

Chemical Management: Know Your Chemicals

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Poll Question

How Confident Are You That Your Current Compliance Strategy Addresses All Chemical Regulations Applicable to Your Products?

- Completely Confident
- Somewhat Confident
- Not At All Confident
- Unsure



Agenda

- Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging
- US Federal Law
- US State Laws
- Connections on Global Chemical Legislation (focus on EU)
- Impact on Small and Medium Businesses



Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging

Phthalates (some examples include: DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, DCHP)

- Phthalates are chemical plasticizers used to soften plastics and make them more pliable
- Currently regulated by US federal regulations, US state regulations and in the EU
 - CPSC/CPSIA – applicable to toys and child care articles
 - Various state laws that cover a wide variety of consumer products & packaging materials



Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging

Heavy Metals (some examples include: Antimony, Arsenic, Barium, Cadmium, Chromium, Lead, Mercury, Selenium)

- Currently regulated by US federal regulations, US state regulations and in the EU
 - CPSC/CPSIA – applicable to toys and children's products
 - Applying to surface coatings and substrate materials
 - Various state laws that cover a wide variety of consumer products & packaging materials

48	82	80
Cd	Pb	Hg
cadmium	lead	mercury
112.411	207.2	200.59

Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging



Flame Retardants

- Uses mainly in manufacturing of materials such as plastics, textiles and surface finishes
 - Typically applied to reduce product flammability
- Currently regulated by US state regulations and in the EU
 - Scope across US states covers a wide range of consumer products

Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging



Per- & Polyfluorinated Compounds (PFAS)

- Widely used in industrial applications (polymers, surfactants and lubricants)
- Also used consumer products such as textile coatings, water and stain repellents, food packaging and fire fighting foam
- Currently regulated in the US and in the EU
 - Increased activity around restrictions for these “forever chemicals”

Basic Introduction to Hazardous Chemicals in Consumer Products & Packaging



Bisphenol-A (BPA)

- BPA is a chemical used to make certain plastics and resins
 - Found mainly in polycarbonate plastics (commonly used in food and beverage containers) and epoxy resins
- Currently regulated by US federal regulations, US state regulations and in the EU
 - Covering consumer products such as children's products, toys and reusable food/beverage containers

US Federal Chemical Requirements

Food and Drug Administration (FDA)

- FDA – Food and Drug Administration
 - Agency of the United States
 - Federal Food, Drug, and Cosmetic Act (FFDCA)
 - Supervision of
 - Food safety
 - Dietary supplementation
 - Pharmaceutical drugs
 - Medical devices
 - Cosmetics



US Federal Chemical Requirements

Food and Drug Administration (FDA)

♣ Food Contact

♣ FDA premarket approval

- Title 21 Code of Federal Regulations - e.g. 21 CFR 177.1520 for polyolefines
- Food Contact Notification (FCN) – e.g. Eastman Tritan FCN No. 729

♣ Compliance policy guides – e.g. CPG Sec. 545.400 & 450 for Pb & Cd release from ceramic ware

♣ Exemptions from regulation - e.g. GRAS status

♣ Cosmetics

♣ No FDA Premarket Review

♣ Labelling Requirements (incl ingredient listing)

- ♣ Claims to not suggest medical effect but focus on cleaning, altering appearance and enhancing attractiveness

♣ To not bear poisonous substances or deleterious substances (e.g. Heavy metals, allergenic fragrances)



US Federal Chemical Requirements

Consumer Product Safety Commission (CPSC)

- ♣ Regulate more than 15,000 consumer products
 - Products cannot cause harm (including chemical hazards)
 - Use of Industry standards is common (ASTM, UL, etc.)
 - Don't usually contain chemical requirements
 - Many industry standards are effectively mandatory even if they are not regulatory
- ♣ Federal hazardous substances act (FHSA)
 - All products technically covered (liquids, putties, pastes and gels in practice)
 - Labeling
 - Some restrictions (liquid filled children's products)
 - TRA always recommend as industry best practice
 - Labeling of hazardous art materials act (LHAMA)



US Federal Chemical Requirements

Consumer Product Safety Commission (CPSC)

- ♣ Consumer Product Safety Improvement Act (CPSIA) - 2008
 - Major changes and significant requirements for children's products
 - Must be tested by a CPSC accredited 3rd party laboratory
 - Must use CPSC defined test methods
 - Must test as directed by CPSC regulation (unable to exempt testing of material based on own risk assessment)
 - Lead in surface coatings - 90 ppm limit for children's product, furniture and household paints
 - Lead in substrates – 100 ppm for all children's products – NEW
 - Phthalates - 1000 ppm for toys and child care articles (DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, DCHP)
 - Soluble heavy metal requirements for toys per ASTM F963 (Sb:60, As:25, Ba:1000, Cd:75, Cr:60, Pb:90, Hg:60, Se:500)

