

**BEFORE THE CALIFORNIA OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT**

**PETITION BY CENTER FOR ENVIRONMENTAL HEALTH FOR
ADMINISTRATIVE RULEMAKING TO REPEAL OR AMEND
PROPOSITION 65 REGULATIONS PERTAINING TO THE
MAXIMUM ALLOWABLE DOSE LEVEL FOR LEAD**

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INTRODUCTION

Pursuant to California Government Code Section 11340.6, the Center for Environmental Health (“CEH”) hereby petitions the California Office of Environmental Health Hazard Assessment (“OEHHA”) to repeal and/or amend its Proposition 65 regulation with respect to exposures to lead. As OEHHA itself has long recognized, the existing safe harbor level, or Maximum Allowable Dose Level (“MADL”), for lead of 0.5 microgram per day ($\mu\text{g}/\text{day}$) is too high to protect Californians from the well-established reproductive effects of lead that can and do occur at levels below 500 micrograms per day (1000 times the 0.5 $\mu\text{g}/\text{day}$ level). Worse yet, since courts have recently allowed defendants in at least some Proposition 65 enforcement actions to average lead exposures over time, the existing regulation has been interpreted to allow lead exposures of up to 7 micrograms a day. OEHHA should repeal 27 Cal. Code Regs. (“C.C.R.”) Section 25805(b)’s MADL for lead to protect Californians, including workers, children, and pregnant women, from unwarned exposures to lead above those permitted by Proposition 65.¹

¹ CEH has submitted with its petition an Appendix comprising a set of documents that CEH believes to support its position, and which should be part of any administrative record based on this petition. Included as Exhibits 1 through 7 of the Appendix is a complete copy of the administrative record from OEHHA’s flawed 1989 rulemaking regarding the Section 25805(b) MADL for lead.

INTEREST OF PETITIONER

CEH is a California-based nonprofit organization dedicated to protecting the public from environmental health hazards and toxic exposures. CEH is a nationally recognized environmental advocacy group that has prosecuted a large number of Proposition 65 cases in the public interest, a substantial portion of which have involved the presence of lead in consumer products. These cases have resulted in significant public benefit, including the reformulation of thousands of products to remove lead and other toxic chemicals to make them safer. CEH also provides information to Californians about the health risks associated with exposure to hazardous substances, where manufacturers and other responsible parties fail to do so.

BACKGROUND

I. OVERVIEW OF PROPOSITION 65 SAFE HARBOR LEVELS

Proposition 65 is a remedial statute that is intended to safeguard public health and therefore “should be broadly construed to accomplish its protective purposes.” *Cal. Chamber of Commerce v. Brown* (2011) 196 Cal.App.4th 233, 258 (citing *People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294)). Proposition 65 generally prohibits companies from exposing consumers to known reproductive toxicants and carcinogens

without a warning unless that company can prove that it fits within a statutory exemption. Health & Safety Code § 25249.6.

A company need not provide a warning under Proposition 65 if it can prove that exposure to a reproductive toxin will cause “no observable effect assuming exposure at one thousand (1,000) times the level in question.” Health & Safety Code § 25249.10(c). Thus, to determine the level at which a warning is required for a reproductive toxin, it is necessary to determine the maximum level of exposure to the chemical that will have “no observable effect” (the “no observable effect level,” or “NOEL”), and then divide that number by a safety factor of 1,000 to determine the “maximum allowable dose levels,” or “MADL.” 27 C.C.R. § 25801(b)(1) and (c). For chemicals for which the data do not permit the calculation of a NOEL, OEHHA’s implementing regulations provide for the use of the “lowest observable effect level” (or “LOEL”), which is then divided by a safety factor of 10 to establish the NOEL (which is then divided by the statutory safety factor of 1,000 to derive the MADL). *See id.*, § 25803(a)(7). If a business can prove that any exposures to a listed reproductive toxicant are below the MADL, the business need not provide a warning for those exposures.

