ALLIANCE FOR AUTOMOTIVE INNOVATION

August 15, 2023

Submitted via e-Rulemaking Portal, www.regulations.gov

Ms. Kelly Summers
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460–0001

Re: Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA), EPA-HQ-OPPT-2020-0720-0024

Dear Ms. Summers:

The Alliance for Automotive Innovation[1] (Auto Innovators) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA's) proposed rule, Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA).[2] Two comment deadlines were included in the Proposed Rule: July 17, 2023, for comments to the Office of Management and Budget (OMB); and August 15, 2023, for comments to EPA. Auto Innovators has submitted comments to OMB focused predominantly on EPA's Economic Analysis[3] of the expected impacts of the Proposed Rule and the hours that EPA estimated in its Information Collection Request (ICR)[4] developed to reflect the burden on industry associated with rule compliance. Our comments here to EPA are focused on several precedent-setting regulatory approaches that warrant in-depth review to ensure EPA is implementing the Lautenberg Chemical Safety Act (LCSA) provisions as intended and directed by statute.

Auto Innovators represents the auto manufacturing sector, including automakers that produce and sell around 95% of the new light-duty vehicles in the United States. The auto industry plays an important and critical role in our nation's economy, accounting for 10 million jobs and 5.5% of the annual Gross Domestic Product. Our mission is to work with policymakers to realize a future of cleaner, safer, and smarter personal transportation and to work together on policies that further

[1] From the manufacturers producing most vehicles sold in the U.S. to autonomous vehicle innovators to equipment suppliers, battery producers and semiconductor makers – Alliance for Automotive Innovation represents the full auto industry, a sector supporting 10 million American jobs and five percent of the economy. Active in Washington, D.C. and all 50 states, the association is committed to a cleaner, safer and smarter personal transportation future. www.autosinnovate.org.

[2] 88 Fed. Reg. 39,652 (June 16, 2023).

[3] U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a) (February 2023), *available at* https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0125 (hereinafter Economic Analysis).

[4] Supporting Statement for an Information Collection Request (ICR) Under the Paperwork Reduction Act (PRA): Regulation of Perchloroethylene under TSCA Section 6(a) (Proposed Rule; RIN 2070-AK84) *available at* https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0124 (hereinafter ICR).

these goals, increase U.S. competitiveness, and ensure sustainable, well-paying jobs for citizens throughout the country.

Auto Innovators supports EPA's continuing implementation of the LCSA and its goals of protecting human health and the environment. We are, however, concerned that the Agency's lack of operational experience to date with regulating industries that assemble products ("complex durable goods" as identified in TSCA), such as automobiles, has resulted in a proposal that focuses on risk mitigation more relevant for workers in sectors where those workers may have direct contact with the raw chemical itself or where facilities do not employ worker protection programs that ensure a safe work environment. The proposal also fails to recognize the specific direction in TSCA Sections 6(2)(D) and (E) to assess the potential risks from replacement parts for complex durable goods and articles outside of EPA's whole chemical approach. These specific sections of TSCA acknowledge that replacement parts warrant special consideration and that articles used in sectors that manufacture complex durable goods[5] may have a very different exposure and risk profile than the chemical being regulated and may present little to no opportunity for worker exposure. By neglecting to address the requirements of these sections and applying an overly expansive application of use prohibitions, we believe EPA has not met the standards of TSCA Section 6(h)(4).

Our understanding is the Proposed Rule would: 1) prohibit most industrial and commercial uses and the manufacture (including import), processing and distribution in commerce, of PCE for these uses; 2) prohibit the manufacture (including import), processing, and distribution in commerce of PCE for all consumer use; 3) prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of PCE in dry cleaning and spot cleaning through a 10-year phaseout; 4) require strict workplace controls, including (as applicable) a PCE workplace chemical protection program (WCPP), 5) require prescriptive workplace controls for laboratory use; 6) establish recordkeeping and downstream notification requirements; and 7) provide a 10-year time-limited exemption under TSCA Section 6(g) for certain emergency uses of PCE in furtherance of National Aeronautics and Space Administration's (NASA) mission.

