Comments of the American Chemistry Council
on
Trichloroethylene (TCE) – Regulation Under the Toxic Substances Control Act (TSCA)
88 Fed. Reg. 74712 (Oct. 31, 2023)
EPA-HQ-OPPT-2020-0465
December 15, 2023

submitted to https://www.regulations.gov

Introduction

The American Chemistry Council (ACC)[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 trichloroethylene (TCE) 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.

TCE is a widely used commercial chemical with important and valuable properties in appropriate applications. ACC represents manufacturers and users of this chemical.

We incorporate by reference and in full the separately filed comments of ACC's TCE Panel on this proposed risk management rule and ACC's comments on the proposed changes to the Risk Evaluation framework rule filed on EPA's deadline (yesterday), December 14, 2023.

General Comments

1. To Improve Risk Management Rulemaking under TSCA, the Scoping Process Should Continue to be Refined.

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]

[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.

[2] 15 U.S.C. § 2605(b)(4)(D).

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 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(s) 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 "presents" unreasonable risk determinations.

Here, we note 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]

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[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.

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.

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 TCE then had a limited comment period attached to it.

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 be able to participate and provide information. We urge EPA to reconsider the adverse effects of its policy choices on fundamental due process.

3. ACC Supports a *De Minimis* Level for TCE.

EPA requested comment on whether there should be a *de minimis* level of TCE recognized to address situations where there are impurities or trace amounts of TCE in products. In short, yes.

ACC urges EPA to develop a consistent process to determine *de minimis* levels for all chemical substances as they move through the risk evaluation and risk management processes under TSCA. EPA expressly noted in the risk management proposal for perchloroethylene (PCE) that the presence of this substance as impurities "does not drive the unreasonable risk" and therefore did not need to be considered in order to evaluate the risk of injury resulting from exposures. EPA should take the same approach in this rulemaking for TCE, and all subsequent rulemakings.

Here, establishing a threshold of 0.5 percent by weight for the TCE restrictions aligns with existing requirements under OSHA's Hazard Communication Standard and would enable companies to determine compliance more readily with the requirements of the rule. It should be noted that prohibiting impurities in downstream products or TCE impurities in feedstocks could severely hamper numerous value chains. Failing to do so would likely result in many companies being out of compliance without their knowledge.

A *de minimis* exclusion should apply regardless of whether the trace level originates as a byproduct, impurity, or both.

4. **TCE Produced as a Byproduct should be Allowed under a Workplace Chemical Protection Program (WCPP) or *De Minimis.***

Clarifications or modifications are needed in the final rule to allow for the continued processing/recycling of streams containing TCE as a byproduct in manufacturing processes. The proposed rule's prohibition of the processing/recycling of TCE unintentionally produced as a byproduct would stop the beneficial reuse/recycling of intermediate streams, which is counter to the Agency's own Waste Management Hierarchy that encourages reuse and recycling versus disposal or incineration. Allowing for recycling in these processes would also align with EPA's proposed Carbon Tetrachloride Risk Management rule (in proposed 40 CFR § 751.707(6)) that allows Processing: Recycling in compliance with the WCPP.

The TCE produced as a byproduct/impurity in manufacture of chlorinated organics cannot be prevented in the production process nor removed from the stream before the reuse process. For example, if streams that include TCE produced as a byproduct cannot be processed/recycled in process, then a stream totaling 370 MMlbs annually would require loading and transportation to an incinerator for destruction, based on data reported by one ACC member company. This representative stream only accounts for one stream that is processed/recycled with a minimal amount of TCE produced as a byproduct.

Without the ability to reuse these waste streams, manufacturers would be required to dispose of this material – primarily through thermal destruction. Existing ACC member facilities do not have the capacity for onsite destruction of this magnitude, if at all. EPA's economic analysis does not consider the cost of off-site destruction of this material which the ACC estimates may total in excess of $700 million per year.

ACC notes that existing hazardous waste incinerators are struggling to keep up with increasing demand for incineration services. The proposal does not factor in the need for increased waste management capacity in the United States, particularly for incineration, if streams are required to be diverted, e.g., destruction by incineration, because of the low levels of TCE byproduct. Likewise, the proposal does not consider the need to build truck loading facilities to support offsite disposal by truck, nor does it include the increased personnel, training, and industrial hygiene costs associated with controls implemented for the increased loading activities. Additionally, the transportation of these streams for disposal would increase the time spent by employees involved in the loading process wearing respiratory protection and other PPE.

5. EPA Should Not Require a WCPP for Zero Exposure Scenarios and *De Minimis* Scenarios.

ACC is aware of at least one example whereby a member company imports a product containing a very small (< 100 ppm) amount of TCE as an impurity. The product is imported in sealed containers that are not opened. The sealed container is sold into rubber processing, where it is a component in a rubber adhesive used in multiple applications, including aerospace and automotive applications. The remaining impurity in the end product is vanishingly small. There is no worker exposure during the import process, so there is no need for a WCPP to monitor pass through of a sealed container before its ultimate destination. We recommend that EPA clarify that manufacturing with no worker exposure (e.g., pass through of sealed containers) be expressly excepted from a WCPP requirement.

Specific Comments

6. Conditions of Use and Entities That Can Meet the WCPP and ECEL Should Not Be Further Regulated.

EPA requested comments regarding replacing the proposed prohibitions with compliance with the WCPP in instances where regulated entities are able to consistently demonstrate compliance with an ECEL through effective controls.[5] EPA has stated that exposures at or below each ECEL would not result in unreasonable risk for chronic cancer and non-cancer and acute non-cancer inhalation endpoints.[6] As such, any entity that can meet the WCPP and ECEL should be exempt from prohibition.

For industrial processing of a chemical intermediate where the chemical is largely confined to a process reactor, and which requires infrequent tasks (such as loading, unloading, and maintenance of the equipment that supplies the reactor with TCE), management of such infrequent tasks (and exposures) should occur independent of an 8-hour health based occupational exposure limit that may have been developed based entirely different exposure conditions.

EPA requested comments on subsections of conditions of use which, by nature of their infrequent occurrence, could meet the 8-hour "acute and chronic" ECEL without having their employees wear high APF levels of PPE on a daily basis.[7] Fundamentally, if a condition of use can meet a WCPP and ECEL, it should be allowed and further regulation is not necessary. However, the question ignores the incongruence of the exposure conditions under which the ECEL was developed[8] and the nature of the condition of use. The 8-hour ECEL was developed to protect against the "most sensitive acute and chronic non-cancer endpoint"; i.e., it was set low enough to protect against both effects, but without considering the different dose-averaging associated with differing durations of exposure. Thus, the application of an occupational exposure limit (OEL) that has vastly different exposure assumptions may not be appropriate for

[5] 88 Fed. Reg. at 74776, Section IX, 17.
[6] Id. at 74721.
[7] Id. at 74778, Section IX, 54.
[8] That is, continuous, uncontrolled exposure for 8 hours per day, 260 days per year, for a 41-year working lifetime starting at age 16.

an infrequent and/or short duration task. Potential exposures and risks for such conditions of use should be managed independently of a chronic OEL (or using an OEL based on the same exposure duration assumptions as relevant to the exposure scenario such as an acute daily limit), as appropriate, while maintaining suitable worker protections. A full suite of occupational safety systems and practices should be applied with exposure controls that may deviate from a specified health based OEL if the basis for its establishment is highly disparate from the conditions where it is being applied.

7. EPA Should Develop a New ECEL for TCE to Conform with TSCA's Science Standards [15 U.S.C § 2625(h)].

TSCA requires that EPA adhere to specific provisions regarding Scientific Standards, including use of Best Available Science (BAS) and Weight of the Scientific Evidence (WOSE) as articulated in Section 26 (h) and (i) of TSCA [15 U.S.C. 2625(h) and (i)] and 40 CFR Part 702. EPA's proposed ECEL for TCE does not conform with these requirements.

EPA's proposed ECEL for TCE would be an outlier among current occupational exposure limits found throughout the world. The GESTIS[9] database of international limit values for chemical agents (i.e., occupational exposure limits)[10] currently lists 8-hour occupational limit values for TCE from 28 national authoritative bodies (i.e., country authorities) around the world including the U.S. Occupational Safety and Health Administration (OSHA) and National Institute of Occupational Safety and Health (NIOSH), Canadian provinces and the European Union. 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 (ACGIH). Most current OELs for trichloroethylene fall between 6 ppm and 50 ppm (27 of 31; see Table 1 below).

