



Environmental Defense Fund

Comments on Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)

Docket ID: [EPA-HQ-OPPT-2020-0720](https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720); 88 Fed. Reg. 39652 (June 16, 2023)

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the proposed risk management rule for perchloroethylene (PCE) under the Toxic Substances Control Act (TSCA) (“Proposed Rule”).¹ These comments are targeted to certain aspects of the Proposed Rule, as outlined below; EDF’s lack of comment on other proposals EPA has put forward in the Proposed Rule does not equate to support of those proposals.

Table of Contents

- 1. EDF supports EPA’s proposal to prohibit many uses of PCE but should go further in expediting regulation timelines and considering only risk-based factors in its regulations.....3
 - A. EPA’s proposed consumer, commercial, and industrial bans are appropriate and meet TSCA’s section 6(a) requirements.....3
 - B. EPA should expedite its phase out of dry-cleaning uses of PCE.....4
 - C. EPA has not demonstrated that it eliminated the unreasonable risk of the petrochemical use of PCE.....4
 - D. EPA should not allow for *de minimis* exemptions.....7
- 2. EPA has failed to fully assess risk to fenceline communities and should update the assessment to include more data and aggregate exposure considerations7
 - A. EPA failed to fully assess the risks of PCE to fenceline communities.....9
 - i. EPA excluded exposure pathways relevant to fenceline communities.....9*
 - ii. EPA considered conditions of use and routes of exposure in isolation.....10*
 - iii. EPA used limited underlying data and non-conservative models to assess risks to fenceline communities.....10*
 - B. EPA should expeditiously update its fenceline risk estimates to include aggregate exposures, reasonably foreseeable increases in releases, and environmental justice considerations12
- 3. EPA must eliminate unreasonable risk to fenceline communities.....13
 - A. EPA must address the risks found in the fenceline screening approach.....14

¹ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, June 16, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

B.	EPA should not rely on other statutes, such as the Clean Air Act, to protect fenceline communities in the absence of evidence that the statutes fully eliminate unreasonable risk	15
C.	EPA has not shown that it will eliminate risk to fenceline communities for the uses that it proposes to permit to continue under section 6(a).....	15
D.	The Agency, rather than owners and operators, should institute exposure controls and demonstrate that they do not increase air releases of PCE.....	17
E.	EPA should require fenceline monitoring of PCE for facilities that would continue to release PCE under EPA’s proposal.....	19
4.	EDF is concerned that the proposed section 6(g) exemptions are inadequately justified	19
A.	EPA’s proposal to provide a time-limited exemption for emergency use of PCE by NASA and its contractors is inadequately justified	20
B.	The Agency’s NASA emergency use exemption notification requirement should require immediate reporting and require notification to the public	21
C.	The Agency’s proposal to create a new process to allow federal agencies to petition EPA for reconsideration of an ongoing use is unjustified under TSCA.....	22
5.	EPA should strengthen its proposed worker protections.	22
A.	EPA should more closely follow the Hierarchy of Controls and move away from framing worker exposures in terms of PPE	23
B.	EPA should require a combination of baseline engineering controls and a WCPP for vapor degreasing	24
C.	EPA’s primary alternative regulatory actions for vapor degreasing should not be the use of PPE	24
D.	EPA appropriately builds on OSHA standards, but should go further in mandating health protective standards.....	25
E.	EPA should apply the same cancer benchmark to workers as it does for the general population.....	26
6.	EPA should improve its economic analysis in promulgating the final rule.....	26
A.	EPA uses outdated discount rates that underestimate the benefits of the rule.....	27
B.	EPA does not provide adequate qualitative discussion of the benefits of non-cancer risk reductions	27
C.	EPA fails to include the benefits of avoided health effects to consumers, bystanders and fenceline communities	28
D.	EPA inappropriately assumes consistent PPE use among workers in the baseline scenario	28
E.	EPA deviates from established risk assessment guidelines without adequate justification	29
F.	EPA underestimates net benefits in the Economic Analysis by limiting the benefits analysis to a 20-year timeframe	30
G.	EPA does not equally treat unquantified costs and unquantified benefits.....	30

1. EDF supports EPA’s proposal to prohibit many uses of PCE but should go further in expediting regulation timelines and considering only risk-based factors in its regulations

EDF strongly supports EPA’s proposal to prohibit all commercial and many industrial and commercial uses of PCE. Under reformed TSCA, EPA’s main task in risk management is to create regulations that will – at the very least – ensure the chemical will no longer pose an unreasonable risk.² EPA’s risk determination found that “PCE, as a whole chemical, presents an unreasonable risk of injury to health under the conditions of use.”³

EPA’s chosen regulatory approach of prohibition is appropriate in light of the severity of the risks that PCE poses and the difficulty of attempting to impose adequately health-protective non-ban restrictions on consumer and bystander use of PCE.

A. EPA’s proposed consumer, commercial, and industrial bans are appropriate and meet TSCA’s section 6(a) requirements

A ban is the most health protective TSCA section 6(a) risk management option to address the unreasonable risks presented by PCE, decreasing exposure to all populations that could come into contact with the chemical throughout its lifecycle.

Under TSCA section 6(a), when EPA determines that a chemical poses an unreasonable risk to health or the environment, the Agency must implement regulations to eliminate the unreasonable risk that the chemical poses.⁴ The first option Congress provided to EPA for regulating to eliminate the unreasonable risk is a prohibition or restriction on the use of the chemical.⁵ EPA properly proposes prohibitions on multiple uses of PCE because the chemical does pose an unreasonable risk to health and because the proposed prohibitions will eliminate the unreasonable risk. Thus, for the conditions of use that EPA proposes to prohibit, it has met its burden to eliminate risk.

EPA correctly notes that PCE “is a neurotoxicant and a likely human carcinogen.”⁶ In the Risk Evaluation for Perchloroethylene (“Risk Evaluation”), EPA determined that PCE poses an

² 15 U.S.C. § 2605(a) (“TSCA section 6(a)”)

³ EPA, “Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-),” December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

⁴ 15 U.S.C. § 2605(a) (“TSCA section 6(a)”)

⁵ 15 U.S.C. § 2605(a)(1)(A) (“TSCA section 6(a)(1)(A)”)

⁶ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, at 39652, June 16, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

unreasonable risk to human health and the environment.⁷ The Agency identified multiple risks driven mostly by neurotoxicity resulting from acute inhalation and dermal exposures, and cancer resulting from chronic inhalation and dermal exposures, for most conditions of use of PCE that were evaluated. It also identified other adverse effects including nervous system depression, kidney and liver effects, immune system toxicity, and developmental toxicity.⁸ In light of the negative effects of PCE, EPA's proposed prohibition on many consumer, commercial, and industrial uses of PCE is appropriate.

B. EPA should expedite its phase out of dry-cleaning uses of PCE

EDF supports the phase-out of PCE dry-cleaning uses but is concerned that these uses are being allowed to continue for up to a decade subjecting workers and residents living above or near dry-cleaning facilities to unreasonable risks throughout this time. EPA's approach is focused on the life-span of specific dry-cleaning machines rather than on addressing the unreasonable risks to workers and those living above or near dry-cleaning establishment. Specifically, EPA's discussion in the preamble focuses on whether the useful life of a dry-cleaning machine is near the end of its useful life or when the machine will be at the end of its useful life. This discussion does not consider the impacts on workers or residents as if whether PCE is phased out in 1 year, 3 years, 5 years or 10 years has little effect on their lives. This disproportionate focus on when it will be economically smoother to phase out the use of machines that use PCE does not take into account that substitutes that have long existed for PCE and that other jurisdictions have or are making the transition.⁹

More importantly, this focus on when it will be economically easier to phase out PCE use in dry-cleaning minimizes the impact on workers who are often Black and Brown¹⁰ and the residents who live near or above the dry-cleaning facilities who bear the brunt of these risks and may also be exposed to PCE from other facilities or from vapor intrusion.

C. EPA has not demonstrated that it eliminated the unreasonable risk of the petrochemical use of PCE

EPA's proposal to allow the use that it terms "industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing" is insufficiently supported and inconsistent with TSCA.

⁷ EPA, "Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-)," December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

⁸ *Id.*

⁹ Toxics Use Reduction Institute, "Alternatives to Perchloroethylene in Professional Garment Cleaning," June 2012, <https://www.turi.org/content/download/7399/134622/file/2012+M%26P+Report+27+Assessment+of+Saf+er+Alternatives+to+Perchloroethylene.pdf>

¹⁰ EPA. "Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a)," ES-23 to ES-24.

The Agency has cited a hypothetical “impact on the price of gasoline,” if the use was restricted, as a reason to allow the use. But TSCA mandates that the Agency regulate PCE so that it no longer presents unreasonable risk of injury to health or the environment, and that risk is to be determined without consideration of costs or other non-risk factors.¹¹ EPA determined in its Risk Evaluation and in its “Perchloroethylene: Fenceline Technical Support – Air Pathway” that this petrochemical use poses risks to workers and to fenceline communities.^{12,13} EPA’s invocation of the price of gasoline indicates that it has not focused on whether its regulatory choice would eliminate the unreasonable risk. This alone makes EPA’s proposal to allow the use inconsistent with TSCA. In its final regulation, EPA must in fact eliminate the unreasonable risk from this petrochemical use.

