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PENDING CALIFORNIA LAWSUIT HAS INDUSTRY IN WAITING

Will the existing "safe harbor" for lead exposure be eliminated?

While California is widely thought to have the country's—if not the world's—most-stringent environmental regulations, California's regulation of lead, a known carcinogen and neurotoxin, could soon become even stricter.

A veteran for-profit legal enforcement group sued the California Office of Environmental Health Hazard Assessment (OEHHA) in early January, seeking to invalidate the existing safe harbor for lead exposure. The Mateel Environmental Justice Foundation asserts the existing safe harbor is too lenient and should be eliminated.

A ruling in Mateel's favor could have sweeping effects for businesses operating in California and for businesses that serve California's large market for consumer products. Thousands of manufacturers, processors, distributors, retailers, and—yes—businesses that work with California's public water supply regularly rely on the safe harbor for lead exposure in daily operations. Lead is one of the most frequently referenced chemicals in Proposition 65 intent-to-sue letters. By one count, 412 of the 1394 Proposition 65 notice letters issued last year involved lead exposure or exposure to lead compounds.

It is no surprise, then, the California Chamber of Commerce and a large coalition of businesses and trade associations have already formally called on OEHHA to "vigorously defend itself" against the lawsuit.

If Mateel prevails, businesses operating in California could be subject to a sudden and unprecedented influx of lawsuits from plaintiff enforcement groups like Mateel. Businesses could be forced to issue costly and extensive warnings or be subject to heavy fines if using products containing even a trace amount of lead. Businesses working with California's water supply would also need to completely eliminate traces of lead and lead compounds before discharging water.

The lawsuit involves California's Proposition 65, which was created in 1986 through a voter initiative. Proposition 65 echoed growing concern among the California electorate over the harmful effects of exposure to toxic chemicals. At the time, Proposition 65 called for the nation's (and the world's) most-stringent regulation of toxic chemicals in consumer products and drinking water. Proposition 65 became the Drinking Water and Toxic Enforcement Act of 1986.

The act requires OEHHA to regularly update and publish a list of toxic chemicals. OEHHA lists chemicals scientifically proven to cause cancer or birth defects or other reproductive harm and the allowable concentrations of the chemicals in California. To date, OEHHA has listed more than 900 different carcinogens and reproductive toxins.

The act also gives OEHHA rule-making authority to issue regulations enforcing the act. OEHHA's regulations enforce Proposition 65 on two fronts. First, the regulations require businesses manufacturing, distributing, or selling consumer products in California to provide warnings/disclosures if their products contain any listed chemicals. Through disclosure, the regulations provide information to consumers needed to make informed decisions about the products they purchase.

Using a more direct approach, Proposition 65 regulations also prohibit businesses from discharging listed chemicals into sources of drinking water. The regulations create specific discharge rules for businesses working with California's public water supply.

One way to avoid the reach of Proposition 65 is to comply with safe harbor levels prescribed by the state. OEHHA establishes concentration guidelines—or "safe harbors"—for each listed chemical. To date, OEHHA has established safe harbor levels for more than 300 different toxic chemicals.

If a product contains a listed chemical in a concentration below the safe harbor level, a business manufacturing, distributing, or selling a product containing a listed chemical is not required to issue a warning. On the other hand, if the product contains a listed chemical at a concentration above the safe harbor level, Proposition 65 requires the business to issue a clear and reasonable warning to the consumer. An example warning reads: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

Businesses working with California's public water supply must also pay careful attention to safe harbor concentration levels. Listed chemicals may only be discharged into California's public water supply if the listed chemical exists at a concentration lower than the applicable safe harbor. If a business intentionally discharges a listed chemical at a concentration above the safe harbor level, that business could face severe penalties. Compliance with the safe harbor limits provide a complete defense to a Proposition 65 enforcement action brought against a company.

OEHHA currently recognizes more than 900 toxic chemicals. One of those toxins is lead. While lead has useful commercial applications in a broad range of contexts (most notably in lead-acid storage batteries commonly used in automobiles), and is still used regularly in everyday building materials, the pernicious effects of lead and lead poisoning

have been widely chronicled.

A known neurotoxin, exposure to lead can wreak havoc on the nervous system and cause numerous brain disorders. Even in small concentrations, California recognizes lead as a carcinogen and a cause of birth defects and other reproductive harm.

The water industry is, of course, no stranger to health concerns related to lead. In April of 1994, the EPA issued an "Environmental Fact Sheet" describing its concern for residents of homes and other buildings with submersible well pumps made with brass fittings. The EPA called on residents to have their drinking water tested for lead exposure, as the EPA believed the brass fittings could leach high levels of lead into drinking water.

