

PROPOSITION 65 DINP THREAT BACKGROUND AND COMPLIANCE OVERVIEW

This Proposition 65 Background and Compliance Overview has been prepared for American Sportfishing Association's (ASA) members to standardize compliance with the California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65). In developing this Proposition 65 Overview, ASA is mindful that each member is unique, both in its products and its operations. ASA recommends that its members tailor these compliance recommendations to their individual needs.

This Overview has three parts: 1) the background of the Proposition 65 Statute; 2) suggestions for documenting and implementing your Proposition 65 compliance program; and 3) the latest threat against ASA members, relating to phthalates (e.g. DINP).

I. OVERVIEW OF PROPOSITION 65 AND ITS REQUIREMENTS

Proposition 65 requires any person "in the course of doing business" who exposes an individual in California *to any detectible* amount of a chemical "known to the state" to cause cancer or reproductive toxicity to give a "clear and reasonable" warning. The state currently maintains a list of about 950 chemicals and chemical families that are subject to the provisions of Proposition 65. Under this unique law, if a warning has not been given, the defendant can avoid liability if at trial *the defendant proves* that the exposure is below certain risk-based exposure levels.

Although primary jurisdiction is vested in the Attorney General and certain designated city and county prosecutors, *anyone* may sue to enforce the Act, as long as the putative plaintiff first gives written notice to the alleged violator and designated public prosecutors, and the public prosecutors fail to commence a civil action within 60 days. Plaintiffs must also execute a "certificate of merit" stating that they have consulted with experts and have a reasonable belief that their claims have merit.

Under Proposition 65, the Attorney General cannot stop a private plaintiff from filing a lawsuit, so there is little to prevent a private plaintiff from forming "a reasonable belief" on the slimmest of evidence. Moreover, the Attorney General does not review the evidence submitted with the certificate of merit, and defendants are unable to obtain it. Therefore, there are no meaningful measures to check bounty hunters who issue notices and use the threat of expensive litigation to extort settlements.

Even where a defendant has commissioned an exposure assessment and could prove at trial that a warning is not required, Proposition 65 cases rarely proceed to trial because of the high cost of litigation and defense. Of the tens of thousands of companies that have been sued, fewer than ten cases have gone to final judgment at trial. In the view of many, Proposition 65 permits legalized extortion of the business community by private plaintiffs, who retain twenty-five percent of any civil penalty and can also recover attorneys' fees and costs.

Regulations implementing the private enforcer provisions of Proposition 65 have been adopted that purport to make it harder for private plaintiffs to obtain reimbursement of their legal fees and costs. Among other things, when a defendant, who has received a 60-day notice of intent to sue, agrees in writing or does provide a warning prior to the private plaintiff filing the lawsuit, the private plaintiff may not be able to collect his or her attorneys' fees and costs to litigate. This has never been tested in court, and there are many legal arguments that plaintiff may use to avoid this sanction. The plaintiff may be reimbursed for the cost of the investigation and pretrial negotiations, if the underlying claim proves meritorious.

Because of the way that Proposition 65 is drafted, the fact that a warning is given is not an admission that the level of exposure exceeds the mandatory warning threshold. As a legal matter, the warning simply indicates that a detectable amount of a listed chemical is present. Businesses should realize, however, that many warning recipients may be unaware of the unique character of Proposition 65, and because the word “warning” is included in the text may assume that a significant level of a listed chemical is present. Nevertheless, by providing warnings, businesses greatly reduce their risk of being sued. We provide an overview of the law in outline form below.

A. Origins

1. The Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”) was adopted overwhelmingly by California voters in November 1986.
2. Proposition 65 was a response to perceived governmental mismanagement of toxins issues.
3. Public attention during campaign focused on drinking water aspects of Proposition 65. It is not only a “clean water” law. The greatest economic impact of Proposition 65 has been the requirement to warn of exposures to listed chemicals.
4. Proposition 65 is also an outgrowth of the continuing movement to privatize enforcement of environmental laws.
 - a. Liability under Federal and State superfund statutes has turned purchasers and lenders into governmental regulators.
 - b. Proposition 65 expands on this trend.
 - 1) “Bounty Hunter” provision, which allows anyone to enforce the act.
 - 2) The statute regulates in absence of governmental action.

