



November 17, 2014

Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, California 95814

Re: Improving Proposition 65

Dear OEHHA,
California's Proposition 65, "The Clean Water Act" sounded like a wonderful idea back in 1986, when the voters of California passed it, not knowing that it would eventually cause significant consumer confusion, increased consumer costs and substantive financial harm to ethical dietary supplement suppliers.

Science-based levels set by both the US Food and Drug Administration and the World Health Organization for safe daily intake of naturally occurring chemicals identified by the State of California as cancer or reproductive toxins are all well above the low, arbitrary, levels adopted by the California Environmental Health Hazard Assessment regulations for Prop. 65.

Consumers should be informed when they are exposed to toxins from commercial activity, but they should also be aware there will always be some small, harmless amounts of naturally-occurring toxins, such as lead, that become part of their foods and food ingredients, even if the foods are organic - and therefore are naturally included in their dietary supplements, multivitamins or herbal products.

However, Prop.65 has caused consumer-beneficial products to be discontinued, reformulated and caused increased consumer costs, while costing millions of dollars to ethical dietary supplement manufacturers.

The World Health Organization's safe levels are more in harmony with respected Toxicologists, considering that the publication *"Inorganic Lead Exposure, Metabolism and Intoxication"* referenced data that said, "...the total lead intake (TLI), including that in food, beverages and inhaled air, is on the order of 300 - 400 mcg per day." They also highlighted other data that asserted that the TLI (Total Level of Intake) ranged from 106 to 206 mcg per day.¹ Either way, the miniscule amounts provided by any commercial product, much less a handful of beneficial dietary supplements are only a small fraction of our daily lead intake.

We respectfully ask you to amend The California Code of Regulations, Title 27, Section "25349.10. Exemptions from Warning Requirement" so that the safety factor for toxins, be changed to 50 times, or even 100 times, rather than the current and arbitrary 1,000 times, in the interests of furthering the intent of Proposition 65 for the benefit of California consumers. A "50 times" safety factor allows prudent safety, according to the FDA data noted above and cited in the attachment, while also allowing daily servings of dietary supplements to have the same lead limit that FDA has placed on bottled water (10 mcg/daily serving of 2 one liter bottles),² rather than the current non-scientific Prop. 65 lead limit, 0.5 mcg/daily serving.

¹ [Inorganic lead exposure: metabolism and intoxication](#), Castellino, N, Sannolo, N, Castellino, P. p.128, CRC Press, ISBN: 9780873719971

² <http://www.fda.gov/newsevents/testimony/ucm170932.htm>

Further, as the attachment shows, dietary supplements contain significantly less lead than common foods.

We also specifically request that OEHHA justifies their establishment of the 1,000 times safety factor, which resulted in their standard of 0.5 mcg/day lead limit. A 10 mcg lead limit (for adults) would allow the great majority of healthy herb and plant concentrates and extracts used in dietary supplements to comply with the Prop 65 limit.

So far, it has cost dietary supplement consumers millions of dollars in increased product prices, and dietary supplement and food companies millions of dollars in defending lawsuits from “bounty hunter” lawyers.

*"In the view of many, **Proposition 65 permits legalized extortion** of the business community by private enforcers, who retain 25 per cent of civil penalty as well as all attorney's fees and costs,"* said Carol Brophy, of law firm Sedgwick Detert Moran & Arnold.³

My father spent well over a million dollars defending against Prop. 65 lawsuits, because our top-selling women's daily vitamin had less lead than occurs naturally in four ounces of boiled spinach.⁴ This is an incredible burden for a small family business, which almost put us out of business.

Moreover, OEHHA itself is at least receptive to the concept of changing this standard. Gina Solomon, Deputy Secretary of California EPA, said on our phone call, June 18, 2013, that there might be consideration of changing the toxin limit enunciated in “25349.10. Exemptions from Warning Requirement” from “*exposure at one thousand (1,000) times the level in question*” to 100 times, which is more reasonable.

In closing, we respectfully ask that you take prompt and positive action to change the “1,000 times” Safety Factor specified in CCR27§25349.10 to a more scientifically justified “50 or 100 times,” thus enhancing the intent of Proposition 65.

Sincerely,
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³ http://www.sdma.com/pr_2008_01_fda/

⁴ <http://www.fda.gov/downloads/Food/FoodScienceResearch/TotalDietStudy/UCM243059.pdf>



Attached References

FDA's lead limit is 0.1ppm lead limits for candy frequently consumed by children.⁵ Also germane is FDA's reprint of a BATF letter stating that lead levels <0.15 ppm pose no risk even for pregnant women, but that lead levels >0.3 ppm are disallowed.⁶ Also FDA's 2011 guidance stating that the maximum allowable lead level in fruit juice is 0.015 ppm, because fruit juice is frequently consumed by children.⁷ And then, please consider that FDA set maximum levels for bottled water at 0.005 ppm and tap water at 0.015.⁸

In August, 2008, the U.S. Food and Drug Administration (FDA) released a report titled, "*Survey Data on Lead in Women's and Children's Vitamins*"⁹ which looked at 324 multivitamins produced by well-known companies found in retail stores around the USA. The report found small amounts of lead in 320 of them.

