Comments of the American Chemistry Council on
Perchloroethylene – Regulation Under the Toxic Substances Control Act

August 15, 2023

EPA-HQ-OPPT-2020-0465

submitted to https://www.regulations.gov

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Introduction

The American Chemistry Council[1] is pleased to submit these comments in response to the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") proposed risk management rule for perchloroethylene under the Toxic Substances Control Act ("TSCA"). ACC represents the business of chemistry in the United States. Our industry is at the forefront of creating the groundbreaking products that are improving the world all around us by making it healthier, safer, more sustainable, and more productive.

Perchloroethylene (PCE) is a widely used commercial chemical with important and valuable properties in appropriate applications. PCE is often noted as non-flammable with no measurable flash point, physical/chemical properties that make it invaluable in certain applications where fire hazard is a concern. ACC represents the manufacturers of this chemical, but ACC's member companies also use PCE to make other things and for other uses, including uses as a reactant, a catalyst, and in processing or as a processing aid. In addition, use of PCE may have critical uses in a wide range of industries, with no suitable substitute.

Our comments here primarily focus on industrial and commercial uses of PCE, and not consumer uses. We incorporate by reference and in full the separately filed comments of ACC's Chlorine Panel.

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

Summary

- EPA should resume making risk determinations taking consideration of exposure conditions (use of PPE) into account on an individual condition of use basis.
- ACC supports inclusion of the recommended *de minimis* level.
- EPA should provide a specific justification as to why an Existing Chemical Exposure Limit (ECEL) is necessary for PCE under specific conditions of use.
- If EPA proceeds with establishing an ECEL in this rulemaking, all industrial stakeholders should have a reasonable period of time to come into and document compliance with the ECEL. Stakeholders should not be required to first prove they can meet a proposed ECEL in order to be allowed to continue operations under an ECEL.
- Uses by federal agencies and industry should be treated with parity in terms of allowing uses to continue under a Workplace Chemical Protection Program (WCPP).
- EPA should improve its understanding and application of industrial hygiene as a discipline through direct engagement and partnership with relevant federal agencies, professional associations and organizations, and industries with expertise in occupational health and industrial hygiene practices and approaches.
- EPA should apply existing performance-based standards regarding exposure control where available rather than prescribing specific details in its rules.

General Comments

1. To Improve Risk Management Rulemaking under TSCA, EPA Should Re-Evaluate and Improve its Approach to Scoping.

Risk evaluations for high priority chemicals kick off under TSCA with a 6-month scoping process:

> The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider…[2]

Scoping is important because it allows the agency to focus its resources, and focus reviews on conditions of use that are more likely to present unreasonable risk:

> It is worthwhile to note that organizations are usually faced with finite resources and time to conduct their assessments; thus, not only are there scientific drivers that demand improved quality but also the realization that resources must be used efficiently. The extent of documentation needs to be balanced by resources and priorities, particularly when the timeliness of the response is critical. The mere presence of a substance in the environment does not necessarily mean that it poses a threat to human health or to the

[2] 15 U.S.C. § 2605(b)(4)(D).

environment; thus, an approach that considers exposure early in the process can better focus resources on those stressors that pose exposure scenarios of concern.[3]

Scoping helps the agency deliver on its statutory throughput requirements for risk evaluation and risk management. Preemption under TSCA is also tied directly to scoping; only those conditions of use that were included in scope will receive preemption with respect to the agency's no unreasonable risk determination or its final risk management action.

Scoping also provides an important notice function to stakeholders so they understand what will be included in a risk evaluation. Where a particular condition of use is not specified, stakeholders are not on notice to provide information about that use, nor are they on notice that the use may later be subject to potential risk management action.

It is important to note that the risk evaluation is bounded by the conditions of use identified and described in the scope. This informs the ultimate conclusion at the end of the risk evaluation – risk determinations based on conditions of use. The risk management rule is then limited to the risk evaluation and the conditions of use that receive either "does not present" or "presents" unreasonable risk determinations. The agency cannot unilaterally expand or add to a scope once it has been set without reopening the risk evaluation. Conditions of use that were not identified in the scoping process cannot be added later – without reopening the underlying risk evaluation.

Here, we note one or more disconnects between the conditions of use identified in the scope of the risk evaluation versus those proposed for risk management action. EPA should provide better clarity in this process with respect to which conditions of use are "in" scope of a risk evaluation. Everything should not be "in" scope for every risk evaluation; this defeats the purpose of scoping and problem formulation in the first place:

> ***The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical.*** This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.[4] [Emphasis added]

Without this clarity, stakeholders also do not have sufficient notice to be able to participate robustly in the risk evaluation process or to prepare for potential risk management action.

2. To Improve Risk Management Rulemaking under TSCA, EPA Should Apply Risk Determinations to Discrete Conditions of Use at the End of the Underlying Risk Evaluation.

[3] Fenner-Crisp PA, Dellarco VL. 2016. Key elements for judging the quality of a risk assessment. Environ Health Perspect 124:1127–1135; http://dx.doi.org/10.1289/ehp.1510483.
[4] Congressional Intent Behind Specific Provisions of the Bill, Congressional Record, Senate, June 7, 2016.

EPA recently revised the risk determinations in its TSCA Section 6 risk evaluations, applying its "whole chemical" policy. This means that instead of making use-by-use determinations of unreasonable (or no unreasonable risk), EPA makes just one determination for all the uses, which functionally moves all of them into the risk management rulemaking. For conditions of use involving worker exposure, EPA's concomitant application of a policy to deliberately ignore the use of personal protective equipment (PPE) means that low-risk real world conditions are discarded and replaced with hypothetical conditions. The consequence of this policy is that many, if not most, worker scenarios become "unreasonable risk" scenarios requiring regulation, even if that regulation is to require and enforce the use of the same PPE already in use.

These policy changes, coupled with the rulemaking schedules for the risk evaluation rule followed by the risk management rule, now mean that instead of having notice at the end of the risk evaluation (in the risk determination) which uses will, and will not, move to the risk management step, EPA is providing no meaningful notice at the end of the risk evaluation. Stakeholders must now wait, if they understand that they are stakeholders at all, for the proposed risk management rule to be published to learn if risk management action is proposed for their use(s) of interest, up to a ban of the use. The current risk management proposal for PCE had only a 60-day comment period, with no stakeholder requests for extension granted.

Many chemicals are upstream, building block materials, and constituents who are tracking potential adverse regulatory actions as the trigger point to engage with a regulatory proposal are unlikely to learn -- until a risk management rule is proposed, if then -- that their product, service, or work force are potentially affected. EPA's current approach to interpreting the statute is not reasonable, and is not providing fair notice to stakeholders to enable them to participate and provide information. We urge EPA to reconsider the adverse effects of its policy choices on fundamental due process.

3. ACC Supports EPA's Proposed *De Minimis* Level.

ACC strongly supports the proposal to establish a *de minimis* exemption as part of the restrictions on PCE use. As the Agency notes, the presence of these substance as impurities "do[es] not drive the unreasonable risk"[5] and need not be considered in order to evaluate the risk of injury resulting from exposures. Establishing a threshold of 0.1 percent by weight for the PCE restrictions aligns with existing requirements under OSHA's Hazard Communication Standard[6] and will enable companies to more readily determine compliance with the requirements of the rule. It is also important to note that prohibiting impurities in downstream products or PCE impurities in feedstocks could severely hamper numerous value chains.

ACC supports inclusion of the *de minimis* exemption for materials containing less than 0.1 percent PCE by weight consistent with hazard communication requirements. Failing to do so would likely result in many companies being out of compliance without their knowledge.

4. EPA Should Remove the Incorrect Preambular Text Regarding Exports of PCE.

[5] 88 Fed. Reg. at 39693.
[6] 29 C.F.R. § 1910.1200.

TSCA section 12(a)(2) does not prohibit or restrict export of a substance subject to a risk management rule under Section 6. Section 12 merely requires that companies wishing to export PCE submit a written notice to EPA providing basic information on the exporting and importing parties, which is then forwarded to the importing party's government.

In fact, it is clear that "domestic manufacture," defined as "refer[ing] to the making or producing of a chemical substance within the United States (including manufacturing for export),"[7] is allowed pursuant to a WCPP. EPA notes that "ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for perchloroethylene . . . under TSCA."[8] Accordingly, EPA should remove the incorrect preambular statement that says "As the manufacture and processing of PCE presents an unreasonable risk to health in the United States, the manufacture and processing of PCE for export would also be prohibited or restricted in accordance with TSCA section 12(a)(2)."[9] EPA should also amend the language of Section 751.611 of the proposed regulation to add "export" to the list of purposes for which distribution in commerce is permitted after 21 months of promulgation of the rule. This is consistent with the clear text of Section 12.

5. **EPA Should Ensure That Uses Required for Environmental, Health, and Safety (EH&S) Permit Compliance are Allowed, and Not Inadvertently Prohibited, under the Final Rule.**

The Hazardous Waste Combustor MACT (HWC MACT), 40 C.F.R §§ 63.1200 – 1221, sets out provisions related to required performance testing at 40 C.F.R. § 63.1207. The regulations require spiking, which must be performed with eligible halogenated solvents, to set operating limits for the units. The purpose of this requirement is to demonstrate destruction and removal efficiencies and permittees consequently receive limits that can accommodate the variety of waste streams generated. Importantly, solvents to be used for spiking may require preparation before the spiking, such as blending with another solvent. To our knowledge, companies subject to these requirements would prepare the solvents by using appropriate PPE (examples include respirators, splash suits, and impervious gloves) and in closed systems. To comply with these provisions, for the years of recertification, it can take hundreds of gallons of material as a few trial burns also have to be conducted prior to performing the testing. Testing is infrequent, occurring every other year or less. EPA's archived Hazardous Waste Combustion Permitting Manual provides additional information on spiking,[10] as does EPA's related 1989 Handbook, which specifically mentions PCE as a Principal Organic Hazardous Constituent (POHC) used for trial burn at Section 4.2.1.[11]

Specific Comments

[7] 88 Fed. Reg. at 39663.

[8] USEPA. Existing Chemical Exposure Limit (ECEL) for Occupational Use of Perchloroethylene. April 15, 2021 Memo to Joel Wolf, Existing Chemicals Risk Management Division. EPA-HQ-OPPT-2020-0720-0023.

[9] 88 Fed. Reg. at 39668-39669.

[10] Hazardous Waste Combustion Unit Permitting Manual | US EPA ARCHIVE DOCUMENT

[11] U.S. Environmental Protection Agency, Handbook, Guidance on Setting Permit Conditions and Reporting Trial Burn Results, Volume II of the Hazardous Waste Incineration Guidance Series (January 1989).

1. **For Industrial and Commercial Conditions of Use, EPA Should Apply a Consistent Approach to Workplace Protection.**

EPA is proposing to prohibit as many as 30 of the 38 industrial and commercial conditions of use for perchloroethylene. However, the industrial and commercial conditions of use that are not proposed for an exemption to a ban would be required to meet EPA's newly proposed ECEL as part of a workplace chemical protection program (WCPP) to avoid worker exposures above the ECEL.

