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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION TWO

MATEEL ENVIRONMENTAL JUSTICE FOUNDATION, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents; CALIFORNIA CHAMBER OF COMMERCE et al., Intervenors and Respondents.	A148711 (Alameda County Super. Ct. No. RG15-754547)

INTRODUCTION

In 1989, the predecessor to respondent Office of Environmental Health Hazard Assessment (OEHHA), the lead agency charged with implementing California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65) (Health & Saf. Code, § 25249.5 et seq.), adopted a regulation setting a "maximum allowable dose level" or MADL for lead as a reproductive toxicant. (Cal. Code Regs., tit. 27, § 25805, subd. (b).)[1]

[1] OEHHA's predecessor, the Health and Welfare Agency (HWA), was the lead agency until 1991. (*Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1267, fn. 4 (*Exxon*).) For ease of reference, we will sometimes refer to the Health and Welfare Agency, while acting as the lead agency for Proposition 65, as OEHHA or the Agency.

All statutory references are to the Health and Safety Code, unless otherwise indicated. In 2008, Proposition 65 regulations were moved from title 22 to title 27 of the

In 2015, appellant Mateel Environmental Justice Foundation (Mateel) sued OEHHA, seeking a writ of mandate (Code Civ. Proc., § 1085) and other relief to compel OEHHA to repeal that part of Regulations section 25805 setting a MADL for lead as a reproductive toxicant, seeking to invalidate the regulatory "safe harbor" level for lead of 0.5 microgram per day ("µg/day"). The trial court denied Mateel's motion for judgment on the pleadings for declaratory relief and/or writ of mandate and entered judgment in favor of OEHHA.[2] This timely appeal followed.

Mateel argues that OEHHA failed to comply with the Proposition 65 mandate that the MADL be based on an exposure having "no observable effect" when it utilized a "surrogate" "no observable effect level" (NOEL) derived from the "permissible exposure limit" (PEL) for lead set by the United States Occupational Safety and Health Administration (OSHA). Mateel further argues that even if the blood lead level OSHA determined should be maintained for men and women who wished to plan pregnancies were appropriate to consider as a NOEL, the OSHA PEL was not set at a level to achieve this target, that OEHHA failed to make a downward adjustment to account for this disconnect between the PEL and the target NOEL, and nothing in the record indicates OEHHA considered this issue in setting the MADL.

We shall affirm.

STATUTORY BACKGROUND

In 1986, Californians adopted Proposition 65 through the voter initiative process. "Proposition 65 requires that, at least once per year, the Governor shall cause to be published 'a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter.' (§ 25249.8, subd. (a).) The listing of a chemical triggers two requirements. The first requirement, contained in section 25249.5,

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California Code of Regulations. Unless otherwise indicated, references to Regulations are to title 27 of the California Code of Regulations.

[2] The court also denied OEHHA's motion for judgment on the pleadings and overruled intervenors' demurrer, which asserted that Mateel's claims were time barred. The timeliness issue is not raised on this appeal.

prohibits businesses from discharging the chemical 'into water or onto or into land where such chemical passes or probably will pass into any source of drinking water.' " (*Exxon, supra,* 169 Cal.App.4th at p. 1268.) We are concerned here with the second requirement, contained in section 25249.6, which requires companies that expose consumers to carcinogens or reproductive toxins to give "clear and reasonable warning" before exposing individuals to the listed chemical. (§ 25249.6; see e.g. *Environmental Law Foundation v. Beech-Nut Nutrition Corp.* (2015) 235 Cal.App.4th 307, 312 (*Beech-Nut*).)

Under section 25249.10,[3] the warning requirement does not apply to "[a]n exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have *no observable effect assuming exposure at one thousand (1,000) times the level in question* for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8." (§ 25249.10, subd. (c), italics added; see e.g., *Exxon, supra,* 169 Cal.App.4th at p. 1268.)

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[3] Section 25249.10 "Exemptions from warning requirement" provides in full: "Section 25249.6 shall not apply to any of the following:

"(a) An exposure for which federal law governs warning in a manner that preempts state authority.

"(b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

"(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant."

Section 25249.8, subdivision (b) describes the standards of scientific validity required for listing the chemical that section 25249.10, subdivision (c) references: "A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity."

"Lead is a toxic metal that, even at low levels, may cause a range of health effects, including behavioral problems and learning disabilities." (*Beech-Nut, supra,* 235 Cal.App.4th at p. 312.) It was identified as a known carcinogen and reproductive toxin under Proposition 65.

" 'The "no observable effect level," or NOEL, is a scientific term denoting the maximum dose level at which a chemical is found to have no observable reproductive effect. [Citation.] The NOEL is determined through scientific inquiry and assessment as detailed in the framework set forth in the regulations. [Citations.] In turn, the NOEL is divided by 1,000 to arrive at the [MADL], which is the threshold warning level for a listed chemical.' [Citations.] Thus, the [MADL] is set as one one-thousandth of the NOEL." (*Beech-Nut, supra,* 235 Cal.App.4th at p. 313.) The NOEL is defined as "an exposure level with no biologically or statistically significant increase in the frequency or severity of adverse effects among the exposed group relative to a control group." (OEHHA, Technical Support Document for the Derivation of Noncancer Reference Exposure Levels (June 2008) p. 39.)[4]

[4] " 'At trial [in an enforcement action], a defendant can secure the protection of the exposure exemption by establishing (1) the NOEL; (2) the level of exposure in question, and ultimately that the level of exposure was 1,000 times below the NOEL.' [Citation.]" (*Beech-Nut, supra,* 235 Cal.App.4th at p. 313; see § 25249.10, subd. (c).)