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

8-hr Limit Value	# of Authorities
100 ppm	2*
20 – 50 ppm	9**
6 – 10 ppm	18†
0.1 – 1 ppm	2‡
0.01 – 0.1 ppm	0
0.001 – 0.01 ppm	2#

* Including OSHA Permissible Exposure Limit

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

** Includes NIOSH Recommended Exposure Limit (REL)
† Includes ACGIH Threshold Limit Value (TLV)
‡ Includes Department of Defense proposed occupational exposure limit for TCE[11]
# Includes EPA's Two Proposed ECELs

The OSHA PEL is on the high end but not an extreme outlier. However, in the United States, the CalOSHA PEL at 25 ppm is a requirement in California and the ACGIH Threshold Limit Value (TLV) at 10 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.

The proposed EPA ECELs are on the other extreme of the group being more than a factor of 1,500 to >45,000 lower than a majority of the OELs and more than 500-fold lower than the lowest current OEL (0.6 ppm). The stark difference between the EPA proposal and current practice necessitates a rigorous re-evaluation using a weight of evidence approach from various sound scientific peer-reviewed literature with involvement from certified industrial hygienists (CIHs) and toxicologists with appropriate training, credentials, and professional experience.

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

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)*.[12] In that NASEM Review, the U.S. Department of Defense's (DOD's) process for deriving an occupational exposure level for TCE is summarized and recommendation for improvements were provided. Updates to the process since the NASEM review were provided by DOD in 2022 and its updated approach is still being evaluated.[13]

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.[14]

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[11] See *Trichloroethylene: Occupational Exposure Level for the DoD*, available at: https://www.nationalacademies.org/event/02-09-2022/docs/DF7EEB6870330C0B6598C1C579A434F866FA6C4420B3?noSaveAs=1.

[12] 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.

[13] See National Academies of Sciences, Engineering, and Medicine (NASEM) Review of DOD's Revised Approach to Deriving an Occupational Exposure Level for Trichloroethylene (TCE). https://www.nationalacademies.org/our-work/review-of-dods-revised-approach-to-deriving-an-occupational-exposure-level-for-trichloroethylene-tce.

[14] 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.

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.

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

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.[15] 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.[16] 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®).[17]

There are several examples of current OEL development processes being applied throughout the U.S. that use principles of systematic review, including applying these principles to a formal weight of evidence review of available data. 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.

10. The Hazard Characterization in The Final Risk Evaluation and Associated with the ECEL is Fatally Flawed.

There are extensive comments in the record for the TCE risk evaluation documenting the errors associated with the hazard characterization of TCE (for example, see Bevan 2018[18], Graul 2018,[19] Bevan 2020[20], and Risotto 2020[21]). The hazard characterization is a fundamental component to the derivation of an occupational exposure limit. EPA should correct its hazard characterization before finalizing any occupational exposure limit it derives.

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[15] 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.

[16] 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.

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

[18] Available at Docket ID EPA-HQ-OPPT-2016-0737-0092.

[19] Available at Docket ID EPA-HQ-OPPT-2016-0737-0103.

[20] Available at Docket ID EPA-HQ-OPPT-2019-0500-0094

[21] Available at Docket ID EPA-HQ-OPPT-2019-0500-0095.

11. Compounded Conservatism in the Dose-response Assessment Contributes to an Unrealistically Low ECEL.

EPA used numerous conservatisms in its dose-response assessment that contribute to the ECEL being much lower than necessary for worker protection for TCE and other substances for which it has derived them.

Human equivalent concentration (HEC) derivation

EPA selected a Human Equivalent Concentrations (HEC) for the most sensitive 1% of the human population (i.e., HEC99). It is interpreted as being the concentrations of TCE in air for which there is 99% likelihood that a randomly selected individual will have an internal dose less than or equal to the internal dose point of departure derived from the rodent study. The 99% likelihood is highly conservative; a 95% likelihood is considered reasonably conservative and more typical of risk assessment methodologies used for setting health-based limits. This reflects that additional adjustment (uncertainty) factors are applied to address residual differences in human variability not captured in the point of departure.

Benchmark Dose

EPA followed its Benchmark Dose Technical Guidance[22] in deriving points of departure. The benchmark dose (BMD) and 95% lower confidence limit on the BMD (BMDL) were estimated using a benchmark response (BMR) to represent a minimal, biologically significant level of change.[23] Standard BMRs of 1 standard deviation (SD) for continuous data and 10% extra risk for dichotomous data were typically used. However, for *frank effects* (e.g., developmental abnormality that impacts survival), a BMR of 1 SD may be used. For dichotomous data, a BMR of 10% was typically employed, although a BMR of 5% may also be employed for *frank effects* and 1% for effects severe enough to result in early mortality.

The (erroneous) selection of the fetal cardiac malformation endpoint dictated the use of a BMR of 1%. Furthermore, the use of 95% lower confidence limit on the BMD ($BMDL_{95}$) as opposed to the BMD as suggested by Simon et al.[24] represents a conservative approach though consistent with the EPA guidance.

Uncertainty Factors

EPA used standard uncertainty factors in deriving the point of departure for TCE (see Table 1 below). As noted above, Simon et al. (2016) recommended the use of Bayesian uncertainty factors for derivation of reference values. The result of the application of the Bayesian approach is a slightly lower composite uncertainty factor (4.7 vs. 10).

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[22] U.S. Environmental Protection Agency. 2012, Benchmark Dose Technical Guidance. EPA/100/R-12/001. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, D.C., Available at: https://www.epa.gov/risk/benchmark-dose-technical-guidance.

[23] U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene. EPA Document #740R18008. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Washington, D.C.

[24] Simon, TW, Y. Zhu, M.L. Dourson, N.B. Beck. 2016. Bayesian methods for uncertainty factor application for derivation of reference values. *Regulatory Toxicology and Pharmacology*, 80: 9-24. https://doi.org/10.1016/j.yrtph.2016.05.018.

Table 1.UFs used to address differences between study conditions and human environmental exposure

		Standard Values	EPA TCE RE Values		Bayesian Approach[#]
			Developmental	Immune	
Extrapolating from animals to humans • (Pharmacokinetic component)* • (Pharmacodynamic component)	UF_A	10 (3) (3)	3	3	3
Human (intraspecies) variability • (Pharmacokinetic component)* • (Pharmacodynamic component)	UF_H	10 (3) (3)	3	3	3
Extrapolating from subchronic to chronic exposures	UF_S	10	1	1	1
Extrapolating from LOAELs to NOAELs**	UF_L	10	1	1	1
Deficiency in the dataset for a critical endpoint	UF_D	10	N/A	N/A	1
Composite UF			10	10	4.7

*Eliminated if PBPK modeling is used
**For NOAEL or BMDL values, the UF_L is 1
[#] Proposed TCE OEL for the Department of Defense based on kidney cancer

12. EPA Should Withdraw the Proposed ECEL, Reset it, and Conduct an Independent Peer Review Before Proposing it in a Risk Management Rule.

Perhaps the most egregious aspect of the proposed risk management rule is the opaque approach to ECEL development, which lacked evaluation by outside experts and discouraged public stakeholder engagement. According to the record, EPA developed its ECELs for TCE in February 2021 and March 2022[25,26] Those memos describing the ECELs were quietly posted to the TSCA Section 6(a) Rulemaking Docket for Trichloroethylene (EPA-HQ-OPPT-2020-0642) on May 20, 2022, and the ECEL was publicly released for comment for the first time as part of the risk management rule on October 31, 2023. No independent verification or peer review of the ECEL, or the process to develop the ECEL, was conducted.

The NASEM Review of DOD's Revised Approach to Deriving an OEL for TCE represents a benchmark for peer review. The NASEM Review contrasts starkly with, and highlights critical deficiencies in, EPA's approach.

EPA should also conduct an independent peer review of its approach to derivation of ECELs. The individual ECELs should also be subject to peer review, which 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.

[25] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. Existing Chemical Exposure Limit (ECEL) for Occupational Use of Trichloroethylene. February 22, 2021. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0642-0024.
[26] U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention. Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of Trichloroethylene. March 31, 2022. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0642-0025.

13. 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 on the ECEL derivations.

