August 15, 2023

The Honorable Michael S. Regan
Administrator
U.S. Environmental Protection Agency
1220 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA) – Proposed Rule, 88 *Federal Register* 39652 (June 16, 3023), Docket No. EPA-HQ-OPPT-2020-0720

Dear Administrator Regan:

The Chlorine Panel of the American Chemistry Council (ACC) submits the enclosed comments on the proposed regulation of perchloroethylene under the Section 6 of the Toxic Substances Control Act (TSCA). ACC's Chlorine Panel represents manufacturers and users of methylene chloride and is deeply concerned about several aspects of the Agency's proposed risk management rulemaking. As described below, ACC's Chlorine Panel recommends that the proposed risk management rule for PCE be revised to –

- Improve the development of the ECEL by reevaluating the data available for central nervous system effects to define the point of departure more appropriately and to better align with exposure limits established by other authoritative bodies

- Conduct a robust assessment of the technical and economic feasibility of possible alternatives to PCE in its various conditions of use

- Remove the default prohibitions for industrial and commercial uses of PCE and allow for WCPP implementation

- Amend the requirements for implementation of the risk management provisions to
    - Extend the compliance timelines for initial exposure assessment and implementation of a performance-based WCPP
    - Provide for the use of control-banding approach to exposures during short-term tasks performed by similar exposure groups
    - Allow for averaging of samples from repetitive tasks to remove any need for resampling.

Moreover, ACC strongly supports the proposal to establish a *de minimis* exclusion for the use of products that contain less than 0.1 percent PCE by weight from the proposed controls.

In addition to the enclosed comments, the Chlorine Panel supports the comments of ACC. Please feel free to contact me at LeaAnne_Forest@americanchemistry.com or at 202-249-6706 if you have questions or wish to discuss the enclosed information.

Sincerely

LeaAnne Forest

LeaAnne Forest
Manager
Chemical Products and Technology Division

Enclosures

Comments of the Chlorine Panel
of the American Chemistry Council
on
Perchloroethylene – Regulation Under the Toxic Substances Control Act
88 *Federal Register* 39652
June 16, 2023
EPA-HQ-OPPT-2020-0720

Table of Contents

SUMMARY

Pursuant to Section 6 of the Toxic Substances Control Act (TSCA), if the Environmental Protection Agency (EPA) determines that a condition of use of a chemical substance presents an unreasonable risk to health or the environment, it must apply one or more risk management measures "*to the extent necessary* so that the chemical substance or mixture no longer presents" an unreasonable risk.[1] Therefore, the risk management rule should be no more stringent than necessary to achieve the statutory goal of eliminating the level of risk EPA has determined to be unreasonable for certain conditions of use. In addition, EPA's rule must be "supported by substantial evidence in the rulemaking record taken as a whole,"[2] consistent with the best available science, and based on the weight of the scientific evidence.[3]

The proposed risk management rule for perchloroethylene (PCE) would establish a requirement for the implementation of a workplace chemical protection program (WCPP) to comply with an existing chemical exposure limit (ECEL) of 0.14 parts per million (ppm). The proposed limits rely on EPA's assessment of the potential chronic, non-cancer risks to exposure to PCE. Based on the Agency's evaluation of the available data on exposures, EPA proposes to prohibit all consumer uses of PCE and several industrial and commercial uses of the substance, including its use as a processing aid in the manufacture of agricultural products, in cold cleaning, and in the cleaning of energized electrical equipment. The proposal also would phase out the use of PCE in dry cleaning over 10 years.

The Chlorine Panel of the American Chemistry Council (ACC-CP) is deeply concerned about the Agency's assessment of health effects for PCE that are the basis for the proposed ECEL. Moreover, Agency's proposal to prohibit industrial and commercial uses of PCE that it has

[1] 15 U.S.C. § 2605(a) (emphasis added).

[2] 15 U.S.C. § 2618(c)(1)(B)(i)(I).

[3] 15 U.S.C. §§ 2625(h) and (i).

determined are unable to implement an WCPP to comply with the ECEL is arbitrary and inconsistent with the Agency's mandate under TSCA.

As described below, ACC's Chlorine Panel recommends that the proposed risk management rule for PCE be revised to –

- Improve the development of the ECEL by reevaluating the data available for central nervous system effects to define the point of departure more appropriately and to better align with exposure limits established by other authoritative bodies

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    - Provide for the use of control-banding approach to exposures during short-term tasks performed by similar exposure groups
    - Allow for averaging of samples from repetitive tasks to remove any need for resampling.

In addition, ACC strongly supports the proposal to establish a *de minimis* exclusion for the use of products that contain less than 0.1 percent PCE by weight from the proposed controls.

EPA'S CONCLUSIONS ON THE TOXICITY OF PERCHLOROETHYLENE ARE NOT SUPPORTED BY THE BEST AVAILABLE SCIENCE

The Agency's proposal for managing risks associated with exposure to PCE relies on its assessment of effects on the central nervous system (CNS) reported in two studies in dry cleaning workers.[4] In addition, the 2020 Risk Evaluation indicates unreasonable cancer risks for various conditions of use (COUs) based on findings of liver tumors in laboratory animal studies. The Agency's assessment of CNS effects misinterprets the findings of the available studies and fails to acknowledge the conclusions of an expert panel convened by the Agency to evaluate PCE's neurotoxic potential. EPA's analysis of carcinogenic potential, moreover, relies on an inadequate analysis of the potential mode of action (MOA), as noted by another expert panel convened by the

[4] USEPA. Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro), CASRN 127-18-4. EPA-740-R1-8011 (2020). (PCE Risk Evaluation)

Agency. As a result, the ECEL proposed for PCE is significantly lower than those established by authoritative bodies around the globe after reviewing the same information as EPA.

EPA's Assessment of Chronic Non-Cancer Effects Misinterprets the Available Information

EPA's proposed ECEL of 0.14 ppm for an 8-hour time weighted average (TWA) relies on studies reporting impairment in visual contrast sensitivity and color discrimination in dry cleaning workers conducted by Echeverria *et al.* (1995)[5] and Cavalleri *et al.* (1994).[6] Although both studies suffer from significant limitations, [7], EPA used a midpoint of the points of departure (POD) from the two studies to generate the proposed ECEL. However, EPA's review of the studies fails to analyze the data from the study by Echeverria *et al.* appropriately and ignores the conclusions of the Cavalleri *et al.* study and of its own peer reviewers in analyzing the data from that study.

Echeverria *et al.* reported deficits in visuospatial function and memory among 65 dry cleaning workers, using a standardized neurobehavioral test battery. The workers were divided into three exposure groups – 11, 23, and 41 parts per million (ppm) for an 8-hour TWA – based on their job function. The researchers observed reductions in visual memory and pattern recognition within the middle and high exposure groups, when compared to the group with lowest exposure, matched based on age and education. No difference was observed in psychomotor function or simple attention. EPA's analysis identifies the middle dose of 23 ppm as a lowest observable adverse effect level (LOAEL), suggesting that, "without an unexposed group, the exposure level for the lowest exposure group cannot be classified as a LOAEL or a no observable adverse effect level (NOAEL)."[8] EPA also argues it could not conduct benchmark dose (BMD) modeling for the study, "without a control group or historical controls," despite noting that a BMD model would "improve precision in the POD."[9]

The Chlorine Panel notes, however, that EPA routinely conducts BMD modeling for studies lacking a control group[10] and has conducted its own analysis of the Echeverria *et al.* results for those effects reported to be statistically significant. As shown in **Table 1**, the Benchmark Dose

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5 Echeverria D *et al.* A behavioral evaluation of PCE exposure in patients and dry cleaners: a possible relationship between clinical and preclinical effects. *J Occup Environ Med* 37: 667–680 (1995).

