

Recent Chemical Listings, Significant Regulatory Developments Increase Risk of Litigation, Create New Compliance Challenges

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 2015 alone, there were 582 *in-court* settlements (out-of-court settlements are not included in the California Attorney General’s publicly available annual settlement report) totaling \$26,226,761, of which \$17,828,941, or nearly 70%, went into the pockets of plaintiff’s attorneys. One law firm had 211 in-court settlements in 2015 totaling \$7,275,125. Remarkably, the firm’s attorney fees totaled \$5,877,825, or 81% of its total settlements.

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 which concludes that no warning is required are nonetheless still at risk of being challenged by a private enforcer who argues that a warning is required based on competing science. Private enforcers typically dispute a business’s exposure assessment concluding no warning is required. 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—or be sued.

When faced with this rather vexing reality, businesses often choose to provide a warning instead of risking a lawsuit because 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 expensive. Rather than risk being embroiled in litigation involving a battle of the experts at trial, businesses often will instead elect to voluntarily provide a warning out of an abundance of caution in order to shield themselves from the inevitable threat of litigation that would otherwise exist if they did not warn. 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 because it has historically been an extremely safe course of action 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.

As discussed below, however, OEHHA’s recent regulatory update to its “clear and reasonable” warning regulations is likely to open up an entirely new type of challenge under Proposition 65 wherein the contents of a warning are challenged as being inadequate. This regulatory development, combined with other

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developments and recent chemical listings, are likely to make compliance with Proposition 65 more difficult in the future and will almost certainly result in increased enforcement activity under the law.

Complying with Proposition 65: Whether, When and How

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).

Looking at Proposition 65 in terms of the “whether,” the “when” and the “how” is helpful because nearly every major development under Proposition 65—whether regulatory or legal—can be categorized under one of these three questions, thus making it easier for businesses to understand at what stage of the compliance process each development becomes relevant.

Accordingly, this article summarizes Proposition 65’s basic requirements and any regulatory/legal developments in order of each question. Next, because it falls outside of the scope of the three questions, this article separately summarizes a recently finalized regulatory proposal by the California Attorney General’s office regarding settlement terms for private enforcement actions under Proposition 65. Last, this article discusses what businesses can anticipate moving forward.

Step 1: 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 includes 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.

Indeed, one of the most controversial aspects of the Labor Code listing mechanism has been OEHHA’s position that the statute imposes a ministerial duty on OEHHA to list the carcinogens and reproductive toxicants identified by reference to the Labor Code sections without further review of the underlying scientific basis for such decisions. OEHHA’s position generally has been upheld with some constraints by courts over the past decade.

Legal and Regulatory Developments Pertaining to the ‘Whether’ Question

• *Monsanto v. OEHHA: Legal Challenge to the Labor Code Listing Mechanism*

In a significant legal challenge to the Labor Code listing mechanism, Monsanto Company recently filed a lawsuit against OEHHA in Fresno County Superior Court challenging OEHHA’s September 2015 proposal to list glyphosate—the active ingredient in Roundup® weed and grass herbicide products—as a carcinogen via the Labor Code listing mechanism based on IARC’s designation in March 2015 that glyphosate is a probable human carcinogen. The proposed listing is not based directly on California’s Director of Industrial Relations hazardous substance list, but rather is based solely and exclusively on IARC’s designation. After IARC’s designation, OEHHA maintained that its duty to list glyphosate under the Proposition 65 Labor Code listing mechanism was ministerial and thus it had no discretion to evaluate the underlying science of IARC’s designation before proposing to list glyphosate.

In its legal challenge, Monsanto alleges that 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.”

Although the lawsuit focused exclusively on the glyphosate listing, the broader business community is nevertheless closely monitoring the case, as it has the potential to have more widespread implications.

• *OEHHA Lists Bisphenol A (BPA)*

Although OEHHA has listed and proposed to list several chemicals over the past year, perhaps no chemical listing has received as much attention as bisphenol A (BPA) because of its use in a variety of consumer products. 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.

