Ongoing Legislative, Regulatory, Litigation Developments Contribute to Compliance Challenges for Business

Background

Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, is the most far-reaching consumer "right to know" law in the nation. Although Proposition 65 prohibits listed chemicals from being discharged into sources of drinking water, the law is best known for its broadly crafted warning requirement. Specifically, Proposition 65 requires businesses with 10 or more employees to provide a clear and reasonable warning before knowingly and intentionally exposing individuals to chemicals that the State of California, through the Office of Environmental Health Hazard Assessment (OEHHA), has determined cause cancer and/or reproductive toxicity. The warning requirement applies to all products sold in California, even if they are manufactured in a different state or country. Since Proposition 65 was enacted, the list of chemicals has grown exponentially to approximately 950 chemicals, making Proposition 65 a consideration—and in many ways a significant burden—for companies in virtually every industry sector.

The original intent of Proposition 65 as a consumer "right to know" law has been overshadowed by provisions built in the statute, as well as subsequent regulatory developments, which together have prompted many both within and outside of the business community to criticize Proposition 65 as a well-intended law that, over time, has been utilized less by the consumer to make informed choices, and more by opportunistic private enforcers solely for personal financial gain.

Proposition 65 contains a private right of action provision that allows private persons or organizations to bring actions against alleged violators of Proposition 65 "in the public interest." This provision, combined with the extraordinarily low bar private enforcers must meet to bring suit, has resulted in an extremely active enforcement climate.

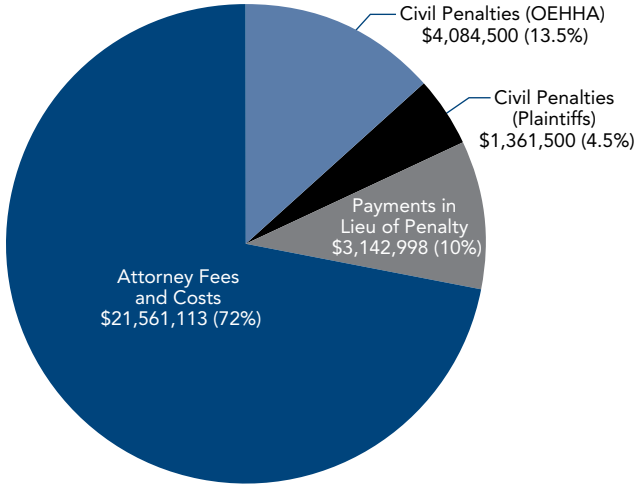
On average, private enforcers collectively serve almost three Notices of Intent to sue *per day*. In 2016 alone, private enforcers served 1,576 notices of violation on businesses in California and across the country. Of the 1,576 notices, 760 resulted in *in-court* settlements (out-of-court settlements are not included in the California Attorney General's publicly available annual settlement report) totaling $30,150,111, of which more than $21.5 million, or nearly 72%, went into the pockets of plaintiffs' attorneys.

The aggressive enforcement climate under Proposition 65 is due in large part to the fact that determining when a warning is required under the law with scientific certainty is nearly impossible, making businesses vulnerable to challenge even when they elect not to provide a warning after conducting their legal and scientific due diligence. This is because "safe harbor" levels set by OEHHA (i.e., levels above which warnings are required to be provided) are expressed in terms of amounts of exposure to a chemical per day and not in terms of the amount of a chemical found in a product or facility.

Determining exposure levels is far more complicated than determining content levels. To do this, a business may need to engage experts to undertake this complex and expensive analysis, also known as an exposure assessment. Businesses that elect not to warn on the basis of an exposure assessment concluding no warning is required are nonetheless at risk of being sued. Private enforcers typically dispute a business's exposure assessment concluding no warning is required, claiming competing science indicates otherwise. Proposition 65 statutorily places the legal burden on the business to prove that no warning is required, a burden which makes defending Proposition 65 cases very expensive. Accordingly, the practical reality facing businesses in today's Proposition 65 climate is that they must either warn—even if such warning is not required by law and they believe the statement would be false—or be sued.

Rather than risk being embroiled in litigation involving a

2016 Proposition 65 Settlements



Total Settlement Payments: $30,150,111

Source: California Office of the Attorney General

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battle of the experts at trial, businesses often elect to voluntarily provide a warning out of an abundance of caution. These types of prophylactic warnings have contributed to the oft-criticized "overwarning" problem under Proposition 65, wherein many Proposition 65 warnings are provided to shield off a legal challenge rather than to warn consumers of actual chemical exposures.

Despite being a criticized practice, overwarning often is the right business decision from a liability standpoint. Since Proposition 65 was enacted more than 30 years ago, legal challenges brought under the law have almost solely and exclusively challenged a business's decision not to warn. Plaintiffs have rarely challenged the *contents* of a provided warning, in great part because the longstanding regulations regarding what constitutes a "clear and reasonable" warning have been relatively straightforward and thus, businesses that provide warnings are less susceptible to legal challenges.

