



U.S. v. Inhance
Impurities v. Byproducts and SNURs
Broader Implications for Industry

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Herb Estreicher

- ◆ Herb Estreicher is a prominent environmental lawyer who holds a Ph.D. in Chemistry from Harvard University in addition to his U.S. law degree. Herb is an 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 many cases before the European Chemicals Agency 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 with 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 clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directive.



Thomas C. Berger

- ◆ Tom has a combined chemical engineering and legal background and assists clients in commercializing new products and maintaining the ability to market them in a cost-effective manner with an emphasis on emerging technologies in the industrial chemicals area.
- ◆ He helps clients navigate the Toxic Substances Control Act (TSCA) premanufacture notification (PMN) review process and negotiates the terms and conditions of TSCA section 5(e) orders and significant new use rules (SNUR). 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 TSCA and TSCA's international counterparts in Australia, Canada, China, the European Union (EU), 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.



James G. 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.
- ◆ James represents clients before State and Federal regulatory agencies and federal courts. He has 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, Authorisation, and Restriction of Chemicals (REACH); Restriction of Hazardous Substances (RoHS); and Waste Electrical and Electronics Equipment (WEEE).
- ◆ James assists clients with obtaining 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.



- ◆ “EPA considers the **manufacturing of certain PFAS from the fluorination of polyolefins** to be a **significant new use** under TSCA.”
- ◆ “LCPFAC [long-chain perfluoroalkyl carboxylates] chemical substances present in polyolefins due to the fluorination process would be **considered byproducts of the manufacturing process** because they are produced during the manufacture of the fluorinated polyolefins and do not have a separate commercial intent.”
- ◆ ‘**Only byproducts that are separated and disposed, burnt as fuel, etc. are exempt**’
- ◆ Fair to say that **every TSCA practitioner** scratched their head and asked themselves, “*Isn’t that an exempt impurity?*”

What is the Issue?

- ◆ SNUR regulations *expressly* exempt certain persons from the obligation to file a notice for permission to engage in a significant new use:
 1. “Person who manufactures or processes the substance only as an **impurity**.”
 2. “Person manufactures or processes the substance only as a **byproduct** which is used by ... organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes.”
- ◆ But regulations do NOT *expressly* exempt:
 - ◇ Person who manufactures or processes the substance only as a **byproduct** without a separate commercial intent (byproduct not separated from host).

Exempt Impurities vs. Non-exempt Byproducts



- ◆ **Impurity:** “a chemical substance which is unintentionally present with another chemical substance.”
- ◆ **Byproduct:** “a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.”
- ◆ **Manufacture for commercial purposes:**
...substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including **byproducts** that are **separated** from that other substance or mixture and **impurities** that **remain** in that substance or mixture...

U.S. v. Inhance, Civil Action
No. 5:22-cv-05055-JFM, Eastern District PA (1)



- ◆ Alleged TSCA violation: manufacturing SNUR chemical without submitting SNUN
- ◆ Motions for summary judgment
 - ◇ Oral hearing Aug 23, 2023
- ◆ Company correctly argues issue of material fact on whether the trace PFAS formed are exempt impurities
- ◆ Govt and NGOs argue no issue of material fact:
 - ◇ The trace PFAS are clearly *non-exempt* byproducts
 - ◇ At best, trace PFAS are both byproducts and impurities

U.S. v. Inhance, Civil Action

No. 5:22-cv-05055-JFM, Eastern District PA (2)



- ◆ The Gov't and NGOs argue the SNUR exemption is only for the manufacture or processing of a SNUR substance “only as an impurity” – *not as a byproduct*
- ◆ They further point out that the impurity exemption under the PMN regs is for “any impurity” and therefore the SNUR exemption must be narrower
- ◆ But what they ignore is that the PMN exemption focuses on the status of the **substance** and the SNUR exemption focuses on the activity of the **person** engaged in manufacturing or processing
 - ◆ A person can simultaneously process a substance as an impurity and for commercial purposes ∴ “only as an impurity” in 721.45(d)

Hasn't EPA Already Conceded that the PFAS Byproducts are Exempt Impurities?