Section 25801 of the Regulations addresses the determination of the NOEL, explaining that for purposes of the warning exemption and "safe harbor," that NOEL is "the maximum level of exposure at which a chemical has no observable reproductive effect" and repeating the statutory requirement that the determination that the "no observable effect" level for purposes of section 25249.10, subdivision (c) "shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of a chemical as known to the state to cause reproductive toxicity." (Regs., § 252801, subd. (b).)[5]

[5] Regulations section 25801 provides:

"(a) The determination of whether a level of exposure to a chemical known to the state to cause reproductive toxicity has no observable effect for purposes of Section 25249.10(c) of the Act shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of a chemical as known to the state to cause reproductive toxicity. Nothing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question.

"(b) A level of exposure to a listed chemical shall be deemed to have no observable effect, assuming exposure at one thousand times that level, provided that the level is determined:

"(1) By means of an assessment that meets the standards described in Section 25803 to determine the maximum dose level having no observable effect, and dividing that level by one thousand (1,000) to arrive at the maximum allowable dose level; or

"(2) By application of a specific regulatory level for the chemical in question as provided in Section 25805.

"(c) For purposes of this article, "NOEL" shall mean that no observable effect level, which is the maximum level of exposure at which a chemical has no observable reproductive effect.

"(d) The chemicals specifically contained in this article do not include all chemicals listed as causing reproductive toxicity for which there is a level of exposure which has no observable effect assuming exposure at one thousand times the level in question. The fact that a chemical does not specifically appear in this article does not mean that it has an observable effect at any level.

ADMINISTRATIVE PROCEEDINGS

In 1989, after an extensive administrative process, the Agency adopted regulations governing its implementation of Proposition 65, including article 8, "No Observable Effect Levels." (Regs., §§ 25801-25821.) The Agency determined the MADL for lead, setting the regulatory safe harbor level for reproductive toxicity at 0.5 micrograms per day. (Regs., § 25805, subd. (b).)[6] In its "Final Statement of Reasons" (FSOR),[7] the Agency explained the need for adoption of these regulations. "The Act [Proposition 65] exempts discharges, releases and exposures which, making certain assumptions, pose no

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"(e) This article establishes exposure levels solely for purposes of Section 25249.10(c) of the Act. Nothing in this article shall be construed to establish exposure levels for other regulatory purposes.

"(f) Whenever the lead agency proposes to formally adopt a regulation pursuant to Sections 25801 through 25821, such as a maximum allowable dose level, the lead agency shall provide each member of the Developmental and Reproductive Toxicant Identification Committee notice of the proposed action, the proposed change to the regulation, and a copy of the initial statement of reasons supporting the proposal for their review and comment. The Committee shall be given at least 45 days to comment. Any such comment by members of the Developmental and Reproductive Toxicant Identification Committee shall become a part of the formal rulemaking record. Nothing in this section shall be construed to require the members of the Developmental and Reproductive Toxicant Identification Committee to submit any comments. This procedure complies with the peer review requirements of section 57004 of the California Health and Safety Code." (Regs., § 25801.)

[6] A microgram is one millionth of a gram. The parties agree that the measurement of blood levels is expressed in the scientific literature and in OEHHA and OSHA documents in slightly different ways. "Blood lead level" is sometimes expressed in shorthand as "PbB." Blood lead levels are commonly expressed in terms of the number of micrograms per deciliter of whole blood (µg/dL), though OSHA often uses "µg/100g" or "µg/100 ml." All of these terms—"µg/dL," "µg/100g," and "µg/100 m"—have the same meaning."

[7] "Government Code section 11346.9 requires agencies to prepare and submit with all adopted regulations a 'final statement of reasons.' (*Id*., subd. (a).) The 'final statement of reasons' updates the 'initial statement of reasons' (*ibid*.), which states 'the specific purpose of each adoption . . . and the rationale for the determination by the agency that each adoption . . . is reasonably necessary to carry out the purpose for which it is proposed.' (Gov. Code, § 11346.2, subd. (b)(1).)" (*Exxon, supra,* 169 Cal.App.4th at p. 1282.)

significant risk of cancer or would produce no observable reproductive effect. The Act specifies that any claim of exemption under Health and Safety Code section 25249.10, subsection (c) must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the substance as a chemical known to the state to cause cancer or reproductive toxicity. However, . . . the Act does not specify levels of exposure to reproductive toxins which have no observable effect, and provides no methods for determining those levels." (FSOR, pp. 4–5.)

The Agency recognized that "[t]here is no fixed way to perform the steps necessary to specifically determine . . . no observable effect. The methods used may vary depending upon the data available, and the objectives of the risk assessor or risk manager. The purpose of these regulations is to provide some 'safe harbor' levels and methodologies, and criteria for exposure assessment, which will assist persons in making certain that their discharges, releases or exposures pose no significant risk or would have no observable effect within the meaning of the Act." (FSOR, p. 4.)

The Agency also recognized that lead had been included on the Governor's initial listing of chemicals known to cause reproductive toxicity because it had been identified by OSHA as a known human reproductive toxicant based upon evidence of its effects on humans (FSOR, p. 77) and the Agency relied on OSHA's PEL of 50 micrograms per cubic meter to establish the reproductive safe harbor level. "OSHA multiplied the OSHA PEL of 50 micrograms per cubic meter by 10 cubic meters (the amount OSHA determined workers breathed over an eight-hour period) to yield a value of 500 micrograms, which [the Agency] then divided by 1,000 to arrive at the 0.5 microgram-per-day standard." (*Beech-Nut, supra,* 235 Cal.App.4th at pp. 313-314.) "The reproductive safe harbor level presumes that one can be exposed to 1,000 times the safe harbor level without suffering any adverse reproductive effects." (*Id.* at p. 317.)

