October 28, 2015

Ms. Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Via email to monet.vela@oehha.ca.gov

RE: PRE-REGULATORY PROPOSAL IN RESPONSE TO CENTER FOR ENVIRONMENTAL HEALTH'S PETITION REQUESTING REPEAL OR AMENDMENT OF THE SAFE HARBOR LEVEL FOR LEAD

Dear Ms. Vela:

The California Chamber of Commerce and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") August 28, 2015 Pre-Regulatory Proposal for responding to the Center for Environmental Health's ("CEH") Petition Requesting a Repeal or Amendment of the Safe Harbor Level for Lead ("Draft Proposal"). Our Coalition consists of a broad coalition of California-based and national organizations and businesses of varying sizes that, collectively, represent nearly every major business sector that would be directly impacted by OEHHA's proposal.

The Draft Proposal consists of two sets of proposed changes to 27 Cal. Code Regs. § 25805(b):

First, OEHHA would amend 27 Cal. Code Regs. § 25805(b) to create a new subsection (2) containing a matrix of thirteen safe harbor Maximum Allowable Dose Levels ("MADLs") for lead, which vary depending on the duration of exposure ("Draft MADL Proposal"). The draft safe harbor MADLs range from 0.2 micrograms ("mcg") per day for daily exposures to a cap of 8 mcg one day in every 116 days or more. In developing these draft safe harbor MADLs, OEHHA states that it used its most current "Leggett Plus" pharmacokinetic model. In turn, the Leggett Plus model relies on a series of assumptions made by OEHHA, including a target blood lead level ("BLL") of 15 mcg per deciliter ("dL").

Second, OEHHA proposes to define all other safe harbor MADLs other than lead as single-day limits in a new subsection at 27 Cal. Code Regs. § 25805(b)(1) ("Single-Day Proposal"). Although the Draft Proposal purports to respond to the petition submitted by CEH, the Single-Day Proposal is not germane to CEH's petition, which solely concerns the safe harbor MADL for lead. The Single-Day Proposal contains no explanation whatsoever as to how it responds to the CEH Petition.

Both prior to and during the October 14, 2015 workshop on the Draft Proposal, the Coalition requested a brief extension of time to provide comments. In particular, the Coalition pointed out

that OEHHA had posted the MatLab files that it used to run the Leggett Plus model on the afternoon of October 13, 2015 — less than 24 hours before the workshop.[1] The MatLab files, which are highly technical and require expertise to review, are necessary to understand OEHHA's implementation of the Leggett Plus model, as well as to evaluate the validity of the model itself.

OEHHA rejected the Coalition's extension request, citing the need to move quickly in light of ongoing litigation in the case entitled *Mateel Environmental Law Foundation v. Office of Environmental Health Hazard Assessment*, Alameda County Superior Court No. RG15-754547. In that case, the court had requested that OEHHA provide a report to the court concerning the status of the Draft MADL Proposal by October 21 — one week before these comments were due. A brief extension of time to submit comments on a proposal to substantially reduce a MADL that has been in existence for 25 years would have been entirely appropriate and would not have impacted the ongoing litigation.

OEHHA has not provided sufficient time for the Coalition to comment on this highly technical proposal. Thus, should OEHHA decide, after reviewing the comments it receives, that it intends to proceed with this proposal, or some version of it, the Coalition requests that OEHHA permit the Coalition to submit additional comments, and we request that OEHHA consider any such additional comments before issuing any formal regulatory proposal.

1. DRAFT MADL PROPOSAL

The Coalition agrees with the concept that the frequency of lead exposure is relevant to determining when Proposition 65 warnings are required. Indeed, this is consistent with the ruling in *Environmental Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307 (2015) ("*Beech-Nut*"), and with the longstanding regulations implementing Proposition 65. The approach taken by OEHHA to implement that concept is problematic from both a policy and scientific standpoint, however, and the Draft MADL Proposal should not be adopted in its current form. The substantial reduction in the safe harbor MADL for lead, coupled with OEHHA's draft proposals to require the arithmetic mean for determining average consumption and to prohibit averaging of concentration levels across "lots," will undermine if not nullify the result in *Beech-Nut* that the business community fought hard to achieve, and will further arm private enforcers with even more opportunities to challenge businesses under Proposition 65..