6 Cavalleri A *et al.* Perchloroethylene exposure can induce colour vision loss. *Neurosci Lett* 179: 162–166 (1994).

7 Both studies are assigned a confidence rating of medium under the Agency's data quality evaluation. However, none of the other 11 human studies investigating CNS effects referenced in the Risk Evaluation were assigned a rating. https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0070

8 USEPA. Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4). EPA/635/R-08/011F. (2012), at 5-14. (PCE IRIS Assessment)

9 PCE Risk Evaluation, at 337.

10 See for example: USEPA. IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS, CASRN 335-46-4) and Related Salts. External Review Draft. EPA/635/R-23/148a (2023).

Lower Limits (BMDLs) for the results of the four visual tests for which significant differences were reported range from 18.22 to 26.48 ppm, with a mean value of 21.0 ppm.

Table 1. Results of Benchmark Dose Modeling of Data from Echeverria et al. Using BMDS 3.3 Software[11]

Visual Test	Adjusted Scores (Standard Deviation)			Benchmark Dose – Lower Limit (BMDL)	Recommended Model
	Low Exposure (11 ppm)	Medium Exposure (23 ppm)	High Exposure (41 ppm)		
Visual Reproductions Score	9.45 (1.21)	8.89 (1.24)	8.08 (1.24)	18.22	• Power • Linear
Pattern Memory/ No. Correct	10.51 (0.82)	10.36 (0.75)	9.70 (0.72)	18.71	Linear
Pattern Memory/ Response Time	5.79 (0.83)	5.78 (0.62)	6.37 (0.65)	26.48	Exponential 3
Pattern Recognition/ No. Correct	14.39 (0.49)	13.97 (0.49)	13.83 (0.70)	20.65	Power

Using the mean BMDL of 21.0 for the four tests as the POD allows for a more precise analysis of the Echeverria *et al.* data than EPA's current approach which uses the middle dose of 23 ppm as a LOAEL – requiring the inappropriate addition of a ten-fold uncertainty factor.[12]

In a study of 35 drycleaners Cavalleri *et al.* reported a subclinical color vision loss (using Color Confusion Index, or CCI) in the workers with higher exposure to PCE (*i.e.*, dry cleaners), when compared to a matched control group, but not in the group with lower exposure (*e.g.*, ironers). Based on the findings, the authors concluded that the data suggest "a mean threshold for colour vision effect of the solvent ranging approximately between 5 and 11 ppm." This conclusion is supported by the fact that the correlation between CCI scores and PCE exposure was dependent on three high values among the dry cleaners. The authors' conclusion was echoed by an expert panel convened by the Agency to review EPA's evaluation of the neurotoxicity of PCE.[13] In contrast, however, EPA has identified 6 ppm as a LOAEL rather than the using the mean dose of the low exposure group of 4.8 ppm as a NOAEL.[14]

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[11] The results of the model runs are included in Appendix A.

[12] PCE Risk Evaluation, at 349 (Table 3-12).

[13] USEPA. Summary Report of the Peer Review Workshop on the Neurotoxicity of Tetrachloroethylene (Perchloroethylene) Discussion Paper. EPA/600/R-04/041. National Center for Environmental Assessment. (2004).

[14] As noted by EPA, BMD modeling is not feasible for analyzing the data from Cavalleri *et al.*

The evidence for increased CCI among workers exposed to PCE is further challenged by the results of the study by Nakatsuka *et al.* (1992) which did not observe color vision loss among 64 dry cleaners exposed to 11 to 15 ppm PCE when compared to matched controls.[15] The study is referenced, but not discussed, in the 2020 Risk Evaluation and was not included in the Agency's systematic review of available studies. The 2012 IRIS assessment for PCE indicates, however, that the test method used by Nakatsuka *et al.* was less sensitive to mild changes in color vision than that used by Cavalleri *et al*.[16] Questions about the conflicting results between the two studies, however, led the German MAK Commission to question the toxicological relevance of the findings of Cavalleri *et al.* in its recent review of PCE.[17]

The Liver Tumors Observed in Laboratory Animal Studies Are Not Relevant to Humans

In addition to concluding that PCE exposure resulted in potential risks of CNS effects among workers, the 2020 Risk Evaluation also found unreasonable cancer risk in all of the industrial or commercial COUs evaluated in the absence of personal protective equipment (PPE). The finding of cancer risk relies on data from a finding of liver tumors in male mice, despite a lack of consistent findings in epidemiological studies and substantial evidence that the rodent tumors result from an MOA that is of questionable relevance to humans.

Several large cohort studies, and a number of case-control studies, have investigated the potential for PCE exposure to cause cancer, including liver cancer. Epidemiologic studies with a larger number of observed events or exposed cases, or a stronger exposure-assessment approach, show a mixed pattern of results. One case-control study with a large number of exposed liver cancer cases and a relatively high-quality exposure-assessment methodology reported an odds ratio estimate of 0.76 (95% CI: 0.38, 1.72) for liver cancer and dry cleaning (Lynge et al., 2006). However, dry cleaners did not have a higher liver cancer risk estimate than laundry workers or other categories of dry cleaning workers in the study. As a result, EPA concluded that the epidemiological data provide "little or no support for associations with . . . liver cancer."[18]

In carcinogenicity bioassays, PCE caused a statistically significant increase in the incidence of hepatocellular carcinomas in B6C3F1 mice following either oral gavage administration or inhalation

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[15] Nakatsuka H *et al.* Absence of blue-yellow color vision loss among workers exposed to toluene or tetrachloroethylene, mostly at levels below occupational exposure limits. *Int Arch Occup Environ Health* 64: 113-117 (1992).

[16] PCE IRIS Assessment, at 4-38.

[17] Hartwig A and MAK Commission. Tetrachloroethylene/1,1,2,2-Tetrachloroethene, MAK Value Documentation, 2017. MAK Collection for Occupational Health and Safety 4(4) (2019) (PCE MAK Documentation) https://doi.org/10.1002/3527600418.mb12718e6319

[18] PCE Risk Evaluation, at 329.

exposure.[19] Both sexes of Crj:BDF1 mice have also been shown to develop an increased incidence of hepatocellular carcinomas when exposed to tetrachloroethylene by inhalation.[20] Both mouse strains have a high spontaneous incidence of liver tumors, however, although the observed incidence in the studies was above the incidence in historical controls. Inhalation studies in rats did not report increased incidences of liver tumors up to 600 ml/m^3.[21]

Available evidence suggests that activation of peroxisome proliferator-activated receptor alpha (PPARα) by PCE may play a role in the development of liver tumors in the laboratory mice, which raises question about the relevance to humans. In laboratory animals exposed to PCE, several effects indicative of PPARα activation have been observed, including increases in the number and size of liver peroxisomes, increased expression of CYP4A peroxisomal marker enzymes, and increased hepatic levels of acyl CoA oxidase.[22] Studies comparing results in rats and mice have shown greater increases in acyl COA oxidase in the livers of mice exposed to PCE than in rat livers after exposure to the same doses. *In vitro* testing indicates that activation of mouse and human PPARα after exposure to PCE is likely mediated primarily by the metabolites, trichloroacetic acid (TCA) and dichloroacetic acid (DCA), as PCE itself was essentially inactive.

Research suggests that hepatocarcinogenesis caused through a PPARα activation may not be relevant to humans.[23] Hall *et al.* (2012) note the importance of considering available information on histological and clinical pathological changes when evaluating the relevance of rodent liver effects to humans.[24] Although EPA acknowledges that PPARα may play a role in the formation of mouse liver tumors, it asserts that PCE likely induces liver tumors through multiple modes of action mediated largely by metabolites." As a result, the Agency applied the default linear extrapolation in assessing the risk of PCE, after reviewing possible alternative MOAs for cancer. In reviewing the analysis, the Science Advisory Committee on Chemicals (SACC) concluded, however, that "the supportive evidence for some of the proposed mouse liver cancer MOA was

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[19] National Cancer Institute (NCI). Bioassay of tetrachloroethylene for possible carcinogenicity. (NCI-CGTR-13; DHEW Publication No. (NIH) 77-813). Bethesda, Md: National Institutes of Health (1977); National Toxicology Program (NTP). Toxicology and carcinogenesis studies of tetrachloroethylene (perchloroethylene) (CAS No. 127-18-4) in F344 rats and B6C3F1 mice (inhalation studies). (NTP TR 311). Research Triangle Park, NC: U.S. Department of Health and Human Services (1986).

