



California Proposition 65 & State Regulations

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preemption

noun | pre·emp·tion | \-'em(p)-shən\

- 3 : a doctrine in law according to which federal law supersedes state law when federal law is in conflict with a state law

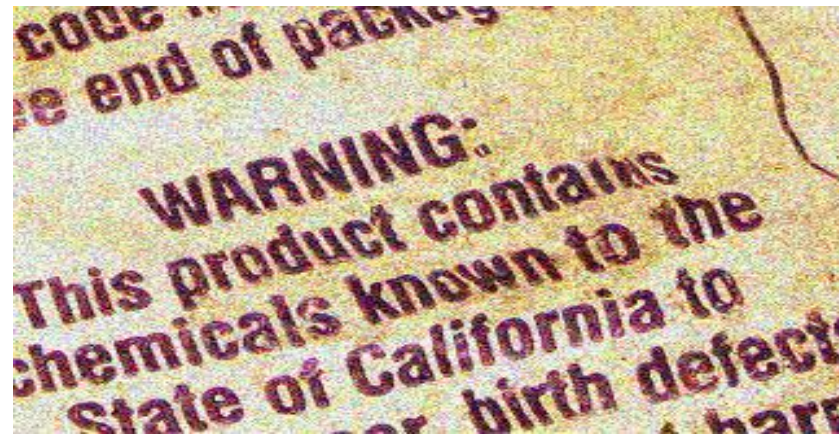
Preemption (CPSIA, Section 231)

- If covered by a Federal regulation (CPSA, FHSA, FFA, PPPA), the State or Local law is essentially preempted
- Preemption does not apply for California Proposition 65
- Preemption does not apply to restrictions not covered by Federal regulation
- State may apply for exemption from preemption



California Proposition 65

- The Safe Drinking Water and Toxic Enforcement Act of 1986
- Administered by the Office of Environmental Health Hazard Assessment (OEHHA)



California Proposition 65

Overview

- State must publish a list of chemicals known to cause cancer, birth defects or other reproductive harm
- Business are required to provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone to a listed chemical
- Allows Californians to make “informed decisions” about protecting themselves from exposure to these chemicals



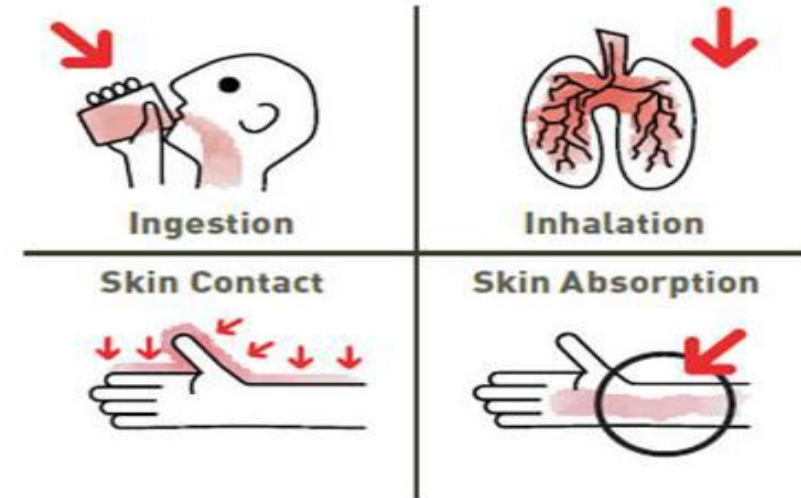
California Proposition 65

Exposure

- Exposure regulation
- Oral, inhalation, transdermal, hand-to-mouth
- Measured in micrograms per day, based product

Exposures can occur via...

- Consumer products' use, manufacture, or sale
- Environmental discharge of listed chemicals
- Occupational exposures to listed chemicals



California Proposition 65

Requirements for Businesses

- Provide clear and reasonable warning before knowingly or intentionally exposing anyone to a listed chemical
- Once a chemical is listed, companies have 12 months to comply with warning requirements
- Companies can comply if chemicals are within “safe harbor” limits

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.