The Fifth U.S. Open Government National Action Plan states: [27]

> 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 detailed, transparent, and credible process for Developing Acute Exposure Guideline Levels (AEGLs).[28] 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[29] to issuance of the final rule in January 2017[30] and included a two-day public hearing in between. Similarly, the European Chemicals Agency has 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.[31] 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.

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[27] https://open.usa.gov/national-action-plan/5/
[28] See https://www.epa.gov/aegl/process-developing-acute-exposure-guideline-levels-aegls
[29] 80 Fed. Reg. 47565.
[30] 82 Fed. Reg. 2470.
[31] See *OEL Process*, https://echa.europa.eu/oel-process

14. 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 that the "proposed requirement for the TCE WCPP is that owners or operators ensure that no person is exposed to TCE in excess of the ECEL as an 8-hr TWA to the extent possible (supported by documentation further described in Unit V.A.2.d.i.)." Since these are new requirements and employers do not have a history of EPA's enforcement of such regulations, it is imperative that EPA provide additional clarification and guidance. EPA should clarify when exceedance of the ECEL represents non-compliance.

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

For the purposes of 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).[32] 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" or set of samples reveuated periodically 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 at a particular facility.

16. The WCPP and ECP Should Assist Employers in Reducing Exposures to TCE to the Extent Necessary so There is no Unreasonable Risk.

EPA's proposed requirement for the TCE WCPP is that owners or operators ensure that no person is exposed to TCE in excess of the ECEL as an 8-hr TWA *to the extent possible* rather than a requirement that *exposures do not exceed the ECEL*. The approach suggests that EPA believes all instances where the air concentration exceeds the ECEL constitute unreasonable risk. However, few if any actual conditions of use conform to the assumptions underlying the ECELthat is, continuous, uncontrolled exposure for 8 hours per day, 260 days per year, 41 working years starting at age 16. Consequently, EPA would be requiring employers to reduce exposures to an extent *greater than necessary* so that TCE does not present an unreasonable risk in conflict with TSCA Section 6(a).[33] This is inconsistent with the admonition in Section 6(a) that regulatory measures be applied only to the extent necessary to remove the unreasonable risk.

17. To the Extent EPA is Proposing Risk Management to Include Compliance with an Occupational Exposure Limit (here an ECEL), It Should be Both Measurable and Achievable.

EPA proposed several options for alternative compliance with the ECEL since the technology does not currently exist to reliably measure airborne concentrations to that level.

[32] Jahn SD, Bullock WH, Ignacio JS, et al. (2015) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA.
[33] 88 Fed. Reg. at 74735.

- EPA proposed that "no person is exposed to TCE in excess of the ECEL as an 8-hr TWA *to the extent possible*"[34] [emphasis added]; that is, the lowest achievable level.

- EPA requested comment on setting such an interim level for TCE based on a limit of detection that is the lowest limit of detection using analytical methods developed by OSHA/NIOSH for personal breathing zone monitoring.[35]

To the extent that an OEL is compulsory, it should be measurable and achievable by the regulated community. A health-based OEL is often an aspirational goal given the conservative assumptions regarding magnitude, frequency, and duration of exposures. A regulatory-adjusted OEL would be set to establish that minimum level of mandatory exposure control and reduction. Between the health-based OEL and the regulatory-adjusted OEL, there might be a range of actions that are expected to ensure exposure control is maintained.

18. The Minimum Achievable Exposure Limit for TCE Appears to be 0.360 ppm, with an Action Level of 0.180 ppm.

EPA requested comment on using OSHA Method 1001, which has a personal breathing zone limit of detection for TCE of 18 ppb, or 0.018 ppm, to set an interim exposure limit of 0.036 ppm, with an action level of 0.018 ppm.[36] Using the industrial hygiene convention of being able to detect 10% of the occupational exposure limit would lead to an interim exposure limit of 0.360 ppm, with an action level of 0.180 ppm.

19. Any Compulsory Occupational Exposure Limits Should be Applied Only to the Extent Necessary Such that the Substance no Longer Presents an Unreasonable Risk.

EPA notes that facilities processing TCE as an intermediate to manufacture HFC-134a have TCE largely confined to the process reactors, which require infrequent loading and unloading activities taking place approximately 20 times per year and resulting in low-ppm TCE exposure levels. To the extent an occupational exposure limit is necessary for this condition of use, it should be modified based on circumstances for specific facilities from the assumptions used in calculating the ECEL – that is, continuous, uncontrolled exposure for 8 hours per day, 250 days per year for a 40-year working lifetime.

20. The ECEL Overestimates Years of Worker Exposure.

The chronic ECEL values estimates an employee will spend 40 years in a position conducting tasks with potential exposure. EPA's assumption of 40 years of exposure is not consistent with available data on employment tenure. The median employment tenure for workers in the chemical industry is 10 years or less, taking into account all age groups, according to the most recent Bureau of Labor Statistics data. Data from the Employee Benefit Research Institute

[34] Id. at 74735.
[35] Id. at 74738.
[36] Id. at 74776, Section IX, 16.

(EBRI), moreover, show that over the past 35 years, the median tenure with one employer of all wage and salary workers ages 25 or older has remained steady at approximately five years. It is most unlikely that a worker will change jobs to work at another TCE manufacturing facility, especially since there is only one domestic manufacturer and very few facilities that produce TCE unintentionally at low levels as a byproduct.

In terms of estimating a high-end employment tenure, the EBRI data show that approximately 80 percent of older workers (ages 55-64) have tenures at one employer of less than 25 years, and the current trend is consistently toward lower tenures.[20] EPA's assumption of 40 years for high-end exposures is very far outside the range of reasonable high-end exposure duration.

Based on the available information, a more appropriate assumption for the central tendency of exposure duration is in the range of 5 to 10 years (not 40 years), while a more appropriate assumption for high-end exposure duration is 25 years. This is consistent with other EPA risk assessment guidance (*e.g.,* EPA Regional Screening Levels).

21. EPA Should Incorporate More Useable Action Levels in Those Risk Management Rulemakings that Include Occupational Exposure Limits.

EPA seeks comment on whether the action level should be set at a different value closer to the ECEL that would trigger increased monitoring to ensure that the ECEL is not exceeded.[37] It is recommended that a value different than 50% should be considered for the Action Level. As EPA indicates, the Action Level is not designed to be health protective, as any exposure below the ECEL would be health protective. As such, a more usable Action Level would be 80% of the ECEL. This level would allow resources spent on IH monitoring to show compliance with a low Action Level to be spent on identifying innovative controls for managing exposure risk.

22. Area Source Monitoring Is Not an Appropriate Substitute for Personal Breathing Zone Monitoring for Purposes of Compliance.

EPA requested comment regarding use of area source monitoring instead of personal breathing zone as a representative sample of exposures.[38] Area source monitoring 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 source monitoring be used. Certainly, the proposed ECEL and action limit for TCE will be difficult to monitor, but area sampling is not an appropriate substitute – and particularly not for compliance purposes.

[37] Id. at 74776, Section IX, 23.
[38] Id. at 74776, Section IX, 25.

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

EPA requested comment regarding the ability of owners and operators to conduct initial monitoring within 6 months after date of publication of the final regulation.[39] It is important that there be an assurance that sufficient lab capacity is 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 that 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.

24. 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[40] uses the Brief and Scala approach[41] 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.[42,43] AIHA offers a free spreadsheet-based tool for Toxicokinetic Extended Shift OEL Adjustment.[44] 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.

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

The monitoring requirements associated with the ECEL under the WCPP, would mandate that each owner or operator

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[39] Id. at 74777, Section IX, 33.
[40] Available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-exposure-limits.
[41] Brief, R.S., and R.A. Scala: Occupational exposure limits for novel work schedules. Am. Ind. Hyg. Assoc. J. 36:467–469 (1975).
[42] 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.
[43] 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.
[44] 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.

> … 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").[45]

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 inhalation exposure to chemical substances or mixtures is reasonably likely to occur and be similar.[46]

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."[47] EPA should confirm that its definition of an exposure group in the proposed rule 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.

26. 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. EPA proposes periodic exposure monitoring is required at least once every five years when all initial exposure monitoring is below the ECEL action level (<0.00055 ppm 8-hour TWA). 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.

[45] 88 Fed. Reg. 74738.
[46] Id. at 74786.
[47] Jahn SD, et al. (2015) A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA, p. 37.

