

The Importance of Implementation in Chemicals Management Policies

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Overview

- Introduction to TSCA
- Importance of Implementation
- Elements Shaping TSCA Implementation
- Implementation Stories
- Moving Forward

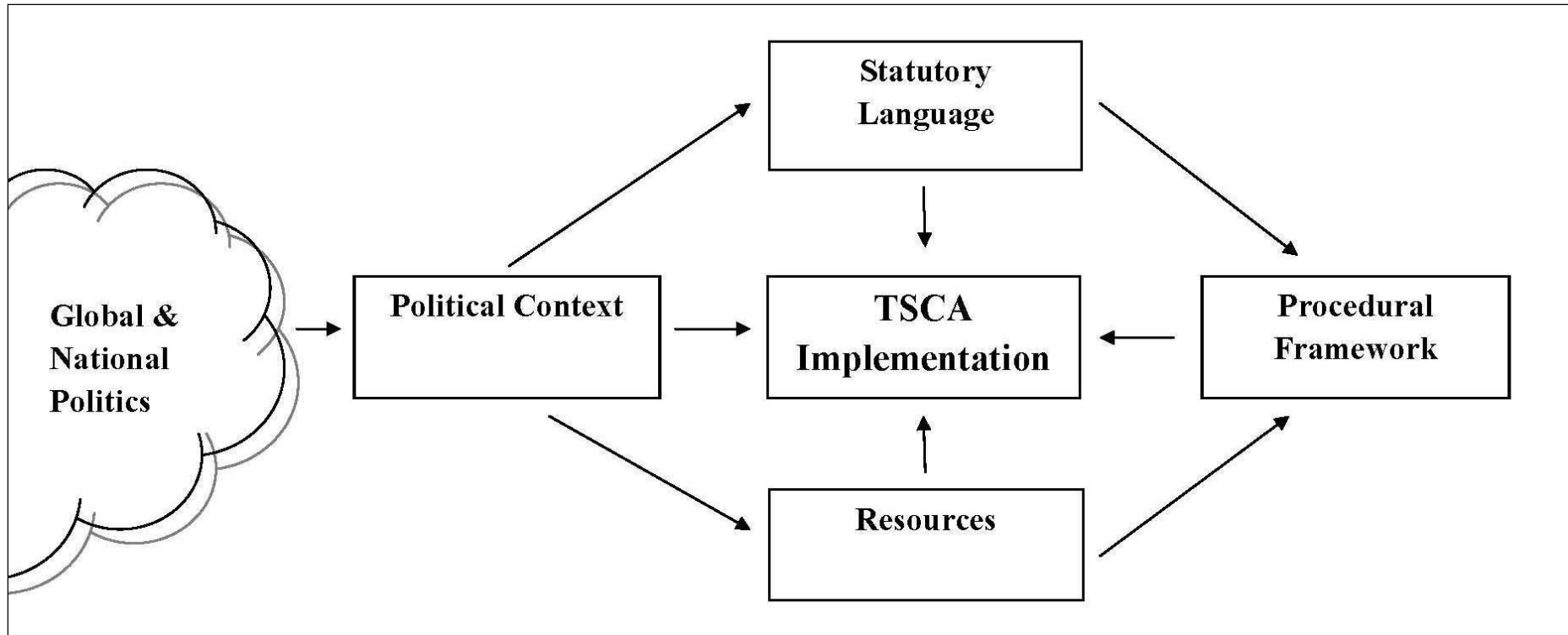
Toxic Substances Control Act

- Primary federal statute regulating the entry into and use of industrial chemicals in commerce
- Established an ambitious regulatory agenda
 - Existing chemicals inventory
 - Pre-manufacture review of all new chemicals
 - Data development and collection
 - Regulation of chemicals that present “unreasonable risks”
- Provided EPA with myriad authorities and tools to achieve this agenda

Why is implementation important?

