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NPAinfo.org

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Ms. Monet Vela  
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Sent Electronically to: [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)  
Subject: "Clear and Reasonable Warnings"

Dear Ms. Vela:

On behalf of the Natural Products Association (NPA), thank you for the opportunity to submit comments to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) regarding the notice of proposed rulemaking to repeal Article 6 and adopt a new Article 6. NPA is submitting this letter as general comments to OEHHA's new Article 6, Clear and Reasonable Warnings.

NPA is the trade association representing the entire natural products industry. We advocate for our members who supply, manufacture, and sell natural ingredients or products for consumers. 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. NPA has set numerous industry standards, such as dietary supplement Good Manufacturing Practices (GMPs), as well as a definition of natural for home care and personal care products. NPA is the oldest and largest trade association in the natural products industry, representing nearly 2,000 members and accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids, and has led the charge to keep the natural products industry in business for over 78 years. 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. Of particular concern to NPA members are the new Article 6 and its two subarticles on "Clear and Reasonable Warnings" because most NPA member companies do business in California and are therefore impacted by these changes. Thank you for the opportunity to comment.

## **Introduction**

NPA supports 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.”<sup>1</sup> 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 it’s 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,”<sup>2</sup> 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 new Article 6 Clear and Reasonable Warnings.

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 Prop. 65. However, we think the changes to its current regulatory status do little to achieve that outcome. For example, NPA does not see how the proposed changes would 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.

While the new Article 6 attempts to provide greater clarity, we believe it will not achieve the goals outlined by either the governor or OEHHA; rather the results of this new Article 6 will be counterproductive and have the opposite effect.

### **Lack of Empirical Evidence**

At the April 14 workshop, OEHHA stated that the basis for the proposed amendments to Article 6 was 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., 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 adequate. Furthermore, OEHHA presented no research or scientific data at present 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 new 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 changes without actual empirical data to support any perceived benefits to consumers and without an assessment of the risk and legal vulnerability for businesses created by these warning changes.

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<sup>1</sup> 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>.

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

## **Greater Clarification on the Definition of Food**

NPA would however like to recommend clarifications to certain aspects in the proposed Article 6, specifically the definition of the term “food.” NPA does not believe the current notice of rulemaking goes far enough to impart clarity over the definition of “food.” The federal definition of the term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article” (21 U.S.C. §321(f).) Included under the umbrella of this definition are dietary supplements and medical foods. California has not adopted the federal definition of the term “food,” which has been the root of more than a dozen lawsuits regarding dietary supplement labeling issues under Prop. 65. In a 2013 case (Stephen Gillett vs. Garden of Life, Inc.), in which the plaintiff charged the defendants with marketing and selling herbal supplements containing lead, without proper warning labels, the defendants argued that any exposure to lead through their products should be exempt from labeling requirements under the naturally occurring exemption for food. Inevitably, this argument called into question whether or not the products fell under the definition of “food”. The Honorable John E. Munter ruled that it was the intent of the California Health and Welfare Agency to adopt the federal definition of “food” for Prop. 65 under California's Sherman Food Drug and Cosmetic Law. Therefore, dietary supplements would be held to the same warning labeling standards under Prop. 65. To undermine future attempts at litigation in these matters, NPA strongly urges the adoption of the federal definition, to remove unnecessary ambiguity regarding dietary supplements and medical foods under current California state law.

## **Reductions in Frivolous Lawsuits Versus Increased Litigation**

OEHHA asserts a reduction in frivolous lawsuits related to Prop. 65 lawsuits for inadequate and 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 over the content of the warning, but whether an exposure warning is even required at all. We believe imposing additional prescriptive requirements to Prop. 65 warnings and requiring the submission of additional information to 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 consumers. Under the 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.

## **Elimination of 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 estimates 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.

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.

