Comments of the American Chemistry Council on Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA); Proposed Rule

Docket No. EPA-HQ-OPPT-2022-0902

August 8, 2023

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EXECUTIVE SUMMARY

The American Chemistry Council (ACC)[1] welcomes the opportunity to provide comments on the proposed updates to new chemicals regulations under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 54100 (May 26, 2023).

ACC has long supported a robust review of new chemical substances under TSCA Section 5. It is critical that the TSCA New Chemicals Program (NCP) function effectively and efficiently to incentivize businesses to manufacture domestically and to onshore critical supply chains, while protecting human health and the environment.

Given the importance of this program, ACC welcomes efforts by EPA to improve the performance of the NCP. However, ACC is concerned that this proposal increases burden on submitters of new chemicals and will ultimately not address the problems plaguing the NCP, including persistent delays well beyond statutory deadlines, insufficient communication with submitters, and lack of transparency.

These comments support several aspects of EPA's proposal, including EPA's efforts to align the existing new chemicals regulations with the 2016 TSCA amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), but they also identify concerns and suggest recommendations for improving the proposal and the NCP overall.

The comments make the following points:

- Requiring or recommending that submitters include more specific information and data for a PMN to be considered complete should not hinder innovation with overly burdensome regulatory requirements prior to introduction into commerce.
- EPA should develop written guidance on what the "known to or reasonably ascertainable by" standard means in the context of new chemical reviews.
- EPA should standardize, document, and communicate its review procedures and how information will be used to inform decision-making. This includes consideration and prioritization of data and information present in the submission over conservative assumptions.
- Additional guidance is needed to support the development of information to support new chemical submissions, and in particular, to help focus efforts on the submission of

[1] ACC represents the leading companies engaged in the multibillion-dollar business of chemistry. ACC members apply the science of chemistry to make innovative products, technologies and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, safety, and security performance through Responsible Care®; common sense advocacy addressing major public policy issues; and health and environmental research and product testing. ACC members and chemistry companies are among the largest investors in research and development, and are advancing products, processes, and technologies to address climate change, enhance air and water quality, and progress toward a more sustainable, circular economy.

relevant and necessary information. Submitters are unlikely to be able to provide some of the specified data elements for sites not controlled by the submitter.

- ACC supports the proposed amendments in which the "applicable review period" would not begin until EPA receives a complete notice. However, EPA should provide further information on what is considered a "complete notice" such that supplemental information that is identified and submitted after the initial submission does not void the initial completeness determination and does not reset the 90-day statutory review period to Day 1.
- EPA should introduce process improvements in the NCP that emphasize enhanced communication with submitters at interim stages of the review process.
- The low volume exemption (LVE) and low release and exposure exemption (LoREX) are important features of the new chemicals program that have fostered innovation while minimizing risks. EPA should not exclude chemical categories from eligibility for LVEs and LoREXs. This approach is unnecessary given the already stringent requirements to meet these exemptions.
- EPA should not arbitrarily eliminate eligibility of a broad class of per- and polyfluoroalkyl substances (PFAS) to qualify for exemptions. This approach is unnecessary, unscientific, and would stifle innovation. Further, it is inconsistent with EPA's own PFAS Strategic Roadmap, which acknowledges the differences among PFAS and aims to identify multiple categories of PFAS instead of treating them as a single category.
- EPA should not broadly revoke existing exemptions on PFAS substances. Existing exemptions should be reviewed on a case-by-case basis.
- EPA should clarify that case managers may not impose a suspension without the submitter's authorization.
- ACC supports the proposal to require an EPA determination before manufacture under an LVE or LoREX may commence, and the proposal to have EPA notify LVE and LoREX holders that a SNUR has been proposed or finalized for their substances.
- ACC supports the proposal to increase public access to more non-confidential information.
- The economic analysis for the proposal is deficient because it does not account for the cost of acquiring reasonably ascertainable information. In particular, it ignores the additional costs for submitters of PMNs for PFAS that, under the current rules, would be eligible for an LVE, but would now be subject to EPA's recently announced PFAS Framework.

DISCUSSION

I. General Comments

A. A well-functioning new chemicals program is essential to American innovation.

New chemical innovation is critical to the development of new products and technologies that contribute to the U.S. economy. Congress recognized this in TSCA Section 2(b)(3):

> It is the policy of the United States that— …
>
> > (3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

A 2022 report of the National Academy of Sciences (NAS) emphasized the criticality of the business of chemistry to the U.S. economy:

> The size of the chemical economy is quite expansive and is a substantial portion of the U.S. economy. All sectors reliant on the U.S. chemical economy are responsible for $5.2 trillion, or 25%, of the U.S. gross domestic product, and the entire chemical enterprise supports 4.1 million jobs in the United States. The United States is home to 10 of the top 50 chemical companies and remains very competitive in the global chemical economy. However, other countries have seen large sustained investments in their chemical and overall research enterprises, including China and several others, and their rapid advances are starting to threaten U.S. leadership in chemistry ….
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> Conclusion 2-1: Chemical research has an outsized economic value based on the spillover of chemical knowledge and products into other areas and the fact that chemical patents, as well as patents that rely on chemical knowledge, have a higher average value than other patents. Chemical patents accounted for 14% of all corporate patents between 2000 and 2020, but they accounted for 23% of all value in the same time period.
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> Conclusion 2-2: Chemistry is a foundational and central scientific discipline, and sustained investment in fundamental chemical research provides the chemical knowledge for technology development, generating unexpected discoveries that are the basis for innovation. These innovations directly influence the chemical economy, environment, and quality of life and also advance knowledge and discovery in many other scientific and technological disciplines, such as the life sciences, information technology, earth sciences, and engineering.

> Conclusion 2-3: The chemical economy is critically important for our national economy and our leadership in the international chemical enterprise. This leadership relies heavily on advances in fundamental chemistry that drive the creation of new tools, technologies, processes, and products and enables environmental considerations. However, our nation's leadership in the chemical industry cannot be taken for granted, and this leadership needs continued and sustained nurturing and support.[2]

The TSCA New Chemicals Program (NCP) must be best in class from a global standpoint to incentivize businesses to manufacture domestically and to onshore critical supply chains. The Biden Administration has prioritized the revitalization of domestic manufacturing and U.S. manufacturing capabilities, and an efficient new chemicals program is an enabling factor.[3] The longer and more uncertain the new chemical review process becomes, the more likely chemical manufacturers will choose another geography for market introduction, and the more likely the United States will import articles made from that substance. The net effect would be an offshoring of U.S. manufacturing jobs, particularly in the chemical industry and related sectors.