[20] Japan Industrial Safety Association. Carcinogenicity study of tetrachloroethylene by inhalation in rats and mice. Hadano, Japan (1993).

[21] PCE IRIS Assessment, at 4-151.

[22] Ibid, at 319.

[23] Klaunig JE *et al.* PPARalpha agonist-induced rodent tumors: modes of action and human relevance [Review]. *Crit Rev Toxicol* 33: 655-780 (2003).

[24] Hall AP *et al.* Liver hypertrophy: a review of adaptive (adverse and non-adverse) changes – conclusions from the 3rd international ESTP expert workshop. *Toxicologic Pathol* 40:971-994 (2012).

minimal and/or circumstantial."[25] The SACC also noted that the evidence for genotoxicity in the mouse liver stemming from PCE exposure, the underlying assumption in applying a linear extrapolation "was not convincing to most Committee members."

The SACC noted that the available data do not provide support for the key events in a mutagenic MOA (i.e., DNA reactivity and mutagenicity in the tumor target tissue). Committee members questioned EPA's focus on the mouse liver tumors when there are little or no data supporting an association with PCE exposure in humans. They noted that, "while there is the potential for a genotoxic MOA in liver cancer, it is unclear how this can account for the induction of liver cancer compared to other MOAs such as cytotoxicity and compensatory proliferation documented for PCE."[26]

EPA'S PROPOSED EXISTING CHEMICAL EXPOSURE LIMIT IS NOT CONSISTENT WITH THOSE OF OTHER AUTHORITATIVE BODIES

In its proposal, EPA notes that the proposed ECEL is well below the occupational limits established by the Occupational Safety and Health Administration (OSHA), the American Conference of Governmental Industrial Hygienists (ACGIH), California's Occupational Safety and Health Administration (CalOSHA), and the National Institute for Occupational Safety and Health (NIOSH). In fact, however, the ECEL would be below the limits established anywhere in the world, which range from a low of 6 ppm in Norway to 50 ppm for Australia.[27] Although none of these values is based on an evaluation as recent as EPA's, many included consideration of the key studies identified in the Agency's Risk Evaluation. Among the most recent is the analysis conducted by Germany's Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) which resulted in a MAK value of 10 ppm for an 8-hour TWA.[28]

Like EPA, the MAK Commission identified neurotoxicity to be the most sensitive endpoint for PCE. Based on its review, the Commission concluded that -

> Qualitatively, the study of Echeverria *et al.* (1995) is regarded as the best study because relevant confounders were considered and indoor air monitoring of tetrachloroethylene was described in detail. After adjusting for the relevant confounders, several neuropsychological tests revealed significant differences

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[25] USEPA. Transmittal of Meeting Minutes and Final Report for the TSCA Science Advisory Committee on Chemicals Meeting via Phone and Webcast held May 26-29, 2020. EPA-HQ-OPPT-2019-0502-0055 (2020), at 80-81. (PCE SACC Report)

[26] USEPA. Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE), Response to Support Risk Evaluation of Perchloroethylene (PCE) (2020), at 210.

[27] IFA. GESTIS International Limit Values. https://limitvalue.ifa.dguv.de

[28] PCE MAK Documentation, at 2259.

> between persons exposed to high levels and low levels of the substance, suggesting a [lowest observable adverse effect concentration] of 40 [ppm] (exposure period: about 14 years). Hardly any effects on test performance were observed in the middle concentration group exposed to only about 20 [ppm], which is regarded as the [no observable adverse effect concentration].[29]

In discussing the results of color vision testing, the Commission concluded that the results "are inconsistent" and that the "toxicological relevance of these findings is unclear."[30]

Regarding carcinogenicity, the MAK Commission noted that it is unclear whether the finding of liver tumors in mice are relevant to humans. In considering the potential for effects on the liver, the Commission noted that –

> Under identical exposure conditions, the concentrations of covalent protein adducts from oxidative metabolism [of PCE] are much lower in the blood of humans than in the blood of rats . . . It can thus be assumed that compared with rats, humans are less sensitive to the hepatotoxicity caused by [PCE]. Mice are assumed to be more sensitive to hepatotoxicity than rats because the capacity to metabolize [PCE] by oxidation is several times higher in mice than in rats.[31]

Given the uncertainty about the significance of the mouse liver tumors, EPA's decision to rely on the CNS effects in developing the proposed ECEL is appropriate. However, the Agency's analysis misinterprets the results of the studies by Echeverria *et al.* and Cavalleri *et al*., contrary to the recommendations of its advisors and standard practice, and results in a proposed limit that is not supported by the best available science and that is inconsistent with values established by other authoritative bodies.

EPA'S ASSESSMENT OF DERMAL EXPOSURES IS FLAWED

EPA's proposed risk management provisions for PCE are based, in part, on its evaluation of risks from dermal exposure to the solvent. Both the 2020 Risk Evaluation and 2021 Revised Risk Determination include a finding of unreasonable risks to workers from acute and chronic dermal exposure in many of the industrial and commercial COUs – even with the most protective glove use (Protection Factor of 20). The models EPA used to estimate the amount of PCE that is retained by workers from dermal contact, however, are not based on any empirical information and overestimated any potential exposure. These "worst-case scenarios" assumed unrealistic dermal exposure durations and failed to recognize basic industrial hygiene (IH) practices, including

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[29] Ibid, at 2180.

[30] Ibid, at 2189.

[31] Ibid, at 2171.

implementation of OSHA-compliant standard operating procedures (SOPs). In the case of the manufacture of PCE and its use as process reactant or intermediate, moreover, EPA failed to incorporate the engineering controls required by the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Synthetic Organic Chemical Manufacturing Industry (SOCMI) [32] and Miscellaneous Organic Chemical Manufacturing (MON), [33] which require closed systems where exposure is tightly controlled.

The manufacture of PCE and its use in the production of other chemicals are COUs that occur in closed system process units where potential dermal contact is limited to short-term tasks in the operation of unit activities. Despite receiving a considerable amount of information on SOPs to minimize the potential for dermal exposure in these and similar operations, EPA estimated dermal exposure using a model that relied on a theoretical framework[34] that assumed the following –

- one dermal contact with undiluted PCE which coats fully one or both hands per work shift;
- workers do not wash their hands at any point during the 8-hour work shift if gloves are not worn; and
- a worker wears the same pair of gloves for the entire 8-hour work shift without stopping to wash their hands and/or change their gloves.[35]

EPA does not provide justification for these assumptions other than the intent to establish a theoretical "worst-case scenario." As a result, the Risk Evaluation substantially overestimated worker exposure to PCE from dermal contact in facilities that manufacture and use PCE as a reactant or intermediate. In reviewing the Agency's assessment of dermal exposures, the SACC noted that "some job tasks likely do not involve routine dermal contact with liquid PCE."[36] The Committee also noted that, in general, that –

> the worker exposures characterized in the [draft risk evaluation] are best described as a screening-level assessment. Due to the lack of readily available monitoring data and low confidence in the data sources, this assessment ***should not be used to decide whether health risks are reasonable or unreasonable***. The results of a screening-level assessment can be used to determine if further refinement and more data are needed.[37]

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[32] 40 C.F.R. Part 63 Subparts F, G, H, I.

[33] 40 C.F.R. Part 63, Subpart FFFF.

[34] Kasting BG; Miller MA. Kinetics of finite dose absorption through skin 2: Volatile compounds. *J Pharm Sci* 95: 268-280 (2006).

[35] USEPA. Final Risk Evaluation for Perchloroethylene – Supplemental File: Releases and Occupational Exposure Assessment. CASRN:127-18-4 (2020).

[36] PCE SACC Report, at 54.