However, with OEHHA's recent regulatory update to its "clear and reasonable" warning regulations, which go into effect in August 2018, it is anticipated that more challenges regarding the adequacy of warning content will arise.

This article discusses legislative, regulatory, and litigation developments in 2017, with an eye toward anticipated developments in 2018.

The Proposition 65 Process: Whether, When and How to Warn

With so many chemical listings and ongoing regulatory proposals and litigation under Proposition 65, it is difficult for businesses to track every development and understand how each development may have an impact on them from a compliance and litigation standpoint. One relatively simple way to understand these developments and how they play into the overall compliance picture is to first understand what steps businesses must take to comply with Proposition 65. Although Proposition 65 is a complicated law, businesses need make only three determinations—some more challenging than others—in order to comply:

- First, they must determine **whether** they release or their products contain a Proposition 65-listed chemical or cause an exposure to a listed chemical (that is, the "whether " question).
- Second, they must determine **when** to warn by assessing whether individuals may be exposed to a listed chemical at levels that necessitate a warning (that is, the "when" question).
- Third, businesses providing warnings must determine what the warnings must say and **how** they must be provided (that is, the "how" question).

The 'Whether' Question

In order to comply with Proposition 65, a business must first assess whether it releases (environmental exposure), or its products contain (products exposure), Proposition 65-listed chemicals, even in trace amounts.

The Governor is required to keep a list of all substances known to cause cancer or birth defects or reproductive toxicity. OEHHA is charged with administering the program and maintaining the list of chemicals on its public website. Since it was first published in 1987, the list has grown to include more than 950 chemicals. This list of chemicals contains a broad spectrum of substances, including those that can be found in dyes, solvents, drugs, food additives, byproducts of certain processes, pesticides, tobacco products, common household items, consumer products, alcoholic beverages, vitamins and hormones.

There are four ways for substances to be included on the list:

1. State's Qualified Experts Mechanism

The Governor appoints the members to the Science Advisory Board and they are designated as the "State's Qualified Experts." The Science Advisory Board evaluates chemicals to determine if they have been clearly shown to cause cancer or birth defects or reproductive toxicity. The Board consists of two independent committees of scientists and health professionals:

- Carcinogen Identification Committee (CIC);
- Developmental and Reproductive Toxicant Identification Committee (DARTIC).

OEHHA staff scientists compile relevant scientific studies on various chemicals for the committees to review before deciding whether to list a chemical.

2. Authoritative Body Mechanism

Chemicals can be listed if an organization designated as an "authoritative body" by the state's Science Advisory Board has identified the chemical as causing cancer or birth defects or reproductive toxicity. The designated authoritative bodies are:

- U.S. Environmental Protection Agency;
- U.S. Food and Drug Administration (FDA);
- National Institute for Occupational Safety and Health;
- National Toxicology Program; and
- International Agency for Research on Cancer (IARC).

3. Formally Required to Label Mechanism

A chemical can be listed if an agency of the state or federal government requires that the chemical be labeled or identified as causing cancer or birth defects or reproductive toxicity. Most chemicals listed in this manner are prescription drugs that are required by the U.S. FDA to contain warnings relating to cancer or birth defects or reproductive toxicity.

4. Labor Code Listing Mechanism

Chemicals also may be listed if they meet certain scientific criteria and are identified by reference in the California Labor Code, which requires the California Director of Industrial Relations to establish a list of hazardous substances using specified criteria, including substances listed as human or animal carcinogens by IARC. This mechanism established the initial chemical list following voter approval of Proposition 65 in 1986 and continues, following some legal controversy over its scope, to be used as a basis for listing as appropriate.

This article discusses the ongoing legal dispute regarding OEHHA's use of the Labor Code listing mechanism.

The 'When' Question

California allows a business to use a chemical without providing

warning as long as exposure does not exceed a specified threshold level, also referred to as a "safe harbor" level. The mere presence of a Proposition 65-listed chemical does not trigger the warning requirement; instead, the threshold question is whether a product or facility would expose persons to a listed chemical or chemicals at levels above the safe harbor level.

Of the more than 950 substances on the list of chemicals known to cause cancer, birth defects or reproductive toxicity, OEHHA has developed threshold—or "safe harbor" levels—for only 300 chemicals to guide businesses in determining whether a warning is necessary. If the chemical is at or below the levels listed, the business has a "safe harbor" from providing a warning. Even then, those safe harbor levels are characterized by type of exposure (i.e., dermal), meaning some listed chemicals have received a safe harbor level for some types of exposures but not others.

If OEHHA has not set a safe harbor level, then it is the business's burden to undertake the necessary expert analysis to establish it and defend it if challenged. Indeed, by way of one example, OEHHA has not yet set a safe harbor level for exposure to bisphenol A (BPA) through ingestion despite repeated calls by the business community for OEHHA to set a level using available data and studies.

