



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

November 12, 2015

Monet Vela  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010  
Sacramento, California 95812-4010

Via Email: [monet.vela@oehha.ca.gov](mailto:monet.vela@oehha.ca.gov)

RE: Pre-Regulatory Draft: Proposing Amendments to Article 5, Extent of Exposure, Addition of Section 25501.1, Naturally Occurring Concentrations of Chemicals, Naturally Occurring Concentrations of Arsenic in Rice and Lead in Some Foods.

Dear Ms. Vela:

On behalf of the Natural Products Association (NPA) thank you for opportunity to submit 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 5, Extent of Exposure, Addition of Section 25501.1, Naturally Occurring Concentrations of Chemicals, Naturally Occurring Concentrations of Arsenic in Rice and Lead in Some Foods.

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 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. We have concerns with the addition of Section 25501.1 to Article 5 of the Safe Drinking Water and Toxic Enforcement Act of 1986. Many of our members conduct business in California and will therefore be significantly impacted by the proposed additions.

### **Executive Summary**

- **NPA does not support the OEHHA pre-regulatory draft proposal regarding naturally occurring concentrations of arsenic in rice and lead in some foods**
- **NPA Applauds OEHHA for Recognizing that the Naturally Occurring Exemption Requires Further Guidance and Clarity to be an Effective Regulatory Tool**
- **NPA Supports Inclusion of the Naturally Occurring Exemption to Other Consumer Products (Cosmetics)**
- **OEHHA's Proposed Draft on the Naturally Occurring Exemption Does Not Adequately Address Variability in Uptake of Natural Background Levels of Chemicals and Trace Elements**
- **OEHHA's Proposed Draft on the Naturally Occurring Exemption Does Not Adequately Address Natural Background Levels for Consumer Products with Ingredient Combinations**
- **NPA Disagrees with OEHHA in How They Developed Naturally Occurring Allowances for Lead**
- **NPA Disagrees with Use of Detection Limits to Develop Allowances for Contaminants**
- **The Method Deviation Used to Calculate the Correction Factor is Not Scientifically Sound**
- **Data and Methods Used to Calculate Inorganic Arsenic Levels Should be Made Available and Transparent**
- **The Proposed Allowances for Naturally Occurring Lead and Arsenic Will Not Decrease Litigation by "Bounty Hunters"**

## Background

California's Proposition 65 or clean water initiative obligates the state to publish a list of chemicals "known to the State to cause cancer or reproductive toxicity" and provide an update at least annually to that list. The implementing regulations for Proposition 65 contain provisions that have the effect of providing exemptions to the warning requirements. These exemptions result from the regulations which exclude certain situations in the definition of exposure. The regulations define exposure to exclude consumption of food that contains a listed chemical if the chemical occurs naturally in the food. Title 27 of the California Code of Regulations also provides that a chemical occurs naturally if it is a natural constituent of the food or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food was raised, or grown, or obtained.<sup>1</sup> According to the regulations, a chemical is naturally occurring only to the extent that the chemical did not result from any known human activity, and "exposure" can only occur to that portion of the chemical which resulted from such human activity.<sup>2</sup> Therefore, the chemical, analyte, or element in question results in part from a natural source and in part from human activity, but "exposure" only results from the part derived from human activity. The "naturally occurring" level of a chemical in a food can be established by determining the natural background level of the chemical in the area in which the food was raised, or grown, or obtained, based on reliable local or regional data. Therefore, if it can be established through chemical analysis and reliable scientific data, the state would have to accept one's natural background levels of a substance in question if it ran counter to the ones developed by the state.

The California Code of Regulations also addresses chemicals in consumer products other than food. The regulations provide that a person responsible for an exposure to a Prop 65 listed chemical does not "expose" an individual within the meaning of Section 25249.6 of the Act<sup>3</sup> to

---

<sup>1</sup> California Code of Regulations, Title 27, Section 25501. Exposure to a Naturally Occurring Chemical in a Food.