In the Proposed Risk Management Rule for Methylene Chloride (88 Fed. Reg. at 28303), EPA proposed the 5-year data refresh because of fatalities: "Given the steep dose response for methylene chloride that may lead up to and include fatalities as a result of inhalation exposure, EPA is instead proposing to require that a minimum initial monitoring frequency be established at 5-year intervals." There is no similar concern for fatalities from (acute) trichloroethylene exposure. As such, recurring 5-year initial monitoring is not warranted.

27. Existing Exposure Monitoring Methods are not Adequate to Support an ECEL.

EPA requested comments on whether there are personal air sampling devices that are capable of detecting indoor air TCE concentrations at or below the ECEL action level of 0.00055 ppm (0.0029 mg/m^3) with the requisite precision and accuracy.[48] Additionally, EPA requested comment on setting an interim ECEL for TCE based on the limit of detection associated OSHA Method 1001, [49] which has a personal breathing zone limit of detection for TCE of 18 ppb, or 0.018 ppm. As such, EPA proposed to set an interim exposure limit of 0.036 ppm, with an action level of 0.018 ppm.

To improve compliance with the WCPP, IH Methods will need to detect below the ECEL-Action Level, not simply the at ECEL. That means methods will need to focus on detection limits *below* half the ECEL, in the *part per trillion (ppt)* range. According to the WCPP, if you are not below the ECEL Action Level, monitoring must continue every six months.

Detection limits are typically set at a fraction of the OEL. Current practices for OSHA and NIOSH require laboratories to quantify results by at least ten percent of the exposure limit (0.000 055 ppm, or 55 ppt). As such, when a chemical has an ECEL that is much lower than the limit of detection, labs will not be capable of quantifying results below the ECEL and assist in demonstrating compliance with the ECEL. As a result, current non-detect results above the ECEL create a challenge for analysts trying to select the best statistical approach to translate those non-detect values into usable values that can be compared against the ECEL, and ECEL Action Level. Conversely, if EPA were to set an interim ECEL for TCE based on the limit of detection associated OSHA Method 1001, it should set the proposed action level at 10X the limit of detection, that is, 180 ppb (0.180 ppm), and the ECEL at 360 ppb (0.360 ppm).

Industrial hygiene laboratories will need to switch from typical methods that use sorbent tubes and sample media solvent desorption (OSHA Method 1001) to a more sensitive method that may involve a completely different approach. EPA's Office of Research and Development (ORD) maintains a Compendium of Methods for determination of toxic organic compounds in ambient air.[50] EPA Compendium Method TO-14 and TO-15 use canister-based sampling and gas chromatographic analysis that can be used for ambient concentrations of volatile organic

[48] 88 Fed. Reg. at 74776, Section IX, 15.
[49] Id. at 74776, Section IX, 16.
[50] See USEPA Ambient Monitoring Technology Information Center (AMTIC), Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air: https://www.epa.gov/amtic/compendium-methods-determination-toxic-organic-compounds-ambient-air.

compounds. However, Method TO-14 appears to have a similar limit of detection as OSHA Method 1001[51] though TO-15 "applies to ambient concentrations of VOCs above 0.5 ppbv."[52]

EPA TO-17 Method uses a sorbent tube/thermal desorption/gas chromatographic-based monitoring method for VOCs in ambient air at 0.5 to 25 parts per billion (ppbv) concentration levels. However, the vast majority of IH samples collected across industry use solvent desorption methods. Use of thermal desorption is not common across industry, as a result very few laboratories have this analytical capability. Thermal desorption technology can detect chemicals at much lower concentrations but the changeover to this new technology can be difficult, expensive, and take a long time. Very few labs have the capability to analyze IH samples using thermal desorption. First, it will require labs to purchase new thermal desorption analytical equipment. Second, this will require equipment set-up and testing validation. Third, as this is not common technology, additional training and expertise will be needed to reliably utilize this equipment. Additionally, most thermal desorption methods are active, requiring a sampling pump, which increases the complexity of the collection process. This change will require significant investment and time before it will be widely available for use by industry.

28. EPA Should Consider the Cost and Time Needed to Develop Methods, and Laboratory Capacity, in Setting an Occupational Exposure Limit as Part of Risk Management.

EPA is requesting comment regarding the amount of time, if any, it would take the regulated community to develop a method to measure at or below the ECEL over an entire work shift.[53] Based on feedback from a commonly used AIHA Accredited ISO17025 Lab, an IH method extension may be possible for TCE. The method would use a 3M/Assay Technology 525AT passive badge, a gas chromatograph paired with a mass spectrometer detector (GC/MS) and follow Method NIOSH 1022. This method should be able to detect at about 0.00011 ppm, which is about 20% of the 0.00055 ppm ECEL Action Level. This method extension would take about 6 months to develop and validate to meet the EPA criteria for a validated sampling method. The cost of the method extension is about $10,000.

EPA should consider that the method extension is only good for the lab where it was validated. To use this method, other labs would need to validate it on their equipment, under their operating conditions, using their analytical expertise. A cost is incurred for each additional lab that would use this method to validate the use within their lab. In addition, the company that sponsored and

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[51] U.S.29. EPA. 1999. Determination Of Volatile Organic Compounds (VOCs) In Ambient Air Using Specially Prepared Canisters With Subsequent Analysis By Gas Chromatography. Compendium Method TO-14A. In *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, Second Edition (*EPA/625/R-96/010b). U.S. Environmental Protection Agency, Office of Research and Development, Center for Environmental Research Information, Cincinnati, OH.

[52] USEPA. 1999. Determination Of Volatile Organic Compounds (VOCs) In Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/ Mass Spectrometry (GC/MS), Compendium Method TO-15. In *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air, Second Edition (*EPA/625/R-96/010b). U.S. Environmental Protection Agency, Office of Research and Development, Center for Environmental Research Information, Cincinnati, OH.

[53] 88 Fed. Reg. at 74776, Section IX, 34.

paid for the original method extension work would have to be willing to allow the method to be shared with other labs.

Ideally, EPA should sponsor a method validation study for any chemical that is being evaluated to verify it can detect below the ECEL Action Level. The method should then be published so that all impacted companies could use the method and work with their labs to validate it for use. There would still be some cost incurred by each company to transfer the method to their lab. But overall, this would be the best, most efficient, and cost-effective way to ensure industry is collecting quality data that meets EPA's needs.

29. Requiring Resampling when Results Indicate Non-Detect is Unnecessary.

The proposed requirement in 40 CFR 751.707(b)(3)(i)(E) to re-monitor within 15 working days when results indicate non-detect is unnecessary. Standard practice using accredited labs to perform IH sampling analysis with results reviewed by IH professionals will lead to generation of reliable data. Requiring an Environmental Professional or Certified Industrial Hygienist to determine whether to re-monitor is an unnecessary step that adds no value. Additionally, incorporating a six-sample rolling average or periodic sample set as the statistical evaluation would incorporate ongoing validation of exposure levels for a particular task thus remove any potential need for resampling based upon a non-detect result.

30. 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 trichloroethylene 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 sizable 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. EPA requested comment regarding the timing of the initial exposure monitoring so that it would be representative of all tasks involving TCE where exposures may approach the ECEL.[54] This timing should be extended from 6 months to 12 months to allow for infrequent routine tasks to be sampled. These tasks can occur monthly or quarterly. Sufficient time is needed to collect the proper number of samples and have them analyzed.

31. 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.

EPA proposes that "Exposure samples must be analyzed using an appropriate analytical method by a laboratory that complies with the Good Laboratory Practice Standards in 40 CFR part 792."[55] 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

[54] 88 Fed. Reg. at 74776, Section IX, 25.
[55] Id.

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.[56] Namely, that compliance with TSCA GLPs is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the American Industrial Hygiene Association (AIHA) Industrial Hygiene Laboratory Accreditation Program (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.

32. The Use of Dermal Protections Appropriate For Tasks Where Dermal Exposure Can Be Expected To Occur.

ACC concurs with EPA's proposal to require dermal protection for tasks where dermal exposure can be expected to occur.[57] However, the text proposed for 40 CFR 751.311(e)(4) should reflect the preamble of the proposed rule. That is, the text should be changed to remove "is possible" to read:

… where dermal contact with TCE can be expected to occur.

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

ACC supports the proposed requirement that the owner or operator must inform persons whose exposures are represented by the monitoring of the results within 15 working days.[58]

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

[56] https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/new-chemicals-exposure-limits.
[57] Id. at 74742.
[58] Id. and proposed 40 CFR 751.311(b)(3)(v).