These safe harbor numbers consist of no significant risk levels (NSRLs) for chemicals listed as causing cancer, and maximum allowable dose levels (MADLs) for chemicals listed as causing reproductive toxicity. The NSRL is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. In other words, an average person exposed to the chemical at the NSRL every day for 70 years would not have more than a one in 100,000 chance of developing cancer.

For reproductive toxicants, before establishing an MADL, one must identify the level of exposure that has been shown not to pose any harm to humans or laboratory animals. This level is known as the "no observable effect level" (NOEL). The statute then requires the NOEL to be divided by 1,000 (also referred to as the 1,000-fold safety factor) in order to provide an ample margin of safety. The number, once divided, is called the MADL. The 1,000-fold safety factor has been criticized in recent years by the business community and key figures in the public health community for being an outdated methodology due to advances in science since the law was passed in 1987. But political challenges have made it almost impossible to amend, and thus it continues to be applied when adopting MADLs for reproductive toxicants.

This article discusses an anticipated appellate decision and comprehensive regulatory package anticipated in 2018 related to this question.

The 'How' Question

As noted above, Proposition 65 requires businesses with 10 or more employees to provide a "clear and reasonable" warning before knowingly and intentionally exposing them to a listed chemical, unless defenses to the warning requirement apply.

Existing Regulations

Existing regulations adopted by OEHHA's predecessor agency in 1988 establish general criteria for providing "clear and reasonable" warnings. Specifically, the current regulations allow businesses to warn however they please so long as the warnings meet existing definitions of "clear" and "reasonable." But the regulations also set forth nonmandatory guidance on general message content and warning methods, which if followed, will deem the warning to be "clear and reasonable" under the law.

For example, the regulations lay out the following prescribed warning language for consumer products:

- For consumer products that contain a chemical known to the state to cause cancer, the warning may read as follows: "WARNING: This product contains a chemical known to the State of California to cause cancer."
- For consumer products that contain a chemical known to the state to cause reproductive toxicity, the warning may read as follows: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

The regulations also lay out warning language and methods for occupational and environmental exposures, alcoholic beverages, and restaurants. Businesses using these so-called "safe harbor" warnings are protected from the threat of litigation so long as they also provide the warnings in the manner prescribed in the regulations, and thus can carry out their business with a sense of certainty.

Alternatively, the regulations allow businesses to provide warnings other than those specified, so long as 1) the method employed to transmit the warning is reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual before exposure; and 2) the warning clearly communicates that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Many businesses have successfully relied on these criteria in providing alternative warnings.

New Regulations Effective August 30, 2018

On August 30, 2016, the California Office of Administrative Law approved California's nearly three-year effort to overhaul Proposition 65's longstanding warning regulations.

The new regulations provide "safe harbor" warning content and methods for consumer product exposures, environmental exposures, occupational exposures, and tailored "safe harbor" warnings and methods for specific types of products and facilities. The new regulations also clarify the responsibility between manufacturers, retailers and others in the supply chain to provide warnings. Although the regulations were adopted on August 30, 2016, there is a two-year phase-in period. Therefore, businesses need not comply with the new regulations until August 30, 2018, but may choose to comply with the new regulations before that time.

A summary of key provisions of the new regulations can be found on the CalChamber website at *www.calchamber.com/productregulation*. To read the full regulation, visit the OEHHA website *https://oehha.ca.gov/proposition-65*.

The newly adopted warning regulations will create new compliance challenges and likely make businesses vulnerable to new types of enforcement challenges wherein the content of a safe harbor warning is challenged. The new warnings are far more specific than the prior safe harbor warnings. This specificity creates more of a compliance hurdle and creates opportunities for plaintiffs to argue that there are defects in warning programs. Additionally, for businesses wishing to contextualize their warnings through the use of supplemental information (for example, "For California consumers only"), the regulations are unclear regarding where, physically, such information can and cannot go.

In 2017, OEHHA made some amendments to its new warning regulations, attempting to clarify various provisions. The amendments are effective on August 30, 2018 as well.

This article discusses the anticipated legal challenges in 2018 relating to use of BPA point-of-sale warnings as "clear and reasonable" warnings after December 30, 2017.

'Whether' to Warn—Past/Current Legal Challenges to Labor Code Listing Mechanism

Between 1986 and 2003, OEHHA never used the Labor Code listing mechanism to list a chemical under Proposition 65. OEHHA first began using the Labor Code to add chemicals to the Proposition 65 list in 2003.

CalChamber's 2008 Statutory Authority Challenge

In 2008, the California Chamber of Commerce brought suit against OEHHA and the Governor of California, challenging OEHHA's use of the Labor Code listing mechanism. CalChamber argued OEHHA did not have statutory authority to list additional chemicals via the Labor Code because the listing mechanism applied only to the creation of the initial Proposition 65 list in 1987, shortly after the passage of the initiative. Thus, the listing mechanism was no longer operable given that the initial list had been established.