Even if a possible increase in the price of gasoline sufficed as a reason to permit the use of a chemical that poses unreasonable risk to continue, EPA has failed to adequately support this concern. The references EPA cites consist only of a slide presentation given by the petrochemical company Honeywell, a slide presentation given by a trade group that represents Honeywell and other companies, and comments filed by the same trade group, along with the American Petroleum Institute. In each of the documents, the companies claim identically that isolate and reformat – products of the catalytic reforming processes in which PCE is used – make up “approximately 45% of the gasoline pool in the United States.”¹⁴ However, the companies provide no support for this figure.¹⁵ Despite this lack of support, EPA repeats the industry’s 45% figure throughout its Proposed Rule, and then uses this purported share of the national gasoline pool to justify its concern for potential gasoline cost increases. This is an insufficient basis on which to propose giving the petrochemical use of PCE special treatment.

¹¹ 15 U.S.C. §§ 2605(a) and (b) (“TSCA section 6(a) and (b)”)

¹² EPA, “Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-),” December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

¹³ EPA, “Perchloroethylene: Fenceline Technical Support – Air Pathway,” December 8, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0092>

¹⁴ American Fuel & Petrochemical Manufacturers, “Perchloroethylene Use in Refining Process,” July 29, 2021 (Reference 66), <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0087>, at 5; Honeywell UOP, “Perchloroethylene (PCE) EPA Review,” June 2021 (Reference 63), <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0031>, at 6; American Fuel & Petrochemical Manufacturers and the American Petroleum Institute, “Comments on the Draft Revision to the TSCA Risk Determination Perchloroethylene,” August 1, 2022 (Reference 64), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0732-0122>, at 3

¹⁵ The one citation given, by the petrochemical trade group American Fuel & Petrochemical Manufacturers, is only of its member company’s slide presentation. American Fuel & Petrochemical Manufacturers and the American Petroleum Institute, “Comments on the Draft Revision to the TSCA Risk Determination Perchloroethylene,” August 1, 2022 (Reference 64), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0732-0122>, at 3, footnote 3

In addition, EPA has failed entirely to engage on the question of whether there are alternatives to PCE for this petrochemical process. It is illogical for EPA to hold back from regulating an unreasonably risky chemical on the basis of a potential increase in the cost of a product without exploring whether the product could be produced in another manner.¹⁶

Third, even assuming that EPA did have adequate support both for its hypothesis that gas prices would increase if EPA regulated the petrochemical use beyond a WCPP, and that adequate alternatives did not exist, the Agency should have performed its analysis under the critical use provision of TSCA section 6(g).¹⁷ If the Agency had determined that the criteria was met for a section 6(g) exemption for the use, then it would have made the analysis public and proposed a time-limited exemption for this use.¹⁸ But EPA appears to have done no such analysis, and has merely referred to a hypothetical critical use and then proposed to allow the use to continue indefinitely. This is contrary to Congress' mandate that EPA ensure the elimination of a chemical's unnecessary risk and exempt unreasonably risky uses of a chemical only when specific criteria are met, and only for a limited time. In finalizing this rule, EPA should not permit the indefinite petrochemical use, and must, at the minimum, evaluate the use under TSCA section 6(g) and make that evaluation public if it believes that a time-limited exemption may be appropriate.

Troublingly, EPA does not stop with proposing to allow the indefinite petrochemical use of PCE, with workplace requirements. EPA also seeks comment on whether it should allow this use to proceed with no WCPP requirements.¹⁹ EDF's response, first, is that EPA must not allow the use without any workplace requirements, as this would plainly pose unreasonable risk to workers.²⁰ Second, there is no justification for EPA to consider such action, particularly in light of the fact that EPA has "confidence that facilities engaging in these conditions of use could meet the

¹⁶ The companies on which EPA relies for its factual assertions themselves identified numerous alternative chemicals (albeit, they opined that PCE was the superior chemical and urged EPA not to disallow its use in their industry). See Press Release of American Petroleum Institute, "API: EPA Risk Assessment Makes Unrealistic Assumptions on Key Refining Chemical, August 2, 2022, <https://www.api.org/news-policy-and-issues/news/2022/08/02/epa-risk-assessment-makes-unrealistic-assumptions-on-key-refining-chemical>; American Fuel & Petrochemical Manufacturers and the American Petroleum Institute, "Comments on the Draft Revision to the TSCA Risk Determination Perchloroethylene," August 1, 2022 (Reference 64), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0732-0122>, at 3

¹⁷ 15 U.S.C. § 2605(g)(3)

¹⁸ 15 U.S.C. § 2605(g)(1)(A)

¹⁹ EDF is not entirely clear about EPA's intention in issuing this request for comment, but we take the Agency's request, together with other language in the preamble, to be asking for comment on whether EPA's understanding that the petrochemical companies are already meeting WCPP requirements, or at the minimum are able to meet such requirements, is incorrect. 88 Fed. Reg. at 39695 and 39708

²⁰ EPA, "Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-)," December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

WCPP requirements.”²¹ Indeed, the companies who employ this petrochemical use are sophisticated operators, and there is no reason – and, certainly, no reason stated by EPA – that they could not meet the workplace requirements. Nevertheless, EPA invites commenters to speculate, “with special attention to the price of gasoline,” that these facilities may be unable to meet the proposed workplace requirements, and that there may be some untenable impact on petroleum refining. EDF urges EPA not only to reject suggestions that the industry is incapable of following a WCPP, but also to return to the drawing board with this use of PCE and ensure that its regulation of the use will meet the TSCA mandate to eliminate unreasonable risk.

D. EPA should not allow for *de minimis* exemptions

Additionally, EPA should not allow any *de minimis* level of PCE in formulations for continuing industrial and commercial uses. The Agency’s revised risk determination readily acknowledges the risks that PCE poses as a whole chemical, with negative health effects including neurological, kidney, liver, immune system, and developmental effects, and liver cancer, from chronic, low-volume exposure.²² Workers and consumers can potentially encounter this toxic chemical through a variety of exposure pathways, and small exposures across multiple pathways could leave them vulnerable to the harms EPA has identified. Put simply, PCE is so toxic, even at relatively low volumes, that a *de minimis* exemption level could still pose a risk to human health and the environment and thus is not a “trifling” concentration– which means that such a *de minimis* level should not be allowed. While EDF believes that a *de minimis* level is inappropriate for PCE, if EPA were to establish one it should not choose a level higher than 0.1% - the *de minimis* level often applied for known or likely carcinogens. In particular, EPA should not establish a higher level because “EPA identified several products available on the market at concentrations of PCE between 0.1% and 1% by weight.”²³ This rationale is not consistent with the statutory standard, nor is the concentration between 0.1% and 1% trifling.

2. EPA has failed to fully assess risk to fenceline communities and should update the assessment to include more data and aggregate exposure considerations

Under amended TSCA, EPA is required to assess the risks to “potentially exposed or susceptible subpopulations,” defined as “a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”²⁴ Individuals living near facilities that manufacture and process toxic chemicals, or “fenceline communities,” are

²¹ 88 Fed. Reg. at 39695

²² EPA, “Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability,” 87 Fed. Reg. 76481, December 14, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0732-0139>

²³ EPA, “Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-),” December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

²⁴ 15 U.S.C. § 2602(12) (“TSCA section 3(12)”)

generally subject to higher exposures to these chemicals than the general population. Under TSCA, EPA must fully assess the risks to fenceline communities of releases from manufacturing and processing of toxic chemicals.

However, as discussed below, EPA failed to fully assess and address the risks to fenceline communities. The Risk Evaluation for Perchloroethylene did not consider risks to fenceline communities because EPA deemed that to be outside the scope of the Risk Evaluation.²⁵ However, it was noted in the draft report for the Science Advisory Committee on Chemicals (SACC) meeting on the Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities (Fenceline Screening Level Approach) that the fenceline screening analysis would be completed for PCE.²⁶ Building off the SACC's recommendation of evaluating multiple years of chemical release data, EPA included the Perchloroethylene: Fenceline Technical Support – Air Pathway (Fenceline Air Pathway) and the Perchloroethylene: Fenceline Technical Support – Water Pathway (Fenceline Water Pathway) as supporting documentation to the PCE Risk Management Proposed Rule to assess fenceline risks to PCE.^{27,28}

EPA did not find risks to fenceline communities for any of the evaluated water pathways (drinking water or incidental dermal or oral exposure in ambient waters), although EPA did not consider of multiple facilities releasing PCE nearby or aggregate water pathways themselves or with other exposure routes.²⁹ EPA found fenceline risks for the air pathway, however, for 65 facilities at distances of 5 to 1,000 meters for 16 Occupational Exposure Scenarios (OES), many of which EPA has proposed to allow to continue under the Proposed Rule. Upon investigating the land use of many of these facilities indicating fenceline risk, for over half of the facilities, EPA identified communities living, playing, and/or working within distances that would put them at risk from exposure to PCE.³⁰ Despite finding these risks to fenceline communities, EPA states: “While the use of this screening approach indicates that EPA is not able to find that there

²⁵ EPA, “Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-),” December 2020, https://www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf

²⁶ EPA, “Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0,” EPA-744-D-22-001, January 2022, https://www.epa.gov/system/files/documents/2022-01/draft-fenceline-report_sacc.pdf

²⁷ EPA, “Perchloroethylene: Fenceline Technical Support – Air Pathway,” December 8, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0092>

²⁸ EPA, “Perchloroethylene: Fenceline Technical Support – Water Pathway,” October 6, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0091>

²⁹ *Id.*

³⁰ EPA, “Perchloroethylene: Fenceline Technical Support – Air Pathway,” December 8, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0092>

are no potential risks to fenceline communities, the screening approach was not designed to facilitate the making of an unreasonable risk determination for these communities.”³¹

