UPDATES TO NEW CHEMICALS REGULATIONS UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

Office of Pollution Prevention and Toxics
Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS
AND
AMERICAN PETROLEUM INSTITUTE
COMMENTS

Attention: EPA–HQ–OPPT-2022-0902; FRL-7906-01-OCSPP

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I. Introduction

The American Fuel & Petrochemical Manufacturers ("AFPM") and American Petroleum Institute ("API") respectfully submit these comments on the Environmental Protection Agency's ("EPA" or "the Agency") Federal Register notice titled, "Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA)" ("Proposed Rule"). The Proposed Rule would amend the review process for Premanufacture Notices ("PMNs") and Significant New Use Notices ("SNUNs") by circumventing the Congressional mandate that the process be completed within a 90-day time period.[1] EPA is further proposing to require a set of physicochemical properties and environmental fate data as part of PMN and SNUN submissions,[2] and to allow oral and email requests for suspensions of the review period.[3] Our comments highlight that:

- TSCA requires EPA to review all PMNs and do so within 90 days, unless extended, yet the proposed rule attempts to circumvent the 90-day time period,
- TSCA does not authorize EPA to require a minimum data set under Sec. 5 and data submissions should be limited to what is "known to or reasonably ascertainable by",
- The additional site and processing information in the proposed rule are far too prescriptive, and
- The associated regulatory impact analysis for the proposed rule underestimates the costs of the provisions to industry.

II. AFPM and API Interest in the Proposed Rule

Together AFPM and API represent the entire petroleum supply chain from upstream exploration and production to midstream processing and transportation, to downstream refining, including base petrochemicals that are the essential building blocks for organic chemistry and plastic products that improve the health, safety, and living conditions of humankind and make modern life possible. AFPM and API members are committed to sustainably manufacturing safe, high-performing fuels and the petrochemicals and derivatives for plastics that growing global populations and economies need to thrive.

AFPM and API members are committed to collaborating with policymakers and other stakeholders to develop sound, risk- and science-based policies to address chemical safety. AFPM and API support a tiered and risk-based approach to achieve an appropriate regulatory balance that addresses real risks and allows the safe manufacture of chemicals.

III. Comments on the Background for the Proposed Rule

In the *Executive Summary* of the Proposed Rule, EPA claims it was not required to review all PMNs submitted to the Agency and that the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Chemical Safety Act" or "LCSA") placed new requirements

[1] *See 88 Fed. Reg. 34100*, "Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2022-0902; FRL-7906-01-OCSPP, published May 26, 2023.
[2] *Id.* at 34101.
[3] *Id.*

for PMN reviews.[4,5] In Unit II, the Agency claims that under the original law, "EPA was not obligated to make a determination or finding regarding unreasonable risk for each notice submitted.[6]

There is no explicit language in either the original TSCA statute or LCSA that says EPA "must review all notices;" rather, the requirement to review is implied by the fact that EPA would not be able to make any risk determinations on substances unless the Agency reviewed all submitted PMNs in their entirety. In other words, Congress directed EPA to review all PMNs and SNUNs back in 1976 and the Agency has done so ever since. To claim otherwise is historically inaccurate.

The only significant additional requirement in the review process that stems from the LCSA is that EPA must now affirm through public notice that a substance does not present an unreasonable risk. The remainder of the review process in Sec. 5(a) is consistent with the original review process, including the 90-day review period. The only real change with the review period is that the LCSA authorizes EPA to extend it for up to another 90 days. The notion that the LCSA placed any new review requirements or changed the standard timeline for a PMN or SNUN review is simply a misinterpretation of the law.

IV. Comments on Specific Proposed Changes to the New Chemicals Process

a. The Proposed Updates to the 90-Day Review Period Undermine Timely Review Under the New Chemicals Program

EPA continues to ignore Congress's intention to require it to complete timely reviews of new chemicals and erodes these protections guaranteed to manufacturers and importers under the TSCA program. EPA is stifling innovation by amending the regulations to specify that the Agency must make a determination on each PMN or SNUN, or simply extend the review an additional 90 days. This effectively allows EPA to toll a decision on new chemicals indefinitely and delays a company's ability to innovate by prohibiting them to commence manufacturing or processing.