CalChamber explained OEHHA's continued use of this listing method would lead to the listing of chemicals without scientific review by OEHHA and would result in too many chemicals being listed without appropriate scientific bases. In addition, CalChamber was concerned that the listing method would harm businesses by subjecting them to enforcement actions alleging Proposition 65 violations based on chemicals that do not in fact cause cancer or reproductive harm.

Both the trial court and the appellate court ruled against CalChamber and in favor of the state, holding that the Labor Code listing mechanism was a valid method for updating the Proposition 65 list.

Current Constitutional Challenges and CalChamber's Amicus Brief

IARC designated glyphosate—the active ingredient in Roundup® weed and grass herbicide products—as a probable human carcinogen in March 2015. In response, in September 2015, OEHHA proposed to list glyphosate as a carcinogen under Proposition 65 via the Labor Code listing mechanism. OEHHA maintained that it had a ministerial duty to list glyphosate under Proposition 65 as a result of IARC's designation, and thus it had no discretion to evaluate the underlying science of IARC's designation before proposing to list it. Notably, OEHHA had previously conducted risk assessments of glyphosate in 1997 and 2007, and found glyphosate is unlikely to pose a cancer hazard to humans.

Monsanto Company and others (collectively, "plaintiffs") filed a lawsuit against OEHHA in Fresno County Superior Court in 2016. Plaintiffs argued the Labor Code listing mechanism, as applied to the proposed glyphosate listing (a lower burden to satisfy than mounting a facial challenge), violates the U.S. and California Constitutions because, among other reasons, it constitutes an unlawful delegation of legislative authority because it "leaves the resolution of fundamental policy issues—i.e., decisions about which chemicals should be placed on the Proposition 65 list—to IARC, an unelected, undemocratic, foreign body that is not under the oversight or control of any California governmental entity." Monsanto further argued that the Proposition 65 listing violated its rights to free speech under the U.S. and California Constitutions, because the listing effectively compels Monsanto to place a Proposition 65 warning on its glyphosate-based products due to litigation risk, despite the fact that it believes the statement to be false.

The Superior Court ruled in favor of OEHHA, and plaintiffs appealed to the California Court of Appeal, Fifth Appellate District. Following the Superior Court's decision, however, OEHHA added glyphosate to the Proposition 65 list on July 7, 2017. This means that the listing will take effect on July 7, 2018, triggering the warning requirement absent an order from the Court of Appeal.

Although the lawsuit focuses exclusively on the glyphosate listing, the broader business community is closely monitoring the case, as it has the potential to have widespread implications. Accordingly, CalChamber filed an amicus (friend-of-the-court) brief in the Court of Appeal supporting the reversal of the Superior Court's decision. In its amicus brief, CalChamber urged the Court of Appeal to reverse the Superior Court's judgment as soon as possible and before the Proposition 65 warning requirement for glyphosate goes into effect on July 7, 2018, citing the practical disruptive and cost impacts that will result in the absence of a speedy resolution. The case has been fully briefed.

In a separate legal challenge, initiated on November 15, 2017, Monsanto Company and various farm/agricultural and business groups filed a complaint in the U.S. District Court, Eastern District of California to challenge the glyphosate listing. The lawsuit raises, among other legal claims, an as-applied First Amendment challenge under the U.S. Constitution, seeking to prevent "mandate[ed] false, misleading, and highly controversial cancer warnings concerning the herbicide glyphosate on a wide variety of food, agricultural, industrial, and lawn and garden products." The plaintiffs further explain that the effects of the listing are already being felt throughout the supply chain. For example, millers are declining to test for glyphosate, placing the

expensive burden on farmers. Both of these cases will be keenly watched through 2018.

"When" to Warn – Appellate Decision and Comprehensive Regulatory Package on Lead Anticipated in 2018

Legal Background and Pending Litigation

• *Environmental Law Foundation v. Beech-Nut*

In March 2015, the business community secured a significant victory in *Environmental Law Foundation v. Beech-Nut Nutrition Corporation*. The *Beech-Nut* case involved claims that manufacturers of fruit juice, packaged fruits, fruit cups, and baby food failed to provide Proposition 65 warnings for exposures to lead, the most oft-targeted chemical under Proposition 65, as a reproductive toxicant. There was no dispute that the products contained trace amounts of lead; instead, the threshold question in the case was whether the amount of exposure exceeded the "safe harbor" level, or MADL, at which a warning was required. The MADL for lead had been set by OEHHA's predecessor agency in 1989 at 0.5 micrograms per day.