A. EPA failed to fully assess the risks of PCE to fenceline communities

Even with the addition of the information in the Fenceline Air and Water Pathway documents, EPA failed to fully assess and estimate the full magnitude of the risks of PCE to fenceline communities. In its analysis based on the PCE Risk Evaluation and Fenceline Air and Water Pathway documents, EPA: 1) excluded exposure pathways relevant to fenceline communities, 2) considered conditions of use (COUs) and routes of exposure only in isolation, and 3) used limited underlying data to assess risks to fenceline communities. These failures to properly assess risks to fenceline communities resulted in an underestimation of risk riddled with uncertainty.

i. EPA excluded exposure pathways relevant to fenceline communities

In the Fenceline Water Pathway and Fenceline Air Pathway supporting analyses, EPA completely disregarded relevant exposure pathways, such as land, groundwater, vapor intrusion, spills, leaks, and other accidental releases. These relevant exposure pathways contribute to risk to fenceline communities and should be considered as exposures to be assessed in the fenceline analysis, rather than as worst-case scenarios. Due to its physical and chemical properties, PCE can move from soil to vapor and soil to groundwater to vapor, leading to potential exposure sources such as vapor intrusion within households, drinking water or recreational water sources, and human consumption of freshwater organisms.³² Vapor intrusion is an exposure route that is of particular concern for fenceline communities, as there is significant documentation of PCE exposure indoors from vapor intrusion from PCE contamination of the surrounding groundwater or land.³³

EPA’s failure to consider all pathways of exposure of PCE to fenceline communities is inconsistent with multiple sections of TSCA. For example, section 6(b) requires EPA to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.”³⁴ Conditions of use include circumstances under which the chemical is “intended, known, or reasonably foreseen to be

³¹ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, June 16, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

³² ATSDR, “Toxicological Profile for Tetrachloroethylene (PERC),” June 2019, <https://www.cdc.gov/TSP/ToxProfiles/ToxProfiles.aspx?id=265&tid=48>

³³ Burk, T., Zarus, G., (2013) “Community exposures to chemicals through vapor intrusion: A review of past ATSDR Public Health Evaluations”, *J Environ Health*, 75(9): 36-41, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692377/>

³⁴ 15 U.S.C. § 2605(b) (“TSCA section 6(b)”)

manufactured, processed, distributed in commerce, used, or disposed of.”³⁵ In addition, EPA should take into consideration all reasonably available information when conducting risk assessments as directed by section 26.³⁶

ii. EPA considered conditions of use and routes of exposure in isolation

In analyzing the risks of PCE in general in the Risk Evaluation, and to fenceline communities specifically in the Fenceline Water Pathway and Fenceline Air Pathway documents, EPA considered each COU and route of exposure in isolation. But to consider COUs and exposure routes in isolation does not provide an accurate picture of humans’ real-world exposure to PCE. EPA did not consider, in aggregate, exposure from multiple COUs within a facility, multiple exposure routes within a single COU, exposure to individuals both living near and working at facilities, or exposures from multiple nearby facilities releasing PCE for the COUs that are not being prohibited under the Proposed Rule. A robust analysis of real-world fenceline community risk recognizes that these exposures happen concurrently and, therefore, aggregately. EPA’s analyses did not take this into account, and therefore likely underestimated the risks to fenceline communities.

First, EPA did not consider exposure from multiple COUs for each facility aggregately. This should be considered because fenceline communities experience all COUs from nearby facilities simultaneously. EPA further neglected to consider multiple exposure pathways within a single COU. Ambient air and water exposures were considered separately and individually rather than aggregately, which underestimated total exposures to the fenceline population. EPA also did not consider fenceline exposure from multiple facilities within a community for either water or air pathways.

EPA further did not consider individuals living in fenceline communities that also work in facilities manufacturing, processing, or using PCE. For these individuals, exposures from working and living at and near facilities are occurring concurrently and therefore, these exposures should also be considered aggregately. Considering risks from multiple exposures, COUs, and facilities aggregately is imperative to accurately quantify risks to fenceline communities that are experienced in the real world. The lack of consideration for aggregate exposures has resulted in an underestimation of risk to fenceline communities from PCE.

iii. EPA used limited underlying data and non-conservative models to assess risks to fenceline communities

To assess fenceline community risk via the ambient air and water pathways, EPA failed to use all available data as required by TSCA section 6(b)(4)(F).³⁷

³⁵ 15 U.S.C. § 2602 (“TSCA section 3(4)”)

³⁶ 15 U.S.C. § 2625(k) (“TSCA section 26(k)”)

³⁷ 15 U.S.C. § 2605(b)(4)(F)

First, EPA’s multi-year air exposure analysis, which uses the average of 5 years of Toxics Release Inventory (TRI) release data, only assesses risks at 100, 100-1,000, and 1,000 meters. This disregards the assessment of risks within 100 meters of a PCE-releasing facility – a distance in which it is not uncommon for communities to live, work, and play (as discussed in our comments on the 2022 Fenceline Screening Approach³⁸). Further, because the multi-year analysis, which uses the Integrated Indoor/Outdoor Air Calculator (IIOAC) model to assess exposures, is limited to distances greater than 100 meters, EPA used only a single year of TRI release data – the average of 5 years -- for its full air exposure screening analysis. This is problematic, as the magnitude of releases can fluctuate from year to year depending on economic or other factors. Use of multiple years of data, especially for the full screening analysis, is also recommended by the SACC.³⁹ EPA should use multiple years of release data *and* (not or) assess distances at less than 100 meters to fully capture exposure risk to fenceline communities.

Another way EPA likely underestimated exposure to PCE and lifetime risk was the use of 33 years as the timeframe for an estimate of lifetime risk. EDF understands that this timeframe comes from the 95th percentile residential occupancy period as determined by the EPA Exposure Factors Handbook.⁴⁰ While this timeframe may be generally applicable, it should not be used for fenceline communities because it is not uncommon for communities living at the fenceline of industrial facilities to reside in these locations for more than 33 years. It also discounts the background exposures to PCE through drinking water or other routes of exposure that occurs throughout a lifetime. The failure to account for more vulnerable individuals, such as those living their whole lives near an industrial facility or multiple facilities, is contrary to TSCA’s requirement to evaluate risks to potentially exposed or susceptible subpopulations.⁴¹ EPA must update these assessments of lifetime risks to account for individuals being exposed to PCE continually for over 33 years, at the fenceline or elsewhere.

Lastly, EPA did not consider increases in production, multiple meteorological scenarios to account for extreme weather events, or irregularity of production and periods of time in which the fenceline communities have greater exposure to PCE. Using the 5-year average of PCE release for a TRI facility and assuming TRI releases are spread out evenly across all operating days fails to account for spikes in releases that may occur due to accidental releases, increases in production, malfunctions, or facility start-up and shut-down. These increases or spikes in

³⁸ EDF Comments on the Science Advisory Committee on Chemicals (SACC); Notice of Public Meeting and Request for Comments on Draft Toxic Substances Control Act (TSCA) Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities, March 22, 2022, https://blogs.edf.org/health/wp-content/blogs.dir/11/files/2022/03/EDF-Comments-to-EPA_Fenceline-Approach_3.22.22.pdf

³⁹ EPA, “Transmittal of Meeting Minutes and Final Report for the Science Advisory Committee on Chemicals Virtual Meeting “Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0” held on March 15-17, 2022,” <https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0415>

⁴⁰ EPA, “Exposure Factors Handbook 2011 Edition (Final Report),” 2011, <https://cfpub.epa.gov/ncea/efp/recordisplay.cfm?deid=236252>

⁴¹ 15 U.S.C. § 2602(12) (“TSCA section 3(12)”)

releases may present a greater risk to fenceline communities at various times of the year. Additionally, start-up and shut-down typically are required during reasonably foreseen climate events such as storms and hurricanes.⁴² By not incorporating multiple meteorological scenarios to account for extreme weather events, which are increasing due to climate change, EPA further underestimates risks to fenceline communities in its analysis.

B. EPA should expeditiously update its fenceline risk estimates to include aggregate exposures, reasonably foreseeable increases in releases, and environmental justice considerations

EPA should assess the aggregate risks to fenceline communities. This does not require that EPA redo, reopen or supplement its risk evaluation. EPA has the data and other information to improve its analysis of risks to fenceline communities. This includes data and information from its multiple fenceline analyses, the Risk Evaluation, and TRI and other agency data. In order to properly evaluate and regulate these risks, EPA should include relevant pathways of exposure, consider routes of exposure and COUs aggregately, and use more underlying data and conservative models, without the need to redo the entire assessment. TSCA section 6(a) requires that EPA mitigate the unreasonable risk presented by the chemical. EPA must apply one or more section 6(a) requirements so that the chemical substance no longer presents such risk. EPA cannot do that properly if it has an incomplete assessment of the unreasonable risks a chemical presents.

First, EPA should consider risks to fenceline communities from routes of exposure not included in the initial analysis, such as from vapor intrusion. EPA should also consider all routes of exposure to PCE and conditions of use aggregately. The lack of analysis regarding multiple routes of exposure, such as through both air and surface water as discussed in section 2A of these comments, has underestimated the fenceline risk from real-world exposure to PCE. EPA must also address the aggregate exposures associated with facilities operating under multiple conditions of use and exposures of fenceline communities to multiple PCE-releasing facilities. EPA already has the data regarding these exposures; the Agency simply has to aggregate these multi-facility exposures in addition to aggregating routes of exposure.

