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What is happening in the Toxic Substances Control Act (TSCA)?

Rose Passarella, Ph.D., J.D. Director

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Significant New Use Rules (SNUR) are still being issued in the majority of Pre-manufacture Notices (PMN) assessments.

We will discuss
-developing PMN exposure scenarios with a data set to reduce questions
-how to reconcile the SNUR with Hazard Communications

We will also discuss the new series of fines that are being issued, why and how to avoid them.

Agenda

CBI Bonus Discussion

01 A (Very) Short Background of the TSCA

02 Status of getting a decision on a PMN or an LVE- Penalties and News

03 What should you include in the exposures scenarios to answer questions before they prolong your assessment?

04 Is a joint submission better for you to get in commerce quicker? Some things to consider in your business decision.

05 Are SNURs being finalized faster? What happens if you have a new use before the SNUR is final?

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A (Very) Short Background of the TSCA

Background TSCA Reform

- Toxic Substances Control Act (TSCA) from 1976 to 2016
- Some Non-Governmental Organizations (NGOs) believed that there was weak federal oversite

- States were acting legislations;
- Regions were enacting legislations;
- Labeling acts; hazard warning (Proposition 65)

- Interrupting commerce
- The 2016 TSCA Reform was to create a strong Federal system to instill confidence

- 2026 Reform. How do you think it is going?
  - I am sure HazCom saw changes in the apparent overlap of OSHA and EPA

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Status of getting a decision on a PMN or an LVE

Internal preparation

Be ready for a Consent Order (CO) or conditions on your LVE.

Final Significant New Use Rules (SNUR) sometimes have different criteria than the original CO.

- Be Diligent and look for the final Rule.
- Sometimes a criterium is eliminated and there is no longer a need for a Significant New Use Notice (SNUN).
- The Terms of the CO and the SNUR usually need to be communicated.
- We are finding the most efficient place is the SDS.
- Need to be diligent updating, depending on the method you use.

Institute the practice of a Pre-Notice Consultation (PNC), especially since there is evidence that criteria may change from the CO, to proposed SNUR, to the final SNUR.

- Looking for the final SNUR may be difficult. PNC may save time.
- Some older proposed SNURs are still not finalized in the Code of Federal Regulations (CFR).

SNURs are still the norm.

Cationic and Solids are still tough substances to push through.

The EPA plans to expedite reviews of new chemicals by grouping similar requests and changing the evaluation process for low-volume exemptions.