California Proposition 65

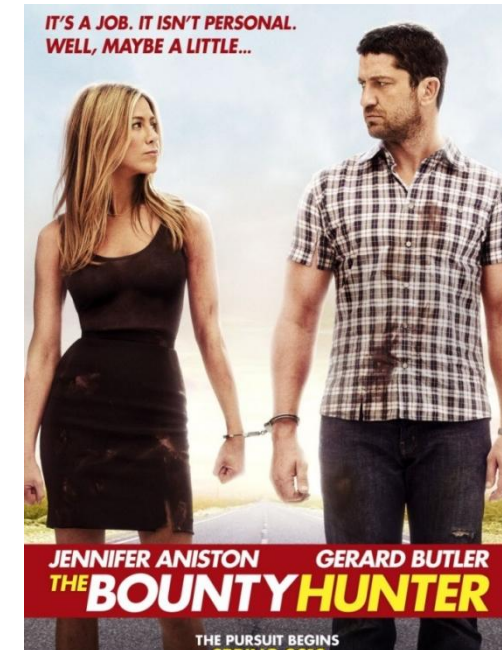
Exemptions

- Businesses with less than 10 employees
- Governmental agencies and public water systems
- Safe harbor levels have been established for many Prop 65 listed chemicals
- Exempt if No Significant Risk Level (NSRLs) for cancer-causing chemicals and Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity are not exceeded

