U.S. regulatory updates: Implications for the UV/EB industry

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The U.S. Regulatory Landscape

Federal Regulations

- EPA - TSCA
- FDA - FSMA
- OHSA - Hazard Communication Standard (U.S. GHS)
- CPSA – Consumer Product Safety Improvement Act

State Regulations

- Right-to-know
- CA Proposition 65
- Washington State Children's products

Customer restrictions – beyond U.S.

- BPA, SVHCs, RoHS, etc.

UV/EB industry at a glance

Includes the entire supply chain

- Manufacturers, raw material suppliers (i.e., import / export traders, distributors), formulators, converters/end users
- Monomers, oligomers, photoinitiators, additives
- Company sizes range from small shops to large multinational corporations

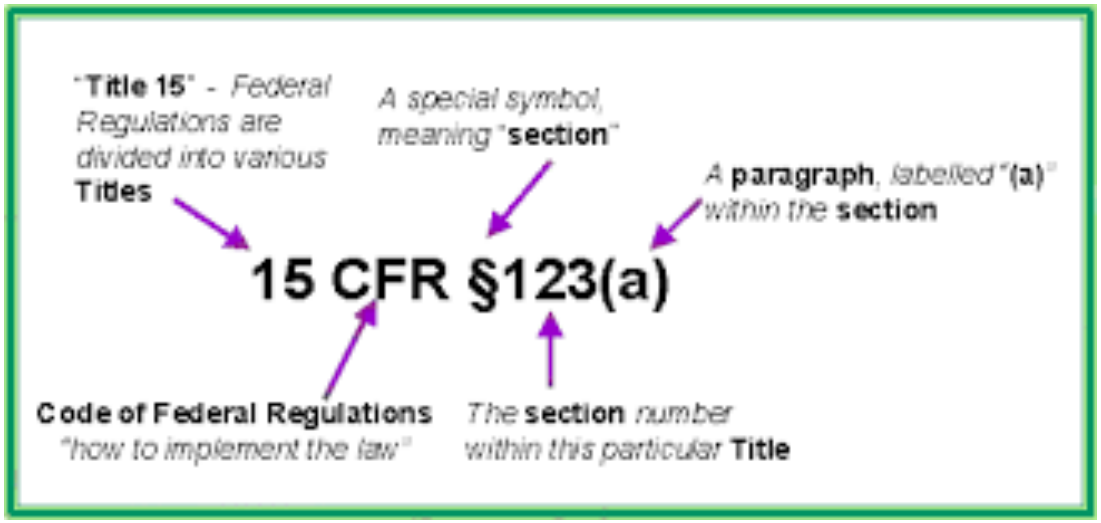
Ingredients generally have higher toxicity concerns (e.g. sensitizer, aquatic toxicity) and are subject to government regulations (e.g. SNURs)

The challenges facing Small and Medium sized companies (SMEs)

- SMEs often do not have dedicated in-house experts nor software tools and/or subscriptions to databases to support compliance
  - Compliance could be compromised by lack of knowledge
  - Employees tasked and taxed supporting multiple roles
- Increased costs due to need for consultants

U.S. Federal Regulations

code of federal regulations



TSCA Compliance – New Chemicals 40 CFR, Part 720

It has become increasingly challenging to have “reactive” chemistries “dropped”/approved by EPA without EPA having concerns

- Monomers – handling issues, aquatic toxicity concerns
- Oligomers – less problematic unless perceived ecotox concerns (acrylates, low MW polyesters)
- Photoinitiators – already under severe scrutiny

Environmental exposure-based release concerns from container wash out

Challenging to predict timeline for approval; commercialization delays

- Communication with Agency is often slow
- The Agency may require ecotox testing **(with Analytical)**; adds 6+ months, $$$
- Negotiating language of SNUR/Consent Order is time consuming

TSCA Compliance - Existing Chemicals

Work Plan Chemicals

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals

- Provides focus and direction to Existing Chemicals Program
- Currently 90 chemicals on work plan list
  - High Concern or High Exposure chemicals (concern to children's health, CMR, PBT, vPvB, detected in biomonitoring program)
  - UV/EB listed chemical - BPA, maleic/phthalic anhydride, NP/NPE
- Review generally leads to restrictions (SNURs)/bans
- Additional burden on industry (12b reporting, CDR, SNUN)

