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The Major Question
 Doctrine
 Generic SNUR Rules
 Update



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Herb Estreicher, Ph.D.

- Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a Ph.D. in Chemistry from Harvard University (1980) in addition to his US law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is an expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.
- Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach to his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.
- Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintains chemical approvals and pesticide registrations in Canada and Europe and advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation, and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.



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James Votaw

- James Votaw has an extensive practice focusing on environmental and health and safety regulation. Within that arena, he concentrates on the regulation of conventional and nanoscale chemicals, pesticides, consumer and industrial products, and industrial processes and wastes.
- For his clients, James obtains pre-market product approvals and exemptions, including the first U.S. approval of a nanoscale pesticide. He negotiates testing orders, defends enforcement actions, advises on restrictions and disclosures associated with the chemical content of products, counsels on release and other environmental reporting, and supports environmental regulatory and liability aspects of commercial transactions (including, but not limited to regulatory due diligence and private label distribution arrangements). Further, he participates in technical rulemaking proceedings, provides strategic and regulatory compliance counseling within existing and emerging industries, initiates compliance training, conducts internal investigations, performs compliance auditing, offers facility permitting services, and develops product compliance plans and systems.
- James represents clients before State and Federal regulatory agencies and federal courts. He has
 extensive experience in compliance counseling on matters related to the Toxic Substances Control
 Act (TSCA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Clean Air (CAA) and
 Clean Water Acts (CWA); the Comprehensive Environmental Response, Compensation, and Liability
 Act (CERCLA); the Consumer Product Safety Commission (CPSC); California's Proposition 65;
 Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH); Restriction of
 Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).

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Major Question Doctrine



- EPA adopted the Clean Power Plan under Section 111(d) of the CAA, which mandated a shift in electricity generation from coal and fossil fuel to alternate energy sources
- The Supreme Court struck down the Plan in West Virginia v. EPA, holding that EPA lacked the authority to adopt the plan based on the major questions doctrine
- Not an entirely new concept but never fully articulated

How to Identify a Major Question



- 1) Is the Agency asserting power to resolve a matter of great political significance or seeking to end an "earnest and profound debate across the country?" If so, ask whether Congress has considered and rejected taking similar action through legislation in the past
- 2) Does the Agency seek to regulate "a significant portion of the American economy" or "require 'billions of dollars in spending' by private persons or entities?"
- 3) Does the Agency seek to intrude in an area that is the special province of state law?

How to Determine Whether Congress Clearly Authorized the Agency to Address the Major Question



- 1) Does the **Statute clearly authorize** the action?
- 2) Is the Agency attempting to deploy an old statute focused on one problem to solve a new and different problem?
- 3) Has the Agency asserted a new power after long interpreting a statute more narrowly?
- 4) Is there a disconnect between an agency's action and its congressionally-assigned mission and expertise?

State Attorney Generals Take Issue with EPA's Proposed Asbestos Ban (1)



- Twelve State attorney generals filed comments stating, "a flat ban on the use of asbestos is a question of major economic significance" and "it is hard to see how the EPA can use the general language of the TSCA to impose a flat ban on all commercial uses of the substance."
- Cited impacts on the chlor-alkali and petrochemical industries
- Makes good points about deficiencies in EPA's consideration of cost and benefits of a ban and its impact on the national economy as required under TSCA Sec. 6 (c)(2)(B)

State Attorney Generals Take Issue with EPA's Proposed Asbestos Ban (2)



- But does this fall under the Major Question Doctrine?
- See Sec. 6 (g) discretionary authority to grant a time-limited exemption where the rule would significantly disrupt the national economy, national security, or critical infrastructure

Major Question Doctrine and NGO Section 21 Petitions



- NGO petition asking EPA to "phase out the anthropogenic manufacture, processing, distribution, use, and disposal of greenhouse gas (GHG) emissions, fossil fuels, and fossil fuel emissions."
- NGO petition asking EPA to protect "public health and the environment from the serious harms associated with anthropogenic emissions of carbon dioxide, including ocean acidification."





2022 Amendments to TSCA Significant New Use Rule (SNUR) Regulations



2022 Amendments to SNUR Regulations



- EPA finalized amendments to the TSCA SNUR Regulations (Part 721)
 - Proposed 2016; Final 87 FR 39,756 (July 5, 2022)
 - Docket EPA-HQ-OPPT-2014-0650 (response to comment document)
 - K&H Alert: <u>https://tinyurl.com/y9m6mzf6</u>
- 1. Align certain SNUR Subpart B worker protection standards with corresponding current OSHA standards
- 2. Require use of "feasible" engineering controls before PPE
- 3. Moderate and clarify compliance standards water discharge limits
- 4. Other changes

Background on SNURs (1)



- One Basic Pathways for Chemical Regulation under TSCA
 - § 5(e) or § 5(f) risk management orders for New Chemicals, in connection with PMN review
 - ♦ § 6(a) risk management rules:
 - Existing chemicals: After 7-year \S 6(b) risk evaluation/management process for "High Priority" chemicals
 - Existing chemicals: After final judgment in TSCA \S 21 suit seeking to compel rulemaking (e.g., as sought for fluoride)
 - New or Existing \S 5(f) Chemicals presenting unreasonable risk, identified in connection with PMN review
 - ♦ § 7 imminent hazard control orders from federal District court
 - TSCA § 5(a)(2) rules regulating "significant new uses" of new or existing chemicals – referred to as SNURs