There are several approaches to calculating a MADL. For instance, a business can develop its own MADL, either by strictly following OEHHA’s risk assessment regulation or by using any other scientifically

valid approach. *See* 27 C.C.R. § 25801(a) and (b). If a business follows OEHHA’s approach set forth in 27 C.C.R. § 25803, the resulting MADL is considered a “safe harbor” level such that the resulting level is deemed “to have no observable effect, assuming exposure at one thousand times the level in question.” *Id.*, § 25803(a)(1).

In recognition of the fact that “[m]ost businesses do not have the resources to conduct their own risk assessments,” OEHHA also establishes its own regulatory safe harbor MADLs pursuant to 27 C.C.R. § 25801(b)(2) and codified in 27 C.C.R. § 25805. OEHHA, Final Statement of Reasons, 22 C.C.R. Div. 2 (“FSOR”), at 77 (§ 12805).² In establishing a regulatory MADL, OEHHA has recognized that it is bound to follow the same minimum standards for risk assessments that businesses must follow to establish a safe harbor MADL. *See ibid.*; *see also* 27 C.C.R. § 25801(a) and (b). For those chemicals for which OEHHA has established a regulatory MADL, the regulations state, “Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such a chemical has no observable effect assuming exposure at one thousand (1,000) times that level.” 27 C.C.R. § 25805(a). The safe harbor MADLs set by OEHHA are expressed as “Level (micrograms/day).” *Id.*, § 25805(b).

² Attached hereto as Appendix, Exhibit 1, Tab 108.

II. EXISTING SAFE HARBOR LEVEL FOR LEAD

Lead is listed by OEHHA under Proposition 65 as a chemical known to cause cancer and birth defects or other reproductive harm. 27 C.C.R. § 27001(b) and (c). The regulatory safe harbor for lead of 0.5 µg/day was first established by regulation in 1989, *see* 27 C.C.R. § 25805(b), and then affirmed by OEHHA in 2013 when it changed the basis for listing lead as a chemical known to cause reproductive harm, *see* OEHHA, Notice to Change the Basis for Listing: 1,2-Dibromo-3-Chloropropane, Ethylene Oxide and Lead (Nov. 22, 2013) (“2013 Lead Rulemaking”).³ In promulgating this safe harbor, OEHHA did not find that this level was based on scientifically valid testing, conducted according to generally accepted principles, that clearly showed – in light of current scientific information – that there would be no observable reproductive effect at 1000 times the 0.5 microgram per day regulatory safe harbor level (500 micrograms per day). There were no studies that OEHHA cited as support for the regulatory safe harbor level it set for lead.

Rather, in originally establishing the MADL, OEHHA based this exemption on a federal Occupational Safety and Health Administration (“OSHA”) permissible exposure limit (“PEL”) of 500 micrograms per day

³ Attached hereto as Appendix, Exhibit 20.

(dividing the 500 microgram PEL by 1000 to get 0.5 microgram).⁴ At the time OEHHA relied on the OSHA PEL and its supporting documentation, that information was already fourteen years old. Instead of finding that there was scientifically valid testing, conducted according to generally accepted principles that clearly showed a level at which there would be no observable effect, OEHHA blithely stated that:

[T]here is experience derived from the occupational setting which suggests that exposure to certain regulated levels does not produce the reproductive effect of concern.

FSOR, at 78. Based on OSHA's 1978 analysis, and without performing any independent analysis of the scientific data either before or after 1978, OEHHA concluded in 1989 that it could use "certain limits for occupational exposures as surrogates for the NOEL." *Ibid.* In doing so, OEHHA candidly admitted that its approach was "arguably unconventional." *Ibid.*

Specifically as to lead, OEHHA concluded based on OSHA's 1979 analysis that 30 micrograms/gram ($\mu\text{g/g}$) blood lead levels was a "functional equivalent reproductive NOEL." FSOR, at 79. But OEHHA did not use this level in crafting the MADL. Although OEHHA recognized that the PEL upon which it was basing the safe harbor was set to ensure that workers' blood levels did not exceed 40 $\mu\text{g/g}$ blood lead levels,

⁴ The OSHA PEL was set at 50 $\mu\text{g}/\text{m}^3$ based on an assumption that workers breathe 10 m^3 in a typical 8-hour shift, thereby resulting in an exposure of 500 μg lead.