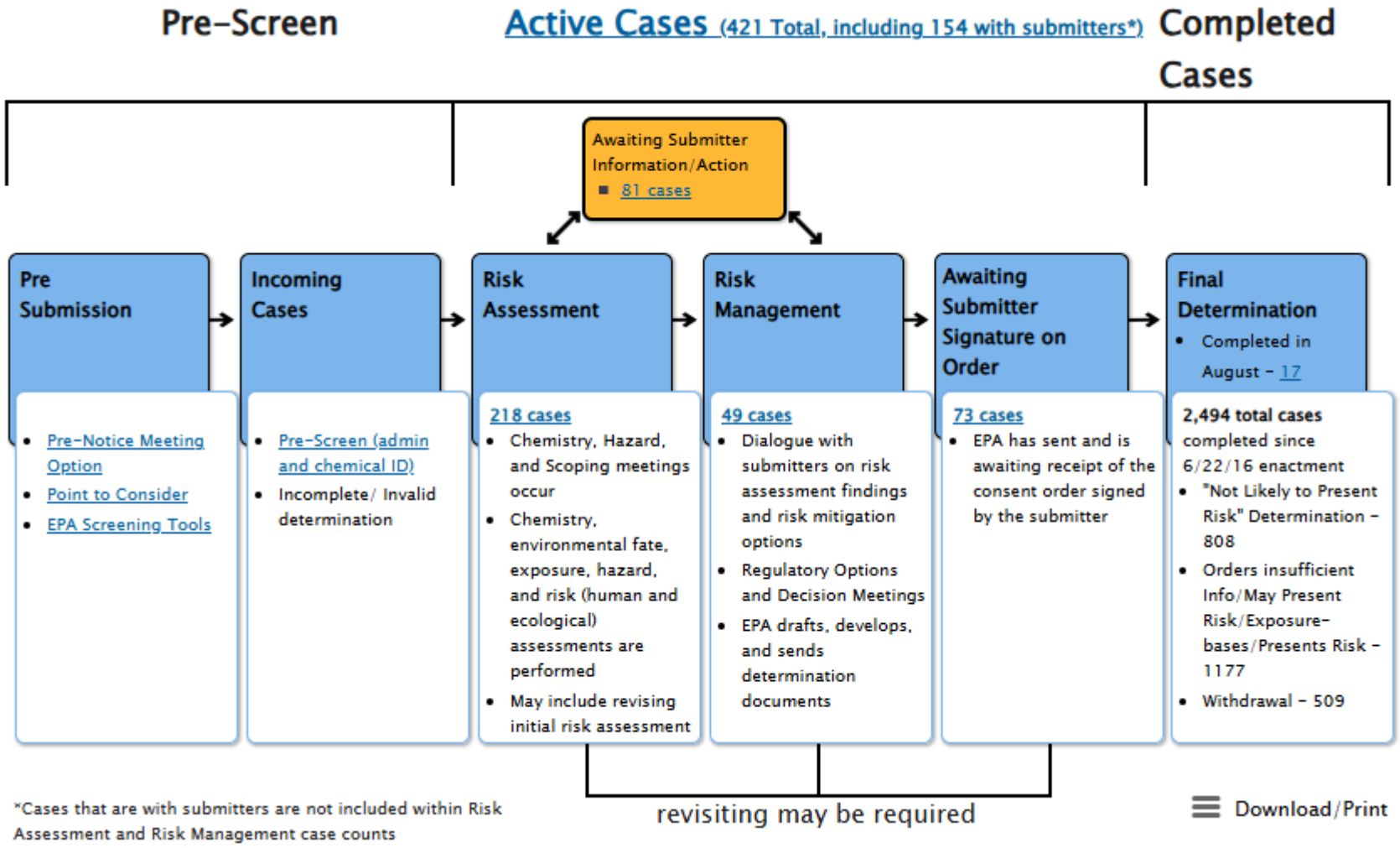
- Groupings are for Data Centers promoting Artificial Intelligence (AI) and the infrastructure that powers them (i.e. high voltage transmission lines and other equipment).
- However as of September 11, the US EPA says fewer than ten notices submitted under expedited review pathway.

The EPA is also looking to AI to speed up chemical reviews, prioritizing the development of tools like the AI Chemist Assistant and EcoVault.

Industry supports the EPA's "continued exploration" of AI solutions, as long as the right safeguards are in place.

Cases Statistics

PMNs, SNUNs, and MCANs under Review by EPA (as of 9/1/2026 cases total)
Total Active Cases: 421
Total Active Cases with EPA: 267
Total Active Cases with Submitters: 154



Other points

- The Inventory contains over 80,000 chemicals of which over 40,000 are active in commerce.
  - Checking the inventory is not enough-- It must be on **and active**.
- Inspections are increasing.
- Penalties for TSCA violation usually emanate from non-compliance for the following sections:
  - § 5 requires manufacturers or importers to notify the EPA of any new substance in commerce.
  - § 8 require manufacturers or importers to keep records, report information, of suspected, but not known risks.
  - § 12(b) requires chemical exporters to submit information about certain chemicals.
  - § 13 requires chemical importers to submit certification statements concerning shipments of chemical substances.
- Depending on the nature of the non-compliance there may be:
  - Injunctive actions to stop the non-complying action;
  - Current civil fines for violations can be up to $49,772 per day for each violation (January 8,2025)
  - Criminal actions as prison terms (1 year), and/or
  - Publicity

Penalties

- The U.S. Environmental Protection Agency (EPA) announced on June 1, 2026, that it has filed an administrative complaint against XXX, a chemical wholesaler for violations of the Toxic Substances Control Act (TSCA). According to EPA, the complaint is the result of XXX's "years-long" failure to report properly its import and domestic distribution of chemical substances. If the 684 counts hold and maximum penalties are sought, EPA's enforcement matter against XXX could yield a massive $34 million penalty for alleged violations of TSCA -- the vast majority of which involve violations for lack of reporting under EPA's **Chemical Data Reporting (CDR) rule.**

- The U.S. Environmental Protection Agency (EPA) announced on June 4, 2026, a settlement with an international agribusiness company for claims of violations of the Toxic Substances Control Act (TSCA) at its facilities in California and Washington. According to EPA, YYY agreed to pay a penalty of $630,737 for failing to report chemical production properly. This is one of the first examples of EPA enforcing the prohibition on manufacture, import, or processing of an **inactive substance**.

