BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

Comments on Perchloroethylene; Regulation Under
the Toxic Substances Control Act
(TSCA)
88 Fed. Reg. 39652 (June 16, 2023)
EPA-HQ-OPPT-2020-0720

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The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents manufacturers and users of chlorinated solvents, including perchloroethylene ("perc" or "PCE"). A list of HSIA's members is attached (Attachment A). We appreciate the opportunity to provide these comments in response to the proposed rule governing the manufacture, processing, and use of perc under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 39652 (June 16, 2023). The proposed rule would greatly restrict the permissible uses of perc and impose limits on worker exposure which are much more restrictive than those imposed by the Occupational Health & Safety Administration (OSHA) or in effect elsewhere in the world. We address in turn both deficiencies in the proposal that show it is not based on best available science or supported by substantial evidence, as required by TSCA, and recommendations to improve Workplace Chemical Protection Program (WCPP) implementation and other aspects of the proposed risk management rule.

As will be discussed more fully below, the proposed rule breaks down into (i) 24 conditions of perc use where EPA found unreasonable risk to workers and proposes to ban the use and (ii) specific requirements for 16 conditions of use that are not prohibited. The 16 allowed uses would be subject to WCPP requirements to be implemented by employers.[1] Most notably, these include an Existing Chemical Exposure Limit (ECEL) of 0.14 parts per million (ppm) (8-hour time weighted average (TWA)) and Direct Dermal Contact Control (DDCC) requirements.

EPA's proposed 0.14 ppm ECEL value is intended to address unreasonable risk for chronic cancer and non-cancer and acute non-cancer inhalation endpoints. These endpoints are addressed in turn in Section II below. Section III then includes several recommendations specific to the proposed rule and WCPP implementation including:

- Additional time is needed for WCPP development and ECEL implementation requirements to accommodate any new occupational exposure limit (OEL), especially one as low as the proposed ECEL.
- Monitoring technologies must be identified and lab methodologies verified for the proposed ECEL.
- Industrial hygiene professionals will need time to plan for revised risk assessments at each facility to accommodate the new ECEL and account for the much lower limits of detection (LODs).
- The WCPP should clarify that values may be evaluated for tasks as well as full shifts.

[1] Table 2, 88 Fed. Reg. at 39690, provides a complete listing of prohibited and allowed uses.

Additionally, EPA's assumption that the 24 prohibited commercial use sectors would not be able to implement a WCPP to achieve compliance with the regulatory limits is unprecedented and inconsistent with the statute. TSCA § 6(a) states that EPA should apply requirements for addressing unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk." EPA asserts that compliance with the WCPP will protect health and the environment. To go further and ban a use without giving the employer an opportunity to implement a WCPP goes far beyond EPA's authority to regulate "to the extent necessary."

In a case of similar overreach by OSHA, involving comparable language in the Occupational Safety and Health Act ("OSH Act") defining an occupational safety and health standard as one "reasonably necessary or appropriate to provide safe or healthful employment," the Supreme Court found a duty on OSHA's part to make a finding that a workplace exposure was unsafe before adopting a workplace standard.[2] OSHA must quantify a "certain" level of risk and conclude that it is "significant" before regulating.[3] These findings must be supported by substantial evidence. The comments that follow show how EPA, in implementing a statute of similar vintage and wording (the OSH Act was enacted in 1970; TSCA in 1976) has departed from the TSCA statutory directive.[4]

The extremely low ECEL proposed by EPA is also some 1000 times lower than workplace limits in effect in other countries.[5] If adopted, this would obviously have major

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[2] *Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al.,* 448 U.S. 607 (1980) (*"Benzene"*).

[3] "By empowering the Secretary to promulgate standards that are 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment,' the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm." *Id.* at 642.

[4] By raising the *Benzene* decision, HSIA does not mean to imply that the risks of perc are in any way comparable to those of benzene. Benzene is a known human leukemogen. The drivers for the perc ECEL, on the other hand, are neurotoxicity and potential cancer risk. Unlike benzene, perc is not a known human carcinogen. Yet the ECEL proposed for perc is only a tiny fraction of the 1 ppm limit for benzene overturned by the Supreme Court. The concerns expressed by the Court in *Benzene* apply many times over to the regulation of perc.

[5] The table at Attachment B compares the ECEL for perc (and those proposed/expected for a number of other compounds) to workplace limits in effect in France, Germany, Canada, and Mexico, as well as the OSHA limits. More generally, see the GESTIS on-line database provided by the Institut fuer Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung: https://limitvalue.ifa.dguv.de/WebForm_ueliste2.aspx, which contains a collection of occupational exposure limits for hazardous substances from 28 countries. We submit that this divergence from every other country in the world also indicates that something is profoundly wrong with EPA's "unreasonable risk"

implications for the competitiveness of American manufacturing, where EPA projects that thousands of users in dozens of use sectors would no longer have access to this building-block chemical. EPA's Alternatives Assessment,[6] discussed in detail in § IV below, ignores two major consequences of adoption of such a low and divergent ECEL. First, the ECEL will result in increased reliance on China and Europe for many important products that could have been produced in the United States. The proposed extreme limit on perc and other chlorinated derivatives will further challenge efforts to increase domestic manufacturing of electric vehicle components and semiconductors, requiring even more imports from China. Second, the Alternatives Assessment does not address the implications of a ban on American exports (see § XI below), currently some $44 million.[7] This would further tilt the trade balance in favor of China, which has grown from 8.7% of total global chemical sales in 2003 into the largest chemical producer in the world, with 43% of global sales as of 2021.

EPA's proposed ECEL is 714 times lower than the OSHA limit, was issued without a public comment period, and is inconsistent with OELs used globally, as seen in Attachment B. The proposed rule would supplant existing workplace requirements to protect workers from effects that have not generally been observed in worker populations. In doing so, and by ignoring in the Alternatives Assessment the primary reasons perc is used -- its high-dissolving capability, low flammability even around sources of open flame, and thermodynamic and fast-drying properties -- EPA is proposing unachievable restrictions that will harm U.S. manufacturing competitiveness for no real benefit.

Significantly, EPA's final rule should also address a major use of perc for which there is no generally available safe alternative: energized electrical cleaning (EEC). As set out in detail in comments by HSIA member CRC Industries, EEC products are designed to remove heavy dirt, grease, moisture, heavy oil, or grime from electrical equipment that must be cleaned while current is running through it, or when residual current exists. This obviously precludes

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findings. It would be truly remarkable if perc, in widespread use for decades, was actually having health impacts on workers that have gone undetected by regulatory authorities around the world.

[6] Alternatives Assessment for Use of Perchloroethylene (January 2023) (hereafter "Alternatives Assessment"), EPA-HQ-OPPT-2020-0720-0104.

[7] The U.S. Census Bureau website shows > 34,500 MT of perc exported in 2022, valued at approximately $44,000,000. https://www.census.gov/library/visualizations/interactive/export-markets.html.

flammable alternatives. Twelve states prohibit the manufacture and sale of PCE-containing general purpose degreasing products, electrical cleaners and electronic cleaners, but they all exclude EECs from the definitions of these products.

As noted above, § III provides recommendations to modify the proposed rule's implementation of WCPPs. The remainder of the comment addresses additional concerns with the impact on small businesses, specific conditions of use, and comments relating to *de minimis*, distribution, and export as discussed in the preamble and the proposed rule.

I. SUMMARY LEGAL FRAMEWORK

TSCA provides EPA authority to regulate the use of chemical substances, to impose reporting, record-keeping and testing requirements, and to limit conditions of use. Section 6(a), relevant here, requires EPA to promulgate regulations to restrict the use of chemical substances where they "present[] an unreasonable risk of injury to health or the environment." Section 6(a) permits EPA to limit, condition, and prohibit the use of any chemical substance where it presents an unreasonable risk. As noted above, Section 6(a) further states that EPA should apply requirements for addressing unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk."

TSCA § 6(c) provides that "In selecting among ... restrictions," EPA "shall factor in, to the extent practicable," considerations such as "the effects of the chemical ... on the environment," "the benefits of the chemical substance or mixture for various uses," and "the reasonably ascertainable economic consequences of the rule." The assessment of economic consequences must include the "costs and benefits" and the "cost effectiveness" of the "proposed and final regulatory action" as well as of at least one alternative. EPA must publish a statement discussing those factors.. If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must 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."

The 2016 Lautenberg Act also added substantive requirements that appear in TSCA § 26. TSCA § 26(h): "In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information. . .employed in a manner consistent with the best available science. . . and shall consider as applicable—(5) the extent of independent verification or peer review of the information. . . ." TSCA § 26(i): "The

Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

Finally, TSCA § 17(c) makes clear that both the final rule and the associated determination of unreasonable risk shall be held unlawful and set aside "if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole."

