TSCA § 6(a) Rules: Role of Non-Risk Factors in Risk Management

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James Votaw

Partner

Washington, DC

202.434.4227

Votaw@khlaw.com

James Votaw

James Votaw is an environmental law partner at Keller and Heckman focusing on regulation of new and existing conventional, biotech and nanoscale chemicals under TSCA and pesticides and pesticidal devices under FIFRA. Among other things, James obtains pre-market approvals, conducts transactional due diligence, and defends enforcement actions under these and other health, safety, and environmental laws.

TSCA § 6 –Regulation of Existing Chemicals (1)

- Requires EPA to regulate chemicals presenting "*unreasonable risk*"
  - "*Unreasonable risk*" not defined in statute or rules
- Statute authorizes wide range of tools to mitigate unreasonable risk
  - ✓ Restrict manufacture, processing, or distribution
  - ✓ Restrict production volumes
  - ✓ Restrict particular uses
  - ✓ Restrict concentrations in products or uses
  - ✓ Require on-product or other warnings
  - ✓ Require instructions for use & disposal
  - ✓ To specify wording of instructions
  - ✓ Keep production method /volume records
  - ✓ Keep customer / distribution records
  - ✓ Require tests to demonstrate compliance
  - ✓ Regulate use of substance / articles
  - ✓ Restrict disposal by any person
  - ✓ Require notice to value chain and the public of risks and restrictions
  - ✓ Require repurchase or replacement

TSCA § 6 –Regulation of Existing Chemicals (2)

- Risk Management Standard *before* to 2016 Amendments:
  - "to the extent necessary to protect adequately against the risk"
  - "using the *least burdensome* means"
  - Not practicable: *Corrosion Proof Fittings v. EPA* (5th Cir 1991)
    - 5th Cir. Overturned partial asbestos ban
    - 'EPA must identify and choose least burdensome remedy'
    - 'EPA must assess toxicity of likely substitute products'
  - No new EPA attempts at § 6 risk management rules until 2014

TSCA § 6 –Regulation of Existing Chemicals (3)

- Risk Management Standard *after* 2016 TSCA Amendments:
  - 'Assess risk without consideration of costs or other nonrisk factors'
  - Regulate "to the extent necessary so that the chemical no longer presents such risks"
  - **No requirement to use "*least burdensome* means"**
- Amended TSCA gives EPA the ability to balance benefits and costs of remedies in at least four ways:
  1. Requirement to consider § 6(c)(2) factors in *selecting* remedies "to the extent practicable"
  2. § 6(c)(2)(C) requirement to consider whether feasible alternatives exist for any (effectively) banned uses when selecting remedies
  3. § 6(g) time-limited exemptions
  4. Determination of what constitutes an "*unreasonable* risk" in a case

TSCA § 6 –Remedy Selection Criteria (1)

- TSCA § 6(c)(2) Considerations:
  - EPA must identify and "factor in" to remedy selection "to extent practicable"

<u>The Substance</u>

- ✓ Effects on health and environment
- ✓ Magnitude of exposure
- ✓ The benefits of the substance for various uses

<u>The Economic Consequences of the Rule</u>

- ✓ Effect on national economy, small business, technological innovation
- ✓ Effect on the environment
- ✓ Effect on public health
- ✓ *Costs and benefits of rule* and one alternative
- ✓ *Cost effectiveness of rule* and one alternative

- EPA must publish "*statement of effects*" addressing all 6(c)(2) considerations
  - "based upon reasonably available information"

TSCA § 6 –Remedy Selection Criteria (2)

- When effective ban is being considered, EPA must consider whether feasible alternatives will be available:
  - Technically feasible?
  - Economically feasible?
  - Benefit health or the environment (at least not worse than current)?
  - Reasonably available when restriction takes effect?
- EPA must consider availability of suitable alternatives:
  - Before proposing ban and when selecting remedy transition periods
  - “To the extent practicable”
  - Based upon “reasonably available information”
- Effective date of remedies:
  - To be set “as soon as practicable” (formerly “feasible”)
  - “Reasonable” transition period (anticipates phase in)

TSCA § 6(g) – Time-Limited Exemptions (1)

- EPA may grant time-limited exemptions in three circumstances
  1. **Critical Use:**
     - Use is a critical or essential use, *and*
     - No technically and economically feasible safer alternative is available; *or*
  2. **Significant Disruption**
     - Rule would significantly disrupt national economy, national security, or critical infrastructure; *or*
  3. **No better, feasible alternatives**
     - Reasonably available alternatives to the banned/restricted use are "substantially" worse w/r/t health, the environment, or public safety
- Based upon "reasonably available information"