Although the FDA stated in the beginning of its report that none of the amounts of lead found in the multivitamins were high enough to be unsafe, without knowing what the numbers in the report actually meant consumers were quite concerned about the safety of these products and stopped buying many of them, including three top-selling SuperNutrition products, which cost our small family business millions of dollars in revenue.

Our top seller now sells at 10% of what it sold before Prop. 65.

Tort lawyers, of course, had a different take on FDA's report. It served as a free guide to extort money by suing dietary supplement companies that manufactured dietary supplements that had more lead than the Prop. 65 limit (0.5 mcg a day), as well as retail stores that sold those supplements.

Research shows that the amounts of lead found in the 320 supplements in FDA's report, which were between 0.0013 mcg and 8.97 mcg per day, are far below FDA's own standards for what is known to be tolerable. "Tolerable" means that the body can metabolize and excrete the lead efficiently enough at that dose that it does not present a health problem.

To define what is safe FDA created a Provisional Total Tolerable Intake level (PTTI) for lead for specific types of people and age groups.¹⁰ They determined the PTTI numbers by taking amounts of lead that are known to cause health problems and reducing those amounts by an arbitrary and non-scientific safety factor of 10 yielding the levels in the table below.

⁵ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077904.htm>.

⁶ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm077878.htm>

⁷ <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm233520.htm>

⁸ <http://www.fda.gov/newsevents/testimony/ucm170932.htm>

⁹ <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm115941.htm>

¹⁰ Carrington CD, Bolger PM. [An assessment of the hazards of lead in food](#). Reg Tox Pharma. 1992 Dec;16(3):265-72.

FDA's Conservative Recommendations for Lead Intake

For Whom	Amount That Is Known To Cause Health Problems	FDA's Recommended Safe and Tolerable Daily Diet Lead Intakes (PTTI)
Children under age 6	60 mcg	6 mcg
Children 7 and older	150 mcg	15 mcg
Pregnant or lactating women	250 mcg	25 mcg
Adult women	750 mcg	75 mcg

A Look at the Summary of FDA's Lead Tests¹¹

For Whom	FDA's safe tolerable lead intake per day (PTTI)	Highest amount found in FDA's report	Average amount of lead in a daily serving of products in FDA's report
Young Children (0-6 years)	6 mcg	2.88 mcg	0.123 mcg
Older Children (7+ years)	15 mcg	1.78 mcg	0.356 mcg
Pregnant or lactating women	25 mcg	8.97 mcg	0.845 mcg
Adult women	75 mcg	4.92 mcg	0.842 mcg

To be clear, FDA found very small amounts of lead in the multivitamins they tested. A microgram (abbreviated either as mcg or µg) is one millionth of a gram. It's as if you cut a sugar cube (which weighs about 1 gram) into one thousand pieces, and then cut one of those tiny pieces into another thousand pieces. That's a microgram.

One example of a problem with California's Prop 65, that allows "legalized extortion of the business community..." is the allowable level for lead in dietary supplements, which is 0.5 mcg per daily dose, plus small additional amounts for calcium carbonate, magnesium oxide, and a few other minerals that are available in multivitamins, which can allow a small increase in Prop. 65's lead limit.

Products that contain high potencies of these minerals can increase the allowable lead limit by a little over 1.0 mcg per day. At most. Prop. 65 allows multivitamins with high potency minerals about 1.5 mcg of total lead per daily serving. This unreasonably low lead limit has cost consumers of these healthy dietary supplements millions of dollars in increased product costs.

According to the World Health Organization's safety data on lead, the Provisional Tolerable Weekly Intake (PTWI) for ingestion of lead from all sources is 25 mcg per kilogram (2.2 lbs.) of

¹¹ <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm115941.htm>

bodyweight.¹² (The PTWI is a dosage that is known to be safe over time, because over time it is known by scientists that the body is exposed to and excretes a certain amount of lead easily.)

To simplify this equation into terms we can understand, the PTWI safe weekly intake of lead for a 150-pound person (150 lbs. = 68.18 kilograms) times 25 mcg is 1704 mcg of lead per week, which is equivalent to 243 mcg of lead per day.

This WHO estimated safe level of 243 mcg/day is 324% above the FDA's estimated safe level for adults (75 mcg), and 485% above Prop. 65 (0.5 mcg). So the FDA recommendations are extremely cautious, and the CA EPA's levels are unreasonably and unscientifically minimal, and both far below the World Health Organization's recommended PTW and FDA's PTTI.