Since enactment of the LCSA, it has been industry's experience that the NCP has not been best in class. Instead, the persistent delays in EPA's reviews of premanufacture notices (PMNs) and significant new use notices (SNUNs), which have extended well beyond the statutory 90-day review period, adversely affect innovation in the chemical industry and the supply chains that rely on these chemistries.

Accordingly, ACC welcomes efforts by EPA to improve the performance of the NCP. ACC supports adequate funding for the NCP and clarifications to the information that submitters should provide in their submissions.[4] However, ACC remains concerned about how the NCP uses that information to make its determinations and the time it takes to make them.

B. ACC supports EPA's efforts to align the NCP regulations with the 2016 TSCA amendments.

Seven years ago, the LCSA made substantial amendments to how EPA reviews PMNs and SNUNs. ACC supports EPA's objective of aligning the NCP regulatory text with amended TSCA

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[2] National Academy of Sciences, The Importance of Chemical Research to the U.S. Economy (2022) at 2, 4, https://nap.nationalacademies.org/download/26568.

[3] White House, The Biden-Harris Plan to Revitalize American Manufacturing and Secure Critical Supply Chains in 2022 (Feb. 24, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/24/the-biden-harris-plan-to-revitalize-american-manufacturing-and-secure-critical-supply-chains-in-2022/.

[4] See, e.g., EPA, Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions (n.d.), https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf; EPA, TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues (July 22, 2022), https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology%20and%20Results.pdf.

Section 5. These comments support several aspects of EPA's proposal, but also identify concerns and suggest recommendations for improving the proposal.

C. Further specificity regarding the information needed to have a complete PMN should not result in hindering innovation with overly burdensome regulatory requirements prior to introduction into commerce.

The preamble to the proposed rule states:

> Before the 2016 Lautenberg Amendments, TSCA allowed the PMN submitter to commence manufacturing or processing upon expiration of the review period, unless EPA made an affirmative finding of unreasonable risk.[5]

This statement is grossly misleading. It implies that EPA was misusing its discretion to selectively use a prior technique of "dropping" a PMN, a practice that allowed the agency flexibility to let manufacture start in appropriate cases rather than holding up PMN clearance for an extended period. The technique could be used for lower risk chemistries based on EPA's review, allowing the agency to focus on those PMNs that required more attention. And in fact, prior to 2016, new substances were only "dropped" from full review after EPA concluded that the substance would not present an unreasonable risk. In the TSCA reform process, the Senate Environmental & Public Works Committee report on what became the 2016 amendments reinforced the continuing need for a "a flexible, targeted review process" and that while the standard for EPA to determine if a chemical presents an unreasonable risk, was not changing, EPA should conduct an appropriate review while supporting the ability of manufacturers and processors to innovate and bring to market new chemicals and products."[6]

The TSCA amendments did change the decisions EPA must make in its review of new chemicals, and the amendments required affirmative determinations for each of these, but they did not change the timeline for EPA to complete its new chemical reviews or exemption reviews. Congress allocated EPA only 90 days in which to review PMNs because it understood that EPA would be reviewing a limited data set, since a new chemical substance likely would have only limited information available. This distinguishes Section 5 reviews from risk evaluations of existing chemicals under Section 6. This is consistent with the Senate Environmental and Public Works Committee's finding that "the information requirements of section 5, coupled with EPA's robust new chemical review process, are protective of health and the environment. Section 5 provides EPA adequate authority to both review and, where warranted, regulate new chemical substances, while preserving the elements of TSCA that promote innovation in new chemistries."[7] EPA itself recently conceded that "New chemical assessments are intended to be

[5] 88 Fed. Reg. at 34101.
[6] S. Rept. 114-67, 114th Cong., 1st Sess. (2015) at 16.
[7] Id.

screening-level" and therefore differ in terms of information requirements and time from a Section 6 risk evaluation.[8]

The proposed requirement for PMN submitters to provide highly detailed information about new chemical substances resembles the information EPA considers in making its Section 6 risk evaluations, which may take EPA up to 3½ years to complete. Yet Congress maintained the 90-day statutory deadline for EPA to complete its reviews of PMNs. In addition, the 2016 amendments "continued the current TSCA practice of not imposing a minimum set requirement on all new chemicals; rather, any requirements to develop new information are determined on a chemical-by-chemical basis."[9] ACC appreciates that EPA has taken inventory of the data elements that it believes are needed to perform refined, qualitative risk assessments. But a list of data elements, without providing the necessary context or relevance, will not by itself resolve the systemic problems associated with the new chemicals review process that lead to significant delays. To further create a transparent process and alleviate confusion, EPA must standardize, document, and transparently communicate its review procedures and how this information will be used to inform decision-making.

The NCP is the key review point for new chemicals. That said, Section 5 must also be viewed within the context of the rest of TSCA. Once a new chemical is added to the inventory, it becomes an existing chemical and other TSCA regulatory tools become available to EPA to address questions or concerns the Agency may later identify about a chemical. Information about these questions may not be known to or reasonably ascertainable by the submitter within the PMN review timeframe. This includes information that could be developed through Section 4 (testing authority), Section 8 (information gathering), and Section 6 (prioritization, risk evaluation, risk management).

D. EPA should provide guidance on what the "known to or reasonably ascertainable by" standard means in the context of new chemical reviews.

1. EPA should clearly define "known to or reasonably ascertainable by"

EPA acknowledges that, under TSCA section 5(d)(1), submitters are only required to supply information that is known to or reasonably ascertainable by them as defined at 40 C.F.R. § 720.3(p). However, that definition is vague. EPA should provide clarification, beyond the regulatory definition, with examples and other guidance, about what "known to or reasonably ascertainable by" means in the context of new chemical submissions, as it has done for the Chemical Data Reporting (CDR) rule. The CDR guidance suggests that reporting entities may need to reach out to suppliers or customers, and that failure to do so would mean that the entities have not met their regulatory obligations.[10] In contrast, in adopting its PMN regulations in 1983,

[8] TSCA New Chemical Engineering Outreach Initiative to Increase Transparency and Reduce Rework (epa.gov).
[9] S. Rept. 114-67, 114th Cong., 1st Sess. (2015) at 15.
[10] Instructions for Reporting 2020 TSCA Chemical Data Reporting, § 4.2, https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf.