II. THE RISK EVALUATION DOES NOT REFLECT BEST AVAILABLE SCIENCE OR THE WEIGHT OF THE SCIENTIFIC EVIDENCE

The OSHA Permissible Exposure Limit (PEL) for perc, adopted in 1971, is 100 ppm.[8] The Threshold Limit Value (TLV©) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) is 25 ppm as an 8-hour TWA. TLVs are health-based values developed based on scientific review of available literature and peer-reviewed studies.[9] Compliance with the TLVs has long been recommended by HSIA members. As described below, substantial evidence does not support the EPA ECEL that departs so dramatically from these existing limits.

A. The proposed ECEL value for PCE was derived from an incorrect assessment of the color vision study by Cavalleri et al. (1994)

EPA derived the 0.14 ppm ECEL value by averaging the Lowest-Observed-Adverse-Effect Level (LOAEL) from two studies (Cavalleri *et al.*, 1994; Echeverria *et al.*, 1995) that investigated PCE neurotoxicity in workers at dry cleaning facilities.[10] This same approach was used previously by EPA to derive a Reference Concentration (RfC) in the 2012 PCE IRIS Assessment.[11]

In Echeverria *et al.* (1995), psychometric performance was measured in 65 Detroit-area dry cleaners; cumulative exposure to PCE was divided into low (11 ppm), medium (23 ppm),

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[8] 29 C.F.R. part 1910, subpart Z.

[9] TLV/BEI Guidelines - ACGIH

[10] Cavalleri, A, Gobba, F, Paltrinieri, M, Fantuzzi, G, Righi, E, Aggazzotti, G, Perchloroethylene exposure can induce colour vision loss, *Neurosci Lett.* 179, 162-166 (1994); Echeverria, D, White, RF, Sampaio, C, 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).

[11] EPA Integrated Risk Information System (IRIS) Review of Toxicological Information on Tetrachloroethylene (2012) (hereafter the "IRIS Assessment"); EPA/635/R-08/011F.

and high (41 ppm) as 8-hour TWAs. There was some suggestion of group differences related to exposure because highly exposed cleaners were older and slightly less educated than the other workers. Highly exposed cleaners had also worked substantially longer (20 years) than either the low (3 years) or moderate (8 years) exposure categories. These and other variables (*e.g.*, medication use) were candidates for statistical adjustment in the multiple regression analyses, but the authors did not report that these variables were actually included in the models. There was a significant association with exposure for visual memory and pattern recognition, but not for tests involving psychomotor function (*e.g.*, symbol digit and trail making) or simple attention. The LOAEL for this study is 23 ppm; the No-Observed-Adverse-Effect-Level (NOAEL) is 11 ppm.

Cavalleri *et al*. (1994) is one of several studies that investigated color vision effects in workers exposed to PCE; it provides the best information on participation, reporting complete participation from all 35 workers at dry-cleaning shops in Moderna, Italy. The workers at the dry cleaning facility consisted of two groups which differed in tasks – dry cleaners and ironers. The difference in tasks also resulted in different exposure scenarios to PCE. As noted by the authors, "the exposure of dry cleaners is not constant throughout the working day, but sudden increases are expected during specific tasks such as the retrieval of just washed garments, or maintenance. As an example, our spot samples documented a tenfold increase (from 2 to 29 ppm nearly) during retrieval of garments. We cannot exclude that such peak exposures, not documented by TWA levels, could exert some effects on colour vision. In ironers similar variations of exposure are unlikely."[12]

There was also a control group consisting of an equal number of workers that were not exposed to solvents (including PCE). There was no mention of selection procedures for the controls, but matching on age, sex, alcohol consumption, and smoking probably limited potential for biased selection.

Using the Lanthony 15 Hue desaturated panel or D15 d test, Cavalleri *et al.* (1994) reported significantly higher color confusion index (CCI) for dry cleaners exposed to average PCE levels of 7.3 ppm (mean CCI 1.19) vs. matched controls (mean CCI 1.09), but not for ironers exposed to mean PCE levels of 4.8 ppm (CCI 1.06), indicating a NOAEL of 5 ppm.

[12] Cavalleri, A, Gobba, F, Paltrinieri, M, Fantuzzi, G, Righi, E, Aggazzotti, G, Perchloroethylene exposure can induce colour vision loss, Neurosci Lett 179, 162-166 (1994).

Exposure was significantly associated with CCI in regression models, but this was driven by exposures above 10-12 ppm (especially two values above 20 ppm), with no evidence of a linear association below 10 ppm. Such findings suggest a threshold at 10-20 ppm (rather than an exposure-response relationship), with no effect from lower exposures. Furthermore, neither duration of exposure nor cumulative exposure (ppm-year) was associated with CCI, suggesting a temporary or at least non-cumulative effect. The authors of the study concluded in their publication that "the mean exposure and the range of TWA levels of PCE in *ironers* and *dry-cleaners* (Table 2) suggest a mean threshold for colour vision effect of the solvent ranging approximately between 5 and 11 ppm."[13]

Cavalleri *et al.* (1994) was reviewed in 2004 by a five-person expert panel convened by EPA's National Center for Environmental Assessment (NCEA) to provide expert commentary on its document titled *Neurotoxicity of Tetrachloroethylene (Perchloroethylene)*. The panel included scientists with expertise in epidemiology (studies of human neurological effects, specifically studies of visual function including visual contrast sensitivity); neurotoxicology and/or neurobehavioral evaluation (testing of human subjects for chemically induced deficits in nervous system performance, especially with solvents such as PCE); and studies of the relationship between neurobehavior and low-level chemical exposures in residential or occupational populations. In response to the charge question "Is there evidence of a dose response or an exposure effect gradient in the studies of Perc, and is there a threshold?," the expert panel concluded:

> **"**A dose-response relationship is supported by three findings: (a) *in a study of dry-cleaning workers, a deficit was observed in dry-cleaners who were highly exposed to Perc, but not in ironers, who had lower exposures (Cavalleri et al., 1994)*; (b) a significant correlation ($r = 0.52$; $p<0.01$) observed between individual Perc exposure (environmental Perc levels measured using personal dosimeters) and colour vision impairment (quantitatively evaluated using the Color Confusion Index) (Cavalleri et al. 1994); and (c) the progression of the impairment observed in dry-cleaners whose exposure was increased (Gobba et al, 1998)."[14]

Surprisingly, in contradiction to the study authors' conclusions and the neurotoxicity expert panel, EPA determined in both the 2012 IRIS Assessment and the 2020 perc Risk

[13] *Id.*

[14] EPA/600/R-04/041, Summary Report of the Peer Review Workshop on the Neurotoxicity of Tetrachloroethylene (Perchloroethylene) Discussion Paper (2004) (emphasis added).

Evaluation[15] that there was no threshold for color vision effects in the PCE-exposed workers, and that instead of a NOAEL of 5 ppm for Cavalleri *et al.* (1994), the LOAEL is actually 6 ppm. How EPA reached this conclusion is quite mystifying. EPA considered the dry cleaners and ironers as a single group of workers even though the two groups of workers had different tasks with different exposure scenarios. EPA claimed in the IRIS assessment that the mean exposure value of the ironers could not be considered a NOAEL because elevated CCI scores were seen in the dry cleaners at lower exposures. This is an extraordinary conclusion by EPA since it is completely at odds with the CCI values from the control (non-PCE-exposed) group where there were also elevated CCI scores, with the control group mean value actually being slightly higher than the mean CCI value for the ironers; the statistical analysis, in fact, showed no significance difference between the ironers and control groups (mean and standard deviations: 1.061 $\pm$ 0.058 for ironers versus 1.073 $\pm$ 0.079 for controls). In contrast to the ironers, the mean CCI value was higher in the dry cleaners compared to the control group, and this difference was statistically significant (mean and standard deviations: 1.197 $\pm$ 0.133 for dry cleaners versus 1.089 $\pm$ 0.117 for controls; P = 0.007) as shown in the following table:

Mean CCI values in PCE-exposed Workers and in the Match Controls (Cavalleri *et al*., 1994)

	No. subjects	Workers	Controls	P value
All workers	35	1.143 $\pm$ 0.128	1.083 $\pm$ 0.104	P = 0.025
Dry cleaners	22	1.192 $\pm$ 0.133	1.089 $\pm$ 0.117	P = 0.007
Ironers	13	1.061 $\pm$ 0.058	1.073 $\pm$ 0.079	Not significant

These data do not support EPA's inference that the elevated CCI scores in the ironers are due to PCE exposure. EPA did not even acknowledge in either the IRIS assessment or the Risk Evaluation that the correlation between CCI scores and PCE exposure was dependent on three high values (>12.5 ppm, two of which were >20 ppm) involving just the dry cleaners. In the absence of these three high values, there was no evidence of a linear association between mean CCI scores and PCE at exposures below 10 ppm. EPA also ignored the fact that there are task differences between the two groups of workers that could have resulted in peak exposures not accounted for in the exposure assessment, which evaluated only 8-hr TWA values. Thus, the

[15] EPA Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro-) (# 740-R1-8011) (December 2020), (hereafter "Risk Evaluation"); EPA-HQ-OPPT-2019-0502-0058.

adverse effect of color discrimination from PCE exposure reported by Cavalleri *et al.* (1994) is a weak finding with very few affected workers. Nor has it been replicated by other investigative groups at these low PCE exposures. Nevertheless, the results indicate a threshold (NOAEL) of 5 ppm.

