AmericanCoatings ASSOCIATION℠

To: EPA Principal Deputy Assistant Administrator Nancy Beck
EPA Deputy Assistant Administrator Lynn Dekleva

From: American Coatings Association (ACA), TSCA Risk Evaluation Working Group
Heidi McAuliffe, ACA VP Government Affairs
Riaz Zaman, ACA Sr. Counsel Government Affairs
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Re: TSCA New Chemical Review Program

The American Coatings Association (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory, and judicial issues. As such, ACA is requesting that EPA consider the following issues related the evaluation of premanufacture notices (PMNs) mandated under the Toxic Substances Control Act (TSCA).

Background

The *Lautenberg Amendments* to TSCA requiring EPA to evaluate PMNs prior to commercialization has led to a significant backlog at EPA and delays exceeding the 90-day statutorily specified period in PMN approvals. These extended delays have further worsened the review process with inconsistent new chemical review procedures. Companies now delay or even cancel the introduction of new chemical technologies to the U.S. market thereby hindering market innovation within the U.S.; whereas prior to the TSCA amendments, companies began commercial activity 90 days after a PMN submission.

In December of 2024, EPA attempted to address problems in the PMN review process by finalizing a revised set of PMN procedural rules detailing required information for a PMN submission. EPA explains that the rule should improve timing of PMN reviews by clarifying data submission requirements while codifying existing data requirements and practices from the current submission procedures implemented in the CDX online PMN filing system.

Current Status

ACA notes the following issues related to delays with PMN, LVE and SNUN processes and the new PMN procedural rules:

- Address the existing backlog of PMN applications to promote innovation in the U.S.
    - Since June 2016, EPA's backlog has remained around 400 to 500 PMNs.
    - Prior to the *Lautenberg Amendments*, ACA member companies file around one to 30 PMNs per year; the paint and coatings industry as a whole spends over

$15 million annually on research and development largely focused on new products and unique applications.

- EPA's focus on evaluating new PMN applications while neglecting to address how it will simultaneously eliminate the backlog, fails to provide relief or direction to industry as they continually face regulatory uncertainty.
- ACA members currently report delays in the SNUN and PMN processes of 8 months to over 3 years.
- As result, ACA members avoid developing new chemistries, attempting to develop new products with chemistries already on the TSCA Inventory, limiting innovation, including innovation in safer technologies.
- As an alternative, manufacturers are increasingly relying on exemptions to introduce new chemicals, such as the polymer exemption or the low-volume exemption. Using these exemptions fails to address the underlying issues and places a further strain on EPA resources. It also limits the international marketability of products, due to international preference for products listed on the TSCA Inventory. Further, use of the polymer exemption should be streamlined for better implementation. ACA has provided related suggestions in an accompanying document addressing TSCA regulatory reform.
- Companies may attempt to move away from the polymer or LVE exemptions to list on the TSCA Inventory, but this requires disruption of supply due to delays in listing on the TSCA Inventory. As a result, a manufacturers cannot distribute the chemical while waiting for listing on the TSCA Inventory, requiring a final SNUR.
- Companies attempting to update a SNUR with new testing information similarly face delays, disrupting placement of the chemical on the market. The terms of the LVE are no longer in effect once EPA issues a consent order, but the consent order does not go into effect until after EPA issues a SNUR. In effect, companies attempting to move from an LVE to a SNUR or consent order face significant delays.
- Companies must delay introduction of a new chemical after receiving a consent order, while EPA finalizes a SNUR. Finalizing the SNUR can take over a year from when EPA issues the consent order. EPA also only authorizes market entry 75 days after issuing a final SNUR, under standard terms in the consent order.