TSCA § 6(g) – Time-Limited Exemptions (2)

- No procedural rules or guidance governing 6(g) exemptions
  - Discretionary but can't be arbitrary
- Many unanswered questions
  - What constitutes a critical or essential use? Critical or essential to whom? A company? An industry? To society?
  - What constitutes a "significant" disruption of the national economy, national security, or critical infrastructure?
  - What constitutes a "substantial benefit" to health, the environment, or public safety?
- Look for emerging policy in proposed risk management rules
  - (future TSCA 30/30)

Defining "Unreasonable" Risk (1)

- Which risks are "unreasonable" is not defined in the statute, rules or guidance
- No bright lines
- EPA bases "unreasonable risk" on a number of "considerations"

> Whether EPA makes a determination of unreasonable risk for a particular chemical substance under amended TSCA depends upon risk-related factors beyond exceedance of benchmarks, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values. In this draft risk evaluation, the Agency describes the strength of the scientific evidence supporting the exposure assessment as robust, moderate, slight, or indeterminate. When the assessment is supported by robust evidence, overall confidence in the exposure assessment is high; when supported by moderate evidence, overall confidence is medium; when supported by slight evidence, overall confidence is low.)
>
> *-- Unreasonable Risk Determination of the Draft Risk Evaluation for Formaldehyde (Mar. 2024)*

Defining "Unreasonable" Risk (2)

- In some cases it appears EPA has treated the ECEL as bright line (e.g.,TCE)
  - ECEL is the concentration at which an adult human would be unlikely to experience the specified adverse effects if exposed during a working lifetime, including susceptible subpopulations
- Risk thresholds underlying ECELs set using most sensitive endpoint based on review of selected studies and application of uncertainty factors
  - In the end, what aggregate "margin of safety" does this represent?
- Formaldehyde – *ECEL is at/below background ambient levels*

Defining "Unreasonable" Risk (3)

- Fairer representation of unreasonable risk would be to present it as being within a **range of possible values**
  - Consistent with the uncertainty present at all stages of risk evaluation
  - Evaluations necessarily are built on a daisy chain of imperfect data, assumptions, and science policy judgments (*e.g.,: search "uncertainty" and ("confidence" in risk evaluation documents*)
  - Calculated specific, benchmarks suggest false precision
    - Likely overstatements of risk with significant margins of safety
- Would allow the Agency more flexibility in defining remedies for exposures that may fall within the range

Role for Non-Risk Information

- EPA does not expend significant effort to gather non-risk information
  - E.g., review economic impact cost/benefit assessments
  - Cursory, conclusory "consideration" of factor given limited information and nop basis for estimates
- Incumbent on industry to get relevant non-risk information into the record, and to assure that it is properly and timely considered "to the extent practicable" by EPA
- The work cannot wait until the risk evaluation is done
  - EPA must propose risk management rules within in one year and finalize in the second; 60-day comment period
  - Far preferable to provide to EPA during risk evaluation (RM teams already working)
    - Data and arguments reflected in proposed rule

Please join us at 10:00 AM Eastern U.S.
Wednesday, June 12, 2024
www.khlaw.com/REACH-3030

Please join us at 1:00 PM Eastern U.S.
Wednesday, April 24, 2024
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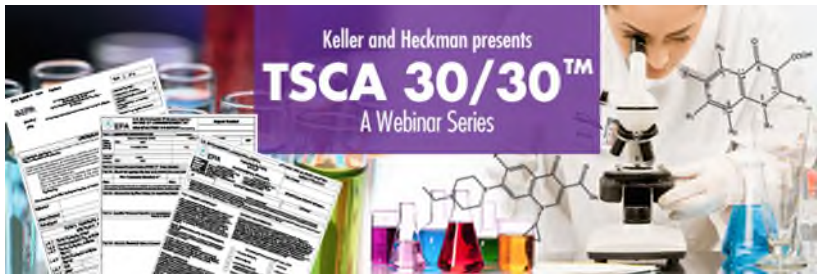

Please join us at 1:00 PM Eastern U.S.
Wednesday, May 8, 2024
www.khlaw.com/TSCA-3030

Thank You

James Votaw
Partner

Washington, DC
202.434.4227
votaw@khlaw.com