However, it is well-known that our bodies will metabolize and excrete lead efficiently so that it doesn't cause any significant health problems as long as the amount of lead that we are exposed to doesn't exceed the World Health Organization's PTWI over extended periods of time, or, to be more conservative, that it doesn't exceed FDA's PTTI.

The multivitamins tested certainly contain significantly less lead than the daily amount of food Americans typically eat, which was reported in 2011 to be almost 5½ pounds a day.¹³ If the average amount of lead in food, as shown in the table below averages about 4.5 mcg per 4 ounces of foods, or the equivalent of 100 mcg of lead daily, that is 200 times the Prop. 65 level!!

Indeed, FDA's publication *Total Diet Study (TDS) Statistics on Element Results* (December 11, 2007),¹⁴ and *Total Diet Study Element Results* (April 15, 2014)¹⁵ which analyzed 200 different foods found in grocery stores four times per year, showed what is in the following table. (The two most recent reports are included for comparison purposes and to provide measurements of different foods.)

Multivitamins and other dietary supplements provide only a small fraction of our daily lead intake. The takeaway is that none of these foods would pass Prop. 65's 0.5 mcg lead limit. If Prop. 65 was applied to common foods, grocery stores shelves would be empty or you would see Prop. 65 warning signs on virtually every product on the shelves.

America's daily food intake of about 5½ pounds a day contains about eight dozen times more than these four ounce servings.

Total Diet Study Food Name	Highest Amount of Lead Per 4 Ounces	
	December 11, 2007	April 15, 2014
Shrimp, boiled	23.8 mcg	20.4 mcg
Italian salad dressing	12.2 mcg	
Mixed nuts, no peanuts, roasted	10.2 mcg	
Liver, beef, fried	9.0 mcg	
Brussels sprouts, fresh, boiled	7.9 mcg	
Sweet potato, fresh, baked	7.2 mcg	
Spinach, boiled	7.0 mcg	
Dry table wine	6.8 mcg	

¹² <http://www.who.int/ifcs/documents/forums/forum5/pronczuk.pdf> - p. 12

¹³ [The Average American Ate \(Literally\) A Ton This Year](#), Aubrey A. National Public Radio, 12-31-2011.

¹⁴ <http://www.fda.gov/downloads/Food/FoodScienceResearch/TotalDietStudy/UCM243059.pdf>

¹⁵ <http://www.fda.gov/downloads/Food/FoodScienceResearch/TotalDietStudy/UCM184301.pdf>

Dill cucumber pickles		5.6 mcg
Macaroni and cheese, prepared from box mix		5.2 mcg
Pineapple, canned in juice		5.2 mcg
BF, cereal, rice, dry, prep w/ water		4.5 mcg
Avocado, raw	4.5 mcg	3.4 mcg
Honey	4.5 mcg	2.0 mcg
Watermelon, raw	4.5 mcg	
Apricots, canned in heavy/light syrup		4.1 mcg
Raisin bran cereal	4.1 mcg	
BF, turkey and rice		3.9 mcg
BF, teething biscuits		3.7 mcg
Raisins, dried	3.5 mcg	
BF, arrowroot cookies		3.5 mcg
Pear, canned in light syrup		3.4 mcg
Cottage cheese 4% milk fat	3.4 mcg	
Cucumber, Raw	3.4 mcg	
Peach, raw	3.4 mcg	
Spaghetti, enriched, boiled		3.0 mcg

Source of Lead in the Environment

Lead is found almost everywhere on earth. It is found in the air, in foods, in lakes, rivers and seawater, and especially soils.¹⁶

Natural soils	22,700 mcg of lead per pound
Indoor air	17 mcg in each 3 cubic feet of air
Outdoor air	55 mcg in each 3 cubic feet of air
House dust	5.3 mcg in each 3 cubic feet of air

Lead is everywhere, including in 99% of the multivitamins tested. (320 out of 324). This is not negligence on the vitamin manufacturers' parts.

All the vitamins tested had lead levels that were safe, according to FDA.

A study published in the Journal of Clinical Investigation confirmed that a typical adult human's body contains approximately 200 mg of lead.¹⁷ Realize that a milligram (mg) is a thousand micrograms (mcg) and we have been discussing the safety of micrograms of lead. 200 mg is 200,000 mcg.

¹⁶ [Lead content of Soil, Plants, Foods, Air, and Chinese Herb Formulas](#), Dhamananda S. Director, Institute for Traditional Medicine, Portland Oregon.

¹⁷ Rabinowitz MB, et al. [Kinetic analysis of lead metabolism in healthy humans](#). J Clin Invest August 1976 58:260-270.