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Monet Vela
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Via Email

Re: Comments on Proposed Addition of Section 25501.1, Naturally Occurring Concentration of Chemicals

Dear Ms. Vela:

The Environmental Law Foundation ("ELF") urges OEHHA to abandon its proposed naturally occurring safe harbor level regulation ("proposed regulation"). The proposed regulation will expose consumers to shockingly high levels of lead without a warning. It is simply a gift to regulated industry with no countervailing benefit. And the Pre-Regulatory Draft ("Discussion Paper") makes it clear that the regulation is based on unsupported logical leaps from spotty data.[1]

Proposition 65 places the burden on the defendant to prove that a product falls into one of the exemptions defined in the statute.[2] But OEHHA is now proposing to relieve defendants of that burden as to foods containing lead and arsenic. The Discussion Document spends little time justifying this decision.[3] But it is clear what the proposed regulation does: the proposal gives regulated industries a head start on defending enforcement actions. It is doing so based on bad assumptions based on bad data. We call upon OEHHA to act in keeping with its reputation as a science-based agency and withdraw this proposed regulation.

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[1] Our comments focus on the naturally occurring level for lead, but we equally oppose the adoption of a naturally occurring safe harbor level for arsenic.

[2] Health and Saf. Code § 25249.10(c).

[3] OEHHA, Pre-Regulatory Draft – For Discussion Purposes Only, Possible Amendment to Article 5 – Extent of Exposure: Addition of Section 25501.1 – Naturally Occurring Concentration of Chemicals (2015) ("Discussion Paper") at 2.

The Proposed Regulation Will Expose Consumers to High Levels of Toxins

The proposed regulation goes far beyond the rationale for the existing naturally occurring exemption, which is to permit "low levels" of carcinogens and reproductive toxicants when they are naturally occurring.[4] The proposed levels, 6.2 ppb for most foods and 8.8 ppb for leafy vegetables, are not low. At a concentration of 6.2 ppb, a consumer of 1 kg of food in a day would consume 6.2 µg of lead in that day. Under the proposed regulation, every consumer would be allowed to consume at least that amount of lead every day without receiving a warning. But the maximum allowable daily limit is 0.5 µg per day. If Californians are consuming this much lead per day, it is a public health crisis. And to allow companies to simply write off 6.2 µg of exposure is irresponsible. It is out of character for OEHHA to suggest it.

The Proposed Regulation Is Not Based on Reliable Data or Good Science

Under OEHHA's own existing regulations, a naturally occurring level of a chemical may only be based on "reliable" data.[5] But the draft discussion relies on data that are highly unreliable for OEHHA's purposes. This alone should have been sufficient for OEHHA not to propose this regulation. Instead, OEHHA made unsupported logical leaps to justify the approach found in the proposed regulation.

OEHHA Relies on Inappropriate and Flawed Studies

One problem with the proposed regulation is that it attempts to distill a single naturally occurring level of lead out of data that are not robust enough to do so. It is clear from OEHHA's own discussion paper that the available data are not sufficient to arrive at a valid safe harbor number. When developing the original naturally occurring exemption, OEHHA recognized that variability in naturally occurring levels was inevitable, and wrote flexibility into the regulation to account for it.[6] But OEHHA has now abandoned that more reasonable approach.

When discussing soil lead levels, papers cited in the draft discussion document use a more lenient standard than the existing regulation, which only applies to chemicals which did "not result from any known human activity."[7] For instance, the USGS paper, while it did

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[4] OEHHA, *Final Statement of Reasons, 22 California Code of Regulations, Division 2, Part 2, Chapter 3, Safe Drinking Water and Toxic Enforcement Act of 1986, Article 5, Extent of Exposure, Section 12501, Exposures to Naturally Occurring Chemicals in Food* (1988), at 3 ("Section 12501 FSOR"). Section 12501 has since been renumbered as California Code of Regulations, title 27, section 25501.

[5] Cal. Code Regs, tit. 27, § 25501(a)(4).

[6] Section 12501 FSOR, at 7.

[7] Cal. Code Regs, tit. 27, § 25501(a)(3).

exclude sample sites less than 8 km downwind of major industrial facilities, did not control for pervasive human-caused lead contamination, such as that from leaded gasoline or lead-based pesticides.[8] OEHHA cannot rely on this paper to establish soil lead levels that did not result from "any known human activity" because the study makes no claim to exclude all lead resulting from known human activity.[9]

And the CDFA study, the basis for the "correction factor," has at least two flaws.[10] The first part of the study compares soil from 1967 with soil from 2001. Setting the baseline of the study at 1967 ignores the fact that human-caused lead was being emitted into the environment long before that date. Any increase in lead levels between 1967 and the present must account for anthropogenic lead that predates 1967.