Our comments address the following issues:

A. Support for EPA's Proposed De Minimis Exemption
B. Support for EPA's Exclusion of PCE Use for the Generation of HFC-125 and HFC-134a.
C. EPA's Assumption that Most Perchloroethylene Uses Cannot Meet the Worker Protection Program Requirements
D. Omission of Consideration of TSCA Section 6(c)(2)(D) or (E) and Failure to meet TSCA Section 6(h)(4) Requirements.
E. Documentation of TSCA Section 9 Consultation with OSHA
F. Deficiencies in EPA's Economic Analysis and EPA's ICR for the Proposed Rule
G. Support for Alternative Effective Dates

[5] As defined in TSCA: The term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

A. Support for EPA's Proposed De Minimis Exemption

We fully support EPA's inclusion of a de minimis exemption of 0.1% for PCE. As stated by EPA, removing the burden of identifying de minimis levels of a chemical that do not contribute in any meaningful way to potential exposures is a commonsense approach that meets the requirement of TSCA Section 6(c)(2), directing EPA to apply risk mitigation measures [only] "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk."[6]

> To aid the regulated community with implementing the prohibitions, and to account for de minimis levels of PCE as an impurity in products, EPA is proposing that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions described in this unit. EPA has determined that the prohibitions are only necessary for products containing PCE at levels equal to or greater than 0.1% by weight in order to eliminate the unreasonable risk of injury resulting from inhalation and dermal exposures from PCE-containing products during occupational and consumer conditions of use.[7]

Auto Innovators members have consistently made the recommendation to include a de minimis exemption for TSCA chemicals that are the subject of risk determinations and risk management proposals. When EPA issues a proposed rule, such as this, automakers use the IMDS as a first screen to identify potential uses of chemical substances. The IMDS has been adopted as the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern to human health and the environment are present in finished articles and components. The threshold for reporting in this system is 0.1% by weight, a threshold that has been almost universally adopted by international regulatory bodies and many states within the United States. IMDS now has over 15 years of data compiled relying on a de minimis level of 0.1%. The presence of any chemical below this threshold is not required to be reported in IMDS based on a low underlying expected risk of exposure from de minimis quantities. In addition, safety data sheets for operations or service chemicals include only include substances which meet Globally Harmonized System (GHS) classification criteria as a hazardous substance, and which exceed a cut-off value/concentration limit (usually 0.1% or 1% depending on hazards).

In addition to the well-reasoned justification for a de minimis threshold presented in this proposal, EPA put forward a similarly sound argument for a de minimis exemption in EPA's "Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal," EPA presented the following justifications for establishing a de minimis threshold:

> Establishment of a threshold could be based on one or more of the following rationales: (1) below the selected threshold level, there is no "reasonable potential for exposure" within the meaning of § 5(a)(5) (i.e., the risk of exposure is very low); and (2) below the selected threshold level, there is a "reasonable potential for exposure" (or, alternatively, there may be such a potential), but the potential does not "justif[y] notification" (i.e.,

[6] 15 U.S.C. 2605(a).
[7] 88 Fed. Reg. at 39,671.

> potential for risk is very low in light of the low level of LCPFAC present in the surface coating).[8]

While EPA deferred adoption of a de minimis level in the final Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule; Supplemental Proposal, EPA committed to continue consideration of a de minimis exemption.

> In this final rule, EPA is not finalizing a de minimis threshold for determining "reasonable potential for exposure" or a safe harbor provision. EPA will, however, continue to engage with interested stakeholders on these two issues.[9]

We are pleased to see that EPA has recognized the importance of this issue and recognizes that there is little value in regulating de minimis levels of a chemical that do not contribute in any significant way to potential exposures. The adoption of a de minimis level for existing chemicals under review would facilitate more timely and cost-effective data collection by our members and allow EPA and the regulated community to focus on exposures of concern.

For the reasons stated above, we urge EPA to include a de minimis level for PCE when this rule is finalized. We further request that EPA identify a de minimis level for other TSCA chemicals below which EPA has no reasonable basis to conclude that there is an unreasonable risk.