In setting the MADL, the Agency acknowledged the difficulties in setting a NOEL for reproductive toxicants: "The difficulty in identifying a NOEL for reproductive toxicants when the effects of concern are based upon human experience rather than

animal bioassays is that there is often no precise data predicting what levels will produce no observable effect. However, there is experience derived from the occupational setting which suggests that exposure to certain regulated levels does not produce the reproductive effect of concern. Hence, the Agency has utilized certain limits for occupational exposures as surrogates for the NOEL in the workplace. The levels set forth in subsection (b) represent one one-thousandth of the occupational exposure limits. This approach is consistent with the purposes of the Act."[8] (FSOR, p. 78.)

When the regulation setting the 0.5 MADL for lead was promulgated, several commentators provided extensive reviews of animal studies, urging that a higher MADL be adopted. At the time, no one argued for a lower MADL. (FSOR, pp. 78–81.) In its FSOR, the Agency explained its refusal to rely on the available animal studies, which would have resulted in an MADL of 35 micrograms per day, an exposure of 35,000 micrograms per day, and anticipated blood levels of 2800 micrograms per100 grams "which not only would produce observable effects, but would likely be incompatible with human existence." (FSOR, pp. 79–80.)

Responding to comments that the 0.5 microgram per 100 grams (0.5 micrograms/100g) level was too high, the Agency quoted from OSHA's regulations: " 'Prevention of adverse health effects for most workers from exposure to lead throughout a working lifetime requires that worker blood lead (PbB) levels be maintained at or below forty micrograms per one hundred grams of whole blood (40 micrograms/100 grams). The blood lead levels of workers (both male and female workers) *who intend to have children should be maintained below 30 micrograms/100 grams to minimize adverse reproductive health effects to the parents and the developing fetus.*' ([29 C.F.R. § 1910.1025, 44 Fed.Reg. 60982].)" **(**FSOR, p. 79, italics added.) The Agency concluded: "Hence, considering *30 micrograms/100 grams to be a functional equivalent*

[8] In its "Initial Statement of Reasons" (ISOR), the Agency acknowledged that "This approach, while arguably unconventional, is consistent with the protective purposes of the Act."

reproductive NOEL, OSHA identifies that level to be 75 percent of the blood limit targeted by the permissible exposure limit (PEL)." (*Ibid.*, italics added.)

STANDARDS OF REVIEW

Mateel filed a petition for writ of ordinary mandamus pursuant to Code of Civil Procedure section 1085. "In determining whether to grant a petition for traditional mandamus, we review for an abuse of discretion. ' " 'Abuse of discretion is established if the respondent [agency] has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence.' [Citation.]" [Citations.]' " (*Exxon*, *supra*, 169 Cal.App.4th at p. 1276.) " 'In determining whether the agency complied with the required procedures and whether the agency's findings are supported by substantial evidence, the trial court and the appellate courts essentially perform identical roles. We review the record de novo and are not bound by the trial court's conclusions.' [Citation.]" (*Ibid.*) "As a general matter, courts 'will be deferential to government agency interpretations of their own regulations, particularly when the interpretation involves matters within the agency's expertise and does not plainly conflict with a statutory mandate. (See *Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 12–13.) . . . [W]e will not disturb the agency's determination without a demonstration that it is clearly unreasonable.' [Citation.] While final responsibility for interpreting a statute or regulation rests with the courts and a court will not accept an agency interpretation that is clearly erroneous or unreasonable, ' " [a]s a general rule, the courts defer to the agency charged with enforcing a regulation when interpreting a regulation because the agency possesses expertise in the subject area." ' " (*Exxon*, at pp. 1276–1277.)

In considering whether the Agency's adoption of a MADL of 0.5 microgram per day comports with the statute and the regulations promulgated thereunder "the scope of our review ' "is limited, out of deference to the agency's authority and presumed expertise: 'The court may not reweigh the evidence or substitute its judgment for that of the agency. [Citation.]' " [Citation.] "In general , , , the inquiry is limited to whether the decision was arbitrary, capricious, or entirely lacking in evidentiary support . . . ."

[Citation.] When making that inquiry, the " ' "court must ensure that an agency has adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purposes of the enabling statute." [Citation.]' " [Citation.]' [Citation.] This limited judicial review is further constrained by the recognition that ' "[i]n technical matters requiring the assistance of experts and the study of marshaled scientific data as reflected herein, courts will permit administrative agencies to work out their problems with as little judicial interference as possible." ' " (*Exxon, supra,* 169 Cal.App.4th at p. 1277.)

ANALYSIS

Whether OEHHA Abused Its Discretion in Establishing a Proposition 65 Warning Exemption Derived from OSHA's PEL

Mateel contends the trial court erred in ruling OEHHA could establish a MADL of 0.5 microgram per day, derived from OSHA's PEL of 500 micrograms per day. Mateel argues the court should not have deferred to OEHHA where the agency's interpretation contradicted the underlying statute as to the meaning of "no observable effect." However, both Mateel and OEHHA recognized that as used in the statute and implemented in the regulations, the term "no observable effect" means "no observable reproductive effect." (Regs., § 25801, subd. (c).)

Mateel urges that the OSHA's purpose in setting a PEL is different from Proposition 65's purpose in establishing a MADL, with differing standards and requirements. OEHHA agrees. We recognize, however, that although the purposes of the PEL lead standard under OSHA and the MADL for lead under Proposition 65 differ in significant respects, the overarching purpose of both is the safety of human beings who come into contact with chemicals that are known to cause cancer or reproductive toxicity.

In setting standards for toxic substances, OSHA is required to give due regard to the question of feasibility.[9] Feasibility is not a consideration under Proposition 65's

[9] "In setting standards for toxic substances, the Secretary is required to give due regard to the question of feasibility. Section 6(b)(5) of the [Occupational Safety and Health Act of 1970] mandates that the Secretary shall set the standard which most

warning requirement, as OEHHA recognized in setting the standard, when it responded to comments that few businesses could comply with the 0.5 microgram per day "safe harbor" level: "The purpose in setting this level, however, is to establish a level of exposure which the Agency can be certain is in fact safe within the meaning of the Act. The fact that some businesses may not be able to comply with the level does not appear to conflict with this purpose." (FSOR, p. 78.) Given the differing purposes and standards of the statutory and regulatory schemes within which OSHA and OEHHA operated in setting lead exposure levels, the question remains whether OEHHA abused its discretion in utilizing OSHA's analysis and data in adopting the 0.5 microgram per day MADL.