The trial court ruled in favor of the defendants, holding that the amount of lead to which average users were exposed did not exceed the MADL of 0.5 micrograms per day. In issuing this holding, the court agreed with the defendants' position that it is appropriate to average exposures based on the amount of lead to which a consumer was exposed over a period of time greater than a single day when there are intervening days of no exposure.

For example, for purposes of the case, the parties agreed that the average consumer of canned peaches consumes canned peaches once every 14 days. Based on that consumption frequency data, the defendants argued—and the trial court agreed—that the appropriate "safe harbor" from which to base a warning decision was 0.5 micrograms per day MADL multiplied by 14 days, the equivalent of 7 micrograms of exposure to lead once every 14 days. The Court of Appeal upheld the trial court's ruling.

• *Mateel Environmental Justice Foundation v. OEHHA*

In a legal challenge that is widely viewed as a hedge against what was anticipated to be favorable ruling for the business community in *Beech-Nut*, in January 2015, another Proposition 65 private enforcer, the Mateel Environmental Justice Foundation, sued OEHHA, contending that the existing safe harbor level of 0.5 micrograms per day was derived impermissibly by OEHHA's predecessor agency back in 1989. Arguing that the agency had failed to identify a true "no observable effect" level for lead in deriving the MADL, Mateel advocated repeal of the lead MADL entirely.

The CalChamber and the California Farm Bureau Federation intervened as defendants alongside OEHHA in the case. In April 2016, the Alameda County Superior Court ruled in favor of OEHHA on the grounds that the agency had appropriately determined a no observable effect level as the basis for the MADL in light of the agency's scientific review. Mateel has appealed the decision, and briefing in the court of appeal was completed in early 2017. To date, no decision has been issued. A decision is expected in 2018.

Beech-Nut 'Backlash' and the Anticipated Regulatory Package

In 2015, a Proposition 65 private enforcer, the Center for Environmental Health (CEH), submitted a regulatory petition to OEHHA, asking OEHHA to repeal or amend the lead safe harbor. On August 28, 2015, OEHHA agreed to consider the petition and released several pre-regulatory proposals establishing a significantly lower lead MADL, as well as other pre-regulatory proposals not identified by the CEH.

CalChamber and a coalition of food, agricultural, dietary supplement, and personal care products organizations submitted a comment letter in response to the pre-regulatory proposals. The majority of OEHHA's pre-regulatory proposals have not yet been released as formal rulemaking proposals; however, OEHHA has indicated its intent to move forward with formal rulemaking in this regard in 2018. Accordingly, it is very likely OEHHA will seek to adopt or modify the 2015 pre-regulatory proposals.

The 2015 pre-regulatory proposals are summarized below:

• Slashing the Lead MADL by 60%

OEHHA proposed to reduce the lead safe harbor by 60% (from 0.5 micrograms/day to 0.2 micrograms/day) for exposures that occur on a daily basis. The proposal marked a significant reduction in the safe harbor that has been in place for more than 25 years, and would present substantial challenges for businesses. Although OEHHA also proposed a series of safe harbor MADLs higher than 0.2 micrograms/day for exposures occurring less frequently than every day (which, like the single-day MADL, are extraordinarily low) consistent with *Beech-Nut*, the reality is that the proposal would increase both litigation risk and warnings. CalChamber expressed these concerns in its comment letter.

• 'Clarifying' That all MADLs Except Lead Are Based on a Single-Day Exposure

OEHHA proposed to "clarify" that all existing MADLs except for lead were established as a single-day MADL as part of the same regulatory package as the lead MADL proposal. In other words, according to this new policy, businesses that rely on OEHHA's MADLs in making warning decisions would not be permitted to average exposures over time consistent with the approach endorsed by the court in *Beech-Nut*.

In an October 28, 2015 letter, the CalChamber and a coalition of business organizations asked OEHHA to eliminate this proposal from further consideration because: 1) OEHHA never published a policy that all safe harbor MADLs are single-day limits only, and its published regulations lead to the opposite conclusion; and 2) OEHHA has not undertaken a scientific analysis concluding exposures must always be based on a single day for the corresponding MADLs. Just as the *Beech-Nut* court found, after considering expert testimony and evidence, that it is toxicologically appropriate to average exposures for lead based on the exposure levels in that case, there is no reason this methodology could not be used for other safe harbor MADLs and exposures where appropriate.

• Requiring Use of Arithmetic Mean When Determining the Average Rate of Exposure

OEHHA proposed to require the use of the arithmetic mean in all circumstances to calculate the average user under Proposition 65. For more than 25 years, the regulations have required compliance with Proposition 65 to be measured based on "the reasonably anticipated rate of intake or exposure for average users of the consumer product" at issue. The term "average" recognizes that different consumers use the same type of product in varying amounts and with varying frequencies. If a Proposition 65 warning were required based on exposures to those few consumers who use a product in large quantities and very frequently, then there would be unnecessary warnings provided to the large base of consumers who use the product in smaller quantities and less frequently. The regulations therefore appropriately refer to the exposure level of "average" users.