EPA's Risk Evaluation concludes that "based on numerous identified functional outcomes in human studies supported by both clinical and mechanistic findings in animals, neurotoxicity following PCE exposure is supported by the weight of the scientific evidence."[16] While an objective review might conclude that high-level exposures (*e.g.*, 50-100 ppm) are probably associated with subtle changes in neurosensory perception, it would likely note that few firm conclusions regarding lower-level exposures can be drawn from the available epidemiologic literature.

Chamber studies by Altmann *et al.* (1990) have suggested that 50 ppm exposure to PCE can produce subtle deficits in Visual Contrast Sensitivity (VCS), although exposures of 10 ppm produced no measurable effect.[17] Seeber (1989) reported effects across most psychometric domains for exposure exceeding 50 ppm, although the interpretation of these results is complicated by potential bias and lack of a consistent exposure-response relationship.[18] Exposures above 40 ppm have also been consistently associated with subclinical deficits in memory and perception.[19] However, there was no consistent pattern of effects from lower-level exposures. The studies on color vision represent a small, inconsistent, and potentially biased literature base. The studies by Nakatsuka *et al.* (1992) and Sharanjeet-Kaur *et al.* (2004) reported opposite effects, although both are seriously flawed.[20] Valic *et al.* (1997) found no effect from

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[16] Risk Evaluation, at 326.

[17] Altmann L, Böttger A, Wiegand H, Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans, *Int Arch Occup Environ Health* 62, 493 (1990).

[18] Seeber, A, Neurobehavioral toxicity of long-term exposure to tetrachloroethylene, *Neurotoxicol Teratol* 11, 579-583 (1989).

[19] Echeverria, D, White, RF, Sampaio, C, 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).

[20] Nakatsuka, H *et al.*, Absence of blue-yellow color vision loss among workers exposure to toluene or tetrachloroethylene, mostly at levels below occupational exposure limits, *Int Arch Occup Environ Health* 64, 113-117 (1992); Sharanjeet-Kaur, Mursyid, A, Kamaruddin, A, Ariffin, A, Effect of petroleum derivatives and solvents on colour vision, *Clin. Exp. Optom* 87, 339-343 (2004).

PCE exposure in the absence of fairly heavy alcohol consumption (4 drinks per day), even with concurrent exposure to other solvents.[21] Cavalleri *et al.* (1994) reported an increased risk among dry cleaners, but this was limited to exposures above 10-15 ppm, and may have been driven by exposures above 20 ppm. As noted above, exposure was significantly associated with CCI in regression models, but this was driven by exposures above 10-12 ppm (especially two values above 20 ppm), with no evidence of a linear association below 10 ppm.[22] It should also be noted that Cavalleri *et al.* found no association with duration of exposure or cumulative exposure, which suggests a temporary effect consistent with color vision studies investigating other chemicals.[23]

Overall, the epidemiologic evidence suggests that high-level exposure (>40-50 ppm) to PCE may be associated with subtle neurobehavioral effects. The data on lower-level exposures are much more difficult to interpret. The general solvent literature suggests that sensory tests involving visual pathways (*e.g.*, color discrimination and contrast sensitivity) would provide the most sensitive endpoints, but the inconsistent and potentially flawed nature of the literature preclude such a determination for PCE exposure. The subtle nature of these effects makes it difficult to tease out risks related to PCE from those related to other factors.

In light of the foregoing, EPA should not determine that subtle behavioral effects at low levels of exposure to PCE constitute unreasonable risk.

B. Altmann et al. (1990) is a poor choice for the basis of the acute toxicity risk value in the Risk Evaluation

The acute effects of PCE in humans and animals have been well reviewed, with the CNS, characterized by CNS depression, being the target of concern. Humans are expected to exhibit CNS effects following acute inhalation exposures of about 100 ppm PCE and higher. Altmann *et al.* (1990) measured changes in visual evoked potentials (VEP) in human volunteers (22 total)

[21] Valic, E, Waldhör, T, Konnaris, C, Michistsch, A, Wolf, C, Acquired dyschromatopsia in combined exposure to solvents and alcohol*, Int. Arch Occup. Environ Health* 70, 403-406 (1997).

[22] Cavalleri, A, Gobba, F, Paltrinieri, M, Fantuzzi, G, Righi, E, Aggazzotti, G, Perchloroethylene exposure can induce colour vision loss, *Neurosci Lett* 179: 162-166 (1994).

[23] Triebig, G, Stark, T, Ihrig, A *et al.*, Intervention study on acquired color vision deficiencies in styrene-exposed workers, *J Occup Environ Med*, 43, 494-500 (2001); Cavalleri, A, Gobba, F, Reversible color vision loss in occupational exposure to metallic mercury, *Environ Res* 77, 173-177 (1998).

exposed to 10 or 50 ppm PCE 4 hours/day for up to four consecutive days.[24] Brainstem auditory-evoked potentials (BAEP) were also measured, as well as visual contrast sensitivity (VCS) in some subjects. The VEP latency values were reported to be statistically significantly higher at 50 ppm compared to 10 ppm on each of the four exposure days. However, the BAEP peak latencies were not significantly different between the two exposure groups and the limited number of VCS tests indicated a non-statistically significant contrast sensitivity loss following exposure to 50 ppm PCE only. Blood PCE concentration was significantly correlated with the VEP peak N150 *only*, and not to all three VEP peak latencies as implied in the draft Risk Evaluation.

While the results seem to suggest that exposure to 50 ppm, but not 10 ppm, PCE affects the visual system, there are difficulties when interpreting the data. First, it is unclear why the VEP peak latencies showed an increase (perceived as a deficit) at 50 ppm, but a decrease (perceived as an improvement) at 10 ppm, when compared to pre-exposure values. The reason for this lack of dose-dependency is unknown. It is unfortunate that the study investigators did not include three exposure concentrations in their study, which would have provided a more convincing case for a biological effect of PCE on the visual system (a bi-phasic response is certainly possible, but needs a biologically sound explanation). Second, the statistical analysis is not described in detail, as pointed out in the data quality review. It is unknown whether the statistical significance indicated by the authors is reliable (*i.e.*, false positive rate) given the large number of multiple comparisons. Factorial analysis of variance was not performed and only a multitude of unadjusted group comparisons were reported. Without specific hypotheses for the various VEP tests there should be some sort of ANOVA analysis to determine an overall p-value before making individual comparisons, or else an appropriate adjustment of a level. Finally, the size of the observed effect of PCE exposure on VEP peak latencies is in the range of 1.0 to 2.5 ms, which is a very small change. Moreover, only 3 of the 6 patterns used to elicit VEPs were affected, the amplitudes of all VEP latencies were not changed, and the BAEP was similar in both exposure groups and with the pre-exposure values.

The changes in VEP latencies reported by Altmann *et al.* (1990) from acute to short-term PCE inhalation exposures appear to be highly selective results and of questionable toxicological significance. EPA should carefully consider the approach used by the German MAK for

[24] Altmann L, Böttger A, Wiegand H, Neurophysiological and psychophysical measurements reveal effects of acute low-level organic solvent exposure in humans, Int Arch Occup Environ Health 62: 493 (1990).

developing an occupational exposure limit for PCE based on acute neurotoxicity.[25] The MAK concluded that the LOAEC and NOAEC values from Altmann *et al*. (1990) are 50 and 10 ppm, respectively, as did EPA. Unlike EPA, however, the MAK decided to base its value on a higher NOAEC value, from studies by Hake and Stewart.[26] As noted above, a limitation of the Altmann study is that there were only two exposure concentrations instead of three or more; the investigators also used a wide space between the two exposure levels (a 5-fold difference). Hake and Stewart used a different measurement of neurotoxicity and reported a LOAEC and NOAEC of 100 and 20 ppm, respectively for exposures that were 7.5 hr/day for 5 days. EPA rates both studies in its systematic review as medium quality.