Further, EPA has stated that implementation of this Proposed Rule “could lead to adoption of engineering controls that ventilate more PCE outside.”⁴³ Increased production may lead to increased ventilation of PCE outside. Therefore, the analysis of risk to fenceline communities via air exposures should include production volumes that account for this reasonably foreseen increase in releases as a result of this proposal.

⁴² Fraser, C. “Refineries, chemical plants release over 4 million pounds of pollution as a result of Hurricane Laura,” *Environment Texas*, August 26 2020, <https://environmentamerica.org/texas/articles/refineries-chemical-plants-release-over-4-millions-pounds-of-pollution-as-a-result-of-hurricane-laura/>

⁴³ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, June 16, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

Lastly, EPA should use the information from the Environmental Justice (EJ) analysis included in its EPA’s Economic Analysis of the Proposed Rule in order to more fully capture the risks to fenceline communities from release of PCE.⁴⁴ The purpose of the EJ analysis was to characterize the baseline conditions of communities and workers affected by the regulation to identify disproportionate impacts on minority and low-income populations. In the Economic Analysis, the Environmental Justice analysis concluded that “workers in affected industries and regions, as well as residents of nearby communities, are more likely to be people of color than the general population in affected states.”⁴⁵

In addition to the demographic data, the EJ analysis provided the total number of other TRI facilities within 1, 3, and 5 miles of PCE-releasing facilities for each COU investigated in the EJ analysis (4 total) which “could contribute to aggregate environmental risks in these communities, assuming that individuals living in closer proximity are more likely to be exposed to toxic releases by these facilities.”⁴⁶ The EJ analysis concluded that given the facility aggregate data, “to be able to assess cumulative impacts on communities it is important to understand what is being emitted and what risks these facilities pose.”⁴⁷ These findings, particularly the disproportionate impacts for fenceline communities and aggregate exposure to multiple facilities, should be considered when addressing risks to potentially exposed and susceptible subpopulations which includes fenceline communities.

3. EPA must eliminate unreasonable risk to fenceline communities

In addition to the requirement that EPA fully assess the risks to fenceline communities, EPA must also demonstrate that its proposed risk management will mitigate the risks to fenceline communities that are found in its analysis. EPA has found that PCE, evaluated as a whole chemical, poses an unreasonable risk to human health.⁴⁸ Where EPA clearly identifies risk, but hedges and says that there is not enough information to determine if the risk is unreasonable and fails to address the risk, the Agency is not meeting its duty to address risks under TSCA.⁴⁹ Further, reformed TSCA particularly requires EPA to specifically consider the impacts of chemical production and use on potentially exposed or vulnerable subpopulations such as fenceline communities. Failing to do so is a failure to comply with TSCA’s requirements. Even

⁴⁴ EPA, “Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a),” RIN2070-AK84, June 2023, 10-21ff, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0125>

⁴⁵ *Id.* at 10-22

⁴⁶ *Id.* at 10-29

⁴⁷ *Id.* at 10-29

⁴⁸ EPA, “Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination”, 87 Fed. Reg. 76481, December 14, 2022, <https://www.federalregister.gov/documents/2022/12/14/2022-27129/perchloroethylene-pce-revision-to-toxic-substances-control-act-tsca-risk-determination-notice-of>

⁴⁹ 15 U.S.C. § 2605 (“TSCA section 6”)

in the absence of an adequate assessment of the risk posed to fenceline communities by PCE, EPA may—and, indeed, must—now regulate to ensure that fenceline communities are fully protected from unreasonable risk. However, EPA’s proposed regulation does not sufficiently eliminate the unreasonable risks that PCE would pose to communities under the conditions of use that EPA has proposed to allow to continue.

A. EPA must address the risks found in the fenceline screening approach

The Agency developed the TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities to evaluate potential exposures and associated risks to humans in proximity to facilities releasing chemicals and waterbodies receiving facility releases of chemicals undergoing risk evaluation under TSCA section 6. EPA asserts: “The Agency believes the screening level methodology presented in this work can be used to ensure potential risks to fenceline communities will not go unidentified and unaddressed for the first chemicals that underwent risk evaluations under TSCA.”⁵⁰ EPA also states in the Proposed Rule that “the screening approach was not designed to facilitate the making of an unreasonable risk determination for these communities.”⁵¹ Subsequently, the risks found to fenceline communities have not been further assessed or addressed with risk management under the Proposed Rule.

EPA has characterized the fenceline approach as robust enough for the Agency to propose no restrictions on a chemical, but not robust enough to propose restrictions on a chemical. This use of the fenceline approach is fatally flawed, as is demonstrated in the Proposed Rule and was also true of the Methylene Chloride Proposed Rule, where risks to fenceline communities were not further assessed or addressed with risk management.^{52,53} Without the use of the screening approach, despite its significant limitations and underestimation of risks, to make unreasonable risk determinations, identified risks to fenceline communities are continuing to go unassessed fully, and unaddressed. This is not acceptable, as Congress directed the Agency to assess and address the risks to potentially exposed or susceptible subpopulations.⁵⁴ A failure to fully assess and address these risks is trivializing this directive from Congress. To fully consider the Congressional directives, EPA must fully assess risks to fenceline communities and eliminate any unreasonable risks found to fenceline communities.

⁵⁰ EPA, “Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0,” EPA-744-D-22-001, January 2022, https://www.epa.gov/system/files/documents/2022-01/draft-fenceline-report_sacc.pdf

⁵¹ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, June 16, 2023, at 39699 <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

⁵² *Id.* at 39699

⁵³ EPA, “Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 28284, May 3, 2023, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0465>

⁵⁴ 15 U.S.C. § 2602(12) (“TSCA section 3(12)”)

B. EPA should not rely on other statutes, such as the Clean Air Act, to protect fenceline communities in the absence of evidence that the statutes fully eliminate unreasonable risk

EPA predicts that implementation of this Proposed Rule, particularly of the workplace exposure controls for non-prohibited COUs, might increase fenceline emissions of PCE:

In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more PCE outside, EPA believes this potential exposure would be limited as a result of the existing NESHAP for PCE for these conditions of use under the CAA.⁵⁵

Based on this statement and the fact that EPA did not propose any environmental release or disposal controls under TSCA, EPA appears to be relying on the PCE NESHAPs under the Clean Air Act (CAA) to address the unreasonable risk to fenceline communities from 10 COUs still allowed under the WCPP, along with potential risks from other non-prohibited conditions of use. EPA does not explain or analyze whether or how compliance with the NESHAPs will ensure no unreasonable risks, which is necessary given the differences in standards. EPA should specifically explain how the NESHAPs for PCE eliminate all unreasonable risks to fenceline communities, rather than only providing a summary statement.

Further, EPA's reliance on the NESHAP does not address equipment leaks and other releases from vapor degreasing operations that may contaminate soil and groundwater leading to exposure in homes and other buildings through vapor intrusion. Vapor intrusion of PCE is associated with leaks, spills and other releases of PCE from vapor degreasing.^{56,57}

C. EPA has not shown that it will eliminate risk to fenceline communities for the uses that it proposes to permit to continue under section 6(a)

Under TSCA section 6(a), where unreasonable risk exists, the Agency is required to use one or more of the options contained in the statute to ensure that the chemical substance being regulated "no longer presents such risk."⁵⁸ Section 6(a) provides EPA with regulatory options to eliminate risk, including prohibitions on manufacturing or using the substance, restricting conditions of use

⁵⁵ EPA, "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)," 88 Fed. Reg. 39652, June 16, 2023, at 39701, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

⁵⁶ Cernansky, R., "It Came From Beneath: Detecting and Mitigating Vapor Intrusion," *Environ Health Perspect.*, 2016 Aug; 124(8), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4970869/>

⁵⁷ Burk, T., Zarus, G., (2013) "Community exposures to chemicals through vapor intrusion: A review of past ATSDR Public Health Evaluations," *J Environ Health*, 75(9): 36-41, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692377/>

⁵⁸ 15 U.S.C. § 2605(a) ("TSCA section 6(a)")

or its use in particular concentrations, requiring warnings, requiring recordkeeping, and issuing restrictions on disposal.⁵⁹ EPA must choose the regulatory option(s) that will eliminate the risk.

EPA proposes to allow multiple uses to continue under section 6(a), with a requirement of compliance with a Workplace Chemical Protection Plan (WCPP), but the Agency has not demonstrated that the WCPP will eliminate risks to fenceline communities from these uses individually. Under the Proposed Rule, the uses that EPA proposes to allow to continue under sections 6(a) and 6(g) account for more than 80 percent of the current production volume of PCE subject to TSCA.⁶⁰ The Agency states that it intends to require a comprehensive WCPP that will “address the unreasonable risk from PCE to potentially exposed persons directly handling the chemical or in the area where the chemical is being used.”^{61,62} While mitigating the unreasonable risks to workers is required under section 6(a), EPA is also required to address the unreasonable risks to fenceline communities resulting from the continuing use of more than 80 percent of the current production volume. EPA makes a vague statement that “EPA recognizes there is exposure to the general population from air and water pathways for PCE” and that there “may be potential risks.”⁶³ As discussed elsewhere in these comments, EPA’s approach to estimating exposures and risks to fenceline communities systematically underestimates these risks. If EPA cannot estimate the risks to fenceline communities, then it cannot determine the appropriate section 6(a) requirement to mitigate these risks. This is inconsistent with TSCA which specifically requires that EPA consider risks to “potentially exposed or susceptible populations.”

