

What you need to know about TSCA Reform

Anthony (Tony) Noce

HALEY
ALDRICH

Toxic Substances Control Act (TSCA)

Overarching chemical control regulation enacted in 1976

Provides EPA with authority to regulate importation, manufacture and processing of industrial chemical substances and their mixtures

Established list of chemicals in commerce

- Originally 62,000 chemicals – now approximately 86,000

Exempted substances are covered by other regulations:

- Food additives
- Drugs
- Cosmetics
- Pesticides

The Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Passed by large bipartisan margins in U.S. House and Senate
- Signed by President and went into effect on June 22, 2016
- Amends and updates Toxic Substances Control Act of 1976
- Received broad stakeholder support
- Gives EPA broad ability to control health and environmental risks, and to demand toxicity information



This is TSCA reform

The Frank R. Lautenberg Chemical Safety for the 21st Century Act

- Fundamentally changes U.S. federal approach to chemicals management
- Central concept is *unreasonable risk*, the evaluation of which:
 - Does **not** include consideration of cost/benefit factors
 - Focuses on conditions of use
 - Includes consideration of potentially exposed or susceptible subpopulations identified as relevant by EPA

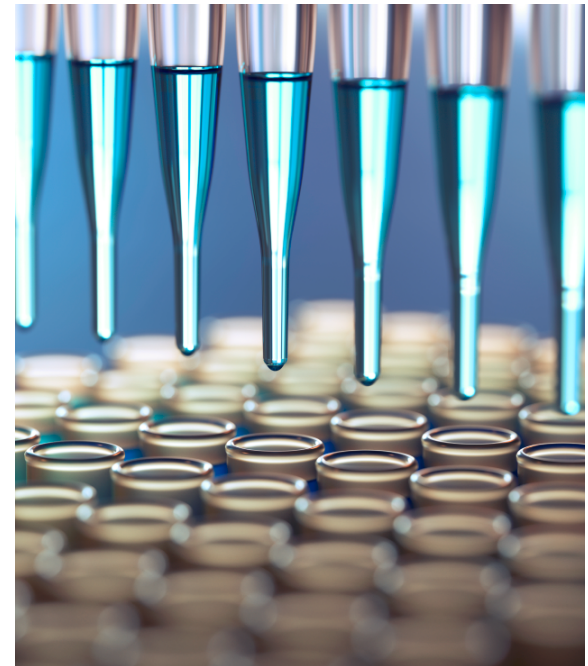
“Science needs to inform policy judgements and regulatory actions, however, science alone is not sufficient for dictating specific policy outcomes.”

Most significant changes

- Mandatory duty of EPA to evaluate existing chemicals with clear and enforceable deadlines
- Chemicals assessed against risk-based safety standard
- Unreasonable risks identified in risk evaluation must be eliminated
- Expanded authority to more quickly require development of chemical information when needed
- Provides EPA with full range of options to address risks of substances including labeling requirements, use restrictions, phase-outs, or other appropriate actions

Most significant changes (continued)

- Requires EPA to make affirmative determination on new chemicals before entry into marketplace
- Requires substantiation of certain CBI claims (while maintaining protection of legitimate CBI)
- New funding source, with up to \$25 million total in annual user fees supplemented by Congressional appropriations



One more major difference from prior law

Promoting cooperation between state and federal regulators while creating a strong national chemical regulatory system, ensuring interstate commerce is not disadvantaged



What hasn't changed?

- A lot, actually – changes focus almost exclusively on Title I, Control of Toxic Substances
- The following Titles within the original Act remain largely unchanged:
 - II Asbestos Hazard Emergency Response
 - III Indoor Radon Abatement
 - IV Lead Exposure Reduction
 - V Healthy High-Performance Schools
 - VI Formaldehyde Standards for Composite Wood Products

What's next?