B. Summary of Proposition 65

1. Proposition 65 only applies to chemicals listed by the Governor as carcinogens or reproductive toxins.
 - a. If it’s not on the list, Proposition 65 does not apply.
 - b. But, the list is big and growing. There are now over 800 chemicals on the list, including many that are normally found in building products and in commercial environments.
 - 1) List includes many common chemicals including:
 - Lead and lead compounds
 - Asbestos
 - Tobacco smoke
 - Engine exhaust
 - Alcoholic beverages
 - Formaldehyde

- Urethane
- Benzene
- Toluene
- Phthalates
- Most pesticides
- Engine oils and lubricants
- Mercury and mercury compounds

2) And many chemicals that may be used as constituents of common materials, such as:

- Di-2 (hexylehtyl) phthalate (DEHP) and Bis(8-methylnonyl) (“DIDP”) Diisononyl-phthlate (DINP) and other phthalates that are used in PVC and other plastics
- Crystalline silica (sand)

2. Two basic requirements of Proposition 65:

- a. Businesses must warn individuals of any exposure to a listed chemical; and
- b. A prohibition on the discharge of listed chemicals where they may pass to a “source of drinking water.”

C. Proposition 65 Statute

“Right to Know” Warning Requirement

- a. No person in the course of doing business shall knowingly and intentionally expose any individual to [listed chemicals] without first giving clear and reasonable warning to such individual. (California Attorney General Position: Do not need to know the exposure exceeds warning level, just that an exposure is occurring.)
- b. Warning requirement goes into effect 12 months after the chemical is listed as a carcinogen or reproductive toxin.

“No Discharge Unless Safe” Prohibition

- a. “No discharge unless safe” prohibition bans any knowing discharge or release of a listed chemical in the course of doing business where such chemical probably will pass into any source of drinking water. (California Attorney General Position: Do not need to know the discharge exceeds threshold level, just that the discharge is occurring.)
- b. “No discharge unless safe” prohibition goes into effect 20 months after the listing of a chemical.

Exceptions to Proposition 65 Warning Requirements

- a. Exposures by businesses with less than 10 employees.

- 1) “Employee” defined broadly. It may include: 1) employees of other divisions or companies owned by same entity; and 2) contract employees performing work under the supervision of manager.
 - 2) Courts are reluctant to dismiss cases on grounds of “less than 10” exemption without allowing plaintiff to complete discovery.
- b. Exposures by governmental agencies.
 - c. Preemption by Federal law. (Extremely narrowly construed.)
 - d. Exposure that poses no significant risk assuming lifetime exposure (carcinogen).
 - 1) General standard is 1×10^{-5} risk of cancer (one excess cancer case per 100,000 exposed populations).
 - 2) California’s Office of Environmental Health Hazard Assessment (“OEHHA”) has established very conservative “no significant risk” levels.
 - e. Exposure that poses “no observable effect” assuming exposure 1,000 times level in question (reproductive toxin). (This is an ultra-conservative standard).

Proposition 65 Enforcement

- a. Violations of Proposition 65 are subject to stiff enforcement, potentially resulting in civil penalties of up to \$2,500 per day for each violation.
 - 1) To calculate a potential penalty, multiply number of persons exposed, times each day of exposure, times number of chemicals.
 - 2) Proposition 65 also expanded penalties for violations of hazardous waste laws, up to \$100,000 per day.
- b. Enforcement actions may be brought by any private party “in the public interest.”
 - 1) No causation or standing requirements in Proposition 65.
 - (a) Actions might even be brought by disgruntled contractors, current or past owners and/or employees.
 - (b) Cottage industry of Proposition 65 “private plaintiffs” who bring lawsuits to “extort” settlements from defendants who will settle to avoid litigation cost.
- c. “Bounty Hunter” provision encourages “enforcement” by “private plaintiffs.”
 - 1) 25% of penalty collected is awarded to individuals bringing a successful enforcement action.
 - 2) California Code of Civil Procedure § 1021.5 provides that “successful” plaintiffs who obtain a public benefit may be reimbursed their reasonable attorneys’ fees. It is customary for plaintiffs to negotiate with a defendant to pay plaintiffs’ attorneys’ fees as part of any settlement. Regulations adopted by the Attorney General provide that any time a warning is given the litigation is deemed to confer a public benefit.