EPA requested comment regarding specific required elements of a WCPP or Prescriptive Controls:[59]

- 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 (Section IX. 27).
- 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 minimum service life of non-powered air-purifying respirators such as the requirements found in OSHA's General Industry Standard for Benzene (Section IX. 29).
- EPA requests comment on the degree to which additional guidance related to use of gloves might be necessary. Additionally, EPA requests comment on whether EPA should incorporate additional dermal protection requirements into the exposure control plan or require consideration of the hierarchy of controls for dermal exposures (Section IX. 31).

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)

Cartridge replacement should be determined on an individual basis using tools provided by respirator cartridge manufactures to set a service life schedule. These manufacturer tools consider workplace variables such temperature, humidity, and work rate to better estimate a more realistic and protective cartridge change schedule. Moreover, a prescriptive standard with respect to respirator cartridge replacement is inadvisable as the cartridge technology may change over time, resulting in an outdated regulatory requirement. A cross-reference to the Subpart I provision 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.

Similarly, EPA has proposed that "each potentially exposed person required to use PPE" be retrained at least once annually or "whenever the owner or operator has reason to believe that a previously trained person does not have the required understanding and skill to properly use PPE."[60] The requirement to re-train annually is not part of the OSHA PPE Standard 29 CFR 1910.132. EPA should not require retraining annually but should align with OSHA 29 CFR 1910.132(f)(3) which mirrors the later portion of the proposed EPA requirement. Requiring annual training is not necessary. Focus should remain on retraining when deficiencies are identified, or changes occur.

[59] Id. at 74775-79, Section IX.
[60] Id. at 74791.

35. Attestations that Engineering Controls Do Not Increase Emissions of TCE to Ambient Air Outside, and Air Monitoring Are Unnecessary.

EPA requested comment on whether owners and operators should be required to attest in their exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air.[61]

EPA states that the proposed requirement is intended to avoid unintended increases in exposures to people, presumably the general population, from TCE emissions to ambient air. The proposed rule would require owners and operators to attest in their WCPP/ECEL exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture emissions of TCE to ambient air. EPA requested comment on how this proposed requirement may impact the availability, feasibility, or cost of engineering controls as a means to reduce workplace exposures to or below the proposed ECEL.

This proposal seems at odds with reasoning that is articulated later in the proposed rule:

In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more TCE outside, EPA believes this potential exposure would be limited as a result of the existing NESHAP for TCE for these conditions of use under the Clean Air Act (88 Fed. Reg. at 74770).

ACC agrees with EPA's premise that NESHAPs for TCE will mitigate potential general population exposures that could occur as a result of greater workplace controls ventilating TCE outside of facilities. As such, EPA should not implement the requirement that owners and operators attest in their WCPP/ECEL exposure control plan that engineering controls selected do not increase emissions of TCE to ambient air outside of the workplace. EPA needs to improve its analysis of potential exposures to fenceline communities so that the results meet the Scientific Standards under the statute [15 U.S.C. § 2625(h)], if it is going to be used to inform risk determinations and risk management.

EPA also solicited comment on the frequency and nature of air monitoring EPA should consider including as requirements in the final rule.[62] This request was in the context of its fenceline analysis in the risk evaluation. Unfortunately, EPA noted that the "fenceline analysis for the air and water pathways for TCE did not allow EPA to rule out unreasonable risk to fenceline communities with confidence."[63] That is, EPA could not conclude whether TCE does or does not present an unreasonable risk to fenceline communities as a potentially exposed or susceptible subpopulation. This outcome points to two significant deficiencies associated with the fenceline screening analysis as part of the risk evaluation. First, as part of a tiered assessment approach, an ambiguous result would compel refinement of the assessment to reduce or eliminate the associated uncertainty. Regretably, EPA has not adequately developed the Problem Formulation

[61] Id. at 74778, Section IX, 50.
[62] Id.
[63] Id. at 74769.

of the risk evaluations so that a transparent and rigorous decision framework underpins the risk evaluation and the critical questions are answered by the evaluation.

In addition, as ACC has noted in previous comments, the fenceline screening analysis is not fit for the purpose of determining whether a chemical substance presents an unreasonable risk of injury to health or the environment. EPA conducted a fenceline screening analysis for potentially exposed or susceptible subpopulations (PESS) living adjacent to facilities manufacturing or using TCE as part of its 2022 Draft Screening Level Approach.[64] The approach evaluated fenceline communities for exposure to air and water releases based on emissions for an individual reporting year (2019) from those facilities; however, additional analyses to evaluate the air risk over a five-year period (*i.e.*, the multi-year analysis) were added later to support the risk determination.[65]

The water pathway screening assessment evaluated acute and chronic water exposures (drinking water, and dermal and incidental ingestion while swimming) across two different scenarios: a 20-day release scenario and a maximum number of days release scenario.[66] Chronic exposures addressed noncancer and cancer risks. Water exposure concentrations were modeled using E-FAST, a screening level model developed by EPA (last updated in 2014). Key results are shown in the table below:

[64] US EPA. 2022. Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0 [Public comment draft]. EPA-HQ-OPPT-2021-0415-0012.
[65] US EPA. 2022. Internal memorandum to J. Wolf, et al. re: Trichloroethylene (TCE): Fenceline technical support - ambient air pathway. EPA-HQ-OPPT-2020-0642-0091.
[66] US EPA. 2022. Internal memorandum to J. Wolf, et al. re: Trichloroethylene (TCE): Fenceline technical support - water pathway. EPA-HQ-OPPT-2020-0642-0062.

Summary of TCE Risks From Water Releases[67]

	Drinking Water	Incidental Ingestion	Incidental Dermal
Acute Noncancer (20-day release)	Risk exceedance for noncancer developmental endpoint for at least one facility	Risk exceedance for noncancer developmental endpoint for at least one facility	Risk exceedance for noncancer developmental and immune endpoints for at least one facility
Acute Noncancer (maximum days of release)	Risk exceedance for noncancer developmental endpoint for at least one facility	Risk exceedance for noncancer developmental endpoint for at least one facility	Risk exceedance for noncancer developmental and immune endpoints for at least one facility
Chronic Noncancer	None	Risk exceedances for both the immune and developmental endpoints for the 20-day and maximum release scenarios	Risk exceedance for noncancer developmental and immune endpoints for at least one facility
Chronic Cancer	No risk exceedance: At least one facility indicated an increased cancer risk at or above 1 in 1,000,0000 (but less than 1 in 100,000) for both the 20-day and maximum days of release scenarios.	Not evaluated because "repeated exposures are not expected to continue across a lifetime."	Not evaluated because "repeated exposures are not expected to continue across a lifetime."

The fenceline risk to TCE *via* the air pathway was presented in the 2022 Draft Screening Level Approach. The TCE fenceline assessment included a pre-screening step, a single-year full analysis, and land-use analyses. The single-year screening analysis utilized AERMOD with 2019 TRI data (stack and fugitive air releases) for various facilities to evaluate possible risks within a 10,000-meter radius of the facility. In EPA's 2022 memorandum on the air pathway,[68] the fenceline assessment was supplemented with a multi-year analysis with TRI data from 2015-2020 to confirm risk results did not vary significantly over time. The single-year and multi-year analyses were accompanied by a land-use analysis to determine whether community members were located in the areas near facilities with cancer risks above the benchmark of 1×10^{-6}.

In the single-year screening analysis, both noncancer and cancer risks were evaluated, but only cancer risks exceeded the benchmark. A total of 99 of 133 evaluated generic or modeled facilities had estimated cancer risks greater than 1×10^{-6} (US EPA, 2022b). All risks above 1×10^{-4} were within 100 meters of the evaluated facilities. The land-use analysis for these facilities determined that 69 of the 85 (actual) facilities had possible risks to fenceline communities (i.e., risks above 1×10^{-6}). The multi-year analysis, which was based on less a sophisticated model and evaluated more limited distances, was relatively consistent with the single-year analysis.