EPA emphasized that submitters are encouraged but not required to reach out to prospective customers for information. In making that decision, EPA considered and rejected proposed requirements to reach out to prospective customers.[11]

Given this discrepancy between the CDR and the PMN guidance, EPA should clearly identify what obligations, if any, submitters have to reach out to prospective customers for information. ACC recommends that EPA continue its policy from 1983. The detailed information elements proposed to be submitted for sites not controlled by the submitter are very unlikely to be available even from prospective customers, making mandatory outreach to them a futile exercise. These data elements may often only be known at a generic level with anything more specific (including potential worker exposures and releases and process details) not known or reasonably ascertainable.

2. EPA should address application of "reasonably ascertainable" definition in guidance

The preamble also does not address what "reasonably ascertainable by" means with respect to information that is not expressly required in the PMN form, but which becomes relevant once EPA reviews the potential risk of the proposed new chemical. EPA should address these sorts of questions in guidance. For example, clarifying guidance should explain how EPA applies the standard in connection with exercise of testing authority for new chemicals. EPA should also clarify in guidance that submitters should not have the review period revert to Day 1 solely because they submit information developed as a normal part of the review process, but EPA reviewers identify "reasonably foreseen" conditions of use not contemplated by the PMN submitter.

EPA should also avoid the potential problems of application of the reasonably ascertainable concept in the context of any check boxes in the PMN form. For example, EPA states in the preamble that it "is also considering adding statements with accompanying check boxes to certain screens of the PMN form … that indicate that information fields can only be left blank if such information is not known to or reasonably ascertainable by the submitter."[12]
One alternative to the check box approach being considered by EPA would make certain fields mandatory such that the submitter would not be able to advance in the form without checking a box. This would be impractical and unnecessarily burdensome. Flexibility to move between screens is important as the forms require detailed information that submitters may develop at different times during assembly of the submission.

3. EPA should define "complete notice"

EPA is proposing to clarify the level of detail expected for the information that a submitter is required to include in a PMN, SNUN, or exemption notice in order for the notice to be considered complete. However, EPA does not provide a clear definition of a "complete" submission, nor does it fully explain the application of the "known to or reasonably ascertainable by" standard in the context of what EPA will consider a "complete" notice.

[11] 48 Fed. Reg. 21722, 21730-31 (May 13, 1983).
[12] 88 Fed. Reg. at 34109.

4. EPA should clarify when its definition of "applicable review period" would result in resetting the 90-day clock to Day 1

As provided in TSCA Section 5(i)(3), the "applicable review period" means 90 days from the date EPA receives a notice under TSCA Section 5(a)(1), or up to 180 days from that date if EPA extends the applicable review period according to the provisions in TSCA Section 5(c).[13] EPA is proposing to add a definition for "applicable review period" to 40 C.F.R. § 720.3 that would define that term as the period starting on the date EPA receives a "complete" submission and ending 90 days after that date, unless extended as provided in Sections 5(b)(1) or 5(c). This proposed definition raises the question of whether any additional information that is identified and submitted after the initial submission would make the initial submission "incomplete," thus resetting the 90-day review period to Day 1. ACC does not support such resetting of the count to Day 1, nor does it regard supplemental information submitted in response to EPA concerns or requests during the review period to make the initial submission "incomplete." The potential for resetting the 90-day clock injects a degree of subjectivity on the part of new chemicals case managers that is not contemplated in the statutory deadline. It further decreases transparency in the new chemicals review process.

As mentioned above, of particular concern is the potential for EPA reviewers to raise questions about conditions of use not intended by the submitter that then trigger resetting the count of days. PMN submitters must provide information about their "intended" conditions of use, but they cannot be expected to provide, at least initially, information about conditions that reviewers may consider to be "reasonably foreseen." If reviewers raise questions about "reasonably foreseen" conditions of use beyond what the submitter has intended and provided information on, doing so should not trigger resetting the count of days on the theory that the original submission was incomplete. Further, EPA should not determine a submission is "incomplete" over a rebuttal of EPA's selection of analogs, use of models, or conservative assumptions when the submitter has provided the required data and supporting rationales.

Further, EPA's coupling of its proposed significant information requirements for new chemical reviews with its proposal for conditions that would "re-start" the 90-day clock to Day 1 implies that EPA intends to call more submissions incomplete and to restart more reviews at Day 1, without providing any meaningful improvements to the Agency's new chemical review process. In maintaining the 90-day new chemical review period in the TSCA amendments, Congress did not intend for EPA to create bureaucratic loopholes like this one. EPA should reconsider its proposed "Day 1" re-start approach and either withdraw it entirely or significantly limit its potential application clearly.

E. <u>EPA should standardize, document, and communicate its review procedures and how information will be used to inform decision-making.</u>

[13] See 88 Fed. Reg. at 34103.

ACC appreciates EPA's efforts to increase the efficiency of the NCP by proposing updates to its regulations. ACC also recognizes that EPA has implemented approaches aimed at streamlining new chemical reviews for certain priority substances.[14] However, EPA should consider additional process improvements to ensure timely new chemicals review with predictable outcomes. Approval of new chemicals is essential to innovative new technologies that are crucial to the Administration priorities being commercialized in the United States. ACC proposes the following four process improvements to increase the efficiency of the NCP and decrease rework:

1. EPA should consider and prioritize information present in the submission

Over the years, EPA has utilized modeling to inform decision-making where EPA typically relies on conservative assumptions and default values in its assessments when needed information is not provided. However, ACC members note that EPA often disregards or misinterprets information present in the submission, including optional pollution prevention information, resulting in unwarranted and overly burdensome risk management requirements. EPA has acknowledged that submitters have also expressed concern that EPA does not always use submitted data in its risk assessments and does not provide enough information on what EPA deems as "acceptable data."[15] TSCA Section 26(k) requires EPA to take into consideration hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator. If EPA does not use the data provided (especially if it is the data listed in this proposal) in a submission, EPA should provide detailed and scientific justification on why conservative model data was used and not the data provided in the submission.

2. For new data requirements, EPA should provide additional documentation, guidance and clarity

To increase the NCP's efficiency and decrease the occurrence of rework, submitters need additional information on the process that EPA uses to make decisions in the risk assessment phase. EPA has explained:

> Where relevant information is not included or included without adequate substantiation, EPA applies conservative assumptions and estimates releases and exposures using Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) models, OECD Emission Scenario Documents (ESD), and/or EPA Generic Scenarios (GS).[16]

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[14] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/integrated-approach-biofuel; https://www.epa.gov/newsreleases/epa-announces-innovative-effort-bring-new-chemicals-used-electric-vehicle.