- d. Insurance generally does not cover Proposition 65 because there is no “physical injury.” In some rare cases, if tort or personal injury claims are asserted by plaintiffs, insurance defense may be available; however, expect a fight from your carrier. Plaintiffs count on high cost of defending a claim to obtain quick settlement from defendants.
- e. Legislation adopted October 2001 (SB471) purports to make it more difficult for private plaintiffs to bring meritless lawsuits, by requiring that a putative plaintiff sign a “certificate of merit” and send it to the Attorney General stating that the plaintiff has consulted an expert and determined that an exposure is occurring. (The certificate AND the expert information on which it allegedly is based, is not available to the defendant.) In practice, the law has had little deterrent effect because it is always possible for a private plaintiff to find “an expert” to certify. Even if the Attorney General determines that the claims are meritless, no one can prevent the private plaintiff from filing a lawsuit. Thus, defendants are forced to choose between litigation and a settlement on plaintiff’s terms.

II. SUGGESTED COMPLIANCE PROGRAM FOR CONSUMER PRODUCTS

Choosing a Proposition 65 compliance method is a business decision that weighs the cost, time, risk and customer expectations. There are two primary schools of thought. 1) Warn for everything; or 2) Reformulate everything to prevent listed chemicals from being present. As a practical matter, most companies use a combination of both depending on the chemical at issue, the specific product, and the risk of litigation for that chemical and product. In the case of fishing tackle, the principal chemicals currently are lead (from contamination as well as intentional use) and phthalates (including DINP & DEHP). Thus, a company may choose to provide prophylactic warnings for some products that may have lead or phthalates.

A. Considerations for implementing blanket warnings.

The provision of a warning is a cheap and effective insurance policy, as it will prevent bounty hunter lawsuits. However, it raises a number of other concerns that may have a deleterious impact on business operations. First, even if a company has two separate SKU’s for every product – one for California and one for the rest of the world – it can be a challenge to prevent third party distributors and retailers from shipping unlabeled product to consumers in California.

This is especially true since most bounty hunters purchase their product exemplars over the internet and many target unaffiliated web sellers, like Amazon. Bounty hunters also sue the retailer as well as the manufacturer. It is common practice for the retailer to seek indemnity for any enforcement costs from the manufacturer. In this way, even small businesses having fewer than 10 employees that import or distribute products may be adversely impacted by this law even though they cannot be sued under Proposition 65 directly.

Second, Californians may not pay much attention to Proposition 65 warnings on product labels – after all they are everywhere and on everything, including food, alcohol and coffee. However, consumers in other states and countries often become concerned when they receive these warnings. In other jurisdictions, warnings actually mean something, and Proposition 65 warnings have created difficulties for companies that use them on products sold out of state.

If a company does choose to use warnings on products, there are some things to remember. First, it is strongly recommended that warnings be **placed on the label of every product**. There are other ways to provide warnings, but they simply do not work well and may not afford the protection from suit. The warning should be at least as prominent as any other cautions or instructions on the label, but no smaller than 10-point type. It does not need to be on the front label, but should be on the exterior package and placed so that it is likely to be seen by the consumer at the time of purchase.

There are two warnings – one for reproductive toxins and another for cancer. Some chemicals are listed only for cancer, others only for reproductive toxins, and some for both risks. It is important that the correct warning for the chemicals in the product be provided. These warnings are:

For carcinogens: WARNING: This product contains a chemical known to the State of California to cause cancer.

For reproductive toxins: WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

For both: WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

There is another problem on the horizon for those who take the blanket warning approach. OEHHA has proposed changes to the regulations implementing Proposition 65 warning. One of the changes would prohibit the provision of a warning unless the manufacturer has evidence that a listed chemical is in the product. Also, the new regulations would require that some chemicals be identified in the warning, this includes identifying lead, phthalates and other chemicals that are commonly subject of litigation by name in the warning text. The regulations have not been adopted. You can check the progress of the proposal at: http://oehha.ca.gov/prop65/CRNR_notices/WarningWeb/Notice2Jan2015.html.

B. *Considerations for implementing a Proposition 65 compliance program that does not require warnings.*

For various reasons, a company may choose not to provide Proposition 65 warnings on some products. One factor weighing in favor of this strategy is the growing group of large retailers who refuse to sell products that have Proposition 65 warnings on the labels. Thus, manufacturers who choose to provide warnings on the majority of their products may still need a program to ensure that certain products may be sold without warnings. There are many ways that a company may implement a “warning free” compliance program, all of them complex and often costly to administer. The following is a generic description of a five step program:

- 1) Identify the regulations and standards that may apply for each type or category of product that the company manufactures or imports from foreign manufacturers;
- 2) Identify the appropriate test methods that will allow the company to confirm compliance and meet customer expectations as appropriate from both a legal and business perspective;
- 3) Implement processes that ensure applicable standards are met during new product development; and

- 4) Implement of a quality assurance and testing program that ensure that manufactured products meet applicable standards.