[37] Ibid, at 51 (emphasis added).

In facilities using PCE in closed systems, any potential dermal exposures are for short durations and, combined with the industry IH practices at these facilities which require removal and disposal of potentially contaminated gloves and hand washing after each task completion, do not justify an 8-hour period for absorption of PCE through skin. A more realistic approach to estimating the dermal dose of PCE in workers in closed system facilities (*e.g.*, manufacturing, process reactant/intermediate use) can be obtained using the IH Skin Perm model.[38] This model takes into account losses to evaporation and estimates the mass that is absorbed and is commonly used by practitioners of IH and exposure assessment to produce reliable estimates of dermal exposure. In addition, IH SkinPerm can be used to evaluate the impacts of differing patterns of exposure on fractional and total dose of absorption, *i.e.*, it allows for the incorporation of realistic exposure patterns.

Recognition of standard work practices and reliance on reasonable and realistic exposure data are critical to meet the statutory requirements of TSCA. EPA's reliance on hypothetical assumptions for modeling the amount of PCE that is absorbed by workers from dermal contact cannot be justified. Assumptions used for estimating worker exposures should be as relevant as possible for the COUs being evaluated. EPA's use of unrealistic dermal exposure assumptions has led to erroneous conclusions regarding the health risks to workers using PCE in closed systems. Because the Risk Evaluation is intended to determine whether PCE presents an unreasonable risk of injury to workers under TSCA § 6(b), which requires rulemaking to mitigate risks found to be unreasonable, it is imperative that it be revised to reflect the "best available science" in advance of any risk management rulemaking.

EPA'S CONSIDERATION OF ALTERNATIVES IS INADEQUATE

When deciding whether to prohibit or restrict a chemical substance that substantially prevents a specific condition of use, as with the current proposal, Section 6(2)(C) of TSCA requires EPA to consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute." Rather than consider the technical and economic feasibility, as required by Section 6(2)(C), the Agency's assessment of PCE alternatives presents –

> (1) a representative list of reasonably available alternatives for consideration by EPA, to the extent practicable and based on reasonably available information, to form a snapshot of the current market; and (2) where practicable, to enable EPA to compare the human health hazards, environmental hazards, potential

[38] IH SkinPerm is a peer-reviewed exposure assessment tool published by the American Industrial Hygiene Association (AIHA) Exposure Assessment Strategies Committee.

> persistence, and bioaccumulative properties of each chemical for each product in each product category.[39]

The Alternatives Assessment does not address the fundamental question of whether the alternatives identified are reasonably available and technically and economically feasible. Indeed, the Agency acknowledges that -

> EPA did not find it practicable to consider alternative processes that may be reasonably available as a substitute for processes involving PCE when the proposed prohibitions or restrictions would take effect . . . This is due to numerous considerations including uncertainties about alternative processes that may be reasonably available, the difficulty of ascertaining whether any alternative processes may be technically and economically feasible, and the challenges of comparing the benefits of alternative processes to the benefits of the PCE-containing processes.[40]

Although the Assessment suggests that consideration of feasibility is included in the Agency's Economic Analysis, the discussion of alternatives in that document is equally inadequate. As in the Alternatives Assessment, the Economic Analysis is mostly limited to a comparison of hazards and physical properties, not an evaluation of the actual feasibility of replacement. It compares physical characteristics and health effects of potential alternatives, and even customer satisfaction, but does not consider the physical/chemical properties of PCE that make it *uniquely* suited to many uses.

As a result, the Economic Analysis comes no closer to meeting the requirements of Section 6(2)(C). In fact, the Agency explains early in the document that it was not able to quantify the costs of replacing PCE and notes that -

> Although certain costs cannot be quantified, this does not mean that they are less important than the quantified costs. . . the most notable unquantified cost includes applications where PCE is more effective, reducing labor time and wait time, and this analysis was unable to quantify these costs. There may be some safety-critical applications, such as adhesives used in aviation, where alternatives would need to undergo extensive safety reviews and testing before they could replace the PCE adhesives. The impact of a prohibition of PCE for these uses could therefore lead to significant unquantified costs.[41]

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[39] USEPA. Alternatives Assessment for Use of Perchloroethylene (2023), EPA-HQ-OPPT-2020-0720-0104, at 7-8. (PCE Alternatives Assessment)

[40] Ibid, at 7.

[41] USEPA. Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a). RIN 2070-AK84. (2023). EPA-HQ-OPPT 2020-0720-0125, at ES-10. (PCE Economic Analysis).

In the absence of a meaningful review of alternatives, it is not surprising that "EPA does not have sufficient information to confidently conclude that these conditions of use can meet requirements of a WCPP for PCE."[42] EPA's failure to meet its obligation to consider alternatives cannot, however, justify its exclusion of thousands of users from the opportunity to implement a WCPP. Of particular concern is the Agency's failure to adequately address the flammability of many of the identified PCE alternatives, despite numerous concerns raised by members of the Small Business Review Panel during its review of the Agency's plan to restrict PCE use.[43]

EPA'S PROPOSAL TO PROHIBIT MULTIPLE CONDITIONS OF USE IS INCONSISTENT WITH ITS STATUTORY MANDATE

The proposed regulation would prohibit PCE use in all consumer applications and in 23 of the 41 industrial and commercial applications assessed. An additional application – dry cleaning – would be phased out over a 10-year period. Under the proposal, the 17 applications not subject to prohibition or phaseout would be required to meet the proposed ECEL and implement a WCPP to ensure that workers are not exposed to levels above the ECEL.[44] For the 23 prohibited applications, EPA indicates that "concerns about the feasibility of implementing an ECEL for these additional industrial and commercial conditions of use" led the Agency to determine that "that prohibition is the best way to address the unreasonable risk from PCE driven by the conditions of use."[45] However the Agency acknowledges that it had not received monitoring data or detailed descriptions of PCE-related activities for many of the COUs proposed to be prohibited before concluding that compliance with the proposed ECEL is not possible. As a consequence, EPA seeks comment on a primary regulatory alternative action that would allow additional COUs to continue to use PCE provided the Agency can determine that these uses "could comply with the WCPP such that risks are no longer unreasonable."[46]

The Chlorine Panel urges EPA to reconsider the decision to prohibit more than half of the industrial and commercial COUs in the absence of monitoring data or process descriptions and instead allow commercial and industrial users to assess the potential for WCPP compliance. The Panel appreciates that the Agency is seeking comment on allowing additional ongoing uses of PCE industrial and commercial uses of PCE prohibited in the proposed rule and encourage the Agency to abandon its default assumptions about WCPP compliance. A default to prohibition when an approach to eliminating unreasonable risk has been identified is not consistent with EPA's mandate

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42 88 *Fed. Reg.* at 39697.

43 Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Toxic Substances Control Act (TSCA) Section 6(a) for Perchloroethylene (PCE) (2023). EPA-HQ-OPPT-2020-0720-0066.

44 EPA has proposed specific prescriptive controls, including a fume hood and dermal protection, for one these applications – industrial/commercial use in laboratory chemicals.

45 88 *Fed. Reg.* 39669.

46 Ibid, at 39683.

to regulate "to the extent necessary so that the chemical substance no longer presents such risk" under TSCA Section 6(a). The Agency has concluded that compliance with the proposed ECEL eliminates unreasonable risk from chronic PCE exposure. A regulation requiring implementation of a WCPP to comply with the ECEL satisfies the statutory mandate. It is not appropriate for EPA to presume that compliance is not achievable within a COU, particularly in the absence of information to support such a presumption.

The Decision to Limit PCE Use as a Processing Aid and in Processing to Only Certain Conditions of Use is Arbitrary and Should be Reversed

EPA's proposal would allow continued use of PCE as a processing aid in catalyst regeneration in petrochemical manufacturing but would prohibit its use as a processing aid in the manufacture of agricultural chemicals. The proposal also would permit use in processing of paint and coatings and adhesive and sealant products while prohibiting use in processing of other chemical products and preparations.

