Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Mateel Environmental Justice Plaintiff/Petitioner(s) **VS.** **California Office of Enviro** Defendant/Respondent(s) **(Abbreviated Title)**	**No. RG15754547** **Minutes**

Department 21 Honorable Winifred Y. Smith , Judge

Cause called for Motion: March 29, 2016.

Mateel Environmental Justice Foundation represented by Verick, William; Williams, David; and Somers, Eric S...

Office of Environmental Hazard Assessment represented by Fiering, Susan S. and Pollak, Harrison.
Dr. George Alexeeff represented by Fiering, Susan S. and Pollak, Harrison.

California Chamber of Commerce represented by Norris, Trenton H..
California Farm Bureau Federation represented by Norris, Trenton H..

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Court and counsel are present in open court regarding the Motion of plaintiff Mateel Environmental Justice Foundation For Judgment On the Pleadings For Declaratory Relief and/or Writ Of Mandate.

The following Tentative Ruling was published and was contested:

BACKGROUND:

On January 13, 2015, Plaintiff filed its Verified Petition For Writ Of Mandate and Complaint For Declaratory Relief and Injunction, which was amended on March 16, 2015 ("Petition/Complaint"), against defendant California Office Of Environmental Health Hazard Assessment ("OEHHA" or "Defendant") and its director. The Petition/Complaint seeks to invalidate the regulatory safe harbor for lead set forth in the California Code of Regulations ("CCR"), title 27, section 25805(b)(1989) (hereafter, "MADL Reg"). Plaintiff alleges that the data that was relied on by OEHHA at the time the MADL Reg was adopted did not support the safe harbor level (Petition/Complaint, paragraphs 17-20).

By leave of court granted on April 8, 2015, California Chamber of Commerce and California Farm Bureau Federation ("Intervenors") filed their Complaint in Intervention.

On July 7, 2015, OEHHA's Motion For Judgment On The Pleadings and Intervenors' Demurrer, both based on the assertion that Plaintiff's claims in this case were time barred, were denied and overruled. At the same time, the court granted Intervenors' Motion To Strike, and paragraph 21 of the Petition/Complaint (regarding scientific studies conducted after the MADL Reg was implemented) was stricken.

On August 19, 2015, Defendant, joined by Intervenors, moved for a stay of this action on the basis that Defendant has initiated a rulemaking process to reconsider the MADL Reg in response to an administrative petition filed by Center For Environmental Health. In its November 3, 2015 order denying the stay, the court noted that the central dispute between the parties both in this case and in the ongoing rulemaking process is a legal issue regarding the proper interpretation of the statute and its implementing regulations, a ruling on which could provide guidance to Defendant as the rulemaking process proceeds. The instant Motion was filed on August 10, 2015, but the hearing was delayed while the court addressed Defendant's stay motion.

MOTION:

Plaintiff moves for a declaratory judgment that the MADL Reg is invalid.

STATUTE AND REGULATIONS:

The statutes and regulations at issue in this case are set forth, in pertinent part, below.

Health & Safety Code section ("H&SC") 25249.6 provides "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

H&SC 25249.8(b) provides " (b) 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.

H&SC 25249.10 provides "[s]ection 25249.6 shall not apply to ... (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.

27 California Code of Regulations section ("CCR") 25801 provides in subsection (a) "[t]he 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."

Subsection (b) provides "[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 on thousand (1,000) to arrive at the maximum allowable dose level..."

Subsection (c) provides "For purposes of [Article 8 of the Proposition 65 Regulations, entitled "No Observable Effect Levels"], 'NOEL' shall mean that no observable effect level for the chemical in question as provided in Section 25805."

27 CCR 25803 sets forth the default standards that apply "[i]n the absence of principles or assumptions scientifically more appropriate, based on the available data...:

(1) Only 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.

(2) Where multiple reproductive effects provide the basis for the determination that a chemical is known to the state to cause reproductive toxicity, the reproductive effect for which studies produce the lowest NOEL shall be utilized for the determination of the NOEL. ..