B. Support for EPA's Exclusion of PCE Use for the Generation of HFC-125 and HFC-134a

We fully support EPA's determination that after consideration of TSCA Section 6(c)(2)(A) and (B) that "continued use of PCE for some TSCA conditions of use may provide benefits that complement the Agency's efforts to address climate-damaging hydrofluorocarbons (HFCs) under the American Innovation and Manufacturing Act of 2020 (AIM Act)[.]"[10]

> Therefore, this rule proposes to allow PCE's continued use in tandem with strict workplace controls for the generation of HFC–125 and HFC–134a, two of the regulated substances that are subject to a phasedown under the AIM Act. While HFC–125 and HFC–134a are two of the regulated substances subject to the phasedown in production and consumption by 85% over the next 15 years, HFCs–134a and –125 can be mixed with other substances to make lower global warming potential blends that are likely to be used to facilitate the transition from certain other HFCs and HFC blends with higher global warming potentials in certain applications.[11]

The auto industry has in the past used HFC-134a in motor vehicle air conditioning and is participating in EPA's implementation of the AIM Act. We are thankful EPA has considered the cross-statutory implications here and urge EPA to include this exemption in any final rule for PCE.

[8] 85 Fed. Reg. 12,479, 12,482
[9] 85 Fed. Reg. 45,109, 45,111.
[10] *Id.* at 39,655.
[11] *Id.*

C. EPA's Assumption that Most PCE Uses Cannot Meet the Worker Protection Program Requirements

EPA chose to propose to prohibit most uses of PCE because it believes only a handful of activities can be performed that will meet the stringent WCPP standards that EPA has developed for those uses which may continue. "EPA is proposing to ban or phaseout most conditions of use of PCE, including use in dry cleaning and spot cleaning, aerosol degreasing, paints and coatings, aerosol lubricants, and wipe cleaning[.]"[12] By adopting this approach, EPA is setting a dangerous precedent of imposing a prohibition on a use or uses when that use or uses could meet the proposed WCPP. This proposed approach is especially alarming considering EPA's recognition that "many workplaces already have stringent controls in place that reduce exposures to PCE; for some workplaces, EPA understands that these existing controls may already reduce exposures enough to meet the inhalation exposure concentration limit proposed in this rulemaking or to prevent direct dermal contact with PCE."[13]

EPA's primary proposed alternative moves in the right direction regarding this issue by allowing additional sectors to qualify for the WCCP approach, but still falls short of setting a safety standard, in this case the WCPP, and allowing regulated facilities to determine if they can meet that standard. EPA should not unilaterally determine which facilities can and cannot meet the safety standards required to mitigate the identified risks.

D. Omission of Consideration of TSCA Section 6(c)(2)(D) or (E) and Failure to meet TSCA 6(h)(4) Requirements.

1. Imported Articles Should be Exempted from PCE Prohibitions

For the reasons appropriately cited by EPA in its "No Action Assurance Letter" on the TSCA Fees Rule, requiring importers of articles to identify the presence of a chemical or chemicals in the tens of thousands of articles that move through the auto industry's global supply chain is impractical, cost-prohibitive and without significant benefit to EPA:

> …the broad scope of the current TSCA Fees Rule unintentionally imposes potentially significant burdens on importers of chemical substances in articles, and manufacturers of byproducts and impurities. Determining whether they may be subject to the TSCA Fee Rule and thus need to self-identify could be difficult or impossible for certain manufacturers across the country. Your request indicates that the inherent uncertainties and difficulties associated with identifying the presence (or not) of one or more of the 20 high-priority chemicals by these stakeholders, especially those that have not previously been subject to a TSCA regulatory requirement, creates a compliance problem and adversely impacts the agency's implementation of the TSCA Fees Rule.[14]

[12] 88 Fed. Reg. at 39,655.
[13] *Id.*
[14] Memorandum from Susan Parker Bodine, Assistant Administrator for Enforcement and Compliance Assurance, to Alexandra Dapolito Dunn, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, March 24, 2020, "No Action Assurance Regarding Self-Identification Requirement for Certain 'Manufacturers' Subject to the TSCA Fees Rule," *available at* https://www.epa.gov/sites/default/files/2020-03/documents/no_action_assurance_regarding_self-identification_requirement_for_certain_manufacturers_subject_to_the_tsca_fees_rule_march_24_2020.pdf.pdf.