<sup>2</sup> 27 CFR 25501(a)(3). "Human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

<sup>3</sup> Section 25249.12, California Health and Safety Code.

the extent that one can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product.<sup>4</sup> This essentially means that while the naturally occurring exemption also applies to products other than foods, it only applies to a limited extent. In other words, if an ingredient occurs naturally in food and the food is used in another product, such as a cosmetic, the substance is not an exposure to the extent that it occurs naturally.

California Environmental Protection Agency's (EPA's) Office of Environmental Health Hazard Assessment (OEHHA) recently held a workshop to address deficiencies in the naturally occurring exemption for listed chemicals in unprocessed foods. In particular, OEHHA's new draft Section 25501.1 looks at lead in fresh foods and arsenic in dry rice. OEHHA stated that the naturally-occurring exemption is difficult to establish in practice. The reasons they gave are that while some chemicals are naturally present in many foods, the same chemicals may be present due to human activities, the two are difficult to differentiate, and therefore further guidance and clarification is warranted.

### **The NPA Does Not Support the OEHHA Pre-Regulatory Draft**

The NPA does not support the addition of Section 25501.1 to Article 5 as outlined in the pre-regulatory draft. We believe that the proposed addition of section 25501.1 lacks scientific validity and logical reasoning. The allowances developed for lead and arsenic understate the contribution from naturally occurring sources and overestimate the contribution from anthropogenic sources. The proposed draft regulations serve neither to protect the public nor decrease the number of predatory lawsuits profited by the empowered Plaintiff's bar. 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." This proposed draft does not further the interests stated by Governor Brown or serve to protect the public with clear warnings. At present, Prop 65 warnings only serve to desensitize California

---

<sup>4</sup> 27 CCR 25501(b). This section also stipulates that where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

consumers with ubiquitous statements placed on foods, which are already in compliance with federal laws to ensure their identity, purity, strength, composition, limits on contamination, and safety.

### **NPA Applauds OEHHA for Recognizing that the Naturally Occurring Exemption Requires Further Guidance and Clarity to be an Effective Regulatory Tool**

The current language in the Safe Drinking Water and Toxic Enforcement Act of 1986 regarding the naturally-occurring exemption is confusing and difficult to achieve for any business, California or other. In order to use the naturally-occurring exemption, firms must prove several negatives, a difficult feat to achieve. First, they must prove that the chemical did not result from any known human activity.<sup>5</sup> Second, they must prove that the chemical was not avoidable by good agricultural or good manufacturing practices.<sup>6</sup> Finally, they must demonstrate through quality control measures that the chemical is not present above the “lowest level currently feasible”, a term used in Title 21 of the Code of Federal Regulations (CFR), Section 110.110, subdivision (c).<sup>7</sup> Affirmation to assert the exclusion of something is not a strong regulatory or guidance tool. The exemption as it is written serves to favor the plaintiff’s bar. Since the adoption of Proposition 65, lawsuits and warnings statements on labels were expected to decrease over the greater clarity provided in the Act. The Safe Drinking Water and Toxic Enforcement Act of 1986 failed in both respects as scientists, attorneys, and executives continue to spend money and resources seeking ways to comply and avoid devastating enforcement actions. The naturally occurring exemption in particular is just not a feasible or practical solution to differentiate the amount of naturally occurring chemicals from those derived from human activity. Any changes to this exemption imposes additional financial burden on our members, many of whom are small businesses already struggling to meet the rigorous labeling and regulatory demands of current California state laws.

---

<sup>5</sup> 27 CCR 25501(a)(3).

<sup>6</sup> 27 CCR 25501(a)(4).

<sup>7</sup> 27 CCR 25501(a)(4).

