

(I) Enforcing EPA's Long Chain PFAS SNUR: Uncertain Scope of Impurity and Byproduct Exemptions (II) Mixed Metal Oxide Compliance Advisory

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I. Enforcing EPA's Long Chain PFAS SNUR: Uncertain Scope of Impurity and Byproduct Exemptions

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

Impurities and 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.”
 - ◇ Prefatory language: “Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.”
- ◆ **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...

Byproducts vs. Impurities

- ◆ There are two different byproduct exemptions from PMN requirements
 - ◇ Byproducts that are burned as fuel, disposed as waste, or from which components are extracted (§720.30(g))
 - ◇ Byproducts that are not used for commercial purposes (§720.30(h)(2))
- ◆ **Impurities** are *commonly* viewed as substances present with other substances that have value (*e.g.*, a small amount of residual catalyst in a polymer)
- ◆ In contrast, **byproducts** (at least under §720.30(g)) are *commonly* viewed as single or multi-component process streams, that, as a whole, have no or minimal commercial value

The question becomes whether a §720.30(h)(2) byproduct can be wholly covered by the §720.30(h)(1) impurity exemption such that a SNUR would not apply

Sources of Impurities

- ◆ **1980 proposed section 4 rule:**
- ◆ There are many sources of impurities including:
 - ◇ Unreacted starting material,
 - ◇ A contaminant in the starting material which persists in or gives rise to by-products in the reaction product,
 - ◇ A contaminant in/on the reaction vessel or other equipment,
 - ◇ By-products formed from the starting material or intermediate by competing reactions,
 - ◇ Chemical substances formed during storage, and
 - ◇ Chemical substances formed by reaction with environmental factors (air, water, sunlight)

Kuryla Letter

- ◆ *“...The manner in which the Agency has defined ‘byproduct’ and ‘impurity’ allows for some overlap between the two concepts. The Agency adheres to the generally accepted meaning of these terms. A byproduct is a substance that is formed unintentionally during the manufacture of an intended substance. The unwanted or secondary substances present in the product i.e. the byproducts of the manufacturing process, are usually referred to as impurities by the manufacturer when [the manufacturer] specifies the composition of [the] product for [its] customers.”*

Byproduct, Impurity, or Both? (1)



- ◆ **July 2010 Q&A DOCUMENT: Recycling and the TSCA Inventory of Chemical Substances Premanufacture Notification and Inventory Update Reporting Requirements**

- ◆ *“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?”*

Byproduct, Impurity, or Both? (2)

♦ **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.”*

This suggests that the substance becomes an impurity at the same time it was formed as a byproduct, suggesting, in turn, that the substance is wholly covered by the impurity exemption...

March 16, 2022 - EPA letter (1)



- ◆ Letter to “handlers” of HDPE and similar plastic containers
 - ◇ https://www.epa.gov/system/files/documents/2022-03/letter-to-fluorinated-hdpe-industry_03-16-22_signed.pdf
- ◆ PFAS can be formed during manufacture of such containers, where fluorine used to create barrier intended to mitigate permeation and protect against degradation
 - ◇ First noted in HDPE containers used for a pesticide
- ◆ EPA issued letter to:
 - ◇ Remind industry of this issue to help prevent unintended PFAS formation
 - ◇ Emphasize TSCA requirements that may apply...

March 16, 2022 - EPA letter (2)

- ◆ EPA considers manufacturing of certain PFAS from the fluorination of polyolefins to be a significant new use
 - ◇ Long-chain perfluoroalkyl carboxylate LCPFAC SNUR (§721.10536) effectively banned (requires SNUN for) manufacture/import/processing of certain LCPFAC substances as of 12/31/2015
- ◆ LCPFAC substances present in polyolefins due to fluorination process considered **byproducts** of manufacturing process
 - ◇ Produced during manufacture of fluorinated polyolefins and do not have separate commercial intent (§720.3(d) [byproduct definition])
 - ◇ Do **not** meet byproducts exemption at §721.45(e)(5) (*viz.*, not burned, etc.), therefore are subject to SNUN requirements

EPA SNUR Authority



- ◆ If §5(a)(2) criteria satisfied (non-risk based!), EPA can issue a SNUR designating significant new use(s) of a substance
- ◆ “To establish a significant new use, EPA must determine that the use is not ongoing.”
 - ◇ Given prevalence of §5(e) orders and CBI identities, EPA typically believes/concludes that “highly unlikely” an SNU is ongoing
 - ◇ EPA designates the publication dates of the proposed rule as cutoff dates for determining whether the new uses are ongoing

Ultra Vires SNUR?

