


New TSCA: UV/EB Coatings *And The Changes Ahead*

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- **Keller and Heckman** is a trusted TSCA outside counsel and developed comments and policy during the implementing provisions of the 1976 Act.
- We represent companies across the chemical supply chain spectrum, including consumer product companies, on compliance, enforcement, and implementation of the new law.
- Many of our attorneys have technical backgrounds and work side-by-side with in-house chemists and other scientists to support our clients in properly identifying chemical substances on the TSCA Chemical Substances Inventory.
- Martha has practiced TSCA law for 25 years, specializing in polymers, coatings, metals, and emerging technologies. She is a Past Chair, ABA SEER Pesticide, Chemical Regulation, Right –to-Know Committee. Through SEER, issued a series of legal briefing papers on TSCA Reform.

Preliminary word

- This presentation provides information about the law. It is not intended to provide legal advice.
- Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances.
- The interpretation and application of the law to an individual's specific circumstance depends on many factors.
- The information provided in this presentation is drawn entirely from public information.
- The views expressed in this presentation are the authors' alone and not those of the authors' clients.

OVERVIEW OF CHANGES

Main Elements - New TSCA

- Emphasis Lies in Existing Chemicals Reform.
- Identification of Substances Actively in Commerce.
- Prioritization of Active Substances into High and Low Priority.
- No Lock-step Information Requirements. EPA Can Order Testing. Alternative Testing to Play Central Role.

Main Elements, cont.

- Agency-Driven Process, Measured Pace.
- Risk-based Safety Standard Evaluated Under Conditions of Use Not Taking into Account Costs or Other Non-risk Factors
- Requires Consideration of Potentially Exposed or Susceptible Populations.
- Science-based Risk Assessments, Industry Pays a Portion of the Cost.
- Broad Authority to Regulate But Bans and Phase-Outs Must Offer Alternatives.

Main Elements, cont.

- Preservation of CBI But More Liberal Disclosure.
- PMN process now has early decision mechanism and agency must publish findings.
- Can regulate chemicals in “articles” only if EPA makes affirmative finding by rule that reasonable potential for exposure to chemical through article (or category of articles) justifies notification.

What has NOT Changed?

- *Pre-existing* definitions
- §4 data compensation provisions for testing
- TSCA §8(b) Inventory
  - Retained, with confidential and "public" portions
- § 8(a) Chemical Data Reporting (CDR) for 2016
- § 8(c) Allegation recording
- § 8(e) Substantial risk notification
- §12 Export notification and export-only exemption
- §13 Import certification requirement

NEW SAFETY STANDARD

New Safety Standard

- For new and existing chemicals, **no "unreasonable risk of injury to health or the environment"** criterion is preserved.
- Adds the need to consider –
  - Conditions of use.
  - Volumes and exposure.
  - Consideration of susceptible populations.
  - Proximity to significant sources of drinking water in priority setting.
  - Persistence and bioaccumulation.
- No consideration of costs or other non-risk factors in prioritization or safety determinations. **"Least burdensome"** restriction requirement for risk management of existing chemicals **is gone.**

NEW CHEMICALS

PMN §5(a)(3) Determinations

- **"(A)"** Determination
  - Substance/SNU presents unreasonable risk
- **"(B)"** Determination
  - (i) information insufficient to permit reasoned evaluation of substance/SNU; ***or***
  - (ii(I)) in absence of sufficient information and evaluation substance may present unreasonable risk; or
  - (ii(II)) substance is/will be substantial quantities, and enters or may enter environment in substantial quantities or is/may be significant or substantial human exposure
- **"(C)"** Determination
  - Substance/SNU is not likely to present an unreasonable risk

§5 - Actions Required

- **“(A)” determination (“presents”):**
  - Must use § 5(f) and may issue order
- **“(B)” determination (“insufficient,” “may present,” or exposure-based):**
  - Must use § 5(e) and must issue order
- **“(C)” determination (“not likely”):**
  - May commence non-exempt production
    - Even before review period ends!
  - If workplace issues proposed to be regulated, Agency must first consult with OSHA “to the extent practicable”

Failure to Make Determination

- If EPA fails to make determination by end of review period, then EPA “shall” refund filing fee
  - No refund if EPA certifies that submitter has not provided all 5(b) information, or has “otherwise unduly delayed the process”
  - EPA, however, “shall not be relieved of any requirement to make such determination”