### **NPA Supports Inclusion of the Naturally Occurring Exemption to Other Consumer Products (Cosmetics)**

NPA has traditionally supported the exclusion of chemical amounts in the naturally occurring exemption that have been shown to occur naturally in foods from any warning labeling requirements if no exposure could be demonstrated from the remaining amount determined to be present from “human activity”. NPA would like to reiterate strong support of the retention of this exemption for foods and would like it extended for non-food ingredients. NPA supports this exemption for naturally occurring chemicals in all foods, including dietary supplements, as well as the exemption of the use of those chemicals in non-food consumer products (e.g. cosmetics). Currently, the regulations only permit the exemption in non-food consumer products when a person responsible for an exposure can show that the chemical was also a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. NPA agrees that removal of this exemption would “diminish the overall significance of food warnings”.<sup>8</sup> There are many herbs in commerce which are not used in human food but used in other consumer products such as personal and home care products. Prop 65 listed chemicals which are determined to be naturally occurring in the supply chain of these products should not be considered as exposure. The naturally occurring exemption should be applied equally across the board for all consumer products.

### **OEHHA’s Proposed Draft on the Naturally Occurring Exemption Does Not Adequately Address Variability in Uptake of Natural Background Levels of Chemicals and Trace Elements**

In addition to the burdens of proving a series of negatives, there are seemingly insurmountable practical issues regarding the supply chain where a business may not know the natural background levels for the exact region where the plant was grown. Simply stated, plants used in consumer products offered for sale in California are grown in areas outside the state and the United States. Many novel botanical ingredients used in dietary supplements and cosmetics are sourced in foreign countries because they do not grow in our climate.

---

<sup>8</sup> 27 CCR Division 2, Part 2, Chapter 3, §25501

The allowances in the exemption chosen for your proposed draft are based on reviews of studies performed using California soils. The arsenic allowances are based upon an arithmetic mean derived from values obtained in rice samples grown in California. Allowances for natural background levels of lead were similarly derived from California soil samples. Background levels of arsenic and lead can vary widely in different regions of the world.

Arsenic appears in nature primarily as sulfides and is transported in the environment by water. Arsenic is typically found speciated in nature into its inorganic (e.g. arsenous (III) acid and arsenic (V) acid) or organic (arsenobetaine, arsenocholine, tetramethylarsine oxide) forms. It is currently believed that inorganic arsenic is considered to be more toxic than organic arsenic, which is commonly found in seafood and shellfish. Arsenic is transported in the environment by water from sources of ore (silver, lead, copper, nickel, antimony, cobalt and iron) to cultivated areas and leaching of arsenate from the soil is typically a slow process because of its binding to hydrous oxides of iron and aluminum. Arsenic concentrations in uncontaminated soil are generally in the range of 0.2–40 mg/kg.<sup>9</sup> In terms of arsenic introduction from human activities, levels of 100–2500 mg/kg and 200–2500 mg/kg have been measured from soil samples taken in the vicinity of copper smelters<sup>9,10</sup> and orchards where arsenical pesticides have been used, respectively.<sup>11</sup>

Drinking water contributes significantly to daily exposure levels from oral intake. Uncontaminated drinking water sources generally contain arsenic at concentrations of less than 10 µg/L, and variations in sources are highly dependent on the arsenic content of the underlying bed-rock. Larger concentrations of arsenic have been reported from spring waters in New Zealand, Romania, the Russian Federation and the United States (400–1300 µg/L).<sup>12</sup> Most foods contain low levels of arsenic (less than 0.25 mg/kg) with the exception of seafood.<sup>12</sup> The

---

<sup>9</sup> World Health Organization. (1981). *Arsenic*. Environmental Health Criteria, No. 18. Geneva, Switzerland.

<sup>10</sup> Diaz-Barriga F. et al. (1993). Arsenic and cadmium exposure in children living near a smelter complex in San Luis Potosi, Mexico. *Environmental Research* **62**: 242-250.

<sup>11</sup> International Agency for Research on Cancer. (1980). Some metals and metallic compounds. In: IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Vol. 23). Lyon, France. pp. 39-142.

<sup>12</sup> World Health Organization. (2000). Arsenic. In: Air Quality Guidelines for Europe, 2<sup>nd</sup> Ed., Chapter 6.1. Copenhagen, Denmark.

estimated daily intake of arsenic widely varies between countries (7 µg/day in Canada<sup>13</sup> v. 126–273 µg/day in Japan<sup>14</sup>)<sup>15</sup> and soil conditions within countries.<sup>13,16,17</sup> Analytical data from 2 California Department of Food and Agriculture (CDFA) studies, conducted in 1967 and 2001, CDFA study reported mean arsenic levels of 8.8 and 7.6 ppm, respectively.

