TSCA REFORM: A WORK IN PROGRESS

The Auditing Roundtable South Central Regional Meeting

August 3, 2016

Matt Paulson

BRACEWELL

OVERVIEW

- Official Name - Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576)
- Signed into law – June 22, 2016
- Significantly revises 1976 Toxic Substances Control Act
- First major environmental statute enacted since 1990 Clean Air Act Amendments

WHAT WAS WRONG WITH “OLD” TSCA?

- Few EPA attempts to regulate existing chemicals due to “least burdensome” regulatory requirement Obama cited failed attempt to ban asbestos when signing bill
- If no action within 90 days of notice of intent, manufacturing may begin
- Claims that stringent CBI protections allowed manufacturers to hide information from public
- Risk evaluations not consistent with best science
- Fees to low

MAJOR AREAS AFFECTED UNDER “NEW” TSCA

- New Chemicals Review
- Existing Chemicals Designation
- Active Chemicals Prioritization
- Risk Evaluations
- Testing Authority
- Section 6 Actions
- Preemption
- CBI

NEW CHEMICALS REVIEW

- Covers new chemicals and significant new uses of existing chemicals
- Prior to manufacturing, importing, or processing, EPA must determine whether they present “unreasonable risk of injury to health or the environment”
- Broader array of factors considered when determining “conditions of use” versus old TSCA
- EPA cannot consider costs or other “non-risk factors” when assessing risk

NEW CHEMICALS REVIEW (CONT.)

- EPA must consider risk to potentially exposed or susceptible populations
- Old TSCA requirement to choose “least cost alternative” removed
- Where unreasonable risk found, use must either be limited or prohibited
- Burden on applicant to provide information necessary to evaluate risk

EXISTING CHEMICALS DESIGNATION

- EPA has one year to promulgate Section 8 rule with list of chemicals manufactured/processed in last 10 years
- EPA will then designate chemicals as “active” or “inactive”
- Risk evaluations for active chemicals will be prioritized

ACTIVE CHEMICALS PRIORITIZATION

- EPA has one year from enactment to issue rule establishing risk-based screening process for prioritizing active chemicals for risk evaluation
- Risk evaluation based on: Hazard and exposure potential
- Conditions of use
- Volume manufactured or processed

RISK EVALUATIONS

- EPA must conduct risk evaluation for each high-priority chemical
- Each evaluation must be completed within three years of initiation
- Companies can request risk evaluations, but must pay EPA costs

RISK EVALUATIONS (CONT.)

- In place of “least burdensome alternative”, EPA to consider the following, to the extent practicable:
  - Benefits of chemical
  - Effects on health and environment
  - Reasonably ascertainable economic consequences
- New TSCA requires EPA to consider at least one “primary alternative”
  - Possible litigation – extent to which EPA should look at other alternatives

TESTING AUTHORITY

- New TSCA give EPA authority to require testing by order
  - *i.e.*, without rulemaking
- Testing orders must be supported by statement identifying the need for info to be provided by testing
- EPA required to reduce use of vertebrate animals in testing

SECTION 6 ACTIONS

- Whenever EPA determines that existing chemical presents unreasonable risk, TSCA Section 6 rule must be issued to limit, ban, or phase out chemical
- Old TSCA requirement that EPA select the least burdensome option eliminated

PREEMPTION

- Federal inactivity under Old TSCA created patchwork of state regulation
- Under new TSCA, States prohibited from imposing new restrictions on chemicals EPA has determined do not present unreasonable risk, limited to conditions of use and risks addressed by EPA
- “Pause Preemption” – states temporarily preempted from time EPA defines scope of risk evaluation, until final risk evaluation published

PREEMPTION (CONT.)

- Limits on Federal Preemption: States can continue to enforce any actions taken prior to 4/22/16 and continue to take new actions under any laws in effect prior to 8/31/03
- State reporting and monitoring requirements, and restrictions in state air quality, water quality and waste treatment/disposal laws not preempted
- States can seek preemption waivers under certain circumstances

PREEMPTION (CONT.)

- Limits on Federal Preemption (cont.)
  - Compliance with act does not shield company from civil liability for failure to take reasonable precautions
  - Does not apply to first 10 chemicals assessed
  - Does not apply to chemicals for which industry requests risk assessment
- So how complicated is it?

A Quick Guide to Preemption in the Lautenberg Act

ECOS

Key Points

Scope of Preemption

The Lautenberg Act limits the scope of preemption to the "hazards, exposures, risks, and uses or conditions of use" included in the scope of the risk evaluation of final EPA action.

Certain existing laws are grandfathered from preemption:

- State laws in place before Aug. 31, 2003
- State/local chemical restrictions in place before Apr. 22, 3016

Other types of state actions not subject to preemption:

- Information obligation purposes
- Air, water, waste and related activities with limitations

Preemption under the original TSCA

While the original TSCA did include state preemption provisions, preemption had little effect on states because EPA did not take many regulatory actions under the original law.