- Act of passing legislation is no guarantee that real changes will occur—it is the implementation phase that determines whether policy goals are achieved
- Four Elements Shaping TSCA Implementation
 - Statutory Language
 - Procedural Framework
 - Political Context
 - Resources

Elements Shaping TSCA Implementation



Implementation Stories: Key Chemicals Management Challenges

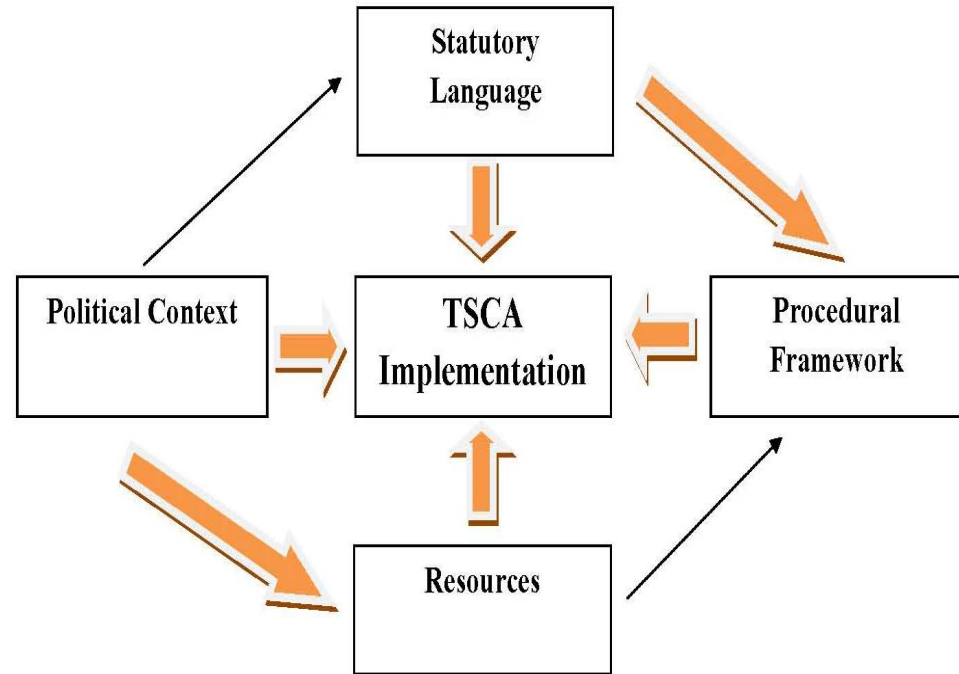
- Prioritizing Chemicals of Concern
- Taking Appropriate and Timely Action on Chemicals

Prioritizing Chemicals of Concern

- Every several years, EPA changed direction by implementing various priority-setting methodologies and systems
- Some examples include:
 - TSCA Interagency Testing Committee Prioritization Methodology for Chemical Testing (1978)
 - Existing Chemical Task Force Chemical Review (1982)
 - RM1/RM2 Tiered Risk Management Process (1991)
 - Use Clusters Scoring System (1994)
 - Chemical Assessment and Management Program (ChAMP) (2007)

