

This Is **WHY I EXPO**



# CA Prop 65 and Other State Regulations

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## This Is WHY I EXPO

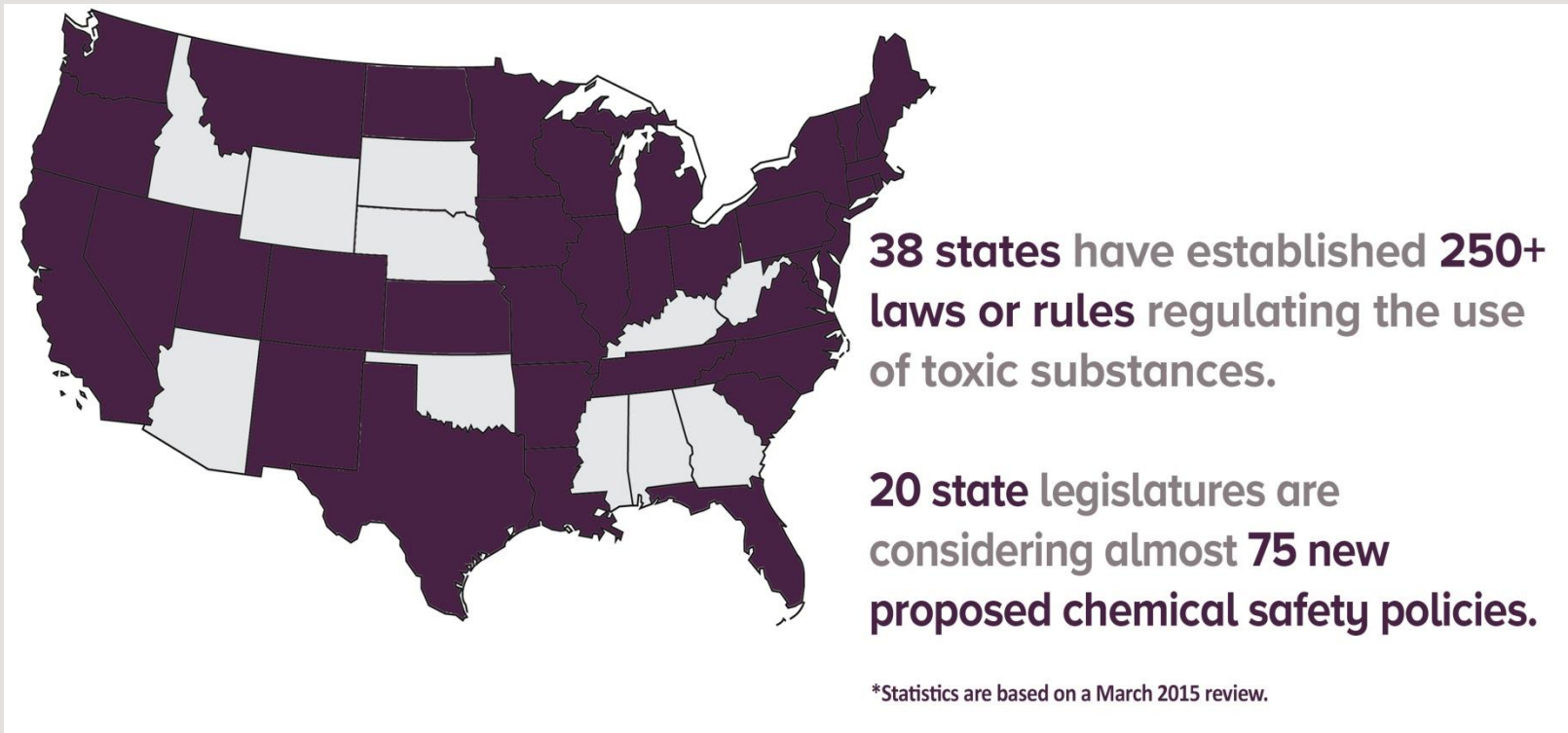
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## Agenda

- TSCA
- California
  - CA Prop 65
  - California Safer Consumer Products Regulation
- US State Regulations
- TSCA Reform
- Lautenberg
- Preemption
- What's Next?