[15] EPA, Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions (n.d.) at 1, https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf.

[16] EPA, TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues (July 22, 2022), https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology%20and%20Results.pdf.

ChemSTEER is a computer-based software program developed by the EPA's Office of Pollution Prevention and Toxics (OPPT) that is used to conduct a screening-level workplace exposure and environmental release assessments for chemicals used in industrial and commercial operations (i.e., workplaces)[17] while ESD and GS provide conservative, screening-level estimates of environmental releases and worker exposures for specific industry sectors or exposure scenarios.[18] EPA acknowledges that some estimates may result in release/exposure amounts that are likely to be higher, or at least higher than average, than amounts that actually occur in real world practice and that when submitters see the level of risk estimated by EPA using such conservative assumptions and default values, as well as the risk mitigation measures developed by EPA as a result, submitters often amend their initial notices to provide additional detailed information.[19]

3. EPA should update the Points to Consider document

EPA should use this opportunity to make substantial updates to the existing "Points to Consider" document in addition to other necessary guidance.[20]

4. EPA should regularly engage submitters

EPA should consider enhanced submitter engagement at interim points in the review process, to improve the efficiency of the review process and reduce the amount of rework by EPA.

F. EPA should not exclude categories from eligibility for LVEs and LoREXs.

The low volume exemption (LVE) and low release and exposure exemption (LoREX) are important features of the new chemicals program that have fostered innovation while limiting risks to Americans. EPA's proposal to arbitrarily eliminate eligibility of a broad class of per- and polyfluoroalkyl substances (PFAS) and persistent, bioaccumulative and toxic substances (PBTs) is unnecessary, unscientific, and would stifle innovation.

It is important to consider the stringent requirements already associated with LVE and/or LoREX submissions:[21]

1. A substance is ineligible for LVE and LoREX if the substance, any reasonably anticipated metabolites, environmental transformation products, or byproducts of the substance, or

[17] EPA, ChemSTEER User Guide (2015), https://www.epa.gov/sites/default/files/2015-05/documents/user_guide.pdf.
[18] EPA, TSCA New Chemical Engineering Initiative to Increase Transparency and Reduce Rework: Analysis of New Chemicals Rework Issues (July 22, 2022), https://www.epa.gov/system/files/documents/2022-07/TSCA%20New%20Chemical%20Engineering%20Initiative%2C%20Analysis%20Methodology%20and%20Results.pdf.
[19] EPA, Analysis of Engineering Information Submitted for TSCA Section 5 New Chemicals Submissions (n.d.) at 1, https://www.epa.gov/system/files/documents/2022-06/Engineering%20Initiative%20Analysis.pdf.
[20] EPA, Points to Consider When Preparing TSCA New Chemical Notifications (draft June 2018), https://www.epa.gov/sites/default/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf.
[21] 40 C.F.R. § 723.50.

any reasonably anticipated impurities in the substance may cause serious acute or chronic effects to humans, or significant environmental effects.
2. No release to groundwater, to land, or to a landfill is permitted unless the substance has negligible groundwater migration potential.
3. Exposure controls are required such that there is no dermal exposure or inhalation exposure to consumers or workers.
4. No releases resulting in surface water concentrations above 1 part per billion are permitted.
5. No ambient air releases from incineration above 1 microgram per cubic meter maximum annual average concentration are permitted.

Submitters are also restricted in the ability to make any changes after EPA review. Moreover, the Agency still requires submission of an LVE or LoREX exemption for which EPA can evaluate the new chemical substance under specific conditions of use. If the submission is approved, the submitter is bound to the uses and the exposure and release controls described in the approved exemption and the submitter is bound to the listed manufacturing sites. Any changes would require a modification submission, also requiring EPA approval.

Further, the use of these exemptions benefits many sectors of the economy. In particular, PFAS LVEs are crucial to the semiconductor industry. However, more broadly, LVEs are used across all sectors and often by small businesses. The LVE and LoREX exemptions limit the production volumes, exposures and potential releases of the chemical compounds, therefore limiting the potential impact to human health and the environment. EPA does not provide risk-based evidence for excluding a broad category of substances from the LVE and LoREX when those types of submissions could be equally if not more restrictive than the PMN process. The proposed provision has the potential to significantly harm small businesses, hinder innovation, offshore critical chemical and supply chains already qualified by downstream users, and impact the ability of manufacturers to bring new products to market.

II. Comments on Information Requirements

ACC acknowledges EPA's efforts to clarify the information requirements for a notice and to make more transparent the level of detail that EPA needs in order to make a reasoned evaluation, but the proposed changes raise several issues that EPA must address prior to finalization of the proposed rule.

The proposed rule identifies a significant amount of information that would be required for the evaluation of new chemical substances. Not all data elements are relevant for each new chemical substance or the submitter's intended conditions of use, nor does EPA provide any information on available guidance for the determination of this information. The submission of unnecessary data is time consuming, burdensome, costly, and inefficient. In addition, EPA should carefully consider whether the provisions to demonstrate the practical utility of the proposed new information pursuant to 5 C.F.R. § 1320.3(l) apply here. We note that it appears that EPA has not

demonstrated practical utility as described in this section. EPA does not explain the justification for the additional data elements, how these data elements will be used to inform the risk assessment process, or how they anticipate they will improve the current new chemical review process without implementing additional process improvements including enhancing submitter engagement.

Considerations for the individual data requirements are provided below.

A. EPA should provide guidance on how to obtain or calculate certain of the physical-chemical properties.

EPA is proposing several new information requirements at proposed 40 C.F.R. § 720.45(j)(1). They include data on surface tension; ultraviolet–visible (UV-VIS) absorption; as well as any particle size distribution analysis; information for aspect ratio, thickness, and number of layers or walls for nanomaterials. Environmental fate characteristics are already addressed by 40 C.F.R. § 720.50; however, fields for environmental fate characteristics are not yet included on the Central Data Exchange (CDX) user interface screen pick list. EPA is proposing to add the relevant environmental fate characteristics to the information requirements at 40 C.F.R. § 720.45(j)(2) and to add form fields to the PMN form by expanding the pick list. Currently, if submitters have physical-chemical or environmental fate test data, they must provide the test data or a standard literature citation in accordance with § 720.50(a)(2)-(3) and must also submit this information in the corresponding PMN form fields in accordance with the proposed changes to § 720.45(j). ACC acknowledges that greater clarity on these elements provided in a drop-down pick list may be helpful. However, follow-on guidance for how to obtain the information that includes details regarding standard, preferred test methods will be critical to the regulated community submitting robust new chemical submissions.