1.1 <u>The Draft MADL Proposal will lead to increased warnings and litigation risk</u>.

OEHHA is proposing to reduce the lead safe harbor by 60 percent (i.e., from 0.5 mcg/day to 0.2 mcg/day) for exposures that occur on a daily basis. The current safe harbor for lead has been in place for over 25 years, and thousands of businesses have relied on it in developing their products, operating their facilities, and instructing their suppliers. The Draft MADL Proposal marks an extremely significant reduction in the safe harbor that will present substantial challenges for businesses to meet.

Although OEHHA is also proposing a series of safe harbor MADLs that are higher than 0.2 mcg/day for exposures that occur less frequently than every day (which, like the single-day MADL, are extraordinarily and unjustifiably low), the reality is that the Draft MADL Proposal will

[1] We note that, without any explanation, the MatLab files have since been removed from the webpage where they were originally posted.

increase both litigation risk and warnings. Of the more than 800 chemicals on the Proposition 65 list, lead is the one that has produced the most pre-litigation notices. Of those notices, the vast majority concern alleged consumer product exposures. To this day, Proposition 65 litigation involving lead remains very active. In light of the litigation risks and burdens placed on businesses, the MADL that will give them the greatest certainty of avoiding an enforcement action (which is the purpose of a safe harbor) is the MADL for single-day exposures.

In particular, for a business to prove that the "level of exposure" does not exceed a MADL, a business must prove the "reasonably anticipated rate of exposure." 27 Cal. Code Regs. § 25821(b). This includes proving the duration of the exposure for purposes of identifying which of the thirteen proposed safe harbor MADLs applies. Thus, as a practical matter, many businesses that seek the certainty of knowing that they will not face an enforcement action will refer to the most conservative MADL — the single-day MADL — in considering their compliance options, even if those exposures clearly occur less frequently than every day.

Due to the burdens of proof placed on businesses rather than enforcers (which OEHHA is not proposing to alter), businesses that do not opt to provide warnings for exposures occurring less frequently face increased litigation risk even if those exposures comply with the draft safe harbor MADLs. Establishing a single-day MADL of 0.2 mcg will therefore exacerbate the "overwarning" and litigation abuse problems that Governor Brown sought to address in his 2013 reform initiative.

1.2 The target BLL of 15 mcg/dL is not adequately justified.

In proposing the draft safe harbor MADLs for lead, OEHHA selected Telisman (2000) as the most sensitive epidemiological study of sufficient quality for male reproductive effects. From Telisman, OEHHA selected a blood lead level ("BLL") of 15 mcg/dL to represent the lowest BLL with no observed effect based on the lack of observed male reproductive effects. This figure is fundamental to OEHHA's analysis but is not adequately justified.

For reasons that are not clear, in addition to observing no effect on sperm in men with BLLs of approximately 15 mcg/dL, the Telisman study also observed no effect on sperm in men with BLLs of approximately 45 mcg/dL, even though effects were observed in men with BLLs of approximately 25, 35, and 55 mcg/dL. OEHHA has not provided any detailed statistical assessment concerning these incongruous findings. A statistical review of this data is warranted before it can be selected conclusively as the most sensitive study of sufficient quality and therefore before it can be used as the basis for OEHHA's fundamental assumption that a BLL of 15 mcg/dL represents the lowest BLL with no observed effect based on the lack of observed male reproductive effects.

Furthermore, OEHHA has not addressed in its discussion why it has not considered using a benchmark dose approach with a point of departure higher than 15 mcg/dL, in light of the absence of an effect at 45 mcg/dL as well as 15 mcg/dL. The Coalition has not had sufficient time to undertake consideration of this approach but believes it bears review by OEHHA, particularly in light of the incongruous results of the Telisman study.