- ◆ EPA states in the preamble (85 FR 45,121 (July 2020)) of the specific PFAS SNUR at issue, when addressing industry concerns with importing materials containing (a) **unintentional degradation byproducts**, or (b) residual LCPFAC used in polytetrafluoroethylene (PTFE) production outside the U.S.:
 - ◆ “To the extent the chemical substance subject to the SNUR is only ‘unintentionally present’ at the point of foreign manufacture, **it is already exempt from reporting by the importer as an imported impurity.**”
 - ◆ “As such, importers are not required to submit a SNUN for or report on a substance based simply on that substance’s presence as an impurity.”
 - ◆ “Additionally, the impurity exemption at 40 CFR 721.45(d) includes domestic manufacture and processing.”

How Does One Reconcile All of This?

- ◆ Can't read out the impurity exemption
- ◆ Impurities produced during manufacture/processing are always byproducts
- ◆ When is an impurity no longer exempt?
 - ◆ *When it is separated from the main product*
 - ◆ Definition of impurity: "unintentionally present with another chemical"
 - ◆ This is why separate byproduct exemptions exist in PMN and SNU regulations for limited use of *separated* byproducts (burning, disposal, land application, extraction)

Applicability of SNUR Notification to Byproducts

Exempt Impurities

'chemical which is unintentionally present with another chemical substance' [721.45(d)]

1. Non-Byproduct Impurities

- ◆ *E.g., Unreacted monomer*
- ◆ *Processing aid residues*
- ◆ *Catalysts*
- ◆ *Foreign matter in source materials*

2. Byproducts

'Produced without commercial intent during the manufacture, processing, use, or disposal of another chemical'

A. Byproducts Not Separated from Host Material

- ◆ *E.g., Barrel fluorination byproducts*

B. Byproducts Separated from Host Material

(1) Exempt Byproducts

- ◆ *§ 721.45(e)*
- ◆ *Disposed as waste*
- ◆ *Fuel use*
- ◆ *Soil enrichment*
- ◆ *Source for extraction*

(2) Non-Exempt Byproducts

- ◆ *Subsequently used for non-exempt commercial purpose*
- ◆ *Subject to SNUN notification*

2010 CDR Q&A

- ◆ Question 6: Chemical substance X is formed unintentionally, without any separate commercial purpose, during the manufacture of another chemical substance, Y. Furthermore, it is not isolated from substance Y. Would it be accurate to describe substance X as an impurity with no reporting obligation?
- ◆ Answer 6: Yes. Chemical substance X is both a byproduct and an impurity. The unintentional byproduct that remains with the intended product (i.e., is not isolated from that intended product) is an impurity. The manufacture of that impurity is not reportable for PMN or IUR purposes. See 40 CFR 711.10(c) and 40 CFR 720.30(h)(1).

PMN vs. SNUR Exemptions

Exemption	720.30 PMN rule	720.30 cite	721.45 SNUR rule
Non-chemical substances	X	(a)	X ^(*)
Mixtures	X	(b)	X ^(*)
R&D	X	(c)	X
TME	X	(d)	X
Export-only	X	(e)	X
§5(h)(4) “upon application and by rule” (e.g., LVE, PE)	X	(f)	
§5(h)(5) “exists temporarily” (by application)		NA	X
Byproducts, burned, disposed, or from which extracted	X	(g)	X
Impurities	X	(h)(1)	X
Byproducts not used for commercial purposes	X	(h)(2)	
Incidental reaction products	X	(h)(3)	
Storage or disposal	X	(h)(4)	
End-use	X	(h)(5)	
Formed during “article” manufacture	X	(h)(6)	X
Physico-chemical modification	X	(h)(7)	
Non-isolated intermediates	X	(h)(8)	
Non-commercial R&D	X	(i)	
Advance compliance SNUN		NA	X
Covered by §5(e) order		NA	X

And There's More...

- ◆ Section 5(e) order exemptions have evolved and are not consistent with PMN or SNUR exemptions
 - ◇ Currently:
 - R&D (both types)
 - "imported" as part of an article
 - Completely reacted or cured
 - ~~- Export only~~
 - ~~- Impurity (h)(1)~~
 - ~~- Byproduct (h)(2)~~
- ◆ Not to mention that each section of TSCA has its own unique exemptions, *e.g.*,
 - ◇ CDR (no export-only)
 - ◇ §8(c) – some but not all "(h)" exemptions (not impurities or byproducts)

Implications

- ◆ If the Court gets this wrong
 - ◆ Any substance that contains a trace SNUR impurity that is produced during the manufacture or processing of the substance would be subject to the SNUR
 - ◆ Thousands of SNUR'd substances
 - ◆ Effectively regulates large numbers of existing substances outside the scope of Section 6
 - ◆ Huge distortion of the regulatory regime