The Agency fails to provide an underlying analysis that actually demonstrates that the proposal would address the risks. Further, TSCA requires that EPA ensure that the uses of the chemical being regulated “no longer present” the unreasonable risk – reducing the unreasonable risk is not the same as eliminating it.⁶⁴

In addition, EPA’s failure to adequately assess the aggregate risks due to multiple exposure routes and sources makes it likely that the Proposed Rule will not adequately eliminate the risks. These ongoing uses may emit PCE to water through stack or fugitive air emissions, which may affect nearby communities. In fact, EPA expects that facility emissions of PCE may actually increase under the WCPP, as discussed above, and EPA has not demonstrated that the

⁵⁹ *Id.*

⁶⁰ 88 Fed. Reg. at 39655

⁶¹ 88 Fed. Reg. at 39672

⁶² However, this ignores the need to address the risks to non-workers who may potentially be exposed to the chemical. In specifically discussing the risks to fenceline communities, the Agency states that the Proposed Rule is “expected to reduce” these risks. However, the Agency fails to provide an underlying analysis that actually demonstrates that the proposal would address the risks.

⁶³ EPA goes on to state that the proposed regulatory action “is expected to reduce the risks identified in the screening approach.” 88 Fed. Reg. at 39699.

⁶⁴ 15 U.S.C. § 2605(a) (“TSCA section 6(a)”)

unreasonable risks from these increased emissions will be eliminated. EPA also fails to address the risk that aggregated facilities and COUs may pose for fenceline communities, and in doing so fails to meet its burden to eliminate the risks of these conditions of use under TSCA section 6(a).

EPA should also consider a delayed prohibition on certain uses where marketplace and policy requirements favor this approach. This prohibition could be similar to but shorter than EPA's 10-year phaseout of the use of PCE in drycleaning (though EDF notes its objections to the proposed drycleaning phaseout above).⁶⁵ The Agency could propose a prohibition with an implementation period of ten years, for example, while requiring compliance with the WCPP and other requirements to ensure the health and safety of fenceline communities during the ten years that these uses continue.

For example, the Agency proposes to allow indefinite ongoing use of PCE for processing as a reactant in order to facilitate the production of HFC-125 and HFC-134a.⁶⁶ It states that HFC-125 and HFC-134a are likely to be used as part of the transition from the use of HFCs with higher global warming potential to alternative chemicals with lower global warming potential.⁶⁷

However, under the American Innovation and Manufacturing Act, EPA is required to reduce the production of HFC-125 and HFC-134a by 85% within the next 15 years.⁶⁸ Allowing ongoing and time-unrestricted use of PCE for the production of HFC-125 and HFC-134a is not a way to ensure that their production will be sufficiently reduced within the statutory period. If HFC-125 and HFC-134a are truly bridge chemicals to more sustainable chemicals with lower global warming potentials, EPA should impose a delayed prohibition on PCE's use as a reactant to ensure that the use of HFC-125 and HFC-134a as bridge chemicals is as short as possible and that the transition to chemicals with lower global warming potentials is actually completed. Implementing a delayed prohibition on this use of PCE, in light of these external conditions which favor eventual prohibitions on PCE, would better allow EPA to eliminate risks to fenceline communities.

D. The Agency, rather than owners and operators, should institute exposure controls and demonstrate that they do not increase air releases of PCE

The COUs that EPA proposes to regulate with a WCPP include manufacturing, use as a solvent for vapor degreasing, use in maskants, use in petrochemical manufacturing, processing for paint and coating products, cleaning and degreasing products, and adhesives and sealants. In the Fenceline Air Pathway analyses, risks to fenceline communities were found for facilities in each of the above COU categories.⁶⁹ Further, under the WCPP, EPA predicts that "efforts to reduce

⁶⁵ 88 Fed. Reg. at 39670-71.

⁶⁶ 88 Fed. Reg. at 39695.

⁶⁷ *Id.*

⁶⁸ 42 U.S.C. § 7675(e)(2)(C)

⁶⁹ EPA, "Perchloroethylene: Fenceline Technical Support – Air Pathway," December 8, 2022, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0092>

exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more PCE outside.”⁷⁰ Therefore, it is reasonably foreseeable that these risks will continue to exist for fenceline communities or will increase due to an increase in the ventilation of PCE outside (such as due to future increased production volume).

However, EPA assumes these risks will be managed by existing NESHAPs (as discussed in section 3B of these comments). Additionally, under the WCPP, facilities will be required to monitor PCE air concentrations as breathing zone samples only a maximum of 4 times per year, or only one every 5 years if initial exposure monitoring is below the ECEL action level of 0.07 ppm 8-hour time weighted average. EPA believes that this monitoring alone will “allow facilities to better understand and manage the total releases of PCE within the facility, and potentially stack and fugitive emissions.”⁷¹ Facilities would need to evaluate controls to determine how to reduce releases and exposures to workers. Under these requirements, EPA believes that “[these analyses] would help facilities to determine the most effective ways to reduce exposures (including possible engineering controls or elimination/substitution of PCE) and whether those methods for exposure reduction impact releases, and therefore may reduce the overall risk to fenceline communities.”⁷² However, monitoring PCE concentrations of indoor breathing zones a few times a year at maximum does not equate to monitoring levels of PCE stack and fugitive releases, which will not give industries the information and data it needs to assess the exposures to fenceline communities. Additionally, controls to reduce exposures to workers may be different than controls to reduce releases outside the facility (unless for example for facilities subject to the Halogenated Solvent Cleaning NESHAP). Requiring owners and operators to attest to whether and why the exposure controls they have selected would not result in increased air releases of PCE would present an extra burden to facilities not subject to the NESHAP and would potentially result in continued risk to fenceline communities from PCE.

Rather, the Agency should assess the risks from potential increases in air releases of PCE by using PCE release levels in the Fenceline Water Pathway and Fenceline Air Pathway supporting analyses equivalent to expected increases and, themselves, should require exposure controls to reduce releases of PCE outside in order to mitigate unreasonable risks to fenceline communities. EPA should also assess the exposure controls and provide evidence that implementation of these controls will not result in unreasonable risks to fenceline communities, which is required under TSCA.⁷³ We also question why EPA is considering requiring industries to assess and attest to whether the exposure controls will not result in increased air releases when EPA assumes that any air releases from continued manufacturing and use of PCE “would be limited as a result of the existing NESHAP for PCE for these conditions of use under the CAA.”⁷⁴ This leads us to

⁷⁰ 88 Fed. Reg. at 39652.

⁷¹ *Id.* at 39672

⁷² *Id.* at 39672

⁷³ 15 U.S.C. §§ 2605 (“TSCA section 6”)

⁷⁴ EPA, “Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA),” 88 Fed. Reg. 39652, June 16, 2023, at 39701, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2020-0720>

believe that EPA is not entirely sure that the NESHAP for PCE will be sufficiently protective of fenceline communities. As we stated in section 3B of these comments, EPA needs to specifically explain how the NESHAPs for PCE eliminate all unreasonable risks to fenceline communities. If this is not possible, EPA needs to institute exposure controls to eliminate the risks to fenceline communities.

E. EPA should require fenceline monitoring of PCE for facilities that would continue to release PCE under EPA’s proposal

To the extent that EPA finalizes a rule that allows for certain uses of PCE to continue, we urge the Agency to require owners and operators to conduct fenceline air and water monitoring, submit this data to EPA (for example, by using its section 8 authority), and make this data available and accessible to the broader public—particularly the affected fenceline communities. EPA should leverage its broad authority under section 6 – for example its section 6(a)(4) authority to require monitoring which is reasonable and necessary to assure compliance with a risk management rule – to require this testing.⁷⁵ As described in section 2A of these comments, EPA’s multiple fenceline screening assessments fail to adequately characterize risk to fenceline communities, which underestimates risks in multiple ways. By requiring owners and operators to conduct fenceline air and water monitoring and make the data available, both the facilities and EPA would be better able to assess ongoing risk to fenceline communities from continued uses. This information would allow EPA to require additional mitigation steps as needed to implement its risk management rule, or for the owners and operators to proactively take exposure mitigation steps under their exposure control plan. Just as transparency of monitoring results to workers is a key component of a worker protection program, such fenceline monitoring results need to be communicated to the community in a manner that is understandable and in the languages spoken by the community.

4. EDF is concerned that the proposed section 6(g) exemptions are inadequately justified

Congress set a high bar for the granting of any exemption from a TSCA section 6 regulation that must eliminate a chemical’s unreasonable risk. Under section 6(g), EPA may not grant an exemption from a risk management rule unless it finds that one or more factors apply:

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the proposed requirement would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.⁷⁶

⁷⁵ 15 U.S.C. §2605(a)(4)

⁷⁶ 15 U.S.C. § 2605(g)

Under the first factor, EPA, in determining whether an exemption is warranted, must take into account both the chemical's hazard and exposure, *and* it must find that the use is critical or essential and that no feasible or safer alternative is available. Regarding the second factor, EPA would need to find not only that a disruption to our country's economy, national security, or critical infrastructure would occur, but also that it would be significant. Finally, the third factor cannot be satisfied unless the condition of use provides affirmative – substantial – benefits.