Implementation

- Ball now in EPA's court; as always, the devil's in the details
- Initial challenges:
 - Resources
 - Organizational capacity
 - Deadlines and legislative mandates
 - Unknowns

Litigation

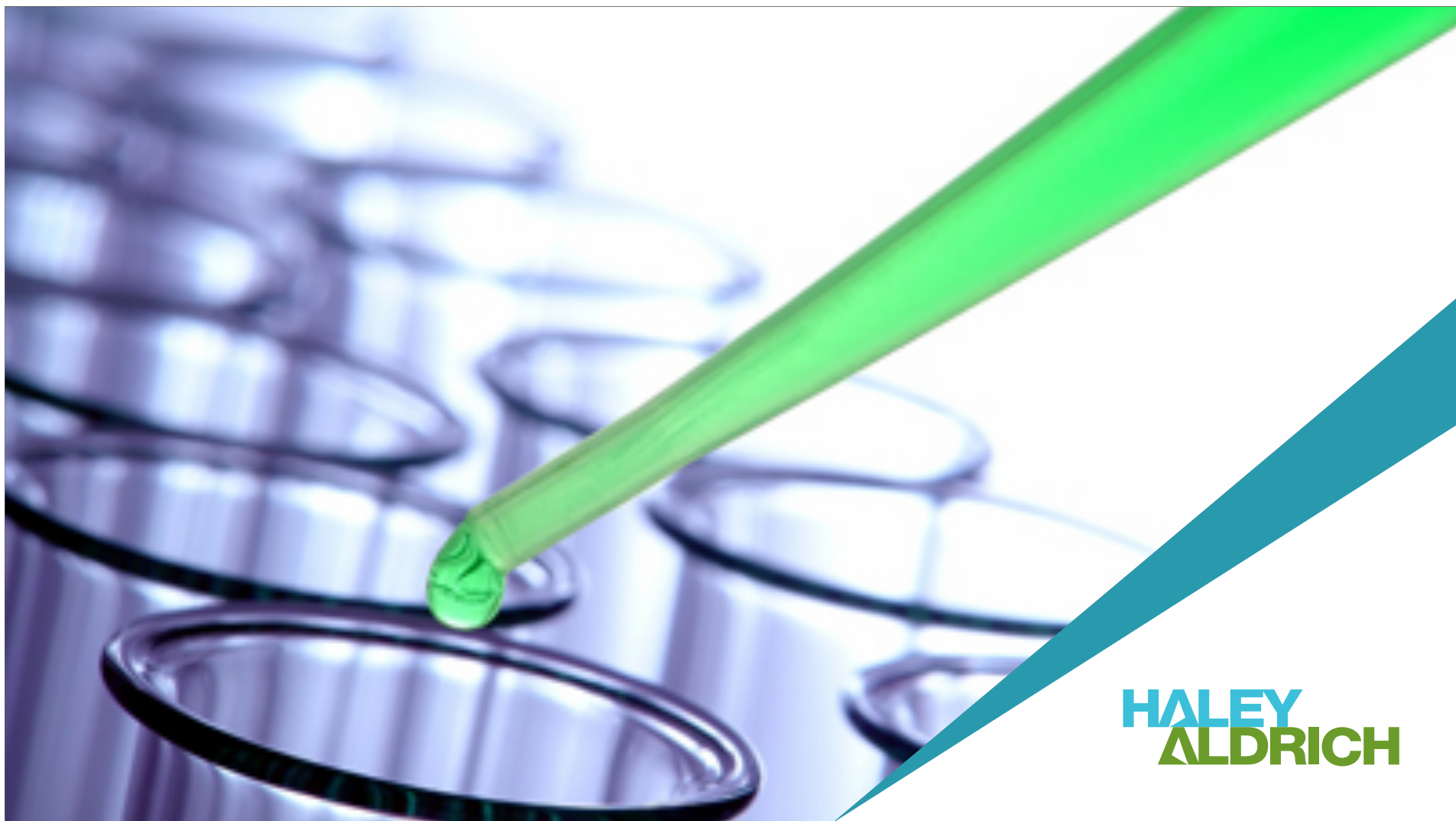
- Built-in flexibility of system is double-edged sword, as it invites challenges about appropriate interpretations

Things for manufacturers to do now

- Review products with eye to identifying chemicals produced or processed that are most important to the business; determine those likely to become “high-priority” targets for detailed risk assessments and EPA regulatory action
- Review state actions being taken on chemical regulation
- Review CBI claims
- Consider completing internal audit of chemical-compliance practices

TSCA reform as a regulatory model

- The European Union has led the way with Registration, Evaluation, Authorisation and Restriction (REACH)
- Opportunity for US to shift paradigm and reestablish itself as leader in efficient and appropriate regulation?
 - Goal of legislation is to protect human health and environment
 - This means system is needed that can quickly identify & address potential problems in most time- and cost-effective way possible



HALEY
ALDRICH