Once OEHHA lists a chemical, businesses have one year from the date of listing to provide warnings for that chemical. Accordingly, the BPA listing became effective on May 11, 2016. 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 proposed an emergency regulation providing retailers with the ability to provide a point-of-sale warning for exposure to BPA in canned foods and beverages. 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. This article discusses OEHHA’s emergency regulation in more detail under the “How” question below.

Step 2: 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 (see BPA discussion below).

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 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 lifeline. 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.

Legal and Regulatory Developments Pertaining to the ‘When’ Question

• *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 a 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 California Chamber of Commerce 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 will be completed by February 2017.

• **Center for Environmental Health Administrative Petition and the Beech-Nut ‘Backlash’**

Another Proposition 65 private enforcer, the Center for Environmental Health (CEH), has challenged the lead MADL on the regulatory front. CEH submitted a regulatory petition to OEHHA on July 3, 2015, asking that OEHHA 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 that do not relate to CEH’s request but which nonetheless fundamentally undermine the *Beech-Nut* ruling and the Governor’s calls for reform.

Although OEHHA’s pre-regulatory proposals have not yet been released as formal rulemaking proposals, the CalChamber anticipates that OEHHA will revisit the issue of lead and propose regulations in 2017.

• **Slashing the Lead MADL by 60%**

In response to the wave of legal and regulatory activity discussed above, OEHHA is proposing 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 current safe harbor for lead has been in place for more than 25 years, and thousands of businesses have relied on it in developing their products, operating their facilities, and instructing their suppliers. The proposal marks an extremely significant reduction in the safe harbor that will present substantial challenges for businesses to meet.

Although OEHHA also is proposing a series of safe harbor MADLs that are higher than 0.2 micrograms/day for exposures that occur less frequently than every day (which, like the single-day MADL, are extraordinarily low) consistent with *Beech-Nut*, the reality is that the proposal will increase both litigation risk and warnings.

• **‘Clarifying’ That all MADLs Except Lead Are Based on a Single-Day Exposure**

Although the CEH did not request that OEHHA make any changes to its regulations beyond repealing the lead MADL, OEHHA has nonetheless 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*.

Notwithstanding its stated position that this proposal is a “clarification” of existing policy, OEHHA has never published a policy that all safe harbor MADLs are single-day limits only. Indeed, OEHHA’s published regulations lead to exactly the opposite conclusion. OEHHA’s own regulations and the regulatory history expressly anticipate that in evaluating whether exposures exceed an MADL, one may average exposures over more than a single day when it is appropriate.

Although the plaintiff in *Beech-Nut* argued that a 1991 declaration from OEHHA employee James Donald that was submitted in a case involving crystalware demonstrated

a “policy” of a single-day limit for one safe harbor MADL (for lead), the trial court disagreed and did not give this view any weight. That ruling was upheld by the Court of Appeal in a binding decision. As a result, this one declaration of an OEHHA employee is not a statement of OEHHA policy, even for the lead safe harbor MADL.

OEHHA’s proposal also is flawed from a scientific standpoint. The record on this proposal does not show that OEHHA has reviewed the scientific literature on all 36 reproductive toxicants at issue to conclude that exposures must always be based on a single day for the corresponding MADLs. OEHHA would need to undertake that analysis before making this categorical statement, for the first time, in a rulemaking process.

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. Accordingly, in its October 28, 2015 letter, the CalChamber and a coalition of business organizations asked that OEHHA eliminate this proposal from further consideration.

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

As part of its pre-regulatory package, OEHHA also 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.

OEHHA’s draft proposal would categorically define what the “average” rate of intake or exposure means in all cases. This

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 that OEHHA 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**

In yet another pre-regulatory proposal to undermine the *Beech-Nut* ruling, OEHHA has 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, an issue that Governor Brown sought to address in his Proposition 65 reform effort.

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 Arsenic in Rice and Lead in Some Foods**

In the only attempt to provide the business community any relief, OEHHA also has 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.

In its comment letter, the CalChamber and a coalition of food, agricultural, dietary supplement, and personal care products organizations 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.

