

# TSCA Regulation of Articles: A Fresh Look

**October 13, 2021**

# Tom Berger



- ◆ Tom Berger assists clients in bringing forth new products and maintaining the ability to market them in a cost-effective manner using an interdisciplinary approach that combines law and science, with an emphasis on emerging technologies in the industrial chemicals area
- ◆ Tom helps clients navigate the TSCA premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). He also counsels clients on US Environmental Protection Agency (EPA) enforcement matters and assists companies in preparing for Agency inspections, responding to information requests and subpoenas, and defending enforcement actions. Tom is a recognized leader in designing and conducting extensive voluntary TSCA compliance audits (often as part of corporate mergers and acquisitions) and assisting clients in managing liability under EPA's "Audit Policy" and other available penalty mitigation policies
- ◆ Tom's practice is based on an in-depth understanding of the chemicals, plastics, and electronics industries, with over 25 years of experience counseling clients on the regulation and approval of new and existing chemicals under the Toxic Substances Control Act (TSCA) and TSCA's international counterparts in Australia, Canada, China, the European Union, Japan, Malaysia, New Zealand, the Philippines, South Korea, and Taiwan. His technical background allows him to frequently undertake matters that involve polymers, inorganic chemistry, and complex chemistry and chemical nomenclature issues
- ◆ As an active member of the environmental and chemical industries, Tom was heavily involved in efforts to "reform" TSCA and works extensively on all aspects of TSCA, including TSCA Inventory, Inventory "reset," Chemical Data Reporting (CDR), and section 6 "fee" rule issues, as well as confidential business information (CBI), section 8 recordkeeping and reporting, and import/export issues
- ◆ Tom has a chemical engineering background and, prior to joining Keller and Heckman, worked as an engineer for a major international chemical manufacturer

# 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 US 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)

# M. Freedhoff on Articles

- ◆ “...Generally speaking, articles are manufactured goods or finished products – and the chemicals in them ARE subject to TSCA...the law is very clear that when a chemical enters the United States, or is distributed or processed in the United States – whether in bulk form or in an article – it can be subject to regulation under TSCA...As such, EPA can – and indeed already has – imposed regulatory requirements on articles imported under TSCA...Furthermore, companies are already required to know what is in their products in order to comply with European Union regulations, which require reporting for products which contain chemicals identified as a [SVHC]..There are currently over 4 million entries in this searchable database, so we know that it’s possible to track chemicals in complex supply chains....”

*OCSPP Assistant Administrator, Dr. Michal Freedhoff, Sept. 28, 2021*

# “Article” Definition

- ◆ A manufactured item that:
  - ◆ is formed to a specific shape or design during manufacture;
  - ◆ has end-use function(s) dependent in whole or in part upon its shape or design during end use; and
  - ◆ either has no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described at 40 C.F.R. § 720.30(h)(5).

*Fluids/particles not considered articles regardless of shape or design*

# “Article” in the Statute

- ◆ “Chemical substance(s)” and “mixture(s)” defined in §3 and used throughout TSCA to describe chemicals and forms of chemicals subject to various requirement
  - ◇ “Article,” however, not defined in §3 and is used only sparsely elsewhere in the statute
- ◆ Prior to LCSA, “article” was meaningfully used only in:
  - ◇ §3 (definitions of the terms “distribute in commerce” and “process”)
  - ◇ §5 (description of test data required to be included in PMN)
  - ◇ §6 (but only when referring to labeling and disposal restrictions that may appear in §6(a) rule)
  - ◇ §7 (rarely if ever used, imminent hazard provision)
  - ◇ §12(a) (export-only exemption)
  - ◇ §13 (import certification)
  - ◇ §17 (federal district court specific enforcement and seizure authority)
- ◆ *Significantly, other than in portions of §12(a), itself an exemption, in no case is the term “article” explicitly used in the context of an article being excluded from a requirement of TSCA*



# New Statutory Provisions

- ◆ Statutory use of “article” unchanged by LCSA, with two exceptions:
  - ◆ Newly-added **§5(a)(5)** provides EPA with explicit authority to regulate chemicals in “articles” under §5, by providing that:
    - *The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification*
  - ◆ Newly-added **§6(c)(2)(E)** allows EPA to restrict chemicals in articles in §6 risk management actions, but only to the extent necessary to address identified risks so that the chemical does not present an unreasonable risk:
    - *In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A)*