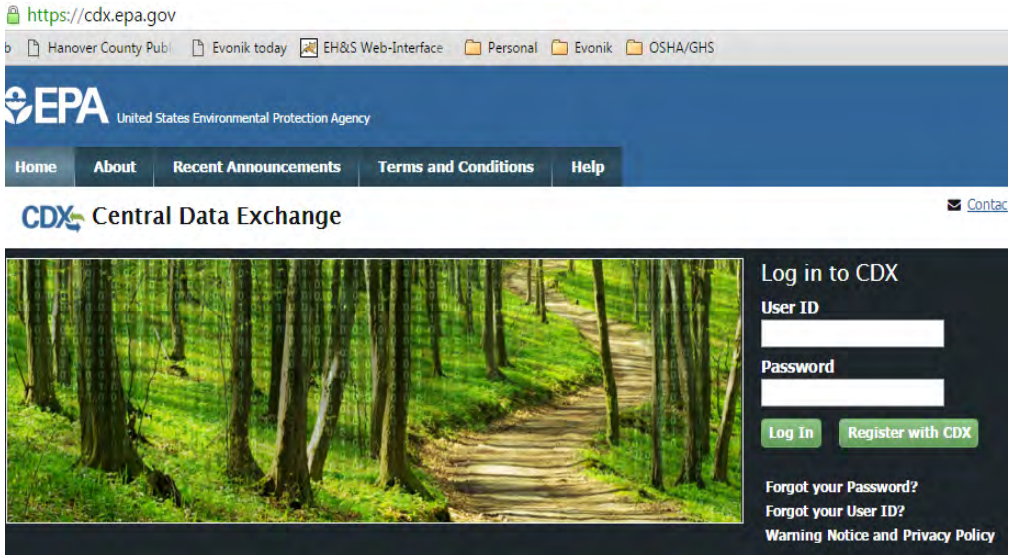
Current Work Plan List

https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf

Chemical Data Reporting

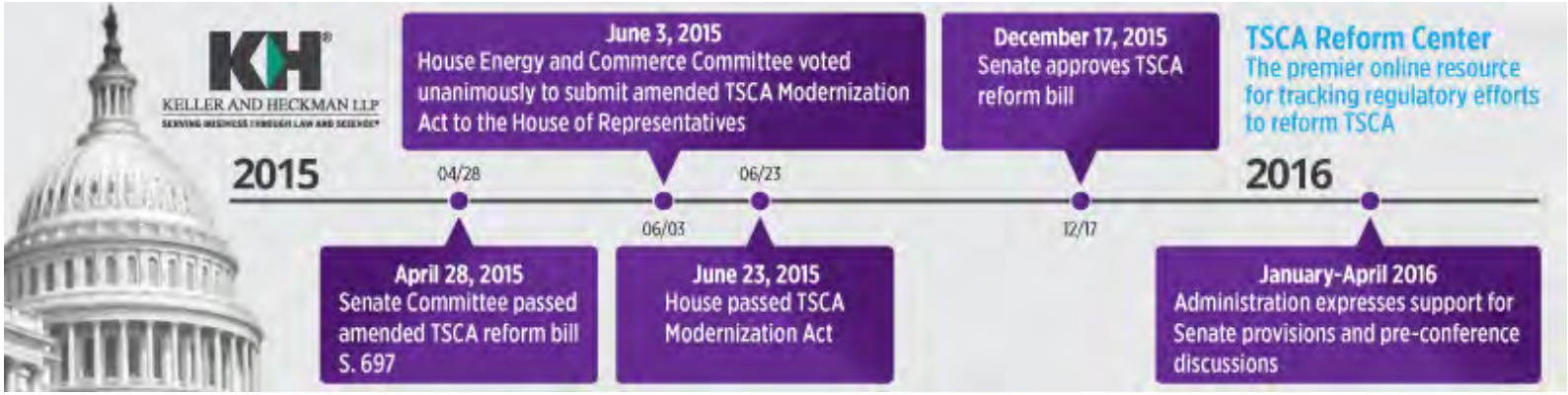
Chemical Data Reporting (CDR)
https://www.epa.gov/chemical-data-reporting