The use of PCE in agricultural chemical manufacturing appears limited[47] and the Agency notes that it was unable to collect additional information on the use. As a result, EPA did not assess risks or the availability of alternatives in this COU. It is unclear how the Agency assessed the potential of the application to comply with the proposed WCPP or whether alternatives are available in the application. The Chlorine Panel supports EPA's proposal to allow PCE use as a processing aid in catalyst regeneration but is unclear what basis EPA relied on to conclude that the use for producing agricultural products should not. Rather than assume that compliance is not achievable and that alternatives are available, EPA should allow the use of PCE as a processing aid in manufacturing agricultural products at facilities that can meet the WCPP requirements. We further note that PCE may be used elsewhere as a processing aid and recommend that EPA also allow for such use when the WCPP requirements can be met.

The Panel also supports the proposal to allow PCE use for processing into formulation, mixture, or reaction products in paint and coating and adhesive and sealant products but disagrees with the proposal to prohibit the use in processing into other chemical products and preparations. This conclusion appears to be based on an assumption that exposures in this COU corresponds to the aerosol packing COU.[48] The assumption is overly broad and should be revisited. As above, the Panel encourages EPA to allow PCE use for formulating other chemical products and preparations at those facilities that can demonstrate compliance with the WCPP.

PCE Use in Cold Cleaning at Facilities Capable of Implementing a Workplace Chemical Protection Program Should Not be Prohibited

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[47] PCE Economic Analysis, at 5-8 (Table 5-2).

[48] PCE Risk Evaluation, at 380.

EPA seeks comment on the ongoing PCE use in the five additional industrial and commercial COUs, including its use as a processing aid for the manufacture of agricultural products and for processing for other chemical products and preparations, as part of its primary regulatory alternative. However, EPA does not seek comment on the use of PCE in cold cleaning, despite its decision to allow continued use in a similar application, vapor degreasing. In fact, the exposure data for cold cleaning, both empirical and modeled, are very similar to that for the degreasing applications (**Table 2**) and the potential for complying with the WCPP are likely very similar.

Table 2. Summary of Exposure Data for Use of PCE in Cold Cleaning and Vapor Degreasing (ppm)[49]

	Cold Cleaning				Open-Top Vapor Degreasing	
	Monitoring Data		Modeled Data		Monitoring Data	
	Central Tendency	High End	Central Tendency	High End	Central Tendency	High End
8-hour TWA	1.4	4.1	0.0024	1.5	2.1	32
Acute Exposure	0.5	1.4	0.0008	0.5	0.7	11
Average Daily Concentration	0.3	0.9	0.00055	0.4	0.5	7.3
Lifetime Average Daily Concentration	0.1	0.5	0.0002	0.1	0.2	3.8

The Panel recognizes that use of PCE for cold cleaning is limited,[50] but notes that PCE's higher boiling point, nonflammability, and aggressive solvency make it well suited to particular cleaning applications. These specialty cleaning uses should continue to be allowed under the Agency's proposal particularly since EPA's analysis suggests that implementation of a WCPP can adequately protect workers from the risks identified by the Agency.[51]

Industrial and Commercial Use of Perchloroethylene for Energized Electronic Equipment Cleaners Should be Granted a Section 6(g) Exemption

PCE's aggressive solvency and non-flammability make it an excellent solvent for use in cleaning energized electronic equipment (EEE). Despite the importance of these cleaners in maintaining equipment without having to shut down electrical systems, EEE cleaners are not

[49] Ibid, at 204 (Table 2-61). EPA risk estimate for dermal exposures is the same for both cold cleaning and open-top vapor degreasing (page 475, Table 4-125).

[50] EPA's Economic Analysis estimates only 871 individuals with PCE exposure in the Liquid and Spray Batch Cold Cleaning use category. (PCE Economic Analysis, at 8-3).

[51] PCE Risk Evaluation, at 389-390 (Tables 4-28, 4-29).

identified as a separate COU in EPA's Risk Evaluation or Risk Management proposal. Rather they are included under aerosol spray degreaser/cleaners or automotive care products, both of which would be prohibited under the proposal. While similar in form with these other cleaners, EEE cleaners serve a different and more critical function. Although the flammable solvents identified by the Agency as acceptable alternatives to PCE[52] may be appropriate for other aerosol products, they are not appropriate for use in cleaning EEE.

The Agency's evaluation of exposures from the use of industrial/commercial use of aerosol products containing PCE, like EEE cleaners, suggests that risks can be appropriately managed with the use of PPE. As a result, EPA seeks comment on allowing the continued use of aerosol degreasers/cleaners contingent on compliance with the proposed WCPP. While we support this approach, it does not work for cleaning EEE, which is generally conducted by contract workers who are not employed by the facility. The facilities where the EEE cleaners are used may not otherwise use PCE and would not be required to implement a WCPP. Moreover, the firm employing the contract worker has no control over the conditions at the facility and cannot be expected to design a WCPP for all circumstances the workers may encounter.

The Chlorine Panel recommends that EPA establish a separate COU for the industrial/commercial use of EEE cleaners and grant an exemption for this use under TSCA Section 6(g) based on the importance of these products to the national economy and the lack of appropriate alternatives to PCE.

The Phaseout of the Industrial/Commercial Use of Perchloroethylene in Dry Cleaning Should be Extended

EPA has proposed to phase out the use of PCE in dry cleaning in 4th and 5th generation equipment over 10 years, while prohibiting the purchase of new equipment with 6 months of promulgation of the rule and preventing PCE use in older (3rd generation) equipment after 3 years. The Chlorine Panel supports the proposed prohibition on purchasing new equipment and the phaseout of older equipment but recommends that the phaseout of the newer equipment be extended to 15 years from the date of promulgation. This would achieve consistency with the National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities (the "Dry Cleaning NESHAP"), which recognizes a useful life of 15 years for such equipment.[53]

Clarification of the Restrictions on Distribution in Commerce is Necessary

Although the 2020 Risk Evaluation concluded that distribution in commerce of PCE does not present an unreasonable risk,[54] the proposal does not identify distribution as an allowable COU.

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[52] PCE Alternatives Assessment, at 44.

[53] 70 *Fed. Reg.* 75884, 75897 (December 21, 2005). National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities, Proposed Rule.

[54] PCE Risk Evaluation, at 42.

Instead, the proposal primarily discusses distribution in the context of the restricted use conditions. Section 751.605 of the proposed regulation notes that the restrictions outlined in the section apply to distribution to consumer uses and prohibited industrial and commercial uses, and to retailers. The proposed regulatory language does not address, nor does the preamble discuss, distribution to the COUs listed in Section 751.607(a) that would not be prohibited by the proposed regulation. Although it is implied that distribution to the COUs subject to WCPP compliance requirements is allowed, the failure to note that fact explicitly in the regulation (and Preamble) will result in unnecessary confusion.

The Chlorine Panel urges EPA to clarify the applicability of the regulation of distribution to the COUs allowed under the rule by adding a definition of "Distribution in Commerce" to the descriptions of COUs in the Preamble and by amending Part 751.607 of the proposed regulation. An appropriate definition is provided in the Risk Evaluation –

> *Distribution in Commerce. The transportation associated with the moving of perchloroethylene in commerce in compliance with existing regulations for the transportation of hazardous materials. The loading and unloading activities related to distribution of perchloroethylene are associated with other conditions of use.*[55]

In addition, Section 751.607 should be amended to add the following –

> *(11) Distribution in commerce to (1) through (16) in this paragraph.*

EPA Should Remove the Preamble Language on Exports of Perchloroethylene

In the Preamble to the proposed regulation, EPA indicates that "As the manufacture and processing of PCE presents an unreasonable risk to health in the United States, the manufacture and processing of PCE for export would also be prohibited or restricted in accordance with TSCA section 12(a)(2)."[56] This statement is not consistent with the conclusion that compliance with the proposed WCPP eliminates unreasonable risk that is the premise of the proposed rule. It is critical that EPA remove the statement in the preamble. TSCA section 12(a)(2) does not prohibit or restrict export of a substance subject to a risk management rule under Section 6. Rather Section 12 would require that companies wishing to export PCE submit a written notice to EPA providing basic information on the exporting and importing parties, which is then forwarded to the importing party's government.