Old preemption provisions will still apply to actions taken by EPA before the Lautenberg Act was adopted, unless EPA subjects those chemicals to a new risk evaluation and regulatory process.

This summary has been created by ECOS, drawing on materials originally developed by the Toxics Use Reduction Institute (TURI) at UMass Lowell. For more information, please see the following:

http://www.ecos.org/documents/ecos-key-issues-and-comments-on-toxic-substances-control-act-tsca-reform/

http://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/TSCA_Preemption_Provisions

Risk Evaluation…

The Lautenberg Act requires EPA to conduct a risk-based evaluation and determine whether a chemical poses an unreasonable risk to human health or environment.

triggers Pause Preemption.

New state prohibitions/restrictions are preempted, starting when EPA publishes the scope of a risk evaluation, and ending when EPA either publishes the risk evaluation or reaches the statutory deadline for publication of the risk evaluation (up to 3 years).

Duration of pause preemption depends on how quickly EPA publishes the scope of the risk evaluation and completes the risk evaluation (likely 2.5 to 3 years).

During pause preemption, states are prohibited from adopting new restrictions, even though EPA will not have taken action yet.

Waiver from Pause Preemption "Required Exemptions"

Considerations on a waiver application from pause preemption include an EPA determination that the state "has a concern" about the chemical "based in peer-reviewed science."

Note: EPA must provide a waiver if the state "has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance" by either 18 months after the date EPA initiated the prioritization process or the date when EPA publishes the scope of its risk evaluation, whichever comes first.

Note: If EPA fails to make a waiver determination within the required time period, the waiver is automatically granted.

EPA determines that…

- There is not enough information to determine whether the chemical presents unreasonable risk.
- The chemical **does or does not** present unreasonable risk.

Exceptions to Pause Preemption

- Chemicals for which EPA grants a manufacturer-requested risk evaluation
- First 10 Work Plan chemicals for which EPA undertakes a risk evaluation.

Long-Term Preemption

For a chemical that is found to **present unreasonable risk**, long-term preemption is effective on the effective date of the rule issued by EPA.

For a chemical that is found to **not present unreasonable risk**, long-term preemption is effective on the date of the EPA determination.

Note: Long-term preemption can apply to both new and existing state restrictions. Also, if EPA requires notification of a chemical use under a significant new use rule, states are preempted from issuing similar notification requirements for the same uses.

Waiver from Long-Term Preemption "Discretionary Exemptions"

Considerations on a waiver application from long-term preemption include "compelling conditions" related to health or environment, and an EPA evaluation of the state's use of science in decision making.

This chart is provided strictly as an educational resource. It is not comprehensive and does not constitute a formal legal analysis. If you need legal information or opinions, please consult appropriate experts.

BRACEWELL

CBI

- Act places certain limits on CBI claims
- Allows EPA to disclose CBI to states
- Health and safety studies not protected from disclosure except where it would reveal manufacturing methods

FIRST YEAR IMPLEMENTATION PLAN

- Risk Evaluation Process Rule
  - Establish procedures for evaluating high priority chemicals
  - Statutory deadline: 6/17
- Fees Rule
  - Authorize EPA to collect fees
  - Statutory deadline: none

FIRST YEAR IMPLEMENTATION PLAN (CONT.)

- Inventory Rule
  - Require industry to report chemicals manufactured/processed in last 10 years
  - Statutory deadline: 6/17
- Prioritization Process Rule
  - Establish process and criteria for identifying high- and low-priority chemicals
  - Statutory deadline: 6/17

FIRST SECTION 6 RULEMAKING SENT TO OMB

- Rule to ban or restrict sale or manufacture of TCE sent to OMB on 7/27/16
- First attempt since 1991 failure to ban asbestos
- Covers use of TCE in dry cleaning and in aerosol spray degreasers
- What's next?
  - Methylene chloride?
  - Asbestos ?

FIRST SAFETY DETERMINATIONS ISSUED 7/22/16

- Four chemicals – only generic names released
- PMNs submitted prior to enactment, but EPA determined further review required under New TSCA
- For all four, EPA determined “not likely to present unreasonable risk”

KEY ISSUES FOR INDUSTRY

- Inventory Reset – be aware of products purchased; what is on inventory; which are high priority; be prepared for disclosure
- Testing Order Authority – will required statement of need become cursory or will EPA justify testing orders?
- Few limits on scope and burden of testing
- EPA can’t consider costs in determining risk, but must consider economic impact in regulating once risk determined

THANK YOU

MATT PAULSON

Partner, Austin
T: +1.512.494.3659

E:matthew.paulson@bracewell.com

This presentation is provided for informational purposes only and should not be considered specific legal advice on any subject matter. You should contact your attorney to obtain advice with respect to any particular issue or problem. The content of this presentation contains general information and may not reflect current legal developments, verdicts or settlements. Use of and access to this presentation does not create an attorney-client relationship between you and Bracewell.