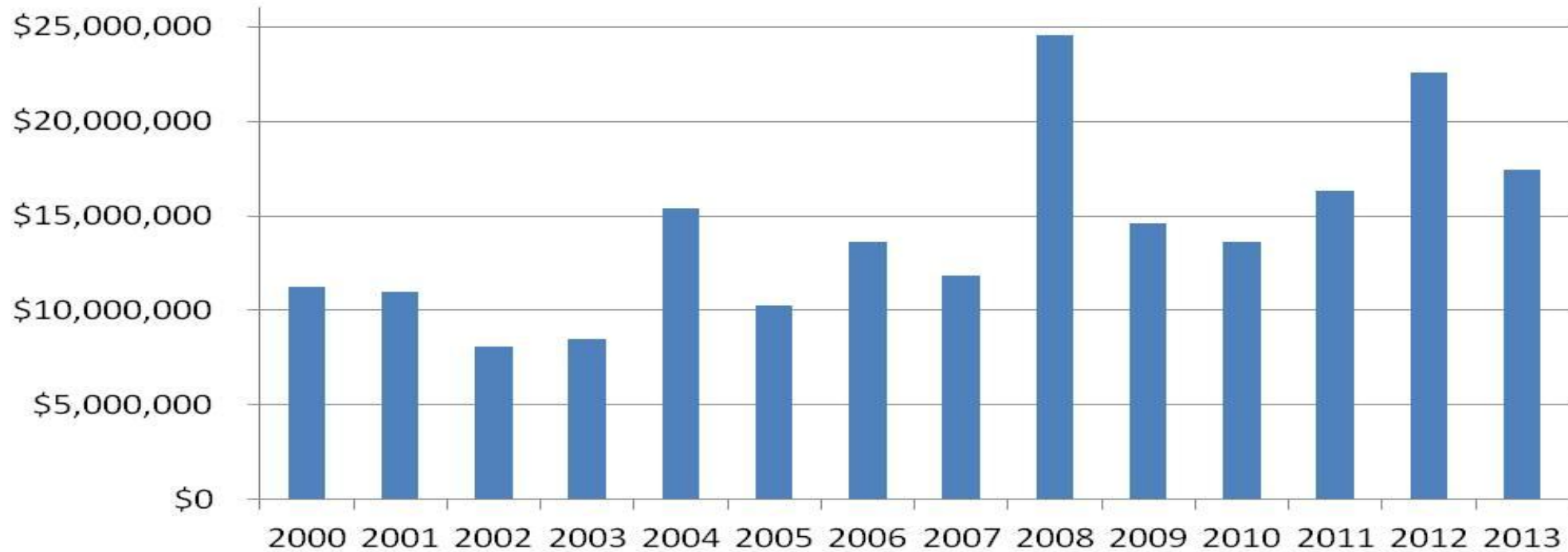


California Proposition 65 *Enforcement*

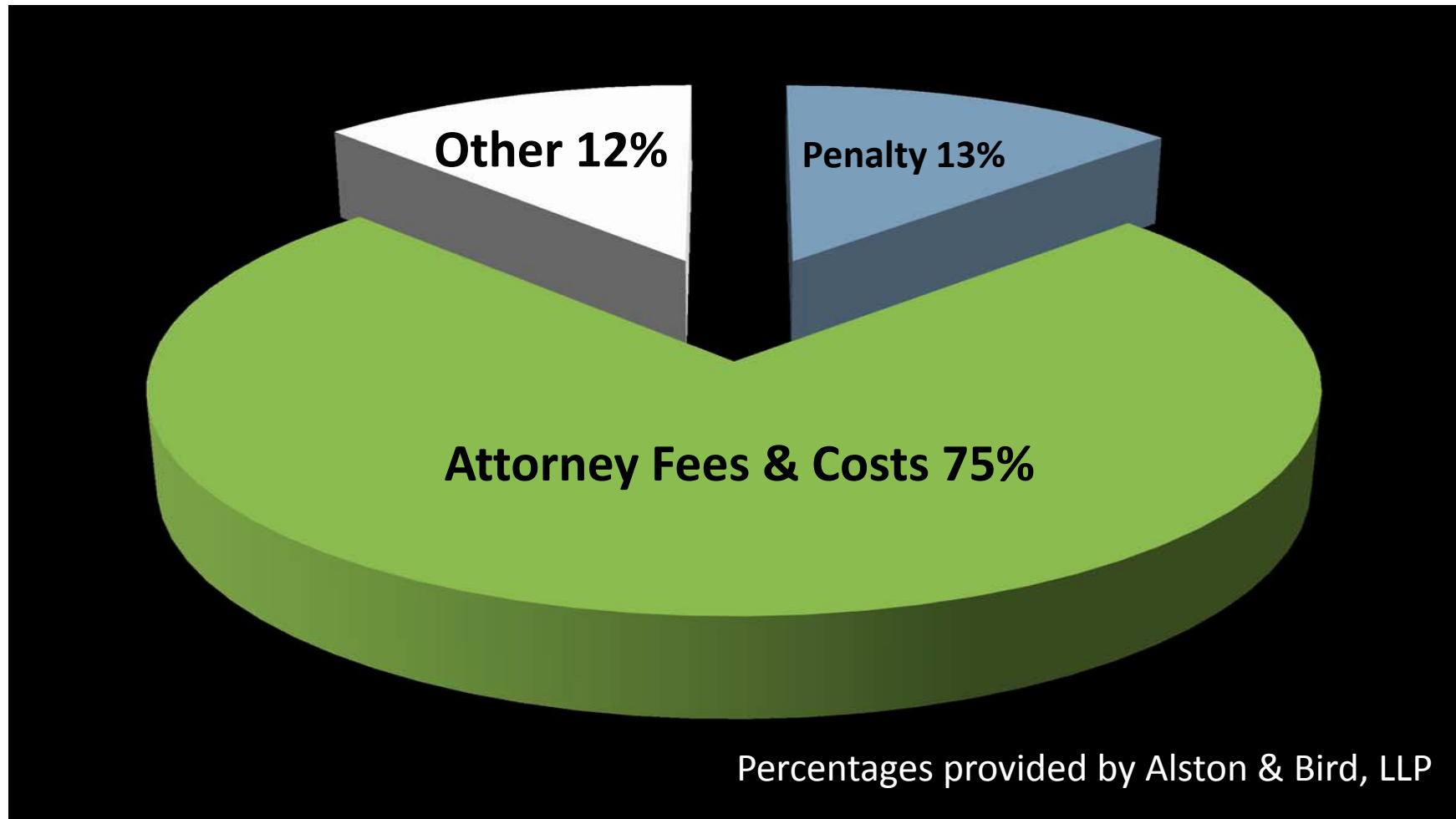
- Enforced by State Attorney General's Office as well as District Attorneys and City Attorneys
- Private Enforcers – any individual acting in the public's interest may enforce by filing a lawsuit (majority of claims)
- Penalties up to \$2,500 per violation, per day
 - Example: Shipment of 500 mugs = \$2,500 per mug
 - **$\$2,500 \times 500 = \$1,250,000$ per day**



All Prop 65 Settlements by Year



Who Wins?