We also note that comments were presented at the October 14, 2015 hearing by a representative of Center for Environmental Health to the effect that the 15 mcg/dL BLL target used by OEHHA is inappropriate in light of lower BLLs that are supposedly used by other agencies or healthcare practitioners. We trust that OEHHA will not be misled by such

statements because it is well-known that other BLL targets or recommendations are based on toxicological endpoints other than the limited endpoints that are relevant under Proposition 65. We similarly note that OEHHA's reference in the materials for the workshop to "other public health guidance values" suffers from a similarly flawed analysis of irrelevant endpoints. While OEHHA and others may be curious about this comparison, it cannot be used in any way as a basis for the appropriate Proposition 65 safe harbor MADL for lead.

1.3 The target BLL of 15 mcg/dL is not appropriate for exposures lasting less than 14 days.

OEHHA uses the target BLL of 15 mcg/dL from the Telisman study for all of the draft MADLs — whether the exposures are frequent (such as every day) or infrequent (such as once over 116 days). This is not scientifically valid because short-term exposures to lead are not physiologically equivalent to long-term exposures. The duration of exposure at a particular BLL — not just the BLL itself — is relevant to considering the toxicity of lead. If a BLL of approximately 25 mcg/dL is associated with reduced sperm count in a chronic exposure setting, then the corresponding BLL necessary to yield the same effect will be higher for short-term durations of exposure. OEHHA's analysis must incorporate this fundamental principle in order to be scientifically valid and to prevent over-warning.

Sokol *et al.* (1990) demonstrates the relationship between lead exposure duration and effect. In that study, 0.6% lead acetate was administered to male Wistar rats in drinking water for 7, 14, 30, or 60 days, after which the researchers evaluated hormone levels and sperm quality. The mean BLLs in the four treatment groups were 42, 60, 58, and 75 mcg/dL, respectively. Although hormone and sperm quality effects occurred after 14 or more days of exposure in this study, there were no effects on either hormone levels or sperm quality after only seven days of exposure.

Thus, spermatotoxic effects from short durations of exposure (less than 14 days) can be interpreted as being proportional to "toxic load," defined as the product of concentration and exposure duration. When extrapolated to estimate human spermatotoxic effects of lead exposure, such a toxic load can be expressed as the product of the maximum BLL associated with no spermatotoxic effects after any duration of exposure (which OEHHA assumed to be 15 mcg/dL) and the maximum duration of exposure associated with no increased risk of those effects (which the Sokol study indicates is at least seven days[2]). Thus, for example, even assuming conservatively that the maximum period associated with no spermatotoxic effect is no more than seven days at a BLL less than 15 mcg/dL, the appropriate target BLL from a single day of exposure would be approximately 105 mcg/dL (7 x 15 mcg/dL) rather than only 15 mcg/dL.[3]

OEHHA should revise the Draft Lead MADL to factor in short durations of exposure of less than two weeks. Otherwise, the Draft MADL Proposal will result in warnings when there is no legal, policy, or scientific basis for them.

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[2] Because the spermatogenic cycle in humans is longer than in rats (approximately 16 compared to 12 days, respectively), the duration of exposure associated with no increased risk in humans may be greater than seven days.

[3] Exact calculations require examining how the biokinetic model predicts the rise and fall of BLLs due to lead exposure on a single day.

1.4 OEHHA fails to explain why an overall ten-year period of exposure is appropriate for all types of exposures.

Based on our review of the information provided by OEHHA, we have determined that, in implementing the Leggett Plus model, OEHHA assumes that exposures occur repeatedly over a ten-year period. OEHHA has not identified this assumption in its explanatory comments, much less explained why ten years is the appropriate period. Many consumer products are used for a period of time far shorter than ten years. The overall exposure period used for the Leggett Plus model affects the MADLs. The table below demonstrates the different MADLs over shorter periods (and using the same assumptions that OEHHA used in its Leggett Plus calculation, notably the target BLL of 15 mcg/dL regardless of exposure duration).