In the Risk Evaluation, EPA scaled the exposure duration of 4 hours in the Altmann study to 8 hours, reducing the NOAEC from 10 ppm to 5 ppm. An uncertainty factor (UF) of 10 for human variability was then used to benchmark acute neurotoxicity risk. Dividing the NOAEC of 5 ppm by the UF of 10 resulted in an 8-hr ECEL of 0.5 ppm. The MAK, on the other hand, concluded:

> "Neurotoxicity is considered the most sensitive endpoint for tetrachloroethylene. In volunteers, repeated daily 4-hour inhalation exposure caused small but significant effects on visual evoked potentials. The NOAEC was 10 ml/m^3 [ppm], but as only weak effects were observed at the LOAEC of 50 ml/m^3, 20 ml/m^3 is regarded as the NAEC. As a doubling of uptake is expected under workplace conditions, a MAK value of 10 ml/m^3 has been set."[27]

C. Perc is unlikely to cause cancer in workers; perc-induced mouse liver tumors are not relevant to humans

The docket of the instant rulemaking does not provide evidence that workplace exposures in accordance with the OSHA limits are insufficiently protective. The proposed rule lacks the fundamental statutory prerequisite that it address an "unreasonable risk." The best available

[25] Tetrachloroethylene/1,1,2,2-tetrachloroethene [Tetrachloroethene], MAK Value Documentation, MAK Collection for Occupational Health and Safety Vol 2, No 2 (2017) (Attachment C).

[26] Stewart, RD *et al.*, Effects of perchloroethylene/drug interation on behavior and neurological function, Final Report Contract No. CDC 201-75-0059, DHEW (NIOSH) Publication No. 77-191 (1977); Hake, CL, Stewart, RD, Human exposure to tetrachloroethylene: inhalation and skin contact, *Environ Health Perspect* 21, 231-238 (1977).

[27] Tetrachloroethylene/1,1,2,2-tetrachloroethene [Tetrachloroethene], MAK Value Documentation, MAK Collection for Occupational Health and Safety Vol 2, No 2 (2017) (Attachment C).

review of the epidemiology studies makes clear that no overall cancer risk was found in workers exposed to perc.[28] The Risk Evaluation recognized the weakness of the association:

> "There is a pattern of epidemiological evidence associating PCE exposure with NHL. There is some evidence for bladder cancer and multiple myeloma (MM) but results are mixed. Additional epidemiological data were available showing weaker support for cancers at other sites, including esophageal, lung, and blood (lymphoma). Studies provide more limited support for associations with breast cancer, with little or no support for associations with kidney, esophagus, or liver cancer, and no useful information for cervical cancer."[29]

The German workplace authorities similarly concluded that the evidence for a linear association between perc and carcinogenicity is lacking:

> "Results from human studies do not point to a genotoxic potential of tetrachloroethylene. In vitro and in vivo studies in mammalian cells do not show a distinct genotoxic potential. From epidemiologic and animal studies there is concern that tetrachloroethylene could be carcinogenic for humans; therefore, tetrachloroethylene has been classified in Carcinogen Category 3B. However, since carcinogenic effects are judged to be not predominantly caused by genotoxic mechanisms, a MAK value can be derived."[30]

Based on these reviews, the Germans declined to regulate perc on the basis of carcinogenicity. EPA, on the other hand, continues to assert that perc is a human carcinogen, without regard to HSIA's extensive comments. The Revised Risk Determination did not even mention the carcinogenicity issue.[31] Yet it is well-established that "[a]n agency must consider and respond to significant comments received during the period for public comment."[32]

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[28] Mundt, KA, Birk, T, Burch, MT, Critical review of the epidemiological literature on occupational exposure to perchloroethylene and cancer, *Int Arch Occup Environ Health* 76, 473-491 (2003) (Attachment D); Comments on the Bladder Cancer and Liver Cancer Systematic Reviews in US EPA's Draft Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) CASRN: 127-18-4. Report prepared by JE Goodman (Gradient), submitted to EPA as Appendix 2 to HSIA comments on draft Risk Evaluation, EPA-HQ-OPPT-2019-0502-0053.

[29] Risk Evaluation, at 329.

[30] Tetrachloroethylene/1,1,2,2-tetrachloroethene [Tetrachloroethene], MAK Value Documentation, MAK Collection for Occupational Health and Safety Vol 2, No 2 (2017) (Attachment C).

[31] EPA, Unreasonable Risk Determination for Perchloroethylene (PCE) (December 2022) (hereafter "Revised Risk Determination"), EPA-HQ-OPPT-2016-0732-0142; *see also* Perchloroethylene (PCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination, Response to Public Comments Received (December 2022), EPA-HQ-OPPT-2016-0732-0141.

[32] *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

In summary, EPA's Risk Evaluation disregarded the robust human data from the epidemiology studies that investigated carcinogenicity in perc-exposed workers; this is inconsistent with the use of "best available science" required by TSCA §§ 6 and 26(h). The human data provide no evidence of overall increased cancer risk liver effects in perc-exposed workers. Therefore, the existing OSHA PEL of 100 ppm, not to mention the ACGIH TLV of 25 ppm, adequately protects workers from carcinogenicity. EPA's proposed lowering of the workplace exposure limit 714-fold to the ECEL value of 0.14 ppm as an 8-hour TWA cannot be scientifically justified.

EPA has erroneously classified perc: "In accordance with EPA Guidelines for Carcinogen Risk Assessment, PCE is considered 'likely to be carcinogenic in humans' by all routes of exposure based on conclusive evidence in animals and suggestive evidence in humans."[33] This is in error for two reasons. First, the evidence from human studies is not even suggestive. Second, EPA chose mouse liver tumors from two-year perc carcinogenicity studies to estimate human cancer risk because these tumors were "suitable for dose-response assessment." Yet, there is no evidence of an association in the cancer epidemiology studies between liver cancer and perc exposure. As stated by EPA, there is "little or no support for associations with kidney, esophagus, or *liver* cancer." As discussed below, this lack of an association between liver cancer and perc exposure in humans is expected from the mode of action (MOA) for the perc-induced mouse liver tumors, which is not considered to be relevant to humans.

EPA concluded in the 2020 Risk Evaluation that there was unreasonable cancer risk to workers (excess cancer risk of 1 in 10,000) in all industrial or commercial conditions of use (COUs) from inhalation and/or dermal exposure to PCE when personal protective equipment (PPE) was not used. The Inhalation Unit Risk (IUR) value used for these assessments was derived from a linear non-threshold dose-response model of male mouse liver tumors from a two-year inhalation study conducted by the Japan Industrial Safety Association (JISA).[34] Both the choice of the tumor type and the linear extrapolation approach were justified by EPA on the basis that, according to the EPA Cancer Guidelines,[35] "a linear extrapolation approach is used

[33] EPA-HQ-OPPT-2019-0502-0058, at 328.

[34] JISA, Carcinogenicity Study of Tetrachloroethylene by Inhalation in Rats and Mice, Hadano, Japan (1993).

[35] EPA Guidelines for Carcinogen Risk Assessment, EPA/630/P-03/001F (March 2005).

when the mode of action [MOA] information is supportive of linearity or mode of action is not understood." In the case of PCE-induced mouse liver tumors, the Risk Evaluation concludes that "PCE likely induces liver tumors through multiple modes of action mediated largely by metabolites," and that "for [liver tumors] an MOA has not been established that would allow for the use of a threshold approach."[36]

EPA claims to have "conducted a weight of the scientific evidence evaluation for several proposed MOAs for liver carcinogenicity."[37] However, a more thorough examination of EPA's MOA analysis of the PCE-induced mouse liver tumors indicates that it was a very weakly supported attempt that does not reflect the "best available science." In fact, the EPA Science Advisory Committee on Chemicals (SACC), in its peer review of the draft Risk Evaluation, did not agree with EPA's interpretation of the proposed liver tumor MOAs and felt that "the supportive evidence for some of the proposed mouse liver cancer MOA was minimal and/or circumstantial."[38] The final report of the SACC peer review also states that "the evidence for genotoxicity in the mouse liver stemming from PCE exposure was not convincing to most Committee members."[39]

EPA dismissed peroxisome proliferator-activated receptor alpha (PPARα) activation as the primary MOA for PCE-induced mouse liver tumors. Based on the extensive database on

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[36] Risk Evaluation at 320, 326.

[37] *Id.*at 316.

[38] TSCA Science Advisory Committee Meeting Minutes and Final Report No. 2020-5; EPA-HQ-OPPT- 2019-0502, at 80-81.