In Unit I.D., EPA claims that prior to the LCSA, "TSCA allowed the PMN submitter to commence manufacturing or processing upon expiration of the review period."[7] The LCSA did not change, or authorize a change, to the review period. The review period and the requirement for EPA to conduct the review, make a risk finding, and propose regulatory actions to address unreasonable risks is and always has been very explicit in TSCA.

Sec. 5(a)(3) clearly states that "the Administrator shall review" PMN and SNUN notices within 90 days. Sec. 5(a)(1)(B)(ii)(II) explicitly requires EPA to take actions, such as making a

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[4] *See* "Frank R. Lautenberg Chemical Safety Act for the 21st Century." H.R. 2576. Enacted June 22, 2016.
[5] *See 88 Fed. Reg. 34100*, "Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2022-0902; FRL-7906-01-OCSPP, published May 26, 2023. p. 34101.
[6] See *88 Fed. Reg. 34100*, "Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2022-0902; FRL-7906-01-OCSPP, published May 26, 2023. p. 34102.
[7] *Id.* at 34101.

risk determination, and for those substances that present an unreasonable risk, develop appropriate risk management actions, within the same 90-day period. EPA can also determine that a substance does not present an unreasonable risk.

In Unit III.A.1., EPA misinterprets the provisions under Sec. 5(a)(1)(B)(ii), where the Agency claims the LCSA "changed the requirements of TSCA Sec. 5(a)."[8] The provisions clearly state that a company can commence manufacturing if it submits a PMN 90 days prior and if EPA "conducts the review…makes a determination…and takes the actions required in association with that determination…within the applicable review period."[9] This is consistent with the requirements Congress directed in the original TSCA statute and also with the approach used by EPA for decades.

To make the 90-day review requirement even more explicit to EPA, Congress added Sec. 5(a)(4)(A), which specifies that any fees associated with the PMN or SNUN submission must be refunded to the submitter if EPA does not complete the review within 90 days.

In Unit III.C., EPA proposes to restart the review process from Day 1 if a company submits clarifying information on the manufacture, processing, or conditions of use that pertain to a PMN submission. There are valid reasons that a company could submit new information that comes to light after submittal. For example, information from a customer that could shed light on details at the user end, which would assist in refining a risk evaluation, should be allowed without resetting the review period to Day 1. For the same reasons as outlined above, EPA cannot undermine the 90-day review period imposed by Congress by creating a perpetual review process.

b. Proposed Minimum Data Set on Physical-Chemical Properties and Environmental Fate

In Unit III.B.2., EPA proposes to "add details to certain information requirements already contained in 40 CFR 720.45."[10] Furthermore, the Agency states that "a submitter would be required to include" the "detailed information" on the PMN form."[11] In essence, this creates a minimum data set of information related to physical and chemical properties and environmental fate. While EPA acknowledges the statutory clarification that information be "known to or reasonably ascertainable by," the Proposed Rule confuses the issue because the Agency consistently uses the terms "requirement" and "required" throughout Unit III.B. and goes on to specifically list the data elements in Unit III.B.A. Furthermore, in Unit III.B.3., EPA outlines options to modify the PMN form and either force the submitter to check a box whenever something is left blank, which is unnecessary because the TSCA statute already requires companies to submit information "known to or reasonably ascertainable by," or not allow the user to advance to the next field. These proposed changes suggest that EPA intends to create a minimum data set for PMN submissions.