The same variations apply to lead and other trace elements and metals. The level of lead in the earth's crust is approximately 20 mg/kg. Lead in the environment derives from natural or anthropogenic sources. Natural sources of lead include predominantly volcanic emission and geological weathering. Background lead levels in soil are reported with a range between 10 and 70 mg/kg<sup>18</sup> and a mean level in soil near roadways of 138 mg/kg.<sup>19</sup> Lead occurs naturally in plants and results from both deposition and uptake. As a result of various breakdown processes, rocks yield lead which is transferred to the biosphere and the atmosphere, and eventually back to the earth's crust in sediment layers. California soils are known to have lower than the world average of lead and arsenic levels. They also have some of the lowest lead levels in the US. A 1978 USDA Soil Conservation Service study reported a mean background lead concentration of 12.3 ppm (or mg/kg), analyzed from surface soil samples. A 2013 USGS report reported a mean background lead concentration of 14.8 ppm in the U.S. This may suggest why background levels in other regions of the US are higher in comparison to California. The naturally occurring allowances developed for lead, arsenic and other future elements from soils in California will not reflect naturally occurring levels in soil elsewhere in the US.

---

<sup>13</sup> Hughes, K. et al. (1994). Inorganic arsenic: evaluation of risks to health from environmental exposure in Canada. *Environ Carcin Ecotox Rev* **12**: 145-149.

<sup>14</sup> Yamauchi, H and Fowler, BA. (1994). Toxicity and metabolism of inorganic and methylated arsenicals. In: *Arsenic in the environment. Part II: Human health and ecosystem effects*. J.O. Nriagu, ed. New York, Wiley & Sons, pp. 35-53.

<sup>15</sup> The United States averages 60 µg/day arsenic. Gartell, MJ et al. (1985). Pesticides, selected elements, and other chemicals in adult total diet samples. October 1978-September 1979. *J Assoc Offic Anal Chem* **68**: 862-875.

<sup>16</sup> Agency for Toxic Substances and Disease Registry. (1991). Toxicological profile for arsenic. Atlanta, GA. US Department of Health and Human Services.

<sup>17</sup> Vondracek V. (1963). Concentration of 3,4-benzpyrene and arsenic compounds in the Prague atmosphere. *Ceskoslovenska hygiena* **8**: 333-339.

<sup>18</sup> Global Environmental Monitoring System. (1985). Assessment of human exposure to lead: comparison between Belgium, Malta, Mexico and Sweden. Stockholm, Karolinska Institute.

<sup>19</sup> International Programme on Chemical Safety. (1995). Inorganic Lead. *In: Environmental Health Criteria* 165. Geneva, Switzerland.

There is also considerable variability in the bioaccumulation of chemicals and trace metals by botanicals. Several factors are responsible including soil composition, rainfall/moisture, soil acidity, and plant identity. There are geographic variations in soil composition which lead to differences in natural background levels of the chemical in the area in which the food was raised or grown. Uptake of chemicals by plants also varies depending on genus and species. Some botanicals are known to bio-accumulate metals and trace elements at a much higher rate than others because of their root systems. You allude to this fact because the proposed OEHHA allowance for the natural background level of lead is higher for leafy vegetables compared to non-leafy vegetables.