It is also important to note that EPA's decision to exempt is discretionary, and that if the Agency does not grant an exemption, it does not need to produce an "exemption analysis and statement."⁷⁷ However, if EPA does decide to grant an exemption from a regulatory requirement, it must take numerous steps: analyze the need for each exemption; prepare a statement describing how the analysis was taken into account; publicize the analysis and the statement; establish a time limit for each exemption; and impose conditions on the exemption that EPA determines are necessary to protect health and the environment.⁷⁸

EPA has proposed a time-limited section 6(g) exemption for emergency use of PCE by NASA and its contractors.⁷⁹ Further, it has proposed to potentially allow federal agencies to apply for additional section 6(g) exemptions whenever they identify an ongoing use of PCE that they believe should be exempted.⁸⁰ The proposal would allow agencies to apply for an exemption, and only allow public comment after EPA has already chosen to approve or reject the exemption.⁸¹

By proposing these exemptions under section 6(g), EPA acknowledges that the unreasonable risk posed by PCE may still exist but asserts that the uses must be permitted to continue for a limited time anyway. The bar for justifying such exemptions is high. We are concerned that EPA has failed to adequately justify these proposed exemptions pursuant to TSCA section 6(g), as detailed below. While EDF does not support the proposed exemptions, to the extent that they are retained, EPA must at the minimum impose WCPP requirements for these conditions of use to protect the worker population.

A. EPA's proposal to provide a time-limited exemption for emergency use of PCE by NASA and its contractors is inadequately justified

EPA proposes to allow NASA and its contractors to continue using PCE for the following conditions of use: industrial and commercial use as solvent for cold cleaning, and industrial and

⁷⁷ 15 U.S.C. § 2605(g)(2)

⁷⁸ 15 U.S.C. § 2605(g)(2) - (g)(4)

⁷⁹ 88 Fed. Reg. at 39681-82

⁸⁰ 88 Fed. Reg. at 39669-70.

⁸¹ *Id.*

commercial use in wipe cleaning.⁸² The Agency states that these uses fall under section 6(g)(1)(A) because they are “critical or essential use[s] for which no technically and economically feasible safer alternative is available.”⁸³ However, the proposed rulemaking provides no indication that NASA or its contractors actually use PCE and further provides no indication that there are no feasible alternatives to PCE for these uses.

EPA states that, during the interagency review period, NASA indicated that there will “likely be” circumstances where a prohibited condition of use “may be” identified as necessary and it is “possible” that there would be no economically feasible safer alternative to PCE in these circumstances.⁸⁴ This hypothetical scenario is not supported by any citation to specific uses of PCE by NASA or by a citation to evaluation of other potential chemicals as inadequate alternatives. The materials which NASA submitted to EPA, and which EPA cites to explain the potential need for PCE, never mention the use of PCE and instead generally outline the fact that materials NASA uses for aerospace applications must meet high standards of specifications.⁸⁵ EPA fails to show that NASA’s demanding specifications require the use of PCE over any alternative for the particular uses that the Agency proposes to exempt. In fact, the Agency acknowledges that these materials do not indicate specific uses for PCE where no economically feasible safer alternative exists.⁸⁶ Relying on unsupported NASA statements that it may need to use PCE and that alternatives may not exist, as well as general information which shows that NASA has stringent material specifications, does not meet the high bar Congress set for the use of chemicals which have “critical” or “essential” uses for which no technically and economically feasible safer alternative is available.⁸⁷

B. The Agency’s NASA emergency use exemption notification requirement should require immediate reporting and require notification to the public

EPA’s emergency use provision would allow NASA and its contractors to use PCE in emergency situations without requiring public notice and would only require NASA to notify EPA of its emergency use within 15 days.⁸⁸ This failure to require public notice, and the proposed unnecessarily long delay in requiring notice to EPA, is inappropriate. EPA must focus on the impacts that the use of PCE could have on the public – including fenceline communities and workers. Even in cases where the Agency or its contractors do need to make emergency use of

⁸² 88 Fed. Reg. at 39681-82

⁸³ *Id.*

⁸⁴ 88 Fed. Reg. at 39681

⁸⁵ Finckenor, M. M. (NASA Marshall Space Flight Center Huntsville, AL, United States). (2018). Materials for Spacecraft. In Bhat, B. N. (Ed.), *Aerospace Materials and Applications* (pp. 403-434). American Institute of Aeronautics and Astronautics, Inc. <https://dx.doi.org/doi:10.2514/4.104893>

⁸⁶ 88 Fed. Reg. at 39682

⁸⁷ 15 U.S.C. § 2605(g)(1)(A)

⁸⁸ 88 Fed. Reg. at 39682

PCE, not providing notice to the public of the use (in spite of the potential risk that the use could pose to the public) deprives potentially exposed populations of critical information about a potential danger to their health. Further, allowing NASA to delay notice of its use of the chemical for 15 days allows too much time to pass before EPA and the public is made aware of the use. Nothing in the materials that NASA provided to EPA, which were made available in the docket for this proposed rulemaking, show that NASA could not provide information to the Agency and the public on the emergency use of PCE sooner than 15 days.⁸⁹

C. The Agency’s proposal to create a new process to allow federal agencies to petition EPA for reconsideration of an ongoing use is unjustified under TSCA

EPA proposes to create a blanket exemption provision that would allow federal agencies or their contractors to file a petition seeking an exemption for an ongoing use that would be subject to prohibition – and EPA would only allow public comment on the exemption request after it grants or denies the exemption.⁹⁰ Under this scenario, the public would have no meaningful ability to comment on the exemption requests. In fact, the public would not even be notified about the exemption request before EPA’s final decision on the exemption. Under the proposed process, EPA would act on the petition within 30 days and publish its decision in the Federal Register.⁹¹ After making this decision, EPA would then accept public comment for 180 days upon its decision.⁹² However, in its proposal EPA provides no indication that it would modify its decision based upon the public comments it receives.⁹³ Only notifying the public about an exemption after the decision is made, and thereby only allowing public comment after the decision, effectively eliminates the public’s ability to meaningfully comment upon an exemption created under this process. If the public is only allowed to comment after a new exemption for a use is finalized and EPA has not clearly indicated its intent to allow public comments to modify its decision, the Agency will fail to meet this basic requirement under the law.

5. EPA should strengthen its proposed worker protections.

For the reasons described above, EDF urges EPA to ban conditions of use where possible. For those COUs that are not prohibited, EPA should include a WCPP that effectively implements the Hierarchy of Controls (HOC), particularly for use of PCE in degreasing, and recognizes that workers are a “potentially exposed or susceptible subpopulation” that Congress identified for specific consideration.

⁸⁹ Finckenor, M. M. (NASA Marshall Space Flight Center Huntsville, AL, United States). (2018). Materials for Spacecraft. In Bhat, B. N. (Ed.), *Aerospace Materials and Applications* (pp. 403-434). American Institute of Aeronautics and Astronautics, Inc. <https://dx.doi.org/doi:10.2514/4.104893>

⁹⁰ 88 Fed. Reg. at 39669

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

A. EPA should more closely follow the Hierarchy of Controls and move away from framing worker exposures in terms of PPE

EDF supports EPA's inclusion of the HOC in its Proposed Rule. However, EDF is concerned that EPA continues to frame worker exposure in terms of PPE, particularly in terms of the use of respirators and the assigned protection factor (APF) of the respirator that would likely be protective. For example, in its discussion in section *V. Rationale for the Proposed Regulatory Action and Alternative Regulatory Actions of the Federal Register*, EPA states in the subsection *PCE WCPP* discussing PCE's use as a reactant:

Additionally, the 2020 Risk Evaluation for PCE supports EPA's conclusion that only small reductions in exposure are needed for WCPP ECEL compliance for processing of PCE as a reactant. Based on analysis in the 2020 Risk Evaluation for PCE describing expected exposures with and without use of PPE, **EPA identified respirators of APF 25 as the minimum respiratory PPE** that is sufficient to mitigate the unreasonable risk driven by inhalation exposures from this condition of use.⁹⁴

And in discussing PCE's use at petroleum refineries

EPA identified respirators of APF 10 as the minimum respiratory PPE that would be sufficient to mitigate the unreasonable risk driven by inhalation exposures from this condition of use.⁹⁵

Also,

EPA determined that specific prescriptive controls (i.e., specific engineering or administrative controls, or PPE) may not be able to eliminate unreasonable risk for some conditions of use when used in isolation. In the 2020 Risk Evaluation for PCE, analysis of occupational exposure scenarios (OES) indicated that many conditions of use still posed risk concerns even with the application of respirators with APF 25 or 50 (Ref. 1).⁹⁶

While EPA is referring to the 2020 Risk Evaluation for PCE, which was developed when EPA's policy was to consider the routine use of PPE as essentially a baseline, the continued reference to the appropriate PPE, which is the least effective means to reduce exposure, does not support the use of the HOC. Also, in the third example, EPA focuses on PPE as the example of prescriptive controls. Here and in other parts of the Federal Register notice, EPA primarily considers PPE rather than engineering controls as potential prescriptive controls.

⁹⁴ *Id.* at 39694

⁹⁵ *Id.* at 39695

⁹⁶ *Id.* at 39696

B. EPA should require a combination of baseline engineering controls and a WCPP for vapor degreasing

EPA should consider imposing a combination of section 6(a)(5) restrictions to mitigate the unreasonable risks from the use of PCE in vapor degreasing, particularly open top vapor degreasing, rather than only relying on the WCPP. Vapor degreasing presents unreasonable risks to workers and fenceline communities. In addition, the use of PCE in vapor degreasing has been a source of soil and groundwater contamination. Specifically, EPA should require baseline engineering controls and a WCPP to address the remainder of the unreasonable risk, rather than only rely on the WCPP. The baseline engineering controls should at a minimum be closed-top vapor degreasing machines or other closed vapor degreasing machines such as vacuum vapor degreasing machines. The use of closed-top or other enclosed machines will reduce solvent loss and thus decrease exposure levels within the facility and released into the environment. This is important given how toxic PCE is as reflected in its proposed ECEL. Many degreasing operations are currently subject to the outdated and unprotective OSHA PEL of 100 ppm – almost 1000 times higher and less protective than the ECEL of 0.14ppm. Requiring baseline engineering controls would make it easier to reach the ECEL using the HOC.