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55 Ibid, at 515.

56 88 *Fed. Reg.* at 39668-39669.

"Domestic manufacture," defined as "refer[ing] to the making or producing of a chemical substance within the United States (including manufacturing for export),"[57] is allowed pursuant to a WCPP. As noted by the Agency "ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for perchloroethylene . . . under TSCA."[58]

Consistent with the clear language of Section 12 of TSCA, EPA should also amend the language of Section 751.611 of the proposed regulation to add "export" to the list of purposes for which distribution in commerce is permitted after 21 months of promulgation of the rule.

The Agency Should Implement a Process for Reconsideration of Its Decision to Eliminate Perchloroethylene Use in Conditions of Use

EPA has requested comment on an appropriate, predictable process that could expedite reconsideration of PCE use in COUs identified by Federal agencies or their contractors after promulgation of the regulation. Notwithstanding the Panel's concerns with EPA's inappropriate conclusion that most industrial and commercial COUs are unable to implement a WCPP to comply with the proposed exposure limits, we believe that developing a process for reconsideration is essential and should be applied to industrial and commercial uses as well. Moreover, the opportunity to request reconsideration should be available to individual facilities as well as COUs.

ACC's Chlorine Panel encourages EPA to implement a process whereby owners/operators in prohibited COUs would be able to demonstrate compliance with the WCPP requirements or to request additional time to phase-out PCE and make the transition to alternative chemicals or processes. Often transitioning to an alternative will take extensive downtime at a facility or potentially require capital expenditures to modifying existing closed-loop designs that transport PCE. The consideration of implementation timing should also factor in the likelihood that affected plant sites would be shut down for a time impacting companies, product availability to their downstream value chains, and their employees. Such a process would help to minimize the impact of the proposed restrictions, while allowing companies to continue to make progress in eliminating unreasonable risks to workers.

ESTABLISHMENT OF A *DE MINIMIS* EXCLUSION IS ESSENTIAL

The Chlorine Panel strongly supports the proposal to establish a *de minimis* exemption as part of the restrictions on PCE use. As the Agency notes, the presence of these substance as

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[57] 88 *Fed. Reg.* at 39663.

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

impurities "does not drive the unreasonable risk"[59] and need not be considered in order to evaluate the risk of injury resulting from exposures. Establishing a threshold of 0.1 percent by weight for the PCE restrictions aligns with existing requirements under OSHA's Hazard Communication Standard[60] and will enable companies to determine compliance more readily with the requirements of the rule. It is also important to note that prohibiting impurities in downstream products or PCE impurities in feedstocks could severely hamper numerous value chains.

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

MULTIPLE RISK MANAGEMENT IMPLEMENTATION REQUIREMENTS NEED REVISION

EPA's proposal would eliminate the manufacture (including import) of PCE for all consumer applications and the 23 prohibited industrial and commercial applications within 12 months of promulgation of the regulation and would prevent the processing of PCE for any of these applications after 15 months. Distribution in commerce of any products containing PCE for use in any of the prohibited applications would be prohibited 21 months after promulgation, and the use of any these products would need to cease after 24 months.

Facilities within one of the 17 COUs that would be allowed to continue to use PCE under the proposed regulation would be required to conduct initial monitoring of their workers within 6 months of promulgation to determine whether they meet the proposed ECEL of 0.14 ppm. Within 3 months of initial monitoring (9 months from promulgation), facilities would be required to designate areas where PCE levels exceed either the proposed ECEL and to provide respiratory protection to any workers entering such a "regulated area" consistent with the requirements of 29 CFR § 1910.134. Within 6 months of initial monitoring (one year after promulgation) facilities would be required to institute engineering controls and work practices to reduce PCE exposures to, or below, the proposed ECEL in regulated areas, if feasible, and to develop an exposure control plan documenting steps it is taking to comply with the proposed limits.

Facilities also would be required to conduct periodic monitoring, based on the results of the initial monitoring. Those exceeding the ECEL action level of 0.07 ppm would be required to conduct monitoring every 6 months; those exceeding the ECEL would need to sample every 3 months.[61] Facilities not exceeding the ECEL action level or the EPA STEL would not be required to monitor for 5 years unless changes are made to the facility operation that would be expected to result in increased PCE exposure.

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[59] 88 *Fed. Reg.*, at 39693.

[60] 29 C.F.R. § 1910.1200

[61] The requirement for periodic monitoring would cease after two consecutive samples taken at least 7 days apart indicate that levels have decreased below the relevant level.

ACC's Chlorine Panel has several concerns with the schedule for implementing the restrictions that EPA has laid out in its proposal and with the procedures required to demonstrate compliance with the proposed limits. These concerns are described below, along with recommendations for allowing additional time and flexibility to the proposed requirements to facilitate a smoother implementation of the proposal.

The Proposed Compliance Timelines Should be Extended to Allow for a More Orderly Transition

For those industrial and commercial uses of PCE that would be prohibited under the regulation, EPA has proposed an aggressive timeline that does not allow sufficient time to identify, test, and implement alternatives substances or processes. Under the proposal, industrial and commercial facilities "processing" PCE for any of the prohibited uses would have 15 months to convert their process following promulgation of the regulation and would only be able to obtain PCE to maintain their operations for a year. In light of EPA's own challenges in evaluating alternatives to PCE, 15 months may not be enough time for these facilities to convert their operations without significant disruption. If a feasible alternative to PCE is found (often there are no feasible alternatives), there would be extensive downtime at a facility, potentially requiring capital expenditures to modify existing manufacturing operations that carry PCE. This is particularly true if the alternative is flammable. The consideration of implementation timing should also factor in the likelihood that affected plant sites would be shut down for a time impacting companies, product availability to their downstream value chains, and their employees.

ACC's Chlorine Panel urges EPA to extend the end date for processing PCE in these prohibited industrial and commercial COUs to 3 years (36 months) from rule promulgation, with an opportunity to be given additional time, if necessary, per the above discussion. To accommodate this extension, manufacturers should be allowed 2 years (24 months) from promulgation to produce PCE for these applications; distribution in commerce of these products should be permitted for at least 42 months from promulgation. No restriction on the timing of the use of these products should be imposed since eliminating their availability will effectively facilitate an end to their use.

EPA also is proposing a very short timeline of 90 days between distribution of prohibited products to retailers (18 months from promulgation) and retail distribution of these products (21 months). The Chlorine Panel urges EPA to extend the "sell-through" period of products already in commerce to 6 months (*i.e.*, 2 years from promulgation). This additional time will help to minimize the unnecessary disposal of products left on retail shelves.

Existing Exposure Monitoring Methods are not Adequate

Implementing a monitoring methodology for the new ECEL will not be seamless. Time will be required for method validation by a lab for measurement of the proposed ECEL and action limit. At present, NIOSH 1003 is the most commonly utilized for IH sampling in the workplace for PCE

since it meets OSHA's accuracy standards and analytical methods. However, the NIOSH 1003 method as currently validated will not achieve the limits of detection (LODs) required for evaluating the proposed ECEL or action limit. Time will be required to coordinate with a lab for method validation at 10% of the proposed ECEL, as recommended by NIOSH for OEL sampling.[62]

EPA's ECEL document[63] also lists EPA Method TO-17 as a potential air sampling analytical method. Initial evaluation of available labs for analysis did not identify an accredited laboratory with the capability to analyze PCE IH samples using the TO-17 methodology.[64] In addition to laboratory capabilities, the EPA TO-17 method allows the use of a sampling media with which facilities have little experience - either the Tenax tube or the SKU Ultra Diffusive sampler. Tenax tubes require conditioning and if not used within a short window (months) need to be sent back to the lab for re-conditioning. This stability limitation could delay results and introduce additional errors that could give biased data.