### **OEHHA's Proposed Draft on the Naturally Occurring Exemption Does Not Adequately Address Natural Background Levels for Consumer Products with Ingredient Combinations**

Another important point that impacts botanical variability issue is that the Act did not address or consider the additive effects that occur when single food botanical ingredients are combined together into other foods (e.g. dietary supplements) or other consumer goods (e.g. cosmetics). The combining of ingredients results in natural background levels from various raw material sources being combined in the final finished product. Some dietary supplements can contain anywhere between two and 50 different combinations of botanical food ingredients. The proposed draft fails to address consumer products with multiple ingredients, each of which will contribute "naturally occurring" background levels for chemicals and trace elements, derived and bio-accumulated by the raw material from the soil. The proposed regulation really only addresses single ingredient raw materials. When you look at provisional tolerable intake levels, many authorities publish separate intake limits for finished products and raw materials where the intake limit for finished products is greater than that set for raw materials. NPA would like to see separate allowances for lead and arsenic depending on whether they came from raw materials or finished products. Finished products like dietary supplements should have higher allowances for naturally occurring lead and arsenic in comparison to the raw materials when multiple botanicals are used.

Many of these ingredients are sourced in climates and regions that are not conducive for growth in California or anywhere in the United States. Despite our differences in how the baseline natural background levels are calculated, NPA would like to work with OEHHA to provide suggestions in establishing natural background levels in the hopes of making the naturally occurring exemption a useful and workable regulation for firms doing business in California.

**NPA Disagrees with OEHHA in How They Developed Naturally Occurring Allowances for Lead**  
*NPA disagrees with the use of detection limits to develop allowances for contaminants.*

You state in your proposed draft that all foods that are not leafy vegetables will use limits of detection in the U.S. Food and Drug Administration's Total Diet Survey as the natural background level for lead and claimed that 95% of the samples in the FDA's survey lacked detectable lead. The use of detection limits from this single study amounts to cherry picking to develop allowances that underestimate the actual contribution from naturally occurring sources and overestimate anthropogenic contributions. NPA urges you to use data from a wide variety of sources and publications in the literature in order to calculate the allowance for naturally occurring sources. A review of pubmed revealed numerous articles on background levels of lead in California, the rest of the US, and foreign countries. Any allowance developed would be highly dependent on the genus and species of the plant rather than based upon general characteristics as to whether it is leafy or non-leafy. NPA urges you to refrain from developing allowances until you have analyzed a greater variety of plants in various geographic regions of California and other states and used the data available in the public domain.

The regulations state that the "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data. While NPA understands you are using the Total Diet Survey as a baseline benchmark, it is our understanding that a business also has the ability to challenge that baseline benchmark based upon their own collected data in the region the plant was grown. This creates an additional and unnecessary cost to businesses and complicates what would otherwise be an easy solution.

OEHHA needs to adopt background levels from a wide variety of plants grown in geographically diverse soils around the world to determine adequate allowances for naturally occurring contributions. Their data model to develop allowances based upon use of detection limits of instrumentation for contaminants in soil samples was also not validated for a wide variety of plants that would be ingested by California consumers. OEHHA should have developed a mean for naturally occurring allowances based upon actual levels detected from plants, similar to their approach for determining allowances for naturally occurring arsenic in rice.

*The deviation used to calculate the correction factor is not scientifically sound.*

The correction factor, as outlined by OEHHA in the pre-regulatory document, “...was applied to the limits of detection from the TDS [Total Diet Study] to account for the amount of naturally-occurring lead in soil compared to the amount that is probably due to anthropogenic sources.”<sup>20</sup> The pre-regulatory document further goes on to describe the derivation of the correction factor as, “...derived from the cropland data described in the CDFA study; it represents an average of the ratios of baseline to upper level soil lead concentrations, using a value of one for areas in which upper level soil lead concentrations did not exceed baseline ranges.”. The naturally occurring lead values currently calculated using the correction factor (0.88) and proposed by OEHHA are 0.0088 parts per million (ppm) in leafy vegetables and 0.0062 ppm in other foods. These levels are extremely low and the NPA questions the methods used to calculate these values.

The NPA would like to address two points regarding the methods used to calculate the correction factor which we believe require further clarification; (1) what justification did OEHHA use when rounding the ratio to a value one in locations where upper level soil lead concentrations did not exceed baseline ranges to calculate the correction factor and (2) how was a ratio calculated when baseline measurements were not taken at the Coulsa/Glenn and Fresno locations. While the CDFA surveyed seven locations, only three of the locations reported upper/baseline ratios less than one; (Oxnard/Ventura (0.635), Santa Maria/San Luis Obispo

---

<sup>20</sup> Chang, A. C., Page, A. L., & Krage, N. J. (2004). Role of fertilizer and micronutrient applications on Arsenic, Cadmium, and lead accumulation in California cropland soils. *California Department of Food and Agriculture*.