News

- The U.S. Department of Commerce, Bureau of Industry and Security (BIS) published on August 6, 2026, a temporary final rule (the Rule) titled “DPAS Directive Allocation Order and Additional Requirements for Recoverable Critical Minerals and Materials to restrict the exportation **of black mass** and tungsten waste and scrap.
- According to BIS, “this temporary rule is necessary to immediately secure the supply of certain recoverable critical minerals and materials (CMMs) to ensure an adequate supply of these materials deemed essential to the national defense.”
- “Black mass” is defined in the Rule to mean “any shredded lithium-ion battery scrap that contains cathode material (which may include aluminum, copper, iron, lithium, cobalt, nickel, and manganese), anode material (graphite, silicon) or other residual battery cell materials.”

- This could affect **CDR or PMN/LVE**

News

- Continuing Resolution Extends EPA’s TSCA Fee Authority
- On September 2, 2026, President Trump signed the Continuing Appropriations and Extensions Act, 2027 (H.R. 6500) that provides continuing fiscal year (FY) 2027 appropriations for federal agencies and extends various expiring programs and authorities.
- H.R. 6500 explicitly extends the U.S. Environmental Protection Agency’s (EPA) authority to levy fees under the Toxic Substances Control Act (TSCA) until December 11, 2026.
- The House and Senate both held hearings early in 2026 on draft legislation that would have amended TSCA and renewed EPA’s fee authority.

- Ledgisters want the authority, under TSCA, to include the ability to prioritize "harmful additives or ingredients in plastic materials“.
- Currently it is under the Clean Air and Clean Water Acts

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What should you include in the exposures scenarios to answer questions before they prolong your assessment?

Internal Preparation:

Key Learnings from current projects

There may be a slight movement to faster assessments, but I still suggest to clients the 2 years for PMNs.

- 6 months for preparation and 12-18 month for the risk assessment.
- The preparation can be shorter if they have all the information.

Exposure scenarios are still being scrutinized, so make sure you have enough details.

- Be as specific as you can in mixing, cleaning containers, engineering controls, waste disposal, PPE, etc.
- The balance is to have a very specific exposure scenario, without locking you into specific practices that are not practicable or sustainable.
- Uses: there is again a balance. Be as broad as you can so you don't have to do a Significant New Use Notice (SNUN) but not so broad to extend the risk assessment.
- Find a close model in ChemSTEER, look at the variables, and the defaults the EPA will assume if you don't supply the value. Even if you can live with the defaults, you should put your own values.

Keep track of what you are substantiating for CBI so, you can re-substantiate when it is expired!

DON'T LOSE IT BECASUSE OF YOUR SDS OR CDR

Managing uncertainty in review timelines and risk determinations:

EPA is still reducing its backlog of pending notices and expediting its review of new notices.

- Therefore, you still need time

EPA will continue to adopt SNURs.

- In 2026, we still should expect the EPA to take significantly longer than the statutory 90-day period to for PMNs and SNUNs, and the regulatory 30-day period to review LVEs
- Perhaps less time than previously.
- Still expect the majority of the risk determinations to be “may present an unreasonable risk”.
- We are seeing some “not likely to present an unreasonable risk” for PMN and Microbial Commercial Activity Notice (MCAN)

- You still need TIME and DATA

TSCA transparency and predictability

The EPA looks at each scenario with respect to the specific facts of the scenario.

Submitters look for broader explanations such as:

- Definitions that adequately describes relevant documentation, relevant toxicological studies, etc.
- Understanding as to why the EPA may use generic scenarios, when the submitter provided specific information for the release and exposure scenarios.
- Reasons why the EPA deviates from established scenarios for more conservative assumptions.

On a practical note:

- Keep using the ChemSTEER for assumptions.
- Provide as much detail as possible.
- Repeat the information if you are using the same information in different sections.
- Do the math carefully.
- If you do get a decision, read the risk assessments carefully, question assumptions, if necessary, and provide more data if needed.