Step 3: 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 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.

Regulatory Developments Pertaining to the ‘How’ Question

• Significant Overhaul of the ‘Clear and Reasonable’

Warning Regulations

In May 2013, in addition to several other proposed reforms, Governor Edmund G. Brown Jr. called for improvements to how the public is warned under Proposition 65. Although legislative efforts to reform Proposition 65 stalled, in fall 2013, OEHHA initiated what ultimately turned out to be a controversial three-year regulatory effort to overhaul the existing warning regulations. According to OEHHA, “the existing safe harbor warnings lack the specificity necessary to ensure that the public receives useful information about potential exposures. Further, the current regulations were adopted over 25 years ago and communication technology has progressed significantly during that time. It is therefore necessary to update the regulations to take advantage of current and future approaches to providing important health-related information to the public.”

In response, the CalChamber pulled together one of the largest business advocacy coalitions ever assembled in California, with nearly 300 organizations and companies from throughout the country, to advocate for improvements throughout the regulatory process. 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 are a significant departure from the rules that businesses have relied on for decades. Accordingly, businesses will have to reassess and potentially overhaul their long-established compliance programs.

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 <http://oehha.ca.gov/medial/downloads/crnrl/art6regtextclean090116.pdf>

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.

BPA Emergency Regulation

As noted above, the BPA listing went into effect on May 11, 2016. On May 11, 2016, in an effort to ensure that canned foods and beverages would not have to be pulled off retail shelves or from distribution centers throughout the state and separately warned on a per product basis, OEHHA adopted an “emergency regulation” to allow temporary use of a standard “safe harbor” point-of-sale warning message for BPA exposures from canned and bottled foods and beverages.

According to OEHHA, “many products produced prior to or immediately after the May 2015 listing of BPA are still in the stream of commerce and will require warnings beginning in May 2016. Given this situation, OEHHA is concerned that businesses will take inconsistent approaches to compliance, particularly in the time period immediately following May 11, when the warning requirement begins.”

A synopsis of the emergency warning regulation is available on the CalChamber website at www.calchamber.com/productregulation. To read the full regulation, visit the OEHHA website <http://oehha.ca.gov/medial/downloads/crnrl/120116bpafinallanguage.pdf>

On December 2, 2016, OEHHA proposed a formal regulation on BPA, which went into effect on January 1, 2017 and will remain in effect until December 30, 2017, after which time manufacturers of canned and bottled foods and beverages will be required to provide warnings pursuant to the general warning regulations.

The formal regulation is substantively similar to the emergency regulation, with one exception: Under the formal regulation, if the manufacturer of canned and bottled foods or beverages does not warn on the product, it must, in addition to providing written notice to the retailer or its agent, provide OEHHA with certain product information in a searchable, electronic format that OEHHA will, in turn, post on its new lead agency website. Specifically, the manufacturer must provide OEHHA with a list of all food products for which a warning is being provided in which BPA was intentionally used in the manufacture of the can lining or jar or bottle seals. The product must be identified by 1) brand name; 2) product description; or 3) Universal Product Code or other specific identifying information. Where BPA is no longer used in the manufacture of the product packaging but the product is still available in commerce, the manufacturer must provide OEHHA with the last expiration or “use by” date for the product where BPA was intentionally used in the can linings or seals.

Attorney General’s Amendments to Settlement Guidelines: Well-Intended, But Likely to Increase Settlement Costs

The California Attorney General reviews private parties’

motions for settlement approval and supporting papers in Proposition 65 cases, and may participate in any settlement proceeding without intervening in the underlying case. The Attorney General also monitors overall trends in Proposition 65 litigation, and has issued annual reports summarizing all private-party Proposition 65 cases initiated since January 1, 2000. These reports are available on the Attorney General's website at www.oag.ca.gov/prop65.

On October 1, 2016, the California Attorney General finalized amendments that will affect settlement terms for enforcement actions filed by private parties under Proposition 65. The objectives of the amendments, according to the Attorney General, were to constrain private parties' use of payments-in-lieu-of penalties, increase transparency and accountability in private settlements, and reduce excessive attorney fees awards.