California Proposition 65

Frequently Targeted Products



Jewelry for adults and children
(lead and cadmium)



Decorated glass and
ceramic drinkware (lead
and cadmium)



Padfolios, desk
accessories, checkbook
covers, phone covers,
luggage tags (lead and
phthalates)



Leather goods, belts,
wallets, footwear,
eyeglass cases (lead)



California Proposition 65

Frequently Targeted Products



Sporting goods and children's toys (lead and phthalates)



Electronics and electrical cords (lead, cadmium, phthalates)



Tableware, picnic products, distilled spirits, wine, beer (lead, phthalates, sulfites)



Plastic items, especially those made with PVC (phthalates)



California Proposition 65

Risk Mitigation

- Review the list of chemicals published and updated by the Office of Environmental Health and Hazard Assessment (OEHHA) found at www.oehha.ca.gov
- Confirm with your suppliers and manufacturers that none of the chemicals have been intentionally added to your product and ask for test reports and/or written documentation
- Evaluate manufacturing processes; identify potential substitutes for chemicals of concern (avoid regrettable substances)
- Collect and compile information on individual formulation constituents
- Test and comply with CA Prop 65 settlements
- Test for usual suspects (lead, cadmium, phthalates)
- Develop a strategy
 - Reformulation
 - Testing and exposure analysis
 - Use warning labels



California Proposition 65

What's Next

Proposed Changes to Article 6 Clear and Reasonable Warnings

- On January 16, 2015, a notice to repeal the current Article 6 regulations and adopt new regulations in Article 6 in Title 27 of the California Code of Regulations was posted on the OEHHA website and published in the California Regulatory Notice Register (CRNR).
- OEHHA has decided not to proceed with the regulation because a number of substantive and clarifying changes to the proposed regulatory language and Initial Statement of Reasons were made after reviewing oral and written comments from the public.
- OEHHA is concurrently opening a new rulemaking record by publishing a new notice to repeal and adopt a new Article 6 in the CRNR on November 27, 2015.



California Proposition 65

What's Next

Proposed Changes to Article 6 Clear and Reasonable Warnings

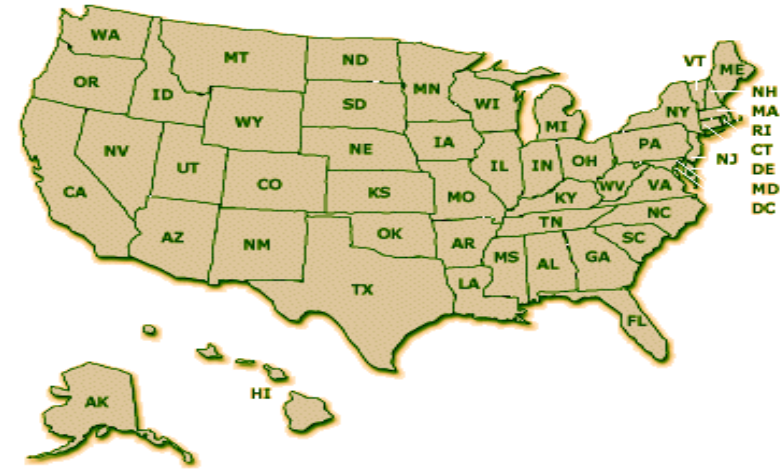
November 27, 2015 Proposal

- Making warnings more visible (due to the use of the familiar exclamation point symbol for most warnings)
- Stating that the product or the location can expose them to a listed chemical (as opposed to the current general practice of simply warning of the presence of a chemical)
- Identifying at least one listed chemical to which they would be exposed **(this is much different than the January 2015 proposal which had a list of 12 mandated chemicals that would have been required to be listed on the label).**
- Providing the URL for an OEHHA web site which will provide general information about listed chemicals, products or locations commonly associated with those chemicals, and general advice for how to reduce or avoid exposures to those chemicals.
- Providing for warnings in non-English languages in instances where product labeling contains information in alternative languages or at locations where signs are posted in those language