Two other methods suggested in the ECEL documentation - NIOSH 3900 and TO-15 - are area sampling methods that use specially prepared canisters that cannot be used for personal breathing zone (PBZ) sampling which the proposal would require and which are required to demonstrate compliance with the Occupational Safety and Health Administration's Permissible Exposure Levels (PELs). PBZ sampling is "personal" because it evaluates an individual's exposure to a chemical as opposed to ambient area sampling (e.g., as described in EPA TO-15 method and NIOSH 3900 methods) that measures the concentration of a substance in a given area.

EPA TO-15 and NIOSH 3900 methods both require use of bulky canisters to collect ambient air samples which are not appropriate for PBZ sampling. IH applications for canister sampling are limited to monitoring short-duration peak exposures and source emissions, not for sampling full-shift employee exposures to compare to full-shift exposure levels (e.g., ECELs and PELs).[65] Although certain inferences can be made about exposure through area sampling by considering the length of time an employee is in the area, the best indicator of a person's actual exposure comes from PBZ sampling since the sample is collected by equipment that is worn by the employee during the workday.

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62 NIOSH Manual of Analytical Methods (NMAM), 5th Edition, Section 2 (December 11, 2017). https://www.cdc.gov/niosh/nmam/pdfs/nmam_5thed_ebook.pdf

63 PCE ECEL Memo, at 5.

64 One Panel member contacted four AIHA accredited laboratories to determine their ability to analyze IH samples using SKC Ultra Diffusive media with TO-17 method analysis. Three of the labs did not have the media for the analysis, a fourth had the media but could not measure to the manufacturer's stated limit of detection.

65 https://www.cdc.gov/niosh/hhe/reports/pdfs/2016-0067-3313.pdf

The Proposed Action Level Should be Deleted

Given the challenges of reliably measuring the proposed ECEL and ECEL action level, and the potential challenges with lab capacity to conduct sample analysis, the Chlorine Panel recommends that the action level be removed from the regulation. Demonstration that exposures are below the ECEL is sufficient for compliance with the requirements.

The Deadline for Initial Monitoring Should be Extended to Twelve Months

To allow proper implementation of an IH program for a new ECEL, at a minimum EPA should revise § 751.607(b)(2) to allow 12 months for the initial exposure monitoring requirement, consistent with the timeframe allowed by OSHA in the standard for beryllium.[66] For PCE at least 12 months is necessary for method revalidation as described above and to incorporate the new ECEL that is significantly lower than existing OELs. Each facility will need to determine whether revision of its corporate exposure assessment strategy is necessary to address the new ECEL evaluation.

A typical exposure assessment/reassessment strategy would include identifying and involving stakeholders in the re-evaluation, such as operations management, process engineers, and health and safety personnel. An exposure assessment/reassessment strategy may include confirming and/or reassessing the following exposure assessment goals and written plans for the ECEL evaluation -

- Methods for systematic information gathering;
- Confirming similar exposure groups (SEG) for the new ECEL;
- Identify decision statistics and number of random samples that will be used to determine whether the exposure profile for a SEG is acceptable, unacceptable, or uncertain;
- Identify exposure thresholds and appropriate exposure monitoring methods to meet thresholds;
- Develop new monitoring procedures for new monitoring methods; and
- Train to the new monitoring technology and/or methodology to ensure the proper execution of an exposure assessment strategy.

To proceed with an exposure reassessment against a new ECEL, each representative air sample that will be evaluated will be subject to a Qualitative Exposure Assessment to help determine the expected exposure category before attempting to perform exposure monitoring. The Assessment includes identifying the following -

- all relevant tasks;
- the frequency/duration of each task;
- estimate of quantity of stressor per task; and

[66] 29 CFR §§ 1910.1024(d) and (o).

- exposure controls in place for each task exposure.

Once the Qualitative Exposure Assessment is complete, personal exposure monitoring takes place. This step includes -

- Obtaining and training with any new monitoring equipment or methods;
- Collecting the appropriate number of random samples (full-shift and tasks);
- Performing statistical analysis on the sample set, as appropriate;
- Comparing to the ECEL; and
- Decision-making related to exposure profile.

In addition to the reassessment strategy and implementation steps listed above, monitoring at the proposed ECEL of 0.14 ppm and the proposed action level of 0.07 ppm likely will require laboratory analysis (rather than direct measurement) that will delay the availability of results and make meeting a 6-month time frame challenging.

To allow proper implementation of the steps and time taken to assess or reassess an IH program for a new ECEL, at a minimum, EPA should revise the proposed Section 751.607(b)(3)(ii) to allow 12 months for the initial exposure monitoring requirement.

Adequate Time is Needed to Plan and Implement a Performance-Based WCPP

The proposal should be revised to allow up to 36 months to evaluate and implement a WCPP. This is consistent with OSHA's promulgation of the Beryllium standard that provided 36 months for evaluating and implementing engineering control requirements in a written exposure control plan.[67] An appropriate compliance deadline for evaluating the hierarchy of controls will allow entities to adequately plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers.

As described above, requiring that initial monitoring be completed within 6 months of the effective date of the rule provides insufficient time to revalidate monitoring technology and assess/reassess an IH strategy and conduct monitoring for a new ECEL. Likewise, additional time is required to allow owners/operators to document their efforts to implement the NIOSH hierarchy of controls – elimination, substitution, engineering controls, and administrative controls – to reduce exposures to the ECEL.

The proposal would require a detailed description of efforts to implement the control hierarchy. Importantly, manufacturing and processing facilities rely upon layers of protection rather than a single engineering or administrative control. Each of these layers would need to be reassessed upon completion of the initial exposure monitoring. The proposal indicates that respirator use would be permitted to supplement the exposure controls only after other feasible

[67] 29 CFR §§ 1019.1024(f), (o).

controls are determined to be insufficient to achieve the ECEL. This does not recognize that currently respirator use is often required as an additional layer of protection on top of engineering controls (e.g., inline sampling for sampling events).

In addition, the discussion of the exposure control plan suggests a rigid consideration of each of the steps in the control hierarchy, requiring that each step in the hierarchy be fully considered until moving to the next step. EPA should allow greater flexibility to facilities when applying the hierarchy of controls to recognize there are often multiple layers of protection and the evaluation does not stop at a step when, for example, an inline sample mechanism is installed for routine samples.

To allow for the multi-layer evaluation with complex chemical facilities, we recommend that the time required to develop the plan under Section 751.607(d)(2) be extended to 24 months from the completion of initial exposure monitoring, for a total of 36 months from rule promulgation to provide adequate time to evaluate and implement appropriate compliance approaches that are the least burdensome and most effective for workers. During the implementation time, existing protections would remain in place for workers including existing OSHA requirements for dermal and respiratory protection implemented by facilities (e.g., hazard assessment)s, administrative controls such as standard operating procedures, and permit requirements.

Direct Read Instruments Must Also be Validated for the New Limits

Direct-reading field instruments are used by operations and maintenance personnel during routine and non-routine tasks/activities. These types of instruments are addressed in specific OSHA standards for general industry, maritime, and construction.[68] Similarly, direct-reading field instruments are utilized for maintenance activities, such as a line break, to confirm air concentrations are safe for downgrading PPE. For example, it is common practice for maintenance tasks involving opening chemical distribution lines to start with employees in full PPE (*i.e.*, full chemical resistant suit, chemical resistant gloves and boots, full face supplied air respirator and hardhat). A direct reading instrument is then used to show that the airborne concentration is below the exposure limit and permit a downgrade of PPE and/or respiratory protection.