Additionally, EPA may want to amend § 704.20 (nanoscale materials) to add the information elements added to the PMN form for nanoscale materials (aspect ratio, thickness, and number of walls).

B. Additional clarification is needed regarding the reporting and use of information related to uses of new chemicals.

EPA is proposing to add to 40 C.F.R. § 720.45(f) a requirement to designate applicable consumer and commercial product categories using Organisation for Economic Co-operation and Development (OECD)-based functional use codes, which would create consistency with TSCA Section 8(a) CDR requirements in 40 C.F.R. Part 711. ACC supports EPA's efforts to standardize reporting of uses and, in doing so, connecting Section 5 to Section 6, as once new chemicals are added to the inventory, they become existing chemicals and are then subject to existing chemical regulatory tools. However, ACC is concerned about the required level of specificity and EPA's ability to restrict the potential uses for a new chemical substance. If the potential new uses for a new substance are restricted based on these functional use codes, there is likely to be an increase

in the number of SNUNs because EPA would have declared any use other than an extremely narrow use a significant new use. This would add a significant burden to both industry and EPA.

Additionally, it is not clear how these proposed detailed data requirements will account for the vast experience EPA already has with estimating emissions, occupational exposures and consumer exposures based on conditions of use. EPA has dozens of generic scenarios for estimating occupational exposures and environmental releases for use with its ChemSTEER model and has been very active with OECD in developing emission scenario documents for the same. As a result, for the commercial product categories listed in Table 1 to Paragraph (f)(2), EPA will already have an existing approach to estimating emissions and occupational exposures with default (conservative) values to parameterize related models where data may not be available.

EPA should provide more clarity through guidance about exposure scenarios and associated exposure parameters so submitters can understand whether generating new data better informs the assessment. Similarly, for consumer uses and exposures, EPA's Consumer Exposure Model (CEM) and other specialized exposure models use generic information regarding the product in which a chemical may be used. Consequently, EPA needs little information beyond the Consumer Product Category in order to calculate reliable estimates.

Moreover, EPA should be using a sentinel exposure approach to estimate consumer exposure that focuses on those product use categories that are likely to lead to disproportionately high exposure. In addition, ACC recommends that EPA consider grouping commercial and consumer product categories among those products that will have similar exposure patterns. For example, in recommending particular human toxicity data for new food additives, the U.S. Food and Drug Administration considers the structure-based toxicological potential and aggregate human exposure potential to identify three levels of concern and the data/information that is expected to address that concern.[22] Given EPA's decades of experience assessing conditions of use for new chemicals, we expect the Agency would be able to group conditions of use with similar levels of exposure resulting in discrete tiers of aggregate exposure. EPA already has the Chemical Categories it may apply to indicate potential testing for a new chemical candidate.[23] A similar approach could be applied for ecological toxicity data as different conditions of use will have different environmental emission rates. However, environmental exposure is also contingent on market volume of a chemical (in addition to the use pattern). Therefore, ACC recommends that EPA monitor the market volume of new chemicals through regularly collected CDR information to confirm that assumptions associated with the environmental safety assessment are consistent as the use of a chemical grows.

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[22] U.S. Food and Drug Administration. 2006. Guidance for Industry: Summary Table of Recommended Toxicological Testing for Additives Used in Food. Center for Food Safety and Applied Nutrition. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-summary-table-recommended-toxicological-testing-additives-used-food.

[23] U.S. Environmental Protection Agency. 2010. Chemical Categories Used to Review New Chemicals under TSCA. Office of Pollution Prevention and Toxic Substances. Available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemical-categories-used-review-new.

ACC is concerned that submitters will see Section 5(e) orders limiting use of their substances to the specific OECD functional use codes identified in the PMN, or SNURs making any uses other than those identified in the OECD function use codes as significant new uses. Such a practice would limit innovation, as new uses for the substance may be discovered well after initial commercialization. Often, it is processors who discover additional uses. Processors who do so should not have to submit SNUNs and wait for EPA review in order to be able to engage in those uses, except in circumstances where it is clear that other uses would pose a risk to health or the environment.

In addition, submitters may be unable to accurately quantify or document consumption rates for downstream articles. For example, if a new chemical's intended use is architectural coatings that have industrial and consumer uses, it may be consumed at very different rates in different applications. In summary, EPA's proposed integration of OECD use codes is a novel approach that holds promise, but additional clarification is needed regarding the anticipated level of specificity required for reporting, guidance on bridging between the proposed codes and EPA's generic scenarios, and EPA's intended use of this information to reach a final determination. EPA should consider developing a pilot of this approach with additional supporting guidance before finalizing.

C. Submitters are unlikely to be able to provide some of the specified data elements for sites, particularly those not controlled by the submitter.

The proposal includes data elements for details concerning manufacturing, processing, and use in proposed § 720.45(g)(1) and (2) and (h)(1) and (2). Although these proposed information requirements would apply to sites controlled by submitters as well as to sites controlled by others, EPA acknowledges:

> Moreover, activities at sites controlled by others are typically not as well characterized by submitters compared to descriptions of the submitters' own activities, since in many cases, the identity and number of sites controlled by others is unknown to the submitters when a notice is submitted ….
>
> EPA recognizes that a submitter may not possess such information about sites not controlled by the submitter. Submitters are only required to supply information that is known to or reasonably ascertainable by them as defined at 40 CFR 720.3(p).[24]

For this information, it is important to recognize that sites controlled by the submitter and sites not controlled by the submitter may often be very different (e.g., manufacturing vs. processing). EPA should not expect that the level of information submitters will have related to their own sites will necessarily be equivalent to the level of information they have about sites not under their control.

[24] 88 Fed. Reg. at 34107-08.

Obtaining the data proposed for sites not controlled by the submitter is likely to be very difficult or impossible. EPA will rarely obtain any data other than an acknowledgement that the information is not known to or reasonably ascertainable by the submitter. This data will often be simply unavailable in advance of commercialization. Other information about sites controlled by others may be confidential to the downstream processor or customer, who likely would be unwilling to share that information with the submitter. Nondisclosure agreements do not necessarily ensure 100% transparency with respect to the downstream value chain or potential customers nor are they easy to develop and manage.