	Model-Calculated MADLs (micrograms)				
	1 month	**3 months**	**6 months**	**1 year**	**2 years**
Every day	0.5	0.3	0.3	0.2	0.2
Every 2 days	1	0.7	0.5	0.4	0.4
Every 3 days	2	1	0.8	0.7	0.6
Every 4 days	2	1	1	0.9	0.7
Every 5 days	3	2	1	1	0.9
Every 6 days	3	2	2	1	1
Every 7 days	4	2	2	2	1
Every 9 days	4	3	2	2	2
Every 10 days	6	3	3	2	2
Every 17 days	10	5	4	3	3
Every 18 days	10	5	4	3	3
Every 26 days	10	6	5	4	4
Every 27 days	10	6	5	4	4
Every 38 days	NA	8	7	5	5
Every 39 days	NA	8	7	6	5
Every 54 days	NA	10	8	6	6
Every 55 days	NA	10	8	6	6
Every 76 days	NA	NA	9	8	7
Every 77 days	NA	NA	9	8	7
Every 115 days	NA	NA	10	9	8
Every 116 days	NA	NA	10	9	8

Thus, this approach yields inappropriately low MADLs — and, as a result, unnecessary warnings — for many consumer product exposures.

For the safe harbor MADLs to be meaningful, OEHHA needs to allow for flexibility by setting out additional MADLs based on overall exposure periods that are much shorter. Alternatively, if OEHHA does not publish safe harbor MADLs with exposure periods shorter than ten years, OEHHA should clarify that businesses can run the Leggett Plus model using a period shorter than ten years to derive the appropriate MADL; as long as that period is appropriate, the resulting MADL remains a safe harbor. These approaches are consistent with OEHHA's concept of a matrix of different MADLs for different durations of exposure.

1.5 The Leggett Plus model does not maintain mass balance, and further review is warranted before OEHHA relies on it.

During the October 14, 2015 workshop, the Coalition highlighted that the original Leggett Plus model released by OEHHA in 2013 had significant mass balance errors, and that these errors were identified to OEHHA in 2014. Mass balance is an important validation check for the Leggett Plus model (or any other pharmacokinetic model). A model that artificially creates or destroys mass is flawed and indicates other errors with the model. The magnitude of invalidity may or may not be small, but nevertheless the model needs to be checked and re-coded to yield valid results.

OEHHA indicated during the workshop that the mass balance errors had been corrected. However, the 2015 Leggett Plus model code still contains a mass-balance error. This error results from OEHHA's addition of a "STOM" transfer rate. The term "STOM" is not defined but it appears to reflect intended input via the stomach — a compartment that is not explicitly included in OEHHA's Leggett Plus model. Although it is not clear, it appears that OEHHA included the STOM rate as a mechanism to introduce oral lead input. Because the Leggett Plus model already introduces a specified oral input directly to the small intestine, the STOM component appears to be redundant. It leads to a lack of mass balance and potentially leads to MADLs that are lower than if the error had been corrected. The STOM factor must be removed from the model before OEHHA relies on it, and OEHHA should document how it has established that the implemented Leggett Plus model maintains total mass balance in a way that explicitly accounts for all compartments.

Thus, further revisions are necessary to the Leggett Plus model before OEHHA can rely on it.

1.6 OEHHA should not apply a 1000-fold uncertainty factor when using human epidemiological data for the subpopulation of concern.

OEHHA's use of a 1000-fold uncertainty factor to derive the draft safe harbor MADLs for lead is unjustified as a matter of science, policy, and law.

Proposition 65 exempts exposures that "will have no observable effect assuming exposure at one thousand (1000) times the level in question." Cal. Health & Safety Code 25249.10(c). The standard toxicological uncertainty factor is 100 — two orders of magnitude — where a factor of 10 is used to account for inter-species extrapolation (using animal data to predict effects in humans) and another factor of 10 is used to account for intra-species variability (differences in effects in individual subjects).[4] Proposition 65 adds one more factor of 10, with no explanation or justification. Many toxicologists, including some at OEHHA, have stated that the 1000-fold uncertainty factor is unjustified as both a scientific and policy matter -- and particularly with respect to a chemical like lead that has been studied extensively. Indeed, one of the authors and original proponents of Proposition 65, David Roe, has said in a variety of public meetings that the 1000-fold uncertainty factor is not scientifically justified today.