Many States are passing new chemical regulations.  
Why?



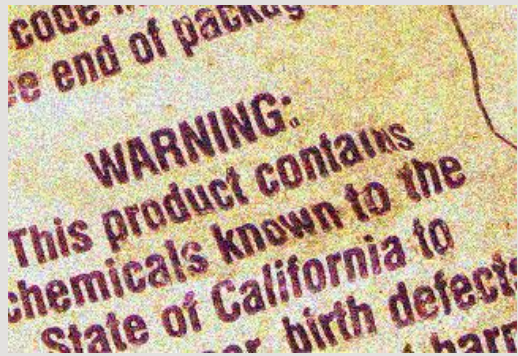
## TSCA

- The Toxic Substances Control Act (TSCA) was passed in 1976 and remained essentially unchanged for 40 years.
- It is administered by the EPA
- Applies to chemicals based on their intended use
- TSCA inventory as it exists today:
  - More than 62,000 chemical substances in commerce in 1976 were presumed safe and “grandfathered” into the initial inventory with no review
    - These substances may remain on the market with no restrictions
  - Over 21,000 new chemicals added to the inventory since 1976

## Criticism of TSCA – Data Gap

- No review of existing chemicals
- No toxicity testing or exposure assessment data
- Burden on EPA not industry to prove safety
- EPA required to only adopt least burdensome regulatory requirement (e.g. asbestos)
- Of the 80,000+ chemicals in inventory, EPA has only been able to require testing for 400 and require a ban on 5

## California



### Cal Prop 65

The Safe Drinking Water and  
Toxic Enforcement Act of 1986



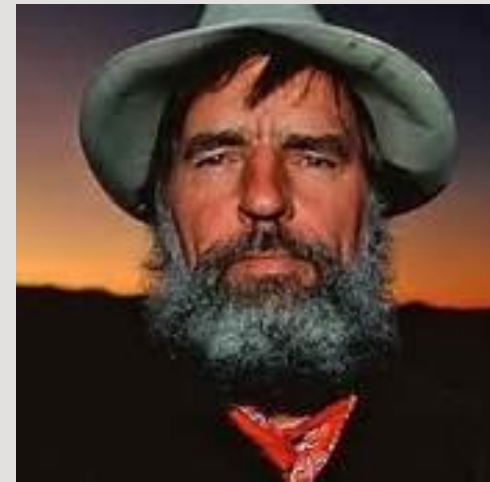
### Safer Consumer Products Legislation

(Green Chemistry Initiatives)  
(2013)

# This Is WHY I EXPO

“There is science, logic, reason;  
there is thought verified by  
experience. And then there is  
California.”

--Edward Abbey





## Prop 65 – The Basics

- California Safe Drinking Water Toxic Enforcement Act (Prop 65) was approved by the voters of California in 1986
- Purpose is to give consumers a chance to make an “informed decision” to protect them from exposure to chemicals.



## Prop 65 – The Basics

- California's Office of Environmental Health Hazard Assessment (OEHHA ) must annually publish a list of chemicals known to cause cancer, birth defects or other reproductive harm.
- In 1986 that list included 30 chemicals
- It now includes 900+ chemicals



## Prop 65 – The Basics

- Once a chemical is listed by OEHHA, companies have 12 months to comply with warning requirements under the regulation
- Prop 65 applies to:
  - Any person in the course of doing business
  - Businesses that employ 10 or more employees
  - Environments and products



## Warnings Only

- Provide a “clear and reasonable warning” before knowingly and intentionally exposing anyone to a listed chemical

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

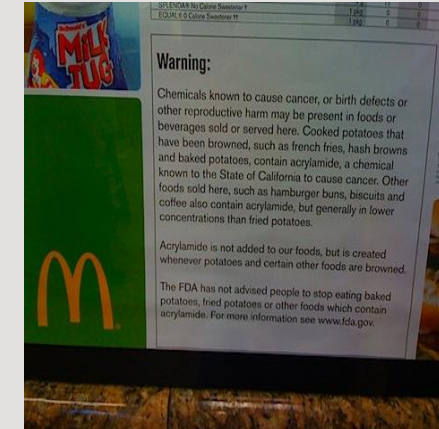
**WARNING:** This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