[39] *Id*. *See also* Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE) Response to Support Risk Evaluation of Perchloroethylene (PCE) (December 2020), EPA-HQ-OPPT-2016-0732-0141 (emphasis added). As EPA summarized the SACC conclusions: "The EPA selected mouse hepatocellular carcinoma as the species and cancer endpoint for POD estimation. A linear extrapolation is used based on the EPA's default policy of applying this to situations where there is evidence of genotoxicity as part of the MOA or little is known. Some Committee members had problems with this decision and questioned whether mouse liver cancer is appropriate when there are little or no data supporting the liver as a PCE-related cancer site in humans. *Although the genotoxicity of the DCVC and TCVC is well-established as a reasonable MOA for kidney cancer, what is not well-established is the relative importance of genotoxicity of these PCE metabolites in mouse liver cancer. Thus, 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*. As for lung tumors, there is absolutely no evidence of this in humans. Despite occurrence in multiple species (mice and rats), extrapolation to humans without any supporting mechanistic data is problematic." EPA then agreed that the evidence for the role of genotoxicity in the formation of liver tumors is not well established" and said "[t]he liver MOA section has been revised to give less weight to the role of genotoxicity in the liver cancer." Nevertheless it still proposes to regulate on the basis of a linear extrapolation.

metabolism and mechanistic studies, PCE appears to produce mouse liver tumors through the activation of the nuclear receptor, PPARα. Most significantly, EPA's refusal to recognize PPARα activation as the primary MOA directly contradicts EPA's own weight-of-the-evidence guidance recently issued by a sister program:

> "PPAR-alpha Agonism - Chemicals that bind to and activate the Peroxisome Proliferator-Activated Receptor (PPAR) stimulate biological responses in the liver (e.g., peroxisome proliferation, induction of lipid metabolizing enzymes, oxidative stress, and hepatocyte mitogenesis). Activation of PPAR–alpha results in an increase in cell proliferation and clonal expansion of preneoplastic foci in the liver. *While the human relevance of this MOA has not been definitively determined, most of the evidence indicates that this MOA is not operative in the human liver*."[40]

The reason this is so important is that TSCA § 26(i) provides: "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence." Strangely, EPA does not appear to have defined "weight of the scientific evidence" in this rulemaking, and the term is nowhere found in the preamble or the proposed rule. Here, however, clear EPA weight-of-evidence guidance indicates that the cancer endpoint on which EPA's risk assessment is based is not relevant to humans.

The PCE MOA follows the established PPARα MOA for liver tumors with the addition of a first Key Event (KE) – the metabolism of PCE to trichloroacetic acid (TCA). The Key Events for the PCE MOA are: (1) metabolism of PCE to TCA; (2) activation of PPARα; (3) alteration in hepatic gene expression including cell growth pathways; (4) increase in cell proliferation; (5) selective clonal expansion of hepatic preneoplastic foci cells; and (6) formation of hepatic neoplasms. Rodent liver tumorigens that function through the PPARα MOA do not induce liver tumors in humans; this is supported by considerable experimental and epidemiological evidence. These arguments have been thoroughly addressed in extensive reviews, and it has been generally accepted by the liver carcinogenesis scientific community that rodent liver tumors with a PPARα MOA are not human liver tumorigens. The mechanisms supporting the PPARα MOA have shown that in the rodent (rat and mice), a three-tier response is seen following activation of PPARα: (1) peroxisome proliferation, (2) cell growth

[40] GUIDANCE ON USE OF WEIGHT OF EVIDENCE WHEN EVALUATING THE HUMAN CARCINOGENIC POTENTIAL OF PESTICIDES for Use by Cancer Assessment Review Committee Members, EPA OFFICE OF PESTICIDE PROGRAMS (JUNE 2023) (hereafter "OPP WoE Guidance"), at 17 (emphasis added); https://www.epa.gov/system/files/documents/2023-06/2023%20CARC%20WoE%20Guidance.pdf.

modification (cell proliferation), and (3) lipid metabolism gene expression. Only the lipid metabolism gene expression, which accounts for the hypolipidemic effects of PPARα drugs, occurs in humans. Modification of cell growth, required for tumor growth, is not seen in humans with PPARα activation.[41] In further support, there have been several large retrospective epidemiological studies that have examined the effects of chronic treatment with the PPARα-activating hypolipidemic drugs gemfibrozil and clofibrate.[42] These studies have shown no elevated risk of mortality from liver cancer associated with over a decade of chronic use of these hypolipidemic pharmaceuticals.

As also noted by the SACC in its review of the draft PCE Risk Evaluation, 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). While some of the liver metabolites of PCE are *in vitro* mutagens/genotoxicants, it is uncertain whether these metabolites are generated at adequate levels in the tumor target tissue to damage nuclear DNA. Although no studies have examined the induction of mutations in the livers of mice exposed to PCE or TCA, as discussed above the available data for a mutagenic MOA for PCE is relatively weak and a compelling case can be made for an alternate MOA that does not involve DNA reactivity/mutagenesis as an early key event for mouse liver tumors.

EPA has speculated on other less specific and poorly investigated MOAs for PCE-induced mouse liver tumors in the IRIS Assessment and the Risk Evaluation. These alternate MOAs are hypothetical and tend to be based on limited information from a single laboratory involving single-dose or short-term exposures.

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[41] Klaunig, JE *et al.*, PPAR-alpha agonist-induced rodent tumors: modes of action and human relevance. *Crit. Rev. Toxicol.* 33: 655-780 (2003); Corton, JC, Evaluation of the role of peroxisome proliferator-activated receptor alpha (PPAR alpha) in mouse liver tumor induction by trichloroethylene and metabolites. *Crit. Rev. Toxicol.* 38: 857-75 (2008); Corton, JC *et al.*, Mode of action framework analysis for receptor-mediated toxicity: The peroxisome proliferator-activated receptor alpha (PPARα) as a case study. *Crit. Rev. Toxicol.* 44: 1-49 (2014); Corton, JC, Peters, JM, and Klaunig, JE, The PPARα-dependent rodent liver tumor response is not relevant to humans: addressing misconceptions. *Arch. Toxicology* 92: 83-119 (2018); Felter, SP *et al.*, Human relevance of rodent liver tumors: key insights from a Toxicology Forum workshop on nongenotoxic modes of action. *Regulatory Toxicol. Pharmacol.* 92: 1-7 (2018).

[42] Klaunig, JE *et al.*, PPAR-alpha agonist-induced rodent tumors: modes of action and human relevance. *Crit. Rev. Toxicol.* 33: 655-780 (2003); Corton, JC, Peters, JM, and Klaunig, JE 2018, The PPARα-dependent rodent liver tumor response is not relevant to humans: addressing misconceptions. *Arch. Toxicology* 92: 83-119 (2018).

D. EPA did not use best available science in its occupational exposure assessments

EPA proposed prohibition, rather than compliance with a WCPP, of most industrial and commercial uses of perc because it concluded that there is a high degree of uncertainty regarding whether compliance with the proposed ECEL is possible. This approach relies, at least in part, on the exposure assessments in the Risk Evaluation for these COUs.

1. Inhalation exposure assessment

Although HSIA provided industrial hygiene (IH) data for manufacturing and feedstock use indicating that they did not pose unreasonable risk for chronic inhalation exposure (or for acute exposure with a 25 APF),[43] otherwise the Risk Evaluation relied on workplace inhalation exposure data that were of low quantity or were not representative of current industry practices for certain commercial or industry uses. Despite these inadequacies, EPA utilized these exposure data in the Risk Evaluation rather than considering alternative approaches that would result in a higher confidence in estimating workplace exposures. Generally, for these COUs there was a lack of workplace inhalation exposure data, or the data were of low quality or not representative of current industry practices. There are numerous ways in which EPA's occupational exposure assessment methodologies could have been refined to better characterize exposures with high confidence, particularly for historical and small data sets, as described in a recent publication by Lynch *et al*.[44] Had EPA developed more robust exposure estimates consistent with best practices for occupational risk assessment,[45] it would have been better able to gauge the likelihood that specific industry sectors would be able to meet the proposed ECEL for perc.

Combining multiple exposure information sources for COUs and COU subcategories with limited information, rather than relying strictly on empirical data, also would have allowed EPA to better understand potential occupational exposures to perc for the purposes of risk management. Owing to EPA's hierarchy of data sources, empirical data are typically preferred over modeling, regardless of the number of data points. Small datasets were a limitation of the

[43] EPA-HQ-OPPT-2016-0732-0097.

[44] Lynch, HN, Allen, LH, Hamaji, CM, Maier, A, Strategies for refinement of occupational inhalation exposure evaluation in the EPA TSCA risk evaluation process, *Toxicol Ind Health* 39: 169-182 (2023a) (Attachment E).

[45] For example, a 2015 textbook from the American Industrial Hygiene Association: Jahn SD, Bullock WH, Ignacio JS, et al. A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. AIHA (2015).

exposure estimates for many of the COU subcategories in the perc risk assessment. AIHA and other occupational health professional associations recommend that if empirical data are limited or of low quality, these data should be supplemented by exposure modeling, or the data be used to parameterize a model.[46] Alternatively, empirical data can be used as a method to validate exposure modeling. Regardless of specific approach, integrating several sources of exposure information generally increases the confidence in the resulting exposure estimate. Again, had EPA followed best practices recommendations for handling small industrial hygiene datasets, it would have been able to better characterize the likelihood of exceedance of the ECEL for specific uses and base its risk management recommendations on this understanding.