(0.842), Monterey/Salinas Valleys (0.699)). The other four locations which were rounded to a value of one included; two locations with ratios greater than one (Coachella (1.417), Imperial Valley (1.124)), and two locations baseline measurements were not reported or taken (Colusa/Glenn and Fresno). Based on the seemingly random rounding, the ratios appear to be cherry picked skewing the correlation factor lower than it would be if the true ratios were used. The NPA did a series of alternative calculations using the following equation;

**Equation 1:**<sup>21</sup>

$$\text{Correction Factor} = \frac{\left(\frac{\text{lower soil lead level}}{\text{upper soil lead level}}\right)_{\text{location 1}} + \left(\frac{\text{lower soil lead level}}{\text{upper soil lead level}}\right)_{\text{location 2}} + \dots + \left(\frac{\text{lower soil lead level}}{\text{upper soil lead level}}\right)_{\text{location n}}}{n \text{ locations surveyed}}$$

The NPA used the ratios as they were reported in the CDFA study and we feel we were successfully able to demonstrate that a number of alternative correction factors can arise from the same data set.

The first in the series of calculations the NPA used data only from locations where both measurements were taken for baseline and upper soil levels of lead.<sup>22</sup> The average of these ratios resulted in a correction factor with a value of 0.94. Using this correction factor, we presented the lead level values as they would have appeared in the pre-regulatory document, in Table 1 below:

In the second of the series of calculations, the NPA used the CDFA cited 1967 benchmark values to calculate the ratios for the Colusa/Glenn and Fresno locations. In the 2004 report CDFA justified not measuring baseline lead levels at the Colusa/Glenn and Fresno locations stating *“No sample was collected to establish the baseline levels, and the concentrations of the 1967*

---

<sup>21</sup> Lower Soil Lead Level is determined to be “baseline” and represent the level that is naturally occurring in the soil. Upper Soil Lead Level is determined to be the level near the surface and represent the level from naturally occurring sources and anthropogenic (man-made) sources combined. In two locations from the OEHHA study, the upper soil lead level was found not to be greater than the lower soil lead level as predicted and the ratio was therefore set at unity (or one) in those locales.

<sup>22</sup> Oxnard/Ventura (0.635), Santa Maria/San Luis Obispo (0.842), Monterey/Salinas Valleys (0.699)), Coachella (1.417), Imperial Valley (1.124)

benchmark soils (Table 9) were used as the reference points”.<sup>23</sup> The average of ratios in this calculation resulted in a correction factor with a value of 1.045. When this second correction factor was used and presented as in the pre-regulatory document the table would appear as below in Table 2:

<b>Table 1: Omitted Coulsa/Glenn and Fresno</b>			
Food Category	Limit of detection (ppm)	Correction Factor	Lead Level (ppm)
Meat and Seafood	0.0070	0.9400	0.0066
Eggs	0.0070	0.9400	0.0066
Milk	0.0070	0.9400	0.0066
Non-leafy vegetables	0.0070	0.9400	0.0066
Leafy Vegetables	0.0100	0.9400	0.0094
Fruit	0.0070	0.9400	0.0066

Finally, in the third series of calculations the NPA would like to demonstrate that the correction factor can be further altered when using the benchmark values in the CDFA study from 2001 are used to calculate the ratios for Coulsa/Glenn and Fresno. The average of ratios results in correction factor with a value of 1.1260.<sup>24</sup> When this third correction factor was applied, the table in the pre-regulatory document would appear as below in Table 3.