# Regulatory Exemptions for Articles

- ◆ Substance *imported* as part of or formed during *manufacture* of “article” exempt from **§5** PMN requirements
- ◆ Persons who import or process substance as part of article also *typically* exempt from TSCA **§5** SNUR/SNUN requirements
  - ◇ Unless specific SNUR otherwise specifies, 40 C.F.R. §721.45(f) exempts from TSCA §5 SNUN requirements substances imported/processed as part of an article (next slide)
- ◆ Articles both subject to and exempt from various portions of **§8** reporting and recordkeeping requirements
  - ◇ *See, e.g.*, 40 C.F.R. §716.21(a)(8) (articles not exempt from TSCA **§8(d)** rule for consumer products containing lead); 40 C.F.R §711.10(b) (imported articles exempt from **§8(a)** CDR requirements)
- ◆ Unless required in context of specific TSCA §5, 6, or 7 action, articles (other than PCB articles) exempt from TSCA **§12(b)** export notification requirement
- ◆ Imported articles exempt from **§13** import certification requirements (unless specifically required in rule or order)



# SNURs- Section 721.45(f)

- ◆ In several proposed and final SNURs (more recently) presumptive 40 C.F.R. §721.45(f) exemption is inapplicable:
  - ◆ Erionite fiber (1991)
  - ◆ Elemental mercury (2012)
  - ◆ Benzidine-based substances (2014)
  - ◆ Toluene diisocyanate (TDI) (proposed) (2015)
  - ◆ Hexabromocyclododecane and 1,2,5,6,9,10-hexabromocyclododecane (HBCD) (2015)
  - ◆ Asbestos (2019)
  - ◆ Certain perfluorinated (LCPFAC) substances (2020)

# What's Next for Articles Under TSCA?

- ◆ EPA has not reversed long standing policy on exempting articles from most TSCA actions:
  - ◆ If anything, Lautenberg Act only further constrained EPA's ability to regulate articles
    - In SNURs [§5(a)(5)]
    - In risk management rules [§6(c)(2)(D)(*replacement parts*) and (E) [*articles generally*];
  - ◆ Dr. Freedhoff's comments only confirmed EPA's existing jurisdiction over chemical substances contained in articles – no new policy

# What's Next for Articles Under TSCA? (2)

- ◆ § 6 risk management rules will provide many more opportunities for TSCA article regulation going forward –
- ◆ (e.g., the five PBT rule bans already in place)
  - ◆ PIP (3:1) – processing and distrib. of articles containing PIP (3:1)
  - ◆ decaBDE – mfg., processing and distrib. of articles containing decaBDE
  - ◆ HCBd – mfg., processing and distrib. of articles containing HCBd
  - ◆ PCTP – mfg., processing and distrib. of articles containing PCTP ( >1 wt %)
- ◆ 10 more risk management rules in the works (1<sup>st</sup> 10 risk evaluations), regulating conditions of use

# What's Next for Articles Under TSCA? (3)



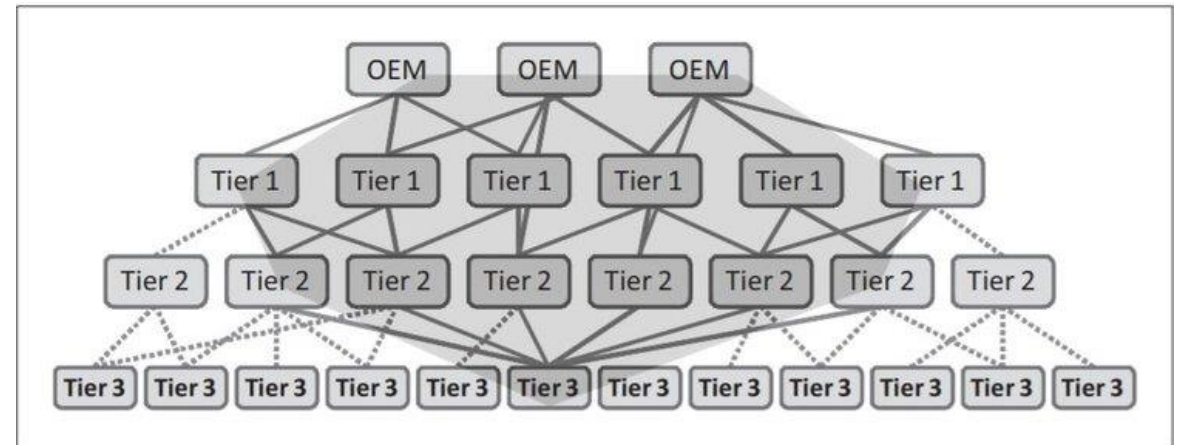
- ◆ TSCA reporting rules applicable to chemicals contained in articles
  - ◆ 2018 TSCA fee rule (?) (next 20 risk evaluation candidates) - *Δ expected*
  - ◆ Proposed PFAS reporting rule (5000+ PFAS substances present in imported articles or domestic articles that may undergo some incidental change)

# What's Next for Articles Under TSCA?

- ◆ Even without a change in EPA policy, it will become increasingly important for companies to know about chemicals in their important products and to have practical tools to interrogate their supply chains
  - ◆ Regulatory compliance
  - ◆ Strategic planning /engagement
  - ◆ E.g.,
    - PIP (3:1) ban
    - PFAS SNUR
    - 20 substances currently undergoing risk evaluation