OEHHA is basing its proposed safe harbor MADL for lead on a BLL of 15 mcg/dL, which OEHHA believes represents the lowest BLL with no observed effect based on the lack of observed male reproductive effects in the Telisman (2000) study. This is a human study that

[4] *See* E.M. Faustman and G.S. Omenn, "Chapter 4. Risk Assessment" in Casarett & Doull's Toxicology, 8th Edition (2013).

involved over 50 subjects, all of whom are in the presumed population of concern (males of reproductive age). Likewise, the Leggett Plus pharmacokinetic model that OEHHA has used to correlate lead exposures to a BLL of 15 mcg/dL also is based on human data and specifically reflects the population of concern. Using this approach therefore eliminates the justification for using at least two of the three orders of magnitude in the 1000-fold uncertainty factor: a factor of 10 to account for inter-species extrapolation and a factor of 10 to account for intra-species differences in human susceptibility. The former uncertainty factor does not apply where human data are used, and the latter uncertainty factor is generally reduced to a factor of 3 whenever a human pharmacokinetic model is used.

Thus, at most a factor of 30 should apply based on the apparent reasoning underlying the unusually high 1000-fold uncertainty factor in Proposition 65. Consequently, the way in which OEHHA has applied the 1000-fold uncertainty factor to derive the MADLs in the Draft MADL Proposal is not valid under standard toxicology principles. The Draft MADL Proposal ultimately understates the appropriate warning threshold and will lead to unnecessary warnings. Therefore, applying the 1000-fold factor is contrary to the policy goal of reducing overwarning and providing fewer and more meaningful warnings to California consumers.

Moreover, beyond both science and policy, application of a 1000-fold uncertainty factor to the human data used by OEHHA is contrary to law. The original purpose of the 1000-fold uncertainty factor in the statute was to address scientific uncertainties to ensure that exposures at the warning threshold will not cause reproductive harm. The 1000-fold factor was meant to be applied to the limited animal data that was available for most chemicals when Proposition 65 was enacted in 1986, and even then it was set at a level that is at least 10 times more stringent than any other regulatory regime, and without explanation or scientific justification.

Proposition 65 regulates speech; indeed, it compels speech. Proposition 65 therefore must be applied in a manner that comports with the First Amendment to the United States Constitution as well as the free speech guarantees in the California Constitution. Commercial speech can be regulated only if the governmental interest is substantial, the regulation directly advances the governmental interest, and the regulation is no more extensive than necessary to serve that interest. *Central Hudson Gas & Elec. Corp. v. Public Service Commission*, 447 U.S. 566, 577 (1980). Proposition 65's regulation of commercial speech must therefore have a basis in sound science and policy, and OEHHA must implement Proposition 65 in that manner. *See, e.g.,* Cal. Health & Safety Code § 25249.10(a).

As explained above, OEHHA's proposed safe harbor MADL for lead does not have a basis in sound science or policy. OEHHA has used a very low BLL of 15 mcg/dL based on human epidemiological data and then calculated the levels of exposure to lead that will result in that BLL in humans using a pharmacokinetic model developed with human data correlating lead exposures to blood lead levels. The resulting figures start at 200 mcg for a single day exposure and go up from there. These are the levels of exposure at which, to a great degree of scientific certainty, and applying very conservative (and indeed unwarranted) assumptions, OEHHA has determined there will be no reproductive effect in humans. While it may be appropriate, from a policy standpoint, to provide warnings to consumers when exposures are nearing this level of 200 mcg of lead in a single day, it is simply unjustified to provide warnings to consumers for exposures to 1/1000th of this level, i.e., 0.2 mcg of lead. Such a regulation is far more extensive than necessary and therefore an unconstitutional infringement on free speech under the *Central Hudson* test.

OEHHA indicates that its interest is to develop an "updated" warning threshold for lead in light of more recent human studies and its Leggett Plus model. OEHHA cannot compel reproductive toxicity warnings for lead based on the Draft MADL Proposal. The draft MADL Proposal, while purporting to update the target BLL and BLL modeling, does not consider the outdated nature of the uncertainty factor in light of the more modern science applied by OEHHA. Accordingly, the Draft MADL Proposal would require warnings at levels far below those intended by Proposition 65. At a minimum, OEHHA should remove a factor of 100 incorporated in the draft MADLs in order to ensure that its safe harbor MADLs for lead comport with the constitutional guarantee of freedom of speech. OEHHA has the authority to do so under section 25249.10(a) of the California Health & Safety Code.