EXISTING CHEMICALS

Pace of new TSCA § 6(b)

Deadline	EPA Must -
Within 6 months	• Be conducting risk evaluations (and publish the list) for **at least 10 chemical substances drawn from the** 2014 TSCA Work Plan.
Within 1 year	• Promulgate a rule setting **risk based screening** process for prioritization. • Promulgate a rule setting **risk evaluation process.**
Within 2 years	• Issue **program guidance** on preparing risk evaluations, other aspects.
Within 3 years	• Propose risk management rules for PBT substances that are scored moderate to high which are not otherwise under review, to be finalized in 18 months.
Within 3.5 years	• Be in the process of working on at least 40 chemicals (20 low priority designations made/20 high priority evaluations underway).

§8(b)(4)–(5) Inventory "Reset"

- Within 1 year EPA must issue rule requiring producers (and **"may" require processors**) to notify EPA within 180 days of each existing substance produced within 10 years prior to enactment.
  - Reported substances = "active"
  - Non-reported = "inactive"
    - EPA cannot delist, or require PMN for inactive upon change to active
- Most recent CDR-reported substances to comprise candidate list of actives
- Must assert CBI for chemical identity if on confidential Inventory or will be moved to public Inventory

§8(b) “Reset” (cont.) - CBI

- EPA will maintain public and confidential Inventories
- Within one year of initial “active” list compilation, EPA must publish rule to establish plan to review all Inventory chemical identity CBI claims
  - Can approve, deny, approve in part, etc.
  - If approved, EPA will protect for 10 years
- EPA has five years to complete

“Inactive” Substances

- Must notify EPA before manufacture, import, or processing
- If CBI status desired must submit/assert CBI claim within 30 days of notice
- EPA will move properly reported substances to “active” list
  - Then subject to review under 6(b)

Agenda

- EPA is required to make 20 **low** priority substance designations within 3.5 years.
- EPA also must be ***conducting*** risk evaluations on 20 **high** priority substances.
  - Only 50 percent of chemicals in risk evaluation have to be 2014 Work Plan chemicals.
- System designed to encourage voluntary nominations for risk evaluation.
  - At least 25 percent (and no more than 50 percent) of the risk evaluations must consist of **voluntary requests**.

* Opportunities To Participate

1. High priority designation* to take **9 months – 1 year.**
2. EPA is expected to prioritize based on existing data and screening techniques.
    1. Can require development of new information but only upon a showing of need, the testing must be tailored to prioritization, and must complete prioritization decision within 90 days of receiving the information.
3. Scope of risk evaluation* issued **6 months after that.**
4. Risk evaluations have to be proposed* and **finished in 3 years.**
5. Risk management proposed* within 1 year/ finalized within 2 years of completing risk evaluation. Extension of up to 2 years possible.
6. Management measures to become effective from "as soon as practicable" **up to 5 years.**

Statute's Priorities

- **2014 Work Plan Chemical List of 89 Substances**
- **Preferred High Priority:** § 6(b)(2)(D)
  - (1) score 3 for persistence and bioaccumulation; (2) known human carcinogen; and (3) high acute and chronic toxicity.
- **PBTs Scoring High/moderate:** § 6(h)(1)
  - EPA must conduct exposure and use assessment but not a risk evaluation.
- **Mercury:** § 8(b)(10)
  - No later than April 2017 and every three years thereafter, EPA must publish in FR inventory of Hg supply, use, and trade.
  - Must recommend actions to further reduce use, EPA has two years to develop reporting rule.
  - 12(c) amended to include Hg compounds.
  - Hg export ban beginning 1/1/2020 for:
    - Hg(I) chloride, Hg(II) oxide, Hg(II) sulfate, Hg(II) nitrate, Cinnabar, or Hg sulphide.

Risk Management Exemptions

- **Replacement parts** for designated complex durable goods and complex consumer goods exempt.
- Other conditional exemptions may be granted, subject to notice and comment, for which time limits and other conditions may apply:
  - **Critical or essential uses** with no feasible safer alternative.
  - **Disruption to national economy**, security, or critical infrastructure.
  - A condition of use that compared to alternatives provides a **substantial benefit** to health, environment or public safety.