EPA highlighted several limitations of the assessment, including the lack of information on precise location of air releases, use of default stack parameters (stack height, stack diameter, exit temperature, etc.), and the use of TRI data. Although not specifically noted by EPA, the lack of exact stack locations can be particularly problematic since most risks above $1x10^{-4}$ are within 100 meters of the emission source. Given the large size of many of facilities, it is possible that if emissions are divided among multiple stacks, or if stacks are located toward the middle of a large

[67] 88 Fed. Reg. 74712.
[68] EPA-HQ-OPPT-2020-0642-0091.

facility, the modeling may not result in off-site risk exceedances. Also, taller stacks (i.e., higher than default of 10 meters) would also reduce ground-level concentrations and risks.

EPA concluded that "exposures to any fenceline communities from these facilities would be eliminated under the prohibitions in this proposed rulemaking." EPA further concluded that "[t]he risks to fenceline communities from exposure further strengthens the impetus for EPA's prohibition of TCE.". It is entirely inappropriate for EPA to impose risk management actions based on screening level analyses that do not meet the Scientific Standards under the statute [15 U.S.C. § 2625(h)].

36. 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.[69] 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 chemical-by-chemical 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 manhours to address the risk.

In the case of chemical exposures, the 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.

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.

[69] *See* 15 U.S.C. § 2625(h).

37. EPA's Proposed Exposure Control Plan Misapplies the NIOSH Hierarchy of Controls and Sets Unrealistic Documentation Requirements for Owners and Operators.

ACC is pleased to note that in the TCE rule, EPA correctly recognizes that, when implementing controls according to the NIOSH hierarchy of controls, controls may be used alone or *in combination* to reduce exposures.[70] ACC believes that a combination of controls is the best way to manage chemical exposure risks in the workplace, and that this approach is aligned with standard practices in workplace health and safety, industrial hygiene, and process safety.

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 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.

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.

In addition, EPA proposes to require the following of owners or operators in their ECP:

> (i) Identification and rationale of exposure controls used or not used as a time-limited measure in the following sequence: elimination of TCE, substitution of TCE, engineering controls, and administrative controls to reduce exposures in the workplace to either at or below the ECEL or to the lowest level achievable of TCE in the workplace
>
> (iii) If exposure controls were not selected, document the efforts identifying why these are not feasible, not effective, or not otherwise implemented.

It remains unclear what level of documentation is required for owners or operators to demonstrate their rationale that a particular control was not feasible to implement, and how many

[70] See, e.g., ACC's comments filed on the proposed TSCA risk management rule for perchloroethylene.

control options need to be evaluated, particularly with regards to the elimination and substitution levels of the hierarchy.

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 TCE 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.

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 (OTM) 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.

The sheer number of potential controls will make it impossible for owners or operators to prove that they have exhausted all potential control options and justified why they were not feasible, not effective, or not otherwise implemented. EPA should eliminate this requirement from the proposed rule and instead require only that owners or operators document which controls have been implemented to reduce employee exposures to below the ECEL.

If EPA requires additional assurance that the hierarchy of controls has been adequately followed, ACC suggests that EPA require that a qualified or competent person sign off that the hierarchy of controls was considered in the implementation of exposure controls. ACC suggests the definitions used by OSHA:

> *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 CFR 1910)

[71] https://www.cdc.gov/niosh/topics/hierarchy/default.html
[72] https://www.osha.gov/otm/section-5-construction-operations/chapter-3

> *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))

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 judgment in determining which controls will be most effective for the specific workplace and tasks performed.

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

The proposed TCE 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 §751.5 are not aligned with the definition of employee and employer as defined by OSHA. 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 TCE is present. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.[73]

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 TCE in the workplace, including providing PPE, fit testing, training workers, conducting medical surveillance, and keeping any necessary records. 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.[74] "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[75].

[73] 88 Fed. Reg. at 74786.
[74] 29 U.S.C. § 654(a).
[75] 29 C.F.R. § 1910.2(c).

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 employers sharing a single worksite. In these situations, the employer still has a duty to their 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 TCE 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 are using the provided respirators whenever TCE exposures may exceed the ECEL, that persons do not engage in non-work activities that may increase TCE 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 TCE 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 its facility, including implementing any permanent engineering controls and correcting any hazards identified. It would also be responsible for training its own employees, setting up a medical evaluation or fit testing program for its employees, and providing needed PPE for its employees. Company A would also be responsible for setting out requirements by 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 TCE, 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. Company A would need to train Contractor Z's employees

on site-specific policies and procedures, or provide these documents to Contractor Z for training its own employees. 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.[76] 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 his or her 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.

Take a slightly different situation, in which Company A contracts with Contractor Z to perform a specific task that uses TCE. 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 definition of "owner or operator;" however, for the reasons described above, this term is unnecessarily confusing to employers who have responsibilities to their employees under OSHA. ACC suggests that EPA strike the definition of "owner or operator" and instead replace it with a standard definition of "employer," such as the one used by the Cambridge Dictionary:

> A person, company or organization that employs people.[77]

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.

Alternatively, EPA could rephrase these requirements to state that owners or operators "shall ensure" that the requirement has been fulfilled. ACC has provided some examples of suggested changes as examples. Such changes could be made wherever the proposed regulation refers to owners and operators:

> §751.311(4)(iv) The owner or operator *shall ensure* that all persons within the regulated have been supplied with a respirator that complies with the requirements of paragraph (e) of this section and *shall ensure* that all persons within the regulated area are using the provided respirators whenever TCE exposures may exceed the ECEL.

[76] OSHA Multi-Employer Citation Policy. Directive CPL 02-00-124. December 10, 1999.
[77] *Employer*, Cambridge Business English Dictionary (1st ed. 2011).

§751.311(2)(d)(1) The owner or operator *shall ensure* that information and training is provided to each person prior to or at the time of initial assignment to a job involving potential exposure to TCE.

§751.311(2)(e)(5)(i) Owners and operators *shall ensure* that all persons required to use PPE prior to or at the time of initial assignment to a job involving potential exposure to TCE have been trained on how to properly use the required PPE.

In areas where EPA has cross-referenced OSHA regulations, the agency notes that provisions applying to an "employer" also apply equally to "owners or operators." As we have described in this section, these two terms are not equivalent.

These suggested changes will reduce unnecessary confusion among employers who oversee multi-employer worksites by better aligning with the standard understanding of responsibilities of employers who oversee multi-employer worksites, while still addressing EPA's concerns that all employees are adequately protected from the hazards of TCE.

39. Worker Training and Certification is 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*[78] 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 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.

[78] OSHA. 2015. Training Requirements in OSHA Standards. Available at: https://www.osha.gov/sites/default/files/publications/osha2254.pdf.

40. 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. Eighteen 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 the docket for this rulemaking.

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.

41. 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 focused on the safe use of PCE-based products used in the automotive industries. 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.[79] 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.[80] FCRI received a Training and Educational Materials Development Grant, which focuses on the development and validation of training materials to ensure their effectiveness in a classroom setting.

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 develops a short quiz that trainees take before and after the training. Results are then compared to see how much trainees learned from the training. The results of FCRI's trainings show positive results and improvement: where there was opportunity for improvement on a question, we saw improvement; with one question (What is the most effective control method?) seeing an increase in correct answers across all trainings of nearly 50% upon completion of the 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 there is a 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.

42. 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

[79] https://www.osha.gov/harwoodgrants/overview.
[80] https://www.osha.gov/harwoodgrants/statistics.

cause unreasonable adverse effects on the environment."[81] 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.[82]

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."[83]

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:

> (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…[84] [emphasis added]

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

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[81] 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
[82] 7 U.S.C. § 136(bb).
[83] 21 U.S.C. § 408.
[84] 15 U.S.C. § 2605(c)(2)(A)(i-iv).

classified as both a restricted pesticide and a general use pesticide, depending on how the pesticide is to be used.[85] 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 TCE, 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 (WPS) promulgated by EPA provides 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 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 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 TCE 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. 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 their requirements for such trainings, and require that EPA reviews and approves 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 TCE-containing products from a retailer. The retailer could be required to keep records of their sales to certified people. EPA

[85] See generally, FIFRA requirements for workers.

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 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. In addition, this kind of certification process would also give EPA a database of users of the product, facilitating compliance and enforcement actions. EPA has indicated that part of the reason for prohibition of the use of TCE is that they are unsure if businesses can meet the ECEL and other compliance requirements laid out in the proposed rule. If EPA oversees a system in which all known workplaces use the chemical, it is very easy to ensure that workplaces are complying with all provisions as laid out in the rule.