Background on SNURs (2)



- Before engaging in a "significant new use" (defined by a rule) manufacturers/processors must submit a *significant new use notice* (SNUN) and EPA must make a risk determination (like a PMN)
 - SNURs are not necessarily based on an "unreasonable risk" finding broad authority
 - Criteria to establish SNUR: Consider "all relevant factors" including,
 - Anticipated future volume
 - Type or form of exposure to humans or the environment
 - Increases in magnitude or duration of exposure
 - Anticipated manner of manufacturing, processing, distribution, and disposal

Background on SNURs (3)



- EPA uses SNURs for Chemical Control essentially in two ways:
 - 1. Follow-up to new chemical PMNs:
 - Gives EPA an opportunity to do risk review for "conditions of use" not contemplated by the PMN
 - Makes control methods from PMN enforceable against other manufacturers
 - 2. Ban disfavored chemical "uses" that have been discontinued, e.g.,
 - Manufacture of many C8 PFAS after voluntary phase out by industry
 - Discontinued asbestos uses
 - Upcoming: All uses of §6(b) "High Priority" Chemicals not considered in risk evaluation

Background on SNURs (4)



- Codified in Part 721
- Subpart A general provisions
- Subpart B/C "Menu" of control terms + recordkeeping
 - E.g., "a significant new use is any manufacturing..."
 - Without requiring gloves
 - Without providing specific respiratory protection
 - Allowing discharges to water [> [X] ppm]
- Subpart E Chemical-specific SNURs
 - Incorporate by reference Subpart B control terms

Amendments: Align with OSHA Standards (1) Keller&

- Subpart B Respiratory Protection Standards
 - Opdate: Refer to current NIOSH respirator certification rules
 - Opdate: Expand menu of respirator types to current forms
 - Preserve old forms to avoid triggering SNUNs for existing users
 - Existing users can "upgrade" to equivalent current format without SNUN
 - Expand menu of potential respiratory exposure forms:
 - E.g., "Particulate/aerosol", "Gas/vapor," combinations

Amendments: Align with OSHA Standards (2) CKeller& Heckman

- Subpart B Hazard Communication Standards
 - ♦ Incorporate by reference OSHA HazCom program as amended
 - Self-updating- Current form of OSHA standard will always apply
 - Clearer that HazCom program required by TSCA is same as OSHA
 - Opdate: Electronic access to SDS allowed as compliance method
 - Opdate: Expand menu to add current HCS/GHS hazard phrases
 - E.g., Preserve old forms to avoid triggering SNUNs for existing users
 - Existing users can "upgrade" to equivalent current format without SNUN

Amendments: Align with OSHA Standards (3) CHeckman

- Subpart B Make OSHA "Hierarchy of Controls" Mandatory
 - Employer must use *engineering controls* to achieve the exposure control required by the SNUR
 - PPE allowed to meet standard only where "feasible" controls are not sufficient
 - Like OSHA, "Feasible" allows consideration of cost same meaning as 29 CFR 134(a)(1)
 - Prospective application (future SNURs)
 - Compliance: Employers will need to document their exposure control feasibility assessment and consideration of alternatives
 - Applies to both dermal and respiratory exposure SNURs

Amendments: Water Release Standards



- Currently:
 - SNUR limits / prohibits releases of a substance to water, measured as a calculated concentration at the actual point of discharge to waters of the U.S. (river, bay) – often after passing through a POTW;
 - Takes into account *dilution* by receiving water at conservative, lowest flow conditions
 - ♦ BUT: Does not take into account any effects of treatment
 - EPA has allowed in some individual SNURs
- Amendment: Compliance calculation now may take into account wastewater treatment effects, in some cases
 - Treatment method and assumed removal efficiency must be specified in the individual SNUR
 - Prospective application only

Clarification: Water Release Standards



- Discharge limits apply only to "Predictable or Purposeful Releases"
 - ♦ Preamble seeks to clarify to which discharges are "P or P"
 - Applies: Any discharge identified in the PMN
 - ◊ Does not apply where:
 - (a) emergency conditions exist <u>and</u>
 - (b) submitting a SNUN is not practically possible before the discharge occurs
- Response to comments seems to confirm that accidental spills are not "P or P" even if the spill does not create an "emergency" in a conventional sense
 - But Discharges arguably resulting from failure to have spill control procedures may be considered "predictable"



FINAL THOUGHTS

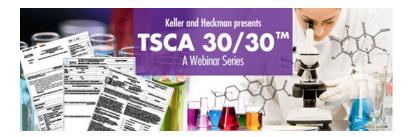




Please join us at 1:35 PM Eastern U.S. Wednesday, August 10, 2022 www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S. Wednesday, August 17, 2022 www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S. Wednesday, September 14, 2022 www.khlaw.com/TSCA-3030



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