OEHHA nevertheless decided to base the safe harbor level on the higher PEL-based blood lead level. As OEHHA admitted, “OSHA identifies that level [30 µg/g blood lead level] as 75 percent of the blood limit targeted by the permissible exposure limit (PEL).” *Ibid.* In other words, even if OEHHA was correct that 30 µg/g blood lead level was a valid NOEL, a NOEL based on 30 µg/g blood lead levels would have yielded a MADL of 0.375 µg/day, not the 0.5 µg/day set by OEHHA.

Worse yet, there was nothing in the OSHA PEL or its rule making file that “suggested” – let alone established – that “exposure to certain regulated levels does not produce the reproductive effect of concern.” The OSHA PEL did not establish a no observable reproductive effect level for lead. To the contrary, in its Federal Register announcement of the lead PEL, OSHA stated that:

While a critical review of the literature leads to the conclusion that blood lead levels of 50 to 60 µg [micrograms]/100 ml are likely sufficient to cause significant neurobehavioral impairments, there is evidence for effects such as hyperactivity as low as 25 µg/100 g. Given the available data, OSHA concludes that in order to protect the fetus from the effects of lead on the nervous system, maternal blood lead levels should be kept below 30 µg/100 g. In general 30 µg/100 g appears to be reasonably protective insofar as it will minimize enzyme inhibition (ALAD and FEP) in the heme biosynthetic pathway and should minimize neurological damage. OSHA agrees with the Center for Disease Control (Ex. 2 (15)) and the National Academy of Sciences (Ex. 86M) that the blood lead level in children should be maintained below 30 µg/100 g. Levels above 30 µg/100 g should be considered elevated.

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OSHA cannot guarantee that 30 µg/100 g is a “no effect” level but it would provide marked protection to the fetus and therefore to the reproductive capacity of the worker.

* * *

In recognition of the inability of the PEL alone to protect the reproductive capacity of all workers at all times, the standard includes a variety of additional protective elements designed to minimize reproductive risks.

OSHA, Final Standard for Occupational Exposure to Lead (29 C.F.R. § 1910), 43 Fed. Reg. 54,354, 54,422-23 (Nov. 21, 1978) (emphasis added).⁵ Thus, at best, OSHA found in 1978 that 30 µg/dL was a LOEL – not a NOEL – in which case OEHHA should have divided that number by 10 to establish a NOEL under its own regulations. *See* 27 C.C.R. § 25803(a)(7). Following that approach would have yielded a MADL of 0.0375 µg/day instead of the 0.5 µg/day chosen by OEHHA.

OEHHA also disregarded the fact that, at the same time it established the PEL, OSHA had set an “action level” for lead of 30 µg/m³. This action level was set by OSHA “at a point commensurate with the beginning of potential risks to reproductive capacity,” and exceeding this action level triggers a host of environmental and biological monitoring programs and medical surveillance procedures that must be followed by employers. 43 Fed. Reg. at 54,423. Had OEHHA used this “action level” as its NOEL or LOEL, OEHHA would have set the MADL even lower.

⁵ Attached hereto as Appendix, Exhibit 7.

OEHHA has admitted these flaws with the lead MADL. Specifically, Dr. James Donald testified in his capacity as Staff Toxicologist and Acting Chief of the Reproductive Toxicology Unit of OEHHA that “the level set by OSHA – 500 micrograms per day – was known at that time to be above the No Observable Effect Level for reproductive effects.” Declaration of James Donald, Ph.D., in Support of Order to Show Cause re: Preliminary Injunction (“Donald Decl.”), *People ex rel. Lungren v. Baccarat, Inc., et al.* (Sept. 6, 1991), San Francisco Superior Court Case No. 932292, ¶ 9.a (emphasis in original).⁶ Dr. Donald further acknowledged that, although lead is listed as a reproductive toxicant based in part on its developmental effects, “[d]evelopmental toxicity of lead was not considered by OSHA in setting this standard.” *Ibid.* In support of his conclusion, Dr. Donald pointed out that, although OEHHA had set the MADL based on a 40 microgram per deciliter blood lead level, “OSHA specifically stated that women who are pregnant, or planning to become pregnant, should maintain a blood-lead level below 30 micrograms per deciliter.” *Ibid.* Having admitted these flaws, OEHHA cannot reasonably dispute that the 0.5 microgram per day MADL fails to satisfy Proposition 65.