### **Limits on Contaminants Based Upon Adoption of a Federal Standard, a Scientific Basis for Warning Levels**

NPA supports warnings on products when they exceed a federal standard (i.e., the Food and Drug Administration (FDA)), based upon sound science and governing well-established provisional total tolerable intake levels (PTTILs) for contaminants. OEHHA should adopt a federal standard such as the FDA’s PTTILs. Prop. 65 could be considered the most stringent standard on the planet as it requires warnings for chemicals even if present at levels well below federal total tolerable intake levels, established with scientific evidence to achieve a public health outcome. The U.S. FDA, Environmental Protection Agency (EPA), Institute of Medicine (IOM), and World Health Organization (WHO) have extensive research on the health impact and toxicity of common chemicals and set reasonable guidelines for total tolerable intake and exposure levels. Violation of federal levels set for contaminants can result in a warning letter from FDA, a ban of the product from store shelves, recalls for the product, detention of the ingredient or product at U.S. ports, or some other enforcement action to protect the public health. For example, Prop. 65 requires a warning statement for food products found to contain greater than 0.5 microgram per serving per day of lead, but the federal level prompting action based upon a safety concern is 75 micrograms per serving per day of lead if the product has conditions of use that limit it to be consumed by adults. The Prop. 65 level is 150 times lower than the serving level of the federal standard. Prop. 65 levels, which are below federal levels, serve no purpose other than requiring a firm to list a warning statement on products. OEHHA also acknowledges the usefulness of the warning when it states that a “Proposition 65 warning does not necessarily mean a product is in violation of any product-safety standards or requirements.” Product safety is and should be tied to meeting good manufacturing practices established by federal statute and codified in the federal regulations (CFR parts 110 and 111 of title 21). Prop. 65 is unable to ban or recall a product for failing to meet the Prop. 65 level, but it does allow for “professional plaintiffs” to intimidate food firms meeting good manufacturing standards and federal limits for these same contaminants because the Prop. 65 levels are much lower than federal standards. It is also unclear how natural product manufacturers can be expected to routinely test for all of the over 800 different chemicals on the Prop. 65 list. Because of the expense in testing for each of the chemicals on the list, it is cheaper for firms to print the warning statement despite being below the level. Because Californians are so used to seeing and ignoring the warning statement on products and stores, it has led to desensitization by the public and outlived its usefulness as a warning statement to advise consumers of a real public health threat.

### **Warning Statements for Chemicals which are Naturally-Occurring Constituents of the Soil**

The warning statement also shows up when “chemicals” are naturally-occurring constituents of the soil the products were grown in. While Prop. 65 provides an exemption from warning label requirements to exclude chemicals that have been shown to occur naturally in foods, the burden of proof is placed on the

manufacturer and is impractical to meet. Most lead in food is of man-made origin, even when deposited to organic fields by weather systems in the form of rain. Under the current Section 12501, farmers and herbal product manufacturers are responsible for man-made pollutants and contaminants in the water, soil or air, no matter who or what originally caused them. Under the strict guidelines of Section 12501, the eruption of volcanic ash and resulting pollution of soil with contaminant debris would be a “man-made” event, for which farmers and finished product manufacturers could not seek exemption, unless they could prove otherwise. Because the burden of proof is on the manufacturer, the manufacturer must prove that any listed chemical in the product is “naturally occurring”. In fact, an accused firm must prove that the chemical was not avoidable by good agricultural or manufacturing practices and that the chemical did not result from any known human or “man-made” activity. Proving two negatives is an unrealistic expectation to meet. The exemption, similar to Prop. 65 as a whole, had good intentions but is currently misguided in its application and clearly lacks a scientific foundation for the levels requiring a warning level.

### **Proper Use of Safety Factors Applied in Regulatory Toxicology**

NPA also requests that Article 6 contain a discussion regarding the proper application of safety factors depending on the scientific data available and a revision of Section 25349.10 *Exemptions from Warning Requirement*. The statement “assuming exposure at one thousand (1000) times the level in question” in Exemptions from Warning Requirement is applied when animal studies are available. The safety factor applied in traditional regulatory toxicology when human studies are available is 100, assuming an absence of chronic studies. Therefore, Article 6 should clarify and differentiate the appropriate safety factor to be applied for a Prop. 65 chemical depending on the data available (human vs. animal). In addition to an expansion on safety factors in Article 6, Section 25349.10 should be amended to state “when human studies indicate the exposure will have no observable adverse effect assuming exposure at one hundred (100) times the level in question or, when no human studies are available, the exposure will have no observable adverse effect assuming exposure at one thousand (1000) times the level in question”. The current safety factor applied in Prop. 65 fails to differentiate the type of evidence used. While it implies human data, it applies a safety factor typically reserved for animal studies, which apply a factor of 10 for intraspecies variation (i.e., some humans can be up to 10 times more sensitive to certain chemicals than the general population), a factor of 10 applied for interspecies variation (extrapolation from animal to human), and a factor of 10 applied for sub-chronic exposure data. A safety factor of 100 is applied for human data because interspecies variation is not a consideration.