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[8] *Id.* at 34104.
[9] See "Toxic Substances Control Act [As Amended Through P.L. 117–286, Enacted December 27, 2022]." Published January 28, 2023.
[10] See *88 Fed. Reg. 34100*, "Updates to New Chemicals Regulations under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2022-0902; FRL-7906-01-OCSPP, published May 26, 2023. p. 34106.
[11] *Id.*

There are no information requirements related to physical-chemical properties and environmental fate in 40 CFR 720.45. TSCA recognizes that chemical substances and their conditions of use are unique and information requirements should be approached in a tiered, risk-based manner. TSCA does not authorize EPA to require a minimum data set under Sec. 5. In fact, the term "known to or reasonably ascertainable by" appears throughout Sec. 5 to make clear that EPA ensures reporting flexibility for the unique circumstances of each substance's conditions of use. EPA must issue a test rule or order under TSCA Sec. 4 to require new data.

c. Proposed Details for Site and Processing Information

Unit III.B.2., EPA goes on to propose a new level of detail for categories of use, manufacture, processing, and use, worker exposures, environmental releases, and pollution prevention. These proposed changes are far too prescriptive and attempt a one-size-fits-all approach to PMN submissions. Furthermore, the details proposed for sites not controlled by the submitter, as outlined in Unit III.B.2.c., are not going to be fully known by the submitter, as certain processing and use information is proprietary and intellectual property. A supplier cannot compel a customer to provide specific information on how a product is used, as it is usually proprietary information that gives the customer a competitive advantage.

Submitters have already demonstrated the difficulty in trying to obtain even the most basic information on conditions of use at sites not controlled by them through both PMN submissions and Chemical Data Reporting ("CDR") submissions. These additional information requirements are unrealistic.

Each chemical substance is unique, as are the conditions of use; therefore, the regulations and the PMN form should allow for flexibility to avoid unnecessary reporting burdens. AFPM and API urge EPA to retain the current PMN form and enhance its guidance and outreach for information that the Agency finds has practical utility during the review process.

d. Proposed Ineligibility of Per- and Polyfluorinated Alkyl Substances (PFAS) for Low Volume Exemption (LVE) and Low Exposure-Low Exposure (LoREX) Exemption

LVEs and LoREX exemptions are critical to chemistry innovation, especially in high-tech applications for semiconductors and electric vehicles batteries. EPA's proposal to make PFAS as a broad category ineligible for those exemptions, based on the premise that PFAS are persistent, bioaccumulative, and toxic, is arbitrary and capricious. First and foremost, all PFAS are not the same. Polymeric PFAS, like most other polymers, tend to be inert and very low in toxicity. In addition, PFAS can vary widely in their molecular structure and physical properties, which directly affects the variability in their toxicity profiles. To lump all PFAS together as a single category makes no sense scientifically or otherwise. AFPM and API urge EPA to retain the eligibility of PFAS substances for LVE and LoREX exemptions because those decisions are already protective and consider if the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance present an unreasonable

risk. There are also eligibility stipulations for environmental releases. Making PFAS ineligible as a category is not supported by science.

e. Allowance of Oral and Email Requests for Suspension of Review Period

AFPM and API support the allowance of oral and email requests for a suspension of the review period. It will benefit both submitters and the Agency to simplify the request procedures.

f. Impact Analysis

In Unit I.E., EPA estimates cost increases of $45,120 per year for industry. This is in light of all the new information requirements, the changes to the PMN form, and the opportunity costs of not being able to commence manufacture once the Congressionally mandated review period ends. AFPM and API urge EPA to redo the impact analysis to more accurately reflect the cost burdens of collecting, collating, and reporting the far more detailed information requirements outlined in this Proposed Rule. Specifically, EPA should include the costs of collecting all of the newly required physical and chemical properties information, in addition to the opportunity costs in its analysis because those costs can be significant.

V. Conclusion

AFPM and API appreciate the opportunity to comment on the Proposed Rule. EPA cannot circumvent the 90-day review clearly imposed by Congress, nor can the Agency require any type of minimum data set for physical-chemical properties, environmental fate, or any other type of information that is not "known to or reasonably ascertainable by" submitters. AFPM and API urge EPA to rescind the Proposed Rule in its entirety and work with stakeholders to enhance education and outreach on the Sec. 5 review process and the information that would assist in the Agency's ability to conduct timely reviews and make appropriate risk determinations. AFPM and API would welcome the opportunity to serve on a stakeholder group.

Sincerely,

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