There are various approaches to determining this exposure level, and courts have applied the term "average" on a case-by-case basis, and with no difficulty, to different patterns of consumption and exposure, based on expert testimony and other evidence. Indeed, the arithmetic mean proposal directly contradicts the court's finding in *Beech-Nut*. In that case, after taking expert testimony and considering other evidence, the trial court determined that the use of the geometric mean was more appropriate than the arithmetic mean in calculating the reasonably anticipated rate of intake for average users of the food products at issue. The Court of Appeal upheld this determination. This proposal is an obvious and misguided reaction to the *Beech-Nut* ruling, and is bad policy and bad science.

Estimates of consumer exposure are only as good as the data and methods used to evaluate the data. There can be bell-shaped exposure distributions, right-skewed distributions, left-skewed distributions, and bi-modal and tri-modal distributions. Requiring the arithmetic mean as a one-size-fits-all measurement of the average will lead to biased calculations of the "reasonably anticipated rate of intake or exposure by average users" in many, many cases. Indeed, as the California Attorney General argued in a Proposition 65 enforcement action almost a decade ago, "the arithmetic mean can lead to a deceptive idea of who is typical."

In its comment letter, the CalChamber coalition asked OEHHA to eliminate the proposal from further consideration. It would make OEHHA an outlier among risk assessment agencies, and would further contradict court rulings as well as the California Attorney General's application of the law. It would substantially increase the number of warnings provided to consumers when there is no sound legal, policy or scientific basis for providing one.

• Prohibiting Averaging of Concentration Levels Across Food Lots

OEHHA proposed to prohibit averaging of concentration levels across lots of food products for purposes of determining the "level in question" under Proposition 65. This proposal would categorically require that the concentration "level in question" be "based on a single lot of the final product in the form it will be purchased by the consumer." It would also define a lot as the "quantity of a food product offered for consumer purchase having uniform characteristics and quality that is generated by one producer during a single production run, on a single processing line."

The proposal is directly at odds with the court's finding in *Beech-Nut* and, equally as problematic, it is unworkable and cost-prohibitive for many companies. Ultimately, the difficulty if not impossibility of complying with the single-lot proposal will lead to overwarning.

In its proposal, OEHHA does not reject the concept that averaging concentration levels may be appropriate to determine the "level in question." Indeed, averaging is important to calculate a reliable concentration level where levels can vary. For example, heavy metals that are present as contaminants in foods through presence in the environment can vary significantly from one unit of sale to another. OEHHA recognizes the need to average concentration levels within a lot. The same considerations apply across lots in many—if not most—circumstances.

Prohibiting averaging of samples across lots as OEHHA categorically proposes, however, is arbitrary and very often will lead to unreliable estimates of concentration levels for purposes of Proposition 65. To evaluate the "reasonably anticipated rate of exposure" by average users to the level in question, exposures must likewise be based on typical concentration levels. Concentration levels can vary from lot to lot, just as they can vary from unit to unit within a lot.

For food products in particular, multiple samples of the same lot of food often can result in different estimates of levels of heavy metals such as lead, which is not present in food in homogenous solution, but rather binds differently to various components. Thus, average users who purchase products from different lots at different times have variable exposure patterns. Indeed, the variability of concentration levels within a lot may be as great as the variability across lots.

Beech-Nut confirms that cross-lot averaging is consistent with the regulations in cases where exposure patterns are variable because of the variability of concentration levels in different lots. Despite arguments to the contrary by the plaintiff and the California Attorney General in that case, the Court of Appeal upheld the use of cross-lot averaging to determine the most reliable measure of the level in question for lead in the foods at issue. In the case of both consumers' consumption patterns and lead levels of foods they consume, it is necessary to collect and evaluate data that most appropriately characterizes the distribution of lead levels in order to reliably measure typical exposures.

In its comment letter, the CalChamber coalition asked that OEHHA eliminate the proposal from further consideration. Ultimately, it should be left to businesses to decide the most appropriate way to obtain representative concentration levels on a case-by-case basis, to make their own compliance determinations, and to be prepared to defend those determinations in court if challenged. For some businesses, this may indeed mean

single-lot testing, but this is not a question that can be answered by a "one-size-fits-all" rule.

• Establishing Naturally Occurring Background Levels of Lead in Some Foods

OEHHA proposed to establish naturally occurring background levels of arsenic in rice and lead in some foods. The Proposition 65 regulations exempt naturally occurring levels of chemicals in foods. When the regulation was adopted in 1988, it was expected to reduce the number of lawsuits and the number of warnings posted by food manufacturers and retailers in order to prevent lawsuits. The regulation has fallen short of these goals; in fact, with one exception, the only defendants that have obtained adjudicated naturally occurring allowances have done so through court-approved settlement agreements.