OEHHA maintains that in adopting the MADL, it was "well aware that exposure to 500 µg/100g of lead *alone* would result in blood lead levels *well below the* 30 µg/100g level that was protective of the fetus and that commenters viewed it as overly conservative in relying on the PEL to set the MADL."

A. *Setting the NOEL Blood Lead Level at 30 Micrograms per Day*

Mateel argues that the Agency violated the statute and the regulations in considering 30 micrograms/100g to be a "functional equivalent reproductive NOEL," based on OSHA's determination that blood lead levels of prospective parents "should be maintained below 30 micrograms/100 grams to minimize adverse reproductive health effects to the parents and the developing fetus." (29 C.F.R. § 1910.1025; 44 Fed.Reg. 60982.) Contending that OEHHA's use of a "surrogate" for a NOEL contravenes the statutory mandate that requires a "safe harbor" be based on a NOEL, Mateel maintains the OSHA studies did not support OEHHA's conclusion that the PEL could be used as a legally valid "no observable effect" level under Proposition 65.

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adequately assures employees' safety and health 'to the extent feasible, on the basis of the best available evidence.' Additionally, in the development of occupational safety and health standards 'considerations shall be the latest available scientific data in the field, experience gained under this and other health and safety laws." (29 C.F.R. § 1910, 43 Fed.Reg. 52977 (Nov. 14, 1978).)

Mateel does not dispute the trial court's finding that "the studies reviewed by OSHA in connection with its establishment of its PEL were of high scientific caliber." Rather, Mateel argues that under section 25249.10, subdivision (c), the science must clearly show the necessary conclusion that there is "no observable reproductive effect" at the level set and posits that the data and studies before OSHA established that there in fact were reproductive effects below the 30 micrograms/100g.

Mateel concedes OEHHA could have relied upon the OSHA PEL to set the MADL if OEHHA found the PEL was "an assessment by an agency of a state or federal government that is the substantial equivalent of the assessment described in subsection (a) of section 25803 and establishes a maximum allowable does level in the manner provided in paragraph (b)(1) of Section 25801 . . . ." (Regs., 25805, subd. (c).) Arguing OEHHA failed to so find, Mateel asserts that OSHA did not conduct a quantitative risk assessment that is the "substantial equivalent" of what is required under Proposition 65.

OEHHA counters, and Mateel apparently does not dispute, that the evidence for the MADL was not only of *comparable* scientific validity to the evidence forming the basis for the listing, but was the *same* evidence. The listing for lead as a reproductive toxicant under Proposition 65 was based on the Hazard Communications Standard set forth in title 29 Code of Federal Regulations section 1910.1200, which incorporated the OSHA PEL for lead. (29 C.F.R. § 1910.1025, subd. (m).)

Moreover, Mateel's description of the scientific assessment that must be conducted is unduly rigid. In 2011, OEHHA amended Regulations section 25803 with "corrections of terminology and revisions of phrasing to more clearly express the intent of the regulation" to allow for alternatives to the experimental NOEL. (FSOR for 2011 Amendment to Regs., § 25803, at p. 3.) The 2011 FSOR explains: "The procedures specified in [Regulations] Section 25803 have always explicitly been defaults that permitted the use of principles or assumptions scientifically more appropriate based upon the available data." (*Id.* at p. 3.) "An alternative NOEL may be used if it is more scientifically appropriate than a default. For example, if data are available for individuals in a study, a statistical model could determine a benchmark dose as the NOEL. Or,

where the range reflects uncertainty in the exposure level, statistical methods could be used to establish the NOEL. It should be noted that the above discussions are examples, and are not intended to limit the methodologies that can be applied. As science progresses, other methodologies may be developed, validated and accepted. The best generally–accepted methodologies should be used in each situation." (*Ibid.*)

The studies and data upon which OSHA relied in establishing the PEL appear comprehensive, scientifically appropriate, and indeed, cutting-edge at the time.[10] OEHHA could consider the OSHA material and could rely upon OSHA's conclusions in adopting the MADL.

Contending that a "surrogate" means a substitute for NOEL, and not a NOEL, Mateel points to the OSHA record where OSHA appears to conclude that blood levels of 30 micrograms/100g is *not* a level at which there are no observable effects.[11] OSHA

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[10] OSHA itself described study upon which it relied for its determination of the air lead level and blood lead level relationship as one that "represents an accomplishment heretofore unseen in attempts to establish air level to blood level relationships. Insofar as this model takes into account particle size and job tenure it has avoided the weakness of earlier studies. The model does, however, incorporate the findings of the earlier studies and is therefore the best synthesis of theory and actual research to date." (43 Fed.Reg. 54400.)