EPA states "uncertainties regarding (i) the feasibility of implementing workplace safety control measures in open-systems or when worker activities require manual application or removal of PCE or PCE containing products, (ii) availability of alternatives, or (iii) whether the use is ongoing or phased out"[12] led EPA to propose these bans. Rather than establishing the ECEL and allowing industry a reasonable compliance period to meet the ECEL, EPA summarily concludes that "prohibition is the best way to address the unreasonable risk from PCE driven in part by the conditions of use."[13] EPA has requested comment on whether to consider a regulatory alternative that would subject more conditions of use to a WCPP, instead of prohibition, than those currently contemplated in the primary alternative regulatory action. However, EPA appears to be requiring monitoring data and detailed descriptions of activities involving PCE for these conditions of use to determine whether these additional conditions of use could comply with the WCPP.[14]

EPA has provided only a 60-day comment period for industries and businesses to learn of and assess the proposed ECEL, provide existing data or, if data does not currently exist, conduct monitoring, or collect monitoring data (if it exists at all) and provide sufficient information that EPA is satisfied that the ECEL and WCPP can be met. EPA seems to be taking the approach that it must have some unspecified, subjective, degree of certainty that a particular business or industry sector can meet the ECEL and the WCPP, but the demonstration that they "can" meet these requirements would be based on their current operations. In other words, companies would need to prove that they are already meeting a proposed ECEL – in which case, there is no justification for the unreasonable risk determination in the first place, and no justification for additional regulatory action.

This approach is circular logic, and inappropriately shifts the burden from the Agency to industry. In addition, the 60-day comment period EPA offers industry and businesses to provide information supporting the primary regulatory alternative action is untenable, and may have due process implications. EPA cannot simultaneously call on industry to provide more information and then provide insufficient time to do so. ACC met with Agency staff to highlight the numerous concerns and challenges with the proposed timeline for providing the Agency with the requested information.

Assuming that EPA requires an ECEL and a WCPP across the board for all conditions of use with worker exposure, covered entities either can meet the ECEL or implement the appropriate

[12] 88 Fed. Reg. 39684.
[13] *Ibid.* at 39669.
[14] *Ibid.* at 39683.

operations changes, PPE changes, respirator use, monitoring and so forth – or they cannot. If they cannot, they could be subject to TSCA fines and penalties. EPA also retains its imminent hazard authority under Section 7. We would expect that if EPA sets an ECEL, it can enforce non-compliance with an ECEL. Because enforcement of the ECEL would eliminate unreasonable risk, proposed bans are inconsistent with TSCA's mandate that EPA require risk management to the extent necessary so that the chemical no longer presents such risk.

EPA also does not appear to have a reasoned basis with respect to its differential approaches to the private sector and public sector. Assuming regulation is required to reduce unreasonable risk to reasonable, the same uses by the public and private sector should receive the same risk management measures. This is also important for the federal agencies themselves, since their supply chains will necessarily involve private sector parties who are not contractors directly to the agency. While ACC does not view a 6(g) exemption for worker exposures as necessary if EPA imposes an ECEL and WCPP, EPA's approach to 6(g) exemptions should be consistently applied to both public sector (government) and private sector entities.

2. For Workplace Occupational Safety Risk Management Measures, EPA Should Align its Approach to Chemical Risk Management with the Discipline of Industrial Hygiene.

EPA's approach to chemical risk management is inconsistent with the current practice of workplace occupational safety and industrial hygiene and therefore does not meet the TSCA scientific standard.[15] Instead of focusing only on a single chemical hazard, it is the role of a workplace safety professional to identify all hazards that exist in the workplace, determine the level of acceptable risk, and implement controls to prevent or mitigate risk from workplace hazards to acceptable levels. EPA's approach under TSCA and its subsequent requirements under an Exposure Control Plan (ECP) make the holistic work of evaluating hazards and implementing mitigations more difficult. Occupational health and safety, and industrial hygiene are fields in which professional judgment based on sound scientific data must be exercised. Each workplace is different, even those who are engaged in the same kind of business or owned by the same company.

EPA's risk management approach should align with current standard practice for occupational safety and industrial hygiene, as described further in these comments. This process often begins with evaluating the hazard against a risk matrix. A risk matrix evaluates the severity of the hazard against the likelihood of it occurring. A risk matrix helps the workplace safety professional assess all hazards in the workplace and properly prioritize time, capital, and man-hours to address the risk.

In the case of chemical exposures, the occupational exposure limit (OEL) provides a quantitative example of the difference between reasonable and unreasonable risk. Regardless, preventing, or mitigating, exposures to below the OEL must still fit in with the broader workplace safety program. Hazards associated with prevention or mitigation must be considered in line with hazards associated with chemical exposure. EPA's definition of feasible control must allow for this kind of flexibility.

[15] *See* 15 U.S.C. § 2625(h).

EPA should consult with industrial hygiene and occupational safety practitioners to better integrate standard practices and best practices for industrial hygiene workplace safety programs into its chemical risk management.

3. The Proposed ECEL for PCE Violates TSCA's Science Standards [15 U.S.C § 2625(h)].

EPA's proposed ECEL for perchloroethylene would be an outlier among current occupational exposure limits found throughout the world. The GESTIS[16] database of international limit values for chemical agents (i.e., occupational exposure limits)[17] currently lists 8-hour occupational limit values for perchloroethylene from 28 national authoritative bodies (i.e., country authorities) around the world including the U.S. Occupational Safety and Health Administration (OSHA), Canadian provinces (2) and the European Chemicals Agency. In addition, OSHA's Permissible Exposure Limits – Annotated Tables notes OELs from the California Division of Occupational Safety and Health (Cal/OSHA) and the American Congress of Government Industrial Hygienists. Most current OELs for perchloroethylene fall between 6 ppm and 25 ppm (27 of 30; see Table 1 below).

Table 1. Occupational Exposure Limits for Perchloroethylene from Various Countries and Authorities Globally (8-hour Time Weighted Average)

8-hr Limit Value	# of Authorities
100 ppm	1*
50 ppm	2
20–25 ppm	20
6-10 ppm	7
0.14 ppm	1**

*OSHA Permissible Exposure Limit
** EPA Proposed ECEL

The OSHA PEL is a clear outlier at 100 ppm; however, in the United States, the CalOSHA PEL at 25 ppm is a requirement in California and the ACGIH threshold limit value (TLV) at 25 ppm, while not compulsory, would be used in a number of settings. Those two values are more in line with the majority of other authorities.

Another outlier is the proposed EPA ECEL which is more than a factor of 100 lower than a majority of the OELs and more than 40-fold lower than the lowest current OEL. The stark difference between the EPA proposal and current practice necessitates rigorous documentation and communication of the approach and actual ECEL derivation, and also communication of the reasons driving the dramatic change for impacted workplaces and workers.

3.a. EPA Should Establish a Clear and Transparent Process for Development of Occupational Exposure Limits (under TSCA, Existing Chemical Exposure Limits) to the Extent They are Necessary for Risk Management Under TSCA.

[16] GESTIS is the Information system on hazardous substances of the German Social Accident Insurance.
[17] Available at: https://limitvalue.ifa.dguv.de/.

One leading benchmark for development of occupational exposure limits is the recent recommendations in the National Academies of Science, Engineering and Medicine (NASEM) *Review of the Department of Defense's Revised Approach to Deriving an Occupational Exposure Level for Trichloroethylene (TCE)*.[18] In that NASEM Review, the U.S. Department of Defense's (DOD's) process for deriving an occupational exposure level for TCE is summarized.

The DOD approach is equally applicable to perchloroethylene as it is a data rich chemical with similar uses to TCE. Two critical features of the DOD approach are the weight of evidence review of available study data and the evidence integration to identify a toxic endpoint of concern. Similarly, Deveau et al. (2015) present a framework for the identification and systematic evaluation of OELs, which can be used to support risk characterization and risk management decisions in situations where multiple potentially relevant OELs exist.[19]

While the process for developing this information in the context of a human health hazard characterization is similar to that for OEL derivation, it is not identical. For example, the subject population for an OEL, the worker population, is different than the general population that is the subject of the human health hazard characterization especially if the toxic endpoint of concern is not related to reproductive toxicity. The worker population is a differentially exposed population, but it is not a susceptible population and worker populations are generally regarded to be healthier than the general population. The derivation of an occupational exposure limit necessitates a problem formulation independent of the human health hazard characterization for the general population.

3.b. EPA Should Use a Weight of Evidence Approach to Integrate Data from Various Sources in Deriving the ECEL for PCE.

DOD has developed a holistic framework for evaluating epidemiological, controlled *in vivo*, mechanistic/*in vitro*, and computational evidence that can be used in deriving OELs.[20] Likewise, Maurer et al. (2023) describe their approach for synthesis of the lines of evidence (LOE) from the available data and literature, which often include diverse and not readily comparable types of data similar to those found in the DOD approach.[21] Also, the Occupational Alliance for Risk Science uses systematic review of the available data and literature, formal evidence integration and an expert elicitation process to develop its Workplace Environmental Exposure Levels (WEELs®).[22]

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[18] National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Washington, DC: The National Academies Press. https://doi.org/10.17226/25610.

[19] M. Deveau, C-P Chen, G. Johanson, D. Krewski, A. Maier, K. J. Niven, S. Ripple, P. A. Schulte, J. Silk, J. H. Urbanus, D. M. Zalk & R. W. Niemeier (2015) The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection, Journal of Occupational and Environmental Hygiene, 12:sup1, S127-S144, DOI: 10.1080/15459624.2015.1060327.

[20] Lent EM, Sussan TE, Leach GJ, Johnson MS. Using Evidence Integration Techniques in the Development of Health-Based Occupational Exposure Levels. International Journal of Toxicology. 2021;40(2):178-195. doi:10.1177/1091581820970494.

[21] Maurer LL, Alexander MS, Bachman AN, Grimm FA, Lewis RJ, North CM, Wojcik NC and Goyak KO (2022) An interdisciplinary framework for derivation of occupational exposure limits. Front. Public Health 10:1038305. doi: 10.3389/fpubh.2022.1038305.

[22] Available at: https://tera.org/OARS/poster.pdf.

There are several examples of current OEL development processes being applied throughout the U.S. that use common elements of systematic review and weight of evidence review of available data and formal evidence integration. While some of these elements were applied in the TSCA risk evaluations, EPA must formalize their approach and establish it for the specific purpose of ECEL development as a part of risk management under TSCA.

3.c. No Independent Verification or Peer Review of the ECEL -- or the Process to Develop the ECEL -- was Conducted.

Perhaps the most egregious aspect of the risk management rule is the opaque approach to ECEL development, which lacked verification with outside experts and discouraged public stakeholder engagement. According to the record, EPA developed its ECEL for perchloroethylene in April of 2021.[23] The memo describing the ECEL was posted to the TSCA Section 6(a) Rulemaking Docket for Perchloroethylene (EPA-HQ-OPPT-2020-0720) on May 19, 2022, and the ECEL was publicly released for comment for the first time as part of the risk management rule on June 8, 2023.

Once again, the NASEM Review of DOD's Revised Approach to Deriving an OEL for TCE represents a benchmark for peer review that probably exceeds what is needed for the EPA ECEL for PCE. However, the NASEM Review also provides a stark contrast to the EPA approach and highlights critical deficiencies in that approach.

EPA should conduct an independent peer review of its approach to derivation of OELs (aka ECELs). The individual ECELs should also be subject to peer review, however, that could occur with the peer review of the draft risk evaluation if the ECEL is ready at that time. As noted above, the ECEL derivation would be similar but not necessarily identical to the human health hazard characterization.