If EPA chooses not to establish a training, certification, and limited access program for TCE, it should clearly justify why such a program is inappropriate. The acute hazards associated with TCE 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 justify why a training, certification, and limited access program is acceptable for pesticides and not for TSCA-regulated substances.

43. EPA is Unnecessarily Duplicating OSHA's Hazard Communication Standard.

EPA proposes to require the implementation of a training program in alignment with the OSHA Hazard Communication Standard (HCS).[86]. The HCS applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.[87] As part of the HCS, employers are required to develop a written hazard communication program that includes, among other things, a list of hazardous chemicals known to be present in the workplace, the methods the employer will use to inform employees of the hazards of nonroutine tasks, and how criteria for labels, safety data sheets, and other forms of warning will be met.

EPA unnecessarily duplicates OSHA's HCS in the proposed TCE rule. Employers who use TCE in their workplace should already include TCE in their written hazard communication program and as part of their employee training. As described in other sections of these comments, the role of a workplace safety professional is to evaluate all hazards in the workplace, including all chemical hazards, and ensure that steps are taken to mitigate the associated risks. OSHA's HCS correctly recognizes that there are often multiple chemical hazards in the workplace and that a single program can address each of them; there is no need for EPA to require a separate hazard communication program for each individual TSCA chemistry. Employers should be allowed to utilize their existing hazard communication program to comply with this requirement.

[86] 88 Fed. Reg. at 74743.
[87] 29 C.F.R. §1910.1200(b)(1)

44. EPA Should Defer to OSHA Regarding Employee Representatives.

EPA has requested comment on whether the owner or operator should be required to permit designed representatives of employees and other workers to enter regulated areas to observe exposure monitoring.[88] ACC generally supports close alignment with OSHA regulations. In this case, we note that OSHA has a detailed Field Operations Manual, which provides guidance for designating employee representatives to assist Compliance Safety and Health Officers (CSHOs) during a walkaround compliance inspection. Given that EPA has not yet clarified how compliance with the proposed TSCA rules will work, ACC suggests that EPA hew to OSHA's guidance in this area.

45. The 50-year 6(g) Exemption for Disposal of TCE from Cleanup Projects Should Either be Removed or in the Alternative EPA Should Describe a Process in the Rule to Allow for Time Extensions.

As EPA is aware, TCE-contaminated sites have been investigated, characterized, remediated since the beginning of Superfund in 1980. Many sites have on-going treatment that have been operating for decades and will likely operate for decades to come due to the physical/chemical characteristics of TCE and site complexities including geology, hydrology, geochemistry, NAPL, etc. For example, sorption and/or diffusion into tight formations that can sequester TCE (i.e., clay) likely results in a very slow desorption and back diffusion of the contaminant into the groundwater during remedial activities; thereby, extending the anticipated overall cleanup timeline.

Moreover, there are likely still unidentified TCE-impacted sites that will need to go through a remediation process. Once identified, the sites need investigation/characterization, technology evaluation, piloting and full-scale installation of the remedial technology. As stated above, this process takes decades with no defined time limit.

EPA has not provided options as to how to address disposal of TCE from cleanup projects after the proposed 50-year exemption, nor has EPA quantified all the incremental costs of this proposed rule. As EPA suggests in the proposed rule: "[c]leanup sites would need to identify and implement alternative disposal or treatment methods and would likely also need to renegotiate RCRA permits or CERCLA agreements to include those changes."[89] These approaches would be more costly to implement and/or increase the duration of cleanups allowing any potential environmental or human health impacts to continue for a longer period of time. As indicated by EPA in the proposed rule, "the information to estimate how often these costs might be incurred or what the specific costs would be per site when they are incurred is not available."[90] Furthermore, the number of sites affected by this prohibition is unknown. Longer cleanup times and higher costs would have a negative impact on any entity and especially small business (i.e. dry cleaners, etc.) responsible for the TCE cleanup, potentially leading to remediation abandonment and overall higher human and environmental risk.

[88] 88 Fed. Reg. at 74741.
[89] Id. at 74717.
[90] Id.

Therefore, it is unreasonable for EPA to set any time limit that would interfere with other EPA and/or State statutes to remediate current or future TCE contaminated sites. If the 50-year prohibition is left in place this would only increase the potential for human health and environmental exposure to TCE contaminated media/wastes. As existing CERCLA and analogous State programs have regulatory authority over clean-up of contaminated sites, it is not clear why the TSCA program is proposing to regulate activities in this area. This is not consistent with Section 9 of TSCA. The 50-year exemption from the prohibition on disposal of TCE from cleanup projects should be eliminated or EPA should include language that allows an extension of this time limit.

46. The 50-year 6(g) Exemption from Prohibition on Essential TCE Laboratory Activities, Including Research and Development for Cleanup and Monitoring, Should be Removed or in the Alternative EPA Should Describe a Process in the Rule to Allow for Time Extensions.

Because remedial activities for TCE-contaminated sites could extend well past the 50-year exemption period, laboratory uses should be allowed to continue concurrently to support remedial activities. Moreover, limiting laboratory use of TCE will also hamstring research and development of more effective TCE remediation technologies. The result would be increased costs, longer cleanup times and increased risk to human health and the environment. The 50-year exemption from the prohibition on essential TCE laboratory uses should be eliminated or EPA should include language that allows an extension of this time limit.

47. EPA's Economic Analysis Is Deficient.

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, 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 failed to disclose the stream of benefits and costs;
- EPA inflated the benefits of cancer risk reduction;
- EPA failed to quantify the number of potentially displaced workers.
- EPA failed to acknowledge the ancillary cost of a black market.
- EPA did not adopt the least burdensome approach to regulation.

I

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.

OMB Circular A-4 states:

> "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 includes the following, which suggest it is aware that a loss in consumer surplus is a possibility, but cannot estimate it quantitatively:

> Unquantified costs include the following: applications where is more effective, reducing labor time and wait time that this analysis was unable to quantify,
>
> The costs of switching to alternatives of TCE are unknown for battery separator manufacture, synthetic paper manufacture, HFC manufacture, use as an intermediate in HCl production, and fluoroelastomer manufacture…
>
> Another example of when downstream users might have additional costs resulting from reformulation is when the reformulated product does not perform as well or is otherwise not a perfect drop-in substitute and they need to make changes in how they use the product. As discussed in Section 7.11, the analysis is unable to quantify these additional potential costs.

EPA should have been more forthright about the loss of producer and consumer surplus—a certainty for any regulation that restricts production/use of a commercial product.[91] It should further acknowledge that estimated compliance costs are an insufficient estimator of opportunity cost which, in our opinion, is significantly higher in light of the likelihood of facility closures (see discussion about displaced workers).

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.

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.

[91] "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.

> 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 includes little discussion or acknowledgement of substitution risk:

> Unquantified costs associated with implementing a respirator program, since respirators have been found to interfere with many physiological and psychological aspects of task performance…
>
> Within their submission, they summarized the following potential solvents and asserted that none are technically or economically feasible alternatives to TCE in their production process.

The lack of discussion about substitution risks is remarkable. For example, the economic analysis accompanying EPA's proposed methylene chloride rule stated:

> 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.

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 allow policy makers to determine if the benefits justify the risks in accordance with EO 12866.

Substitution risk need not be for the same endpoint nor operate via the same toxicological mechanism nor apply only to drop-in substitutes. All that matters is that the substitution risk arises 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.

EPA Failed to Disclose the Stream of Benefits and Costs.
OMB guidelines recommends disclosure of the stream of benefits and costs across time:

> To present your results, you should include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars…

The Agency's economic analysis does not provide a table with the undiscounted benefits and costs. Rather it provides just the annualized present value estimates of costs and benefits and net benefits. It should include such a table in its economic analysis for the final rule.