[11] In its discussion of "reproductive effects" the OSHA document accompanying the final OSHA standard for occupational exposure to lead states:

"There is little direct data on damages to the fetus from exposure to lead but there are extensive studies which demonstrate neurobehavioral effect in children. OSHA believes that the fetus would be at least as susceptible to neurological damage and heme inhibition as would older children and therefore data on children is relevant to the fetus. [¶] . . . [¶] . . . . Behavioral disturbances in children such as hyperactivity have been associated with blood lead levels between 25 and 55 µg/100 ml. Animal studies have confirmed these findings. [¶] . . . [¶] While a critical review of the literature leads to the conclusion that blood lead levels of 50 to 60 µg/100 ml are likely sufficient to cause significant neurobehavioral impairments, there is evidence for effects such as hyperactivity as low as 25 µg/100g. 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/100g. In general, 30 µg/100g 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. . . . [¶] . . . [¶]

found "conclusive evidence that exposure of the fetus and infant to lead induces neurological damage manifested by behavioral disorders [and other conditions, including mental retardation]. These effects occur at blood lead levels below 30 µg/100 ml, but generally are manifest at 50 µg/100 ml." OSHA concluded that "[i]n general, 30 µg/100g appears to be reasonably protective . . . and should minimize neurological damage." However, OSHA could not "guarantee that 30 µg/100g is a 'no effect' level but it would provide marked protection to the fetus and therefore to the reproductive capacity of the worker." (43 Fed.Reg. 54422) Mateel argues that OEHHA could not equate a level that "should minimize neurological damage" with one at which there are "no observable reproductive effects."

OEHHA responds that the risk assessor may use something other than a NOEL derived from an animal study, if it is scientifically more appropriate to do so, as it contends was the case here. According to OEHHA, the claim that OSHA found "conclusive evidence of adverse reproductive effects" at the blood lead level of 30 micrograms/100g is simply not true. OEHHA contends Mateel misreads the OSHA administrative record and misunderstands the science.

There is limited data on the effects of lead on the fetus but there is more extensive information on the susceptibility of infants and children to neurological damage from lead. . . . Given the severity of neurological disease and the evidence indicating effects at low lead levels this conclusion raised particularly difficult issues when establishing this final standard. OSHA recognizes that a PbB level is not a measure of body burden, that the fetus would only be exposed during the period of gestation, and given the independent hematopoietic system of the fetus that maternal-cord blood leads may not be an accurate reflection of blood lead level in the fetus. However, even if these considerations may suggest a lessening of risk to the fetus, OSHA believes that blood lead levels of pregnant women should be maintained below 30 µg/100 ml in order to protect the fetus. [¶] In general, OSHA believes that the evidence overwhelmingly indicates that the blood lead levels of both male and female workers who wish to plan pregnancies should be maintained below 30 µg/100 in order to prevent adverse effects from lead on the workers' reproductive abilities. To do this would minimize the risk of genetic damage . . . . OSHA cannot guarantee that 30 µg/100g is a 'no effect' level but it would provide marked protection to the fetus and therefore to the reproductive capacity of the worker." (43 Fed.Reg. 54422.)

OEHHA asserts the issues presented here involve only reproductive toxicity under Proposition 65 (harm to female or male reproductive function) and developmental toxicity (harm to the developing fetus). Mateel does not appear to challenge this assertion. Because Proposition 65 considers developmental toxicity to be the result only of prenatal exposures to a chemical, postnatal exposures that affect the child are not considered developmental toxicity for purposes of Proposition 65.[12] Therefore, Mateel's assertion that OSHA's comments and findings establish that there is evidence of reproductive harm from blood lead levels below 30 micrograms/100g, ignores that the actual studies upon which OSHA relied showing neurological effects below that level involve postnatal exposure, not prenatal exposure and are therefore not relevant to Proposition 65, which, as currently interpreted, "precludes listing on the basis of developmental effects resulting solely from postnatal exposures." OEHHA argues the two studies underlying OSHA's comments and cited by Mateel at trial involved postnatal exposure and not prenatal exposure. In sum, the studies upon which OSHA relied did not conclude there were adverse effects from *prenatal* lead exposures below 30 micrograms/100g. OSHA did not distinguish between developmental effects caused by prenatal and postnatal exposures, because the distinction was not material to setting a PEL. Under Proposition 65, only prenatal effects are material to setting a MADL.

Mateel asserts that the adoption of 30 micrograms/100g as a "no observable effects level" is inconsistent with OSHA's statement that keeping maternal blood levels below 30 micrograms/100g will "*minimize* enzyme inhibition (ALAD and FEP [free erythrocyte-protoporphyrin]) in the heme biosynthetic pathway and should *minimize* neurological damage." (43 Fed.Reg. 54422, italics added.) Recognizing that the

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[12] "[D]evelopmental endpoints resulting from postnatal exposure are not covered by Proposition 65." (OEHHA, Proposition 65 Maximum Allowable Dose Level (MADL) for Reproductive Toxicity for Methyl Bromide as a Structural Fumigant (June 2004) p. 3); see also Candidate for Proposition 65 Listing via the Authoritative Body Mechanism Found Not to Meet Scientific Criteria (June 1999) p. 2 ["As currently interpreted, the Proposition 65 statute precludes listing on the basis of developmental effects resulting solely from postnatal exposures"].)

"science here is complex," OEHHA counters that OSHA noted the relevant studies concerning enzyme inhibition at low lead exposures did not report any observed biological significance with respect to the heme biosynthetic pathway at blood lead levels below 30 micrograms/100g. The only scientific data on prenatal effects concerned lower activity of the enzyme ALA-D at blood lead levels of 10–20 micrograms/100g, but there was no evidence to demonstrate ALA–D inhibition at such low blood levels would result in lower production of hemes. OSHA observed: "At such low levels of lead exposure the biological significance of this inhibition is unclear . . . ." (43 Fed.Reg. 54396.)

Pointing to OSHA's statements that blood lead level of 30 micrograms/100g will "minimize adverse reproductive health effects to the parents and the developing fetus" and would be "reasonably protective" of the fetus, Mateel argues these statements cannot be construed to mean "no observable effect" at that level. However, as OEHHA explains, the concept of "no observable effect" is not the same as "no effect." The no observable effect level is defined according to what scientists are able to observe from a particular study. Whether determined by an experimental NOEL, or by another accepted methodology, it "does not represent a biological threshold and cannot establish that the lower exposure levels are necessarily without risk." (U.S. Environmental Protection Agency, Benchmark Dose Technical Guidance (June 2012) pp. 3–4.)

