Prop 65 Regulatory Activity Raises New Compliance Questions for Industry

**Summary:** This news alert explores recent developments in California under Proposition 65, including programmatic changes, new chemical listings, and related litigation. Companies that operate in California should be aware of these developments and the implications for their business.

Over the past year, California has seen a significant amount of activity under Proposition 65 (Prop 65), a law which requires businesses to warn consumers if they will be exposed to listed chemicals above threshold amounts, including both programmatic developments and actions on individual chemicals. The state has proposed regulations that would update consumer warning requirements and that would affect settlement terms, attorney’s fees, and penalty amounts resulting from private enforcement. The state also finalized regulations that will guide the development of a website providing supplemental information to consumers and finalized regulations that will result in the automatic listing of chemicals that are given certain designations by an international cancer research organization. At the individual chemical level, bisphenol A was recently listed under Prop 65, a no significant risk level will go into effect for the phthalate DINP in the coming weeks, and a listing for styrene may be announced soon. Finally, this report concludes by noting certain chemical/product combination trends that have appeared in recent enforcement notices.

**Programmatic Developments**

*Attorney General Proposed Modification: Settlement Terms, Attorneys Fees, and Penalty Amounts*

On September 25, 2015, the California Office of the Attorney General published a **proposed rulemaking** (AG Proposal) that would affect settlement terms, attorney’s fees and penalty amounts in civil actions filed by private plaintiffs under Prop 65 and would aim to provide increased transparency and judicial oversight of settlement agreements. A subsequent **amendment to the proposed rulemaking** was issued on February 4, 2016.

The proposed rulemaking would have the following effects:

1. The guidelines regarding the recovery of plaintiffs’ attorney’s fees would be modified to:
a. Call for a showing that the public benefits derived from the settlement are “significant;”
b. Make the presumption that a public benefit is conferred by reformulation of a product, rebuttable; and
c. Require contemporaneous record-keeping for investigation costs sought to be recouped in the settlement.

2. The regulations regarding civil penalties would be amended to add new requirements where the terms of a settlement waive civil penalties in favor of conduct by the defendant by requiring that a defendant’s conduct be related to the purpose of the litigation and provide environmental and significant public health benefits to California.

3. The regulations related to settlements and additional settlement payments would be modified in the following ways:
   a. Private enforcers who enter into a settlement in the absence of a filed complaint, would be required to serve the Attorney General with the settlement and a Report of Settlement within five days after any violation alleged in the notice is subject to a settlement;
   b. Parties to settlements that include additional settlement payments would be encouraged to submit their settlements for judicial approval; and
   c. The Attorney General would establish a list of criteria to determine whether it will object to the inclusion of additional settlement payments.

Proposition 65 Website Regulations

On January 25, 2016, OEHHA adopted a regulation regarding the establishment of a website, operated by OEHHA, which would provide supplemental information to the public regarding exposures to listed chemicals. The regulation was initially proposed on January 16, 2015, alongside a proposal to repeal and revise Article 6 of Prop 65 Clear and Reasonable Warning Requirements.

Content for the website will be developed through responses to OEHHA information requests, which will be issued to businesses providing a Prop 65 warning for exposures to substances contained in their products. In response to a request, a business “must provide … when reasonably available” a range of information about the relevant exposure to OEHHA. However, a business that receives a request for information would not be required to develop new information.

OEHHA may request the following types of information:

1. Concentrations of the chemical for which a warning is provided;
2. The location of the chemical in the product;
3. The estimated level of exposure to the chemical or chemicals in the products;
4. The anticipated routes and pathways of exposure; and
5. “Any other related information.”

The regulation becomes effective on April 1, 2016, although the timing for the website to come online is not clear. Further, OEHHA has not asserted a time frame during which businesses could anticipate requests for information.

Labor Code Listing Mechanism

On October 1, 2015, a regulation requiring chemicals given certain designations by the International Agency for Research on Cancer (IARC) to be listed under Prop 65 went into effect. The new regulation is known as the Labor Code Listing Mechanism. To meet the Labor Code Listing Mechanism criteria, the chemical or substance must be classified by IARC as:

- Carcinogenic to humans (Group 1);
- Probably carcinogenic to humans (Group 2A) with sufficient evidence of carcinogenicity in experimental animals; or
- Possibly carcinogenic to humans (Group 2B) with sufficient evidence of carcinogenicity in experimental animals.
Any person may petition OEHHA for the listing of a substance via the Labor Code Listing Mechanism.

**Developments for Individual Chemicals**

**Diisononyl Phthalate (DINP) Developments**

On December 20, 2014, the warning requirements for the phthalate DINP went into effect without a No Significant Risk Level (NSRL), prompting a significant number of notices from citizen enforcers. In response, industry requested from the state multiple Safe Use Determinations (SUDs) for DINP, including vinyl flooring, vinyl carpet tile, fabric in outdoor furniture, and PVC roofing products. In November 2015, an SUD was granted to Chemical Fabrics & Film Association, Inc. for the use of DINP in certain single-ply polyvinyl chloride roofing membrane products. On April 1, 2016, an NSRL of 146 mg/day will go into effect for DINP, meaning that no labeling requirement will apply to a product if the product would expose consumers to less than that amount of DINP.

**Bisphenol A (BPA) Developments**

On May 11, 2015, OEHHA listed BPA as a substance known to the state to cause reproductive toxicity (female endpoint) without establishing a maximum allowable dose level (MADL). BPA was also listed in 2013 and then almost immediately delisted. Under the listing, as of May 11, 2016, Prop 65 warnings will be required for all exposures to BPA unless the person causing the exposure can show that the exposure is 1,000 times below the no observed effect level for the chemical. OEHHA has not yet defined such a level.

