

November 14, 2014

**Submitted via Electronic Mail and U.S. Mail**

P65Public.Comments@oehha.ca.gov

Ms. Monet Vela  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-58D  
Sacramento, CA 95812-4010

Re: Potential Regulations Workshop for Proposition 65

Dear Ms. Monet:

I am submitting these comments for your consideration to update the regulations governing Proposition 65. I am the Owner of Raw Indulgence, Ltd. – Raw Revolution Natural & Organic Live Food Bars. We are a family business, with no outside investors, that is dedicated to creating natural and healthy organic food bars. However, due to the fact that heavy metals – particularly lead – naturally exist in the environment, we are finding it extremely burdensome and difficult to comply with Proposition 65. We acknowledge that there is an exemption for small companies and would assert that 9 employees is extremely small for a manufacturing operation with many part time line workers and is not per se reflective of a company's revenues or profits. I also understand that if I am exempt based on size, my larger retail customers may still be subject to litigation if any of our products ever test slightly high.

All of our bars are made with 100% certified organic products, and Raw Indulgence is a Certified Organic Processor in accordance with the U.S.D.A. Certified Organic program established at 7 U.S.C. §§ 6501 *et seq.* and 7 CFR §§ 205.1 – 205.690. This regulation is comparable to the California state Organic statute as well. Under this standard all farming, handling and processing of all of our ingredients and finished goods is traceable, monitored and audited to prevent contamination by heavy metals. We have taken the initiative and incurred the cost to insure adherence to this most strict current government standard (both California and Federal) to insure the quality and purity of our products.

However, since lead naturally occurs in the environment, some of our bars have lead levels slightly above 0.5 micrograms per bar. We have therefore found ourselves subject to a lawsuit asserting that we must provide a warning for pregnant women. Because all of our components are 100% natural, we should be exempt from this lawsuit under the "naturally occurring" exemption established at 27 California Code of Regulation § 25501. But due to the extremely strict nature of that regulation, and the prohibitive cost to meet that standard, we are unable to establish that the lead in our bars is "naturally occurring" in the manner required by the regulation.

Since all of our components are natural, and our process is natural, the only way for lead to be in our products is from components absorbing lead from the soil at the organic farms at which they are grown. Certified organic farms cannot use any synthetic products at the farm for a period of three years

preceding harvest of the crop. 7 CFR § 205.202(b). In addition, “The producer must manage plant . . . materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination or crops, soil or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.” 7 CFR § 205.203(c) (underline added). Given these restrictions, and the fact that organic farms must be certified through an independent evaluator (who usually asks for a site history, or has the ability to test the soil if a concern is identified), it is extremely unlikely that the lead in the soil at organic farms is from an anthropogenic (non-natural) source.

Unfortunately, this common sense evaluation is insufficient to meet the standard of the “naturally occurring” regulation under Proposition 65. That regulation requires *the defendant* to prove that “A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity.” 27 CCR § 25501(a)(3). For a certified organic product, it is extremely likely that any chemical (such as lead) is naturally occurring because there is no other way for that chemical to be introduced into the product. However, the Proposition 65 plaintiffs argue that perhaps the lead got into the soil at the organic farms through aerial deposits or due to some unknown activity at the farm fifty years ago. Therefore, defendants are asked to test every farm for every component in their product. This is neither practical nor financially viable.

The regulation suggests that on site testing can be perhaps just one way to prove that a chemical is “naturally occurring.” 27 CCR § 25501(a)(2). However, the way the regulation has been interpreted basically requires testing in almost every instance. Furthermore, to hold defendants to the standard of having to prove a negative eviscerates the purpose of this exemption.

Given the goals of organic farming – to produce natural items – it is unfair to require organic companies, who are trying to provide healthy and sustainable alternatives to consumers, to comply with such a strict standard, which in reality is economically and technically infeasible to meet. We therefore request that OEHHA recognize the special circumstance of organic companies and revise the “naturally occurring” regulation to ease the burden of trying to prove this negative. We request that OEHHA add the following provision to 27 CCR § 25501:

- (a)(5) A chemical in a product that is certified “100 percent organic” or “organic” in accordance with 7 CFR §§ 205.1 – 205.690 is deemed to be “naturally occurring.” If a person alleged to be responsible for an exposure can demonstrate that the product is certified “100 percent organic” or “organic” in accordance with 7 CFR §§ 205.1 – 205.690, that person is deemed to have met the burden that the chemical is “naturally occurring” and the burden shifts to the plaintiff to prove that the chemical in question is not “naturally occurring.”

Alternatively, we request that OEHHA create a regulation finding that the exposure level for lead for pregnant and lactating women from products that are certified “100 percent organic” or “organic” in accordance with 7 CFR §§ 205.1 – 205.690 is 1.0 microgram per day instead of 0.5 micrograms per day. As you know, the 0.5 microgram per day exposure level is extremely low, and given that the Attorney General has already recognized other exemptions of 1.0 micrograms per day of lead for other products, it would be common sense to apply this threshold for organic products.

It appears that small natural and organic food and supplement companies have become specific targets of private enforcers, probably because of our minimally processed natural ingredients and our

tendency to be smaller family businesses with limited resources with which to defend and prove under the burdensome presumptions in favor of plaintiffs.

This in essence is causing a "tax" on all of our consumers, in California and otherwise and a burden on our industry, a very small and incredibly important segment of the food industry. While it is true that overall organic product sales are growing and many organic products justify a premium price, our experience is that in the packaged goods segment, most consumers are not willing to pay a substantial premium for organic foods and these products are more expensive than conventionally grown products to produce. I think you'll find that if you interview independent organic producers, which like the rest of the economy, these small companies make up the vast majority of businesses, that we tend to sacrifice profit for mission and thus tend to be less profitable and have fewer financial resources than the large conventional producers to comply with these regulations, especially when our levels are borderline and truly pose no danger to consumers.

Without providing some consideration to those companies that are the leading stewards in promoting healthy eating and sound ecology, the end game of Prop 65 is thwarted. We simply do not have the kind of resources of a Warner-Lambert to establish exception levels that can be adopted by the industry as a whole. If non-organically grown cocoa can have a 1ug limit, then why shouldn't dates, or other high nutrition whole foods that periodically exceed the limits, be entitled to the same treatment without millions in settlements and litigation to establish those exceptions?

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Alice Benedetto". The signature is fluid and cursive, with a large initial "A".

Alice Benedetto, RN  
Owner, Raw Indulgence , Ltd.