Further, facilities using closed-top degreasers would reduce the amount of PCE spilled and leaked. A volatile organic chemical (“VOC”), PCE is known to migrate from contaminated soil and groundwater into overlying buildings, a process known as vapor intrusion.⁹⁷ Vapor intrusion of PCE is associated with leaks, spills and other releases of PCE from vapor degreasing.^{98,99}

C. EPA’s primary alternative regulatory actions for vapor degreasing should not be the use of PPE

Despite EPA’s discussion in the preamble about the hierarchy of controls, EPA is proposing to require PPE as alternative regulatory actions. This is puzzling given EPA’s statement that “Turning to the use of PPE, however, does not consider other more preferable controls in the hierarchy of controls, including elimination, substitution, engineering, and administrative controls.” Why are EPA’s primary alternative regulatory actions for vapor degreasing prescriptive PPE? In totally bypassing the HOC, EPA has chosen the least effective and most burdensome approach to address the unreasonable risk. This approach disproportionately places the burden on workers in general because of the burden of respirators. Specifically, given the toxicity of PCE and the resultant ECEL of 0.14 ppm, workers may be required to use a SCBA.

⁹⁷ Minn. Dep’t of Health, “Trichloroethylene (TCE) and Tetrachloroethylene (PCE) Exposures and Vapor Intrusion.” Nov. 20, 2018, <https://www.health.state.mn.us/communities/environment/hazardous/docs/vihcpinfo.pdf>

⁹⁸ Cernansky, R., “It Came From Beneath: Detecting and Mitigating Vapor Intrusion,” *Environ Health Perspect.* 2016 Aug; 124(8), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4970869/>

⁹⁹ Burk, T., Zarus, G., (2013) “Community exposures to chemicals through vapor intrusion: A review of past ATSDR Public Health Evaluations”, *J Environ Health*, 75(9): 36-41, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4692377/>

Further, under this option, EPA would only require initial monitoring within 12 months after publication of the final rule and periodic monitoring once every five years to determine the respiratory protection needed.¹⁰⁰ Aside from issues of the effectiveness of respirators as EPA has discussed in this Federal Register, the prescriptive use of respirators will not necessarily mitigate the unreasonable risk that workers will face. Within a five-year period, there may be process changes, increases in the amount of the chemical used, changes in equipment, or other changes that will affect the exposure level of PCE in the workplace. It is unrealistic to assume that changes such as these will not affect occupational exposure levels, particularly for open systems or when worker activities require manual application or removal of PCE or PCE-containing products. These changes could result in exceedances of the ECEL. This is certainly more likely with an ECEL as low as PCE's (The ECEL's low level is clearly warranted given the toxicity of PCE) than if the outdated PEL for PCE were controlling or for a chemical with a higher occupational exposure limit. Yet EPA would allow the use of a respirator with an APF that is insufficiently protective for multiple years. Therefore, under EPA's construct, workers may experience unreasonable risks for multiple years.

EPA's alternative regulatory actions for vapor degreasing are not consistent with the HOCs and are unlikely to mitigate the unreasonable risk for at least a subset of workers.

D. EPA appropriately builds on OSHA standards, but should go further in mandating health protective standards

We support EPA's general approach of leveraging and supplementing existing OSHA standards, and there are several ways in which EPA appropriately builds on the OSHA standards and addresses OSHA-identified limitations in its standards. For example, EPA appropriately recognizes that the outdated 1971 OSHA PEL for PCE is insufficient to address identified risk. EPA also defines workplaces and workers more broadly than under OSHA. Specifically, EPA's definition of "owner or operator" broadly encompasses any person who "owns, leases, operates, controls, or supervises a workplace covered by this part."¹⁰¹ A broad definition is important to capture workplaces that would not be covered by OSHA standards. Likewise, EPA's definition of "potentially exposed person" ("any person who may be occupationally exposed to a chemical substance or mixture in a workplace as a result of a condition of use of that chemical substance or mixture"¹⁰²), and its use of this term throughout the WPCC requirements, is appropriately broad to address various types of employers, including both occupational users and occupational non-users. EPA must ensure that its reference to OSHA standards in its TSCA management of PCE does not replicate OSHA's jurisdictional limitations. To do this, EPA should include language in the final regulatory text that explicitly indicates that "owners or operators" – as defined in the Proposed Rule – are subject to the workplace standards, whether or not those standards are based on OSHA regulations.

¹⁰⁰ 88 Fed. Reg. at 39652

¹⁰¹ *Id.* at 39684

¹⁰² *Id.*

E. EPA should apply the same cancer benchmark to workers as it does for the general population

In the Proposed Rule, EPA used a cancer benchmark of 1×10^{-6} for fence-line communities and the general population, and a less protective benchmark of 1×10^{-4} for workers and occupational non-users. EPA also asserts, that as a matter of risk management policy, “EPA considers the range of 1×10^{-6} to 1×10^{-4} as the appropriate benchmark for increased cancer risk for the general population, including fence-line communities” and that “it is preferable to have the air concentration of PCE result in an increased cancer risk closer to the 1×10^{-6} benchmark, with the 1×10^{-4} benchmark generally representing the upper bound of acceptability for estimated excess cancer risk.”¹⁰³ These statements raise the question of whether excess cancer risks above 1×10^{-6} are truly acceptable or protective, and why different benchmarks are used for workers and the general population.

Under TSCA section 3, EPA is required to assess and manage risks to “potentially exposed or susceptible subpopulations.”¹⁰⁴ Both workers and the general population fall under the umbrella of potentially exposed and susceptible subpopulations and therefore should have the same benchmarks applied. Additionally, there are no genetic susceptibility or other biological differences between workers and the general population. There are no risk-based considerations presented that would account for the differences in these benchmarks. This differential treatment is based on non-risk factors and is therefore prohibited under TSCA section 6(b)(4), as was discussed in our comments to EPA on the Proposed Risk Management of Asbestos Part 1.^{105,106}

The Agency should use the same benchmark approach for all individuals so that risks faced by workers are considered equitably. It is scientifically illogical to treat the same person differently based on whether they are exposed at work or home. EPA should apply the more protective cancer benchmark of 1×10^{-6} . We encourage EPA to change their approach to cancer benchmarks so that risks faced by workers are considered equitably.

6. EPA should improve its economic analysis in promulgating the final rule

EPA has successfully fulfilled its obligations to consider the costs and benefits of the Proposed Rule as required by TSCA section 6(c)(2). However, EPA’s Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a) (“Economic Analysis”) significantly underestimates the direct benefits of the Proposed Rule through a number of exclusions and flawed assumptions. While EPA is not required to justify the finalization of the Proposed Rule, the Agency should bolster its analysis for the final rule to more accurately reflect the overall

¹⁰³ *Id.*

¹⁰⁴ 15 U.S.C. § 2602(12)

¹⁰⁵ 15 U.S.C. § 2605(b)(4) (“TSCA section 6(b)(4)”)

¹⁰⁶ EDF, “Comments on Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of TSCA,” April 12, 2022, <https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0057-0373>

benefits. The Agency’s underestimation of direct benefits from the Proposed Rule results from the following issues detailed below.

A. EPA uses outdated discount rates that underestimate the benefits of the rule

In the Economic Analysis for the Proposed Rule, EPA used discount rates – used to assess future benefits of a regulation through discounting the value of future harms – of 3% and 7%. This is inconsistent with the Biden Administration’s latest updates to Circular A4, which directs agencies to use a single discount rate of 1.7% based on 30 years of data.^{107,108} The updated draft Circular A4 will supplant the prior 2003 guidance,¹⁰⁹ which directed agencies to use the unreasonably high discount rates of 3% and 7%. In general, a lower discount rate will result in higher estimated benefits, particularly when assessing long-term impacts of a rule.¹¹⁰ In the case of the current proposal, the benefits of avoided cancer is dwarfed, particularly under the 7% discount rate scenario, due to the long latency period involved in cancer deaths.¹¹¹ In updating its Economic Analysis for the final rule, EPA should change its discount rate to 1.7% to align with the new Circular A4.

