

California Proposition 65/BpA and The Vision Council

- California state law from 1986
 - > Safe Drinking Water and Toxic Enforcement Act
- Requires labeling/warning on products that contain any one of nearly 1,000 chemicals on the CA Prop 65 Listing of Chemicals
- Prop 65 violation suites can be brought forth by the state or “private enforcers”
 - > CA allows for “Private Right of Action”
- May 11, 2015 - BpA added to list of Prop 65 Chemicals.
- May 11, 2016 – products containing BpA will require labeling/warning.

The Vision Council Member Interactions BpA & Proposition 65

- **February 2, 2015** – Issue a Member Wide Alert on American Chemical Council Lawsuit on the addition of BpA to the Prop 65 list of Chemicals
- **May 13, 2015**– Issue a Member Wide Alert that the American Chemical Council has lost its Lawsuit and BpA Relisted and will be enforceable May 11, 2016. OEHHA expected to issue a BpA Safe Harbor
- **November 18, 2015** – Issue a Member Wide Alert Prop 65 'Safe Harbor List' Update - OEHHA has delayed the Prop 65 Safe Harbor list is **delayed and it is OEHHA's intention to have one in place before the May 11, 2016 enforcement date.**
- **December 17, 2015** – Hosted two member webinars related to Prop 65 BpA Compliance.

The Vision Council Member Interactions BpA & Proposition 65

- **January 22, 2016** – Rick Van Arnam learns from OEHHA officials that the agency is no longer considering the adoption of a BpA Safe Harbor.
 - > **February 1, 2016** – Issue a Member Wide Alert informing members

- **March 8, 2016** – Issue a Member Wide Alert introducing the California Proposition 65 – BpA Labeling Guide

- **March 17, 2016**- OEHHA issues The proposed “safe harbor” level is 3 micrograms per day for dermal exposure
 - > **March 18, 2016** TVC Issues a Member Wide Communication
 - » *Now we have details on a possible testing protocol (Dermal Exposure) and a potential safe harbor number (3 micrograms per day).*

CA Prop 65 – TVC Member Resources

- California Proposition 65 Guide for Ophthalmic Suppliers
- California Proposition 65 BpA Labeling Guide
- Access to Rick Van Arnam, TVC Regulatory Affairs Counsel.
- Access to Michael Vitale, TVC Technical Director



THE **VISION** COUNCIL



GOVERNMENT & REGULATORY AFFAIRS PROPOSITION 65 SUMMIT

2016 Vision Expo East

April 14, 2016

California Proposition 65

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- > **Duty to warn law since 1985; not a ban**
 - > **Substances found to cause cancer, birth defects or reproductive harm**
 - > **Phthalates; lead; + 800 other substances; now BpA**
 - > **Based on exposure**
 - > **Consumer product exposure**
 - > **Occupational and environmental exposure**
 - > **History of private enforcers targeting optical products**

Exceptions to Prop 65

- > **Companies with 9 or fewer employees**
 - > Must consider related companies
- > **Federal, state and local agencies**
- > **Substances within safe harbor limits**
 - > Based on exposure, not ppm
 - > Exposure testing is expensive
 - > Not every substance has a safe harbor limit

Bisphenol A

- > **Trace amounts found in polycarbonate**
- > **Was added back onto Prop. 65 list May 11, 2015**
- > **As of May 11, 2016, BpA is ripe for enforcement.**

BpA Safe Harbor

- > **OEHHA published notice on March 17, 2016**
- > **3 micrograms per day**
- > **Comment period to end on May 16, 2016**
 - > **After May 11th enforcement date**
 - > **Will only apply to dermal contact**
- > **Will 3 micrograms per day cover us?**
- > **Must prepare for May 11th.**

Compliance for Consumer Product Exposure

- > **Product exposure warning:**
 - > ***WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm***
 - > ***WARNING: This product contains a chemical known to the State of California to cause cancer***
 - > ***WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm***

Compliance for Consumer Products

- > **Can be on product packaging or on product**
 - > **Clear and Reasonable**
 - > **No font requirements**
 - > **Must be conspicuous**
 - > **Must be given prior to exposure**
- > **Can be on point of sale signage**
 - > **Clear and Reasonable**
 - > **Must be available prior to exposure**
 - > **Warning must be linked to your product**

Compliance for Work Place Exposure

- > **Work place exposure warning:**
 - > ***WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm***
 - > **Or – compliance with :**
 - > **Hazardous Communication Standard (29 CFR 1910.1200)**
 - > **California Hazard Communication Standard (8 CCR 5194), or**
 - > **Pesticides and Worker Safety Requirements (3 CCR 6700)**
 - > **Typically this will require posting a sign**

Disposal of Swarf or Products Containing Named Substances

- > Violation for discharging or releasing listed chemical substance into water or land if it will pass into drinking water**
- > Ok as long as you use a solid waste disposal or hazardous waste disposal facility**

Prop 65: New Proposed Changes

- > Possible changes to the warning language:
- > Two years after date of promulgation.
- > Change warning language.
 - > Include the following symbol.



Proposed Changes

- > **Proposed Revision for Consumer Products –**
 - > ***“WARNING: This product **can expose** you to **[NAME OF ONE OR MORE CHEMICALS]** a chemical [or chemicals] known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to [www.P65 Warnings .ca.gov](http://www.P65Warnings.ca.gov)”***

Proposed Changes

- > **Proposed Revision for Environmental Exposure –**
 - > ***“WARNING: Entering this area **can expose** you to **[NAME OF ONE OR MORE CHEMICALS]** a chemical [or chemicals] known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to [www.P65 Warnings .ca.gov](http://www.P65Warnings.ca.gov)”***

Proposed Changes

- > **Allow manufacturers to partner with retailers and to provide retailers with point of sale warning signs**
 - > **Retailers would have to post them.**
 - > **Shifts compliance to the retailer.**
 - > **Should ease inventory issues.**

Prop 65 FAQ

- > Do I have to comply with the warning requirements?**
 - > Letter of the law, yes. But it's a business decision.**

- > If I sell to an entity that is exempt from Prop 65, am I exempt too?**
 - > No.**

- > Are my internet sales exempt from Prop 65?**
 - > No. Must post warning on web site. True for companies with no physical presence in California.**

Prop 65 FAQ

- > **Am I covered by a retailer's warning sign posted at its door?**
 - > **Not likely. To be effective, warning signage must be associated with your product.**

- > **Can I use point of sale warning signs.**
 - > **Yes, but must be associated with your product. Highly subjective.**

Prop 65 FAQ

- > How big does the product warning have to be?**
 - > No size requirement; Clear and Reasonable**

- > What happens if my product is separated from its warning by the retailer?**
 - > Product could be considered noncompliant. Warning needs to be communicated to customer prior to exposure.**

Prop 65 FAQ

- > **Then how do I get the retailer (or OD/Dr) to provide the warning?**
 - > **Engage them and explain the ramifications.**
 - > **Consider legally sufficient point of sale signage option.**

- > **Can I put my warning on a warranty card? Or on the invoice? Or with use instructions?**
 - > **Goal is to be “clear and reasonable” prior to possible exposure. Warnings on these documents are suspect.**

Prop 65 FAQ

- > **Should I warn for cancer, and reproductive toxicity?**
 - > Warn for what is in your product.
 - > BpA must warn for “birth defects and other reproductive harm.”
 - > State frowns on over warning.
- > **If we provide sufficient warnings, or fall into a safe harbor, are we insulated from law suits?**
 - > Theory, yes; application, no.
 - > Make it hard for the bounty hunters.

Questions

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