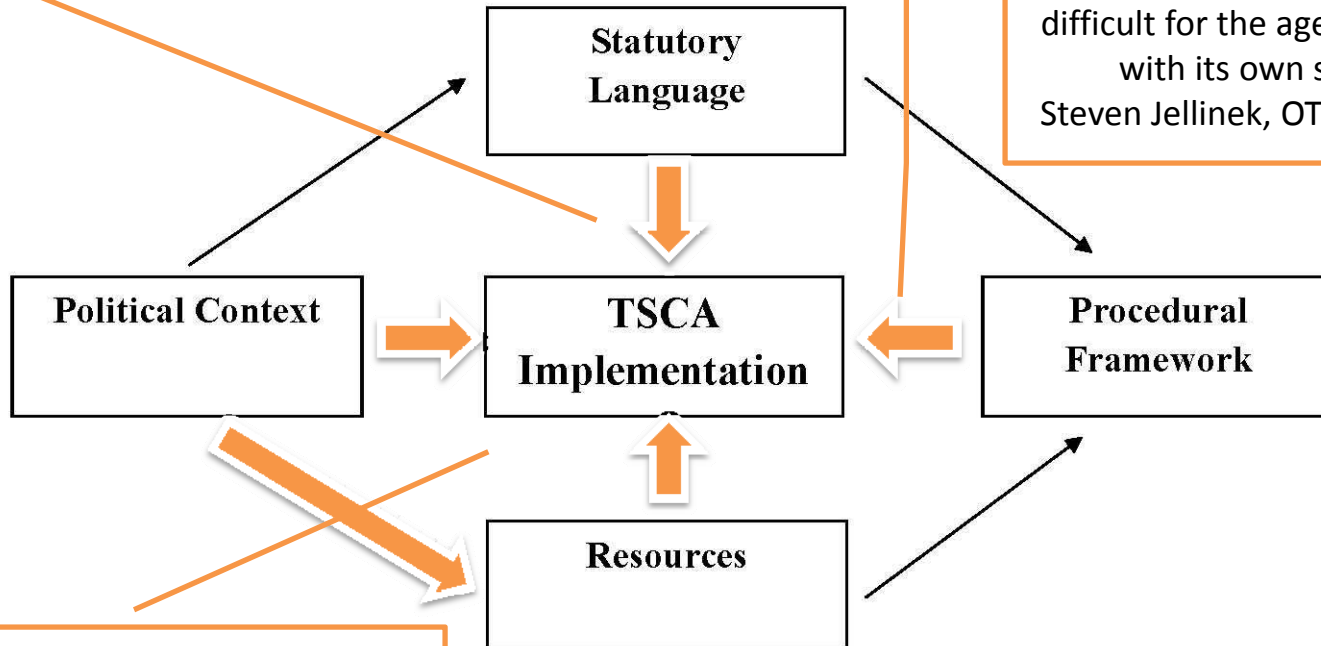
Prioritizing Chemicals of Concern

- Statutory
 - Lack of a clear mandate
- Procedural
 - Lack of substantive rule-making authority
- Political
 - Inconsistent vision and leadership
 - Competing priorities at EPA
- Resources
 - Lack of investment in existing chemicals work



“One of the problems, in a sense, with the statute is it is replete with tremendous flexibility and very little guidance on where to start and what to do first.”
Linda Fisher, OPPTS AA 1989-1993

“There was no guidance from Congress as to what is a concern. And at the same time, they throw in these hurdles—these procedural and legal hurdles—that make it difficult for the agency to come up with its own standards.”
Steven Jellinek, OTS AA 1977-1981



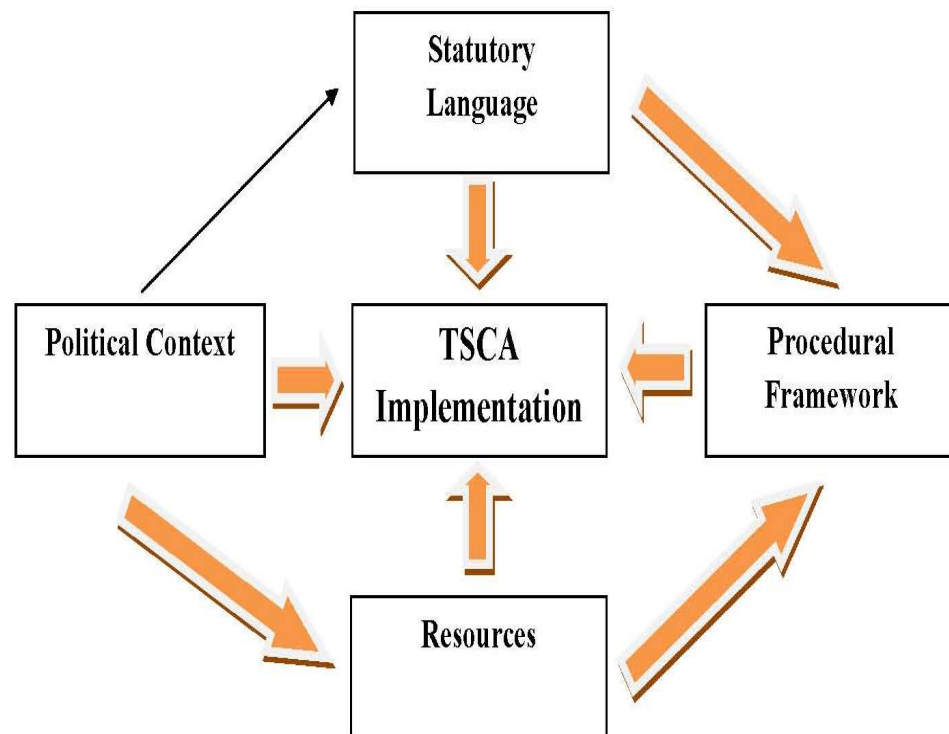
“The Agency as a whole is putting a lot of time and effort...on existing chemicals than we could ever hope to put, with our limited resources on new chemicals. That is why we...should concentrate our emphasis on the unique provisions that TSCA gave to EPA and the country.”
Steven Jellinek, OTS AA 1977-1981

Taking Appropriate and Timely Action on Chemicals

- EPA exercised authority to undertake specific regulatory action on a small number of existing chemicals, but failed to broadly ban all uses of an existing chemical
- EPA collected information using a variety of authorities in the law, including:
 - Chemical-by-chemical test rules
 - Model rules (PAIR, CAIR)
- Movement toward voluntary efforts over time