The reason it is so difficult for businesses to rely successfully on the naturally occurring exemption is because the regulation requires businesses to prove a series of negatives: 1) that the chemical did not result from any known human activity; 2) that the chemical was not avoidable by good agricultural or manufacturing practices; and 3) that the chemical is not present above the "lowest level currently feasible," a term that is not defined in any meaningful way.

The CalChamber coalition thanked OEHHA for the proposal, but provided the following recommendations to make the exemption more workable and effective: 1) propose additional allowances for other foods; 2) increase the naturally occurring allowances to address variability; 3) include naturally occurring allowances for mineral compounds and other food ingredients; and 4) remove the term "unprocessed" in the title of the regulation to clarify that the background levels apply to processed foods containing naturally occurring constituents.

Notably, in July 2017, OEHHA proceeded with formal rulemaking to establish naturally occurring background levels of inorganic arsenic in white and brown rice. The proposed naturally occurring concentrations are 80 parts per billion (ppb) for white rice and 170 ppb for brown rice. The comment period closed on September 7, 2017. It is anticipated that OEHHA will adopt the proposed regulation in 2018.

'How' to Warn—Anticipated Litigation in 2018

On May 11, 2015, OEHHA added BPA to the Proposition 65 list as a female reproductive toxicant. The BPA listing was done through the State's Qualified Experts (SQE) listing mechanism based on DARTIC's determination on May 7, 2015 that BPA was shown to cause reproductive toxicity based on the female reproductive endpoint. The listing received significant attention because of the chemical's use in a variety of consumer products. Indeed, more than 23,000 food and beverage products are currently listed on OEHHA's website as containing BPA.

The BPA listing went into effect on May 11, 2016. However, because BPA is commonly used in linings in canned and bottled foods and beverages, which often have a long shelf life of more than two years, OEHHA adopted an emergency regulation and a later formal regulation that, among other things, allowed retailers to provide a point-of-sale warning for exposure to BPA in canned foods and beverages through December 30, 2017. This was done to avoid a wave of litigation over BPA exposures in canned foods and beverages, and for suppliers and retailers to provide consistent warnings to consumers through posted signs in retail locations.

Although industry has requested an extension of the warning regulation, OEHHA has declined to do so. This means that, after December 30, 2017, BPA warnings must meet the existing definitions of "clear" and "reasonable," and, after August 30, 2018, BPA warnings must meet the requirements under the new regulations. While there is a maximum allowable dose level for BPA from dermal exposure of 3 micrograms per day, there is no safe harbor threshold for ingestion.

If businesses in the supply chains of products containing BPA (more than 23,000 products) elect to continue with retail point-of-sale warnings after December 30, 2017, rather than placing warnings on the products themselves, there will most likely be a flurry of 60-day Notices of Violation challenging the adequacy of those warnings. Although it may be argued that OEHHA's approval of point-of-sale warning signage for the 18-month period of the temporary regulation implies the warning is clear and reasonable, it is unclear whether a court would deem such warnings adequate.

Legislative Oversight and Action

Political Climate

In May 2013, noting that Proposition 65 has been abused by "unscrupulous lawyers driven by profit rather than public health," Governor Brown proposed certain reforms to strengthen and restore the intent of Proposition 65: 1) end frivolous, "shakedown" lawsuits; 2) improve how the public is warned about dangerous chemicals; and 3) strengthen the scientific basis for warning levels.

These proposed reforms, according to the Governor, were intended to eliminate the practice of bringing "nuisance lawsuits to extract settlements from businesses with little or no benefit to the public or the environment." As an example, the Governor cited a case wherein one group brought 45 Proposition 65 notices of violation against banks based on second-hand smoke near bank entrances or ATMs. The group claimed that the banks had failed to post warnings, and alleged that the banks controlled the behavior of smokers in those areas. In responding that there was no basis for the claim and misrepresentations within the notices, the Attorney General warned that the group's notices could "constitute unlawful business practices."

After announcing his reforms, Governor Brown convened multiple stakeholder meetings to develop legislation. Reforming Proposition 65 statutorily is difficult because it requires a two-thirds vote of each house of the Legislature and the amendment must "further the purpose of the law." Unfortunately, stakeholder groups could not agree on a solution, and the Legislature did not propose any Proposition 65 reform legislation in 2014.

Ever since the Governor announced these reforms, the

business community has been hopeful that there would be attempts, whether legislative or regulatory, to implement reforms consistent with the Governor's stated goals. Unfortunately, the opposite has happened, with new listings and complicated regulatory regimes making it even more challenging to comply and more likely to be challenged.