EPA Inflated the Benefits of Cancer Risk Reduction.
It is appropriate to monetize a reduction in cancer cases when that reduction is observable. This is in accordance with Circular A-4:

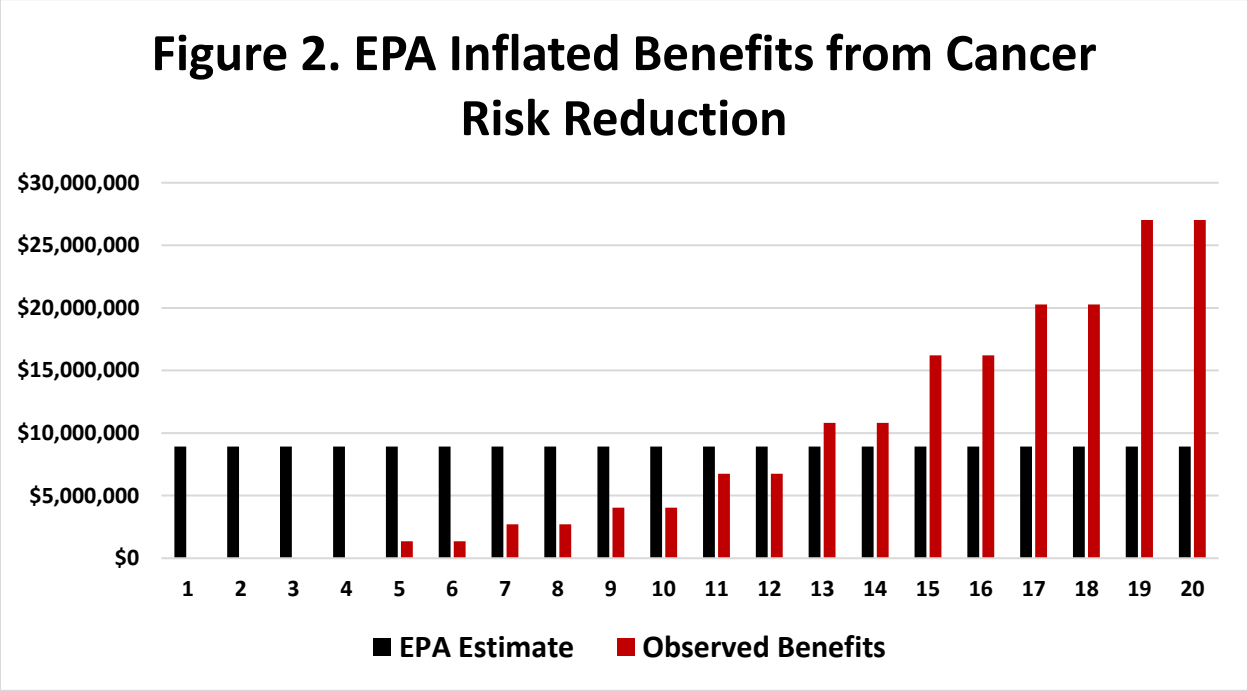
> A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status *will be observed* [emphasis added] in the target population. In such situations, you must carefully consider the timing of health 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 (for a given risk reduction measure, e.g., WCPP compliance), annualized benefits are not sensitive to the analysis timeframe.

EPA's approach (based on a "micro-risk reduction") is flawed because it inflates benefits. The Agency should have 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. This is a cessation lag model the Agency should have employed because it reflects risk reductions when they are observed, per OMB guidance. In reviewing the economic analysis for another TSCA risk management proposed rule (perchloroethylene), we found (see Figure) that the resulting monetized value of cancer risk reduction was 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.



EPA Failed to Quantify the Potential Number of Displaced Workers.
EPA should acknowledge distributive impacts of regulation, 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 states:

> 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. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups.

In its economic analysis, EPA acknowledges the following uncertainty in unquantified costs:

> Potential facility closures resulting from challenges to switching to TCE alternatives.

The Agency also acknowledges the possibility of displaced workers:

> Firms may discontinue operations if alternatives are unsuitable or greatly increase labor and costs for performing work. Therefore, economic impacts of prohibiting the commercial use of TCE may be significant for some uses. Vapor degreasing is one use of TCE where switching to a suitable alternative may be challenging . . . One compliance strategy may be to close or move their TCE vapor degreasing operation to a country where it is still permitted. It is unclear whether the proposed rule will affect the rate of firm closures and, if so, by how much. In addition, there is no standard generally accepted approach for estimating the cost impacts of a firm closure. Thus, EPA is unable to quantify any costs associated with potential firm closures for this analysis.
>
> Given these costs, affected facilities may opt to comply with the proposed rule by closing or shifting operations abroad where TCE use is not regulated. While EPA believes these facilities will be able to comply with the WCPP, some unknown number of facilities may close or move operations abroad. . . workers may experience job loss, at least temporarily. . . . Finding alternative work may be more challenging for older workers or workers with specialized skills that are not in demand elsewhere, or workers in communities with limited job opportunities.
>
> The baseline characterization suggests that workers in affected industries and regions, as well as residents of nearby communities, are often more likely people of color that the general population in affected geographic areas.

In its economic analysis, the Agency provides an estimate of workers in industries impacted by the proposed rule. Of particular interest is the number of workers in sectors where the Agency is proposing a WCPP for a limited period of time. For these sectors, the Agency could use off-the-shelf software (e.g., IMPLAN) to estimate potential job losses, which would include not just direct loss of jobs but indirect and induced job losses. In the recent proposed risk management rule for PCE, we found potential job losses in dry cleaning that were 50% higher than the direct jobs at risk according to EPA's analysis. In the economic analysis for its proposed risk management rule for methylene chloride, EPA's economic analysis failed to identify any job losses for polycarbonate resin producers, even though such U.S. producers would be prohibited from using methylene chloride to produce polycarbonate, which would result in facility closures impacting 1,500 direct jobs and 8,500 indirect and induced jobs.

In the case of the TCE proposed rule, sectors required to comply with a WCPP face a stark choice because the ECEL is set so low as to be, in many cases, a de facto ban. These sectors can expect displacement of workers—in other words, direct, indirect, and induced job losses. EPA should estimate these jobs quantitatively. The Agency should also make clear that these job

losses will disproportionately impact communities of color—the same communities that stand to benefit from reduced exposure from TCE.

The Agency should also acknowledge the significant adverse impact of job loss on the welfare of workers. 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. (We note that the recently revised Circular A-4—which will be operational for final rules after January 1, 2025, includes guidelines on weighting such impacts.) As Cass Sunstein,[92] 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?

The Agency should follow the advice in Circular A-4 and consider regulatory alternatives that reduce or eliminate potential unemployment effects. In particular, the Agency should consider setting an achievable ECEL that would minimize job loss.

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.

The prohibitions proposed by the Agency could foment a black market in TCE for uses where its efficacy is greater than available substitutes. And because the Agency acknowledges that it did not always consider efficacy, such impacts cannot be ruled out. 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 TCE in certain consumer products, EPA's monetized estimate of benefits will be reduced. The same possibility holds for any use of TCE where the Agency anticipates exposure reduction; a black market will lower the estimated risk reduction benefits of the proposed rule.

The Agency should consider and acknowledge the possibility of a black market and construct additional regulatory alternatives that would better foreclose the possibility of a black market.

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

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.

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.

The Agency should consider and construct additional regulatory alternatives that better represent a least burdensome approach (e.g., relying on OSHA standards in lieu of layering on the additional WCPP, or raising the proposed ECEL value, etc.).

In sum, EPA's economic analysis does not comport with standard practice, let alone best 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.

48. EPA's Alternatives Assessment is Inadequate.

In the TSCA risk management process, EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect."[93] In short, where EPA intends to prohibit a use, it must ensure that alternatives will be reasonably available, meeting the elements of the requirement. EPA did not do this.

EPA should provide a use and alternatives analysis for *each* condition of use included in the underlying risk evaluation. Here, EPA failed to do that, as is illustrated in Table 5-2 of the Economic Analysis.[94] For several uses, EPA explains that it did not perform an alternatives analysis because the agency did not find it "practicable" to do so due to the complexity of the analysis. This is not sufficient. One of these uses happens to be of exceptionally high importance to the Biden Administration's policy goals—namely, battery separator manufacture. Without battery separators, the batteries needed for electric vehicles are impossible.[95] EPA should perform a thorough and complete alternatives assessment on each identified condition of use and republish the conclusions. Careful review of safety and hazard tradeoffs, such as flammability, should be considered for TCE and any evaluated alternatives.

[93] 15 U.S.C. § 2605(c)(2)(C).
[94] See EPA's *Economic Analysis of the Proposed Regulation of Tricholoroethylene Under TSCA Section 6(a) (October 2023), ch.5, available in the docket.*
[95] See, e.g., "Without the separator, a battery's functionality is **void.** The porous polyolefin films control the leakage of ions when an auxiliary battery is ideal (self-discharge). The microporous layer doesn't allow electrical conductivity, thereby always acting as an isolator." [emphasis in original] Description of function of battery separator at www.wellpcb.com/battery-separators.html.