- ◆ What happens if a use is ongoing?
- ◆ EPA, 1992, P-86-501 and 503:
 - ◇ *“...A general allegation of previous commercial activity is not in itself adequate evidence to determine whether a specific use is new or ongoing. To decide if a particular use is ongoing EPA must consider specific evidence that a person has already engaged in that particular use...When proposing the SNUR for P-86-503 ... EPA considered the possibility that because of the bona fide inquiry and [NOC] for the other PMN substance, ongoing use outside the scope of the proposed SNUR might have occurred. However, a bona fide inquiry only alerts EPA to potential commercial activity. It does not give detailed information on specific uses such as those in the proposed SNUR...”*

II. EPA's Mixed Metal Oxide Compliance Advisory

EPA Announces Dual Action on Ceramics



- ◆ Announced “Streamlined” § 5 new chemical review for new chemicals that are mixed metal oxides (MMOs) used in green energy applications
- ◆ Published “Compliance Advisory” asserting that MMOs are not mixtures and require listing on TSCA Inventory (or exemption) prior to manufacture

“Streamlined” § 5 New Chemical Review for MMOs (1)



◆ **Mixed metal oxides**

- ◆ Ceramic materials comprised of varying mixtures of inorganic metal oxides formed by fusion or sintering
- ◆ Used in lithium-ion batteries and semiconductors – support electric cars, bulk energy storage from alternative energy sources (wind, solar, etc.)
- ◆ Also used in a range of other applications, e.g., catalysts, adsorbents, pigments

“Streamlined” § 5 New Chemical Review for MMOs (2)



- ◆ **How the § 5 process will be “streamlined” is not discussed**
 - ◇ Presumably: templates / standard assumptions for:
 - Exposure modeling for expected use scenarios
 - Hazard assumptions
 - Appropriate risk management controls (e.g., template consent order for battery cathode applications)
 - Based on experience with a number of cases
 - ◇ Similar to recent streamlining for “new” biofuels
 - ◇ EPA to offer training on the streamlining program
 - ◇ <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-mixed-metal>
- ◆ **Reviews may be more consistent, but may not be *quicker***

New MMO Compliance Advisory



- ◆ Advisory is referenced in the “streamlining” announcement
- ◆ Purports to “reaffirm” that MMOs are considered for TSCA purposes to be **single chemical entities** and ***not mixtures***
 - ◇ Mixtures do not require TSCA Inventory listing, but each *component* of a mixture does (unless exempt)
 - ◇ Implication of the Advisory is that each MMO combination requires its own TSCA Inventory listing (or exemption)
- ◆ Controversial because it runs contrary to past EPA guidance on “statutory mixtures”

Background: Inventory Representation of Statutory Mixtures (1)

- ◆ 1977 Original Inventory Rules – identified inorganic glasses, ceramics frits and cements as “mixtures” (report individual metal oxides)
- ◆ 1978 Candidate Inventory list – EPA added categorical Inventory listings for six categories of mixtures and assigned a CAS to each category
 - ◇ Ceramic Materials and Wares, Chemicals [CASRN 66402-68-4]

***This category encompasses the various chemical substances manufactured in the production of ceramics.** For purposes of this category, a ceramic is defined as a crystalline or partially crystalline, inorganic, non-metallic, usually opaque substance consisting principally of combinations of inorganic oxides of aluminum, calcium, chromium, iron, magnesium, silicon, titanium, or zirconium which conventionally is formed first by fusion or sintering at very high temperatures, then by cooling, generally resulting in a rigid, brittle monophase or multiphase structure. (Those ceramics which are produced by heating inorganic glass, thereby changing its physical structure from amorphous to crystalline but not its chemical identity are not included in this definition.) This category consists of chemical substances other than by-products or impurities which are formed during the production of various ceramics and concurrently incorporated into a ceramic mixture. Its composition may contain any one or a combination of these substances. Trace amounts of oxides and other substances may be present.*

Background: Inventory Representation of Statutory Mixtures (2)



- ◆ 1986 correspondence with industry - 'EPA intends that the categorical listing will cover all chemical formed during the production of ceramics'
- ◆ 1995 Statutory Mixtures Guidance – Repeats the earlier guidance
 - ◇ Inorganic glasses, ceramics, frits and cements ... are considered to be statutory mixtures under TSCA. Manufacturers of these products are not required to report them
 - ◇ Still on EPA's website: <https://www.epa.gov/tsca-inventory/products-containing-two-or-more-substances-formulated-and-statutory-mixtures-tsca>
- ◆ **2007/8: Correspondence with industry suggested changed position:**
 - ◇ 'Categorical listings do not cover all chemicals formed during ceramic 'production'
 - ◇ Not identified as a change of position

Background: Inventory Representation of Statutory Mixtures (3)



- ◆ **Spring 2010 Unified Agenda** – EPA announces intent to “clarify” the scope of the categorical listings for statutory mixtures
 - ◇ Acknowledges “inconsistent” guidance offered to industry in the past
 - ◇ EPA would identify which materials covered by the categorical listings are deemed to be on the inventory and which would require their own status
 - ◇ Dropped from Unified Agenda without action or explanation

2022 MMO Compliance Advisory



- ◆ **2022 Compliance Advisory** is first subsequent broad public statement of position since 2010
 - ◇ Represents EPA's current enforcement position
 - ◇ Advisory does not acknowledge past "inconsistent" guidance or industry reliance on that guidance
 - ◇ So far, EPA has not elected to resolve the inconsistency with a correction program
 - Cf. Activated Phosphors (2010): Allowed 18 months for 'corrective' PMNs
 - ◇ Current position never tested before the EAB or a court
 - May be difficult if EPA does not acknowledge a change in position
 - Fact that it has listed many MMOs on the Inventory is not dispositive



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Wednesday, October 19, 2022

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Keller and Heckman is hosting its TSCA Basics Course on Thursday, November 3, 2022, in Washington, DC.

More information at:

<https://www.khlaw.com/events/2022-tsca-basics-course>

Thank You

Any questions?

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