To the extent that EPA is relying on generic scenarios for exposure and releases from certain conditions of use, EPA should detail a process by which submitters can provide information to update the scenarios to reflect current practices. EPA should provide greater transparency regarding the current exposure scenarios and exposure parameters it uses for individual consumer and commercial product categories. In most cases, EPA will be using conservative assumptions and submitters can determine whether it is necessary for them to submit refined data or information to estimate emissions and exposures more accurately. If there are product use scenarios where EPA genuinely has no information related to emissions and exposures, it would be appropriate for EPA to seek such information for those specific uses.

Among the proposed additions to the PMN information requirements are worker exposure and environmental exposure data for exempt substances, such as byproducts and impurities. This data is also very unlikely to be known to or reasonably ascertainable by the submitter. EPA should justify why it seeks to collect this information on exempt substances.

D. EPA should explain how it plans to use the optional pollution prevention information.

EPA is proposing to add optional pollution prevention information at 40 C.F.R. § 720.45(k). The PMN form in CDX currently includes an optional text field for submitters who wish to provide pollution prevention information about the chemical substance, such as information about using alternative fuel sources, reducing the use of water and chemical inputs, modifying a production process to produce less waste, implementing water and energy conservation practices, or substituting for riskier existing products. Industry's experience, however, is that EPA reviewers appear to routinely ignore this information. EPA should clarify how it will use pollution prevention information or what might prompt it to consider this information, if provided, in the review of new chemicals.

III. Amendments Related to Pre-Screening Submissions, Incomplete Submissions, Correction of Errors, and New Information

A. ACC supports the proposed amendments in which the "applicable review period" would not begin until EPA receives a complete notice

EPA is proposing to add a definition for "applicable review period" to 40 C.F.R. § 720.3, which EPA would define as "the period starting on the date EPA receives a complete notice under section 5(a)(1) of the Act and ending 90 days after that date or on such date as is provided for in sections 5(b)(1) or 5(c) of the Act." ACC supports this proposed definition and its implementation in the new chemical review process.

EPA is proposing amendments to 40 C.F.R. § 720.65(a) and (b) to state that if EPA receives a notice with errors and EPA requests (as part of the prescreen process or, at latest, within 30 days of receipt of the notice) that the submitter remedy such errors, the applicable review period would not begin until EPA receives a corrected notice. ACC supports the proposed amendments in which the "applicable review period" would not begin until EPA receives a corrected notice.

EPA has presented an analysis of common issues that cause it to have to rework engineering assessments. The analysis showed that information on material balance parameters, environmental releases and environmental release media, and engineering controls resulted in nearly 80% of all rework in the NCP. ACC therefore encourages EPA to provide further guidance on the information that EPA requires for engineering assessments and consider efficient ways to enhance its engagement with submitters after the engineering assessment is completed and prior to submissions moving to the risk assessment stage of the review process to ensure that information is reflective of the manufacturing, processing and use of the new chemical substance. This would increase the likelihood that EPA will have robust information for material balance parameters, environmental releases and engineering controls, thereby significantly decreasing the amount of rework performed by the Agency.

B. EPA should increase its engagement with submitters during the review period.

EPA often reaches out to the submitter after it completes its risk assessment to explain the findings of the risk assessment and any proposed prohibitions or limitations on the manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance. If the submitter disagrees with the potential risks identified in the risk assessment, the submitter may provide additional information to demonstrate that risks are lower than EPA estimated. The lack of submitter engagement until the completion of the risk assessment is an inefficient use of EPA and submitter resources. It leads to significant delays in the review of new chemicals, and results in amendments and refinement of the risk assessments based on these amendments.

Instead, EPA should introduce process improvements in the NCP that emphasize enhanced communication with submitters at interim stages of the review process. Such communication would go a long way toward avoiding rework. Work does not need to be redone due to missing information if timely consultation with the submitter before that work is done results in the work

being done with the needed information in hand. Additional information about where a submitter's chemical is in the process would also be helpful.

EPA asserts that "restarting" the review period after new information is received would result in a reduction in rework and increased efficiency in the new chemical review process. The opposite is more likely to be true. Restarting the review period will primarily have the effect of reducing – on paper anyway -- the numbers of submissions under review for greater than 90 days. EPA has not supported its claim that restarting the review period will increase the efficiency of new chemical reviews or reduce the submission of amendments to address an overly conservative EPA risk assessment. As described, EPA's "restart" proposal is not well-supported.

C. EPA should clarify that submitters are not required to request suspensions and that case managers should not do so without the submitter's authorization.

EPA is proposing to amend the regulations pertaining to suspensions to allow submitters to request suspensions for up to 30 days via oral or e-mail request. ACC members report that suspensions of the review period are rarely initiated by the submitters but rather are requested by EPA. In addition, submitters have reported multiple instances where they have been informed that the case manager has suspended the review period without receiving a specific request from the submitter. EPA should clarify that submitters are not required to "request" a suspension of the review period. EPA should limit suspensions of the review period to cases where the Agency is considering new or clarifying information and must indicate at what stage (e.g., Engineering Evaluation, Risk Assessment) the submission is in the review process and an estimate of the time to completion.

IV. Comments on LVEs and LoREXs

A. EPA should not exclude all PFAS from eligibility for LVEs and LoREXs.

ACC believes this proposed change is unwarranted. PFAS are a diverse group of manufactured fluorinated organic chemicals with significantly varying chemical and physical properties[25] with, as noted by EPA, potentially varying effects and toxicity levels.[26] In fact, the National Academies of Sciences, Engineering, and Medicine (NASEM) in a recent report rejected a single class approach to assessing the potential hazards of organohalogen flame retardants (OFR) stating:

> OFRs include a wide range of substances with differing characteristics, structures and intended uses. In addition, flame retardants have different physical, chemical and toxicological profiles, meaning no two chemicals are exactly alike and are not universally interchangeable" and concluded "it is not scientifically accurate or appropriate to make broad conclusions or impose a one-size-fits-all regulatory

[25] AGS – Association of Geotechnical and Geoenvironmental Specialists – PFAS – Nomenclature.
[26] Our Current Understanding of the Human Health and Environmental Risks of PFAS | US EPA.

approach for OFRs. The findings also track with past reviews conducted by the Academy, which focused on using chemical specific data to evaluate OFRs.[27]

Similarly, OECD, in its Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, stated "The decision to broaden the definition compared to Buck et al. is not connected to decisions on how PFASs should be grouped in regulatory and voluntary actions."[28] OECD has also emphasized that the term "PFAS" does not inform whether a substance is potentially harmful or not.[29] It does not speak to characteristics such as toxicity, environmental fate, and bioavailability among diverse PFAS chemistries. Some PFAS are small molecules that can enter cells, bioaccumulate, and move easily through the environment. Others are large, stable molecules that are too large to pass through cell membranes and therefore would not bioaccumulate or otherwise interact with biological systems.