EPA's No Action Assurance Letter acknowledges the challenges and extreme burden, if not impossibility, that EPA would have created by requiring importers of articles to identify the presence (or not) of de minimis quantities of chemicals that may have been used in the manufacture of articles.
Further, we see no analyses that demonstrate that EPA assessed or identified any risks associated with articles as separate from the chemical itself and has proposed risk mitigation measures that do not meet the requirements of TSCA Section 6(c)(2)(E).

TSCA Section 6(c)(2)(E) states:

> In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture **only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article [**emphasis added] or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).[15]

There is no analysis or discussion in EPA's final risk determination for PCE[16] or this Proposed Rule that describes how EPA determined that imported articles may contribute to the unreasonable risk determination. If EPA had conducted such an analysis, it would likely have found that imported articles do not pose an unreasonable risk to workers and consequently should not be subject to the same stringent prohibitions proposed for other conditions of use.

By ignoring the direction of TSCA Section 6(c)(2)(E) in this proposal, EPA is fundamentally making it "inapplicable," a precedent that undermines the very intent of this section of the LCSA. Auto Innovators urges EPA to clarify its interpretation of the applicability of d 6(c)(2)(E) and conduct the analyses required by the statute.

2. *Lack of Consideration of TSCA Section 6(c)(2)(D) – Replacement Parts*

We see no recognition of TSCA Section 6(c)(2)(D) in this proposed rule. While EPA has explicit authority in TSCA Section 6(c)(2)(D) to exempt replacement parts, EPA has not exercised or explained its reasons for not utilizing this authority.

TSCA Section 6(c)(2)(D) states that the Administrator "shall" exempt replacement parts unless the Administrator finds that replacement parts contribute significantly to the risk identified in a risk evaluation:

> The Administrator **shall** exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts **contribute significantly to the risk, identified in a risk**

[15] 15 U.S.C. § 2605(c)(2)(E).
[16] Unreasonable Risk Determination: Perchloroethylene, U.S. Environmental Protection Agency (December 2022), *available at* https://www.epa.gov/system/files/documents/2022-12/PCE_Final%20Revised%20RD_12-5-22.pdf.

> **evaluation conducted under subsection (b)(4)(A)**, to the general population or to an identified potentially exposed or susceptible subpopulation.[17]

Our research, based on available data in the International Material Data System (IMDS)[18] on use of PCE in the automotive sector, indicates hundreds of thousands of replacement parts may have been manufactured in the presence of PCE and, as a result, may either contain small amounts of the chemical, bound up in the article, or have residues and impurities associated with PCE.[19] As a volatile organic compound, it would be expected that the residue would evaporate rapidly; however, trace residues could potentially remain.

Federal safety law requires auto manufacturers to have available replacement and service parts for 15 years after a vehicle is manufactured that allow a vehicle to be repaired as produced. There are millions of replacement parts in commerce that are essential to maintain and repair in-service vehicles, so they remain safe and reliable. It is critical that any final risk management rule exempt replacement parts that may have been manufactured prior to the effective date of the rule and allow them to clear the channels of trade as a legal commodity.

In this proposal, EPA did not identify any risks associated with replacement parts, as separate from its industrial use category. Auto Innovators members believe that EPA has not assessed the risks associated with replacement parts as separate from the chemical itself and has proposed risk mitigation measures that do not meet the requirements of TSCA Section 6(c)(2)(D). Consequently, EPA should exempt replacement parts unless a finding that such replacement parts contribute significantly to the risk identified in a risk evaluation conducted under subsection (b)(4)(A) has been made.

The Proposed Rule's regulatory requirements have been based on EPA's determination that the proposal meets the standards of TSCA Section 6(h)(4). That section refers to the fact that the EPA Administrator has identified the risks associated with the subject chemical and that the restrictions being promulgated will address those risks.

> In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.[20]

In the absence of an assessment of the applicability of TSCA Section 6(c)(2)(D) or (E) it is not evident how EPA has met the requirements of Section 6(h)(4).