## Warnings Only

- Warnings must be given prior to sale
  - On product or shelf signage
  - On selling websites that ship to California residents
- Warnings are not required on websites that don't sell the product
- Warnings are not required outside the state of California



# This Is WHY I EXPO





## Prop 65 is an Exposure Regulation



### Methods of Exposure:

- Oral
- Inhalation
- Transdermal
- Hand-to-mouth



### Measuring Exposure:

- In most cases, exposure is measured in micrograms per day, based on average use of the product. Very difficult and expensive to defend a claim, since burden is on maker.



### Recent Lead and Phthalate Cases:

- Newer cases involving lead and phthalates have mirrored CPSIA content limits

## Enforcement of Prop 65

- By 60-day Notice
- Who enforces Prop 65?
  - State Attorney General's Office enforces Prop 65
  - District and City Attorneys
  - **Private Enforcers aka Bounty Hunters**
    - Any individual may bring an action to enforce





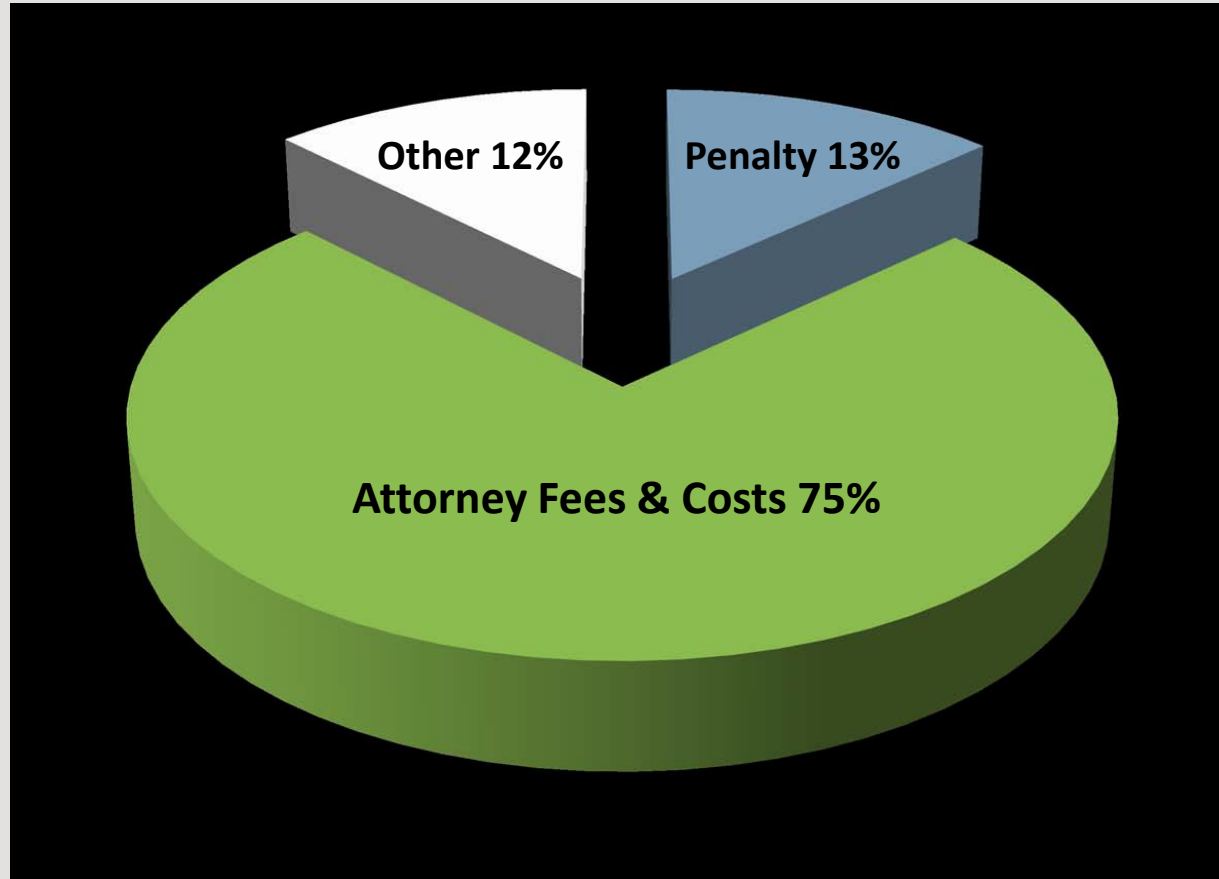
# Examples of Enforcement

- California recently put BPA on the Prop 65 list as a reproductive toxicant
- Hazard based decision based on exposure
- California adopted a limit for BPA dermal exposures of 3 µg/day
  - FDA daily intake limit from food is about 2700 µg/day
- Prop 65 bounty hunters only have to show your product **contains** BPA
- You have to show the exposure is below the 3 µg/day limit