Because a NOEL is not conclusive evidence that the exposure will have no effect, which might have been detected in a more sensitive study, it is not surprising that OSHA, was unable to "guarantee that 30 μg/100g is a 'no effect' level but [found] it would provide marked protection to the fetus and therefore to the reproductive capacity of the worker." Therefore, OSHA's conclusions that such blood levels would "minimize" adverse reproductive health effects and be "reasonably protective" of the fetus are not inconsistent with a conclusion that 30 micrograms/100g will have no observable reproductive effect.

Mateel has failed to show OEHHA's determination that 30 micrograms/100g blood lead level will have "no observable effect" was arbitrary and capricious.

B. ***Setting the MADL at Exposure to 500 µg of Lead per Day***

Mateel argues that even if OEHHA could use the 30 micrograms per day OSHA blood level target for reproductive toxicity as a "surrogate" NOEL, the lead MADL was not set to achieve that level. The OSHA PEL of 500 micrograms per day was not set to achieve the blood lead level of 30 micrograms/100g. OSHA found its PEL would result in mean blood lead levels for workers that would be 35 micrograms/dL and that 30 percent of workers would have blood lead levels greater than 40 micrograms/dL. (43 Fed.Reg. 54423.) OEHHA does not dispute that it derived the 0.5 microgram per day "safe harbor" MADL from the OSHA PEL without any downward adjustment to account for that difference.

The trial court accepted OEHHA's explanation that "the blood level science in play in the PEL proceedings included factors that defy direct comparison with 'an exposure level [that] will have no observable effect' in the Proposition 65 setting, because the overall blood lead level includes lead that is already present before the additional exposure, whether from air in the workplace or from a consumer product, i.e., 'previous body burden.' " As OEHHA explains, OSHA relied on a model predicting blood lead levels based on exposure to the PEL of 500 micrograms per day, combined with the lead already in workers' bodies, which was the result of other significant sources of lead. The model looked at all sources of lead exposure, and took into account that workers at that time started with a significant "lead body burden," even before the occupational exposure at issue. (See 43 Fed.Reg. 54401–54402, 54427.) OSHA was concerned with total blood levels in workers and it set its PEL accordingly, taking into account workers' existing lead body burdens. In contrast, Proposition 65 is concerned only with the blood lead level that results from the isolated exposure caused by a particular business. It does not consider background levels of lead from other sources. "For purposes of the Act, 'level in question' means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include

exposure to a listed chemical from any other source or product." (Regs., § 25821, subd. (a).)

Mateel argues that there is no evidence in the record that OEHHA actually considered the OSHA analysis or that it based its determination of the MADL on a determination that in view of the "lead body burden," that exposure to 500 micrograms per day would result in lead blood levels at less than 30 micrograms per day. However, during the public comment period for the MADL, commenters pointed out that lead levels considered in setting the OSHA PEL were the sum of all occupational and non-occupational exposures from other sources and that there were high background levels of blood lead in the population such that the actual exposure needed to result in a lead blood level of 30 micrograms per day would be 30 percent higher than the PEL or over 653 micrograms per day. In its FSOR, OEHHA responded to comments that the level set was far too low, quoting from the OSHA document discussion of the reproductive effects of chronic over-exposure to lead. Certainly OEHHA was aware of the "lead body burden" issue and that the OSHA PEL was set with this in mind.

We cannot say that in adopting a MADL of 0.5 micrograms per day the Agency acted in a manner that was " ' "arbitrary, capricious, or entirely lacking in evidentiary support." ' " (*Exxon, supra,* 169 Cal.App.4th 1264, 1277.)

C. *Listing Cases Do Not Advance Mateel's Argument*

Mateel relies upon *Styrene Information & Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082 (*Styrene*) and *Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741 (*Western Crop*), to support its argument that in order for OEHHA to base its MADL on the OSHA PEL, OSHA must have met the Proposition 65 "no observable effect" standard in adopting the PEL. Mateel argues that because the PEL could be adopted by OSHA without meeting that standard, OEHHA could not use it to derive the MADL. We disagree. As the trial court recognized, both *Styrene and Western Crop* are distinguishable as "listing" cases.

In *Western Crop, supra,* 80 Cal.App.4th 741, the plaintiff sought to prohibit the Governor from publishing a list of chemicals known to cause reproductive toxicity

pursuant to Proposition 65, where the DART Committee[13] (the state qualified experts for identifying chemicals as causing reproductive toxicity) had not rendered an opinion. The Court of Appeal held the trial court did not err in denying a writ of mandate. (*Western Crop*, at p. 745.) Even if the federal criteria for listing of toxic chemicals by the EPA were less demanding than that for Proposition 65, OEHHA could find that a particular chemical had been formally identified by the EPA as causing reproductive toxicity by determining whether the reasons for the EPA placement met the criteria of section 25249.8 of causing reproductive toxicity. (*Western Crop*, at pp. 745, 752, 754.) This could be done where it was possible for OEHHA to determine from the record of the federal listing proceedings that there was substantial evidence EPA placed the particular chemical on the EPA list "because it meets the state's criteria of 'causing . . . reproductive toxicity.' " (*Western Crop*, at p. 754.)