US Federal Chemical Requirements

Environmental Protection Agency (EPA)

♣ Toxic substances control act (TSCA) Notification Requirements

- No Notification if on existing inventory (86K chemicals)
 - Private inventory vs public inventory
- 90 day notice needed if not in inventory
- Significant new use rules (SNURs)

♣ TSCA VI

- Formaldehyde in composite wood materials
- Essentially a mill certification program
- Testing of final product not required / accepted



US Federal Chemical Requirements

Environmental Protection Agency (EPA)

- ♣ Volatile organic compounds (VOC)
 - Various limits based on product type (aerosol versus liquid)
 - Cleaners, air fresheners, adhesives, polishes / waxes
- ♣ Federal insecticide, fungicide, and rodenticide Act (FIFRA)
 - Pesticides
 - Registration
 - Labeling



US Federal Law - TSCA

- ♣ TSCA was amended in 2016
 - ♣ Provided a new mechanism for restricting chemicals
 - ♣ Allows EPA to restrict chemicals more easily
 - ♣ Allows EPA to restrict chemicals in consumer products more easily
 - ♣ First five restrictions were recently enacted
 - ♣ More restrictions will likely follow in the coming years
- ♣ **Update:** On March 8th The EPA announced an additional 60 day comment period for the 5 new rules they recently enacted. They also issued a 180-day “No Action Assurance” indicating that they will exercise its enforcement with regard to PIP (3:1). Based on the comments that the EPA receives, changes could potentially be made to the 5 new rules in the near future.



US Federal Law – TSCA - PBT Chemicals

New Rules: Deca-BDE, PIP (3:1); 2,4,6-TTBP, HCBd, PCTP

Chemical	Uses (related to promotional products)	Restriction	Date of coming into force
<i>DecaBDE</i>	<i>Flame retardant –textiles and plastic enclosures for electrical products</i>	<i>Prohibited in products or articles</i>	<i>January 6th, 2022</i>
PIP (3:1)	Plasticizer, a flame retardant – not likely as used in more industrial applications	Prohibited in products or articles	March 8 th , 2022
2,4,6-TTBP	Intermediate/reactant – not likely as used in fuels and industrial applications	No final restriction in products or articles	-
<i>PCTP</i>	<i>Used in the production of natural and synthetic rubbers to increase pliability – possible if manufacturing natural and synthetic rubbers</i>	<i>Max 1% in products or articles</i>	<i>March 8th, 2021</i>
HCBd	Flame retardant in building materials, solder paste, recycled plastics, and automobile parts – possible in recycled plastics but not likely	Prohibited in products or articles	March 8 th , 2021

US State Laws – Chemical Requirements Overview



♣ Flame Retardant Restrictions

- PBDEs – 13 states have enacted restrictions starting
 - ↳ Requirements – all products in some states. Most have a 1000 ppm restriction. DC, WA, ME prohibit.
- TDCPP, TCEP, HBCD, TBBPA – 4 states (MD, NY, WA, VT) have enacted restrictions starting
 - ↳ Requirements - Children’s products and furniture in some states. Most have a 1000 ppm restriction. NY prohibits (TDCPP / TCEP only)
- “All Flame Retardants” – 5 states (CA, MN, RI, ME, MD) have enacted new laws that restrict all flame retardants or entire classes of flame retardants (e.g. organohalogen) starting
 - ↳ Requirements – Children’s products and furniture in some states. 1000 ppm restriction

US State Laws – Chemical Requirements Overview

Bisphenol A

- States – CA, CT, DE, IL ME, MD, MA, MN, NY, VT, WA, WI
- Products Covered
 - Reusable food or beverage containers, pacifiers, straws, baby bottle liners, Infant formula/ baby food plastic container, jar or can, receipt paper
- Limit
 - Banned



US State Laws – Chemical Requirements Overview

Toxics in Packaging Clearing House (TPCH)

- States – CA, CT, FL, GA, IA, IL, ME, MD, MN, MO, NH, NJ, NY, PA, RI, VA, VT, WA, WI
- Products Covered
 - ↳ Packaging
 - Definition of packing in US has differences from EU
 - US: any material that is discarded after the product is used (e.g. milk container)
- ♣ Limits
 - ↳ Pb, Hg, Cr VI and Cd cannot be intentionally added
 - ↳ Sum of Pb, Hg, Cr VI, and Cd shall be no more than 100 ppm total
 - ↳ **UPDATES as of February 2021 – added PFAS and Phthalates**
Currently no US states have adopted and are enforcing the updates made to the TPCH
- ♣ *Note: Most compliance is through declaration of conformity. Actual testing of every packaging element is not a common practice and considered a very conservative approach.*