3.d. EPA Must Significantly Improve Transparency Regarding its Process for Establishing Proposed ECELs.

The Biden Administration has made a commitment to open government and regulatory transparency. Unfortunately, EPA has released the proposed ECELs by generating internal memorandums of limited detail to justify its conclusions and quietly placing them in the associated docket(s) a year or more later without notice or request for public comment. In the year since ECELs were posted to several dockets for the first ten chemicals for risk evaluation, EPA has *not sought* public dialogue with stakeholders, experts, or the regulated community.

EPA did address the Small Business Regulatory Enforcement Fairness Act (SBREFA) by holding a (closed) Small Business Advocacy Review Panel (SBAR Panel) between January and October

[23] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. *Existing Chemical Exposure Limit (ECEL) for Occupational Use of Perchloroethylene*. April 15, 2021. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0023.

2021.[24] However, participation was limited, and the SBAR report was not made available until the proposed rule was released more than 18 months later.

The Fifth U.S. Open Government National Action Plan states:[25]

> Transparency is a cornerstone of open government and can be an important driver of more-equitable outcomes, innovation, and accountability. By making available information about the condition of society, the economy, and the environment, as well as government decisions, activities, data collections, and program outcomes, the public can hold the Federal Government accountable.

Public release of Federal Government research, information, and data can also enable greater evidence building, civic engagement, and public and private sector decision-making; accelerate private sector breakthroughs for scientific innovations; and identify novel business opportunities.

More meaningful engagement of the public in the work of government results in better policy design and program administration — as policies more closely reflect and respond to the needs of individual communities — and also builds virtuous cycles of public trust and confidence in the Federal Government and in democratic institutions.

EPA had a very detailed, transparent, and credible process for Developing Acute Exposure Guideline Levels (AEGLs).[25] In addition, a recent final rule from OSHA amending its existing standards for occupational exposure to beryllium and beryllium compounds evolved from a Notice of Proposed Rulemaking in August 2015 to issuance of the final rule in January 2017 and included a two-day public hearing in between. Similarly, there is a very detailed and robust process for development of occupational exposure limits that involves the engagement of a variety of experts and stakeholders with a resulting level of confidence in the ultimate outcome.[26] There are numerous other examples and approaches EPA could and should use to inform the public and regulated industry of its proposed ECELs, and to solicit public feedback regarding the technical aspects of their derivation, and the benefits and cost associated with their implementation.

3.e. EPA Should Provide Additional Clarity and Guidance Regarding Compliance with an ECEL as Part of a WCPP.

With respect to its proposed ECEL, EPA says it is "proposing that each owner or operator of a workplace subject to the ECEL must ensure that no person is exposed to airborne concentration of PCE in excess of 0.14 ppm (0.98 mg/m3) as an 8-hour TWA (ECEL), with an action level identified as 0.07 ppm (0.47 mg/m3) (ECEL action level)."[26] It is unclear how this proposed requirement would be met – so additional clarification would be valuable, if not essential.

[24] https://www.epa.gov/reg-flex/sbar-panel-methylene-chloride-risk-management-rulemaking-under-toxic-substances-control.
[25] https://open.usa.gov/national-action-plan/5/.
[26] 88 Fed. Reg. 39673.

3.f. Compliance with the ECEL Should be Based on at Least Six Personal Breathing Zone Monitoring Samples.

For the purposes of compliance, EPA should clarify when exceedance of the ECEL represents non-compliance. ACC recommends that compliance (or lack thereof) be based on at least six personal breathing zone monitoring samples based on guidance from the American Industrial Hygiene Association (AIHA).[27] The AIHA guidance notes that there is a point of diminishing return in collecting more than six to ten monitoring measurements based on statistical sampling theory. Given the repetitive nature of tasks associated with exposure scenarios at many manufacturing, processing, and industrial use facilities, a "rolling average" could be calculated based on the prior six measurements. In addition, ACC recommends that the Assigned Protection Factors (APF) for PPE be used where appropriate when determining compliance against the ECEL.

3.h. EPA Should Describe How the ECEL May be Adjusted for Shifts Greater Than 8 Hours.

EPA's New Chemicals Exposure Limits Section 5(e) Order Boilerplate Insert Under the Toxic Substances Control Act (TSCA) New Chemicals Program[28] uses the Brief and Scala approach[29] and stipulates "for non-8-hour work-shifts, the NCEL for that work-shift (NCELn) must be determined by the following equation: NCELn = NCEL x (8/n) x [(24-n)/16], where n = the number of hours in the actual work-shift." Additionally, there are toxicokinetic models for adjusting the OEL such as the maximum adjustment half-life (MAHL) model.[30,31] AIHA offers a free spreadsheet-based tool for Toxicokinetic Extended Shift OEL Adjustment.[32] Another option would be to adjust the IH monitoring result for shifts greater than 8 hours (e.g., 12-hour shifts) to an 8-hour TWA. ACC recommends that EPA use an approach similar to those described above for application of an ECEL to shifts of greater than 8 hours.

3.i. EPA Should Acknowledge the Current Industrial Hygiene Practice for Establishing Similar Exposure Groups (Segs) in Determining Representativeness of Compliance with the ECEL.

To comply with the ECEL,

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[27] Jahn SD, Bullock WH, Ignacio JS, et al. (2015) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA.

[28] Available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-exposure-limits

[29] Brief, R.S., and R.A. Scala: Occupational exposure limits for novel work schedules. *Am. Ind. Hyg. Assoc. J.* 36:467–469 (1975).

[30] Verma, D.K. 2000. Adjustment of Occupational Exposure Limits for Unusual Work Schedules, Journal of the American Industrial Hygiene Association, 61:3, 367-374, DOI: 10.1080/15298660008984545.

[31] Armstrong, T., D.J. Caldwell, D.K. Verma. 2005. Occupational Exposure Limits: An Approach and Calculation Aid for Extended Work Schedule Adjustments. J. Occupational and Environmental Hygiene, 2: 600–607.

[32] Available at: https://www.aiha.org/public-resources/consumer-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools/toxico-kinetic-extended-shift-oel-adjustment.

> …each owner or operator would be required to determine each potentially exposed person's exposure by either taking a personal breathing zone air sample of each potentially exposed person or taking personal breathing zone air samples that are representative of each potentially exposed person's exposure performing the same or substantially similar operations in each work shift, in each job classification, and in each work area (hereinafter identified as an "exposure group").[33]

According to the proposed rule,

> Exposure group means a group consisting of every person performing the same or substantially similar operations in each work shift, in each job classification, in each work area where exposure to chemical substances or mixtures is reasonably likely to occur.[34]

Standard industrial hygiene practice includes the use of a Similar Exposure Group (SEG) in exposure monitoring campaigns. A SEG is a "group of workers having the same general exposure profile for an agent because of the similarity and frequency of the tasks they perform, of the similarity of the materials and processes with which they work, and similarity of the way that they perform the tasks."[35] EPA should confirm that its definition of an exposure in the proposed rule group aligns with the current standard approach for establishing SEGs.

In addition, EPA should clarify when data from one facility may be representative of other facilities where similar tasks are performed whether the other facilities are or are not under the control of the owner/operator of the facility where the data were collected.

3.j. Area Sampling Is Not an Appropriate Substitute for Personal Breathing Zone Monitoring for Purposes of Compliance.

EPA requested comment regarding use of area sampling instead of personal breathing zone as a representative sample of exposures.[36] Area sampling may be useful for quantifying peak concentrations, monitoring the effectiveness of controls, or measuring (as a measure of) background levels. However, it does not provide a reliable estimate of a worker's average (inhalation) exposure. For that, a personal breathing zone monitor is necessary. As part of its request for comments, EPA does not indicate why it is suggesting that area monitoring be used. Certainly, the proposed ECEL and action limit for perchloroethylene will be difficult to monitor, but area sampling is not a substitute – and particularly not for compliance purposes.

[33] 88 Fed. Reg. 39673.
[34] *Ibid.* at 39716.
[35] Jahn SD, et al. (2015,) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA, p. 37.
[36] 88 Fed. Reg. 39673.

4. EPA Should Further Clarify and Refine Monitoring Requirements for Compliance with the ECEL.

EPA requested comment regarding the feasibility of entities complying with and monitoring for a potential ECEL of 0.14 ppm. EPA aims to obtain more information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations. (VIII.46).[37]

4.a. Sufficient Capacity Needs to be Available for Compliance with the ECEL.

It may not be feasible to comply with requirements to conduct initial monitoring within 6 months after the rule is final due to a lack of laboratory capacity. A large number of entities will be required to comply with a new exposure limit that necessitates a new, lower detection limit. This will stress the industrial hygiene consultants who collect such samples and the laboratories that analyze the samples. EPA should confirm that there is sufficient capacity for companies to comply with the proposed requirements. If there currently is not sufficient capacity among firms that would support those regulated entities who need to satisfy the requirements of the proposed rule, EPA must ensure there is adequate time for such capacity to be established as part of the timeline for compliance with the rule.

4.b. The Proposed Periodic Monitoring Requirements Are Appropriate Except for the Recurring 5-Year Initial Monitoring Requirement.

EPA requested comment on the timeframes for periodic monitoring outlined in Table 1 of the proposed regulation.[38] EPA proposes periodic exposure monitoring is required at least once every five years when all initial exposure monitoring is below the ECEL action level (0.07 ppm).[39] This requirement for initial monitoring every five years is unnecessary and overly burdensome for firms that have demonstrated compliance and whose processes have not changed in five years or more. It deviates from the monitoring frequencies in the OSHA Substance Specific Regulated Chemicals Standards. A lack of alignment between regulatory programs can create confusion for regulated entities resulting in possible compliance gaps. Additional monitoring should be based on local risk assessment reviews and *management of change* practices that seek to understand where changes have occurred so monitoring can be conducted to quantify changes in exposure risk. The other Periodic Monitoring Requirements proposed are appropriate, because the three-month/six-month strategy aligns with other OSHA practices with which regulated entities will be familiar.

[37] *Ibid.* at 39708.
[38] *Ibid.* at 39706, VIII.13.
[39] *Ibid.* at 39674, Table 1.

4.c. EPA Should Clarify Monitoring Requirements for Infrequent Tasks.

The proposed rule is silent regarding monitoring and compliance for infrequent tasks, (i.e., where workers are potentially exposed to perchloroethylene for fewer than 30 days per year). The proposed rule appears to be focused primarily on potential exposures that occur on a daily basis and for a significant portion of the working day. EPA should clarify requirements for monitoring and compliance for potential exposures whose frequency and duration vary from an "all day, every day" scenario.

5. The Requirement that Each Monitoring Event be Compliant with Good Laboratory Practice (GLP) Standards Under 40 C.F.R. Part 792 is Inconsistent with Current Standard Industrial Hygiene Practice and the Regulations Themselves.

The scope of the EPA GLP Standards is described as follows: "This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing." Monitoring does not fall into these three categories. While it is appropriate that industrial hygiene compliance monitoring include protocols and practices to ensure the quality and integrity of the data, EPA should follow practices currently used by IH practitioners.