<b>Table 2: 1967 benchmarks for the calculation Coulsa/Glenn and Fresno ratios</b>			
Food Category	Limit of detection (ppm)	Correction Factor	Lead Level (ppm)
Meat and Seafood	0.0070	1.0450	0.0073
Eggs	0.0070	1.0450	0.0073
Milk	0.0070	1.0450	0.0073
Non-leafy vegetables	0.0070	1.0450	0.0073
Leafy Vegetables	0.0100	1.0450	0.0105
Fruit	0.0070	1.0450	0.0073

The NPA believes the preceding calculations giving rise to correction factors of; 0.94, 1.045, and 1.126 is persuasive evidence which demonstrate the correction value proposed by OEHHA was not scientifically appropriately derived.

<sup>23</sup> Oxnard/Ventura (0.635), Santa Maria/San Luis Obispo (0.842), Monterey/Salinas Valleys (0.699)), Coachella (1.417), Imperial Valley (1.124), Colusa/Glenn(1.412), and Fresno(1.188)

<sup>24</sup> Oxnard/Ventura (0.635), Santa Maria/San Luis Obispo (0.842), Monterey/Salinas Valleys (0.699)), Coachella (1.417), Imperial Valley (1.124), Colusa/Glenn(1.718), and Fresno(1.446)

Food Category	Limit of detection (ppm)	Correction Factor	Lead Level (ppm)
Meat and Seafood	0.0070	1.1260	0.0079
Eggs	0.0070	1.1260	0.0079
Milk	0.0070	1.1260	0.0079
Non-leafy vegetables	0.0070	1.1260	0.0079
Leafy Vegetables	0.0100	1.1260	0.0113
Fruit	0.0070	1.1260	0.0079

### **Data and Methods Used to Calculate Inorganic Arsenic Levels Should be Made Available and Transparent**

OEHHA has stated in the pre-regulatory document that the proposed levels of inorganic arsenic levels were derived using 2012 and 2013 data from California Rice Commission (CRC) and 2013 data from the Food and Drug Administration (FDA), Analytical Results from inorganic Arsenic in Rice and Rice Products Sampling. While the results and the analytical methods of the FDA study are available both the 2012 and 2013 CRC data and analytical methods are unpublished. The NPA would like the data and analytical methods from the 2012 and 2013 studies to be made available. If the analytical methods differ between the FDA and CRC studies, it may not be scientifically appropriate to average them to calculate the inorganic arsenic levels in rice. Furthermore, the FDA is still conducting the risk assessment for long term effects of inorganic arsenic in rice. NPA believes that the results of the risk assessment will give a more diverse understanding of the true impact of inorganic arsenic levels as samples of the rice were grown not only in the US, but also internationally. OEHHA is making an observation from only California (5 locations) and therefore NPA would like OEHHA to consider waiting for the results from the FDA risk assessment.

### **The Proposed Allowances for Naturally Occurring Lead and Arsenic Will Not Decrease Litigation**

While the addition of Section 25501.1 to Article 5 seeks to further clarify whether a food product is exempted from Prop 65, the NPA believes the amendment is counterproductive and will certainly not serve to decrease litigations and “professional plaintiff” lawsuits by an already

charged Plaintiff's bar. While most fresh foods already meet the criteria for naturally occurring, the only businesses that are prepared to prove that the lead and/or arsenic in the fresh food is naturally occurring are USDA NOP (National Organic Program) certified foods as they have already qualified their supply chain. Conventional farms will be more difficult to prove the series of negatives in the exemption and therefore will be susceptible to and even targeted by "bounty hunter" lawsuits. According to the California Attorney General's office there has been an average of 300 Prop 65 settlements annually over the last 10 years with more than 650 settlements coming in 2014 alone.<sup>25</sup>

## Summary

NPA applauds the efforts of Governor Brown to reduce the incidence of frivolous lawsuits in the state of California by "professional plaintiffs" under the private enforcement provisions of Prop 65. However, we think the proposed draft regulation of Section 25501.1 to Article 5 would do little toward achieving that outcome. The NPA does not support OEHHA's draft regulation proposal on the addition of Section 25501.1 to Article 5 for a variety of reasons discussed above. For example, NPA does not see how the proposed changes would enhance the effectiveness of the clear and reasonable warnings through OEHHA's attempt to clarify the naturally occurring exemption. In fact, this will have the opposite effect and lead to a continued path of consumer apathy from overexposure to warnings. Currently, businesses must prove a series of negatives in order to achieve the exemption.