While the CalChamber expressed support and appreciation for the Attorney General's stated objectives, two key aspects of the proposal will fall short of its stated objectives and, worse, may increase businesses' costs in resolving private enforcement claims. Indeed, an attorney who represents private enforcement groups in Proposition 65 actions was recently quoted in *Inside Cal/EPA* as predicting that very outcome, noting that the proposal is likely to have unintended consequences and fail to accomplish the stated objectives of the Department of Justice (*Inside Cal/EPA*, "Prop. 65 'Enforcer' Argues A.G.'s Litigation Penalty Reforms Will Hike Fees," October 8, 2015).

Although the proposal contain several amendments, the following two amendments are noteworthy:

• **Rebuttable Presumption of 'Significant Public Benefit' for Reformulation**

One amendment would create a rebuttable presumption that changes in a settling defendant's practices which reduce or eliminate the exposure to a listed chemical are presumed to confer a "significant public benefit" justifying an award of fees to the settling plaintiff. In order to establish this presumption, supporting evidence must show that the product at issue either is or was at one time exposing consumers to Proposition 65-listed chemicals at unlawful levels and the product as reformulated would no longer do so. By way of contrast, today, product reformulation is deemed sufficient to confer a "significant public benefit" even if no unlawful exposures had ever occurred.

This amendment is intended to curb private enforcements whose settlement outcome confers little public benefit. The underlying concern is that today, many businesses agree to reformulate their products to settle a case even if their products had never even exposed consumers at unlawful levels. The amendment, although well-intended, is drafted in a way that has the potential to increase the costs of, and to disrupt, the settlement process in the private enforcement proceedings, when both parties are equally invested in ensuring that the settlement is finalized.

The proposal raises the risk that private enforcers, as part of negotiations, will ensure that all their fees and costs will be covered in the event that additional, high-cost evidence, such as exposure assessments, must be generated to respond to inquiries from the Attorney General or a court. Thus, settling defendants may be put in the untenable position of having to justify the terms of the settlement—at their own expense—by undertaking precisely the same costly exercise that they hoped to avoid in the first place. The increased scrutiny that the Attorney General proposed comes too late in the process when the parties simply want to settle the case and move on.

The Attorney General's goal and the public interest would be served best by imposing increased scrutiny early in the private enforcement process, and requiring plaintiffs at an early stage to provide some degree of evidentiary support that use of a product presents a level of exposure likely to exceed the relevant warning level. This "up-front" approach would be more likely to deter private enforcers from pursuing unnecessary actions in the first place, since they would have no opportunity to later shift the burden of generating the necessary evidence to the settling company in the context of settlement negotiations.

• **Additional Settlement Payments**

Another amendment will require that payments-in-lieu-of penalties, also referred to as "Additional Settlement Payments" (ASPs), not exceed the amount of any noncontingent civil penalty. A "noncontingent" civil penalty is one that must be paid by the business irrespective of what additional actions that entity may take; a "contingent" civil penalty is one that may be waived if the business undertakes additional, specified actions under the settlement.

ASPs have been components of Proposition 65 settlements for many years. These payments are not specifically authorized by Proposition 65 and are not subject to the statutory allocation of 25% to the named plaintiff and 75% to OEHHA, since they are not civil penalties subject to that allocation. Accordingly, a fairly significant amount of settlement payments are not allocated to OEHHA to support its Proposition 65 implementation duties. Further, settlements containing these payments frequently are vague about the purpose to which they will be put, and/or what third party guarantees may receive these funds, and for what purpose.

The amendment is an attempt to enhance transparency and accountability in ASPs and ensure that those payments further the intent of the law. However the best and most effective course of action for the Attorney General to take would have been to prohibit ASPs in any Proposition 65 settlement, whether court-approved or out-of-court.

Can Businesses Expect Any Relief in 2017?

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.

The CalChamber and its coalition of more than 200 entities actively engaged on this issue, and expect to do so again in 2017.

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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