# Extremely Difficult to Identify All Chemicals in Supply Chains

- ◆ Article manufacturer supply chains may involve hundreds or thousands of components and supply chains for each five or more tiers deep
- ◆ Importers may be two or more steps away from the manufacturer in the distribution chain
- ◆ Examples of challenges:
  - ◆ Number of components
  - ◆ Supplier protection of formulations
  - ◆ Supplier protection of supply chain
  - ◆ Impurities vs. intentionally added
  - ◆ Reporting thresholds
  - ◆ Nomenclature/identity
  - ◆ Enforcement consequences of “wrong” answer



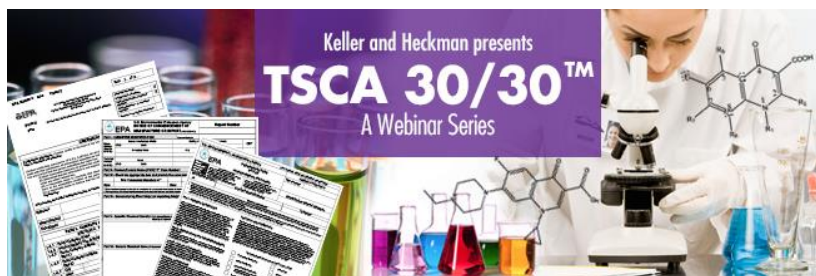


# Agencies Should Develop a Record on Article Content Research Challenges



- ◆ EPA has long recognized these challenges, e.g.,
  - ◇ Original Inventory reporting rule [42 FR at 53805 (10-03-1977)]
  - ◇ Original PMN rule [48 FR at 21726 (05-13-1983)]
  - ◇ TSCA Fee rule no action assurance (2020)
- ◆ But:
  - ◇ Recent EPA burden estimate for proposed PFAS reporting rule omitted investigation burden on article importers – *booked at zero \$ because ‘unknown’*
  - ◇ Recent Apples-to-Oranges comparison to SVHCs in articles reporting and SCIP database - *‘industry must “simply survey their supply chains”’*
- ◆ Public Comments: Consider FACA process to develop a record on the burden/costs of regulating articles for meaningful future cost benefit analysis

# Final Thoughts



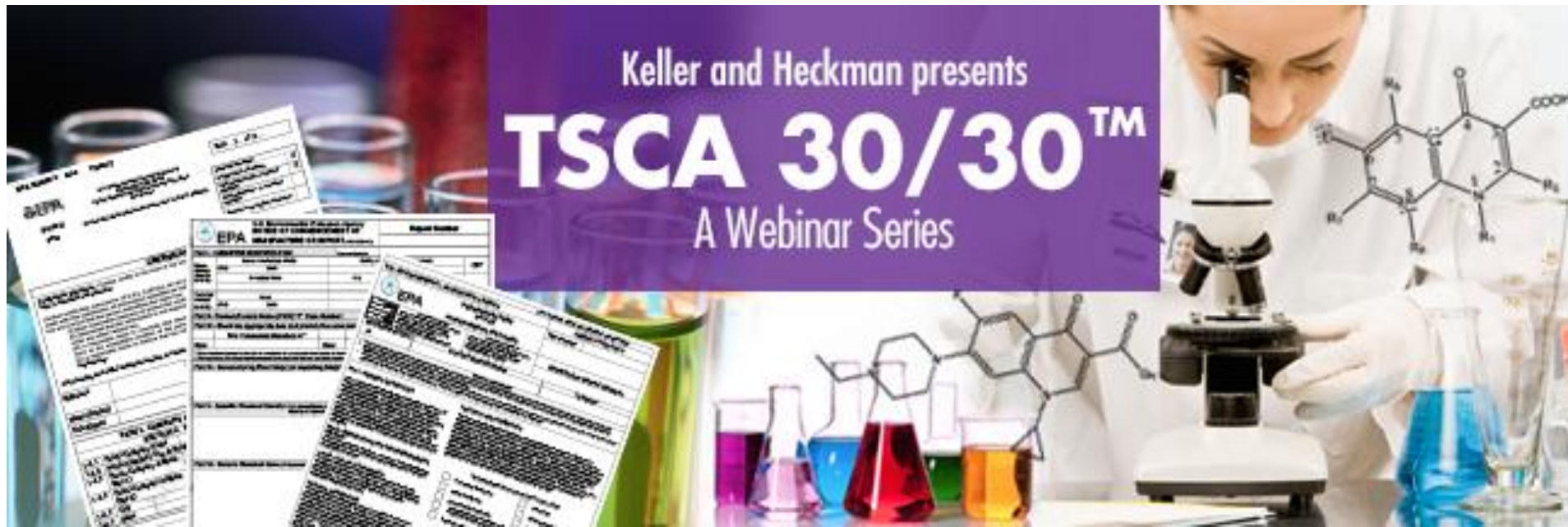
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# Thank You

Any Questions?

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