More fundamentally, EPA is improperly citing its authority under TSCA Section 26(c) to regulate categories of chemicals, where the chemicals must be in some way "suitable for classification as such for purposes of this Act." Until now, EPA has repeatedly declined NGO recommendations to treat all PFAS as a single category. For example, under the Clean Air Act, EPA recently emphasized the need for substance-by-substance evaluations of PFAS.[30] The proposed classification of all PFAS into a single category is at odds with the EPA PFAS Strategic Roadmap, which acknowledges the differences among PFAS and aims to identify multiple categories of PFAS instead of dealing with them as a single category.[31] In effect, such a category would assign equivalent risk potential to both small, non-polymeric PFAS and high molecular weight fluoropolymers that meet criteria for low concern for harm to human health and the environment. [32] As described in the next section, EPA should take a more tailored approach.

B. Revocation of existing PFAS exemptions should be case-by-case.

With little fanfare, the preamble raised the question of whether EPA should take the drastic action of revoking all existing LVEs for PFAS:

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[27] National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. https://doi.org/10.17226/25412.
[28] Organization for Economic Co-operation and Development (OECD). 2021. Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. OECD Series on Risk Management, No. 61, OECD Publishing, Paris.
[29] Id.
[30] 88 Fed. Reg. 26382, 26414 (Apr. 28, 2023).
[31] PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 (2021) at 20, https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.
[32] Henry, B.J., *et al.* 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integr Environ Assess Manag, 14: 316-334. https://doi.org/10.1002/ieam.4035. Open access; Korzeniowski, S.H., *et al.* 2022. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integr Environ Assess Manag, 19: 326-354. https://doi.org/10.1002/ieam.4646. Open access.

> With these considerations in mind, EPA solicits comment on revoking previously granted LVEs for PFAS pursuant to the process set forth in 40 CFR 723.50(h)(2) and requiring those who wish to continue manufacture to submit a PMN.[33]

EPA should not adopt a mandatory program of forcing current PFAS LVE holders to lose their LVEs and instead submit PMNs for their LVE chemicals. EPA stated in 2021 that "the agency generally expects that pending and new LVE submissions for PFAS would be denied"[34] and announced the PFAS Low Volume Exemption Stewardship Program to encourage voluntary relinquishment of existing PFAS LVEs.[35] Moreover, EPA already has existing authority under 40 C.F.R. § 723.50(h)(2) to determine whether the manufacture of the new chemical substance being manufactured under an LVE does or does not meet the terms required for an exemption as described in § 720.50.

EPA claims to be unable to utilize its authorities in the statutorily designated timeline is a matter of EPA's priorities, not that it is powerless to impose stronger controls on PFAS substances currently manufactured under LVEs. Under the current program, EPA has broad authority to impose volume controls, use limitations, release requirements, or occupational exposure controls as part of granting or reviewing LVEs. It is our understanding that EPA has regularly exercised these authorities during reviews of PFAS LVEs, requiring manufacturers to commit to lower production volumes, or restrictions on release, occupational exposure, or uses.

In addition to the steps and authorities mentioned above, EPA's proposal is unclear as to whether (a) a PFAS LVE holder could continue to manufacture a chemical manufactured under an LVE during the PMN review process and (b) whether such chemicals could continue to be processed or used. Prohibition of the manufacturing, processing, or use of a PFAS chemical currently manufactured under an LVE until the outcome of the PMN review process and the agency's determination could cause unnecessary disruptions to important supply chains and significant increased costs for both LVE holders and the Agency. PFAS substances currently manufactured under LVEs are small volume, high value substances with applications in many industries, including semiconductors, automotive, aerospace, and pharmaceutical manufacturing, as well as lubricants, gaskets, seals, and chemical intermediates in industrial processes.

Submission and review of a PFAS PMN application would likely take years, in light of the recently announced PFAS Framework document.[36] That framework indicates that in virtually every case, EPA will regard a PFAS as a potential PBT, and then would require testing, possibly extensive testing that could take years to complete. EPA would not begin to review a PFAS

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[33] 88 Fed. Reg. at 34114.
[34] EPA Announces Changes to Prevent Unsafe New PFAS from Entering the Market. https://www.epa.gov/chemicals-under-tsca/epa-announces-changes-prevent-unsafe-new-pfas-entering-market.
[35] PFAS Low Volume Exemption Stewardship Program, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/pfas-low-volume-exemption.
[36] Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) (June 28, 2023), https://www.epa.gov/system/files/documents/2023-06/PFAS%20Framework_Public%20Release_6-28-23_Final_508c.pdf.

PMN until after it had received the test results. Thus, between the time that EPA revoked a PFAS LVE and the time it approved a PFAS PMN and issued an order under TSCA Section 5(e) or 5(f), the former LVE holder and its customers would be unable to manufacture, process, or use the PFAS chemical on which it had depended for years, possibly decades. The result would potentially undermine strategically important industries that rely heavily on PFAS manufactured under LVEs and initiatives to enhance U.S. competitiveness and leadership in those industries (e.g., the CHIPS Act of 2022).

Accordingly, EPA should not revoke all PFAS LVEs. If, after review, it decides to revoke individual PFAS LVEs on a case-by-case basis, it should permit continued manufacture, processing, and use of the PFAS during the PMN review process.

A blanket approach of revoking existing LVEs for all PFAS is a draconian response that is not necessary and would inflict severe costs on the economy. We recommend that EPA take a risk-based, case-by-case approach to evaluating PFAS manufactured under LVEs. Instead of a blanket approach, the agency could identify the type of PFAS covered in each LVE, their uses, and potential for environmental or human exposure. The agency could make a preliminary evaluation of the type of PFAS (i.e., non-polymeric vs. polymeric) and associated uses that may raise concerns and require an LVE review and, potentially, a transition to a PMN based on concerns about potential risk using the process described at 40 C.F.R. § 723.50(h)(2). Existing PFAS terminology and nomenclature frameworks such as those in Buck et al. 2011 or OECD 2021 could be used to inform such an exercise.