US State Laws – Chemical Requirements Overview

Currently Enacted Toxics in Packaging Legislation

States	Chemical	Scope	Limit
WA, CA, MN, IA, NY, NJ, NH, CT, RI, MO, IL, WI, PA, VA, GA, FL, MD, VT, ME	Lead, Mercury, Cadmium & Chromium (VI)	All packaging	100 ppm total for the sum
ME	Ortho-phthalates	Food packaging and disposable gloves	100 ppm for the sum
NY	PFAS	Food packaging	No detectable amount (effective January 1, 2022)
WA	PFAS	Food packaging	No detectable amount (not effective until alternative is identified)
ME	PFAS	Food packaging	No detectable amount (by January 1, 2022 but only if alternative is identified)

US State Laws – Chemical Requirements Overview



State Chemical Reporting Requirements

- States – WA, OR, ME, VT and NY
 - NY law was recently enacted and no reporting is required at this time
- Product scope
 - Children's Products
 - E.g. - Toys, cosmetics, children's jewelry, child care articles, clothing, portable infant or child safety seats for cars.
- *Note: ME has a different product scope for each chemical.*
- Reporting Frequency
 - Every year or every other year.
 - WA, VT and OR require reporting of items that are sold in the state for the time period between the last reporting period to the current one.
 - ME technically requires reporting within 30 days of being sold within the state.
- Chemicals
 - WA (85), ME (12), VT(86), OR (68)

US State Laws – Proposition 65

- ♣ Safe Drinking Water and Toxic Enforcement Act of 1986
- ♣ List of chemicals that are known to the State of California to:
 - ♣ Cause cancer or
 - ♣ Birth defects or
 - ♣ Other reproductive harm
- ♣ The list of chemicals is updated and maintained by the California Office of Environmental Health Hazard Assessment (OEHHA)
- ♣ Enforcement through CA Attorney Generals Office, consumer advocacies and citizens of CA (bounty hunters)
- ♣ Court cases can provide limits by material




OEHHA


US State Laws – Proposition 65



Approaches for Addressing Proposition 65

- ♣ Testing of all products for chemicals that have been targets of enforcement
 - Test for chemicals based on existing settlements, reformulate or label product if product exceeds limits
- ♣ Conduct testing and toxicological assessment to determine potential exposure
 - Conduct risk based testing of Proposition 65 chemicals & perform toxicological assessment of the product and additional testing as needed
- ♣ Alternate approach – Label all Products (examples for consumer products listed below)
 - Automatically label products that either contains a proposition 65 chemical, and possibly that are at risk of containing a Proposition 65 chemical

 **WARNING:** This product can expose you to [name of chemical], which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

 **WARNING:** Cancer - www.P65Warnings.ca.gov.

US State Laws – Proposition 65

Enforcement

- Chemicals
 - ***Lead, Phthalates***, Cadmium, Flame retardants, BPA
- Materials
 - Ceramics, glass, brass, PVC/vinyl, coatings, leather, plastic
 - Risk based approach used is application of CPSIA scope for children's products when testing for Lead & Phthalates
- Examples of Targeted Promotional Products
 - Food contact items (including ceramic drinkware, glassware, kitchen utensils)
 - Apparel (most recently BPA in socks)
 - Accessories such as jewelry and various types of bags
 - Phone accessories and charging cords/devices

Connections on Global Chemical Legislation (focus on EU)

EU REACH

- ♣ Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
- ♣ Regulation (EC) No 1907/2006
- ♣ Administered by the European Chemical Agency (ECHA)

- ♣ Requires all manufacturers, importers and users have to register their substances as such or in preparations above a quantity of 1 tonne per year.

Connections on Global Chemical Legislation (focus on EU)

EU REACH

- ♣ Requirements on final products - SVHCs
 - ♣ Substances of **very high concern**
 - ♣ Currently 219 substances on candidate list
 - ♣ Compliance testing typically confirmed via screening or risk-oriented spot check
 - ♣ Information obligation
 - ♣ Communication along the supply chain if SVHC on candidate list is present in product above 0.1% (w/w). Furthermore information to be made available within 45 days upon consumer request
 - ♣ Notification: Submit notification to ECHA if any the SVHC above 0.1% (w/w) and the total amount of the SVHC exceeds 1 tonne per annum per producer or importer.