B. EPA does not provide adequate qualitative discussion of the benefits of non-cancer risk reductions

As noted in the Economic Analysis, the 2020 Risk Evaluation identified numerous non-cancer risks associated with PCE exposures. EDF recognizes that EPA does not have the data needed to quantify all avoided health effects. However, EPA does not provide adequate qualitative discussion of the benefits of the Proposed Rule. EPA mentions several non-cancer health endpoints associated with exposure to PCE (e.g., impaired cognition and substance use

¹⁰⁷ White House, “Executive Order on Modernizing Regulatory Review,” April 6, 2023, <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/06/executive-order-on-modernizing-regulatory-review/>

¹⁰⁸ “Over the last thirty years, [the discount rate] has averaged around 1.7 percent in real terms on a pre-tax basis. OMB arrives at this figure by considering the 30-year average of the yield on 10-year Treasury notes minus the average annual rate of change in the consumer price index (CPI) over the period within that 30 years that 10-year Treasury Inflation Protected Securities are not available (currently, 1993 to 2002), and the yield of 10-year Treasury Inflation Protected Securities over the period they are available (currently, 2003 to 2022).¹⁴³ This produces a real 10-year rate of 1.7 percent, and corresponds to a social rate of time preference of 1.7 percent.” OMB, “Draft for Public Review, Circular A-4,” April 6, 2023, <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>

¹⁰⁹ OMB, “Circular A-4,” September 17, 2003, https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/

¹¹⁰ Howland, E., “White House bolsters review process for power sector, other rules with expanded cost-benefit analysis,” Utility Dive, April 12, 2023, <https://www.utilitydive.com/news/biden-executive-order-regulatory-review-oir/647421/>

¹¹¹ Rothschild, R., “Cost-Benefit Analysis and the Problem of Long-term Harms from Environmental Pollution,” Yale Journal on Regulation, May 26, 2023, <https://www.yalejreg.com/nc/cost-benefit-analysis-and-the-problem-of-long-term-harms-from-environmental-pollution-by-rachel-rothschild/>

disorders) and correctly notes that “these consequences have high social costs,”¹¹² but no specific cost information is provided. To provide greater perspective on the potential magnitude of the unquantified benefits, EPA should include the current estimate of the loss of lifetime earning associated with a one-point decrease in IQ, as well as willingness to pay (or, if unavailable, cost-of-illness estimates) for each of the health outcomes listed in Section 8.8. Additionally, EPA should incorporate qualitative consideration of liver toxicity, given the “consistent supporting evidence in rodents and sufficient quantitative information” for several hepatic endpoints associated with PCE exposure.¹¹³

C. EPA fails to include the benefits of avoided health effects to consumers, bystanders and fence-line communities

In the Risk Evaluation, EPA highlighted consumers and bystanders as a “potentially exposed and susceptible subpopulation” that includes “pregnant women and/or women of reproductive age”.¹¹⁴ However, EPA fails to monetize – or even qualitatively describe – the benefit of the avoided health impacts to these population in the Economic Analysis. In addition, EPA has also not considered the benefits to fence-line communities. As described in detail above, EPA has failed to adequately address the risk to fence-line communities for non-prohibited COUs in its Proposed Rule. Nonetheless, there are undoubtedly benefits to the fence-line communities living near the commercial and industrial facilities currently manufacturing, processing, or using PCE that EPA does propose to prohibit under this rule. Despite its many flaws, the fence-line assessments identified risk of PCE to fence-line communities from the air pathway. EPA could monetize the avoided health impacts from this risk identified in this screening approach; at a minimum, EPA should qualitatively describe these benefits.

D. EPA inappropriately assumes consistent PPE use among workers in the baseline scenario

EPA makes several unjustifiable assumptions in the Economic Analysis regarding personal protective equipment (PPE) among workers. In the baseline benefits calculations, EPA assumes that PPE protection is widespread and significantly reduces occupational exposures. However, evidence indicates that PPE usage in occupational settings is limited and often ineffective. In a 2001 survey conducted by the National Institute for Occupational Safety and Health (NIOSH) and BLS, only 3% of employees reported occupational use of respirators within the past 12 months.¹¹⁵ Of the establishments requiring respirator use, only 59% provided their workers with

¹¹² EPA, “Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a),” RIN 2070-AK84, June 2023, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0125>, at 8-1

¹¹³ EPA, “Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-)” 740-R1-8011, December 2020, www.epa.gov/sites/default/files/2020-12/documents/1_risk_evaluation_for_perchloroethylene_pce_casrn_127-18-4_0.pdf, at 327

¹¹⁴ *Id.* at 276

¹¹⁵ EPA, “NIOSH/BLS Respirator Usage in Private Sector Firms,” February 18, 2020, <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0029>, at 3

training on proper usage.¹¹⁶ Moreover, respirators are not a viable option for all employees.¹¹⁷ Workers may be unable to wear a well-fitting respirator due to medical problems (such as impaired lung function) or facial hair that prevents an adequate seal.¹¹⁸ Additionally, workers may be unwilling to consistently wear PPE due to heat, discomfort, or difficulties performing tasks due to communication and/or vision problems.¹¹⁹ Despite this, EPA has assumed that workers are provided with correct PPE and appropriate fit testing and training and engage in constant respirator usage. Assuming universal use of PPE in the baseline scenario will underestimate the benefits of risk management approaches, including both prohibitions and a robust worker protection program. Therefore, EPA should re-assess the baseline scenarios used for the benefits analysis as well as the calculated benefits of the Proposed Rule using PPE assumptions that more accurately reflect real-world usage.

E. EPA deviates from established risk assessment guidelines without adequate justification

In the Economic Analysis, EPA applies a “lowering factor” to calculate excess cancer risks for the low estimates of benefits. One rationale for this decision is “to account for the shorter exposure durations being considered.”¹²⁰ Although workers affected by the rule would likely have experienced years of past exposures to PCE – which would contribute to increased susceptibility to cancer after the Proposed Rule is implemented – EPA appears to incorrectly assume that workers are newly exposed and will benefit only during the 20-year timeframe selected for analysis. EPA also justifies use of the lowering factor to account for “the life stage at which the changes in exposure occur.”¹²¹ Specifically, EPA proposes the use of this modification to estimate lower cancer risks for older individuals, conditional upon these individuals not having developed cancer for the portion of their lifetimes that have already elapsed. This approach appears to assume that the age distribution of all liver, kidney, brain and testicular cancers is the same as the age distribution for the subset of these cancers that are directly attributable to PCE exposures; however, no scientific evidence is provided to support this assumption. Moreover, this approach is not recommended in EPA's Guidelines for Carcinogen Risk Assessment and does not align with recent proposed regulatory impact analyses under

¹¹⁶ *Id.* at 2

¹¹⁷ EDF, “Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA),” July 7, 2023, <https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0270>

¹¹⁸ OSHA, “Technical Manual Section VIII: Chapter 2,” Accessed July 31, 2023, <https://www.osha.gov/otm/section-8-ppe/chapter-2>

¹¹⁹ *Id.*

¹²⁰ EPA, “Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a),” RIN 2070-AK84, June 2023, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0125>, at 8-20

¹²¹ *Id.*

TSCA.^{122,123} EPA must either provide a well-supported, biological rationale for modifying the IUR for PCE in older individuals or remove the lowering factor from the low estimates of benefits.

F. EPA underestimates net benefits in the Economic Analysis by limiting the benefits analysis to a 20-year timeframe

EPA's Guidelines for Preparing Economic Analyses recommends selecting a time period of sufficient duration that the benefits for all future years become negligible when discounted to the present. Moreover, there is precedent for use of up to a 100-year timeframe in EPA rulemakings.¹²⁴ In the Economic Analysis, EPA acknowledges that the benefits for the proposed option in the 100th year of implementation would still be non-negligible after discounting, suggesting that this maximum duration should be used. However, despite this, EPA opted to restrict the calculated benefits of the Proposed Rule to a 20-year timeframe. EPA's primary justification for the shortened timeframe is the assumption that PCE will become obsolete within the next 20 years, even in absence of the current Proposed Rule, though no rationale is provided for this assumption. Usage of PCE in the U.S. expanded in the 1950s and remains widespread today.¹²⁵ Therefore, EPA should re-evaluate its assumption that PCE would be replaced by newer chemicals in the next 20 years. EPA should re-calculate the net benefits in the Economic Analysis using a timeframe at least as long as a typical working lifetime of 45-50 years.

G. EPA does not equally treat unquantified costs and unquantified benefits

In addition to the Proposed Option, the Economic Analysis for the Proposed Rule considers an "Option 3" that would prohibit additional use categories. In summarizing the total annualized net benefits (Tables ES-8 through ES-12) for these options, EPA denotes the unquantified costs via "+U" but fails to address the unquantified benefits (many of which are discussed above). This gives the false sense that unquantified costs outweigh the unquantified benefits, which EPA has no information to support.

In summary, EPA underestimated the benefits of the rule, ultimately resulting in an inappropriately low net benefit. The Proposed Rule will provide critical health protections from reducing PCE that should not be delayed. In order to move expeditiously, we recommend that EPA fix the following targeted issues in the Economic Analysis in promulgating the final rule. These are relatively simple calculation changes that should not draw out finalization of the rule:

¹²² EPA, "Guidelines for Carcinogen Risk Assessment," March 2005, https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf

¹²³ EPA, "Asbestos Part 1: Chrysotile Asbestos; Regulation of Certain Conditions of Use Under Section 6(a) of the Toxic Substances Control Act," 87 Fed. Reg. 21706, April 12, 2022, <https://www.regulations.gov/docket/EPA-HQ-OPPT-2021-0057>

¹²⁴ EPA, "Hazardous and Solid Waste Management System; Disposal of Coal Combustion Residuals From Electric Utilities," 80 Fed. Reg. 21301, April 17, 2015, <https://www.regulations.gov/docket/EPA-HQ-RCRA-2009-0640>

¹²⁵ IARC, "Tetrachloroethylene", June 2018, <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono106-002.pdf>

- Adopt the discount rate of 1.7% based on the updated Circular A4;
- Remove the assumption of PPE use in the baseline scenario;
- Remove the lowering factor for older populations unless it can support the methodology;
- Evaluate the rule over a longer timeframe, at least 45-50 years; and
- Better address unquantified benefits of the rule, at a minimum by using a similar “+U” in the Executive Summary tables as is done for unquantified costs.

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EDF appreciates EPA’s consideration of these comments.