Currently, manufacturing facilities use direct-read instruments such as Photo Ionization Detector (PID) as a portable vapor and gas detector in the field for a variety of organic compounds, including PCE. PIDs are available in portable hand-held models and in a number of lamp configurations. Results are almost immediate; however, specific lamps and correction factors must be applied and there are many limitations and concerns for continuing their use with the proposed ECEL. Although PIDs are capable of measuring PERC at the ECEL level, measurements would be unstable, with widely fluctuating readings, due to interference from other volatile organic compounds, water vapor, and other factors. Without the ability to measure air concentrations

[68] For example: 29 CFR § 1910.146 (Permit-Required Confined Spaces) requires that confined spaces must be tested with direct-reading instruments before entry.

consistently and accurately, employees will have to remain in full PPE for the entire duration of the task creating other physiological concerns such as heat stress. Additionally, the protocol for inspection and maintenance of PCE-containing equipment when confined space entry is required will have to be revaluated to identify technology that can measure to the ECEL in the field or account for additional time for laboratory analysis before the task can be performed.

Consistent with the need for up to 36 months to implement the WCPP, time is needed to evaluate the feasibility and implementation of alternate direct-reading monitoring capabilities in the field.

EPA Should Allow Facilities to Apply Respirator Protection Factors for Short-Term Tasks to Demonstrate Compliance

With the low levels of the ECEL as an 8-hour TWA, the proposed respiratory protection language in Section 751.605(f)(5)(ii) should be clarified that an exceedance of the ECEL does not automatically default to a required use of the assigned protection factor (APF) for the full shift. Employers should be allowed to implement IH assessments to compare to the ECEL TWA that separately measure i) a task where potential exposure may occur (i.e., 30 minutes for a sampling event); and ii) the "rest of day" exposure, (*i.e.*, 7.5 hours), where such tasks are not anticipated to have potential PCE exposure.

Such an approach allows a "control-banding-by-task" (CBT) approach that focuses on task-based scenarios that occur in well-characterized similar exposure groups (SEGs) instead of the full 8-hour data. This approach of specifying controls for specific product uses is recognized under the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation (ECHA 2020). Such task-based control strategies are common in many industrial operations, particularly in chemical manufacturing. This is because the nature of many of the tasks with potential exposure are of short-duration or intermittent frequency. There are many guidance documents and reviews that reinforce the importance of task-based exposure controls and application of control banding concepts.[69] For this reason, it is very rare for a worker in chemical manufacturing to wear respiratory protection devices for the full shift.

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

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[69] National Institute for Occupational Safety and Health (NIOSH). 2009. Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB). https://www.cdc.gov/niosh/docs/2009-152/default.html.

1. The IH risk assessment creates an SEG for employees that conduct a routine maintenance task once a day;
2. A 30 min. "task" personal breathing zone (PBZ-T) sample is taken on an employee conducting the maintenance task, during which time the employee is wearing a respirator with a specific APF for the maximum use concentration (MUC), as required by the respective facility's Standard Operating Procedure and Hazard Assessment and/or the WCPP;
3. After the PBZ task sampling period, a separate PBZ sample is taken over the remaining 7.5 hours (PBZ-D),
4. The APF associated with the respiratory protection is applied to the results of the PBZ sample for the maintenance task and added to the results of the PBZ sample for the remaining 7.5 hours to calculate an 8-hour TWA:

$$[(\text{PBZ-T} \times .5)/\text{APF} + (\text{PBZ-R} \times 7.5)]/8 = \text{8-hour TWA}$$

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

To allow for the CBT approach, Section 751.607(f)(5)(ii) could be modified to read as follows *(suggested revisions in italics):*

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

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

EPA Should Allow for the Use of a Six-Sample Rolling Average

It is recommended that at least six samples are collected to evaluate against the ECEL. A six-sample rolling average would be used to demonstrate i) the MUC of the APF is appropriate for a SEG and evaluate compliance with the ECEL; and 2) establish and evaluate regulated areas. This approach is based on AIHA guidance for assessing and managing occupational exposures, which states that according to statistical sampling theory, there is a point of diminishing returns above

approximately six to ten measurements.[70] Given the repetitive task exposure scenarios at PCE manufacturing facilities a "rolling average" could be calculated based on the prior six measurements. OSHA also recognizes that statistical methods should be utilized to account for error factors in the sample results.[71]

The Requirements for Dermal Control Need to be Clarified

Where the proposed regulations generally reference "direct dermal contact", the regulations should clarify in 751.605(f)(6) that based upon a hazard assessment, a facility could determine that gloves are sufficient for dermal PPE on task-by-task basis, such as sampling and loading/ unloading tasks. The dermal control reference in the proposal is very broad and should be qualified to allow for a facility to evaluate potential dermal exposure based upon the task.

Resampling when Results Indicate Non-Detect is Unnecessary

The requirement in 751.607(b)(3)(i)(E) to remonitor within 15 working days when results indicate non-detect is unnecessary. Facilities use accredited labs to perform IH sampling analysis and the results are reviewed by IH professionals. Requiring an Environmental Professional or Certified Industrial Hygienist to determination whether to re-monitor is an unnecessary step that adds no value. Additionally, incorporating a six-sample rolling average 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.

The Requirement that Exposure Monitoring be Compliant with Good Laboratory Practice Standards Should be Deleted

The scope of the EPA's Good Laboratory Standards (GLP) is described as follows: "This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing."[72] Monitoring does not fall into these three categories. While it is appropriate that industrial hygiene compliance monitoring include protocols and practices to ensure the quality and integrity of the data, EPA should follow practices currently used by IH practitioners.

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

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[70] Jahn SD *et al.* A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. Washington, DC: AIHA (2015).

[71] https://www.osha.gov/otm/section-2-health-hazards/chapter-1

[72] 40 C.F.R. § 792.1(a)

or Environmental Professional as defined at 40 CFR § 312.10.

EPA should apply the policy described in its New Chemicals Exposure Limits section 5(e) under the Toxic Substances Control Act (TSCA) New Chemicals Program which states that "compliance with TSCA GLP Standards is not required where exposure monitoring samples are analyzed by a laboratory accredited by either: (A) the AIHA IHLAP; or (B) another comparable program approved in advance in writing by EPA."[73]

EPA Should Align Its Owner/Operator Definition with OSHA Regulations

In the Preamble to the proposalhe proposed, EPA notes that it supplements OSHA requirements for controlling exposure to PCE. However, the Agency's definition of "owner or operator" conflicts with OSHA's requirements that are applicable to "employers" defined as "a person engaged in a business affecting commerce who has employees." [74] EPA proposes the use of the term owner or operator to describe the entity responsible for implementing the WCPP for workplaces where an applicable condition of use is occurring and PCE is present. The term includes any person who owns, leases, operates, controls, or supervises such a workplace.[75]

EPA's proposed definition suggests that the person or company overseeing the worksite is responsible for all aspects of managing perchloroethylene in the workplace, including providing PPE, fit testing, and worker training – regardless of whether the individual is an employee. 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.

The Chlorine Panel recommends that EPA review its requirements for owners or operators to ensure alignment with OSHA requirements.

EPA'S FENCELINE SCREENING ANALYSIS IS NOT SUITABLE TO INFORM RISK MANAGEMENT ACTIONS

The preamble to the proposed rule includes a substantial discussion of EPA's screening analysis to identify whether there may be potential risks to people living near the fenceline of facilities releasing PCE.[76] The analysis relies on the Agency's 2022 screening level approach to assessing fenceline impacts,[77] despite acknowledging that the approach "was not designed to

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73 https://www.epa.gov/sites/default/files/2015-06/documents/draft_ncel_insert_042115.pdf

74 29 C.F.R. § 1910.2(c).

75 88 *Fed. Reg.* 39672.

76 Ibid, at 39699-39701.

77 https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-screening-level-approach-assessing-ambient-air-and

facilitate the making of an unreasonable risk determination for these [fenceline] communities."[78] While the screening analysis does not impact the proposed regulations for facilities using PCE, the Agency suggests that "the proposed regulatory action . . . is expected to reduce the risks identified in the screening approach." The Chlorine Panel is concerned about the suggestion of risks to fence line communities based on an approach that the Agency readily acknowledges was not designed to make such determinations. We urge the Agency to revise or delete the language.

[78] 88 *Fed. Reg.* 39699