Round Table Discussion



**WHAT SHOULD INDUSTRY DO TO ENSURE THE
COURT DECIDES THIS CORRECTLY?**



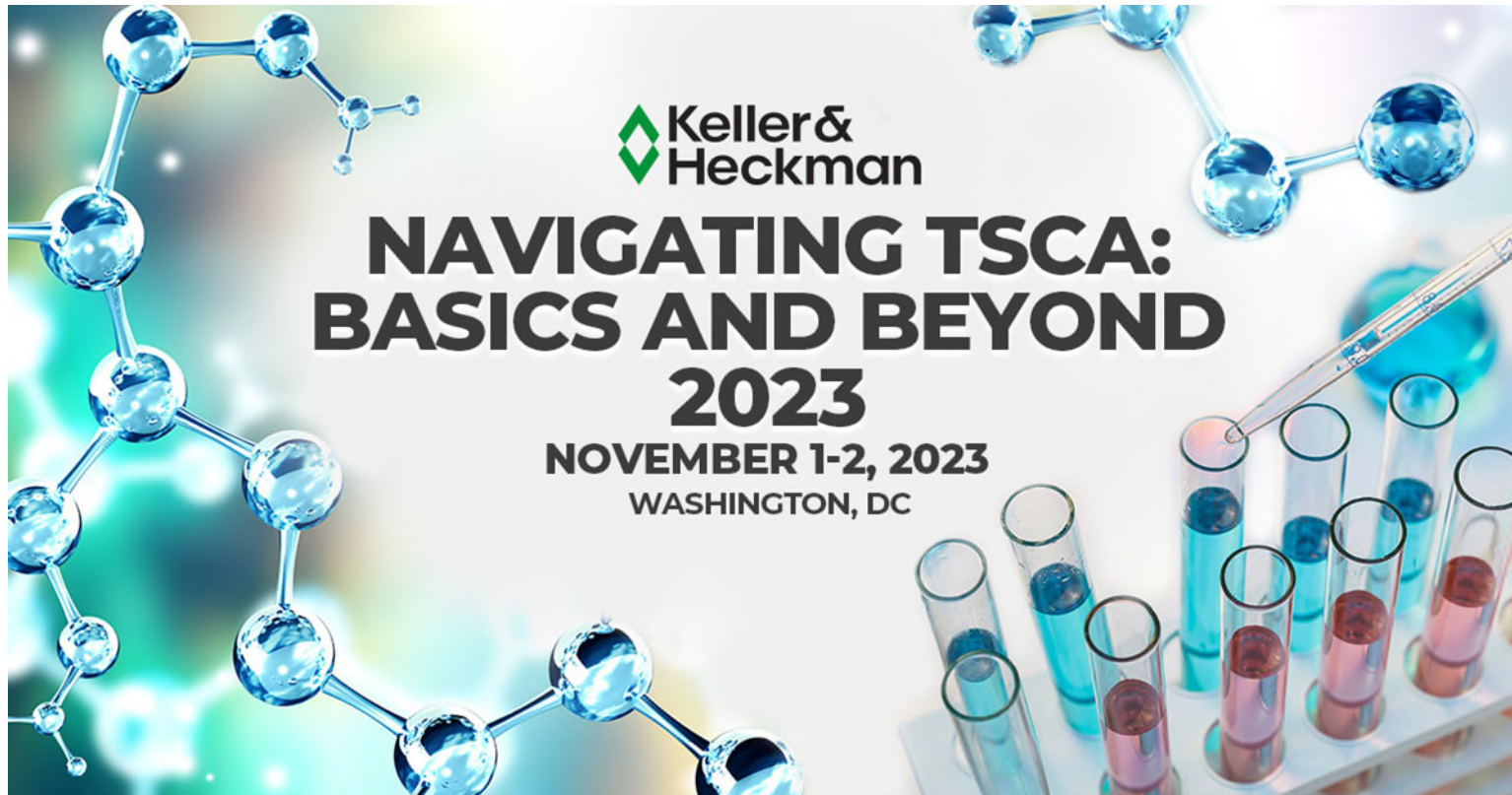
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Keller and Heckman is hosting the seminar, Navigating TSCA: Basics and Beyond on November 1 -2, 2023, in Washington, DC!

More information at: <https://www.khlaw.com/events/navigating-tsca-basics-and-beyond-2023>

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Thank You



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