Styrene affirmed a trial court finding that OEHHA could not properly include styrene and vinyl acetate on its Proposition 65 list based on monographs of the International Agency for Research on Cancer (IARC) where the findings in the IARC monograph categorized the chemicals as "possibly carcinogenic . . . based on inadequate evidence of carcinogenicity in humans and limited evidence of carcinogenicity in experimental animals." (*Styrene*, *supra*, 210 Cal.App.4th at p. 1092.) The court identified the question as one of statutory construction, as Proposition 65 "requires the publication of a list of chemicals 'known to the state to cause cancer or reproductive toxicity within the meaning of this chapter.' (§ 25249.8, subd. (a).)" (*Id.* at p. 1096.) The court recognized that "[w]hile OEHHA may have an interpretive advantage over the courts in determining whether a particular chemical causes cancer, it does not have such advantage in determining whether the appropriate standard under the statute is one of known cause or possible cause." (*Id.* at p. 1100, fn. omitted.) The IARC monograph, upon which OEHHA relied to list the chemicals did not satisfy the Proposition 65 standard that "chemicals may be included on the Proposition 65 list only if there is a

[13] Developmental and Reproductive Toxicant Identification Committee.

sufficient showing that they in fact cause cancer or reproductive toxicity." (*Id.* at p. 1101.)

As the trial court here recognized, the statutory language at issue in the listing cases—"chemical is known to the state to cause cancer or reproductive toxicity" (§ 25249.8, subd. (a)) differs from that involved in determining "the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question . . . ." (§ 25249.10, subd. (c).) We recognize that the "safe harbor" statute requires the lead agency act "based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8." (§ 25249.10, subd. (c).) Here the OSHA studies and the science underlying the agency's listing of lead as reproductive toxicant were not just "comparable." They were the same as that OEHHA used as the basis for its MADL derivation. Mateel does not deny this.

Moreover, the role OEHHA plays in listing a chemical under section 25249.8, subdivision (b) is more constrained than its role in determining a MADL—a regulatory "safe harbor" under section 25249.10, subdivision (c). In listing a chemical, the agency does not exercise independent scientific judgment. When listings are based on evaluations and identifications made by entities designated as "authoritative bodies," such as the federal Food and Drug Administration, OSHA, and the EPA, the lead agency is limited to reviewing the administrative record before the authoritative body to determine whether the findings of that body meet the Proposition 65 criteria for listing—that is, a sufficient showing that the chemicals at issue "in fact cause cancer or reproductive toxicity." (*Styrene, supra,* 210 Cal.App.4th at p. 1101.) In setting the MADL, however, the lead agency acts independently, and is not required to find that OSHA concluded that its PEL was a "no observable effect" level under Proposition 65. Rather, OEHHA was able to independently determine based upon the science in the record before OSHA that 30 micrograms/100g blood lead level would have no observable reproductive effect, consistent with Proposition 65.

D. *Presumption that OEHHA Found the Necessary Facts Based on the Statutory and Regulatory Standard*

"[A]n agency's decision will be upheld unless the decision was arbitrary, capricious, or entirely lacking in evidentiary support. [Citation.] When reviewing an agency's decision, the court must ensure that an agency has adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purposes of the enabling statute. [Citation.]" (*California Assn. for Health Services at Home v. State Dept. of Health Care Services* (2012) 204 Cal.App.4th 676, 686 (*California Assn. for Health Services at Home*).

Mateel contends that the administrative record does not reflect that OEHHA *actually considered* all relevant factors for determining that its "safe harbor" MADL of 0.5 microgram per day would lead to blood lead levels less than 30 micrograms/100g, where the OSHA PEL was set to achieve a 35 micrograms per day mean blood lead level for workers. Mateel argues nothing in the record supports OEHHA's claim that it considered the previous lead "body burden" factors it now relies upon to explain that exposure to a level of 500 micrograms per day would translate into a no observable reproductive effects level of under 30 micrograms per day and OEHHA.

Mateel contends that whether OEHHA took into account and tried to quantify the body burden issue must be based on the contemporaneous administrative record and that the lead MADL is invalid because the record fails to reflect that OEHHA actually considered all relevant factors for determining that the 0.5 microgram per day level would achieve its surrogate NOEL of 30 micrograms per day.

Initially, we are mindful that Evidence Code section 664 establishes the presumption that "official duty has been regularly performed." (Evid. Code, § 664.) "In the absence of evidence to the contrary, we presume that an agency carries out its official obligations." (*McAllister v. California Coastal Commission* (2008) 169 Cal.App.4th 912, 931, 932 [court assumes the Coastal Commission understood and applied the policies and standards of the Coastal Act].)

The cases cited by Mateel are distinguishable, although they acknowledged the highly deferential "arbitrary and capricious" standard of review applicable to review of agency decisions. *California Assn. for Health Services at Home, supra,* 204 Cal.App.4th 676, concluded that in its annual review of Medi-Cal reimbursement rates paid to providers of home health agency services for the years 2001 through 2005, the department had been "relying on out of date and irrelevant data in concluding that its rates were sufficient . . . ." (*Id.* at p. 679.) Specifically, the court concluded the department had relied on a study that did not look at the relevant time period, but had looked at data from 1992 through 1997, in violation of its mandate to conduct an annual review. (*Id.* at p. 688.) The court concluded "no reasonable person could rely on this data to concluded, as [DHS] did here, that its rates were sufficient to provide the access to services required under [section 1396a (a) 30 (A) of the Medicaid Act (42 U.S.C. §§ 1396a–1396v)]." (*Id.* at pp. 680, 689.) Consequently, it found "the Department acted arbitrarily and capriciously in reaching its conclusions." (*Id.* at p. 689.) Here, in contrast, OEHHA's MADL was based upon the OSHA PEL, which in turn was based upon scientific studies conceded to be of high quality, including a state-of-the-art modeling technique.

In *California Hotel & Motel Assn. v. Industrial Welfare Commission* (1979) 25 Cal.3d 200, the court found that in issuing an order fixing wages, hours and conditions of employment, the commission failed to include an adequate "statement of basis," as required by Labor Code section 1177. (*California Hotel & Motel Assn.*, at pp. 204, 213-214.) Such statement fulfilled several functions, described by the court, including a central function of facilitating judicial review of the agency action. (*Id.* at p. 210.) Proposition 65 does not contain a "statement of basis" requirement. Moreover, OEHHA responded to the comments it received and explained its reasoning in the FSOR. The agency received no comments arguing that the MADL was set too low, that a blood lead level of 30 micrograms per day would have observable reproductive effects, or that exposure to 500 micrograms per day would cause blood lead levels to exceed 30

micrograms per day. Consequently, there was no reason for the agency to have explicitly addressed these issues, raised for the first time nearly 30 years later.