⁶ Attached hereto as Appendix, Exhibit 8.

III. THE TOXICITY OF LEAD

The serious problems with the existing safe harbor level for lead are only worse when considered in light of current science. As set forth above, even in 1989 OEHHA's establishment of a 0.5 µg/day safe harbor level for lead relied upon scientific data that was already over 10 years old, and OEHHA did not even set a sufficiently protective level based on those data. Since then, OEHHA has failed to re-evaluate the regulatory safe harbor level it set for lead in light of additional knowledge, including additional knowledge and findings that OEHHA itself has made about the neurodevelopmental effects of low-level lead exposure and the lack of a scientific basis for finding a no observable effect level for low-level lead exposures.

Over two decades ago – soon after it had first promulgated the 0.5 µg/day MADL – OEHHA acknowledged that the science upon which the level was based was already outdated. As Dr. Donald testified on OEHHA's behalf in 1991:

[s]ince OSHA developed its standard in 1979, additional studies of lead have found it to be harmful at doses lower than previously thought to be harmful. For example, while OSHA concluded that a blood-lead level of 30 micrograms per deciliter 'minimized' risks to a pregnant woman, recent studies have found that levels of 10-15 micrograms per deciliter during pregnancy are associated with developmental effects in the offspring.

Donald Decl., ¶ 9.b. In other words, by 1991 OEHHA had already determined that the safe harbor level for lead should be substantially

reduced. Using a target blood lead level of 10-15 micrograms per deciliter as the NOEL would yield a MADL of 0.0125-0.1875 µg/day instead of the 0.5 µg/day chosen by OEHHA. Or, if those blood lead levels are considered a LOEL, the resulting MADL would be 0.00125-0.01875 µg/day.

Dr. Donald also testified in 1991 that “it is arguable that any amount of lead is harmful.” Donald Decl., ¶ 9.c. As discussed below, a plethora of data developed since 1991 confirms that lead is a stunningly toxic heavy metal, and that there is no level below which lead exposures do not cause a harmful reproductive effect.

Studies have repeatedly shown that there is no safe level of exposure to lead and that even minute amounts of lead exposure can permanently reduce mental capacity in children. See OEHHA, *Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment* (Apr. 2007), at 5-9;⁷ U.S. Department of Health & Human Services, Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Lead* (Aug. 2007), at 20, 23;⁸ Budtz-Jorgensen, E., *et al.*, “An International Pooled Analysis for Obtaining a Benchmark Dose for Environmental Lead Exposure in Children,” *Risk Analysis*, Vol. 33, No.

⁷ Attached hereto as Appendix, Exhibit 10.

⁸ Attached hereto as Appendix, Exhibit 11.

3:450 (2013);⁹ U.S. Centers for Disease Control & Prevention, “Blood Lead Levels in Children” Fact Sheet ([2014]).¹⁰ Researchers have been unable to identify a level of lead exposure below which no adverse effects will occur. See United Nations Environment Programme, “Lead Exposure and Human Health” (excerpted from “Global Opportunities for Reducing the Use of Leaded Gasoline” (Sept. 1998)), at 3-4 (noting “a scientific consensus that there is no demonstrable threshold dose for the manifestation of lead’s toxicity”).¹¹ Lead exposures for pregnant women are of particular concern in light of evidence that even short-term lead exposures *in utero* may have long-term harmful effects. See J. Carlisle, *et al.*, “A blood lead benchmark for assessing risks from childhood lead exposure,” *Journal of Environmental Science & Health Part A*, Vol. 44, 1200, 1201, 1205 (2009).¹²

OEHHA itself has concluded that there is no safe threshold for exposures to lead. For instance, in 1997, OEHHA reviewed the then-existing literature on the neurodevelopmental and neurobehavioral effects of low-level lead exposure. Cal. EPA, Air Resources Board, *Technical Support Document, Proposed Identification of Inorganic Lead as a Toxic*

⁹ Attached hereto as Appendix, Exhibit 22.