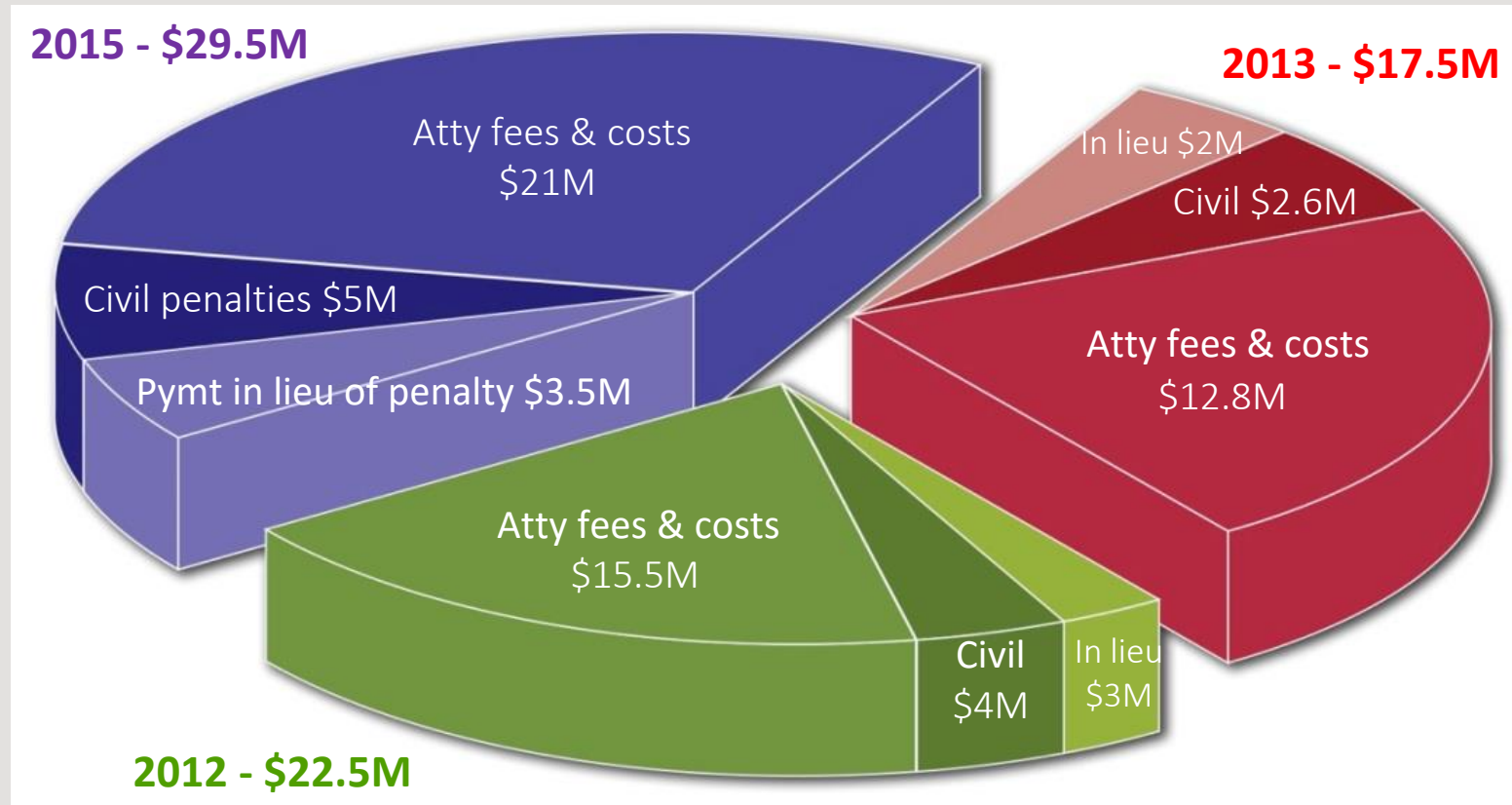
## Penalties

- Failure to comply is enforceable by penalties up to \$2,500 per day per violation
- Private enforcers can enter into settlements and split the money with State
- The court approves and enters judgment against business owner.
  - Example: Shipment of 500 mugs = \$2,500 per mug
  - **$\$2,500 \times 500 = \$1,250,000$  per day**

## Who Wins?



## Total Settlements by Year



Source: <http://oag.ca.gov/prop65>

## Trends

- Products noticed for violation:
  - Lead
  - Leather
  - Brass (key chains, pens, pen holders)



## Trends

- Phthalates
  - Gym bags
  - Recreational gear bags
  - Shower/bath accessories
  - Checkbook covers
  - Fitness balls
  - Hats
  - Wireless cable charger
  - Travel cases



# What Can Suppliers/Importers Do To Comply?

- Check Chemical List published and updated by the OEHHA and can be found at [www.oehha.ca.gov](http://www.oehha.ca.gov)
- Test for all 900+ chemicals? Not reasonable
- Know what chemicals are in the product and test the product if it contains chemicals noted on the OEHHA list
- Engage a certified toxicologist to review the product to determine if an exposure exceeding safe harbor limits exists
- LABEL with appropriate Prop 65 warning statement

# What Can Distributors Do To Comply?


- Ask the customer if the will or could be distributed in California and tell the supplier
- Check Chemical List published and updated by the OEHHA and can be found at [www.oehha.ca.gov](http://www.oehha.ca.gov)
- Confirm with the supplier than none of the 900+ chemicals are in the product
- Ask for test reports
- LABEL with appropriate Prop 65 warning statement



# Reform of Prop 65

- Ask the customer if the will or could be distributed in California and tell the supplier
- Check Chemical List published and updated by the OEHHA and can be found at [www.oehha.ca.gov](http://www.oehha.ca.gov)
- Confirm with the supplier than none of the 900+ chemicals are in the product
- Ask for test reports