Given the implications of requiring warning labels and the perceived widespread use of BPA, OEHHA proposed two regulations on March 17, 2016:

1. **Emergency Regulation for Exposures to BPA from Canned and Bottled Foods and Beverages.**
   - This emergency regulation would allow manufacturers and retail sellers to comply with Prop 65 by providing retail sellers with a standard point-of-sale warning for exposures to BPA from canned and bottled food, in lieu of a label affixed to the product itself.
   - Upon approval by the OAL, the regulation will be effective immediately, for 180 days. During this time period, OEHHA intends to commence a regular rulemaking process to adopt the regulation as an interim measure for a one year period from the date of adoption, to allow for an orderly transition to providing warnings for BPA exposures.

2. **Proposed Adoption of an MADL for Dermal Exposures to Bisphenol A from Solid Materials.**
   - The proposed regulation would establish an MADL of 3 micrograms per day for dermal exposures to BPA in solid materials, which the regulation defines as “materials in solid form [which] include, but are not limited to items such as paper and plastics.”
   - Comments on the proposed regulation are due on May 16, 2016; which is after the warning requirements for BPA go into effect. The adoption of this MADL by OEHHA would eliminate the uncertainty about the presumptively safe dose level. However, any manufacturers seeking to take advantage of an adopted MADL would need to conduct an exposure assessment that would take into consideration multiple factors, including consumer use patterns and rate of transfer, all of which are subject to challenge. Nevertheless, an assessment showing that the exposure associated with a particular product is below the proposed MADL may provide the business selling the product a level of comfort in deciding not to provide a warning.
   - This proposed MADL is two orders of magnitude below the MADL proposed for the 2013 listing for BPA. The 2013 listing of BPA was related to developmental toxicity, and therefore, studies used as the basis for the MADL were focused on fetal development and prenatal exposures. The 2015 listing of BPA was for female reproductive toxicity and the proposed MADL is therefore based on different studies.
Styrene Developments

OEHHA issued a Notice of Intent to list styrene on February 27, 2015. Due to an impending California Administrative Procedures Act deadline, OEHHA will likely list this chemical under Prop 65 in the coming weeks, or else elect to allow the Notice of Intent to lapse.

Other Substances

<table>
<thead>
<tr>
<th>Substance</th>
<th>Listing Status</th>
<th>Date Issued</th>
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<tbody>
<tr>
<td>Beta-myrcene</td>
<td>Listed</td>
<td>Labeling Required March 27, 2016</td>
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<tr>
<td>BPA</td>
<td>Listed</td>
<td>Labeling Required May 11, 2016</td>
</tr>
<tr>
<td>Aloe vera, whole leaf extract</td>
<td>Listed</td>
<td>Labeling Required December 4, 2016</td>
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<tr>
<td>Goldenseal root powder</td>
<td>Listed</td>
<td>Labeling Required December 4, 2016</td>
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<tr>
<td>Topiramate</td>
<td>Listed</td>
<td>Labeling Required November 27, 2016</td>
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<tr>
<td>Teriparatide</td>
<td>Listed</td>
<td>Labeling Required August 14, 2016</td>
</tr>
<tr>
<td>Abiraterone acetate</td>
<td>Notice of Intent to List</td>
<td>Issued on January 29, 2016</td>
</tr>
<tr>
<td>Pentachlorophenola and by-products of its synthesis</td>
<td>Notice of Intent to List</td>
<td>Issued on October 30, 2015</td>
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<tr>
<td>Tetrachlorvinphos</td>
<td>Notice of Intent to List</td>
<td>Issued on September 9, 2015</td>
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<tr>
<td>Parathion</td>
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<td>Issued on September 9, 2015</td>
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<tr>
<td>Malathion</td>
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<tr>
<td>Glyphosate</td>
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Litigation Developments

The chemicals involved in the most enforcement actions were lead and lead components, DEHP, and DINP. Recent notices have been issued regarding the following chemical/product combinations:

- DINP in Vinyl/PVC Gloves, Ponchos, Hoses, and other PVC or Vinyl coated products
- DEHP in Earphone/Headphone Components
- DEHP in Vinyl products (tape, envelopes, cords, etc.)
- Lead and lead compounds in dietary supplements
- Lead in brass and metal polishing products
- Lead and lead compounds in various brass objects (brass locks, fittings, screws, etc.)
- Lead and lead compounds in spices (ground ginger, turmeric, curry powder, etc.)
- Lead and lead compounds in seafood (seaweed, dried shrimp, crabmeat, etc.)
- Lead and lead compounds in wallets, handbags, purses, clutches, belts, etc. made with leather, vinyl or imitation
- Lead and lead compounds in ceramic mugs with exterior decorations and other ceramic products
- Nicotine, Formaldehyde (gas), and Acetaldehyde in Electronic Cigarette Devices or related accessory liquids
- Cadmium in various Cacao-based foodstuffs
- Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) in tents
- Coconut oil diethanolamine condensate (coamide diethanolamine) in cosmetics and shampoos
- Benzophenone in lotions, sunscreens, etc.

Beveridge & Diamond regularly counsels clients in California and worldwide on Prop 65 compliance questions and warning requirements, and has litigated major Prop 65 matters. With special input from our San Francisco office, the firm provides California-based insights, tracks regulatory developments, and assists clients with Prop 65 negotiations, adding state-specific chemical restriction expertise to the firm’s national regulatory compliance practice. For more information about how Prop 65 relates to your business, please contact Mark Duvall.

Updated March 31, 2016