¹⁰ Attached hereto as Appendix, Exhibit 23.

¹¹ Attached hereto as Appendix, Exhibit 15.

¹² Attached hereto as Appendix, Exhibit 13. Three of the four authors of this study were OEHHA staff scientists.

Air Contaminant, Part B Health Assessment (Mar. 1997).¹³ This review considered several then-existing large-scale epidemiological studies of the effect low-level lead exposure had on intelligence in children. *Id.*, at 5-3. OEHHA explicitly attempted to locate a threshold below which there would be no neurodevelopmental effect of lead exposure. *Id.*, at 5-4 to 5-5. Based on these studies of the effect that low-level lead exposure had on children's intelligence, OEHHA concluded that there was a continuum of effects on intelligence down to the lowest observed levels of blood lead and that it was impossible to identify a threshold blood lead level below which there would be no adverse health effects in humans. *Ibid.*

This OEHHA finding was confirmed four years later in OEHHA's *Prioritization of Toxic Air Contaminants – Children's Environmental Health Protection Act* (Oct. 2001).¹⁴ Like the 1997 OEHHA-CARB *Health Assessment*, OEEHA's 2001 *Prioritization of Toxic Air Contaminants* found that there is no identified inorganic lead exposure threshold below which adverse effects do not occur. *Id.*, at 1. OEHHA found the studies it had earlier relied upon to support its no-threshold finding to be of sufficient quality to rely on again. *Id.*, at 2-4. OEHHA found that key animal studies also supported its no-threshold conclusion: "[t]he enormous number of studies of lead in animals supports that observed in humans." *Id.*, at 4.

¹³ Attached hereto as Appendix, Exhibit 19.

¹⁴ Attached hereto as Appendix, Exhibit 18.

OEHHA performed its own simplified meta-analysis of the effects low-level lead exposure has on intelligence. *Id.*, at 3. OEHHA found there to be a 0.33 decrease in IQ points per 1 µg/dL increase in blood lead level. *Ibid.* Significantly, this OEHHA estimate came with a 95% confidence interval of between 0.32 and 0.34 µg/dL. *Ibid.*

In non-Proposition 65 contexts, OEHHA has addressed the society-wide implications of low-level lead exposure, noting that a shift in the normal distribution of IQ scores downward by 4 points would mean that the number of children scoring below 80 increases by 50%, and that a similar downward shift of 3.3 IQ points would result in a 39.5% increase in the number of children scoring below 80. OEHHA, *Prioritization of Toxic Air Contaminants*, at 4.

Federal agencies have also repeatedly concluded that there is no safe level for lead exposures. As stated by the United States Environmental Protection Agency (“EPA”), “currently available studies provide evidence of adverse health effects associated with blood lead levels and environmental exposures well below those previously identified, and we note that there is now no discernible threshold for such effects in contrast to the thresholds that had previously been inferred.” EPA, *Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of*

Scientific and Technical Information (Nov. 2007), at 5-13.¹⁵ In its 2013 *Integrated Science Assessment for Lead*, EPA included a “Summary of evidence supporting reproductive and developmental causal determinations.” EPA, *Integrated Science Assessment for Lead* (June 2013), at 4-708, Table 4-48.¹⁶ According to this summary, studies have found reproductive effects at blood lead levels much lower than the 30 µg/dL that OEHHA claimed was a “surrogate” NOEL in 1989. For instance, studies have found effects on “Sperm/semens production, quality and function” at blood lead levels as low as 5.31 µg/dL – nearly 6 times lower than OEHHA’s surrogate NOEL. *Id.*, at 4-710. And, because these studies are finding effects at levels that low, these data at best establish a LOEL and any resulting level would need to be divided by 10 to determine the LOEL under OEHHA’s regulations.