US State Regulations

- California's Safer Consumer Products Regulation
- Northeast Recycling Council (NERC)
- Illinois Lead Poisoning Prevention Act
- Washington State Children's Safe Product Act
- Maine's Toxic Chemicals in Children's Product Law
- Vermont SB.239
- Bisphenol A (BPA)
- Other State Legislations



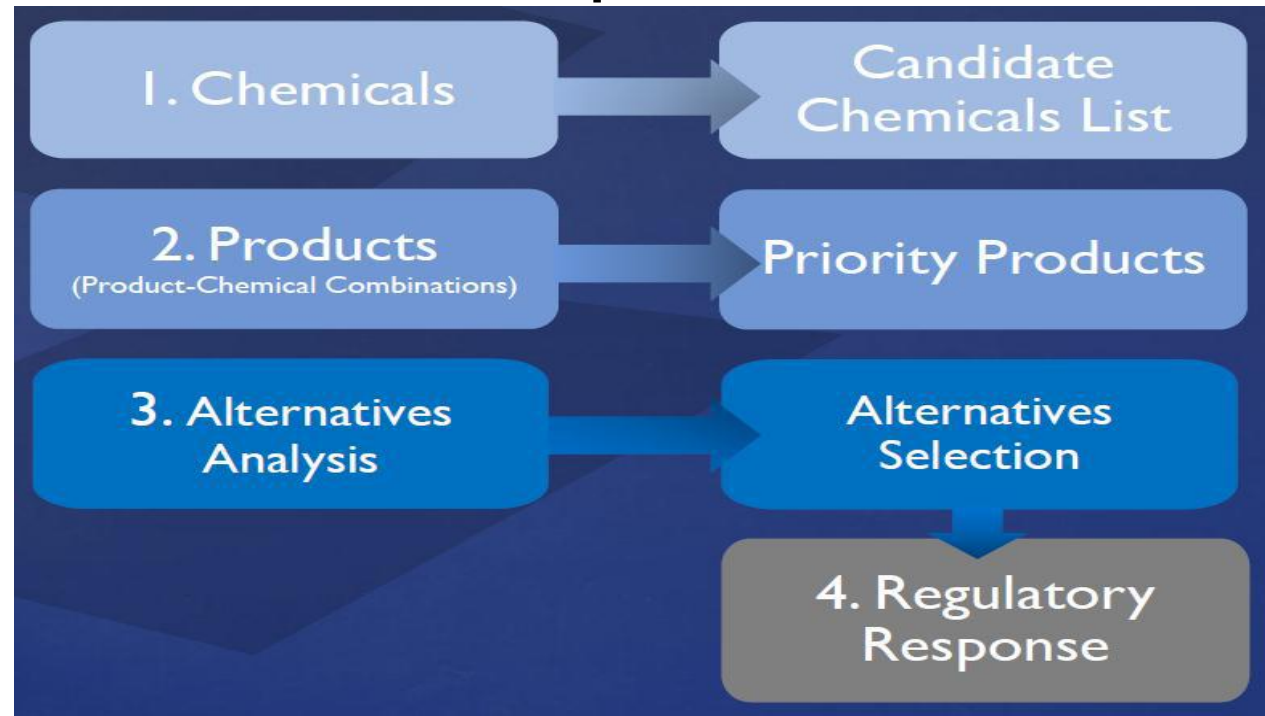
California Safer Consumer Products Regulations

- 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 Product 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



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)



NERC Toxins in Packaging

Overview

- Developed in 1989 to reduce the amount of four heavy metals in packaging components distributed in the United States
- Has been adopted by nineteen states
- The sum of the concentrated levels of incidentally added Lead, Mercury, Cadmium and Hexavalent Chromium present in any packaging component cannot exceed 100 ppm



NERC Toxins in Packaging

What are packaging materials?