Finally, the proposed rule does not adequately describe its proposed process of transitioning from an LVE to a PMN in terms of industry's ability to continue to manufacture, process, or use a PFAS chemical produced under an LVE during the PMN review process. While the LVE Stewardship Program allows for the continuing processing, distribution, or use of existing stocks of PFAS chemicals for which LVEs have been voluntarily withdrawn, that same process should *not* be followed for PFAS substances with continued economic importance. Instead, manufacturers and their customers need clarity and assurance that they can manufacture, process, distribute, and use the PFAS substance under the terms and restrictions of the applicable LVE during a PMN review process, which could take several years. Without such assurance, commercially important substances would be put in perpetual limbo, creating chaos in the marketplace.

C. EPA should consider that PBTs may be able to be used under controlled circumstances.

The proposed amendments to 40 C.F.R. § 723.50(d) would allow submission of an LVE or LoREX application for a chemical which may prove to be a PBT, although EPA may reject it after case-by-case review for PBT status. ACC does not support the amendments to 40 C.F.R. § 720.50(d) that would make categories of chemicals classified as PBTs with anticipated environmental releases and potentially unreasonable exposures to humans or environmental

organisms ineligible for LVE or LoREX. ACC contends that EPA should make a determination on individual chemical substances under the conditions of use as identified in the exemption notice to determine if the hazard of the chemical substance combined with the potential exposure from the manufacturing, processing or use of the chemical will not pose an unreasonable risk.

D. ACC supports the proposal to require an EPA determination before manufacture under an LVE or LoREX may commence.

The current regulations at 40 C.F.R. § 723.50(g)(2) allow a submitter of a LVE or LoREX exemption to commence manufacture of a chemical substance upon expiration of the 30-day review period if EPA has taken no action. EPA's current practice when delays occur during the review period is to request a submitter to suspend the review period while EPA completes its review and determines whether to approve or deny the exemption notice. EPA is proposing to amend the regulations at 40 C.F.R. § 723.50(g) to require a notification of approval of an LVE or LoREX from EPA prior to commencement of manufacture of the chemical substance under the exemption. ACC supports this proposed change.

In addition, EPA should be required to notify all LVE and LoREX holders if their substances are later added to the TSCA Inventory. Since LVEs and LoREXs are exemptions from the need to be on the Inventory, once a chemical is added to the Inventory, all LVEs and LoREXs for that chemical should automatically expire, with prompt notification to the holders of those exemptions.

V. Comments on SNURs

A. ACC supports the proposal to have EPA notify LVE and LoREX holders that a SNUR has been proposed or finalized for their substances.

EPA is proposing to add language to 40 C.F.R. § 723.50 to require EPA to inform an LVE or LoREX holder for a chemical substance whenever the chemical substance becomes subject to a proposed or final SNUR that describes the chemical substance by a generic chemical name due to a confidentiality claim for its specific chemical identity. ACC supports EPA's efforts to inform LVE/LoREX holders, while protecting all CBI claims, when their substance becomes subject to a SNUR since they may otherwise be unaware of those requirements.

However, EPA does not intend to proactively inform current LVE and LoREX holders about SNURs that predate this rule. We encourage EPA to inform exemption holders about SNURs that predate this rule. Particularly, if an LVE/LoREX substance were added to the Confidential Inventory, the Exemption holder could be unaware that it is the same specific chemical and now subject to restrictions. In addition, EPA should also inform LVE/LoREX holders, while protecting all CBI claims, if their exempt substance is added to the TSCA Inventory as the result of the submission of a PMN. Without such notification, the exemption holder may be unaware

of reporting requirements under TSCA including the reduced threshold for reporting under the CDR rule.

B. EPA should consider use of Regulatory Flags.

Special flags are used throughout the TSCA Inventory to identify those substances on the Inventory that are the subject of an EPA rule or order promulgated under TSCA, manufactured under a polymer exemption, as well as to indicate types of full or partial exemptions from TSCA reporting requirements. [37] As acknowledged in the "Points to Consider" document, a commitment to adhere to the conditions as outlined in the submission has the potential to expedite the review process, if EPA's finding on the notification is "not likely to present an unreasonable risk."[38] EPA should consider options for other regulatory flags that would enable further program efficiencies and assist the Agency in meeting its 90-day statutory requirements.

VI. Additional Comments

A. ACC supports the proposal to increase public access to more non-confidential information.

EPA is proposing to update 40 C.F.R. § 720.70(b) by revising the language that describes the content of the document that EPA publishes in the Federal Register to announce the receipt of PMNs submitted to EPA. Specifically, to provide access to information, EPA has built an online searchable data base called ChemView (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview), and makes the PMN and all attachments and amendments available on ChemView. In addition, EPA provides a list of new chemical submissions received on the New Chemicals website. ACC supports timely access to information on PMN submissions and reviews.

B. The economic analysis is deficient because it does not account for the cost of acquiring reasonably ascertainable information.

The Economic Analysis predicts only modest increases in costs to submitters from the proposed rule. It ignores the additional costs for submitters of PMNs for PFAS that, under the current rules, would be eligible for an LVE. Under the PFAS Framework, those submitters would face substantial testing costs and years of delay in their ability to introduce innovative chemistry into the marketplace. The Economic Analysis in Table 3-10 should have addressed those costs in the Post-Rule PMN, the "Fees and Delay Costs" number. Additionally, in section 3.4 Change in Agency Cost, EPA estimates in Table 3-12 that the cost for EPA to review a non-PFAS PMN will be the same as reviewing a PFAS PMN. This is an erroneous assumption that these values would be the same, given the process described in the PFAS Framework document. EPA will spend

[37] How to Access the TSCA Inventory | TSCA Chemical Substance Inventory | US EPA
[38] Draft Points to Consider Document (epa.gov)

significantly more time reviewing and requesting additional test data and developing 5(e) orders and SNURs for PFAS substances.

In addition, EPA notes in section 3.3.1 that while submitters will likely spend more time preparing the initial notice under the proposed rule due to the notice information changes, EPA assumes that the burden of providing EPA with additional information would have been incurred in the baseline during the amendment process. Thus, it is assumed that submitters will not incur any additional notice preparation burden. But then EPA proceeds in Table 3-9 to subtract out the time spent on potential amendments (thereby removing the timing accounted for the increased informational requirements). EPA needs to clearly add the additional burden of providing EPA with the additional information elements (time and cost of additional testing) as a separate item.