- Provide transparency on the (1) evaluation of new PMN applications to ensure consistency in reviews and (2) minimize potential conflicting and/or irrelevant requirements when EPA also issues a significant new use rule (SNUR).
  - ACA members report that EPA does not have a consistent approach to evaluating PMNs, because the evaluation strategy might change depending on the identity of the reviewer, creating greater uncertainty for manufacturers.
  - A GAO Report recently identified lack of consistency in PMN review process:

    > *NCD (New Chemicals Division) has not developed a systematic process that ensures the division consistently allows all key practices, which could help the division manage the program's performance more effectively.*[1]

    GAO recommends:

[1] GAO, Report to Congress: *NEW CHEMICALS PROGRAM: EPA Needs a Systematic Process to Better Manage and Assess Performance* (Jan 2025) at p. 20-21, available online at: https://www.gao.gov/assets/gao-25-106839.pdf

The Administrator of EPA should ensure NCD implements a systematic process that aligns the division's performance management approach with key management and assessment practices. (Recommendation 2)[2]

- EPA's practice of issuing a SNUR along with a Section 5(e) consent order triggers perhaps unintended requirements on downstream users of chemical products containing the chemical. EPA requirements are triggered by the issuance of a SNUR, such as reporting at lower thresholds under the Chemical Data Reporting (CDR) reporting requirement and reporting exports under section 12(b). Consequently, any user of a SNUR substance and the PMN submitter must demonstrate compliance with the SNUR conditions and any other requirements that the SNUR triggers, imposing additional record-keeping requirements on downstream users.

- Provide further guidelines related to estimating reasonably foreseen uses and data relevant to downstream uses, while further explaining how this data will be used during the PMN review process, especially where speculative uses are not within those intended to be commercialized.
  - EPA's requirement for submitters to include *reasonably foreseen* uses does not have clear parameters. Providing clear guidelines would help ensure that EPA receives the necessary information to focus their resources on evaluating the most salient data related to risks affecting human health and the environment.
  - EPA's reliance on default assumptions when there are incomplete data sets, especially related to downstream sites not controlled by the PMN submitter, results in conservative assumptions leading to overly broad restrictions. Guidance for estimating values under the due diligence standard and identifying which types of data would be most relevant in the agency's evaluation (i.e. worker safety, environmental fate, etc.) would help garner more complete submissions with better data quality.

- Allow EPA to evaluate applications on individual fluorinated chemicals (PFAS) for the LVE (low volume) and LoREX (low release and low exposure) exemption from the PMN procedure
  - PFAS chemicals are currently ineligible for the LVE and LoREX exemption based on a false assumption that all fluorinated chemistries (PFAS) meet the same criteria for persistence, bioaccumulation and/or toxicity. The LVE and LoREX process established expedited reviews for use in limited conditions so that the risk is mitigated. Due to the regulatory climate surrounding PFAS, companies only apply for LVE or LoREX exemptions based on the need to meet specific performance requirements.

- Adhere to statutory time limits imposed on EPA when reviewing PMN submissions.
  - Although EPA requires complete submissions prior to beginning the 90-day PMN review period, there does not seem to be the same level of responsibility on EPA for their timely review of PMNs.

[2] *See* footnote number 2.

- EPA also frequently extends the time of PMN review based on 40 CFR 720.75(c)(4). This rule allows extensions for "good cause" without establishing clear criteria for the extension. Accordingly, EPA must also be held accountable to complete review within 90 days, while providing clear criteria for a "good cause" extension.

- Improve the CDX interface to (1) accept large data files without timing out and (2) allow for multiple people to serve as contacts from the PMN submitter.
  - Currently, companies have reported being automatically timed out of CDX when submitting large data sets resulting in having to restart the upload process.
  - In addition to a primary contact, EPA should allow for at least two additional company representatives to receive notifications. The current system, as it is configured, causes delays when the primary contact is away for an extended period of time.

ACA would like the opportunity to discuss this matter with EPA and work towards a viable solution and promote innovation at U.S. based companies. Innovation within the paint and coatings industry drives improvements in product safety, including lowered emissions and toxicity and put U.S. companies at a competitive advantage. Please feel free to contact us if we can provide additional information.

Sincerely,

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