Although the 1000-fold uncertainty factor as OEHHA proposes to apply it in this circumstance is flawed as a legal matter, the Coalition nonetheless supports efforts to revise the scientifically unjustified 1000-fold uncertainty factor legislatively in order to avoid adverse policy outcomes and constitutional challenges. OEHHA's exercise in reviewing the safe harbor MADL for lead shows these flaws in stark relief, and OEHHA should not proceed to modify the safe harbor MADL for lead until this significant issue is resolved.

1.7 OEHHA misapplied the 1000-fold uncertainty factor in rejecting the Foster/Singh study.

OEHHA notes that the most sensitive animal study of sufficient quality for male effects was a study in cynomolgus macaques (Foster *et al.* 1998; Singh *et al.* 1993). Using that study, OEHHA derived a NOEL by dividing by ten the lowest observed effect level at 0.955 mg/kg lead, as specified under 27 Cal. Code Regs. § 25803(a)(8). This NOEL then yielded a MADL of 6.7 mcg/day using the conventional approach and conservative, default factors specified in the regulations. 27 Cal. Code Regs. § 25803(a). OEHHA declined to propose this number as the MADL because it concluded that exposures at 6700 mcg/day (1000 times 6.7 mcg/day) would result in BLLs exceeding 60 mcg/dL, and that this is too high based on reviews of occupational exposures performed by the US EPA, which — according to OEHHA — show male reproductive effects in humans at BLLs greater than 25 or 45 mcg/dL.

For the same reasons discussed above, it is improper for OEHHA to use the 1000-fold uncertainty factor as a screening mechanism for otherwise valid NOELs derived from animal data. If the NOEL is a certain number based on an animal study of sufficient quality, and the 1000-fold uncertainty factor generates a safe harbor value below human exposures shown to cause an adverse effect, there is no need or justification for OEHHA to apply an additional uncertainty factor. In essence, OEHHA's approach is "double-counting" an animal-to-human translation factor. As noted above, the 1000-fold uncertainty factor provides a very conservative margin to ensure that the MADL is far below the actual level at which reproductive effects may be observed. In other contexts, policymakers would apply an uncertainty factor of 100, ten times less than what Proposition 65 mandates. Where there is a strong and scientifically valid animal study from which a NOEL can be derived, OEHHA's screening approach to reject valid animal data is inappropriate from a scientific, policy, and legal perspective.

1.8 The Draft MADL Proposal should use the same prefatory language as used for existing safe harbor levels.

The prefatory language in proposed Section 25805(b) states that the draft MADLs represent the exposures "to any individual" that are "exempt from the warning requirement." This could be

read to mean that an exposure to any individual — even if that individual is not an "average user" — controls when warnings are required. This reading is not consistent with the longstanding regulations, which require that "[f]or exposure to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for *average users* of the consumer product." 27 Cal. Code Regs. § 25821(c)(2) (emphasis added). The draft language in the proposed regulations should be clarified to ensure that it is exposure for average users that controls.

In addition, the proposed language specifies that the draft safe harbor MADLs are "[m]aximum allowable dose levels" and that they "represent the exposures . . . to any individual" for purposes of determining if the business is "exempt from the warning requirement." This could be read as requiring the draft MADLs to be limits rather than safe harbor levels on which businesses may rely in the absence of developing their own MADLs based on current science. Under the existing regulations, a business is not required to rely on a published safe harbor and is entitled to prove a less stringent MADL. 27 Cal. Code Regs. § 25801(a). The Draft Proposal is surely not intended to change this principle and should be clarified to ensure that this right to develop an alternative MADL remains.