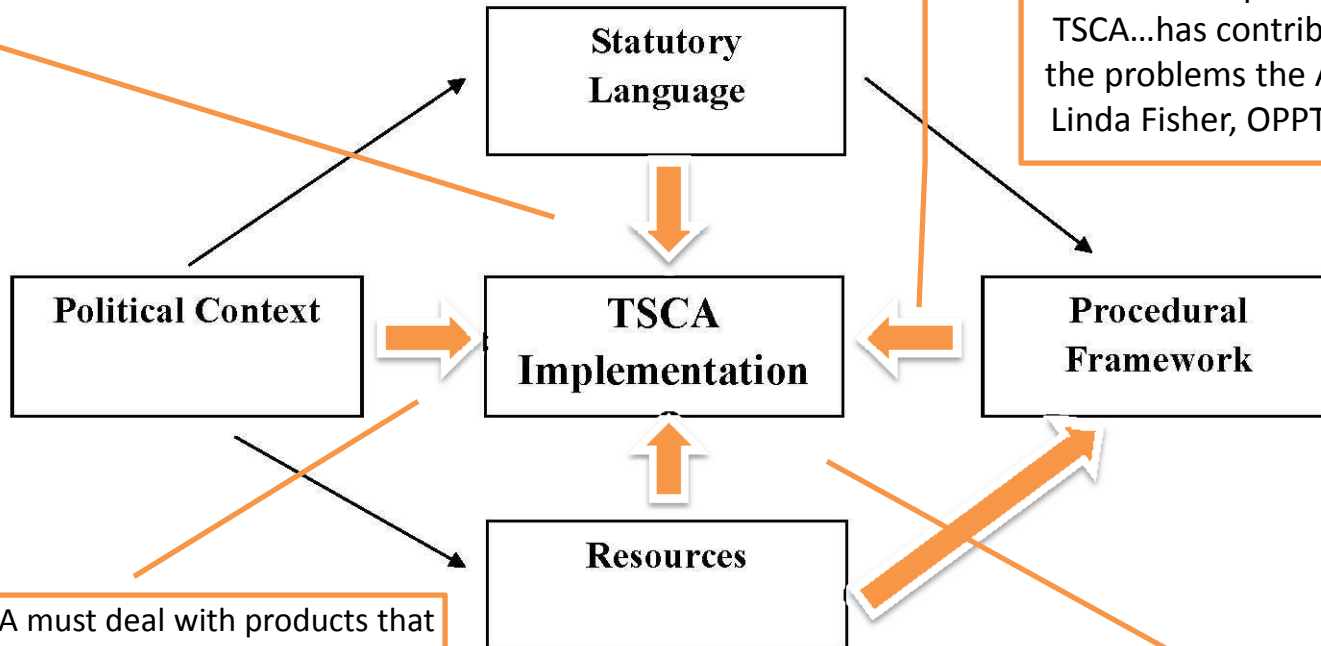
Taking Appropriate and Timely Action on Chemicals

- Statutory
 - Limitations resulting from the “unreasonable risk” standard
- Procedural
 - High standard of judicial review
 - Burdensome rule-making
 - Burden of proof on EPA
- Political
 - Shift to voluntary approaches
 - Jurisdictional struggles
 - New regulatory challenges
- Resources
 - Large investment of resources necessary to meet high burdens



“ ‘Unreasonable risk’ is so central to the Act that the way it is interpreted by EPA and the courts will determine the impact and effectiveness of TSCA.”
The Conservation Foundation, J. Clarence Davies, 1979

“I am not sure TSCA was drafted by people that worked in or managed a bureaucracy... conceptually, a lot of it made sense, but the process they built in to accomplish things under TSCA...has contributed to some of the problems the Agency has had.”
Linda Fisher, OPPTS AA 1989-1993



“Under TSCA, EPA must deal with products that someone in society believes have some utility... While there may be some problems...with some of these substances, before the Agency can take an action against a product, we ought to...crank the benefits into its decisionmaking process...Whether or not that proves to be overly restrictive in dealing with what we think are real problems and real risks, remains to be seen.”
Steven Jellinek, OTS AA 1977-1981

“In terms of the rulemaking process, the time between proposed and final is more a matter of resources and how many people we have on hand to devote to reviewing the public comments.”
Linda Fisher, OPPTS AA 1989-1993

Moving Forward

- Learning from EPA's innovative efforts on key chemicals management challenges
- Respecting the many statutory, procedural, political, and resource factors that have beset effective results for TSCA