Likewise, in 2007, the federal Agency for Toxic Substances and Disease Registry (“ATSDR”) – an arm of the federal Centers for Disease Control and Prevention (“CDC”) – conducted a review of the then-balance of scientific evidence concerning, among other toxic endpoints, the neurodevelopmental toxicity of lead. In its *Toxicological Profile for Lead*, ATSDR concurs with OEHHA’s finding of a lack of threshold for neurodevelopmental effects of lead exposure. ATSDR, *Toxicological*

¹⁵ Attached hereto as Appendix, Exhibit 12.

¹⁶ Attached hereto as Appendix, Exhibit 14.

Profile for Lead (Aug. 2007).¹⁷ ATSDR found that recent studies suggest an IQ decline of 1-5 points is associated with a general increase of 10 µg/dL in blood lead. *Id.*, at 23. Importantly, ATSDR also found that lead has caused neurobehavioral impairment in developing animals and at blood lead levels comparable to those reported in children. *Ibid.* The ATSDR notes that studies in animals, particularly monkeys, have provided key information for the interpretation of a cognitive basis for IQ changes. *Ibid.* The ATSDR found that the dose-response slope for the neurodevelopmental effects of lead exposure is not linear, and is steepest at the lower, rather than higher, levels of exposure. *Id.*, at 25. CDC has separately concluded that “there is no apparent threshold below which adverse effects of lead do not occur.” CDC, *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention* (Mar. 2002), at 4.¹⁸

In sum, while there can be no serious question that the 0.5 µg/day safe harbor level was set too high in 1989, the science since then has confirmed that the level must be much lower to satisfy Proposition 65’s mandate that a warning be provided unless the exposure will have no observable effect at 1000 times the level in question. *See* Health & Safety Code § 25249.10(c).

¹⁷ Attached hereto as Appendix, Exhibit 11.

¹⁸ Attached hereto as Appendix, Exhibit 9.

IV. OEHHA'S FAILURE TO UPDATE THE SAFE HARBOR LEVEL WHEN IT CHANGED THE BASIS FOR LISTING LEAD AS A REPRODUCTIVE TOXICANT

In 2013, OEHHA changed the basis for listing lead as a chemical known to cause reproductive toxicity under Proposition 65 from the Labor Code mechanism to the “formally required to be labeled or identified” mechanism. *See* 2013 Lead Rulemaking. At that time, OEHHA determined that the OSHA PEL – which now requires specific warnings to workers about the reproductive risks of lead exposures – provides a sufficient basis to list lead as a reproductive toxin since OSHA, an agency of the federal government, has formally required lead to be labeled or identified as causing reproductive toxicity. *See* Health & Safety Code § 25249.8(b). This is uncontroversial since the science that supported OEHHA’s conclusion decades ago that lead causes reproductive harm is still valid in light of current science establishing the same thing.

Unfortunately, however, in re-listing lead as a reproductive toxicant in 2013, OEHHA failed to re-evaluate the safe harbor level in light of current science. OEHHA’s failure in this regard has severe consequences since, as discussed above, the science that has been developed since the late 1970s or 1980s has evolved substantially and has demonstrated that the existing safe harbor level is not sufficiently protective, and that lead causes reproductive harm at much lower levels than previously believed.

OEHHA apparently takes the position that it was under no obligation to re-evaluate the MADL when it re-listed lead as a reproductive toxicant in 2013. Under OEHHA's interpretation of Proposition 65, the science around lead exposure should essentially be frozen in time. This absurd construction of the statute does not withstand scrutiny. To the contrary, it in passing Proposition 65, Californians wanted to be protected from unwarned exposures to chemicals based on the latest and best science.