2. Dermal exposure assessment

In both the Risk Evaluation and the Revised Risk Determination, EPA found unreasonable risks to workers from acute and chronic dermal exposure in the manufacture of perc and its use in the production of other chemicals (feedstock or intermediate use), even with the most protective glove use (Protection Factor of 20). Although EPA assumed glove use in the Risk Evaluation for dermal protection, the models EPA used to estimate the amount of PCE that is retained by workers from dermal contact was not based on any supporting information and overestimated any potential exposure. These "worst-case scenarios" assumed unrealistic dermal exposure durations and fail to recognize basic industrial hygiene (IH) practices, including implementation of OSHA-compliant standard operating procedures (SOPs) and OSHA-compliant PPE Hazard Assessments, as well as engineering controls required by the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Synthetic Organic Chemical Manufacturing Industry (SOCMI)[47] and Miscellaneous Organic Chemical Manufacturing (MON),[48] which require closed systems where exposure is tightly controlled. Thus, they are clearly inapplicable to facilities that manufacture perc or use perc as a process reactant or intermediate.

[46] Mulhausen J, Milz, S, Hewett, P, et al. Chapter 8: Quantitative Exposure Data: Interpretation, Decision-Making, and Statistical Tools. A Strategy for Assessing and Managing Occupational Exposures. 4th Edition. AIHA, pp. 124-141 (2015).

[47] 40 C.F.R. Part 63 Subparts F, G, H, I.

[48] 40 C.F.R. Part 63, Subpart FFFF.

The manufacture of PCE and its use in the production of other chemicals (*i.e.*, refrigerants) 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. "Closed systems (including rigorous containment by technical means) generally relate to high integrity plant/machinery where the opportunity for exposure is negligible, both in terms of frequency and magnitude."[49] Following several meetings with OPPT staff, HSIA submitted to the docket two documents that provide comprehensive details on the layers of protection in place to protect workers. Example protections implemented for typical tasks involved in the manufacturing of carbon tetrachloride and the Standard Operating Procedures (SOPs) for these tasks including details on training, both process and task specific, to properly perform tasks and prevent exposure, glove selection criteria, glove inspection procedures, personal protective equipment (PPE) use, and inspections to ensure engineering controls were operating properly.[50] HSIA emphasized repeatedly to OPPT staff that these comments apply equally to manufacture of the other chlorinated solvents, including PCE, and their use as intermediates in manufacturing fluorochemicals. The typical short-term (5-30 minutes) tasks that could potentially involve contact with liquid phase PCE are loading transport equipment, conducting minor maintenance and line openings, packaging wastes, and collecting process samples. Although not expected, should accidental contact with PCE occur during the performance of these tasks, concentrations and amounts are minimal. Incidental, intermittent, or splash contact may only occur if there is an accidental spill, overspray conditions, or unexpected failure of a control device.

Despite the engineering controls, PPE, training, and SOPs in place to prevent any exposure and potential for exposure limited to the short-term tasks described above, EPA estimated dermal exposure to PCE for workers using Kasting and Miller (2006) with the following assumptions: (1) one dermal contact with undiluted PCE which coats fully one or both hands per work shift; (2) workers do not wash their hands at any point during the 8-hour work shift if gloves are not worn; and (3) a worker wears the same pair of gloves for the entire 8-hour

[49] European Chemicals Agency (ECHA), Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.14: Occupational Exposure Assessment, Version 3.0 (2016).

[50] SOPs for Personal Protection at CTC Manufacturing Sites; HSIA Response to EPA's Questions on Standard Operating Procedures (SOPs) at Carbon Tetrachloride and Other Solvent Manufacturing Facilities (September 27, 2021). EPA-HQ-OPPT-2020-0592-0003. Although EPA has had this documentation for almost two years, it did not revise the assessment in its Revised Risk Determination and made no reference to the submission.

work shift without stopping to wash their hands and/or change their gloves.[51] Incredibly, EPA provides no documentation or justification for these assumptions other than the intent to establish a theoretical "worst-case scenario." As a result of these assumptions, EPA very substantially overestimated worker exposure to PCE from dermal contact in facilities that manufacture and use PCE as a reactant or intermediate.

According to EPA, risk evaluations under TSCA § 6(b) are not screening level risk assessments, but are intended to "use scientific information, technical procedures, measures, protocols, methodologies and models consistent with the best available science." Therefore, EPA should use in its dermal exposure models data and assumptions that are relevant and appropriate to actual workplace practices for the COUs being evaluated, information which EPA has had now for several years.[52] Unfortunately, the Risk Evaluation fails to acknowledge basic IH practices.

As noted in the information provided to EPA on use of PPE at chlorinated solvent production facilities with closed systems, any potential dermal exposures are for short durations and, combined with the industry standards for good 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. Moreover, PCE will evaporate from the skin and gloves between exposure periods.

Lynch *et al*.[53] reviewed the methodology in the Risk Evaluation for estimating dermal exposures of workers to several chlorinated chemicals for the COUs involving manufacturing and feedstock use. They also provided best practice recommendations which can be broadly applied to any of the exposure scenarios used in the Risk Evaluation. The authors recommended

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[51] Risk Evaluation, Supplemental Information on Releases and Occupational Exposure Assessment.

[52] In this regard, the SACC concluded 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." See Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE): Response to Support Risk Evaluation (epa.gov) at 217. In spite of having had very reliable monitoring data for these COUs for years, EPA has continued to ignore this input.

[53] Lynch, HN, Gloekler, LE, Allen, LH, Maskrey, JR, Bevan, C, Maier, Analysis of dermal exposure assessment in the US Environmental Protection Agency Toxic Substances Control Act risk evaluations of chemical manufacturing, *Toxicol Ind Health* 39: 49-65 (2023b) (Attachment F).

a "tiered, integrated approach to dermal exposure assessment that emphasizes collecting qualitative data; employing validated, peer-reviewed models that align with current industrial practices; and gathering empirical sampling data when needed." They also recommended that a more realistic approach to estimating the dermal dose of DCM in workers in closed system facilities (manufacturing and process reactant/intermediate use) be obtained by using the IH Skin Perm model.[54] This tool is commonly used by practitioners of IH and exposure assessment to produce reliable estimates of dermal exposure. And, as noted in the Risk Evaluation, "this model takes into account losses to evaporation and estimates the mass that is absorbed." 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, as well as the "objectivity" criterion of the Information Quality Act. EPA's reliance on hypothetical assumptions for modeling of 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.

3. Flawed assumptions regarding use of PPE in Revised Risk Determinations

In justifying its Revised Risk Determination for all COUs of perc, EPA excluded consideration of PPE use on the basis that this change "reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being 'outdated and inadequate for ensuring

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

protection of worker health,' or because [EPA] finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements."[55]

EPA has generalized this concern to all COUs for perc, yet it is not pertinent at all to the manufacture of perc, or its use as a fluorochemicals feedstock, based on the information provided by HSIA to EPA on industry best practices for industrial hygiene. The perc manufacturers, of which there are only three in the United States, submitted to EPA two documents that provide comprehensive details on the typical tasks involved in the manufacture of carbon tetrachloride and more generally, chlorinated solvent manufacturing including perc, and the SOPs for these tasks including PPE use.[56] These documents also provide a summary of the extensive training that are in place for employees (new and seasoned) to ensure SOP requirements are followed. There are no exceptions – the SOPs and training apply to all workers.

For the manufacture and feedstock COUs for perc, EPA must assess in the Risk Evaluation the circumstances under which perc is intended, known, or reasonably foreseen to be manufactured. Where PPE use is required by all US manufacturers and that information has been "clearly articulated" to EPA, EPA must take that information into account in its Risk Evaluation.

4. NYSDEC monitoring data of dry cleaning facilities

A major oversight in EPA's exposure assessment of the dry cleaning industry is the omission of New York Department of Environmental Conservation (NYSDEC) data collected under 6 NYCCRR Part 232, which regulates dry cleaning. Under this regulation, New York requires yearly compliance inspections with trained inspectors registered with the state (*e.g.*, an engineer or Certified Industrial Hygienist) (6 NYCRR 232-2.11). The inspector must collect badge monitoring data, which is then provided to NYSDEC. *These data cover all dry-cleaning facilities in New York state and are collected under normal operating conditions*. The air sampling for PCE involves using passive badge monitoring and requires at least two hours of area sampling (two machine loads). These samples are collected in both the cleaning and

[55] Revised Risk Determination, at 4.