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[17] 15 U.S.C. § 2605(c)(2)(D) (emphasis added).
[18] The IMDS is the global standard for reporting material content throughout the automotive supply chain and for identifying which chemicals of concern to human health and the environment are present in finished materials and components. The threshold for reporting in this system is 0.1% by weight, a threshold that has been almost universally adopted by international regulatory bodies and many states within the United States. IMDS now has over 15 years of data compiled relying on a de minimis level of 0.1%. The presence of any chemical below this threshold is not required to be reported in IMDS based on a low underlying expected risk of exposure from de minimis quantities.
[19] EPA's proposed de minimis exemption may address much of this issue.
[20] *Id.* § 2605(h)(4).

For this reason, it is critical that any final risk management rule exempt replacement parts manufactured prior to the effective date of the rule and allow them to clear the channels of trade as a legal commodity.

E. Documentation of TSCA Section 9 Consultation with OSHA

If EPA believes certain workplace risks are not being adequately controlled or that workers not covered by Occupational Safety & Health Administration (OSHA) standards are at a greater exposure risk, then EPA has an obligation under TSCA Section 9(a) to consult with OSHA before superseding OSHA authority. The more straightforward approach would be to identify real and actual risks and then to coordinate with OSHA to update and enforce its requirements and compliance program; TSCA should not be used in place of or as a workaround to OSHA's requirements. For workers not covered by OSHA standards, we recommend EPA and OSHA work together to find an appropriate means for providing any necessary requirements, preferably under the Occupational Safety and Health Act, if unreasonable risk is determined. Any such result from coordination and consultation with OSHA should also be made publicly available to further transparency, process, and due diligence. In the case of this proposal, any such information has not been made available to the public, i.e., via the docket, to date, as would be expected under the requirements of 15 U.S.C. § 2608.[21]

F. Deficiencies in EPA's Economic Analysis

In the brief amount of time available to study EPA's Economic Analysis developed in support of the Proposed Rule, we have identified several concerns that result in a sizeable underestimation of the compliance costs and burden. We have submitted comments to EPA on previous rulemakings[22] to provide them more accurate burden information, most recently in our July 3, 2023, comments regarding the underestimation of compliance costs for the proposed methylene chloride risk management rule. Despite multiple efforts to provide EPA with more accurate compliance hours and costs, we do not see any recognition of that representative data in this proposal or the associated ICR and Economic Analysis. Per the Proposed Rule, "EPA was unable to quantify all incremental costs of this proposed rule."[23] As we have in multiple previous comments on EPA's economic analyses associated with TSCA rules compliance, we encourage EPA to review the estimates of compliance that we have provided and would be willing to work with EPA to develop more realistic estimates of compliance.

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[21] 15 U.S.C. § 2608(a)(1) states that "the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)
(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register."

[22] Comments submitted on TSCA fees by the Alliance for Automotive Innovation (June 15, 2020), Docket ID No. EPA-HQ-OPPT-2019-0677-0110; Comments submitted on TSCA Section 8(a)(7) by the Alliance for Automotive Innovation (Dec. 27, 2022), Docket ID No. EPA-HQ-OPPT-2020-0549-0163.

[23] 88 Fed. Reg. at 39,655.

We offer the following observations for EPA's consideration.

1. *Rule Familiarization*

It is not clear how EPA arrived at the determination that only 272 respondents would need to familiarize themselves with the Proposed Rule. This seems like an unusually low number. For example, in the automotive manufacturing sector alone, we estimate 55 vehicle assembly facilities will need to review this Proposed Rule.

From our experience we can say 1.00 hour for the staff at a facility to determine the applicability of the rule to their site is a gross underestimation of the time required to review and understand the scope and relevance of the requirements to a particular manufacturing facility. It should be noted a facility is unlikely to review only a portion of the rule (the .33/hour estimate), especially given the information presented later in the document, including the guidance for applying for a TSCA Section 6(g) exemption and the more specific direction in the regulatory text.