Indeed, Proposition 65 explicitly requires the Governor and OEHHA as his designee re-evaluate the list of chemicals known to cause cancer and reproductive harm at least once per year "in light of additional knowledge." Health & Safety Code § 25249.8(a). And the statute explicitly links the safe harbor level to the listing decision by requiring that safe harbor levels be "based on evidence and standards which form the scientific basis for the listing" of the chemical. Health & Safety Code § 25249.10(c); 27 C.C.R. § 25801(a). Since OEHHA must re-evaluate the evidence and standards which form the basis for listing a chemical at least annually, so too is the agency obligated to update the science that forms the basis for any corresponding safe harbor level.

Furthermore, in determining the safe harbor level, "[o]nly studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity shall be utilized for the determination of the NOEL." 27 C.C.R. §

25803(a)(1). In other words, the safe harbor level must be tied to the basis for the listing. If the basis for the listing changes – as it did with lead in 2013 – then the evidence, standards, and studies which form the basis for the listing should necessarily change with the listing. Nevertheless, when OEHHA changed the basis for the lead listing in 2013, it did not bother to update the 0.5 µg/day safe harbor level even though current science shows this level to be insufficiently protective under Proposition 65.

V. AVERAGING LEAD EXPOSURES UNDER PROPOSITION 65

To determine whether a particular exposure exceeds the MADL, it is necessary to multiply the “level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium.” 27 C.C.R. § 25821(b). If a business can prove that the level of exposure to the chemical from its product is less than the MADL, the business is not required to provide a warning for that exposure.

The plain language of OEHHA’s safe harbor level for lead establishes a “per day” limit of 0.5 microgram. And that limit was explicitly developed based on the OSHA PEL, which is a single day PEL and does not permit averaging.

This commonsense, protective approach is particularly appropriate in the context of a reproductive toxin like lead which is known to cause

reproductive effects based on short-term exposures at crucial stages of fetal development. Indeed, there is no science that clearly shows that a lead exposure must occur over a particular time period in order to cause reproductive effects.

Furthermore, OEHHA's longstanding view is that the safe harbor MADL for lead represents a single day exposure limit. As Dr. Donald testified on OEHHA's behalf in 1991:

[I]n determining the pattern and duration of lead exposure that is relevant to the reproductive effects that formed the basis for the listing of lead as a reproductive toxicant, it is appropriate to analyze the level of exposure on any single day. If one were instead to analyze the 'average' level of exposure over a long period of time, e.g., by averaging the amount of exposure on days on which lead is ingested with other days on which lead is not ingested, one would underestimate the potential harm that could be caused by large doses on a single day.

Donald Decl., ¶ 12.d. Likewise, the California Attorney General's Office, which is the public prosecutor responsible for enforcing Proposition 65 on a statewide basis, takes the position that a warning is required whenever a business knowingly and intentionally exposes an individual to lead in an amount that exceeds 0.5 microgram in a single day. *See* Brief of Amicus Curiae Attorney General Kamala B. Harris in Support of Appellant, *Env't'l Law Found. v. Beech-Nut Nutrition Corp., et al.* (Aug. 21, 2014), Cal. Court of Appeal Case No. A139821, at 8-18.¹⁹

¹⁹ Attached hereto as Appendix, Exhibit 17.

Nevertheless, in *Env't'l Law Found. v. Beech-Nut Nutrition Corp.* (2015) 235 Cal.App.4th 307, the Court of Appeal affirmed the trial court's ruling that the defendants in that case – manufacturers and suppliers of baby and children's fruit juice products – could average lead exposures from their products over a period of 14 days. *Id.*, at 327-29.²⁰ The net effect of the court's ruling is to increase the safe harbor level from 0.5 microgram per day to up to 7 micrograms per day (since a single day exposure of 7 micrograms averaged over 14 days would yield an exposure of 0.5 microgram per days). A 7 microgram exposure in a single day would equate to a NOEL of 7,000 micrograms, a level far above any observable effect level. The Court of Appeal affirmed this conclusion despite Dr. Donald's testimony on behalf of OEHHA that the regulatory MADLs established by the agency are single day exposure limits which cannot be averaged over time. *Id.*, at 321; *see also* Testimony of James Donald, Ph.D., *Env't'l Law Found. v. Beech-Nut Nutrition Corp., et al.* (Apr. 17, 2013), Alameda Superior Court Case No. RG-11597384, at 691-96.²¹ The Court declined to afford any deference to Dr. Donald's testimony because, *inter alia*, there was insufficient evidence “to demonstrate that his views represent the authorized formal policy of OEHHA.” *Beech-Nut*, 235 Cal.App.4th at 329. Based on *Beech-Nut*, defendants in numerous other

