

GOVERNMENT & REGULATORY AFFAIRS UPDATE

2016 Executive Summit
Lens Division Meeting

January 29, 2016

THE VISION COUNCIL
EXECUTIVE SUMMIT



Unique Device Identifier

- > Request for Exception.
 - > Submitted by members in Aug/Sept 2015.
 - > Meeting with FDA on October 2, 2015.
 - > Continue follow up and expect a decision soon.
 - > Optimistic for a positive result.
 - > Only focused on lenses.

- > Compliance date September 23, 2018.

Bisphenol A

- > Chemical of issue to the optical industries.
 - > Trace amounts found in polycarbonate.
- > Was added back onto Prop. 65 list May 11, 2015.
 - > Subject to 1 year grace period before enforcement could occur.
- > Thus, as of May 11, 2016, BpA is ripe for enforcement.
- > THERE WILL BE NO SAFE HARBOR AT THIS TIME.

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 cancer]."*
 - > 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.

Compliance for 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 [or cancer].”*
- > Can be on product packaging, or point of sale signage.
- > Must make the warning available prior to exposure.

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 state licensed solid waste or hazardous waste facility.

Post Webinar Questions

- > **Font requirements?**
 - > No. Warning must be "clear and reasonable."
 - > Warning must be proximate to exposure and conspicuous.
 - > Warning must be available prior to exposure.

Post Webinar Questions

- > **What is a consumer product?**
 - > Not crystal clear. Not defined.
 - > "Consumer products exposure" is
 - > 1. an exposure that results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good,
 - > 2. or any exposure that results from receiving a consumer service.
 - > *If you handle a consumer product, and you know it contains a Prop 65 substance, then you have a duty to warn someone you transfer it to unless the product's label contains a warning.*

Post Webinar Questions

- > Which label do I put the warning on?
 - > Label is any written, printed or graphic material upon a product or its immediate container.
 - > Labeling includes accompanying materials.
- > But, is it available prior to the exposure.

Post Webinar Questions

- > What is a business with 9 or fewer employees?
 - > This includes all employees, not just those present in California.
- > What about separately incorporated subsidiary?

Prop 65: New Proposed Changes

- > We filed comments to NPRM.
- > 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)”.*
 - > Will establish font requirements.

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”.*
 - > Will establish font requirements.

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.

Questions

- > Rick Van Arnam, Esq.
- > Barnes, Richardson & Colburn, LLP
- > 100 William Street, Suite 305
- > New York, NY 10038

- > (212) 725-0200, ext 126
- > rvanarnam@barnesrichardson.com