OEHHA has expressed a willingness to provide some businesses with protection through an increased issuance of Safe Use Determinations (SUDs). A SUD is a written statement issued by OEHHA as to whether a particular type of exposure does not exceed the safe harbor level and, therefore, does not require warnings. A SUD is not formally binding in any litigation but nonetheless represents helpful guidance. The process can be costly, and can take years to complete. OEHHA does not appear to have the resources to move forward with SUD requests expeditiously. Even if OEHHA issued more SUDs, millions of products sold within California will still be in the crosshairs of an extraordinarily complicated and misused law, meaning Proposition 65 will continue to pose significant challenges for businesses moving forward.

Greater Transparency in Proposition 65 Cases—AB 1583

Despite the two-thirds vote requirement, in 2017, the Legislature passed and the Governor signed a CalChamber-supported Proposition 65 bill—AB 1583 (Chau; D-Monterey Park). The bill promotes transparency and fairness in Proposition 65 cases via three components:

• It makes the Certificate of Merit discoverable to the public, subject to legal privileges.

Under current law, a private enforcer is required to serve a 60-day notice of violation before filing an enforcement action against an alleged violator. As part of this requirement, the private enforcer is required to submit a "Certificate of Merit," which declares that the enforcer has consulted with at least one expert who has reviewed factual information relating to the alleged violation and believes the claim is reasonable. The private enforcer also must submit factual information providing the basis for the alleged violation and supporting the Certificate of Merit to the Attorney General. The factual information is not, however, discoverable by the alleged violator in litigation. This has left the alleged violator unable to know the scope of the alleged violation. AB 1583 makes the factual information discoverable in litigation, furthering notions of fairness and transparency; however, legal privileges still apply. Accordingly, while alleged violators may discover the factual basis for the private enforcer's claim under AB 1583, they generally will be able to do so only following litigation regarding the scope of privileges attaching to such information.

• It requires the Attorney General to formally communicate to the private enforcer and the alleged violator when a claim is determined to have no merit.

The Attorney General generally contacts private enforcers when concerns about submitted Notices of Violation, including Certificates of Merit and underlying factual information, arise. However, the Attorney General is not required to do so. AB 1583 requires the Attorney General, if he/she concludes the claim has no merit, to communicate that belief via a letter to the private enforcer and the alleged violator. The bill also requires such communications to be publicly available. However, if the Attorney General fails to send such a letter, it may not be taken as an endorsement or approval of the Notice of Violation.

Although this provision may cause private enforcers to be more cautious in asserting frivolous claims, a letter from the Attorney General stating its belief that the claim lacks merit will not and does not preclude the private enforcer from moving forward with litigation. Additionally, the bill does not require the Attorney General to make a finding on each Notice of Violation.

• It requires the Governor's Office of Business and Economic Development (GO-Biz) to post information about Proposition 65 on its website.

AB 1583 requires GO-Biz to post a notice intended to help businesses learn about Proposition 65 requirements to avoid Proposition 65 violations. The notice will read:

Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, requires businesses to provide a clear and reasonable warning before knowingly and intentionally exposing anyone to chemicals that are known to cause cancer or birth defects or other reproductive harm. It is important to know that a product that receives certification from the United States Food and Drug Administration does not necessarily meet California standards for chemical exposure. Businesses should be aware of the levels of harmful chemicals in their products and of applicable Proposition 65 requirements. For more information on Proposition 65 and how to comply with its requirements, please visit https://oehha.ca.gov.

Making Proposition 65 information more readily available may assist in the education of businesses—especially out-of-state businesses—regarding the law's requirements.

Legislature Holds Proposition 65 Oversight Hearing

On August 22, 2017, the Assembly Environmental Safety and Toxic Materials Committee held an oversight hearing on Proposition 65. The committee chair, Assembly Member Bill Quirk (D-Hayward) called the hearing to consider successes, concerns, and possible reforms. The hearing consisted of presentations by various stakeholders—including academics, OEHHA, business groups, and private enforcers. No future action items were noted.

More information, including a video of the hearing and written testimony may be obtained at: *http://aesm.assembly.ca.gov/oversighthearings.*

CalChamber Position

The CalChamber supports the underlying intent of Proposition 65, which is to ensure that consumers can make reasoned and informed choices when they purchase consumer products or enter certain establishments. Unfortunately, the intent of Proposition 65 has been undermined by ever-increasing attempts to use the law solely for personal profit. For this reason, the CalChamber supports the Governor's recent calls for reforms to end frivolous, "shakedown" lawsuits, improve how the public is warned about dangerous chemicals, and strengthen the scientific basis for warning levels.

While achieving these goals legislatively has proven to be difficult, the CalChamber remains committed to initiating or otherwise supporting legislative efforts that seek to restore the original intent of the law. Indeed, legislative reforms aimed solely at addressing the law's unintended consequences can be achieved without undermining the underlying intent of law.

Whether changes are proposed in the legislative or regulatory forum, the CalChamber will continue to engage policymakers and OEHHA to ensure that any proposed changes to Proposition 65 are in line with the Governor's calls for reform.

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