²⁰ Attached hereto as Appendix, Exhibit 21.

²¹ Attached hereto as Appendix, Exhibit 16.

Proposition 65 cases have used the decision in an attempt to have their cases dismissed, stayed, or otherwise limited.

ARGUMENT

I. OEHHA SHOULD REPEAL OR AMEND THE MADL FOR LEAD.

The safe harbor limit for lead of 0.5 microgram per day was never scientifically valid. Even in 1989 when the level was first established, the record before the agency clearly established that exposures to lead of 500 micrograms per day will have an observable reproductive effect. Thus, even when it was promulgated the regulation exceeded the agency's statutory authority and was invalid.

Worse yet, decades of peer-reviewed research conducted since the limit was established have underscored that the level is not sufficiently protective. These studies further establish that exposures to lead of 500 micrograms will have an observable effect, and that there is no level below which there is not an observable effect. Therefore, OEHHA should repeal the 0.5 microgram per day MADL for lead, or amend it to establish a level that is protective of public health and compliant with Proposition 65.

OEHHA's failure to update the MADL for lead is particularly inexcusable in light of: (1) OEHHA's acknowledgment that the 0.5 microgram per day MADL was not set low enough even based on the state of the science in 1989 when the level was first established (*see* Donald

Decl., ¶¶ 9.a. & 9.b); (2) OEHHA's repeated conclusion that lead causes reproductive harm at levels much lower than previously thought; and (3) OEHHA's change to the basis for the listing in 2013 without any corresponding evaluation of the level.

Further exacerbating the problem, the Court of Appeal's decision in *Beech-Nut* has potentially converted the 0.5 microgram per day level into a 7 microgram per day level. While CEH believes that the decision in *Beech-Nut* is limited to the facts of that case, defendants in Proposition 65 enforcement actions involving other products have already begun raising the decision as a defense to enforcement actions pursued by CEH and other enforcers (including the California Attorney General). While the issue of averaging can and should be separately addressed by OEHHA, the serious scientific and legal flaws with the 0.5 microgram per day level could be even worse in the meantime due to the repercussions of *Beech-Nut*.

II. OEHHA SHOULD ISSUE A REGULATION CLARIFYING THAT THE MADL FOR LEAD IS A SINGLE DAY EXPOSURE LIMIT AND THAT AVERAGING EXPOSURES OVER TIME IS NOT PERMITTED.

As reflected in Dr. Donald's testimony in *Beech-Nut*, OEHHA's longstanding policy is that the MADL for lead is a single day exposure limit and that averaging over time is improper. Unfortunately, because this policy was not codified in an agency regulation, the trial court and Court of Appeal disregarded this policy and permitted the defendants in that case to

average lead exposures over a 14 day period that has no basis in science or law. To remedy this, OEHHA should promulgate a regulation clearly establishing that the lead MADL is a single day exposure limit and that averaging over time is not permitted when assessing compliance with the regulatory MADL.

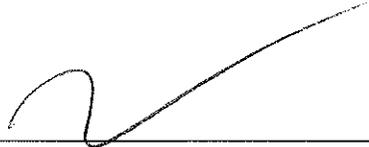
CONCLUSION

For the foregoing reasons, CEH respectfully requests that OEHHA grant this petition.

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Respectfully submitted,

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By 

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