-regulatory draft amending Article 6 Clear and Reasonable Warnings. In OEHHA’s Initial Statement of Intent, the Agency states that its proposed changes to Prop 65 Article 6 Clear and Reasonable Warnings are to address the Administration’s vision and would “reduce unnecessary litigation and require more useful information to the public on what they are being exposed to and how they can protect themselves,”² and would provide certainty for businesses subject to the Act. Based on our review of the pre-regulatory draft and the OEHHA presentation and comments expressed during the April 14, 2014, workshop, NPA is submitting the following comments regarding the amendments to Article 6 Clear and Reasonable Warnings.

The NPA applauds the efforts of the Governor to reduce the incidence of frivolous lawsuits in the State of California under the private enforcement provisions of Proposition 65. However, we think the modifications to the current regulatory status of Proposition 65 do little to achieve that outcome. For example, the proposed changes would not extend to warnings in court approved settlements for those companies that are named in the court approved settlements, but would apply to other companies selling the same products. This will have the opposite effect intended by the governor, since this will essentially place all other persons and companies engaged in sales of products in the State of California at risk for litigation, even though they have carefully amended their product warnings to conform to the warning provisions in the court approved settlements involving the same or similar products.

NPA Does Not Support the OEHHA Pre-Regulatory Draft – NPA does not support the amendments Article 6 Clear and Reasonable Warnings as outlined in the Pre-Regulatory Draft. We believe the proposal in its current form is unworkable and will not achieve the goals outlined by either the Governor or OEHHA; rather the results of the amendments will be counterproductive and will have the opposite effect.

Lack of Scientific Evidence to Support Amendments - At the April 14 workshop, OEHHA stated that the basis for the proposed amendments is to address dual concerns, 1) current warnings are vague and do not provide the public with enough information to make informed choices and 2) to provide more flexibility and certainty to businesses to reduce or eliminate frivolous lawsuits. When asked what scientific evidence OEHHA has to support the assertion that current Prop 65 warnings are inadequate and fail to provide “clear and reasonable” warnings, OEHHA stated it relied on anecdotal evidence (i.e.,

¹ Press Release, Office of Governor Edmund G. Brown, Jr., Governor Brown Proposes to Reform Proposition 65. (May 7, 2013), available at <http://gov.ca.gov/news.php?id=18026>.

² OEHHA Draft Initial Statement of Reasons, p.4, March 7, 2014, available at <http://oehha.ca.gov/prop65/warnings/pdf/ISORWarningreg030714.pdf>

phone calls from the public and consumer group requests) versus conducting consumer studies based on empirical evidence to determine if the warnings are in fact inadequate. Furthermore, OEHHA presented no research or scientific data to suggest that more specific Prop 65 warnings will provide greater clarity to inform consumers. OEHHA also claims that it is trying to address the problem of “overwarning,” that is consumer apathy to exposure warnings due to overexposure. However, again the Agency has no data to support that safe harbor warnings result in “overwarning.” Additionally, OEHHA stated it has not conducted trending analysis of Prop 65 lawsuits to determine the percentage of recent Prop 65 actions based on inadequate or poorly communicated warnings versus the lack of any warning of exposure. NPA believes the proposed amendments to Article 6 will result in tremendous financial and resource challenges to businesses and will have the potential to create more compliance pitfalls resulting in a glut of new threatened or actual litigation. Consequently, the proposal will yield more rather than less frivolous lawsuits based on noncompliance issues unrelated to the quality of an exposure warning. It is arbitrary to move forward with these proposals without actual scientific data to support any perceived benefits to consumers and without an assessment of the risk and legal vulnerability for businesses created by these new warning regulations.

Reductions in Frivolous Lawsuits Versus Increased Litigation – OEHHA asserts the pre-regulatory draft proposal will reduce frivolous lawsuits related to Prop 65 lawsuits for inadequate or inconsistent warnings. As we commented earlier, NPA questions how many recent lawsuits, frivolous or otherwise, are based on inadequate or inconsistent warnings. A review of recent Prop 65 lawsuits and settlements indicate that the current genesis for the vast majority of threatened or actual lawsuits is not the content of the warning, but whether an exposure warning is required. We believe imposing additional prescriptive requirements to Prop 65 warnings and requiring the submission of additional information to the OEHHA without addressing the core cause of most litigation is likely to trigger more frivolous lawsuits based on minor non-compliance issues unrelated to providing an adequate “clear and reasonable” warning of exposure to a consumer. Under the current Article 6 provisions, companies can meet their regulatory responsibilities by determining if their product contains a listed chemical and then providing a “clear and reasonable” warning using either safe harbor language or more specific warning language when appropriate. Due to the complexities involved with designing and implementing exposure assessments, NPA urges OEHHA to reconsider the extensive amendments related to the elimination of safe harbor warnings and the addition of more prescriptive warnings and information that must be submitted to OEHHA until the Agency conducts a more thorough assessment of its impact on businesses.

Eliminating Safe Harbor Warnings – OEHHA proposes to eliminate safe harbor warnings in part due to their concern of “overwarning.” However, as noted earlier in our comments, the Agency has not provided empirical evidence supporting this contention. Prohibiting safe harbor warnings unless companies can establish exposure risk creates a regulatory dilemma and legal vulnerability for companies, particularly for exposure related to the use of foods and other consumer products. This places an unreasonable burden of proof on businesses. Moreover, even when a business conducts an exposure assessment, they still find themselves having to defend their assessment against a private enforcer that challenges the assessment. In short, lawsuit mitigation is not achieved here.

