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Re: Calculating Exposure - Facility-Based Averaging

The American Beverage Association and the Grocery Manufacturers Association (hereinafter “Food Coalition”) thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment’s (OEHHA) July 2019 amended proposal to require facility-by-facility averaging of food products (the “Proposal”) at the level of final manufacture or packaging. The Food Coalition members also have joined in the California Chamber of Commerce comments; we write separately to emphasize how concerning and burdensome this Proposal is for our member companies.

I. Overview

Proposition 65 has been a significant burden on the food industry. Private enforcement of Proposition 65 is increasingly targeting the food industry. In 2008, there were approximately 106 food companies targeted in Proposition 65 notices. In 2017, that number had risen to approximately 1138 food companies targeted in notices.

Against the weight of this significant burden, OEHHA should not adopt the costly and unnecessary modified proposal it released in July 2019. California officials have expressed concerns about “over warning” and “shake down” lawsuits under Proposition 65, and the Proposal almost certainly will increase both of these negative phenomena.

The Food Coalition appreciates that OEHHA has elected not to move forward with its manifestly unscientific proposal to mandate the arithmetic mean rather than allow courts to apply the best science to a particular set of facts.

II. The Proposal Is Totally Unnecessary; Its Aim May Be Achieved Under Existing Law

In adopting the California Administrative Procedure Act, the Legislature noted that “Substantial time and public funds have been spent in adopting regulations, the necessity for which has not been established.” Cal. Gov’t Code § 11340(c). OEHHA has not established any necessity for this proposed regulation, which is indeed not necessary. No statement of necessity appears in OEHHA’s July 5, 2019 Notice of Modification.

OEHHA's October 2018 Initial Statement of Reasons provides the following statements to describe the "problem to be addressed by the proposed regulation": Regulations that are not sufficiently specific and that lack clarity "can lead to incorrect or inconsistent determinations." (ISOR at 3.) These general words, however, offer no justification for OEHHA's specific proposed regulation. It cannot be the case that all proposed regulations that are more detailed are "necessary," yet that is what this statement asserts. OEHHA offers neither incorrect nor inconsistent determinations that might justify this regulatory change.

In explaining the proposed amendment to section 25821(a), OEHHA states that "the amounts of listed chemicals in food products can vary significantly based on when and where the food was grown, processed or packaged." (ISOR at 4-5.) There are five citations provided for various portions of this statement. (ISOR at 4-5, fns. 6-10.) None of these purported authorities identify a problem that is addressed by OEHHA's proposed regulation or otherwise support the necessity of the regulation.

- OEHHA cites to the FDA's Total Diet Study (2017)¹ in support of the concept that "the amount of listed chemicals in food products can vary significantly." OEHHA simply cites to this 167 page report in the whole; it does not cite to any specific data that presents a concern for it, which materially impairs one's ability to comment upon this. From our review, the majority of the data does not show significant variation. Moreover, this data is not presented by company or by manufacturing facility, and so there is no evidence that this data would vary significantly for a particular Proposition 65 defendant or facility. Absent some unexpected stipulation among or between the parties in a particular case, we would not expect data from one company's product to be admissible in an exposure assessment for another company's product. Thus, this FDA report does not establish any need to limit a particular Proposition 65 defendant's ability to average data from its different manufacturing facilities.
- Next, for the same proposition, OEHHA cites to an article about the food manufacturing process and the concept of "smart manufacturing."² The article evaluates the business of the food industry and how to make better "manufacturing decisions in dynamic environments." How much product should a company make, how should it staff production, which ingredients make the best product, what alternate ingredients are available if an ingredient is unavailable? Neither these business issues, nor the proposed software-based solution in the article, have anything to do with evaluating the amount of a Proposition 65 chemical in a food product. Although this article uses the phrase ingredient variability, it certainly does not establish that food ingredients are variable

¹ Food and Drug Administration (2017). Total Diet Study - Elements Results Summary Statistics. Market Baskets 2006-2013. US FDA, Center for Food Safety and Applied Nutrition, April 15, 2014, Revised April 2017.

² 7 F Riddick, E Wallace, J Davis (2016). Managing risks due to ingredient variability in food production, Journal of Research of the National Institute of Standards and Technology, Volume 121, 17-32.

with respect to Proposition 65 chemicals or that any such variability arises from different facilities as opposed to other factors.