Application of GLP Standards is not a current practice of industrial hygiene practitioners, consultants, and laboratories and will result in significant delays in processing samples as current capacity is not sufficient, and future capacity cannot be increased, to meet the Agency's requirements. Furthermore, collection of occupational monitoring samples need not be conducted under GLP regulations where planning and collection is overseen by a Certified Industrial Hygienist or Environmental Professional as defined at 40 C.F.R. § 312.10.

EPA should apply the policy described in its *New Chemicals Exposure Limits section 5(e) Order Boilerplate insert under the Toxic Substances Control Act (TSCA) New Chemicals Program*.[1] Namely, that compliance with TSCA GLPs is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA IHLAP; or (B) another comparable program approved in advance in writing by EPA.

Similarly, EPA has accepted AIHA IHLAP accredited laboratories associated with study plans in response to test orders for occupational monitoring data.

6. EPA's Proposed Exposure Control Procedures and Plan are Improved.

EPA's proposed requirements for exposure control procedures and plan are improved from those proposed in the Methylene Chloride Risk Management rule in that they acknowledge the elements of the NIOSH Hierarchy of Controls (elimination, substitution, engineering controls, administrative controls, and personal protective equipment) may be used alone -- **or in combination --** to reduce exposures. While EPA's approach to this requirement is improved, there is still a lack of clarity as to what constitutes sufficiency and achieves compliance. EPA will need to issue further compliance guidance for those firms subject to the rule.

7. Requirements for Direct Dermal Contact Controls Should be Limited to Those Tasks Where Dermal Contact is Anticipated Without Regard to the Use of PPE.

Requirements for Direct Dermal Contact Controls (DDCC) within the exposure control procedures and plan should be limited to those tasks where dermal contact is anticipated. ACC agrees with the requirement that "all persons reasonably likely to be exposed from direct dermal contact to perchloroethylene in a laboratory setting are provided with dermal personal protective equipment."[40] The use of PPE for dermal protection should be targeted to specific areas where *persons* [are] *reasonably likely to be exposed from direct dermal contact to perchloroethylene*. Tasks where perchloroethylene is present but dermal contact is not anticipated (e.g., lab tasks such as pipetting) should be excluded. The exposure control procedures and plan requirements should acknowledge that where existing controls preclude contact, they should be excluded. The aim of the DDCC should be to minimize dermal contact for tasks where contact is anticipated (i.e., reasonably likely) in the absence of PPE.

Because lab use will be one of the allowable COUs under the proposed Risk Management Rule, there needs to be some understanding that there are tasks that handle small volumes (i.e., milliliters) of perchloroethylene under very controlled conditions where exposure is not anticipated. When PPE is worn, it is to protect the worker from unexpected, unanticipated contact. On the other hand, if exposure could occur during certain activities -- such as collecting a sample by hand -- dermal exposure to the hands could occur and use of gloves as dermal protection is appropriate. This clarification is important, because an overly broad reading of dermal exposure could be understood to apply to any exposed skin (e.g., back of the neck, back of an ankle) – and the only way to completely prevent exposure would be use of a full Class A suit.

8. EPA Should Use a 15-day Notification Timeframe for Results of Workplace Monitoring.

ACC agrees with the proposed requirement that the owner or operator must inform persons whose exposures are represented by the monitoring results within 15 working days.[41]

9. EPA Should Apply Existing Occupational Safety Performance Standards in Its Risk Management Rules Rather Than Prescribing Every Specific Element.

EPA requested comment regarding specific required elements of a WCPP or Prescriptive Controls:

- EPA is soliciting comment on requiring warning signs to demarcate regulated areas, such as the requirements found in OSHA's General Industry Standard for Beryllium (VIII.14).
- EPA is requesting comment on whether there should be a requirement to replace cartridges or canisters after a certain number of hours, such as the requirements found in OSHA's General Industry Standard for 1,3-Butadiene, or a requirement for a

[40] 88 Fed.Reg. 39721.
[41] *Ibid.* at 39719.

minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (VIII.16).

- EPA is soliciting comments on the requirements proposed for appropriate PPE selection, the effectiveness of PPE in preventing direct dermal contact with PCE in the workplace, and general absorption and permeation effects to PPE from direct dermal exposure. In addition, EPA understands that some workplaces rinse and reuse PPE after minimal use and is therefore soliciting comments on the impact on effectiveness of rinsing and reusing certain types of PPE, either gloves or protective clothing and gear. EPA also requests comment on the degree to which additional guidance related to use of PPE might be appropriate (VIII.17).
- EPA is soliciting comment on prescribing specific dermal PPE, such as gloves, for each condition of use that should be considered as EPA develops the final regulatory action. Additionally, EPA is soliciting comment on prescribing specific respirators or APFs for respirators for each condition of use that should be considered as EPA develops the final regulatory action (VIII.25).

EPA should defer to, and incorporate as necessary, existing performance-based programs for exposure reduction rather than enumerating specific elements in its regulations. Although EPA notes that some of these requirements might be similar to prescriptive requirements in existing OSHA Standards for Toxic and Hazardous Substances (29 C.F.R. § 1910 Subpart Z), we recommend that EPA cite to the following OSHA requirements as more appropriate:

> Occupational Health and Environmental Control (29 C.F.R. § 1910 Subpart G)
> Personal Protective Equipment (29 C.F.R. § 1910 Subpart I)
> General Environmental Controls (29 C.F.R. § 1910 Subpart J)

Prescriptive standards with respect to respirator cartridge replacement are inadvisable as the cartridge technology may change over time, resulting an outdated regulatory requirement. A cross-reference to the Subpart I provisions for Personal Protective Equipment, specifically 29 C.F.R. § 1910.134 – Respiratory Protection, would be more appropriate with respect to the requirements for a Respiratory Protection Program that would adapt over time to new technology and situations.

10. Implementation of the WCPP Should Allow Use of the APF to Demonstrate Compliance with the ECEL Over a Full Shift.

With the low levels of the ECEL as an 8-hour TWA, the proposed respiratory protection language in 40 C.F.R. § 751.605(d)(5) should be clarified so that an exceedance of the ECEL does not automatically default to a required use of the APF for the full shift. Employers should be allowed to implement industrial hygiene (IH) assessments where separately measured high- and low-exposure tasks are aggregated and compared to the ECEL TWA. For example, the IH assessment for an 8-hour workday might include: i) a task where potential PCE exposure may occur (i.e., 30 minutes for a sampling event); and ii) the "rest of day" exposure, (i.e., 7.5 hours), where such tasks are not anticipated to have potential PCE exposure.

Effectively, this approach allows control banding to be focused on task-based scenarios that occur in well-characterized SEGs instead of the full 8-hour data ("Control Band by Task Approach"). This approach of specifying controls for specific product uses is also included for compliance under European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. Furthermore, task-based control strategies are common in many industrial operations, particularly in chemical manufacturing. This is because the nature of many of the tasks with potential exposure are of short-duration or of intermittent frequency. There are many guidance documents and reviews that reinforce the importance of task-based exposure controls and application of control banding concepts (NIOSH, 2009[42]; Zalk, 2010[43]). For this reason, it is very rare for a worker in chemical manufacturing to wear respiratory protection devices for the full shift.

In the Control Band by Task Approach, the use of the APF for a required respirator can be considered in evaluating compliance against the ECEL for a short-term task. For example, to compare to an 8-hr TWA ECEL, one would collect a short-term air sample (e.g., 30 minutes) while a task is being performed, and apply the APF associated with the respiratory protection that is required and used for that task. An additional and separate air sample would be collected for the remainder of the shift to calculate an 8-hr TWA.

The following is a narrative is an example of how the Control Band by Task Approach could be implemented:

- The IH risk assessment creates a SEG for employees that conduct sampling once a day;
- A 30-min. *task* Personal Breathing Zone (PBZ) sample is taken on an employee conducting in-line sampling, during which time the employee is wearing a respirator with a specific APF that has been selected in compliance with the Maximum Use Concentration (MUC) appropriate for the sampling period and as required by the facility's Standard Operating Procedure and Hazard Assessment and/or the WCPP;
- After the PBZ task sampling period, for the "rest-of-the-day" tasks over the remaining 7.5 hours, a separate *rest-of-day* PBZ sample is taken for the same employee;
- The value for the 30-min. *task* PBZ sample is divided by the APF associated with the respiratory protection used for that task taken, and then added to the value for the 7.5-hr. *rest-of-day* PBZ sample to calculate an 8-hour TWA:

[(*task* PBZ value x 0.5 hr.)/APF] + (*rest-of-day* PBZ value x 7.5 hr.)/8 hr. = 8-hr. TWA

This approach would be effective in confirming that the controls are in place for the short-term tasks and that the respirator use is sufficient (meets the MUC requirements) to cover any potential risk of exposure for that SEG task. The rest-of-the-day PBZ sample separates tasks where potential exposure is not expected and confirms the engineering controls are in place.

[42] National Institute for Occupational Safety and Health (NIOSH). 2009. Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB). Available online at: https://www.cdc.gov/niosh/docs/2009-152/default.html.
[43] Zalk, D.M. 2010. Control Banding; A Simplified, Qualitative Strategy for the Assessment of Risks and Selection of Solutions, 210. Delft, The Netherlands: TU Delft Publisher.

To allow for the Control Band by Task approach, 40 C.F.R. § 751.605(d)(5)(ii) could be modified to read as follows:

> For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 C.F.R. § 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL. *An employer may also utilize the MUC to evaluate a specific task measured separately within a full shift for comparison to the ECEL.*

The proposed language would provide that the MUCs could be used for short-duration exposure as described in the example above for the CBT approach. The task-based exposure average is then combined with the exposure estimate for the remaining portion of the shift.

It is recommended that at least six samples are collected to demonstrate the MUC of the APF is appropriate for a SEG and evaluate compliance with the ECEL. This is based on AIHA guidance for assessing and managing occupational exposures, which states that according to statistical sampling theory, there is a point of diminishing returns above approximately six to ten measurements.[44] Given the repetitive task exposure scenarios at PCE manufacturing facilities a "rolling average" could be calculated based on the prior six measurements.

11. EPA's Economic Analysis Is Deficient and Should be Revised.

A benefit-cost analysis for this rulemaking would entail estimating and comparing the expected risk reduction benefits (minus any substitution risks) against the expected loss in producer and consumer surplus and the expected compliance costs.

Seen in this way, we find that EPA's analysis is incomplete and otherwise deficient:

- EPA failed to estimate the loss in consumer and producer surplus;
- EPA failed to identify and quantify substitution risks;
- EPA inflated the benefits of cancer risk reduction;
- EPA failed to acknowledge the adverse impact on displaced workers;
- EPA failed to acknowledge the ancillary cost of a black market;
- EPA did not adopt the least burdensome approach to regulation.

In the remainder of this section, we elaborate on these findings.

[44]AIHA, A Strategy For Assessing and Managing Occupational Exposures, 4th ed., 2015.

11.a. EPA Failed to Estimate the Loss in Consumer and Producer Surplus.

When conducting a benefit-cost analysis of a regulatory restriction of market activity, the change in consumer and producer surplus is a social cost that must be acknowledged, quantified, and monetized.

Particularly relevant here are these admonitions from OMB Circular A-4:

> "Opportunity cost" is the appropriate concept for valuing both benefits and costs."
>
> "The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus) of that product, taking into account the mitigating effects of potential substitutes."
>
> "You should include these effects in your analysis and provide estimates of their monetary values when they are significant. . . .gains or losses in consumers' or producers' surpluses . . ."