(3) The quality and suitability of available epidemiologic data shall be appraised according to generally accepted scientific principles to determine whether the study is appropriate as the basis for an assessment..." and "...

(5) The NOEL shall be based on the most sensitive study deemed to be of sufficient quality."

Lead was listed as known to cause reproductive toxicity on February 27, 1987 (27 CCR 27001(c)) and the MADL Reg was enacted on July 10, 1989.

SUMMARY OF PLAINTIFF'S ARGUMENTS:

Plaintiff points out that when Defendant's predecessor, the Health and Welfare Agency ("HWA"- hereafter included in the definition of "Defendant"), enacted the MADL Reg, the Final Statement of Reasons (Administrative Record ["AR"] 2849-2934), hereafter "FSOR") confirmed that lead was "identified by the federal occupational safety and health administration ("OSHA") as [a] known reproductive toxicant[] based on evidence of [its] effects on humans" (FSOR, page 77). It then stated "[t]he difficulty in identifying a NOEL for reproductive toxicants when the effects of concern based on 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-thousandth of the occupational exposure limits." (FOSR, page 78.) The OSHA- permissible exposure limit ("PEL") of 50 micrograms per cubic meter of air was used to calculate a daily exposure of 500 µg/day, which was then divided by 1,000 to yield "an allowable level" of .5 µg/day. (Ibid.) Plaintiff argues that this demonstrates recognition by Defendant that there was no evidence of similar scientific validity or quality to the evidence upon which the listing was based, available to establish a safe harbor, and that by relying on the OSHA PEL Defendant did not comply with its "statutory mandate to determine a NOEL."

Plaintiff also asserts that when it established its PEL, OSHA found that "there is no evidence of a 'no effect' level." (Administrative Record ["AR"] 4237.) OSHA also set the PEL to achieve a target blood level of 40 µg/100 g of whole blood even though it had found that a blood level of 30 µg/100 g was desirable, and that reproductive effects could occur in fetuses where maternal blood lead levels are even lower. (AR 4360-4361.) In arriving at the PEL, OSHA was also subject to the "test of feasibility," whereas no such test applies to the setting of a NOEL under Proposition 65.

Plaintiff argues that the MADL Reg is invalid because it conflicts with Proposition 65. Defendant did not even attempt to make a finding that exposures at 1,000 times the MADL would have no observable effect. Defendant's reliance on the OSHA PEL was unscientific and arbitrary, as demonstrated by Defendants use of the words "suggests" and "surrogates" in the FSOR at page 78. In sum, a PEL is not a NOEL, and the statute requires a NOEL.

SUMMARY OF DEFENDANT'S ARGUMENTS IN OPPOSITION:

Defendant argues that, in this circumstance, the court's review is highly deferential. (Citing, inter alia, Exxon Mobil v. OEHHA (2009) 169 Cal.App.4th 1264, 1277.) Its interpretation of the terms "have no observable effect" and its promulgation of the .5 µg/day lead MADL was consistent with the scientific evidence in the record, with its own regulations, and with the purpose of the statute. The decision was not arbitrary and capricious. The proper inquiry is not to determine the "correct" interpretation of the regulatory provisions, but rather "whether the interpretation offered by [the agency] is reasonable in light of the regulation's language and purpose." (Id, at 1280.)

Defendant asserts that there is a difference between the concept of statutory exposure with "no observable effects" (27 CCR 25801(c)) and the scientific term referring to a level derived from a study and expressed in milligrams of chemical per kilogram of bodyweight per day (e.g., 27 CCR 25803(a)(2)), and argues that there is no single way of determining whether a level of exposure will have "no observable effect." One approach is to determine the NOEL obtained from an experimental study, often conducted on laboratory animals, but A NOEL established in this way is not conclusive evidence that the exposure will "have no observable effect."