PREEMPTION

New TSCA Preemption

- **<u>Except As Otherwise Provided</u>, New And Existing State Laws Cannot –**
  - Collect information (e.g. testing) already required by EPA.
  - Prohibit/restrict a high priority substance once a final section 6(a) rule is promulgated.
  - Duplicate notification for a use already subject to EPA notification.
- **Grandfathers Other Existing State Laws**
  - State laws enacted by April 22, 2016 remain in effect (even where there may be potential conflict in the future with EPA actions?).

New State Laws § 18(b)

- "Preemption Pause" on new state laws so EPA has time to act -
  - Starts when scope of risk evaluation is defined.
  - Ends when risk evaluation is published or 3.5 years passes after risk evaluation is initiated.
  - States have an additional 18 months after scope of risk evaluation is defined to propose/finalize new action.

New State Laws, cont.

- Also preempted by final EPA action.
  - No Unreasonable Risk: When EPA finds that a high priority chemical meets the safety standard.
  - Unreasonable Risk And Adoption Of 6(a) Measures: When EPA enacts a rule to regulate a chemical that does not meet the safety standard.

States May Continue To -

- Regulate substances EPA designates as low priority although likelihood of this assumed to be low.
- Adopt laws authorized by another federal law. §18(d)(1)(A)(i).
- Impose reporting, monitoring, or "other information obligation" not otherwise required by TSCA or another federal law. §18(d)(1)(A)(ii).
  - Does this apply to labeling, warnings, and use instructions?
- Enact air, water, hazardous waste, and disposal laws. §18(d)(1)(A)(iii).
  - May restrict a chemical.
  - But cannot directly conflict with action taken by EPA under TSCA.
- Enact requirements equivalent to EPA's and co-enforce. §18(d)(1)(B).

State Waiver Process § 18(f)

- Discretionary:
  - Applies where EPA has taken final action on chemical.
    - Compelling conditions;
    - No undue burden on interstate commerce;
    - Does not cause violation of federal law; and
    - Based on best available science/weight of scientific evidence.
- Mandatory:
  - Applies during “preemption pause”.
    - No undue burden on interstate commerce;
    - Does not cause violation of federal law; and
    - Based on peer-reviewed science **OR**
    - State takes action within 18 months of prioritization initiation.
      - Enacts statute or proposes/finalizes administrative rule.

OTHER CHANGES

CBI

NO required substantiation nor time limit for:

- Specific production/import volumes
- Specific processes
- Specific uses
- Percentages of constituents in a mixture
- Marketing and sales information
- Supplier and customer identities

§14(c)(2)

CBI, cont.

(Re)substantiation required for everything else, including chemical identity

- **When:**
  - Generally, submit CBI claim concurrent with info. and substantiate per rules EPA "has or may" promulgate
  - To maintain confidential Inventory listing, file CBI claim with notice of active manufacture/processing under § 8(b) (within 1.5 yrs.) and substantiate claim at a later date (within 5 yrs.)
  - After designation of substance as high-priority
  - If EPA determines info. important to § 6 actions or chemical presents unreasonable risk under § 6
  - If necessary in connection with FOIA request
  - If EPA has reasonable basis to believe info. Ineligible for protection
- **Duration: 10-years**, with opportunity for unlimited 10-year extensions

§§ 14(c), (e) and (f)

Information NOT Protected

- **Health and safety studies**
  - Except:
    - Process information, explicitly including molecular formulas and structures (NEW)
    - Concentrations of individual chemicals in mixtures
- **General manufacturing, processing and use information**
  - *e.g.*, Volume aggregates (or ranges if authorized by EPA)
- **Information related to ban or phase-out chemicals**
  - Rebuttable presumption
  - Limited exceptions (*e.g.*, critical uses)

***General Caveat*:**

- Confidential information "mixed" with non-confidential information does not lose its protection

§14(b)

§15/16 - Prohibited Acts and Penalties

- No change to prohibited acts, or inspection/subpoena authority
- Penalties Increased:
  - **Civil**: Maximum penalty $25,000 → $37,500
  - **Criminal**: Maximum penalty $25,000 → $50,000
    - Persons that know that violation places individual in imminent danger of death or serious bodily injury subject to fine of $250,000, imprisonment not more than 15 years, or both
    - Organizations – also subject to fine not more than $1 million