Connections on Global Chemical Legislation (focus on EU)

EU REACH

- ♣ Requirements on final products – Annex XVII
 - ♣ Restrictions limit or ban substances that pose an unacceptable risk to human health and the environment
 - Examples of most critical substances promotional products
 - Azo Dyes in leather & textiles
 - Nickel release from metal materials with prolonged skin contact (e.g. Sun glasses, jewelry)
 - Polycyclic Aromatic Hydrocarbons in rubber or plastic materials
 - Lead in jewelry and mouthable products
 - Cadmium in plastic materials, coatings & metals
 - Phthalates in toys or child care articles
 - PFCAs in apparell with water/oil/dirt repellent function

Connections on Global Chemical Legislation (focus on EU)

POP Regulation

- ♣ **Persistent Organic Pollutants (POP) Regulation**
- ♣ Regulation (EU) 2019/1021 / Recast of Regulation (EU) 850/2004
- ♣ Prohibition, restriction, release provisions and waste management of bioaccumulate substances, which pose risk to our health and environment
- ♣ Includes pollutants as indentfied in the Stockholm Convention
- ♣ Examples: PFOA & PFOS, certain pesticides, certain flame retardants as PBDEs, SCCP

Impact on Small and Medium Businesses

- Important for Suppliers and Distributors to be educated about applicable regulations to your products
- All parties in the supply chain should conduct due diligence in ensuring products are compliant with existing regulations
- Need to know regulations applicable to your product(s) for intended markets of distribution
- Enlist a 3rd party to help support you with chemical management such as an accredited laboratory or legal counsel



Impact on Small and Medium Businesses

- Can cause delays with importing products
- Can cause delays getting products to customers
- Risk of enforcement / financial implications
- Brand reputation



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Resources

- FDA: U.S. Food and Drug Administration ([fda.gov](https://www.fda.gov))
- Consumer Product Safety Commission (CPSC): [***.cpsc.gov](https://www.cpsc.gov) , [***.recalls.gov](https://www.recalls.gov)
- EPA: U.S. Environmental Protection Agency | US EPA
- Safer States: Safer States :: Home
- CA Prop 65: Proposition 65 - OEHHA ([ca.gov](https://www.ca.gov))
- EU REACH: Understanding REACH
- EU POP: Understanding POP



Resources – TSCA/PBT Chemicals

♣ Final Rules (with info on applicable industries)

- DecaBDE - *****[.federalregister.gov/documents/2021/01/06/2020-28686/decabromodiphenyl-ether-decabde-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under](https://www.federalregister.gov/documents/2021/01/06/2020-28686/decabromodiphenyl-ether-decabde-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under)
- PIP (3:1) - *****[.federalregister.gov/documents/2021/01/06/2020-28692/phenol-isopropylated-phosphate-31-pip-31-regulation-of-persistent-bioaccumulative-and-toxic](https://www.federalregister.gov/documents/2021/01/06/2020-28692/phenol-isopropylated-phosphate-31-pip-31-regulation-of-persistent-bioaccumulative-and-toxic)
- 2,4,6-TTBP - *****[.federalregister.gov/documents/2021/01/06/2020-28690/246-tristert-butylphenol-246-ttbp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under](https://www.federalregister.gov/documents/2021/01/06/2020-28690/246-tristert-butylphenol-246-ttbp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under)
- HCBd - *****[.federalregister.gov/documents/2021/01/06/2020-28693/hexachlorobutadiene-hcbd-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca](https://www.federalregister.gov/documents/2021/01/06/2020-28693/hexachlorobutadiene-hcbd-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca)
- PCPT - *****[.federalregister.gov/documents/2021/01/06/2020-28689/pentachlorothiophenol-pctp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca](https://www.federalregister.gov/documents/2021/01/06/2020-28689/pentachlorothiophenol-pctp-regulation-of-persistent-bioaccumulative-and-toxic-chemicals-under-tsca)

♣ Regulation - *****[.ecfr.gov/cgi-bin/text-idx?SID=291d87a0176992e5b5e4608bde05cd7c&mc=true&node=pt40.34.751&rqn=div5#sp40.34.751.e](https://www.ecfr.gov/cgi-bin/text-idx?SID=291d87a0176992e5b5e4608bde05cd7c&mc=true&node=pt40.34.751&rqn=div5#sp40.34.751.e)

♣ EPA PBT rule Info - *****[.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under)



Resources

- PPAI: ***.ppai.org
- PPAI Product Responsibility: *****ppai.org/inside-ppai/corporate-responsibility/product-responsibility/
- TUV Rheinland: ***.tuv.com
- Questions: MauriceN@ppai.org