The current regulations place the burden of proof solely on manufacturers to prove a series of negatives, an insurmountable and unrealistic expectation. California's limits on common contaminants like lead, cadmium, arsenic and mercury, are typically lower than the federal provisional total tolerability intake levels established for contaminants in food. While FDA can enforce bans or mandatory recalls because their limits are based upon a scientific body of evidence, Prop 65 limits on common contaminants like lead and arsenic, described in the proposed draft, are not based in any science and do not serve to protect the public. NPA urges

---

<sup>25</sup> Cumulative Proposition 65 Settlement Report 2014 (<https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/2014-prop65-full-rpt.pdf>)

OEHHA to work more closely with CDFA and US FDA to ensure that warnings are based upon general principles of regulatory toxicology as well as federal and state regulatory authorities for food.

We believe that the proposed addition of section 25501.1 lacks scientific validity, rigor and logical reasoning in addition to not decreasing frivolous lawsuits. The manner in which the correction factor was derived is not logically or scientifically appropriate. The NPA would also like OEHHA to consider using the FDA data analysis on lead in fresh foods as the tests have been performed for decades. The FDA has found that levels of lead have been under the tolerable intake levels.

The proposed draft does not rely on enough analytical data from soil samples around the State and outside of California to calculate proper naturally occurring background levels. OEHHA's methods for developing allowances was not validated on a wide variety of plant species. Their allowances for naturally occurring contributions rely on detection limits of instrumentation using soil samples that in some cases were not found to contain any lead. The proposed draft develops a "fudge" factor to separate the fraction that is naturally occurring from the fraction present from "human activity". OEHHA's study results ran counter to their hypothesis in some cases because their assumption was that deep soil levels always contain chemicals and contaminants at levels less than or equal to the upper soil levels. Deep soil levels, representing background levels from natural sources, were found in some California regions to contain higher amounts of lead than the upper soil level, representing natural and anthropogenic contributions. These findings ran diametrically opposed to the study hypothesis to the extent that their scientists forced the correction factor to be unity of one in those cases, rather than calculate a correction factor using actual numbers from their dataset. In other cases, they did not analyze the lower soil depth for the background level. For these reasons NPA does not support the application of junk science, poor methods, inadequate hypotheses, and development of fudge factors lacking scientific rigor.

Lastly, NPA believes that the findings of inorganic arsenic was restricted to a small region in California and therefore doesn't give a diverse understanding of the true impact of arsenic levels in soil globally. While the FDA is still pending the long-term risk assessment for

inorganic arsenic in rice, NPA would like for OEHHA to reconsider the proposed draft until FDA releases their assessment. Furthermore, NPA would like the data and analytical methods from the CRC 2012 and 2013 studies to be made available to evaluate the analytical methods used. The results from the tests should be made public out of transparency so industry and stakeholders can comment on the science that OEHHA used to come to their conclusion to deem if the results are scientifically valid.

In conclusion, NPA appreciates the opportunity to comment on this draft regulation regarding a pre-regulatory draft proposing amendments to Proposition 65 (Prop 65) Article 5, Extent of Exposure, Addition of Section 25501.1, Naturally Occurring Concentrations of Chemicals, Naturally Occurring Concentrations of Arsenic in Rice and Lead in Some Foods. NPA fully supports the naturally occurring exemption for foods, extension to cover chemicals found naturally occurring in ingredients used in non-food consumer products (e.g. cosmetics), continued efforts by OEHHA to bring clarity and guidance on the naturally occurring exemption, and OEHAA to strongly consider each point raised in these comments.

Thank you for your attention to these important matters and the opportunity to submit comments. 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).

Sincerely,

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

Daniel Fabricant, Ph.D.

CEO, Executive Director

Natural Products Association