- OEHHA also cites to a European Food Safety Authority paper addressing the presence of lead in food and lead exposures in different subpopulations.³ This paper principally describes lead in wide groupings of food categories that offer no meaningful information for Proposition 65 analysis, which focuses on particular food companies and particular food products. We did not locate anything in the paper establishing that lead levels for certain food products from a particular company vary because of the facility where they are produced. Indeed, we did not identify any differentiation between variations in naturally occurring lead, which is not an exposure under Proposition 65 and other lead, which is. Moreover, the paper notes that the over 140,000 results analyzed suggest that lead in food appears to be declining: “Lead levels were estimated to have been reduced by about 23 % between 2003 and 2010.”
- Next, OEHHA cites to a single article for the proposition that the amount of a chemical can vary based on when and where the food is grown. The referenced article evaluates human exposure to arsenic through rice.⁴ This article does not state that the manufacturing or packaging location of rice impacts the variability of arsenic exposure. The silence on this point implies that the variable OEHHA is proposing to control is not a source a variability. Certainly, this article does not support the proposition that the location of manufacturing or packaging rice impacts the arsenic content. On balance, this article supports not adopting the proposed regulation more than it supports adopting the regulation. There is no evidence that requiring single facility averaging would in any way address any alleged issues of variability purportedly identified in this article.
- Finally, OEHHA cites to a single article for the proposition that the amount of a chemical can vary based on when or where the food is processed or packaged. Yet, nothing in the cited article identifies a problem that is addressed by this proposed regulatory amendment. The article, *Phthalates and diet: a review of the food monitoring and epidemiology data*⁵, undertook a review of the available food monitoring survey and epidemiological data in order to identify primary foods associated with increased exposure to phthalates.⁶ Due to the fact that the studies evaluated included data from different countries, the authors occasionally noted where phthalates were more prevalent in foods in certain countries. However, the authors’ conclusions all relate to which foods

³ 8 European Food Safety Authority (2012). Scientific Report of EFSA. Lead dietary exposure in the European population, EFSA, Parma Italy, EFSA Journal 10(7):2831.

⁴ Davis MA, Signes-Pastor AJ, Argos M, Slaughter F, Pendergrast C, Punshon T, Gossal A, Ahsan H, Karagas MR (2017). Assessment of human dietary exposure to arsenic through rice, *Sci Total Environ* 586:1237-1244.

⁵ Serrano SE, Braun J, Trasande L, Dills R, Sathyanarayana (2014). Phthalates and diet: A review of the food monitoring and epidemiology data. *Environmental Health*, 13:43

⁶ “Thus, we reviewed the food monitoring survey and epidemiology data on dietary phthalate exposure with the aim of identifying primary foods/diets associated with phthalate biomarker levels. We additionally calculated total daily intakes of dietary DEHP in the US population based on all available data from North America, Europe and Asia.”

appear to contribute to phthalate exposure, not how location of manufacturing or packaging impacts that exposure. That is, certain types of foods are more receptive to phthalate transfer than other foods because of their chemical characteristics. Nothing in this article identifies the processing, manufacturing or packaging location as an issue impacting phthalate exposure, nor does it indicate a need to address those issues when evaluating phthalate exposure. Again, given the article's silence on the specific subject of the regulation, the article on balance supports no action rather than OEHHA's proposal.

Thus, most of OEHHA's citations do not speak to the specific Proposal OEHHA has made and citations that might be interpreted as having some relevant information actually favor no action rather than OEHHA's Proposal. Moreover, none of the data that generally addresses possible variability, establishes that the variability is not natural, or from exempted air or water. Therefore, none of the data establishes that any variability is relevant to Proposition 65. *See* 27 C.C.R. §§ 25501-25504.

OEHHA's next purported justification for the regulation is as follows:

“Calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California. It is inconsistent with this purpose to average concentrations of a chemical in a food based on samples of foods from different manufacturers or producers, or that were manufactured in different manufacturing facilities, because these are not necessarily representative of the products an actual California consumer would purchase or use.” (ISOR at 5.)

What OEHHA fails to address in this justification for its proposed regulation is whether there is a barrier today to these goals being met. And, there is not. The California Attorney General, local prosecutors, and private enforcers may today focus their enforcement actions on products sold in a particular county, city, or store. They also may allege that all canned food of a particular type produced at the facility responsible for Can XYZ with production code 1234 has violated Proposition 65. Stated another way, Proposition 65 plaintiffs have the ability to allege that the “level in question” is not a statewide level, but a more localized level. If the plaintiff's allegations were limited, the affirmative defense that exposure does not require a warning would need to address the scope of the plaintiff's allegations and the asserted “level in question”. OEHHA's Proposal wrongly requires local analyses and averaging when the plaintiff alleges a statewide issue. If the issue to be defended is statewide, it stands to reason that the level in question is and should be statewide.