Table 10-16: Summary of Three-Year Average Incremental Burden Hours and Costs for Primary Option[24]

Activity	Number of Respondents	Average Annual Responses Per Respondent	Average Annual Burden Per Respondent (2021$)	Average Annual Total Labor Burden	Average Annual Total Labor Costs (2021$)	Average Annual Total Non-Labor Costs (2021$)	Average Annual Total Costs (2021$)
Agency Burden	-	-	-	-	-	-	-
Rule Familiarization	272	0.33	1.00	272	25,345		$25,345
Downstream Notification (SDS)	29	1	0.67	19	2,702		$2,702
Develop Exposure Control Plan	272	1	12.33	3,354	229,733		$229,733
Conduct Regular Inspections	272	1	4.00	1,088	74,528		$74,528
PPE Program Plan Documentation	272	1	4.54	1,235	84,589		$84,589
Records Documenting Plan Implementation	272	1	6.81	1,852	126,884		$126,884
Records of Dermal Exposure	272	1	0.23	63	4,285		$4,285
Respiratory Monitoring	272	3.05	131.13	35,668	1,864,333	$2,729,561	$4,593,893
Respiratory Recordkeeping	272	3.05	24.37	6,629	617,690		$617,690
Respiratory Notifications	272	3.05	5.81	1,579	147,131		$147,131
All Activities	**272**		**190.29**	**51,759**	**3,177,220**	**$2,729,561**	**$5,906,781**

To review a 71-page Federal Register notice containing not only a complex preamble but also a set of requirements for the proposed WCPP takes longer than one hour for a full review by an individual reviewer. Further, not only will plant managers, industrial hygiene staff, and compliance officers at each manufacturing facility review the rule, but corporate attorneys and other senior management

[24] ICR at 15.

officials will likewise review the requirements. Based on an earlier survey done by Auto Innovators,[25] we estimate a minimum of 10 hours per automotive manufacturing facility to familiarize themselves with this proposal at a wage rate more commensurate with 2023 average wage rates.
Labor costs are equally underestimated. EPA's estimate of wage rates is drastically inconsistent with current wage rates in the automotive sector and the seniority of staff required to review and verify all the components associated with reporting. For example, EPA has used an annual labor cost of $93.00 for firms that will review the rule. For corporate managers and senior technical staff in the automotive sector, these numbers are twofold lower than actual industry standard billing rates. We believe the average cost for rule familiarization should reflect a minimum of 10 hours per facility at a wage rate more commensurate with 2023 average wage rates. The labor costs need to account for the combined hours and salary rates for the range of occupations that will review this proposal, including plant managers, compliance officers, industrial hygienists, attorneys, and senior managers.

We believe it is critical that EPA take whatever steps are necessary to better estimate the burden of rule familiarization and other compliance requirements associated with this proposal and all future TSCA rulemakings. In previous comments we have recommended that EPA conduct a survey to better understand the steps facilities subject to TSCA must undertake when a new rule is proposed or finalized. We continue to believe such an approach would provide more accurate data and would obviate the necessity of repeating these types of comments each time an Economic Analysis is reviewed.

2. *Identifying Suppliers*

There is no estimate in the Economic Analysis (or the ICR) for costs each company will incur to contact suppliers and obtain information on any imported articles or components that may contain PCE. The hours associated with identifying suppliers that will need to be contacted are dependent on the number of articles that have been identified by the importer. At a minimum, both original equipment manufacturers (OEMs) and suppliers will need to identify the downstream suppliers that may or may not include PCE in any of their processes and prepare a survey for their suppliers. The number of articles each OEM will need to verify with suppliers will vary. For suppliers, this task is even more complex, because suppliers will have to reach beyond direct suppliers. It is not possible currently to estimate the total hours per supplier.

3. *Regrettable Substitution*

In its Economic Analysis EPA provided no estimate of the hours and costs associated with the efforts that will be required to identify feasible substitutes. Facilities will need to review any available hazard and exposure information for the potential substitutes to avoid a substitute chemical that might later be found to present unreasonable risks or be subject to future regulation.

The costs associated with the activities that EPA recognizes will be necessary to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and then create the manufacturing modifications necessary to adapt to a substitute will be significant. As we have offered on numerous occasions, we would welcome the opportunity to work

[25] Auto Innovators comments to Sharon Block, Office of Management and Budget, re: ICR Reference No: 202106-2070-002, TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (July 28, 2021).

with EPA to better estimate these costs. In the absence of such critical economic impact data, we find it difficult to understand how EPA determined its economic analysis to be complete and accurate.