### **Economic Impact**

NPA appreciates OEHHHA’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 implementing these changes and ongoing costs and challenges related to keeping the website maintained, updated and data protected. OEHHHA 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, OEHHHA 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 1970s, California is often found at the bottom of lists highlighting states that support business. California ranked dead last in the Chief Executive’s list of best and worst states for business published on May 24, 2014.<sup>3</sup> CEO comments about doing business in California tell a grim story: “California goes out of its way to be anti-business and particularly where one might put manufacturing and/or distribution operations.” Or,

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<sup>3</sup> <http://chiefexecutive.net/California-is-the-worst-state-for-business-2014#sthash.pGzMUkXX.qvmN6Vfk.dpuf>

“California could hardly do more to discourage business if that was the goal. The regulatory, tax and political environment are crushing.” These comments support NPA’s apprehensions about further regulatory changes to Prop. 65 and the belief that California will continue to 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.

## **Concluding Statements**

In summary, NPA has outlined its overarching concerns with OEHHA’s new Article 6. These comments support our contention that changes to Article 6 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 concerns that are addressed in detail in the California Chamber of Commerce’s comprehensive comments and economic report 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.<sup>4</sup> NPA believes the old Article 6 Clear and Reasonable Warnings were adequate and appropriately allow business to prove that the Prop. 65 warnings they issue are “clear and reasonable” by any means they wish. They set forth criteria to establish when warnings will automatically be deemed “clear and reasonable” for purposes of Prop. 65. Businesses using “safe harbor” warnings were protected from the threat of litigation and can carry out their business with a sense of certainty.

An area of particular interest to business was the governor’s promise to strengthen the scientific basis for warning levels. The numerical factors or multipliers, termed safety factors in regulatory toxicology, 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 EPA and 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 PTTILs. FDA set lead PTTILs ( $\mu\text{g Pb/day}$ ) as low as 6  $\mu\text{g}$  for children, 25  $\mu\text{g}$  for pregnant/lactating women and 75  $\mu\text{g}$  for adult women, an exposure risk level far exceeding the 0.5  $\mu\text{g/day}$  exposure risk threshold established under Prop. 65.<sup>5</sup> NPA requests 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 the policy on what safety factors should be applied for risk thresholds as a function of the type of data available should be revisited to ensure the current risk-level multipliers are supported by scientific evidence and to ensure that 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 Food and Agriculture Organization of the United Nations (FAO) and WHO. We note that OEHHA has not addressed this important reform. NPA believes that the proposed Article 6 is unworkable until it addresses the provisions within the Act that govern the requirements associated with assessing risk to determine if an exposure warning is required.

Prop. 65 unfairly places the burden of proof solely on manufacturers to prove that a warning is not required rather than on the state government to prove that a warning is required. This is in contrast to the Federal Food Drug and Cosmetic Act, which places the burden of showing something is unsafe on the government. It also requires the accused firm to prove negatives, an insurmountable and unrealistic expectation. The Prop. 65 levels on common contaminants like lead, cadmium, arsenic and mercury, are typically lower than the federal PTTILs established for contaminants in foods. While FDA can enforce

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<sup>4</sup> Clear and Reasonable Warning Regulations and The Business Cost of Proposed Changes to Article 6 of Proposition 65, California Chamber of Commerce. (April 8, 2015)

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

bans or mandatory recalls because its limits are based upon a scientific body of evidence, Prop. 65 levels are not based in any science. Therefore, Prop. 65 limits have no purpose to protect the public. Prop. 65 warnings confuse and desensitize California consumers with ubiquitous statement on foods, which are already in compliance with federal laws to ensure their identity, purity, strength, composition, and safety. Prop 65 does not establish a safety line for contaminants where a warning statement can convey meaning, but it does line the pockets of “professional plaintiffs” looking to settle for significant sums. It should be noted that products, disputed in Prop. 65 lawsuits for failing to bear the warning statement, are not pulled from store shelves because of demonstration of a public health risk or harm to consumers. NPA believes that OEHHA would best serve the Agency’s prior intent by modifying Article 6 with significant changes. We recommend OEHHA work more closely with the California Department of Food and Agriculture and the U.S. FDA to modify this regulation to make sure it is in line with general principles of regulatory toxicology as well as federal and other state regulatory authorities for food which have adopted Title 21 of the code of federal regulations.

Thank you for your attention to these important matters and the opportunity to comment. Should you have any questions, please contact me directly at (202) 223-0101 Ext. 101 or via email at [Daniel.fabricant@NPAinfo.org](mailto:Daniel.fabricant@NPAinfo.org).

Best regards,

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

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