- LABEL with appropriate Prop 65 warning statement

# New Prop 65 Warnings

- As of August 30, 2018, warnings must contain the use of the phrase: “This product can expose you to...” AND specifically name the chemical
- Warning must be preceded by a bold black-outlined, yellow equilateral triangle with an exclamation point in the center 
- For internet sales, warning must be included
- When foreign languages are used, warning must also be in those languages

## Current vs. New Clear and Reasonable Warnings

**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 birth defects or other reproductive harm.



**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information, go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).



**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information, go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)



**WARNING:** Cancer- [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

# New Prop 65 Warnings Guiding Principles

- The warnings must be given at or before the point of purchase (prior rules applied to *use* or purchase) therefore **avoid**:
  - Package insert warnings
  - Warnings on invoices

## Prop 65 Warnings

- A product specific warning that automatically provides the warning to the purchaser prior to or during the purchase transaction without requiring the purchaser to seek out the warning
- On-product:
  - On-product warning (package, label)
  - Product-specific warning on sign at point of display
- Catalog:
  - In a manner that clearly associates it with the item being purchased

# Prop 65 Internet Warnings

- Internet:
  - A warning transmitted on the display page
  - A hyperlink marked “warning”
  - Prominently display the warning prior to completion of the purchase
- Note
  - A product sold online must be accompanied by an online warning even if it also bears an on-product warning.
  - This online warning requirement applies to downstream customers as well (if you have an e-commerce portal, you must provide this warning requirement)