- Master shipping cartons
- Individual product packaging (gift box, plastic bag, header card, blister pack etc.)
- Components used on shipping cartons (glue, tape, inks, staples, stickers etc.)



NERC Toxins in Packaging

Who is responsible?

- Manufacturers of packaging and packaging components
- Suppliers of packaging and packaging components
- Product manufacturers or distributors who use packaging



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Illinois Lead Poisoning Prevention Act

Overview

- Effective January 1, 2010
- Warning labels are required for certain products:
 - Toys, child care articles (up to 6 years) and children's jewelry (up to 12 years) if lead in surface coating is >40 ppm
 - Child care articles and children's jewelry if lead in substrate is >40 ppm
 - Adult items if lead in surface coating or substrate is >600 ppm



Illinois Lead Poisoning Prevention Act

Warning Statement

The warning statement must appear on the product itself or the product's immediate container and must include the following wording:

“WARNING: CONTAINS LEAD. MAY BE HARMFUL IF EATEN OR CHEWED. MAY GENERATE DUST CONTAINING LEAD”



Washington State Children's Safe Products Act *Overview*

- Identification of chemicals with potential adverse effects on children (focus on the highest priority chemicals)
- Requires manufacturers of children's products to notify the Department of Ecology when "Chemicals of High Concern to Children" (CHCC) are present in the product
- Sixty-six (66) chemicals are currently identified as CHCC's



Washington State Children's Safe Products Act *Reporting*

Reporting is based on two factors:

1. Size of the manufacturer
2. Tier of children's product

Tier	Product Type
1	products intended to be put in mouth, applied to a child's body, or mouthable product for age 3 years or under
2	products intended to be in prolonged direct contact with skin (more than 1 hour)
3	products intended for short periods of direct contact with skin (less than 1 hour)
4	products that during reasonably foreseeable use and abuse of product would not come into direct contact with skin or mouth



Washington State Children's Safe Products Act *Reporting Schedule*

Manufacturer Categories	Product Tier 1	Product Tier 2	Product Tier 3	Product Tier 4
Largest Annual sales > \$1 Billion	8/31/12	2/28/13	8/31/13	case-by-case
Larger Annual sales \$250M to <\$1B	2/28/13	8/31/13	8/31/14	case-by-case
Medium Annual sales \$100M to <\$250M	8/31/13	8/31/14	8/31/15	case-by-case
Small Annual sales \$5M to <\$100M	8/31/14	8/31/15	8/31/16	case-by-case
Smaller Annual sales \$100K to <\$5M	8/31/15	8/31/16	8/31/17	case-by-case
Tiny Annual sales < \$100K	8/31/16	8/31/17	8/31/18	case-by-case



Maine's Toxic Chemicals in Children's Product Law

Overview

- Maine has designated five chemicals as priority:
 - » Bisphenol A (BPA)
 - » Nonylphenol/Nonylphenol Ethoxylates (NP/NPE).
 - » Cadmium
 - » Mercury
 - » Arsenic
 - » Formaldehyde (NEW)
 - » Phthalates (NEW)
- Manufacturers using these chemicals in certain product categories are required to report to Maine DEP when used in an amount greater than the de minimis.
- Manufacturers must report by the deadline specified; however, if you are a manufacturer introducing a product that was not offered for sale at that time, you must file the applicable report with the Department within 30 days of the product being offered for sale in Maine.
- One time reporting requirement



Maine's Toxic Chemicals in Children's Product Law

Chemicals

BPA – Prohibits the sale of reusable food and beverage containers made with BPA;
Prohibits the sale of baby food packaging and infant formula packaging made with BPA;
Requires manufacturers using BPA in toys, child care articles, and tableware to file a report with the Department.

NP/NPE – Requires manufacturers using NP/NPE in household and commercial cleaning products, cosmetics and personal care products, and home maintenance products to file a report with the Department.