We would also point out that, where substitutes may exist, the uncertainty created by EPA's focus on several related solvents hinders the testing and selection of substitutes, as industry is concerned about the possibility of regrettable substitution. If EPA could provide some certainty, at least at the federal level, regarding substitutes, identifying PCE substitutes would be a more viable option for any current uses that EPA is prohibiting. For example, EPA could provide a listing of viable substitutes that it would recognize as acceptable. To add even more uncertainty to the identification of a viable substitute, several states have become very active in the chemical management area, and in addition to trying to track chemicals of concern at the federal level, manufacturing facilities are also faced with states stepping out ahead of EPA in regulating certain chemistries.

G. Support for Alternative Rule Effective Dates

EPA has proposed the deadlines for compliance with regulated activities as reflected below and is requesting comments on an alternative timing proposal.

> Under a compliance timeframe that is 6 months longer than the proposed regulatory action, the prohibitions for the manufacturing, processing, distribution in commerce, and use of PCE for certain occupational conditions of use described in this unit would take effect 18 months for manufacturers, 21 months for processers, 24 months for distributing to retailers, 27 months for all other distributors (including retailers), and 30 months for industrial and commercial uses after the publication date of the final rule.[26]

As discussed in our comments regarding substitution, moving to alternatives is not an easy or rapid process. Making chemical changes for industries with multi-tiered supply chains is a monumental task, even when the final tier (i.e., OEMs) may be moving away from usage. Since 2020, gaps, inefficiencies, and constraints in the supply chain have been readily apparent and impactful in the current economic state of the country. The alternative dates will provide additional necessary time to ensure/prevent additional supply chain-related impacts. While we support EPA's proposed longer compliance timeframes, we are concerned that in some cases, even the longer proposed timeframe may not be adequate. EPA should include the opportunity to revisit these timeframes if identification of substitutes requires a longer transition period. As with issues associated with compliance burden, we have previously offered, and would welcome the opportunity to engage with EPA on developing more realistic timeframes.

H. Conclusion

We fully support EPA's identification of a de minimis level for PCE and applaud this sound approach to implementation of the LCSA. By adopting a de minimis level, EPA is appropriately applying the requirement of TSCA Section 6(c)(2), directing EPA to apply risk mitigation measures [only] "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk."[27]

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[26] 88 Fed. Reg. at 39,683.
[27] 15 U.S.C. 2605(a).

We also support the proposed exclusion from regulation of PCE use for the generation of HFC-125 and HFC-134a. This use is essential if the automotive sector is to meet the goals of the AIM Act.

We urge EPA to reconsider its far-reaching approach to prohibit the use of PCE in specific sectors and for specific uses. Unless EPA has relevant data to demonstrate that a sector or use cannot continue because EPA's proposed WCPP cannot be met, EPA should set the safety standard and allow each sector to determine whether they can meet that standard.

We are also concerned that EPA omitted any consideration of TSCA Section 6(c)(2)(D) or (E). It is not clear if this is an unintended consequence of EPA's whole chemical approach, but regardless, by ignoring these two key provisions added by the LCSA EPA has failed to meet the requirements of TSCA Section 6(h)(4).

Our comments also reflect our continued concern with EPA's underestimate of burden hours associated with this and previous risk management proposals. We continue to encourage EPA to work with the regulated community to better understand the complexities of rule familiarization and data collection necessary to determine sector inclusion.

We have made several recommendations to make this rule more workable and to address what we believe are inadequacies in implementing specific sections of TSCA such as Section 6(c)(2)(D) and (E). We request EPA (1) allow regulated facilities to determine whether or not they can meet EPA's proposed ECEL rather than EPA making that determination for them; (2) implement a de minimis exemption to focus regulation on exposures of concern; (3) exempt imported articles as they do not pose a risk of exposure to automotive manufacturing workers; and (4) exempt replacement parts consistent with the direction of TSCA Section 6(c)(2)(D). Finally, in responding to EPA's request for comment on its alternate proposed approach, we support the longer timeframe for compliance and the expansion of the list of uses that could adopt a WCPP.

Thank you for your consideration of these comments. We additionally ask that you share these comments with other staff in the Office of Chemical Safety and Pollution Prevention (OCSPP) who are developing risk management proposals for additional TSCA chemicals. These comments raise critical implementation issues that are relevant to EPA's implementation of the LCSA and should be used to inform not only this proposal but future risk management proposals as well.

Sincerely,

Catherine Palin
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