OEHHA further asserts, without support, that “Calculations of the concentration of a chemical in a food product for purposes of determining whether a warning is required should reflect an exposure that a consumer might reasonably receive from a product purchased at a specific time and place in California.” (ISOR at 5.) There is no support whatsoever in Proposition 65 that

warnings should be determined based on purchases “at a specific time” and that is flatly contradicted by numerous other Proposition 65 materials from the implementing agency. *See e.g.*, 27 CCR § 25821(b) (“an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth”), and the Final Statement of Reasons in support thereof. As noted above, there is no restriction in current law on a plaintiff limiting its allegations to a “place” in California that is less than the entire state. Proposition 65 specifically allows for a plaintiff to do that. It is the plaintiff’s obligation to investigate its case and frame its complaint (and notice letter, where necessary) accordingly. A plaintiff today that wishes to focus on violations in a particular region may do so.

OEHHA also asserts, without citation or scientific support, that “It is not consistent with the purposes of the Act to average across samples gathered from different locations.” (ISOR at 5.) If this is true, then it is not consistent with the Act for a plaintiff to be entitled to sue a defendant for a location that it has not sampled, yet that practice has been in place for over 30 years and OEHHA is not proposing to change it. Moreover, OEHHA does not address the credible scientific information weighed favorably by the Court in *Beech-Nut* - that “Single samples are less accurate because lead adheres differently to the different nutritional components of food. Additionally, lead is not homogeneous within a product because it is held in suspension, not in solution. Because of these variables it is necessary to average data points in order to obtain a reasonable and reliable estimate of the actual lead levels in each product.” *Beech-Nut Corp.*, 235 Cal. App. 4th at 315; *see also, id.* at 327. This scientific evidence supports the Court’s approach and the existing regulatory language and has not been addressed or rebutted by OEHHA.

OEHHA states that “The Act and its implementing regulations in Section 25821 do not specify procedures for determining the concentration of a listed reproductive toxicant, or ‘level in question’, in a food product when the concentration in the product varies.” There need not be an established procedure to achieve the purpose OEHHA describes, however. The plaintiff has the ability to influence what is put “in question” by shaping the allegations in its notice letter or complaint or both. The current regulation establishes a performance standard that has been capably applied by private parties and enforced through the courts; the proposed change establishes a more burdensome and more costly prescriptive standard.

OEHHA’s Proposal, thus, serves only to establish an uneven playing field where Proposition 65 plaintiffs may make statewide allegations, but Proposition 65 defendants would be forced to defend statewide allegations on a more localized facility-by-facility basis. This is manifestly unfair and illogical, and not justified by any current problem in Proposition 65 implementation. OEHHA has not justified this proposed change as reasonably necessary to carry out the purported purpose of the regulation.

III. The Proposed Revision to Mandate Facility-Based Calculation of the Average Concentration Under Proposition 65 Would Impose Tremendous Costs, and Is Grossly Inequitable

OEHHA's Proposal to mandate that the "level in question" for food products be based on analytical results specific to a particular food manufacturing or packaging facility would either grossly increase food costs or food warnings in California, or both. This proposed change should not be adopted.

Even forcing averaging at the level of a food manufacturing facility would be prohibitively expensive. It is beyond dispute that forcing the collection of facility-by-facility data would increase costs for all companies with more than one manufacturing facility that might send product to California because all system-wide testing programs would need to be redesigned to be facility-by-facility programs. There are over 250,000 food facilities registered with the U.S. Food and Drug Administration. (See <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm236512.htm>). Based on the size of the California economy, the Food Coalition estimates that at least 60,000 of these registered facilities send finished foods to California (registered finished food facilities number approximately 155,000). These registrations do not include the individual bakeries and supermarkets in California that serve food to customers, including food that is manufactured or packaged on site. We estimate there are at least 3,000 such facilities. Requiring each facility that manufactures or packages products for the California market to have separate testing based on multiple samples could impact approximately one-third, or 20,000 of the registered facilities. We estimate that at least two thirds of the 3,000 unregistered supermarkets and bakeries are part of a multi-location company and thus would be economically impacted by this Proposal. The Food Coalition, based on quotes from reputable labs, estimates that testing for the chemicals that have been the subject of Proposition 65 notices targeting food products costs approximately \$1,000 per sample. Three extra samples per year at each of 22,000 facilities would result in an additional cost of \$66,000,000 per year. The exceptional cost of this Proposal has been further confirmed by an informal poll of selected food companies, which have reported expected additional testing costs of approximately \$600,000 per company or more per year.