To avoid these ambiguities, the prefatory language in the Draft Proposal should follow the format of the existing prefatory language in Section 25805(a). Section 25805(a) states as follows: "Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level." At a minimum, to avoid confusion, OEHHA should not use the terms "maximum allowable dose levels" and "any individual" in the proposed changes to Section 25805(b).[5]

2. SINGLE-DAY PROPOSAL

The Single-Day Proposal would mark a new policy by OEHHA that is not consistent with the law or science, and OEHHA should not adopt it.

2.1 The Single-Day Proposal is not consistent with the law.

In its presentation during the workshop, OEHHA claimed that the Single-Day Proposal "*clarifies* that all existing MADLs were established as single day exposure limits." (emphasis added). OEHHA has never published a policy that all safe harbor MADLs are single-day limits only. Indeed, OEHHA's published regulations lead to exactly the opposite conclusion.

Although the plaintiff in *Beech-Nut* argued that a 1991 declaration from OEHHA employee James Donald that was submitted in a case involving crystalware demonstrated a "policy" of a single-day limit for one safe harbor MADL (for lead), the Alameda Superior Court disagreed and did not give this view any weight. That ruling was upheld by the First District Court of Appeal in a binding decision. As a result, this one declaration of an OEHHA employee is not a statement of OEHHA policy, even for the lead safe harbor MADL.

For MADLs other than lead, we are not aware of any public statement by any employee of OEHHA (authorized or unauthorized) — let alone any formal policy — that all safe harbor

[5] These same ambiguities apply to the prefatory language in proposed Section 25805(b)(2), which concerns the Single-Day Proposal. As discussed below, the Single-Day Proposal should not be adopted.

MADLs are single-day limits. Indeed, in informal polling of attorneys and consultants who practice regularly in this field on behalf of businesses — many for more than 20 years — we have yet to identify any statement by an OEHHA employee, even informally, to the effect that OEHHA's policy or practice is to treat all safe harbor MADLs as single-day limits. We therefore object in the strongest terms to OEHHA's statement that this proposal "clarifies" existing policy.

Indeed, this proposal *changes* OEHHA's policy. The regulations and the regulatory history expressly *anticipate* that in evaluating whether exposures exceed a MADL, one may average exposures over more than a single day when it is appropriate:

> The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that the chemical is known to the state to cause reproductive toxicity. (For example, 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.)

27 Cal. Code Regs. § 25821(b). The regulatory history explains that "[s]ince some reproductive effects, such as teratogenic responses or birth defects, may reflect an acute response during a brief period of intrauterine exposure, exposure to chemicals producing such effects should be assessed on the basis of short term exposure. . . . *If it is scientifically more appropriate to evaluate a reproductive toxicant for chronic toxicity, this section does permit it*." Final Statement of Reasons, 22 Cal. Code Regs. Section 12801 (June 1989) (emphasis added).

The *Beech-Nut* court referred to this regulatory provision and history in concluding that Section 25821 does not require that exposures must be assessed based on a single day in evaluating whether those exposures exceed a MADL. Far from clarifying an already existing law, OEHHA is trying to re-write the law on this issue. Indeed, even as recently as October 21, 2015, OEHHA, in reporting the status of the Draft Proposal to the *Mateel* court, stated that "MADLs are the highest exposure that can occur on a single day." Def. Response to Court Ruling Dated Aug. 31, 2015 Re: Motion for Stay Litigation. This statement and other recent statements by OEHHA are contrary to the law, and repeating them will not make the law otherwise.

2.2 OEHHA's Single-Day Proposal is not scientifically appropriate.

OEHHA stated in its presentation at the workshop on October 14, 2015 that "all existing MADLs were established as single day exposure limits." There are 48 such safe harbor MADLs, which OEHHA and its predecessor agency have established over a period of more than 25 years. Throughout that period, the regulation cited above, now codified at 27 Cal. Code Regs. § 25821(b), has been in effect, stating that exposures of shorter or longer duration may be appropriately used in determining the reasonably anticipated rate of exposure. Nevertheless, our review of the documentation underlying the establishment of these existing safe harbor MADLs — which is necessarily incomplete due to OEHHA's refusal to grant our requested extension — has revealed no statement by the agency that any of these levels were intended to be established as "single-day exposure limits."