The scare prompted Congress to pass Section 1417 of the Safe Drinking Water Act which prohibited contractors from installing pipes or other plumbing fixtures designed to carry drinking water unless those fixtures were "lead free" (defined as no more than 8.0% lead). The federal government acted again when it passed the Federal Reduction of Lead in Drinking Water Act in 2011 which updated the Safe Drinking Water Act. The new rules, which went into effect January 4, 2014, ban the "use" of lead in pipes, plumbing fittings or fixtures, solder and flux. The new regulations require products to be "lead free," defined as not containing more than a weighted average of 0.25% lead relative to wetted surfaces.

Central to Mateel's pending lawsuit, Proposition 65 sets forth a procedure by which safe harbors are calculated. For reproductive toxins, Proposition 65 matches the safe harbor level to the "maximum allowable dose level" of each reproductive toxin. OEHHA calculates the dose level for each reproductive toxin as an exposure 1000 times lower than the "no observed effect level" in the most sensitive animal study for each reproductive toxin. For carcinogens, safe harbor levels are equated to "no significant risk levels"—calculated using the same 1000 times safety factor.

OEHHA set the prescribed safe harbor concentration level for lead as a reproductive toxin in 1992 at 0.5 microgram per day (µg/day), the most-stringent regulation of lead exposure in the world. The 0.5 µg/day safe harbor level is 60 times lower than the average exposure permitted by the U.S. Environmental Protection Agency's drinking water regulation and the EPA's Air Quality Standard (30 µg/day), and 160 times lower than the exposure allowed by the EPA's Superfund lead-based soil cleanup program. Businesses operating in California have relied on the existing safe harbor for lead—and have struggled to comply with it—for more than 20 years.

OEHHA derived the existing 0.5 µg/day safe harbor using the federal Occupational Safety and Health Administration (OSHA) permissible exposure limit for airborne lead in the workplace. In turn, OSHA relied on numerous scientific studies regarding the effects of lead as both a carcinogen and as a neurotoxin.

Decades after OEHHA first established the 0.5 µg/day safe harbor for lead exposure, Mateel now seeks to rescind it. Mateel argues that the scientific studies OSHA (and OEHHA) relied on in setting the existing safe harbor are outdated and inadequate.

In its complaint filed with the Alameda County Superior Court, Mateel wrote:

> [b]y promulgating, implementing, maintaining and enforcing a safe harbor for lead that is based on data from 1978 and that did not meet or even attempt to meet the statutory requirements for setting a safe harbor level, [OEHHA is] undermining Proposition 65's goal of protecting California residents from unwarned exposures to reproductive toxins.

Mateel argues:

> OEHHA's continued maintenance and enforcement of the 0.5 µg/day regulatory safe harbor level for lead exposure frustrates and unduly complicates Mateel's program of enforcing Proposition 65 and reducing the exposure of California residents to lead.

In support of its position, Mateel points to more recent scientific studies which, in Mateel's view, demonstrate "there is no threshold exposure level below which the neurodevelopmental toxicity of lead cannot be seen to occur."

Thus, Mateel argues, no safe harbor for exposure to lead as a reproductive toxin should exist.

Some commentators label the scientific studies Mateel relies on as controversial. Many view the current safe harbor for lead as excessively stringent. In fact, the EPA in its literature assumes daily exposure to lead for adults—solely from exposure to background levels of lead in soil—ranges from 3 to 6 µg/day. Thus, from background exposure alone, the EPA assumes we are all exposed to six to 12 times the existing 0.5 µg/day safe harbor concentration.

Nevertheless, the Alameda County Superior Court will now be asked to decide whether the existing safe harbor should be allowed to stand, or whether OEHHA should be prohibited from maintaining and enforcing Proposition 65 based on the now existing 0.5 µg/day safe harbor for lead exposure.

A ruling favorable to Mateel could have wide-ranging economic and legal consequences for businesses serving the California market, including businesses operating in California's water industry. Not only would companies need to significantly alter compliance programs, a ruling in Mateel's favor might call numerous settlements and judgments into question that relied on the 0.5 µg/day safe harbor level.

If the court eliminates the safe harbor, businesses operating or marketing products in California may also be subject to an enormous and unprecedented influx of Proposition 65 enforcement lawsuits brought by groups like Mateel. Without a safe harbor to rely on, defendants would need to prove in court a safe level of lead exposure, creating enormous expense and a tremendous burden on California's already-strained judicial system.

Trade associations and California businesses are expected to file amicus briefs in support of OEHHA's defense to the lawsuit. OEHHA could also amend the existing safe harbor limit on its own through its rule-making process.

For now, businesses serving the California market—especially the water industry—should stay tuned. WWJ

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