Defendant further asserts that 27 CCR 25803 provides flexibility in determining the level of exposure that will "have no observable effect." It has always permitted a risk assessor to determine the statutory exposure that will "have no observable effect" using something other than a NOEL, if it is scientifically more appropriate to do so. Recent amendment to 25803 clarifies that the statutory level that will have "no

observable effect" may be determined by using a "no observed effect level in a scientific study or, alternatively, may be calculated by means of a generally accepted scientific methodology such as the benchmark dose methodology." (2011 FSOR at p.3 [Exh. F to RJN].) Further, subsection (a)(2) of 25803 provides "[w]here a study (e.g., epidemiological publication) reports a range of exposure levels associated with no observed effect, the NOEL may be selected from within the range or calculated by benchmark dose or other accepted scientific methodology."

Defendant points out that when the MADL Reg was promulgated, several commentators provided extensive review of animal studies and urged that a higher MADL be adopted. No one argued at that time for a lower MADL. Of course, no human studies have ever been done. Rather than to rely on the available animal studies, which would have resulted in an MADL that was "incompatible with human existence" (FSOR, page 80), Defendant looked to OSHA's discussion of human occupational evidence, and concluded that OSHA was treating a blood lead level of 30 µg/100 g as "a functional equivalent reproductive NOEL..." (FSOR, page 79.) OSHA relied on scientific data modeling to predict the level of lead exposure that would lead to certain blood lead levels (AR 4238), and set its PEL accordingly. Defendant used the PEL as a surrogate for the NOEL, dividing the µg/day exposure by 1,000, to establish the current MADL.

Defendant also points out that the PEL is based on a determination of the blood lead level that will result from the occupational lead exposure taking into account the existing body-burden of lead already in the worker's body from non-occupational exposures, and argues that it was reasonable for Defendant to conclude that the 500 µg/day exposure alone, i.e., not taking into account the body burden, will result in a blood lead level well below 30 µg/100 g., a level that OSHA determined would protect the fetus from harm. Defendant also explains the difference between "no effect level" and "no observable effect level," and argues that when OSHA stated that it could not determine a "no effect level" for lead, it was not stating that it was impossible to derive a NOEL for lead, or to determine an exposure that would have "no observable effect."

DISCUSSION:

It is clear to the court from its review of the portions of the administrative record presented by the parties in connection with this Motion, in particular the FSOR, 29 CFR Ch. XVII, §1910.1025 (AR 4190-4228), and Federal Register Volume 43, Nos. 220 and 225 (AR 4229-4447), that the studies reviewed by OSHA in connection with its establishment of its PEL were of high scientific caliber. Indeed, as pointed out by Defendant in its opposition, OSHA described the modeling done by the Center for Policy Alternatives, upon which much of its own analyses were based, as "an accomplishment heretofore unseen in attempts to establish air level to blood level relationships" and "the best synthesis of theory and actual research data." (AR 4338.)

The court notes that Plaintiff does not criticize the science upon which the PEL was based. Rather, while OSHA's findings and conclusions as to what levels of lead in the blood are protective of reproductive health may be appropriate for establishing guidelines for workplace exposures that would best achieve the goal of maintaining "the majority of blood lead levels" at the target levels (AR 4240), Plaintiff argues, in essence that the Proposition 65 statutory language simply does not permit scientific studies regarding human blood lead levels to be considered as an alternative to scientific studies that directly involve observations of exposures to lead in increasing amounts until a negative effect is observed, i.e., a study whose express purpose is to establish a NOEL. Since no such study can be conducted on human subjects, and the animal studies that had been done prior to 1989 appeared to show that their results could not be extrapolated to humans in a way that would be consistent with the purposes of Proposition 65, if Plaintiff's position is correct, the result would be the absence of any "safe harbor" level of lead.

As anticipated, this Motion, and indeed Plaintiff's entire case, turns on an issue of statutory interpretation. Recognizing that the level of deference to an agency's interpretation and application of its own regulations is quite high, Plaintiff's primary focus is on the language of the statute itself. In fact, Plaintiff expressly argues that Defendant is entitled to no deference because the regulation in question was based on an improper interpretation of the statute, which, in Plaintiff's view, clearly requires that any regulatory safe harbor must be based on a NOEL that is established by means of a scientific study. In support of this argument, Plaintiff relies in substantial part on the requirement set forth in H&SC 25249.10(c) that a safe harbor level must be "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 Plaintiff's view, Defendant's admittedly "unconventional approach" of using a "surrogate" for a NOEL clearly contravenes the statute. The court disagrees.