§26 Fees, Funding

- Congress must maintain 2014 funding levels for fees to be assessed
- Consultation process anticipated prior to rulemaking - no deadlines
  - Funds adjusted every 3 years
- Lower fees for small businesses in consultation with SBA
- Fees to defray 25% of costs (or $25 million, whichever lower) of administering §§4,5,6 and CBI under §14 except –
  - No specified limit on defraying the cost of risk evaluations under § 6(b)
  - Voluntary requests must be fully funded by requesters, or up to 50% for Work Plan chemicals
  - Balancing costs among manufacturers, processors, consortia

WHAT TO EXPECT

UV/EB

Complex formulations, individual components must be on the TSCA Inventory or otherwise exempt –

- E.g.,
  - Resin
  - Diluent
  - Solvent
  - Surfactant
  - Preservative
  - Photoinitiator (optional)

Acrylate Chemistry

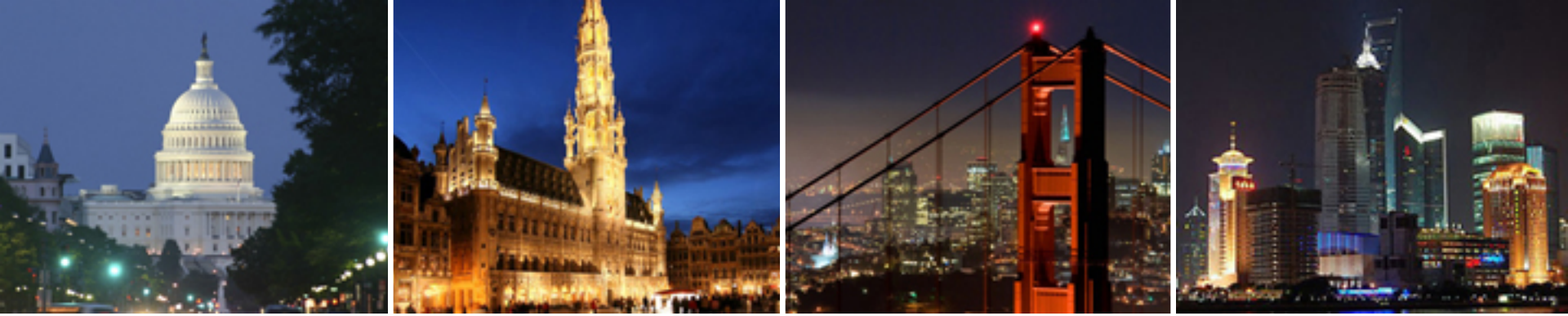
- In general, UV/EB curing acrylates have low systemic toxicity, but they can cause skin and eye irritation. Some individuals may also become sensitized to these chemicals.
- Most acrylate oligomers and monomers have a low vapor pressure, and inhalation of vapors is unlikely to occur at room temperatures. Some of these products may form stable aerosols which can be inhaled.
- Other human health and environmental considerations include positive carcinogenicity findings in NTP study of TMPTA, similar concerns for certain photoinitiators, and ecotoxicity concerns.
- The higher molecular weight and lower net acrylate functionality of acrylate oligomers result in a lower level of physiological activity than the acrylate monomers.

Considerations for UV/EB

- Plan to participate in the Inventory Reset. Plan to pay higher fees.
- Assess effect of planned mercury regulations.
- Priority determinations ahead for coating chemistries.
  - Substance-by-substance approach preferred in light of TMPTA NTP study? Consider developing information on reproductive toxicity of acrylates; currently limited.
- Carefully prepare your PMNs
  - Key drivers are volume, uses, and ecotoxicology.
  - Greater emphasis on direct consumer uses and susceptible population exposures.
  - Address aquatic toxicity prior to filing to predict and plan for outcome.

When to Participate -

- 40 or more regulatory actions on existing chemicals in next 3 ½ years. In addition:
  - *A plethora of* general rulemakings and guidelines development to establish new programs.
  - *An expansive* rulemaking to regulate a number of high/moderate PBTs.
  - *Multiple* deadlines embedded throughout the risk evaluation process may be litigated or replaced by court-ordered deadlines.



Thank you

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