August 19, 2019

Monet Vela
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Dear Ms. Vela:

The Center for Environmental Health, Clean Water Action, and the Natural Resources Defense Council thank the Office of Environmental Health Hazard and Assessment ("OEHHA") for the opportunity to comment on the proposed modifications to the pending amendments to Article 8 of Title 27 of the California Code of Regulations, section 25821 ("Section 25821").We offer the following comments.

1. **We Incorporate By Reference CEH's Previous Comments Regarding The Proposed Modifications to Section 25821.**

OEHHA's new proposed modifications did not address any of the comments CEH submitted with respect to the original proposal. We therefore incorporate by reference its previous comments dated December 3, 2018.

2. As CEH Previously Commented, Section 25821 and the Final Statement of Reasons Should Clarify That Averaging the "Level in Question" Is Not Always Appropriate.

As CEH previously pointed out, while averaging of the "level in question" of a chemical in food products may be appropriate in certain circumstances, Section 25821 should clarify that it is not appropriate in all circumstances. The latest proposed modifications exacerbate CEH's concerns by adding new language that could allow a company to average products containing ingredients that are sourced from different manufacturers or producers. CEH's prior comments gave the following example, which illustrates the problem with this approach:

> By way of example, if a cookie bakery produces a cookie Batch A using molasses of known high lead content and then manufactures a second Batch B with low lead molasses, averaging of Batch A and Batch B is not allowed and contrary to the statute. The exposures from Batch A require a warning under the statute as they are knowing and intentional exposures. The fact that Batch B may not require a warning does not allow for unwarned exposures to consumers who eat cookies from Batch A.

To avoid this situation, Section 25821 should clarify that averaging of different units of a food product is only appropriate under certain facts and circumstances such as when a business knows that levels of some food products grown in a particular locale will require a warning but is not clear on which specific units exceed the warning threshold for a particular chemical. For example, a canned food processor might process mixtures of foods produced in different locations and thus not be able to identify which specific cans contain food from a particular locale.

3. OEHHA Should Not Backtrack From Its Proposal That The Arithmetic Mean Should Be Used To Calculate The Rate Of Intake or Exposure.

OEHHA first proposed amending Section 25821 to clarify that the arithmetic mean should be used to calculate the rate of intake or exposure in 2015. See Notice, Pre-Regulatory Workshop For Potential Regulatory Amendment, Section 25821, Aug. 28, 2015. As OEHHA then stated:

> the geometric mean is not the appropriate metric for identifying average consumption levels of a food or consumer product. A single consistent measurement – e.g., amount of a food product eaten or ounces of a consumer product used on the day consumed – is used to calculate the average consumption amount.

> This supports the use of the familiar arithmetic mean (calculated by adding measurements and then dividing by the number of measurements that were added) as the appropriate metric for identifying average consumption of a product by people using the product.
>
> The geometric mean underweights the rate of exposure of those people who consume significantly more of a food or product than more typical consumers. In most cases, use of the geometric mean will produce a lower average consumption amount than the arithmetic mean, which weights all the values for intake rate equally and does not discount exposures of people consuming nearer to the higher end of the range. OEHHA believes it is appropriate to weigh all individual consumers equally. Thus, the reasonably anticipated rate of exposure for purposes of Proposition 65 should be calculated as the arithmetic mean.

Pre-Regulatory Draft, Possible Amendments to Section 25281(c), Aug. 28, 2015. And, more recently in connection with the proposed amendments now being considered, OEHHA stated:

> The use of the familiar arithmetic mean (calculated by adding the measurements and then dividing by the number of measurements that were added together) is the appropriate metric for identifying average consumption of a product by individuals consuming or using the product, and is being proposed to add clarity and consistency to the exposure calculation.
>
> Because Proposition 65 is intended to warn Californians of significant exposures to listed chemicals, a determination of the exposures to a chemical in a food or consumer product should be based on the full range of exposures experienced by Californians. It is appropriate to weigh all individual consumers equally for purposes of calculating intakes or exposures. The arithmetic mean accounts for consumption levels at both the low and the high end of the range, weighing the intake of each consumer equally.

Initial Statement of Reasons, Proposed Amendments to Sections 25281(a) and (c), Oct. 2018, pp 7-8. CEH supports OEHHA's prior positions on clarifying that the arithmetic mean is the appropriate metric, and is puzzled as to why OEHHA is withdrawing this proposal. By failing to clarify this issue, OEHHA is fostering uncertainty and increasing the risk that different courts will reach differing conclusions as to a scientific issue that can and should be resolved by the agency in a manner that ensures consumers will not be unwittingly exposed to listed chemicals without a required warning. CEH urges OEHHA to reconsider this proposed modification to its August 2015 and October 2018 proposals.

Conclusion

We appreciate OEHHA's effort to clarify and improve Section 25821. Addressing each of the preceding comments will enhance these improvements by reducing ambiguity

and ensuring that individuals in California are provided with clear and reasonable warnings prior to exposure to toxic chemicals.

Sincerely,

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