## Looking Ahead

- We can expect the new warning style to raise questions and concerns
- We can expect enforcers to carefully scrutinize products—particularly ecommerce portals

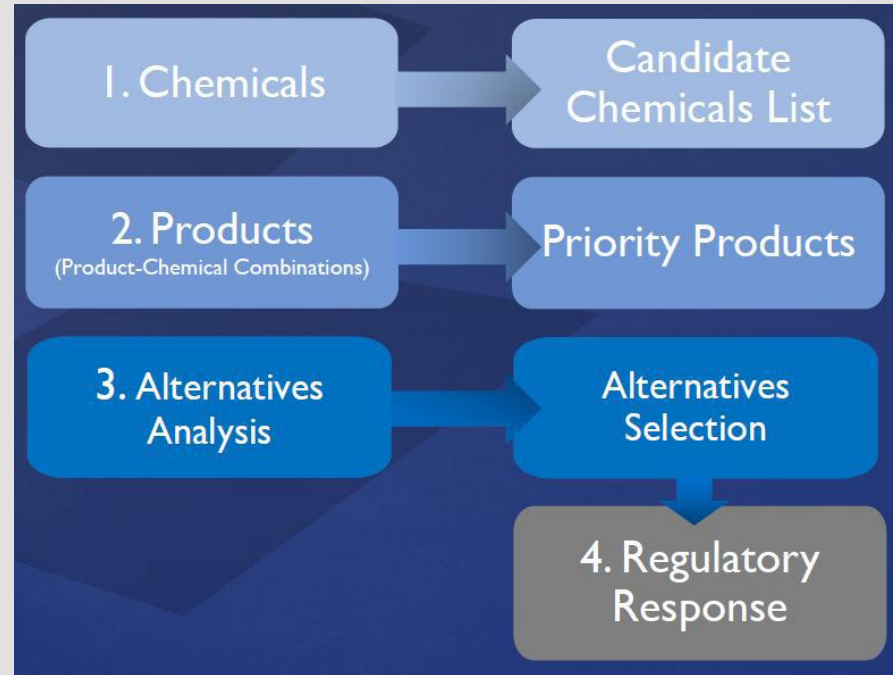
# California Safer Consumer Products Regulations

- Intended to reduce toxic chemicals in consumer products
- Asks manufacturers two questions:
  - Is the chemical necessary?
  - Is there a safer alternative?
- Requires manufacturers to conduct a thorough analysis of alternatives
- Effective October 1, 2013 and will be phased in over the next several years



## California Safer Consumer Products Regulations

### 4 Step Process



# California Safer Consumer Products Regulations

- The Priority Products and Candidate Chemicals:
  - Spray Polyurethane Foam (SPF) Systems containing unreacted diisocyanates
  - Children's Foam Padded Sleeping Products containing Tris (1,3-dichloro-2-propyl) phosphate or TDCPP
  - Paint and Varnish Strippers with methylene chloride
- On July 15, 2016, DTSC released proposed "Priority Products List" regulation
- DTSC scheduled a public hearing on the proposed regulations on August 29, 2016
- Regulations have been issued

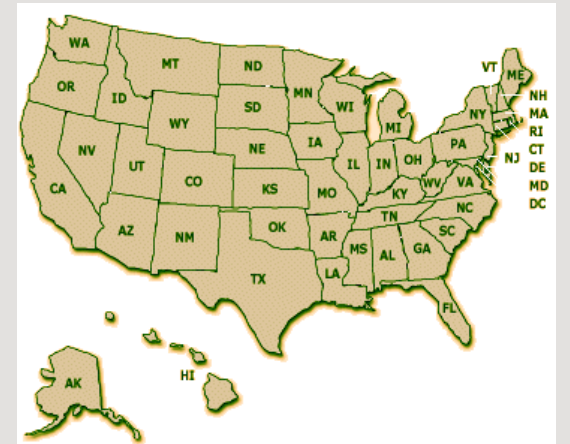
# California Safer Consumer Products Regulations