[56] SOPs for Personal Protection at CTC Manufacturing Sites; HSIA Response to EPA's Questions on Standard Operating Procedures (SOPs) at Carbon Tetrachloride and Other Solvent Manufacturing Facilities (September 27, 2021); EPA-HQ-OPPT-2020-0592-0003.

pressing areas to evaluate whether ventilation and control measures are working adequately, and if they are in compliance with state standards.

HSIA informed EPA about the NYSDEC data in its comments on the draft PCE Risk Evaluation, and also provided EPA an Excel spreadsheet file that contained critical data from the New York State Part 232 Dry Cleaning Compliance Inspection Report for the years 2013 to 2015. HSIA also provided EPA "A Report on Drycleaning Plant Emissions based on Test Data from Plants in the New York State" prepared by Tatch Technical Services in 2002 for HSIA. The report provides a review of 300+ dry cleaning plant inspections in New York State and an independent analysis of PCE emissions.

Instead of incorporating the NYSDEC data from 2013 to 2015 into the Risk Evaluation or at least contacting the NYSDEC to discuss the data so that the exposure assessment for dry cleaning facilities would reflect the "best available science," which could have been done before completing the Risk Evaluation, EPA simply responded "the data did not include appropriate metadata (sample type and exposure type) and was thus rated 'unacceptable' as determined through EPA's systematic review process. Therefore, this data was not incorporated into the risk evaluation."[57] EPA further stated "the data provided are 2-hr area samples. EPA's preference is to use PBZ monitoring data over area data. Furthermore, 2-hr data are not expected to be representative of dry-cleaning worker's full-shift exposure."

Subsequent to the issuance of the final Risk Evaluation, there were several meetings between HSIA and OPPT staff to obtain more complete and up-to-date monitoring data from NYSDEC. These meetings were initiated by OPPT staff, which was surprising since EPA could have communicated directly with NYSDEC to obtain the data. Although OPPT staff confirmed that the data were received from NYSDEC, EPA has not made public whether the NYSDEC monitoring data have been analyzed, and if so, what methods were used to convert these data to 8-hour time-weighted equivalents. Given the comprehensive nature of these data (which provide a complete picture of PCE exposures for all dry-cleaning establishments in New York over multiple years), it is imperative that the results be used to assess employee exposure in the Risk

[57] Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE) Response to Support Risk Evaluation of Perchloroethylene (PCE) (December 2020); EPA-HQ-OPPT-2016-0732-0141, at 78-79.

Evaluation and for the economic analysis in the proposed rule. The report with EPA's analysis of the NYSDEC data should also be made available to the public.

E. EPA did not use best available science in its systematic review

The preamble states "EPA considers the PCE ECEL to represent the best available science under TSCA section 26(h) because it was derived from information in the 2020 Risk Evaluation for PCE, which was subject to peer review, and which is the result of a systematic review process that investigated the reasonably available information in order to identify relevant adverse health effects."[58] This was not the view of the outside peer reviewers, who have been generally critical of the systematic review process EPA employed in the Risk Evaluation.

TSCA §§ 6 and 26 require EPA to use the best available science and weight of the scientific evidence when considering study quality and relevance for multiple lines of evidence. EPA developed its fit-for-purpose systematic review approach because other existing approaches did not satisfy these TSCA statutory requirements. However, the TSCA systematic review approach used for the Risk Evaluation does not include sufficiently detailed guidance for evidence integration and weight of evidence methodology, and EPA did not consistently apply a weight of evidence approach in the Risk Evaluation.

EPA's Scientific Advisory Committee on Chemicals (SACC) recommended a number of improvements in the systematic review process, as did many commenters on the draft Risk Evaluation.[59] More specifically, the Committee to Review EPA's TSCA Systematic Review Guidance Document convened by the Board on Environmental Studies and Toxicology of the National Academy of Sciences was unable to conclude that the TSCA systematic review process is comprehensive, workable, objective, and transparent.[60]

III. ECEL AND WCPP IMPLEMENTATION CONCERNS

Monitoring methodologies, laboratory availability, monitoring protocols and control development, training and implementation all require time to implement a new ECEL,

[58] 88 Fed. Reg. at 39659.

[59] EPA-HQ-OPPT-2019-0437-0078, 0083. *See* a summary and EPA's response at EPA-HQ-OPPT-2016-0742-0122.

[60] The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, National Academy Press (2021).

particularly one significantly lower and more conservative than the PEL currently in effect. EPA should extend the time in § 751.607 to implement the WCPPs required under the regulations.

A. Time is needed for monitoring methodology validation and lab availability

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. NIOSH 1003 is a validated method that meets OSHA's accuracy standards and analytical methods. NIOSH 1003 is the most commonly utilized method for IH sampling in the workplace for PCE. However, the NIOSH 1003 method as currently validated will not achieve the 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. NIOSH Manual of Analytical Methods (NMAM), 5th Edition, Section 2 (December 11, 2017).[61]

EPA's ECEL document lists EPA Method TO-17 as a potential air sampling analytical method. Initial evaluation of available labs for analysis did not identify an AIHA accredited laboratory with the capability to analyze PCE IH samples using the TO-17 methodology. A member company contacted five AIHA accredited laboratories to determine their ability to analyze IH samples using SKC Ultra Diffusive media with TO-17 method analysis. Three 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, and the fifth could not be reached.

In addition to laboratory capabilities, the EPA TO-17 method allows the use of sampling media that the facilities do not currently have experience with, either the Tenax tube or the SKC Ultra Diffusive sampler. Note that Tenax tube requires conditioning and if not used within a short window (months) it must be sent back to the lab for re-conditioning. This stability limitation could introduce additional errors that could give biased data.

Further, NIOSH 3900 and TO-15, the two methods suggested in the ECEL documentation, are both area sampling methods that use specially prepared canisters. These are not methods that can be used for personal breathing zone (PBZ) sampling. PBZ sampling is required by OSHA's substance-specific standards to ensure compliance with OSHA's

[61] https://www.cdc.gov/niosh/nmam/pdfs/nmam_5thed_ebook.pdf

PELs. HSIA supports EPA's proposal to also rely on PBZ samples, as stated in the proposal, "where PCE is present in the workplace, each owner or operator would be required to determine exposure by either taking a PBZ air sample of each potentially exposed person or taking representative PBZ air samples (e.g., by exposure grouping)." The 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. Industrial hygiene applications for canister sampling are limited to monitoring short-duration peak exposures and source emissions as described in two NIOSH Health Hazard Evaluations of coffee roasting facilities, not for sampling full-shift employee exposures to compare to full-shift exposure levels (*e.g.*, ECELs and PELs). https://www.cdc.gov/niosh/hhe/reports/pdfs/2016-0067-3313.pdf. 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.

The proposed requirement of Good Laboratory Practices (GLP) is inconsistent with current workplace monitoring that is conducted to AIHA Industrial Hygiene Laboratory Accreditation Program (AIHA-IHLAP) standards, which most IH labs follow. Perc samples could not be analyzed at AIHA-IHLAP labs and would need to be sent to EPA or the handful of commercial labs that follow GLP. As most IH professionals are not familiar with GLP requirements, additional time would also be required to train IH personnel and consultants regarding IH requirements. The required training and implementation of GLP requirements could cause an unnecessary implementation delay. Additionally, the likely backlog at the available -- but limited -- GLP labs could result in samples not being analyzed before their hold time expires.

EPA's expectation of GLP testing for workplaces is also inconsistent with EPA's TSCA § 5(e) order template, which states: "Compliance with TSCA GLP[s], however, is not required under this New Chemical Exposure Limit Section where the analytical method is verified by a laboratory accredited by either: the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP") or another comparable program approved in advance in writing by EPA." A similar provision should be considered in the instant rulemaking.

B. 12 months is needed for personal monitoring assessment, implementation and training

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 § 751.607(b)(2) to allow 12 months for the initial exposure monitoring requirement. A typical IH reassessment at a facility, as described below in this subsection, takes approximately 12 months. OSHA also allowed 12 months for the initial exposure assessment in the beryllium standard (29 CFR 1910.1024(d), (o)). For the perc rule, at least 12 months for the exposure reassessment is needed for the method revalidation as described above and to incorporate the new ECEL that is a thousand times lower than existing OELs. Each facility will need to determine whether a corporate exposure assessment strategy will need to be reassessed for 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, PSM engineers and HESS personnel. An exposure assessment/reassessment strategy may include confirming and/or reassessing the following exposure assessment goals and written plans for the ECEL evaluation:

1. Methods for systematic information gathering;
2. Confirming similar exposure groups (SEG) for the new ECEL;
3. 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;
4. Identify exposure thresholds and appropriate exposure monitoring methods to meet thresholds;
5. Develop new monitoring procedures for new monitoring methodologies; and
6. 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 Qualitative Exposure Assessment includes identifying the following:

1. All tasks
2. The frequency/duration of each task
3. Estimate of quantity of stressor per task
4. Exposure controls in place for each task exposure

Once the Qualitative Exposure Assessment is complete, the Quantitative Exposure Assessment (personal exposure monitoring) takes place. This step includes:

1. Obtain and train to any new monitoring equipment or methodologies;
2. Collecting the appropriate number of random samples (full-shift and tasks)
3. Performing statistical analysis on sample set, as appropriate
4. Comparing to exposure level
5. Decisions 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 proposed § 751.607(b)(3)(ii) to allow 12 months for the initial exposure monitoring requirement.