The second part of the CDFA study compares soil from a depth of 20 cm and from a depth of two meters.[11] But conclusions drawn from this aspect of the study rely on a large, untested, assumption—that the lead found at the two-meter depth is naturally occurring, and that the lead at the 20 cm depth is human-caused. Even if it is true that lead's soil mobility is low enough that this method is effective for establishing a natural occurring soil lead level (and OEHHA has produced no evidence that this is the case, while the CDFA study merely assumes it[12]), there is likely to be enormous variability in lead soil mobility between soil types. The CDFA study, which is based on only a smattering of sampling sites, is simply incapable of supporting a conclusion about naturally occurring lead levels across the state.

Even If the Data Were Valid, OEHHA Draws Unsupported Conclusions

After reviewing the extensive data on plant uptake, OEHHA concludes that the studies are too variable to rest its decision on.[13] But instead of acknowledging that the data are not reliable enough to support a naturally occurring level, it pivots to a new strategy. OEHHA assumes that all food products (besides leafy vegetables) contain lead at a level equal to the detection limits from the TDS study. It then adjusts the level by a "correction factor" based on the CDFA study. OEHHA's actual conclusions, therefore, ignore most of the studies cited in the Discussion Paper.

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[8] Holmgren et al., *Cadmium, Lead, Zinc, Copper, and Nickel in Agricultural Soils of the United States of America* (1993) 22 J. Environ. Qual. 335, 336, available at http://nature.berkeley.edu/classes/espm-120/Website/Holmgren1993.pdf.

[9] See Cal. Code Regs, tit. 27, § 25501(a)(3). Granted, OEHHA's actual decision does not rely the data from this study, nor the data from most of the other studies it mentions.

[10] Discussion Paper at 5; Chang et al., *Role of fertilizer and micronutrient applications on arsenic, cadmium and lead accumulation on cropland soils in California.* (2004) Final Report Submitted to California Department of Food and Agriculture ("CDFA Study"), available at https://www.cdfa.ca.gov/is/docs/CDFAFinalReport.pdf.

[11] Discussion Paper at 6; CDFA Study at 52.

[12] CDFA Study, at 33.

[13] Discussion Paper at 7.

The proposed regulation sets the "background" level of lead in food as the detection limit of the TDS study, 7 ppb.[14] If true, this is an astonishing fact. Assuming, conservatively, that the average Californian eats 1 kg of meat, seafood, eggs, milk, vegetables, and fruit per day, if the actual background of lead were 7 ppb, then Californians would consume 7 µg of lead each day, 14 times the MADL. Widespread testing by ELF and other environmental groups has shown enormous variation in lead levels, using testing protocols with more sensitive levels of detection. OEHHA's assumption that *all* products contain 7 ppb of lead sets far too high of a baseline and leads to an inflated safe harbor level. OEHHA's proposed regulation appears to choose a number that protects industry as much as possible.

The correction factor of 88 percent is also far too high. As discussed above, the CDFA study that OEHHA cites for its support does not exclude the possibility that its "baseline" lead levels include anthropogenic lead sources. Thus the proportion of soil lead that is naturally occurring is likely to be much lower.

An even larger analytical gap is that using the CDFA study as the sole basis for the "correction factor" assumes that *all* of the lead in a food is traceable to a plant's uptake of lead in the soil. But it has been established many times that lead can be introduced to a food's supply chain by many mechanisms. By assuming that all lead in food is from soil, and that 88 percent of that lead is naturally occurring, the regulation will mask the significant contributions to lead in food that come from other, manmade sources.

The data also do not support including meat, seafood, eggs, or milk in this regulation. The sole support for the 0.88 correction factor is the CDFA study on lead in soil. Seafood, obviously, does not grow in soil. And OEHHA presents no evidence for how lead accumulates in other animals, whether they are used for meat, milk, or eggs. OEHHA simply applied the correction factor to these categories of foods without analysis or explanation. There is no support in the studies cited or the discussion paper that justifies adopting any safe harbor level for animal products.

The Distinction Between Leafy Vegetables and Other Foods Is Unsupported

OEHHA adopts a higher naturally occurring level for leafy vegetables.[15] But the Discussion Paper does not explain where the figure for leafy vegetables comes from. It states that leafy vegetables have higher levels of lead than non-leafy vegetables and that the TDS study detected lead in a higher proportion of leafy vegetables than in other foods. It appears from the agency's PowerPoint presentation at the October workshop that the 10 ppb background level is based on the average of detections for leafy vegetables. But this approach runs into

[14] This decision came after rejecting a more logical approach, based on plant lead uptake rates. OEHHA correctly realized that the data would not support such an approach, but pressed on nonetheless.