The record on this proposal similarly does not show that OEHHA has reviewed the scientific literature on all 36 reproductive toxicants at issue to conclude that exposures must always be based on a single day for the corresponding MADLs. OEHHA would need to undertake that analysis before making this categorical statement, for the first time, in a rulemaking process.

Nothing in the record allows OEHHA to categorically foreclose this scientific evidence from being developed on a case-by-case basis. Just as the *Beech-Nut* court found, after considering expert testimony and evidence, that it is toxicologically appropriate to average exposures for lead based on the exposure levels in that case, there is no reason why this could not be shown for other safe harbor MADLs and exposures.

Ultimately, it is the burden of a business facing a Proposition 65 enforcement action to prove that it is toxicologically appropriate to average exposures for a MADL. The Coalition is not asking to reverse that burden or to redefine categorically that all MADLs should be *multi-day* limits. But OEHHA should not halt inquiry on whether it is scientifically appropriate to average exposures for a MADL on a case-by-case basis and preclude courts from considering scientifically valid data on these issues.

* * *

For the foregoing reasons, the California Chamber of Commerce urges OEHHA to reconsider this proposal and certainly to not move forward with the levels or concepts proposed.

Thank you for considering our comments. We appreciate the opportunity to participate in this very important pre-regulatory process and would welcome further opportunities to provide OEHHA with the views of the businesses directly affected by Proposition 65.

Sincerely,

Anthony Samson
Policy Advocate
California Chamber of Commerce

On behalf of the following organizations:

African American Farmers of California
Agricultural Council of California
American Beverage Association
American Cleaning Institute
American Chemistry Council
American Coatings Association
American Forest & Paper Association
America Frozen Food Institute
American Herbal Products Association
American Home Furnishing Alliance
Amway
Associated Roofing Contractors of the Bay Area Counties, Inc.
Automotive Specialty Products Alliance
AXIALL LLC
Bicycle Product Suppliers Association
Breen Color Concentrates
California Attractions and Parks Association

California Citizens Against Lawsuit Abuse
California Citrus Mutual
California Construction and Industrial Materials Association
California Farm Bureau Federation
California Furniture Manufactures Association
California Grocers Association
California Hotel & Lodging Association
California League of Food Processors
California Manufacturers & Technology Association
California Metals Coalition
California/Nevada Soft Drink Association
California Paint Council
California Retailers Association
California Small Business Alliance
Chemical Industry Council of California
Consumer Electronics Association
Consumer Healthcare Products Association
Consumer Specialty Products Association
Council for Responsible Nutrition
El Centro Chamber of Commerce
El Dorado County Chamber of Commerce
Exxel Outdoors
Family Winemakers of California
Far West Equipment Dealers Association
Flexible Vinyl Alliance
Grocers Manufacturers Association
Independent Lubricant Manufacturers Association
Industrial Environmental Association
International Fragrance Association, North America
ISSA, The Worldwide Cleaning Industry Association
Juvenile Products Manufacturers Association
Lonseal, Inc.
Los Angeles Area Chamber of Commerce
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
Motor & Equipment Manufacturers Association
National Confectioners Association
National Council of Textile Organizations
National Electrical Manufacturers Association
National Federation of Independent Businesses
National Shooting Sports Foundation
Nisei Farmers League
North Orange County Chamber
NOW Foods
Nutraceutical Corporation
Oxnard Chamber of Commerce
Pacific Water Quality Association
Palm Desert Area Chamber of Commerce
PepsiCo

Personal Care Products Council
Plumbing Manufacturers International
Rancho Cordova Chamber of Commerce
Redondo Beach Chamber of Commerce
San Fernando Valley Chamber of Commerce
South Bay Association of Chambers of Commerce
SPI: The Plastics Industry Trade Association
Sporting Arms and Ammunition Manufacturers Institute
The Art and Creative Materials Institute, Inc.
Toy Industry Association
Treated Wood Council
USANA Health Sciences, Inc.
Water Quality Association
West Coast Lumber & Building Material Association
Western Growers Association
Western Plant Health Association

cc: Matthew Rodriguez, Secretary, CalEPA
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