Internal Preparation

Companies need to develop their information management infrastructure to stay prepared for ongoing or potential regulations that may impact their supply chain, whether it be timing to approval of new chemical substances, preparing for PFAS regulations or PBT regulations.

Best practices for navigating the regulatory road ahead include but are not limited to:

- Reviewing your supply chain thoroughly – maintain detailed records of chemicals used in production, including concentrations and whether they are intentionally or unintentionally added.

- Looking for exemptions and eligibility – check whether your products qualify for exemptions under Federal or State-level regulations.

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Is a joint submission better for you to get in commerce quicker? Some things to consider in your business decision.

To joint submit or not to joint submit

You are submitting a PMN.

The probability is high that you will get a SNUR.

The good news in that the EPA will issue a Consent Order (CO), so you can sell you product before the final SNUR is published.

Here is what needs to be understood:

- Only you can operate under the CO.
- You can sell your product, complying with the terms of the CO to the first downstream user (1st DSU). **THAT'S IT!**
- If you sell your product with the new chemical substance (NCS) to a 1st DSU that makes a product where the NCS is totally consumed, then the 1st DSU can sell the product.
  - You need to get assurances from them that they are using the NCS according to the restrictions in the CO.
- If you sell your product to a 1st DSU who uses the NCS to make a final product that still contains the NCS, **they can't sell it.**
  - You will get assurances that the 1st DSU is complying with the CO, but the EPA considers the assurances that the 2nd DSU will comply with the conditions of the CO to be too attenuated.
  - So, 1st DSU cannot see the product the 2nd DSU. Then why should the 1st DSU buy the product with the NCS from you???

To joint submit or not to joint submit

A potential solution is to submit the PMN as a joint submission

In this way both submitters can sell to their own 1st DSU and get the direct assurances of following the terms of the CO.

However:

You can only be in commerce only after both sign the CO

Sometimes things happen in business relationships…

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Are SNURs being finalized faster? What happens if you have a new use before the SNUR is final?

Lessons from recent SNURs and their implications for product development;

You will get a CO, and it will take a long time to get a final SNUR so you can go commercial.

There doesn’t appear to be a consistent limit of particle size for which the EPA considers respirable or not.

Often resulting in high Applied Protection Factor (APF) rating for a respirator (supplied air)

PBTs will have a no release to water restriction.

Many chemicals will have a no or very low (ppb or ppt) release to water restriction.

Consider using certified waste haulers.

Since it take a long time to get a final SNUR published:

What happens if you have a new use that you want the substance to be uses commercially?

You submit a Submit a Significant New Use Notice (SNUN)!

Your SNUN gets rejected because there is no SNUR published.

- You can wait for the SNUR to get published: about a year!
- Then submit your SNUN and wait for the risk assessments on the new use: about a year!

Or you can file an amendment to the CO describing you're the exposure scenario for the new use

- Caveat: if you had a joint submitter that signed the CO they will know the new use

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Bonus: CBI

TSCA CBI Substantiations Began to Expire in 2026

The EPA will publish the process for implementing the statutory requirements of expiring CBI claims, how companies will be notified and how to request and substantiate the need for an extension of CBI claims.

In the Spring 2026, the first list of claims expiring in June 2026 was published on its TSCA CBI website and direct notices were sent to submitters via the Central Data Exchange (CDX).

This is not a lot of time to respond since a lot happens in 10 years.

- Most notably the person who submitted the claims maybe gone so even if the EPA notified the company, the person they notify may be gone.
- You have to know if you have any claims to re-substantiate.

To request an extension of an expiring CBI claim, companies must submit a request via CDX no later than 30 days prior to the expiration date of the claims. The request must include substantiation of the need to extend the period of CBI protection.

Additionally, if EPA denies the claim, the submitter will be notified at least 30 days prior to the intended disclosure of the information. **Denials do occur.**

If EPA does not receive a request for extension at least 30 days prior to the claim expiration, EPA "is not required to safeguard the CBI from disclosure, and the information may be made public without further notice to the submitter."

This is tight timing.

Tips:

Begin now!

Check agents/authorize official

Do you need still CBI?

Rose Passarella, Ph.D., J. D.

+1 302-287-3650

Rose.Passarella@intertek.com

intertek.com

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