Eliminating safe harbor warnings will also result in similar products, containing the same levels of a listed chemical, bearing different warnings. In some cases, given the grandfathering of only pre-existing court-approved settlements, products with higher levels of a listed chemical could bear a warning as to content only while products with lower levels of a listed chemical could bear a warning as to exposure. The stronger exposure warning language and “exploding chest” pictogram will likely give the misimpression that consumer products with the new label pose a greater risk of exposure or harm than those products allowed to continue to use their “protected” warning. Consumers will not understand that a food or a consumer product with the new warnings in the proscribed, large font with the “exploding chest” pictogram is addressing the same sort of exposure risk, and at the same levels (or lower), than a food or other product allowed to use a different warning. This will create an unfair disadvantage to products bearing the new warning, a misrepresentation of “safety” regarding exposure risk, and a misunderstanding of the difference (none) between the products.

Financial Impact – NPA appreciates OEHHA’s goal of using technology to provide additional information regarding Prop 65 warnings, yet we caution the Agency to be realistic about its resources and capacity for implementation of the proposal and ongoing costs and challenges related to keeping the proposed website maintained, updated and the data protected. OEHHA does not present an economic impact analysis for the cost to the Agency, a cost that will be passed ultimately to the California taxpayers that support the Agency. Furthermore, OEHHA has not presented an economic impact analysis concerning costs to businesses, which will be considerable due to the heavy burdens that will result from new exposure warning labels for all foods and other consumer products.

In spite of having an economy that has ranked in the top ten worldwide since the 1970’s, California is often found at the bottom of lists highlighting states which support business. California ranked dead last in the Chief Executive’s list of best and worst states for business published on May 24, 2014.³ CEO comments about doing business in California tell a grim story: “California goes out of its

³ <http://chiefexecutive.net/California-is-the-worst-state-for-business-2014#sthash.pGzMUKXX.qvmN6VFk.dpuf>

way to be anti-business and particularly where one might put manufacturing and/or distribution operations." Or, "California could hardly do more to discourage business if that was the goal. The regulatory, tax and political environment are crushing."⁴ These comments support NPA's apprehensions that California will see a decline in its economy due to an increase in ubiquitous Prop 65 warnings and related shake-down lawsuits that become a barrier to attracting new businesses to the state and force companies to flee to more business-friendly states.

Strengthening The Scientific Basis For Warning Levels – An area of particular interest to businesses was the Governor's promise to strengthen the scientific basis for warning levels. The numerical factors or multipliers adopted by OEHHA to establish risk levels for listed chemicals seem to be far in excess of those established by Federal agencies such as the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA). For example, FDA sets safe/tolerable daily exposure levels assessed with respect to safe/tolerable exposure levels that have been developed for particular age and sex groups, referred to as provisional total tolerable intake levels (PTTILs). FDA set lead PTTILs ($\mu\text{g Pb/days}$) as low as 6 μg for children, 25 μg for pregnant/lactating women and 75 μg for adult women, an exposure risk level far exceeding the 0.5 $\mu\text{g/day}$ exposure risk threshold established under Prop 65.⁵ We are requesting information about how these Prop 65 multipliers were established, the scientific rationale behind their use, and scientific peer reviewed research citations to support their inclusion. We believe this policy needs to be revisited to ensure the current risk-level multipliers are supported by scientific evidence and to ensure future modifications to the process used to evaluate legitimate exposure risk are founded on established scientific principles in line with those established in internationally-recognized risk assessment methodologies and adopted by Federal Agencies such as FDA through their Codex Alimentarius activities with the FAO/WHO. We note that OEHHA has not addressed this important reform in its proposal. NPA believes that not only is the current proposal unworkable but also that OEHHA should table amending Article 6 Clear and Reasonable Warning until it also addresses the provisions within the Act that govern the requirements associated with assessing risk to determine if an exposure warning is required.

§ 25607 Opportunity to Cure – The pre-regulatory proposal is fatally flawed but to the extent this section remains, NPA recommends that OEHHA expand proposed § 25607 Opportunity to Cure to apply to retailers of all sizes. OEHHA offers no rational basis for limiting this provision to retailers with less than 25 employees, and NPA finds it illogical not to broaden the opportunity to cure to retailers of all

⁴ <http://chiefexecutive.net/California-is-the-worst-state-for-business-2014#sthash.pGzMUKXX.qvmN6VFk.dpuf>

⁵ <http://www.fda.gov/food/foodborneillnesscontaminants/metals/ucm115941.htm#ftn2>

sizes. There is no difference in the products offered for sale at smaller retailers, and the “risk” to consumers is neither changed nor increased based on the size of the retailer selling the products.

The Current Prop 65 Article 6 Clear and Reasonable Warnings Are Adequate – NPA believes that the current regulations appropriately allow businesses to prove that the Proposition 65 warnings they issue are “clear and reasonable” by any means they wish, but also set forth criteria to establish when warnings will automatically be deemed “clear and reasonable” for purposes of Proposition 65. Businesses using these so-called “safe harbor” warnings are thus protected from the threat of litigation and can carry out their business with a sense of certainty.

Conclusion - In these comments, NPA has outlined our overarching concerns with the OEHHA Pre-Regulatory Draft Proposal, and these comments support our contention that the Pre-Regulatory Draft will not result in the reforms outlined by the Governor or OEHHA’s stated goals, which are to reduce frivolous lawsuits and improve the quality of exposure warnings. We have numerous other specific concerns that are addressed in articulate detail in the California Chamber of Commerce’s comprehensive comments submitted on behalf of over 100 concerned California-based and national businesses and associations. NPA is a signatory to these comments and supports the arguments and conclusions outlined therein.

Thank you for this opportunity to comment. We appreciate the opportunity to participate in this important pre-regulatory draft process.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Daniel Fabricant". The signature is written in a cursive, flowing style.

Daniel Fabricant, Ph.D.
CEO/Executive Director
Natural Products Association