- Manufacturers/importers of chemicals subject to reporting
- Reporting period is **Jun 1 - Sept 30, 2016** for years 2012, 2013, 2014 and 2015
- Threshold for reporting is 25,000 lb. unless the chemical is regulated, then the threshold is 2,500 lb.
- Reporting requirements include volume, workers exposed, use(s), function(s), if used in products intended for children
- All submissions must be made electronically through EPA's CDX software www.cdx.epa.gov



TSCA Reform

- House (H2576) and Senate (S697) both passed their respective versions of TSCA reform bills
- Final language of bill being drafted
- Could be given to President for signature before May Congressional recess



A modernized TSCA will enhance protection of public health and the environment, while preserving America's role as the world's leading innovator

What does TSCA reform mean to UV/EB industry?

Manufacturers/Importers who currently file PMNs will have to demonstrate their new chemical is safe for use

- Essentially a self-imposed Use SNUR
- No longer “TSCA listed” chemicals with no restrictions

Inventory reset; possibility of revising nomenclature rules

- Re-nomination of all existing substances to TSCA
- Processors/Users must make sure the raw materials they use have been nominated

What does TSCA reform mean to UV/EB industry?

Existing Chemicals will be re-evaluated for safety by the EPA

- Initial focus – likely current Work Plan Chemicals
  - high hazard/high volume/CMRs/PBT/vPvB
  - Bill will require ~30/year; EPA currently doing ~2/year
- Could impact photoinitiators, acrylate monomers/oligomers
- EPA may request test data
- May volunteer to have chemical(s) evaluated; strategic advantages
- Probable outcome – SNURs, restrictions/bans

FDA – FSMA and impact to Food Contact Materials

January 4, 2011 – President Obama signed into law the FDA Food Safety Modernization Act
(80 Fed. Reg. 55908)

Significant reform – shifts focus from **RESPONDING** to contamination to **PREVENTING** it

Most significant impact to suppliers of **Food/Food Additives** (anything that is incorporated into food, intentionally or not, e.g. indirect food additives from packaging or processing)

- **HARPC** - Requires Hazard Analysis and Risk-Based Preventive Controls
- **Food is Safe** - Need to demonstrate that the food/food additive is safe; free from biological, radiological, chemical, physical hazards
- **Supply-Chain Program** - receiving facilities of raw materials or other ingredients identified as potential hazards will require a “supply-chain applied control” (approved suppliers, audits, etc.)
- **FDA Registered Facilities Only** - Facilities handling only food-contact substances exempt from HARPC and GMP

Foreign Supplier Verification Program (FSVP)

November 27, 2015 - **Foreign Supplier Verification Program** (FSVP) was codified into law

- Applicable to raw materials, ingredients, finished food and **FOOD-CONTACT SUBSTANCES**
- Effective Date - Jan 26, 2016
- Compliance deadline – Jul 26, 2017 (18 months after effective date)

FSVP requires:

- Importers must conduct hazard analysis
- Importers must establish and follow written procedures ensuring they only import from approved suppliers
- Importers need to ensure foreign supplied material doesn't impact safety of food

What do FSMA & FSVP mean to UV/ EB Supply Chain?

FSMA is not applicable to Food Contact materials if sourced/manufactured in the U.S. (coatings, packaging, etc.)

Non-US sourced materials used to manufacture a food contact material may be subject to FSVP

- Waiting for Guidance from FDA
- Likely will require at least a risk assessment

Users/Customers – may not have full understanding of requirements and may ask for documentation beyond what is necessary

- May ask for documentation of HARCP or other risk assessment
- Need to educate/inform
- May have to modify internal protocols to assess risk, even if not required

OSHA – HCS2012 (U.S. GHS)

Deadline was June 1, 2015

- Many companies are still not providing compliant safety data sheets
- Classifications of substances/raw materials in flux
  - Must monitor raw material classification changes and evaluate impact to products
  - Challenging to strategize label/SDS changes based on compliance deadlines and inventory/stock

Different classification requirements in the U.S. and EU; e.g. Repro Tox Cat 2B (examples - TPO, MEHQ)

Symbol(s)

Signal word : Warning

hazard statement : H361 - Suspected of damaging fertility or the unborn child.