Notwithstanding Plaintiff's argument that Defendant is using "linguistic sophistry," the court finds

Defendant's explanation of the distinction between the statutory language, "the exposure will have no observable effect", and the scientific term "NOEL," to be useful and informative to the analysis. Recognition of this distinction leads to the conclusion that Plaintiff's interpretation of the statutory language is unduly constrained, which leads the court to reject Plaintiff's assertion that Defendant is due "no deference," and to conclude that the interpretation of the statute upon with Defendant's implementation of 27 CCR 25801 and 25803 was based was reasonable. (Yamaha Corp. of America v. State Board of Equalization (1998) 19 Cal.4th 1, 12.) The court further concludes that Defendant's implementation of the MADL Reg was consistent with the flexibility built into the regulatory scheme, i.e., that the evidence and standards considered by OSHA in the setting of its PEL were reasonably considered by Defendant to be of "comparable scientific validity to the evidence and standards which form the scientific basis for the listing [lead] as known to the state to cause reproductive toxicity." The court therefore defers to Defendant's statutory and regulatory interpretations upon which is decision to base its implementation of the MADL Reg on a "surrogate" for a NOEL.

The court also rejects Plaintiff's argument that, even if the blood lead level that OSHA determined should be maintained for men and women who wished to plan pregnancies were appropriate to consider in this context, the PEL itself was not set at a level that would achieve this target. As correctly argued by Defendant, 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." (E.g., AR 4339.) While Plaintiff is correct that the FSOR does not discuss the fact that OSHA recognized that the PEL would not achieve the goal of maintaining the blood level of all occupationally exposed workers below 40 µg/100 g, let alone 30 µg/100 g (AR 4240), the absence of such direct mention of the body burden issue does not establish that the issue was not considered by Defendant at the time. Again, the court defers to Defendant's interpretation and application of the underlying data to arrive at its ultimate conclusions.

In sum, the determination of how properly to set the MADL was made by an expert scientific agency reviewing complex scientific data and interpreting its own regulations in light of its scientific expertise, and its decisions were neither arbitrary nor capricious nor entirely lacking in evidentiary support. (Exxon Mobile v. OEHHA, supra, 169 Cal.App.4th at 1277.)

INTERVENOR'S OPPOSITION:

Intervenors filed a separate opposition for the express purpose of "emphasiz[ing] the importance of the lead safe harbor to the appropriate implementation of Proposition 65 and to inform the Court's understanding of the potential consequences of Mateel's challenge." While the court does not endorse Plaintiff's unkind characterization of Intervenors' brief in footnote 3 to its reply, it does conclude that policy arguments such as those raised by Intervenors have no part to play in the context of this Motion.

RULING:

Plaintiff's Motion For Judgment On The Pleadings is DENIED.

The parties' respective Requests for Judicial Notice are GRANTED.

The order will be issued by the court.

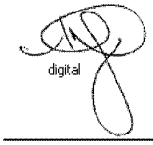
PLEASE NOTE: This tentative ruling will become the Court's order, and no hearing will be held, unless either party contacts the opposing counsel or unrepresented party, along with the Clerk of Department 21, by 4:00 p.m. on the court day before the scheduled hearing, to state an intent to appear at the hearing to contest the tentative ruling. The Clerk of Department 21 may be contacted by email to Dept.21@alameda.courts.ca.gov.

Pursuant to amended Local Rule 3.95, effective June 4, 2012, the court will no longer provide a court reporter for civil law and motion hearings or any other hearing or trial in civil departments. Parties may arrange and pay for the attendance of a certified shorthand reporter.

Ruling on Motion for Judgment on the Pleadings Taken Under Submission

Minutes of 03/29/2016
Entered on 03/29/2016

Chad Finke Executive Officer / Clerk of the Superior Court

By 

Deputy Clerk

SHORT TITLE:	CASE NUMBER:
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