Second, if OEHHA believes that Proposition 65 issues should be analyzed facility-by-facility for foods, or packager-by-packager, then Proposition 65 Notices of Violation and Certificates of Merit sent by private parties also should be limited to the facility and food producer for which the plaintiff has credible evidence of an exposure above the relevant safe harbor. It would be grossly unfair and completely illogical for OEHHA to move forward with this Proposal to amend Section 25821(a) on the basis that levels are variable and cannot be extrapolated by defendants, but to simultaneously take the position that identical results may be extrapolated statewide by Plaintiffs for the Plaintiffs' notices and certificates of merit. Thus, a concurrent proposal to amend Section 25903 of the Proposition 65 regulations to require the noticing party to identify

the food product codes on the container and to limit the notice to the manufacturing or packaging facility where the final food product was made is absolutely essential to the just, fair, logical and non-arbitrary implementation of this new OEHHA perception of food data. Although the Food Coalition disputes the need for OEHHA's Proposal for many reasons, the logic of the Proposal applies equally to notice letters and the scope of actions they would authorize as it does to the defense of a product covered by Section 25821.

Next, while OEHHA asserts that the manner in which the *Beech-Nut* Court applied Section 25821(a) was incorrect, OEHHA does not explain why. If OEHHA is correcting an error that it believes was made by a Court, it should identify the error more specifically and explain the scientific or policy basis for its disagreement. The *Beech-Nut* decision cited by OEHHA includes a description of two different approaches to averaging lead values for Proposition 65 analysis, one put forward by Dr. Barbara Petersen and one put forward by Dr. Britt Burton-Freeman. *Environmental Law Foundation v. Beech-Nut Corp., et al.*, 235 Cal. App. 4th 307, 314-316, 319-321 (2015). The Court's opinion makes clear that there was no "error" in the Court's evaluation of the evidence placed before it.

As is evident from the existing regulations, and as the *Beech-Nut* Court affirmed, averaging is a permissible part of applying Proposition 65 concepts to food production. *See id.* at 324. Moreover, the Court noted that plaintiff's expert used the same data as defendants' expert as the basis for the "level in question," so the issue of averaging across various production facilities was not presented to the trial court through either an evidentiary or legal disagreement: "We note Burton-Freeman [plaintiff's expert] also relied on the exact same data as Petersen [defendants' expert] in determining that the products contain excessive levels of lead." *Id.* at 326; *see also id.* at 326-327 (discussion of legal and evidentiary issues presented to trial court and waiver). The decision cited by OEHHA does not support the proposition that the Court "incorrect[ly] conclu[ded]" that "existing regulations allow averaging of the measured concentrations of a listed reproductive toxicant in a food product across similar products manufactured by different manufacturers, in different states and countries, and over extended periods of time" because the plaintiff and defendants in that case were performing their "averaging" based on the same data. *Id.* at 326.

IV. The Proposal Will Have a Significant Adverse Economic Impact on Business

OEHHA's ISOR in support of the Proposal states incorrectly that it will have no significant adverse impact on business:

"The proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states because the proposed amendments to the regulation do not impose any new requirements upon private persons or businesses beyond those that are already required by Proposition 65." (ISOR at 12.)

The Food Coalition strongly disputes this assertion. The Proposal purports to “correct” existing case law and the practice of averaging. This clearly is a *new* requirement. To say otherwise is preposterous. This will force expenditures on testing or label changes, or both. There also will be a significant cost to re-doing existing product compliance assessments pursuant to this new mandate. Cost estimates are described above in section III. OEHHA has offered no facts or evidence to support its assertion that the regulation does not impose any new requirements and its own statements that it intends to correct a purportedly mistaken Court opinion belies this assertion.

V. There Is a Reasonable Alternative to the Proposal

According to the ISOR, “The proposed regulatory action will not adversely impact small business because it is simply a clarification of the intent of the existing regulations. ... OEHHA has determined that there is no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to the attention of OEHHA, including alternatives that would lessen any adverse impact on small business or would be as effective and less burdensome on small business.” (ISOR at 11.) As noted earlier, this is a new regulatory requirement, not a clarification of an existing requirement.

This new regulation will have a significant adverse economic impact on businesses, large and small.

There is a reasonable alternative to the Proposal that would lessen any adverse impact on small business: leave the existing regulations in place as they are. This alternative was brought to the attention of OEHHA in a letter from the California Chamber of Commerce dated November 17, 2015.

VI. Conclusion

For the reasons noted above, the Food Coalition urges OEHHA to withdraw its July 2019 Proposal to amend Section 25821 of the Proposition 65 regulations.

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