We outline each of the four steps below.

1. Identify the Regulations and Standards that Apply to Each Product

Many ASA members manufacture a wide range of consumer products, including but not limited to tackle, bait and lures, fishing accessories, outdoor accessories, gift items, children's items, and clothing. These items are regulated by several federal and state laws and may also be the subject of voluntary standard setting. The applicable regulations depend upon the item's design, materials and expected use. The pertinent federal and state requirements may include standards set by the FDA, the CPSC, the FHSA, the EPA, and the implication of Proposition 65. Most companies are aware of these standards and have programs to comply with them. In many cases, testing and compliance with federal standards provide some guidance that will be helpful when developing a Proposition 65 program as well.

To investigate Proposition 65 chemicals, the best starting place is to identify the constituents of all of the materials that are used to make the product. As a matter of law, material suppliers must be able to provide a Safety Data Sheet ("SDS") that identifies the chemical constitutes, and even includes a section that states whether any Proposition 65 listed chemicals may be present. One thing to be aware of when using the SDS is that these documents do not cover contaminants that may be present. If there is a doubt about the purity of the ingredient, the supplier should be able to provide more detail upon request.

2. Apply Testing Standards for the Company's Primary Products.

Based on the identification above and further discussions with the personnel responsible for production, quality assurance and testing, the Company should create a list of products that may contain Proposition 65 listed chemicals. Using this list, the Company should test the products and perform an exposure assessment to determine if the level of exposure exceeds the warning requirement. In some cases, it may be possible to use tests that are required to implement other laws to also test for Proposition 65 compliance. For example, CPCS, OSHA and FDA have a number of test methods that may be adapted for Proposition 65 investigation. However, it is likely that the Company may need to retain a qualified Proposition 65 consultant, or train in-house personnel to perform this assessment.

One note of caution, there are a number of large commercial laboratories that advertise that they can assist businesses with Proposition 65 compliance. Be wary of any laboratory making this claim, as most reputable labs do not provide "legal" or compliance advice, but simply perform testing. These "compliance labs" often give a document that stats a "pass" or "fail" for Proposition 65 compliance, and do provide the actual laboratory analysis that shows the test method, the method of detection, and other details that will be necessary if your test is challenged by a bounty hunter or a public prosecutor. In most instances, Proposition 65 compliance *cannot* be assured by a "total content" test, or any single "wipe test." Without the actual test documentation, the "certification" from these compliance labs is at best hearsay and misleading – more often these results are inadequate or wrong.

Part of these compliance labs sales pitches is that they claim to be testing products to a standard approved by a California court in a consent judgment. Unless you are a party to the consent judgment, the test chosen by these labs may not apply to your product or chemical at issue. Each year many unsuspecting companies pay for testing that proves worthless when challenged by Proposition 65 private enforcers. Instead, Proposition 65 compliance can only be determined by an *exposure assessment*,

which involves looking at the average use of the product, not simply the amount of the chemical contained in the substrate. Proposition 65 is unlike any other statute because compliance can only be determined by an exposure assessment, not simply a test of the content of or emissions from the product. What you will need is either an in-house expert or a consultant, usually based in California, who has actual experience doing these assessments. If you use a consultant, they will review the product and determine what tests should be run.

3. Implement a New Product Compliance Procedure

Compliance begins whenever a new product or even a new variant of an existing product is contemplated. At this point, the regulations that apply to each new product should be identified, the materials that will be used to manufacture it must be reviewed, and component parts that may be purchased from third parties must be taken into account. Reference to the regulations that the product must meet will enable the Company to select appropriate raw materials. Follow the same steps as in 2 above.

Two things deserve emphasis. First, when the Company uses components purchased from a vendor, the Company must require the product vendor to identify all of the regulations that the component must comply with, to certify compliance with those regulations, and provide the test results to prove that the component complies with the regulation. Your company is entitled to rely on the certifications of its vendors, but should consider obtaining its own test results if the Company has not worked with the vendor previously, or if the product is particularly complex or contains the materials with which the Company is not familiar.