In its economic analysis, the Agency acknowledges that a loss in consumer surplus is a possibility, but cannot estimate it quantitatively and claims it is likely to be small:

> "By eliminating some of the choices that purchasers have available to them, there is likely to be a consumer surplus welfare loss that would result from options to restrict or limit these products. However, the specific value cannot be estimated without knowing the quantity of the prohibited product that is sold and the elasticity of demand. . . however, when a wide variety of close substitutes are available, the demand for a specific product is likely to be elastic…Thus, the welfare loss is likely to be small."
>
> "There may be some applications [products formulated with PCE] where PCE is more effective or reduces labor time and wait time, but this analysis was unable to quantify these costs."
>
> "No known alternatives have been identified for the use of PCE in maskants for chemical milling... The economic impacts of prohibiting this use are not known, but it could include substantial economic impacts that are not estimated..."
>
> "Little is known about the use of PCE as a processing aid outside of the petrochemical industries, and this use is prohibited under the proposed option, so it is not known whether this prohibition would cause important economic impacts."

EPA should be more forthright about the loss of producer and consumer surplus—a certainty for any regulation that restricts production/use of a commercial product[45]—and should quantify and monetize the minimum surplus at risk in the final rule.

As shown in Figure 1, consumer welfare in a competitive market is the area AXP_1, and producer surplus is the area BXP_1. Historical annual data on the market-clearing price allow an underestimation of point A (the maximum price consumers have paid) and an overestimation point B (the minimum price producers have accepted) to meet apparent consumption, which can then be used to estimate the minimum welfare gain from a forecast of apparent consumption. Using market data on price and quantity for the United States since 2010,[46] we estimate a minimum consumer surplus of $7.6 million and minimum producer surplus of $10.0 million (total $17.6 million) over the 20-year timeframe of analysis, annualized at 7% discount rate.

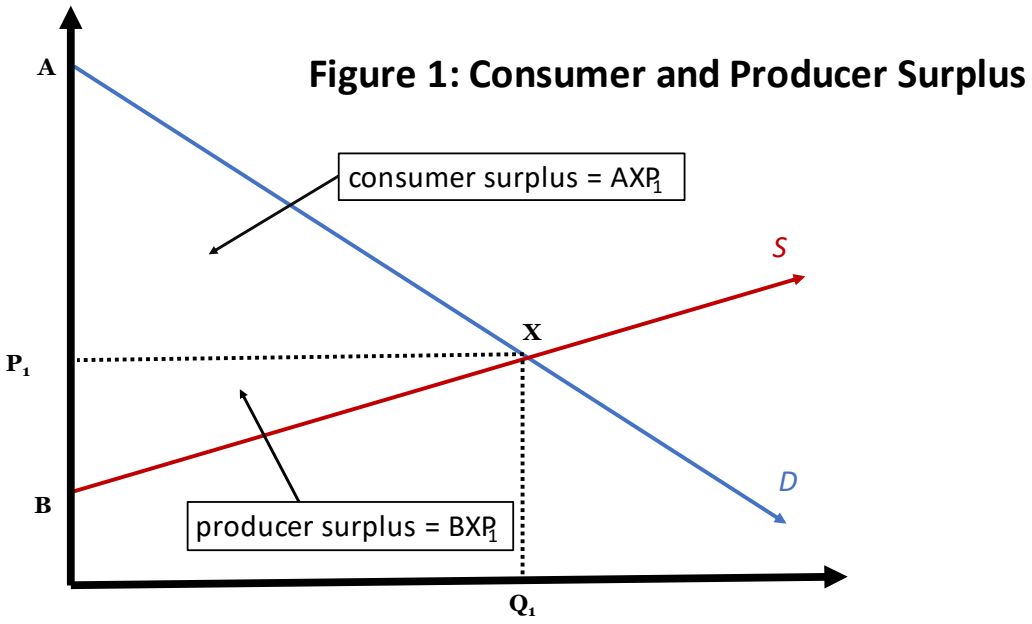

Figure 1: Consumer and Producer Surplus

We conclude that the magnitude of this welfare loss is sizeable and should not be ignored.

11.b. EPA Failed to Identify and Quantify Substitution Risks.

When prohibiting or restricting commercial use of a substance based on risk, a regulatory agency should consider new risks posed by the expected market response. To do otherwise would be akin to flying blind.

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[45] "Banning a product can never improve the well-being of consumers properly understood…This proposition remains valid even when risk is incorporated into the analysis" Higgs, R., 1994. Banning a risky product cannot improve any consumer's welfare (properly understood), with applications to FDA testing requirements. *The Review of Austrian Economics*, *7*(2), pp.3-20.

[46] We obtained annual data on apparent consumption from S&P *Chemical Economics Handbook* for chlorinated methanes (June 2021). We obtained annual data on the nominal price of U.S. imports of perchloroethylene from the U.S. International Trade Commission (www.dataweb.itc.gov), which we converted to real prices.

This is in accordance with OMB Circular A-4:

> "Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks."
>
> "Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis."
>
> "Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks."
>
> "One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side."

In its economic analysis, the Agency remarkably includes no discussion or acknowledgement of substitution risk. We note that in the economic analysis accompanying its proposed methylene chloride risk management rule, EPA includes a brief discussion of this matter:

> "not knowing which replacements…will choose or what probability of an adverse event associated with a replacement might be, it is impossible to quantity and/or put a value on these potential countervailing effects."
>
> "we have provided information on such potential hazards in the analysis of alternatives for individual uses, but cannot quantify the probability or magnitude of such costs."

We believe that it is possible for the Agency to do what it claims it cannot. And we believe it must. A statute that requires regulation to address unreasonable risks in commerce cannot ignore the possibility that markets will adjust in ways that increase other risks, and these other risks must be subtracted from the potential risk reduction benefits of the regulation to generate an estimate of net benefits.

And yet EPA, in its Economic Analysis, admits it is, in many cases, ignoring substitution risk. Table 5-2 provides a list of conditions of use from the EPA risk evaluation that are not analyzed in terms of alternatives. Specifically, we call attention to the following condition of use, which is <u>prohibited</u> under every option considered by the Agency:

> "Incorporation into formulation, mixture, or reaction products: Chemical alternatives are accounted for in later stages of the chemical's life cycle."

By ignoring this condition of use, EPA is ignoring the possibility of significant substitution risks to workers under its regulatory proposal. The Agency cannot determine whether it is doing more good than harm when it chooses to ignore substitution risk. By

the Agency's own admission in its economic and alternatives analyses, alternatives to other uses of perchloroethylene often exhibit hazards of similar or greater magnitude.

Substitution risk need not be for the same endpoint, nor operate via the same toxicological mechanism, nor apply only to drop-in substitutes for perchloroethylene. All that matters is that the substitution risk arise as an expected consequence of the rule. To ignore substitution risk or dismiss it as difficult to characterize is simply not acceptable. The Agency can and must do a better job at identifying and characterizing substitution risk expected under this and future TSCA risk management rules.

11.c. EPA Inflated the Benefits of Cancer Risk Reduction.

It is appropriate to monetize a reduction in cancer cases when that reduction is observable. In accordance with Circular A-4:

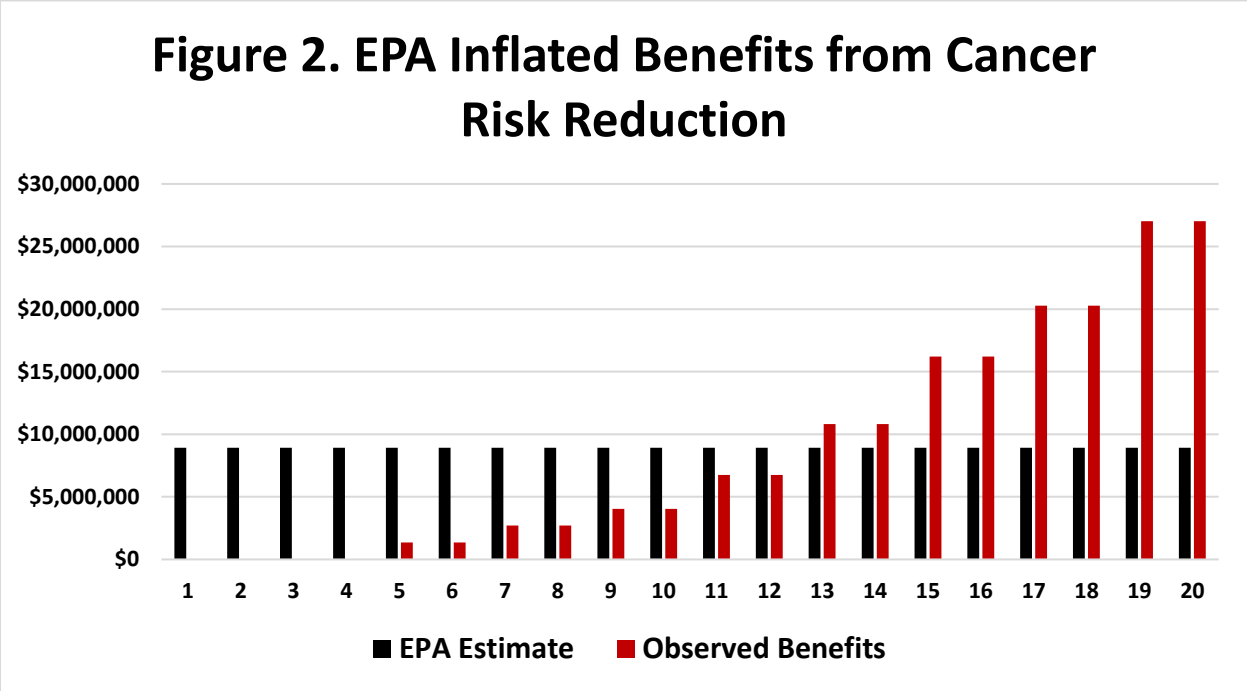
> "A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status *will be observed* [italics added] in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect."
>
> "For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population. When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period."

However, in its Economic Analysis, EPA monetizes reduced cancer risk from chronic exposure starting in year 1, even though the observable risk reduction will be realized only years, perhaps decades, after the rule is finalized. As EPA wrote:

> "Since the benefits in each year of reduced exposure risks are estimated to be the same, annualized benefits are not sensitive to the analysis timeframe."

We believe EPA's approach (based on a "micro-risk reduction") is flawed because it inflates benefits. To show this, we created a model of cancer risk reductions in which cancer cases arise slowly a few years after the rule is imposed, and gradually increase before reaching an asymptotic level by year 20. This is a cessation lag model the Agency should have employed because it reflects risk reductions when they are observed, per OMB guidance. We find (see Figure) that the resulting monetized value of cancer risk reduction is 66% that of EPA's inflated estimate.

We recommend that EPA change its monetized cancer risk reduction benefits to align with OMB Circular A-4.



11.d. EPA Failed to Acknowledge the Adverse Impact on Displaced Workers.

Distributive impacts of regulation are to be acknowledged, in accordance with President Biden's EO 14094, Modernizing Regulatory Review:

> Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law.

Such impacts have long been subject to guidance on the conduct of benefit-cost analysis. OMB Circular A-4 says:

> Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency.

Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. EO 12866 admonishes the regulator to "*be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups* [emphasis added].

In its economic analysis, the Agency suggests the rule could cause substantial unemployment in industries that depend on perchloride. For example, the Agency mentions the probability that some dry cleaners—62 with 560 employees--use equipment designed for perchloroethylene and may go out of business under the proposed rule. In addition, EPA states: "little is known about the use of PCE as a processing aid outside of the petrochemical industries, and this use is prohibited under the proposed option."

Using IMPLAN, a widely available economic software program, we find that a loss of 560 jobs in dry cleaning establishments would result in a loss of 734 total jobs. Unemployment effects may also occur in other sectors of the economy that rely on perchloroethylene. For example, in sectors where the WCPP is particularly expensive, firms may opt to cease production. The unemployment may be short-term or long-term, and the distributional impact should be given appropriate weight in the Agency's analysis. And this weight might be substantial. As Cass Sunstein,[47] former regulatory czar in the Obama Administration, noted:

> We know that in terms of subjective welfare, it is extremely bad to lose one's job. People who lose their jobs suffer a lot. Job loss can severely harm one's self worth and experience of daily life. A sudden loss of income can threaten housing and food security, often causing disruptions to family life and schooling. A loss of a job also creates a nontrivial long-term loss in income. If you are out of work for a year, the economic toll might be very high over a lifetime. We know that a long-term loss in employment has more serious adverse consequences than a short-term loss, but both are bad. Shouldn't those welfare effects be included?

We recommend that the Agency follow the advice in Circular A-4 and consider regulatory alternatives that reduce or eliminate potential unemployment effects.

11.e. EPA Failed to Acknowledge the Ancillary Costs of a Black Market.

As noted previously in this section, Circular A-4 recommends that agencies pay attention to ancillary costs:

> "Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks."
>
> "Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis."

We note that the prohibitions proposed by the Agency are likely to foment a black market in perchloroethylene for uses where its efficacy is greater than available substitutes. Because the Agency acknowledges that it did not always consider efficacy, such impacts cannot be ruled out.

[47] Sunstein, C.R., 2021. Some costs & benefits of cost-benefit analysis. *Daedalus*, *150*(3), pp.208-219.

If a black market arises, it could impact the rank ordering of the main alternatives in the analysis. For example, if a black market arises for perchloroethylene in certain consumer products, EPA's monetized estimate of benefits will be reduced. The same possibility holds for any use of perchloroethylene where the Agency anticipates exposure reduction; a black market will lower the estimated risk reduction benefits of the proposed rule.

We recommend that the Agency consider the possibility of a black market and construct additional regulatory alternatives (e.g., restrict use without an outright prohibition) that would better foreclose the possibility.

11.f. EPA Did Not Adopt the Least Burdensome Approach to Regulation.

Executive Order 12866 includes the following principle for federal regulation:

> Each agency shall tailor its regulations to *impose the least burden on society* [italics added], including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

The proposed rule does not represent the least burdensome approach to addressing unreasonable risk. Although such an approach is no longer required under TSCA (such an approach was required prior to the 2016 amendments), the statute does not preclude such an approach, and—as previously noted—agencies are compelled to do so under EO 12866. Furthermore, the Agency is required to take the least burdensome approach with respect to information collection requests under the Paperwork Reduction Act:

> "To obtain OMB approval of a collection of information, an agency shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information:
>
> (i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;
>
> (ii) Is not duplicative of information otherwise accessible to the agency; and
>
> (iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public."

We note that the proposed rule includes a new Information Collection Request (ICR) that has been submitted to OMB for approval (EPA ICR No. 2740.01).

According to the supporting statement for this ICR, the majority of the paperwork burden is associated with the proposed WCPP, which is being imposed on top of long-standing OSHA regulations. The Agency has not shown that the OSHA requirements are insufficient to address

the unreasonable risk determination made by EPA. Therefore, EPA cannot conclude that it has minimized burden with respect to this ICR.

We recommend that the Agency consider and construct additional regulatory alternatives that better represent a least burdensome approach (e.g., labeling in lieu of prohibition for some/all consumer uses; exempting sectors with de minimis risk; and relying on OSHA standards in lieu of layering on the additional WCPP).

Importantly, EPA's economic analysis does not comport with standard practice for benefit-cost analysis because it ignores significant impacts that are likely to be determinative—i.e., affecting the construction of reasonable regulatory alternatives and the ordinal ranking of alternatives. Furthermore, the Agency's proposed rule does not reflect a least burdensome approach to regulation nor to the paperwork requirements of the rule, which is preferred according to executive order, allowed under the statute, and required under the Paperwork Reduction Act.

12. EPA's Alternatives Assessment Does Not Comport with Accepted Principles in the Field, Missed Consideration of Key Factors, and Was not Sufficiently Tailored to Specific Conditions of Use.

The alternatives assessments conducted by EPA, one as a standalone supporting document and another embedded in the economics analysis, are insufficient to determine existence of feasible alternatives.[48] Neither assessment was performed in accordance with accepted principles in the field. The assessments lack key steps that would be reflected in a field-standard alternatives assessment, such as in the framework created by the National Academy of Sciences (NAS)[49]. Alternatives assessment brings a range of scientific disciplines to bear; when applied in the TSCA Section 6 context to inform risk management, these must conform with the scientific standards set out in section TSCA section 26(h), requiring EPA to make science-based decisions using ''scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.''[50]

EPA's standalone assessment can be described as a hazard screening and does not consider exposure, and therefore risk, in its comparative assessment. It relies heavily on hazard screening for comparisons of alternatives to PCE. However, the level of risk associated with each chemical alternative would vary greatly depending on not only the chemical, but the conditions of use. Risk must also take into account physical risk factors such as flammability, which the assessments do not comprehensively do.

The NAS framework includes a comparative exposure assessment alongside the human health and ecotoxicity assessment.[51] It also considers performance.[52] Performance affects many characteristics of a chemical alternative. Poor performance may require more product to be used,

[48] See EPA Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a), (EPA Docket EPA-HQ-OPPT-2020-0720-0125, RIN 2070-AK84), June 2023.
[49] National Research Council, *A Framework to Guide Selection of Chemical Alternatives* (2014).
[50] 15 U.S.C. § 2625(h).
[51] NAS Framework at 69.
[52] *Id*. at 135.

therefore increasing the exposure to the user and therefore risk, as well as the costs of purchasing more product. EPA's assessments do not adequately take tradeoffs in performance into account.

Another key element of the NAS framework is lifecycle thinking. The EPA's standalone assessment states that it does not cover manufacturing, repackaging, distribution in commerce, disposal, and recycling. It only covers stages during the conditions of use.[53] These omissions greatly increase the likelihood of a regrettable substitution. Especially in disposal and recycling, the environmental hazards associated with the omitted stages in this assessment could lead to major problems in the future. For example, the assessment only considers global warming potential and ozone depletion potential of the alternatives as they exist during the stage in the condition of use. It does not address the potential for these chemical alternatives to change throughout their lifecycle into chemicals that may have a greater impact on the environment.

The TURI Assessment of Alternatives to PCE for the Dry Cleaning Industry included as a supporting document in the docket analyzes more key considerations than the EPA standalone assessment.[54] The TURI assessment looks beyond hazards to also consider performance, finances, and waste management.[55] There is some life cycle thinking in TURI's assessment. If the EPA would use this assessment as a supporting document, it should work to improve the comprehensiveness of its own assessment, or to contract out these assessments to alternatives assessment (AA) experts, especially for large or heavily impacted conditions of use. The TURI assessment is still lacking key considerations but is a step in the right direction.

The alternative assessment included in the economic analysis does not compliment nor build on the standalone alternatives assessment conducted by the EPA. Neither assessment considered all conditions of use and together they did not cover all uses prohibited or heavily restricted by EPA.[56] The standalone assessment categorizes conditions of use by "product category" while the assessment in the economic analysis categorizes them by "use category".[57,58] It is difficult and unintuitive to compare these assessments due to their differing levels of refinement and specification. It is challenging to do a crosswalk between them. The economic analysis AA drew more specific conclusions and did not consider alternative chemicals that were under risk management consideration, while the standalone AA did not draw any clear conclusions on availability of alternatives and did not remove chemicals that remain under risk management consideration. Combining these two assessments into one alternatives assessment with consistent format and parameters would have more clearly communicated the availability of chemical alternatives to PCE.

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[53] See EPA, *An Alternatives Assessment for Use of Perchloroethylene* (EPA Docket EPA-HQ-OPPT-2020-0720, RIN 2070-AK84), Jan. 2023. at p 8.
[54] See TURI, *Assessment of Alternatives to Perchloroethylene for the Dry Cleaning Industry* (EPA-HQ-OPPT-2020-0720-0187), June 2012.
[55] *Id.* at 4.
[56] See EPA, Appendix C: Conditions of Use Not Analyzed Further (EPA-HQ-OPPT-2020-0720-0140)
[57] See EPA, *An Alternatives Assessment for Use of Perchloroethylene* (EPA Docket EPA-HQ-OPPT-2020-0720, RIN 2070-AK84), Jan. 2023. at p 25-26.
[58] See EPA Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a), (EPA Docket EPA-HQ-OPPT-2020-0720-0125, RIN 2070-AK84), June 2023. at 5-7.

EPA should realign the economic analysis with the alternatives assessment, follow AA frameworks of accredited organizations such as the NAS, and outsource at least some of the assessments to ensure completeness and scientific quality.

EPA must provide improved justifications for its conclusory statements and the agency should array the use and alternatives analysis in tables, as was done in the alternatives screen, so that stakeholders can do a side-by-side comparison of all the elements in the use and alternatives analysis.

13. EPA Should Align Its Owner/Operator Definition to OSHA's Regulations.

The proposed PCE risk management rule supplements the OSHA standard, specifically noting that elements not covered in the EPA rule default to the OSHA regulation. The WCPP provisions proposed in § 751.109(b) are not aligned with the definition of employee and employer as defined by OSHA. Specifically, for access to medical records in § 1910.1020 and medical surveillance and monitoring records in § 1910.1052, the new WCPP definitions could potentially apply an employer/employee relationship between an owner/operator and a party that is not an employee of the owner/operator. Where EPA defaults to the OSHA standard, EPA should clarify that the rule is not intended to apply to a broader scope than the OSHA standard.

More specifically, EPA proposes the use of the term "owner or operator" to describe the entity responsible for implementing the WCPP for workplaces where an applicable condition of use is occurring and PCE is present. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.[59]

ACC understands that the intent in defining 'owner or operator' rather than 'employer' is to ensure that workers that have not previously been covered under OSHA, such as state and local government employees, are protected under TSCA. However, EPA's proposed definition implies that the person or company overseeing the worksite is responsible for all aspects of managing perchloroethylene in the workplace, including providing PPE, fit testing, and worker training. These requirements directly conflict with OSHA compliance and enforcement policy, and present significant concerns for multi-employer workplaces or employers who have a mobile workforce.