Cadmium/Mercury/Arsenic – Requires manufacturers using cadmium, mercury, or arsenic in Bedding, Childcare Articles, Clothing, Cosmetics, Craft Supplies, Footwear, Games, Jewelry and Embellishments, Safety Seat, Occasion Supplies, Personal Accessories, Personal Care Product, School Supplies, Toys to file a report with the Department.



Maine's Toxic Chemicals in Children's Product Law

Formaldehyde

By **December 18, 2015** manufacturers selling certain categories of children's products in Maine which contain intentionally added formaldehyde are required to submit a report to the Department.

Product categories to be reported include the following:

- Bedding
- Childcare Articles
- Clothing
- Cosmetics
- Craft Supplies
- Footwear
- Games
- Jewelry/Embellishments
- Safety Seats
- Occasion Supplies
- Personal Accessories
- Personal Care Product
- School Supplies
- Toys
- Jewelry/Embellishments
- Safety Seats
- Occasion Supplies
- Personal Accessories
- Personal Care Product
- School Supplies
- Toys



Maine's Toxic Chemicals in Children's Product Law

Phthalates

- By **December 18, 2015** manufacturers selling certain categories of children's products in Maine which contain intentionally added di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), or diethyl phthalate (DEP) are required to submit a report to the Department.
- Product categories to be reported include the following:
 - Clothing and Footwear
 - Craft Supplies
 - Building and Home Maintenance Products
 - Cosmetics and Personal Care Products
 - Household and Commercial Cleaning Products
 - Household Furniture and Furnishings
 - Personal Accessories and Jewelry



Maine's Toxic Chemicals in Children's Product Law

Reporting

- Manufacturers are now required to report to the Maine DEP the use of cadmium, arsenic, and mercury in certain categories of children's products which are sold in the State of Maine.
- Reports must be submitted to Maine DEP no later than **November 28, 2014**.
- Bedding, Childcare Articles, Clothing, Cosmetics, Craft Supplies, Footwear, Games, Jewelry and Embellishments, Safety Seat, Occasion Supplies, Personal Accessories, Personal Care Products, School Supplies, Toys



Vermont SB.239 – An Act Relating to the Regulation of Toxic Substances

- Applies children's products (under 12 years of age)
- Signed into law on June 10, 2014.
- List of 66 CHCC's - same as Washington State's CSPA List
- PQL and analytical test method to be provided
- Domestic manufacturers, private labeler and/or importer of record are responsible for reporting
- **Chemicals of High Concern in Children's Products Rule became effective December 10, 2015 and requires disclosure notices starting on July 1, 2016.**



Oregon SB 478 – Toxic Free Kids Act

- On July 1, the Oregon Senate passed SB 478, the Toxic-Free Kids Act. On July 3, the Oregon House passed the same bill which was signed by Governor Kate Brown .
- The Oregon bill establishes a Chemicals of High Concern List which will start as identical to the Washington State Department of Ecology's Reporting List of Chemicals of High Concern to Children. Thereafter, the Oregon Health Authority shall review and revise the list every three years. The Oregon bill explicitly states that any of the chemicals on the Washington State list that are also regulated by the Federal Government will be subject to the federal requirements, not the state.



Oregon SB 478 – Toxic Free Kids Act

Notable Differences

The Oregon bill contains some notable differences from the Washington State Law. Unlike Washington State:

- This bill extends the reporting requirement to any component part of a product, which would include inaccessible component parts;
- Contaminants exceeding 100 ppm must be reported, or the manufacturer must apply for a reporting exemption, even if a manufacturing control program is in place;
- Before the third notice (six years) of reporting a chemical of high concern, the manufacturer of mouthable products, children's cosmetics, or products made for or marketed to children under the age of three years must remove or make a substitution for the chemical or request a waiver. If substituting another chemical, the manufacturer must conduct a hazard assessment "that explains how the children's product, and any substitute chemical the children's product contains, is inherently less hazardous than before the substitution was made."
- In essence, this will force manufacturers to eliminate the potential for "regrettable substitutions".