US Label

US Requires labeling of products as Repro hazard containing ≥ 0.1% of a C ategory 2 Reprotox hazard

EU Label

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not a hazardous substance or mixture.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

No particular hazards known.

2.2. Label elements

Not a hazardous substance or mixture.

EU Requires labeling of products as Repro hazard containing ≥ 3% of a C ategory 2 Reprotox hazard

California


SIMPLE ANALYSIS
BY MICHAEL "SLIDSY" SUTHERLAND
SAFETY BELT, HELMET, GOOGLE, AND BREATH MASK, LAW ENFORCED
Welcome to California
WARNING: This state contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm

Proposition 65…changes not for the better

- Likely will require new “Clear and Reasonable Warnings”
- Creation of a new stand alone website

  http://oehha.ca.gov/prop65.html

Recently listed chemicals that may affect UV/EB industry

- Benzophenone – Effective Date June 22, 2012 (No NSRL established)
- BPA – Effective Date May 11, 2015 (no MADL established)
- Styrene – Effective Date April 22, 2016 (proposed NSRL – 27 ug/day)

Challenge: many chemicals have not had safe exposure levels established

How is zero measured?

Exposure can be subjective

Bisphenol A (BPA)

BPA is being targeted globally

- Recently added to California's Prop 65 list; currently no MADL established

  How is Zero measured?
- Recommended in the EU for inclusion on the Candidate List of Substances of Very High Concern (SVHC)
- Maximum allowable residual limit in China for food contact application – 0.05% (500 ppm)

Yet…FDA Determined BPA is safe for direct food contact applications

- FDA reviewed hundreds of studies
- Current approved uses in food containers and packaging are safe
- FDA conducted studies and confirmed no effects were shown from low-dose exposures to BPA
- FDA did grant a petition to prohibit use in certain baby products; not because of safety but because BPA was no longer used in these applications

Other compliance certifications…

Heavy Metals

- RoHS, CONEG, Dodd-Frank

Consumer Product Safety Act

- Phthalates, lead

Allergens

Human Trafficking

Company specific negative lists; e.g. Nestle

CMRs

SVHC’s

Good communication within the supply chain is key!

Don’t forget the rest of the world…

Canada GHS – 2017 Deadline

REACH 2018 deadline

New Inventories – Taiwan, Thailand

New proposed inventories – Brazil, Mexico

Korea REACH

The global regulatory landscape is very dynamic

How to manage compliance

Make compliance a priority within your company

- Management needs to recognize the importance and value of compliance
- Dedicated resources to support compliance
  - Internal product stewardship FTE
  - Dedicated time to support if assigned to an employee with other roles
  - Support using outside consultants
- Make tools or resources available to support compliance
  - Subscriptions to databases (e.g. Ariel) or subscriptions (e.g. BNA, ChemWatch)
  - Participation in Trade Associations Regulatory Groups – RADTECH, ACC, SOCMA
  - Training/Conferences (SCHC, Global Chem, TSCA Workshops)

A company with a strong product stewardship and compliance program will support sustainable strategic growth

- Will build credibility as a supplier
- Will be able to conduct risk assessments related to relevant hazards
- Can communicate with and assist customers with their compliance needs
- Avoid fines, penalties and negative attention from violations

Relevant Links

EPA New Chemicals Program
https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

EPA Central Data Exchange – For filing of PMNs, CDR reporting and other EPA reporting programs
https://cdx.epa.gov/cdx/Login

CA Prop 65
http://oehha.ca.gov/prop65.html

CA OEHHA Email Alerts
http://www.oehha.ca.gov/Listservs/default.asp

FDA Food Safety Modernization Act
http://www.fda.gov/Food/GuidanceRegulation/FSMA/

Foreign Supplier Verification Program
http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm

For additional information

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