Under OSHA, employers are responsible for providing a workplace free from serious recognized hazards and complying with standards, rules, and regulations issued under the OSH Act.[60] "Employer" is defined as:

> a person engaged in a business affecting commerce who has employees, but does not include the United States (not including the United States Postal Service) or any State or political subdivision of a State.[61]

This definition of employer necessarily recognizes that there are employers who either a) have mobile workforces that do not report to the same location on a regular basis, or b) have multiple

[59] 88 Fed. Reg. 39672.
[60] 29 U.S.C. § 654(a).
[61] 29 C.F.R. § 1910.2(c).

employers sharing a single worksite. In these situations, the employer still has a duty to its employees to provide PPE and the attendant fit testing and medical evaluation, provide the tools needed for their work, and provide appropriate safety training. EPA's proposed definition of "owner or operator," along with the list of requirements that the owner or operator would need to meet under the rule, conflicts with this understanding.

EPA proposes to require the owner or operator to, among other things:

- Institute one or a combination of elimination, substitution, engineering controls, or administrative controls to reduce exposure to or below the ECEL, and maintain the effectiveness of these controls;
- Provide information and training for each person prior to or at the time of initial assignment to a job involving potential exposure to PCE and annual refresher training, in a manner that is understandable to the person being trained;
- If needed, supply respiratory and/or dermal PPE and ensure that is used and maintained in a sanitary, reliable, and undamaged condition, and provide training on the proper use of PPE at the time of initial assignment and annual refresher training;
- If needed, ensure that all persons within the regulated community are using the provided respirators whenever PCE exposures may exceed the ECEL, that persons do not engage in non-work activities that may increase PCE exposure, and ensure that persons do not engage in activities which interfere with respirator seal and performance.

Many of these requirements would traditionally fall to the individual *employers*, not the owner or operator of a worksite. For example:

> Company A is a chemical manufacturing facility that uses perchloroethylene in a fixed manufacturing process. Company A is undergoing a planned maintenance shutdown. As part of this turnaround, Employer A hires Contractor Z to conduct specialized work.
>
> Under existing OSHA standards, Company A would be responsible for the overall hazard mitigation at their facility, including implementing any permanent engineering controls and correcting any hazards identified. They would also be responsible for training their own employees, setting up a medical evaluation or fit testing program for their employees, and providing needed PPE for their employees. Company A would also be responsible for setting out requirements with which Contractor Z would need to comply: for example, that employees of Contractor Z must not enter specific demarcated areas where there may be exposure to perchloroethylene, or that certain PPE is needed in the area.
>
> However, Company A would *not* be responsible for actually providing PPE to Contractor Z's employees, nor setting up fit testing or medical evaluations for Contractor Z's employees, or for general safety training on hazard recognition or the correct use of PPE of Contractor Z's employees. At most, Company A would need to train Contractor Z's employees on site-specific policies and procedures. In a situation like this, with multiple employers on a single site, where each employer has responsibilities to their employees,

OSHA has a defined Multi-Employer Citation Policy that is used to determine which employer(s) to cite when an OSHA standard is violated[62]. This policy provides some idea of each employer's responsibility to their employees, as well as to hazard recognition and mitigation on the site more broadly. EPA's proposed requirement that the *owner or operator* conduct these activities, rather than the *employer*, directly contradicts decades of OSHA policy and puts these employers in a difficult position.

Certainly if Employer A notices that an employee of Contractor Z is not wearing their respirator properly, or is engaging in activities that could interfere with the respirator's protectiveness, Company A should alert Contractor Z – and if it does not, it would likely be cited in addition to Contractor Z. However, it is Contractor Z's employee and therefore Contractor Z's responsibility to correct the behavior; and it would be Contractor Z's citation under OSHA if it chose not to correct its employee.

Taking a slightly different situation, in which Company A contracts with Contractor Z to perform a specific task that uses perchloroethylene. In this situation, Contractor Z would be responsible for setting up the demarcated area and utilizing engineering controls to ensure that exposures are below the concentration limit, even though it is not the owner or operator of the workplace.

ACC's appreciates EPA's intent to cover additional workplaces with its proposed definition of "owner or operator,"; however, for the reasons described above, this term is unnecessarily confusing to employers that have responsibilities to their employees under OSHA requirements. ACC suggests that EPA strike the proposed definition of "owner or operator" and instead replace it with a standard, commonly accepted and commonly understood definition of "employer," such as the one endorsed by the Cambridge Dictionary:

A person, company or organization that employs people.[63]

This change would address EPA's concerns about workplaces using TSCA chemistries that are not currently covered by OSHA, while reducing any unnecessary confusion on the part of employers as to their responsibilities under OSHA and EPA.

14. Worker Training and Certification can be an Effective Tool for Risk Management that Should be Considered in this Proposed Rule.

Worker training and, in some cases, certification, features heavily in both OSHA and EPA standards for addressing risks from chemical and non-chemical hazards. OSHA's *Training Requirements in OSHA Standards*[64] references 63 standards that require an element of worker training under OSHA's general industry standards, 27 of which are focused on chemical hazard. This includes both chemical-specific standards (methylene chloride, asbestos, etc.) but also

[62] OSHA Multi-Employer Citation Policy. Directive CPL 02-00-124. December 10, 1999. https://www.osha.gov/enforcement/directives/cpl-02-00-124.
[63] *Employer*, Cambridge Business English Dictionary (1st ed. 2011).
[64] OSHA 2015. Training Requirements in OSHA Standards. Available at: https://www.osha.gov/sites/default/files/publications/osha2254.pdf

standards intended to address chemical hazards generally (hazard communication, HAZWOPER, personal protective equipment, etc.).

In addition to training requirements under OSHA, several EPA standards also require some element of worker training. For example, EPA's Risk Management Plan (RMP) rule requires facilities using extremely hazardous substances to develop a risk management plan to identify the potential effects of a chemical accident and identify steps the facility is taking to prevent such an accident. RMP requires that workers be trained in how to safely carry out their responsibilities and receive refresher training every three years.

In addition, the Office of Pesticide Programs (OPP) has implemented a worker protection standard for employees in the agriculture industry, as well as a standard requiring users of registered use pesticides to be trained in how to safely use the pesticide. Worker training and certification is clearly viewed as an acceptable measure for risk management in the workplace across the EPA, and should be considered in rulemakings under TSCA as well.

14.a. Existing Literature Indicates That Training and Certification is an Effective Risk Management Tool.

ACC commissioned a systematic review of existing literature to better understand the effectiveness of worker training and certification at improving safety outcomes. Our research question was "Is there data to support a change in behavior due to safety training?"

Search terms and syntax used to conduct the review identified over three thousand unique references that were then screened in Distiller to focus on occupational safety training, resulting in 421 studies. A human reviewer examined these studies, including them in the final data base if:

- The population in the study was an occupational group. Patient safety studies were excluded from this analysis,
- Described an occupational safety training program,
- Compared the effectiveness of two types of training programs, or compared the effectiveness of a training program against no training program, and
- Included a measure or discussion of success or failure.

The final database identified 96 relevant studies. 18 of these studies were classified as 'key studies' because they had longer follow-up periods or quantitative measures of behavioral change. Of these 96 studies, 56 answered the initial research question. 52 of these 56 studies showed a benefit to occupational safety training. Three of these were classified as meta-analysis or systematic reviews. Some of the endpoints evaluated include improvements in worker's knowledge, reduced incidence of injury, declines in unsafe practices, and improvements in safety performance. A summary of the systematic review, including the 96 abstracts, can be found in this docket.

The existing body of literature demonstrates that safety training is effective over a wide range of topics and industries. While training did not necessarily lead to an injury-free workplace, this

review demonstrates the value of occupational safety training in improving outcomes for workers. EPA should consider worker training and certification an appropriate and effective tool to mitigate unreasonable risks.

14.b. The Foundation for Chemistry Research and Initiatives (FCRI) Implementation of an OSHA Susan Harwood Training Grant also Demonstrates Effectiveness of Training and Certification.

In addition to the existing body of literature, the Foundation for Chemistry Research & Initiatives (FCRI), a 501(c)(3) tax-exempt organization established by ACC, applied for and received an OSHA Susan Harwood Training Grant in order to develop a worker training and certification program. The OSHA Susan Harwood Training Grant Program awards grants to nonprofit organizations on a competitive basis to provide training and education programs for employers and workers on the recognition, avoidance, and prevention of safety and health hazards in their workplaces.[65] The Harwood Grant program has existed in various forms since 1978, and over the last five years, more than 200,000 employees have received training though the Harwood Grant Program.[66] FCRI received a Training and Educational Materials Development Grant, which focuses on the development and validation of training materials to maximize their effectiveness in a classroom setting.

FCRI developed training materials focused on the safe use of perchloroethylene-based products used in the automotive industries. Training materials were reviewed and approved by OSHA prior to their use.

The training was designed to be completed in two hours or less, and focused primarily on hazard identification in the workplace, along with hazard mitigation. The six modules developed for the training include:

- What is perchloroethylene?
- Hazards of perchloroethylene
- Exposure controls
- Hazard communication
- Perc-specific scenario: Hazard ID and controls
- Resources for Safe Use

To measure knowledge gain due to the training, FCRI developed a Level 2 Training Assessment. This assessment includes a short quiz that trainees take before and after the training. Results are then compared to see how much trainees learned from the training.

FCRI conducted an initial pilot training for 15 trainees on May 31, 2023. The Level 2 Training Assessments showed positive results: where there was opportunity for improvement on a question, there was improvement; with one question (What is the most effective control

[65] https://www.osha.gov/harwoodgrants/overview.
[66] https://www.osha.gov/harwoodgrants/statistics.

method?) seeing an increase of more than 70% of participants correctly answering upon completion of the training.

While the initial results are promising, FCRI continues to recruit trainees for additional classroom training sessions. In addition, FCRI is adapting the classroom training materials to an online, web-based training system that will allow other workers to benefit from this training.

ACC believes that the results of the literature review, along with the initial results from the FCRI pilot training, show that worker training and certification can be a valid option for managing risk in the workplace. We understand that EPA is currently developing an updated Memorandum of Understanding (MOU) with OSHA to continue working through the workplace protection aspects of TSCA Section 6(a) risk management rules. ACC urges EPA to consider all facets of workplace safety in developing its risk management rules, including worker training, and to ensure experts from OSHA and other stakeholder groups are involved in the development of such options.

14.c. EPA's Implementation of FIFRA is Substantially Similar to TSCA and Allows for Worker Training and Certification as a Risk Management Measure.

FIFRA provides useful learnings regarding the value of worker training and certification to manage chemical risk. FIFRA governs the registration, distribution, sale, and use of pesticides in the United States. Generally, before a pesticide may be sold or distributed in the United States, it must be registered with the EPA. Before EPA may register a pesticide under FIFRA, the applicant must show that using the pesticide according to the specifications "will not generally cause unreasonable adverse effects on the environment."[67] The term "unreasonable adverse effects on the environment" is defined as:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from the use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.[68]

The Federal Food, Drug, and Cosmetic Act (FFDCA) describes a tolerance as "safe" when there is "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue."[69]

On the surface, it appears that the requirements under FIFRA to evaluate economic, social, and environmental costs and benefits would run counter to EPA's requirement to assess unreasonable risks without regards to costs or other nonrisk factors. However, when promulgating a risk management rule under TSCA, EPA is required to consider the following nonrisk factors:

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[67] https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities#:~:text=The%20Federal%20Insecticide%2C%20Fungicide%2C%20and,pesticides%20in%20the%20United%20States.
[68] 7 U.S.C. § 136(bb).
[69] 21 U.S.C. § 408.