Second, whenever new materials or additives are used in a product, the Company should carefully scrutinize the materials and conduct pre-production testing. For the most part, testing conducted to EU and/or Canadian standards should be sufficient to qualify the materials and product for the North American market. However, if the products or components are coming from Asia, care should be taken not only to test samples before purchase, but also retest a representative number of the delivered products. Purchasing and Quality Assurance personnel should play an important role in new product development.

4. Implement a Quality Assurance Program to Verify Compliance.

If the pre-production testing and verification program is sound, production quality assurance and compliance may be focused on ensuring that there are no failures or problems due to manufacturing variances or equipment malfunctions. Large companies may have an in-house lab that monitors quality and conducts routine testing. This program should continue to be the primary tool for monitoring the quality and compliance of the manufactured product to Proposition 65 standards. Smaller companies may wish to randomly select products and send them to outside labs for compliance testing.

III. OVERVIEW OF PHTHALATE LITIGATION THREAT AGAINST ASA MEMBERS

In 2008, Congress adopted the Consumer Product Safety Improvement Act of 2008 (“CPSIA”), which banned six different plasticizers – phthalates – in children’s products.¹ Phthalates are a family of chemicals that are constituents of soft vinyl and other plastics. The CPSIA banned phthalates are

¹ <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/>

DEHP, DBP, BBP, DINP, DIDP, and DNOP. All but one of these phthalates (“DINP”) was on the Proposition 65 list of chemical at the time the CPSIA was adopted.

The CPSIA triggered a flood, literally thousands, of Proposition 65 bounty hunter litigation against consumer products made from or containing plastics. Even though it is unlikely that any warnings are required for these phthalates, all of the defendants have settled – rather than litigate. It has become standard requirement in every consent judgment to require the plasticizer that is the target of the Proposition 65 litigation to be reformulated to the CPSIA standards for children’s toys - .01 percent, or 1000 ppm. There is no Proposition 65 requirement for this, but most bounty-hunters refuse to settle unless this reformulation occurs. The Proposition 65 bounty hunters use this “reformulation” obligation as justification for their high fees and also as “evidence” of the great public benefit they are achieving.

On December 20, 2013, California’s Office of Environmental Health Hazard Assessment (“OEHHA”) put DINP on the Proposition 65 list as a carcinogen. The listing was extremely controversial, as the evidence used to list the chemical was only animal data, and the cellular mode of action that caused the cancer in the animals is not present in human beings. Moreover, the listing studies were based on “force feeding” the animals large amounts of DINP – there was no data that dermal exposure caused cancer. The American Chemistry Counsel (“ACC”), a trade association of plasticizer manufacturers, sued OEHHA seeking to set aside the listing. ACC did not prevail at trial, in part, because it challenged OEHHA’s statutory authority to list on animal data, rather than prove that the chemical is not a human carcinogen, which would have allowed the chemical to stay on the list, but prevented bounty hunter litigation. (*See Baxter v. Denton* (2005) 120 Cal.App.4th 333.) ACC has filed an appeal, but a decision will take at least another year. In the meantime, the private enforcers are circling.

On December 20, 2014, the Proposition 65 warning requirement for DINP exposures in California took effect. Beginning the next day, private enforcers begin issuing notices of intent to sue to companies whose products contained DINP. To date, over 180 notices have been issued by about a dozen different “bounty hunters.” Each notice went to several companies and involve a wide range of items that are also produced by ASA members – including packaging, vinyl clothing (vests, boots, gloves), tool grips, and fishing lures. In August 2015, one of the new bounty hunters, Kingpun Cheng, targeted our members selling soft vinyl fishing lures. We believe more of these notices will be issued in the near future.

ASA members use vinyl and soft plastic in many products they sell. As such, the amount of DINP that a consumer may be exposed to from touching fishing tackle and accessories – even wearing vinyl gloves – is well below the level at which a Proposition 65 warning is required. Consequently, the bounty hunter claims are without merit. The problem, as always, is the cost to defend these meritless claims – a factor that bounty hunters count on to divide, conquer and keep coercive litigation going for years.

IV. CONCLUSION

ASA is continuing to monitor Proposition 65 litigation against members, especially the new DINP threat. If your company has been served with a notice, please contact _____.

The above material has been prepared for ASA members by Carol Brophy, Sedgwick, LLP. It should not be considered a substitute for consultation with your attorney. Neither the author nor the Association make any express or implied warranty in regard to the use of the materials set forth. Each member and his or her attorney must depend upon his or her own knowledge of the law, their product line and expertise in the use of these materials.