[15] Discussion Paper at 8.

the same analytical problems. It ignores the non-detects and thus sets the level far too high. And it assumes that all of the detected lead came from soil, excluding other, human-caused, explanations.

The Proposed Regulation Is Unlawful

OEHHA is charged with implementing Proposition 65 and promulgating regulations that conform to the statute's requirements and "further its purposes."[16] But OEHHA has no authority to issue a regulation that frustrates the statute's purposes, as the proposed regulation does. The proposed regulation also conflicts with the existing naturally occurring regulation by allowing defendants to expose consumers to lead and arsenic without demonstrating that they have reduced contamination to the lowest level feasible.

OEHHA Does Not Have Authority to Issue This Regulation

OEHHA does not possess the statutory authority to issue this regulation. OEHHA's only statutory authority for adopting Proposition 65 regulations is found in Health and Safety Code section 25249.12(a), which allows the agency to adopt regulations that implement the statute and "further its purposes." But an agency has "no authority to promulgate a regulation that is inconsistent with controlling law." *Mineral Associations Coalition v. State Mining and Geology Bd.* (2006) 138 Cal.App.4th 574, 583.

In its Discussion Paper, OEHHA justifies its authority by pointing to California Code of Regulations, title 27, section 25501(a)(2), which states that a " 'naturally occurring' level may be established by determining the natural background level of the chemical."[17] OEHHA relies on this language to justify this proposed regulation. But determining the natural background level is only the first step in the process under section 25501. The regulation requires more than simply identifying the natural background level—after establishing that level, it is then necessary to determine what portion of the chemical in the food is naturally occurring; a warning is still required if the remaining chemical causes an exposure.[18] Therefore, under OEHHA's own regulations, it is not simply the case that the determined natural background level has a 1:1 relationship with the naturally occurring level of a chemical in a food.

The Proposed Regulation Removes the Requirement to Reduce Naturally Occurring Chemicals to the Lowest Level Feasible

The proposed regulation guts the current naturally occurring regulation by removing the requirement to show that a defendant has reduced the level of a chemical to the lowest level feasible. Currently, in order to take advantage of the exception, a defendant must show that

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[16] Health & Saf. Code § 25249.12(a).

[17] Discussion Paper at 2; citing Cal Code Regs., tit. 27, § 25501(a)(2).

[18] Cal. Code Regs, tit. 27, § 25501(a)(3).

its use of the naturally occurring chemical was not avoidable, and that it utilized "quality control measures that reduce natural chemical contaminants to the 'lowest level currently feasible."[19] But the proposed regulation simply "deems" certain levels of lead and arsenic as naturally occurring.[20] This allows companies to simply subtract a substantial amount of lead from their products without showing that they reduced contamination to the lowest feasible level. This is a major and unjustified shift in the law.

Removing the requirement that naturally occurring chemicals be unavoidable is especially problematic in light of the unreliable data that OEHHA used. The TDS data show that the vast majority of food has undetectable levels of lead. ELF's testing of foods confirms this truth: many foods do not contain lead at unlawful levels, even when using testing protocols that are much more sensitive than the 7 ppb limits of detection in the TDS study. Thus, even if the lead in a product is natural, manufacturers can eliminate consumer exposures to lead by simply setting a specification for lead and rejecting lots that violate the spec. Given that a significant number of foods do not contain lead at problematic levels, this procedure is a feasible avoidance measure that would reduce exposures to lead, whether naturally occurring or otherwise, essentially to zero.

Conclusion

The irony is that OEHHA could have simply left the status quo and consumers would be better off. Under the existing regulatory scheme, enforcement actions would have to be based on better data than that underlying the proposed regulation because a defendant wishing to prove that levels of lead in its product occurred naturally must show that the specific lead contained in its specific product had no human origin. By tying each product to specific sourcing decision, the courts will base their decisions on better, more localized data that can show what, if any, level of a chemical is naturally occurring. Indeed, as shown by the trial court litigation in *Environmental Law Foundation v. Beech-Nut Nutrition Corp.* (Alameda Super. Ct., 2013, No. RG 11597384), aff'd, (2015) 235 Cal.App.4th 307, courts have on occasion found that a defendant has not met its burden to prove that lead is not sufficiently naturally occurring in the particular products at issue. Under the proposed regulation, OEHHA would largely excuse defendants from this burden and simultaneously sweep a significant amount of lead into the category of naturally occurring lead.

The proposed regulation does not live up to OEHHA's normal standards for good science and health-protective policy making. We ask the agency to end consideration of this poorly conceived regulation.

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[19] Cal. Code Regs, tit. 27, § 25501(a)(4).

[20] Draft Pre-Regulatory Text, Cal. Code Regs, tit. 27, § 25501.1(a).

Sincerely,

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Environmental Law Foundation