(i) The effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;
(ii) The effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such a substance or mixture;
(iii) **The benefits of the chemical substance or mixture for various uses, and;**
(iv) **The reasonable ascertainable economic consequences of the rule,** including consideration of –
(I) The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health…. [emphasis added].[70]

These additional considerations required when promulgating risk management rules under TSCA are substantially similar to the considerations under FIFRA's unreasonable adverse effect standard.

EPA's pesticide registration process also has strong parallels to TSCA's requirement to evaluate substances by their conditions of use. Pesticides are assessed for impacts on human health and the environment before they are allowed to be registered, and pesticides may be classified as either restricted or general use pesticides, depending on how the pesticide is to be used and the potential for unreasonable adverse effects on the environment. A single pesticide may be classified as both a restricted pesticide and a general use pesticide, depending on how the pesticide is to be used. This reflects the requirement in TSCA to evaluate chemicals based on their conditions of use and the recognition that not every condition of use will present unreasonable risk to human health or the environment.

Finally, FIFRA also regulates hazardous substances: pesticides are substances designed with the intent to cause biological activity and are recognized to have both acute and chronic exposure hazards – as does PCE, along with many other substances that EPA is planning to or has already evaluated under TSCA.

For these reasons, EPA's implementation of FIFRA provides a model for EPA to consider when promulgating risk management rulemakings. In particular, the Certification Program for Restricted Use Pesticides and the Agricultural Worker Protection Standard promulgated by EPA provide a useful model when considering the implementation of a worker training and certification program for TSCA chemistries.

The Certification Program for Restricted Use Pesticides establishes federal standards for the certification and recertification of applicators of restricted use pesticides and requirements for pesticide applicator certification plans. The program creates different categories of commercial applicator certifications based on how and in what industry the pesticide will be used. Applicators must demonstrate competency in both general subjects (labeling, safety, etc.) as well

[70] 15 U.S.C. § 2605 (c)(2)(A)(i-iv) [emphasis added].

as competency in category-specific information. EPA sets the required competency standards, and states, local governments, and tribal organizations create the trainings and manage the certified applicator registrations. Finally, restricted use pesticide dealers must create and maintain records of all sales to certified applicators.

The Agricultural Worker Protection Standard (WPS) requires employers and commercial pesticide handlers to provide specific information and protections to workers, handlers, and other persons when pesticides are used. Workers must be trained using EPA-approved materials in an area that is conducive to training, and trainers must meet specific requirements to be qualified to conduct training.

EPA's implementation of these standards shows that training, certification, and limited access programs can be used to mitigate the risk from hazardous substances. EPA should consider standing up a similar program or set of programs for PCE and other TSCA chemistries.

For example, EPA could require OSHA or the states to create training materials that cover both general chemical hazard safety information (hazard communication, the Exposure Control Plan, etc.) and industry-specific training (i.e., safe use of PCE in the auto industry). If there are concerns that OSHA or the states are not capable of creating such materials, third parties such as safety and health experts or trade associations could create them instead. EPA could lay out its requirements for such trainings, and require that EPA review and approve the materials before they are used.

Owners and operators could then take the training and prove their competency to the administering body in order to receive a license to purchase PCE-containing products from a retailer. The retailer could be required to keep records of their sales to certified people. EPA could also establish a requirement for retailers to be certified as well in order to sell and distribute these products, again mimicking the requirements under the Certification Program for Restricted Use Pesticides Standard.

This kind of system would help ensure that only owners and operators who have established their knowledge of the hazard and are prepared to meet their obligations under TSCA would be able to purchase and use these products in the workplace.

If EPA chooses not to establish a training, certification, and limited access program for PCE, it should clearly justify why such a program is inappropriate. The acute hazards associated with PCE are not an acceptable response, as EPA has clearly shown that other substances with severe acute hazards, such as pesticides, can be safely managed with such a program. TSCA's unreasonable risk requirement is not materially different than FIFRA's unreasonable adverse effect requirement. EPA should explain why a training, certification, and limited access program is acceptable for pesticides and not for TSCA-regulated substances.

14.d. EPA's Proposed Exposure Control Plan (ECP) Misapplies the NIOSH Hierarchy of Controls and Sets Unrealistic Documentation Requirements of Owners and Operators.

EPA proposes to require the owner or operator of a facility to document its efforts to use elimination, substitution, engineering controls, and administrative controls to reduce exposure to or below the ECEL or EPA STEL in an exposure control plan. Specifically, EPA would require that the owner or operator include and document in the control exposure plan (i) identification of available exposure controls and rationale for using or not using available exposure controls in the following sequence to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable, and the exposure controls selected based on feasibility, effectiveness, and other relevant considerations; and (ii) if exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or otherwise implemented.

These ECP requirements are (1) not feasible to implement as written and (2) belie an understanding of how the hierarchy of controls is implemented in practice. The proposed ECP requirements imply that the safety professional or industrial hygienist must sequentially exhaust all options in each level of the hierarchy before moving to the next, i.e., examine all possibilities to *eliminate* PCE before considering substitution; then, examine all possible alternatives for *substitution* before applying engineering controls, and so on. It is unclear what level of documentation is required for employers to demonstrate their rationale that a particular control was not feasible to implement, and how many options need to be evaluated.
Elimination and substitution are often not feasible controls for chemical hazards. NIOSH states that elimination and substitution are "the most difficult actions to adopt into an existing process"[71] and that these methods are best used during the design or developmental stage of a work process. It would be more appropriate to eliminate the chemical hazard during the design of a new facility, or if a manufacturing process is being completely retooled. Otherwise, the elimination step would call for retrofitting an entire facility, which is almost certainly not an economically feasible action. It is unclear if EPA's proposed requirement to document controls that are not feasible would require, for example, a detailed engineering study with associated costs to retrofit a facility. It is also unclear what level of capital expenditure EPA considers to be economically unfeasible.

The substitution level of the hierarchy poses similar challenges in a chemical manufacturing facility. While substituting a new chemical in place of PCE may not require the retrofit of an entire facility, in the chemical manufacturing arena it would almost certainly require retooling at least one full process. At least one ACC member has indicated that it could take 6-10 years to conduct the necessary research, product quality studies, pilot scale studies, engineering design, installation, startup, and production qualification and over $50 million for each of several products where PCE is used as a processing aid *if a suitable alternative is even available*.

Substituting one chemical with another in a commercial setting, such as furniture refinishing, also poses its own set of challenges. While alternative solvents exist, using these solvents does not necessarily decrease risk. A different solvent may require that workers use more of the product, or it may take longer to work, resulting in a different level of risk to the employee than one may expect based on the hazard analysis. EPA implicitly acknowledges this: the alternatives assessment that EPA provides in the docket lists N-methylpyrrolidone (NMP) as a possible alternative to PCE. However, the NMP risk evaluation also found unreasonable risk for the paint and coating condition of use in the final revised risk evaluation.

[71] https://www.cdc.gov/niosh/topics/hierarchy/default.html.

In addition, substitution might result in trading the toxicological risk with another risk like flammability, which is not an issue with PCE. Alternative solvents could require installation of explosion-proof and/or intrinsically safe equipment and lighting. Those costs need to be considered as well.

Thus, the first level of the hierarchy that can often be seriously considered in the workplace is engineering controls – and there are many options here for employers to choose from. As an example, the OSHA Technical Manual on Controlling Lead Exposures in the Construction Industry provides six different categories of engineering controls (isolation, substitution, change of process, wet methods, local exhaust ventilation, and general ventilation) and then provides detailed descriptions of controls that can be used for various tasks.[72] The open abrasive blast cleaning task has no fewer than 13 options for engineering controls that can be used to reduce exposure.

EPA's proposed ECP belies an understanding of how the NIOSH hierarchy of controls is applied in practice. It implies a rigidity to the hierarchy of controls that is contrary to how the hierarchy is actually applied. For example, the OSHA Hazardous Waste Operations and Emergency Response Standard (HAZWOPER) identifies training of workers (an administrative control) as a critical component of an occupational safety program that must be performed before a worker is allowed to step foot on a job site. In fact, EPA's proposed WCPP actually requires an administrative control – setting up an exclusion zone – to be implemented before any other controls in order to prevent ONUs from accessing areas where PCE is present.

The vast majority of employers apply multiple levels of the hierarchy, and often several controls within one level, at the same time, for a single task. This application, often referred to as a layers of protection model, reflects the fact that it is often multiple errors that lead to an incident or exposure. Applying multiple controls from the hierarchy will often provide more protection for workers, particularly in an environment where multiple hazards exist.

It is perhaps more useful for the agency to think of controls as layers of protection. Some controls are preventative (i.e., preventing exposure to the hazard entirely), or mitigative (i.e., mitigating the exposure to the hazard). This approach would be in line with current practices in the fields of occupational safety and industrial hygiene and acknowledges what all safety professionals know to be true: no one control is infallible, and therefore layers of protection should be implemented to prevent exposure to workplace hazards. This approach falls in line with existing OSHA standards and current best practices in the fields of occupational safety and industrial hygiene, including those related to chemical hazards (e.g., hazard communication, HAZWOPER, etc.). This approach also addresses EPA's concerns related to PPE. EPA states that PPE is the lowest in the hierarchy of controls because it is a mitigative control. A worker in a respirator may encounter a hazard, but any potential exposure is mitigated due to the use of the PPE. Consequently, the risk is reduced.

[72] https://www.osha.gov/otm/section-5-construction-operations/chapter-3.

Substitution, engineering controls, and administrative controls can all be either preventative or mitigative controls, and they work together as layers of protection to prevent or mitigate exposure depending on when they are applied throughout the work task that is performed. EPA's proposed requirements for an exposure control plan are not reasonable. EPA should eliminate the first two requirements of the exposure control plan and consider requiring that owner operators describe what controls have been implemented to reduce employee exposures to below the ECEL. OSHA provides some definitions for a 'qualified' or 'competent' person that may be useful to EPA in defining this person:

> *Qualified person*: one who, by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated their ability to solve or resolve problems related to the subject matter, the work, or the project (29 C.F.R. § 1910)
>
> *Competent person*: one who is capable of identifying existing and predictable hazards in the surroundings of working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them. (29 CFR 1926.32(f))

These definitions are found throughout OSHA's standards and should be familiar to workplace safety practitioners. Requiring a qualified or competent person to certify that the hierarchy of controls has been used when considering exposure controls provides benefits to both EPA and the regulated community. The regulated community is given a definition and a process with which it is familiar, reducing the impact of regulatory burden. EPA, in turn, benefits knowing that an expert has reviewed and approved the exposure control plan.

Ultimately, the exposure monitoring data that EPA proposes to require will provide proof of an effective exposure control plan, not the amount of documentation that EPA chooses to require related to the hierarchy of controls. EPA should adjust this requirement as stated above and allow workplace safety professionals and industrial hygienists to use their professional judgement in determining which controls will be most effective for the specific workplace and tasks performed.

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Thank you for the opportunity to comment. Questions may be directed to Karyn Schmidt, Senior Director, Regulatory & Scientific Affairs, Karyn_Schmidt@americanchemistry.com, or Paul DeLeo, Senior Director, Regulatory & Scientific Affairs, Paul_DeLeo@americanchemistry.com.

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