We conclude the record before us is sufficient to enable our review. Given the issues raised before the Agency at the time and considering the purposes of Proposition 65, the Agency has "adequately considered all relevant factors, and has demonstrated a rational connection between those factors, and the choice made . . . ." (*California Assn. for Health Services at Home*, *supra*, 204 Cal.App.4th at p. 686.)

E. *New Argument Regarding OEHHA's Asserted Failure to Comply with Specific Provisions of the Government Code Will Not be Considered*

Mateel argues for the first time in its appellant's reply brief that OEHHA failed to comply with certain specific provisions of the Government Code in its decisionmaking with regard to its setting of the MADL. Mateel contends that had OEHHA actually relied upon OSHA studies and testing or on other scientific documents, under those Government Code sections it would have identified those documents in its ISOR or FSOR. Specifically, Mateel contends the agency failed to comply with Government Code sections 11346.2, subdivision (b)(3) and 11346.9, subdivision (a)(1) requiring it to identify in its ISOF or its FSOR and to make available for public review, data or any "technical, theoretical, and empirical study, report or similar document" the agency relies upon in proposing the regulation and with Government Code section 11347.3, requiring it to maintain a file of each rulemaking, which must include "[a]ll data and other factual information, technical, theoretical, and empirical studies or reports, if any, on which the agency is relying in the adoption . . . of a regulation . . . ." (*Id.*, subd. (b)(7).) Mateel notes the Federal Register Notices containing the OSHA documents were not part of the administrative record until August 4, 2015, when the parties stipulated to augment the trial court record to include them.

Mateel did not cite to these Government Code sections in its pleadings or arguments to the trial court. Nor, as we have stated, did it refer to them in its opening brief. Although for good cause, we occasionally may exercise our discretion to consider issues first raised in a reply brief (Eisenberg et al., California Practice Guide: Civil

Appeals and Writs (2017) ¶ 9:78.1, p. 9-27), "[m]ore often, however, issues not properly addressed in the opening brief will be disregarded on appeal . . . . [Citations.]" (*Id.*, ¶ 9:78.2, p. 9-27.) "Points raised for the first time in a reply brief *ordinarily will not be considered* because such consideration would either deprive respondent of an opportunity to counter the argument or require the effort and delay of an additional brief by permission. [Citations.]" (*Ibid.*) Mateel has forfeited any claim that OEHHA failed to comply with these Government Code sections or that any such failure prevents application of the presumption that it actually considered the scientific studies and evidence before OSHA when OEHHA determined the MADL.

F. *Intervenors' Arguments*

California Chamber of Commerce and California Farm Bureau Federation intervened in support of respondent. They argue the lead "safe harbor" provides certainty as a presumptively valid warning threshold, allowing businesses to sell their products and services and workplaces to comply with the law and to avoid unnecessary warnings. Without the safe harbor, they argue that these businesses will be "vulnerable to Proposition 65 enforcers" in pursuit of injunctive relief and civil penalties provided by the statute. (§§ 25249.7, 25249.12)[14] They contend invalidating the "safe harbor" MADL for lead would result in uncertainty, would lead to a proliferation of unnecessary warnings by businesses seeking to avoid lawsuits. They further argue that this proliferation of unnecessary warnings " 'could distract the public from other important warnings on consumer products.' " (*Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652, 661.) Intervenors also point out that like warning about obvious and generally known risks, over-warning may have the additional pernicious effect of causing users and consumers to ignore the warnings and possibly reducing the efficacy of warnings generally. As the California Supreme Court has noted with respect to warnings

[14] Proposition 65 provides monetary incentives for private enforcers, who may retain 25 percent of the civil penalties obtained in an enforcement action under section 25249.12, subds. (d) and (k)(2)(B)(i), as well as attorney fees under the private attorney general statute. (Code Civ. Proc., § 1021.5.)

in the context of products liability: "Requiring manufacturers to warn their products' users in all instances would place an onerous burden on them and would ' "invite mass consumer disregard and ultimate contempt for the warning process." ' [Citations.]" (*Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 70.)

Intervenor David Roe, principal drafter and author of the Proposition 65, argues in his brief that Proposition 65 was designed to keep up with current science, OEHHA has full authority to adopt and modify regulations, standards and permits as necessary to conform with and implement the law and to further its purposes. (See § 25249.12.) He urges that Proposition 65 prescribes minimum exemption levels for its warnings and that if the lead MADL is invalidated, there is full authority for OEHHA to adopt a replacement MADL based on current best science. In response, OEHHA agrees it has discretion to adopt or revise the regulatory warning threshold for any listed chemical, but argues that it has no legal duty to do so, unlike the statutory requirement that it annually update the list of chemicals covered under Proposition 65. (§ 25249.8, subd. (a).) Consequently, should the existing safe harbor be invalidated, there is no guarantee that OEHHA would ultimately adopt a new safe harbor for lead.

Given our determination that the Agency did not abuse its discretion in setting the MADL, we need not address intervenors' arguments.[15]

DISPOSITION

The judgment is affirmed. OEHHA is awarded costs on appeal.

[15] At oral argument, the Attorney General acknowledged that today many studies show that blood levels of 30 micrograms/100g are not protective of reproductive health. We do not intend that anything in this opinion should discourage OEHHA from revisiting its MADL for lead based on current science.

_____
Kline, P.J.

We concur:

_____
Stewart, J.

_____
Miller, J.

A148711

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Trial Court:	Alameda County Superior Court
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