Other States Regulating Chemicals of Concern

States with bans on certain flame retardants:

- TRIS, TDCPP, TDCP, TCEP, TCPP, PBDEs, decaBDE, and others
- Found mainly in children's clothing and furniture due to potential cancer risk through skin absorption or mouthing
- Connecticut, Delaware, Illinois, Massachusetts, Maryland, Maine, Missouri, North Carolina, New Jersey, New York, Oregon, Vermont, Washington...



Bisphenol A (BPA)

Overview

- Primarily used in polycarbonate plastic as well as epoxy resins and polysulfone materials
- Used in baby bottles and water bottles for decades
- Also used in coatings on the inside of almost all food and beverage cans
- FDA ban on use of PC in infant bottles/spill proof cups



Bisphenol A (BPA)

Current Legislation

Wisconsin

- BPA banned in baby bottles and sippy cups (<3 years)
- Children's items must be labeled "BPA-Free"



BPA also banned other states, mostly in baby bottles and sippy cups (no labeling required).

- CA, CT, DE, ME, MD, MA, MN, NY, WA, VT
- Legislation pending in other states



Plastic Bag Suffocation Warning

- Labeling and warning requirements for certain plastic bags
- California, Massachusetts, New York, Rhode Island and Virginia



**"WARNING: To avoid danger of suffocation,
keep this plastic bag away from babies and children.
Do not use this bag in cribs, beds, carriages or play pens.
This bag is not a toy."**



Stuffed Toy Labeling

- Massachusetts, Ohio, Pennsylvania
- Stuffed toys and dolls for the states of PA, MA and OH must conform with the stuffed toy licensing and labeling laws
- Manufacturers must register and pay fees must be paid to each state



Stuffed Toy Labeling

- Manufacturers must submit detailed information about the filler content of the toy
- Specimens of each toy selected at random
- Uniform sewn in label to comply with all three states must contain:
 - » PA license number of manufacturer or vendor
 - » Name and principal place of business of the manufacturer or vendor
 - » Statement that “all new materials” (with type of material)



Rhode Island Jewelry Legislation

- First state to adopt ASTM F2923-11 as mandatory
- Children's jewelry manufactured after December 18, 2012 must conform to the requirements of ASTM standard F2923-11, Specification for Consumer Product Safety for Children's Jewelry



Restriction of Hazardous Substances

- California, Minnesota and New Jersey have adopted RoHS requirements for Electronic Devices
- EN 1122 and EN 62321 method



Drawstrings

- CPSC Final Rule on Drawstrings and Ties took effect on August 18, 2011
- Final Rule is codified in 16 CFR 1120 but does not pre-empt state requirements for drawstrings
- Additional requirements in New York and Wisconsin



State Requirements – *Hood and Neck Drawstring and Ties*

	New York Law	Wisconsin Law	16 CFR 1120
Type of Apparel	All children's clothing	All children's clothing	Upper outerwear
Sizes	2T-12	0-16	2T-12
Requirements	No hood or neck drawstrings allowed	No hood or neck drawstrings allowed	Drawstrings and ties cannot be used in the head or neck area



State Requirements – *Waist of Upper and Lower Clothing Drawstring*

	New York Law	Wisconsin Law	16 CFR 1120
Type of Apparel	Children’s upper and lower clothing	Children’s upper outerwear	Children’s upper outerwear
Sizes	2T-16	0-16	2T-16
Requirements	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be attached to the garment’s midpoint - 3 inch rule 	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be sewn at the midpoint of the channel, so it cannot be pulled out of the channel - 3 inch rule 	<ul style="list-style-type: none"> - No toggles, knots or other attachments - The drawstring must be sewn at the midpoint of the channel, so it cannot be pulled out of the channel - 3 inch rule



Product Responsibility Resources

PPAI: www.ppai.org

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

Consumer Product Safety Commission: www.cpsc.gov; www.recalls.gov;
www.cpsc.gov/PromotionalProducts/

UL: www.ul.com or Brian.Coleman@ul.com

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