In April 2015, the DTSC finalized a 3 year work plan with the following product categories:

- Beauty, personal care and hygiene products
- Building products (adhesives, paints, sealants, etc.)
- Household, office furniture and furnishings
- Cleaning products
- Clothing
- Fishing and angling equipment
- Office machinery (i.e. ink cartridges)

## US State Regulations

- Northeast Recycling Council (NERC): applies to toxics in packaging act
- Illinois Lead Poisoning Prevention Act: Labeling requirement—essentially drops lead limits to 40ppm
- Washington State Children's Safe Product Act: reporting requirement
- Maine's Toxic Chemicals in Children's Product Law: reporting requirement
- Vermont SB.239: reporting requirement
- Oregon SB 478 – Toxic Free Kids Act: reporting requirement
- And more...



## Regulatory Categories

- Children's products
- Flame retardants
- Bisphenol A (BPA)
- Plastic bag suffocation warnings
- Stuffed toy labeling
- Jewelry
- Restriction of Hazardous Substances
- Drawstrings

## TSCA Reform

- Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act
  - After 40 years, finally reconciled bipartisan bill
  - Signed into law on June 22, 2016
  - Effective immediately

## Lautenberg Significant Changes

- “Resets” TSCA inventory—Active chemicals
- Mandates risk evaluations for new *and existing chemicals*
  - New chemicals: require a safety determination before entering the market
  - Existing chemicals: provides for prioritization for risk evaluations
  - EPA must establish a method to prioritize chemicals

## Lautenberg Significant Changes

- Sets deadlines for mandatory actions
- Defines and strengthens risk evaluation—costs and benefits cannot be factors
- Includes new definitions
- Sets limits for confidential business information claims
- Includes new fees and increased penalties
- Offers some preemption



## Lautenberg Significant Changes

- Defines susceptible subpopulations and strengthens protections
- Creates provision to investigate potential cancer clusters

## Lautenberg Impact on Promotional Products Industry

- Products and components subject to TSCA:
  - Printing inks
  - Paints / coatings
  - Fabric treatment chemicals: flame retardants, water repellants, wicking treatments
  - Writing instruments
  - Adhesives on sticky notes
  - And more...

# Lautenberg Impact on Promotional Products Industry

- An entity's role in the supply chain is key
  - If you are an importer, you are a manufacturer
- More complicated compliance challenges
  - There are many points of intersection between regulations enforced by other agencies including FDA and CPSC
- More required information on hazards, use and exposure
  - Product type in which a chemical is used
  - Current and foreseeable uses
  - Exposures throughout the supply chain including downstream use
  - Focus on susceptible subpopulations

# Lautenberg Requirements

- EPA must issue procedural rule for prioritization process by June 2017
- Risk-based screening process—likely to start with chemicals on the 2014 update of the TSCA Work Plan for Chemical Assessments
  - Review your chemical sourcing / portfolio to determine if any may be candidates for high priority designation

## Regulation of Chemicals

- If a chemical you manufacture, import, process or use is regulated, there is potential disruption to the supply chain
- May be required to identify substitution chemicals / alternative sourcing
- Will be essential to evaluate not just efficacy and performance, but relative “safeness” of substitution chemicals

## Preemption (CPSIA, Section 231)

- Does NOT preempt California Prop 65
- Pre-existing state regulations specifically exempted
- When EPA starts evaluating a chemical, state activities related to rulemaking are paused until after the evaluation is complete or the deadline expires
- If EPA determines a chemical to be low risk, state regulation is pre-empted

## What's Next?

- December 2016:
  - EPA lists first 10 new work plan chemicals
- June 2017:
  - Final method for prioritizing chemicals
  - Final risk evaluation method for high priority chemicals
- June 2018
  - Proposed alternative toxicity testing strategy

## Product Responsibility Resources

**PPAI:** [www.ppai.org](http://www.ppai.org)

**PPAI Corporate Responsibility:** <http://www.ppai.org/inside-ppai/corporate-responsibility/>

**UL:** [www.ul.com](http://www.ul.com)

**Questions?** [AnneS@ppai.org](mailto:AnneS@ppai.org) 972-258-3041