C. Adequate time is needed to evaluate monitoring data, plan for, and implement a performance-based WCPP

24-36 months is needed by facilities to evaluate and implement a WCPP. This is consistent with the OSHA beryllium standard that provided 36 months for evaluating and implementing engineering control requirements in a written exposure control plan (29 CFR 1019.1024(f), (o)). An appropriate compliance deadline for evaluating the hierarchy of controls will allow entities adequately to 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 owner/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 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). 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 give 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 (§ 751.607(d)(2)) be extended to 2 years from the completion of initial exposure monitoring, for a total of 24-36 months from the effective date, 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 protections would remain in place for workers through the existing OSHA requirements implemented by facilities such as hazard assessments, including dermal and respiratory protection requirements, and administrative controls such as SOPs and permit requirements.

To allow adequate time to plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers, EPA should allow 24-36 months after the effective date for full implementation of the exposure control plan in proposed §

751.607(d)(2). Adequate time would also allow for full implementation of any necessary engineering, administrative or other controls for compliance with the new ECEL.

D. IH measurement and WCPP implementation should allow for the use of the APF factor for tasks to comply with the ECEL in a full shift

With the low levels of the ECEL as an 8-hour TWA, the proposed respiratory protection language in 40 CFR § 751.605(D)(5) should be clarified so that an exceedance of the ECEL does not automatically default to a required use of the APF for the full shift. Employers should be allowed to implement 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.

Effectively, this approach allows control banding to be focused on task-based scenarios that occur in well-characterized similar exposure groups (SEGs) instead of the full 8-hour data ("Control Band by Task Approach"). This approach of specifying controls for specific product uses is also included for compliance under European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (ECHA 2020). Furthermore, task-based control strategies are common in many industrial operations, particularly in chemical manufacturing. This is because the nature of many of the tasks with potential exposure are of short-duration or of intermittent frequency. There are many guidance documents and reviews that reinforce the importance of task-based exposure controls and application of control banding concepts.[62] For this reason, it is very rare for a worker in chemical manufacturing to wear respiratory protection devices for the full shift.

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

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

that is required and used for that task. An additional and separate air sample would be collected for the remainder of the shift to calculate an 8-hr TWA.

The following narrative illustrates how the Control Band by Task Approach could be implemented:

1. The IH risk assessment creates a similar exposure group (SEG) for employees that conduct sampling once a day;
2. A 30 min. "task" PBZ sample is taken on an employee conducting in-line sampling, during which time the employee is wearing a respirator with a specific APF that has been selected in compliance with the maximum use concentration (MUC) appropriate for the sampling period and as required by the facility's Standard Operating Procedure and Hazard Assessment and/or the WCPP;
3. After the PBZ task sampling period, for the "rest of the day" tasks over the remaining 7.5 hours, the same employee will take a separate PBZ "rest of day" sample;
4. The APF associated with the respiratory protection used for the PBZ "task" PBZ sample will apply to the 30 min task sample taken, and then added to the PBZ rest-of-the day 7.5 hour sample to calculate an 8-hour TWA:

[(PBZ task value x .5)/APF] + (PBZ rest-of-day value x 7.5) /8 = 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 rest-of-the-day PBZ sample separates tasks where potential exposure is not expected and confirms the engineering controls are in place.

To allow for the Control Band by Task approach, 40 CFR § 751.605(D)(5)(ii) could be modified to read as follows *(New language 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 provides 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.

It is recommended that at least six samples are collected to demonstrate the MUC of the APF is appropriate for a SEG and evaluate compliance with the ECEL. This is based on AIHA guidance for assessing and managing occupational exposures, which states that according to

statistical sampling theory, there is a point of diminishing returns above approximately six to ten measurements (AIHA 2015). Given the repetitive task exposure scenarios at PCE manufacturing facilities a "rolling average" could be calculated based on the prior six measurements.

Statistical methods for evaluation against an OEL are also utilized by OSHA. OSHA recognizes that statistical methods should be utilized to account for error factors in the sample results.[63]

E. Direct read instruments must be validated for the new limits

Direct-reading field instruments are currently utilized for maintenance activities, such as a line break, to confirm the 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 (namely a full chemical resistant suit, chemical resistant gloves and boots, a full face supplied air respirator, and a 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 utilize instruments such as a Photo Ionization Detector (PID) as a portable vapor and gas detector for direct reading in the field for a variety of organic compounds, including perc. 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 have to be applied and there are many limitations and concerns for continuing their use with the new lower EPA ECELs. Although there are PIDs technically capable of measuring perc at the ECEL level, measurements would be unstable, with widely fluctuating readings, at such a low level due to the interferences from other volatile organic compounds, humidity, and other factors. In the absence of being able to measure air concentration consistently and accurately below the ECEL, an employee will have to remain in full PPE for the entire duration of the task, creating other physiological concerns such as heat stress. Absence of direct read monitoring equipment also impacts inspection and maintenance of PCE-containing equipment when confined space entry is required. Monitoring that currently takes a few minutes would require a week or more. The protocol for inspection and maintenance of PCE-containing equipment when

[63] OSHA Technical Manual, Chapter 1, https://www.osha.gov/otm/section-2-health-hazards/chapter-1 (last viewed on August 14, 2023.)

confined space entry is required will have to be reevaluated 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.

F. Requirements to resample when results indicate a non-detect are unnecessary

The requirement in § 751.607(b)(3)(i)(E) to re-monitor 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 prior to communicating the results to the employee. Requiring an environmental or IH professional to make a determination that re-monitoring is not necessary is an unneeded step that adds no value and creates the potential for enforcement, as it is not clear what will suffice as justification for this determination and how it is documented.

G. Requirements for direct dermal contact are vague

The 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 a 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 a facility to evaluate potential dermal exposure based upon the task.

IV. EPA FAILED TO CONSIDER THE IMPACTS OF THE PROPOSED RULE ON SMALL BUSINESSES OR TO DETERMINE WHETHER EFFECTIVE ALTERNATIVES ARE AVAILABLE, AS REQUIRED BY TSCA AND SBREFA

A. The proposed rule discriminates against small businesses

EPA has adopted an unprecedented reading of TSCA that allows it actively to discriminate against small businesses, by prohibiting almost all small business uses outright without even providing an opportunity to those businesses to continue to use perc in compliance with a WCPP:

> "Prohibition is the preferred option for occupational conditions of use where greater uncertainty exists relative to a sector's ability to comply with provisions of the proposed

> PCE WCPP, such as an ECEL or DDCC. EPA's 8-hour TWA ECEL for PCE is significantly lower than the OSHA PEL and there is a degree of uncertainty as to whether chemical users under the conditions of use in some sectors will be able to comply with such a level and thus whether the unreasonable risk would be addressed. This uncertainty includes consideration of the difficulties related to respiratory protection, which are discussed in more detail in Unit V.A.1.b., and which include how respirators may present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998) as well as consideration for that fact that not all workers may be able to wear respirators. Similarly, there is also uncertainty regarding certain chemical users' ability to prevent direct dermal contact with PCE, in particular during use in open-systems or when worker activities require manual application or removal of PCE or a PCE-containing product through rags, aerosols, spray guns, roll applicators, fingers, hands, or other materials. Additionally, prohibition is the preferred option for occupational conditions of use where reasonably available information suggests minimal ongoing use or when feasible safer alternatives are reasonably available. The uncertainties related to whether users under certain conditions of use could comply with the requirements of a PCE WCPP, combined with the severity of the risks of PCE, the prevalence of alternative processes and products (Unit V.B), and in some cases reasonably available information indicating a use is no longer ongoing (Refs. 56, 3), has led EPA to propose prohibitions for most industrial and commercial uses of PCE, as well as for the upstream manufacturing, processing, and distribution in commerce for those uses."[64]

HSIA submits that EPA's "uncertainty" as to whether most users can comply with its ECEL is not a sufficient reason to eliminate any compliance option for these users, most of which are small businesses. Also problematic is EPA's assertion that "minimal ongoing use" or "the prevalence of alternative processes and products" or "information indicating a use is no longer ongoing"; none of these is sufficient justification for a ban under TSCA § 6. Nowhere does TSCA authorize EPA to ban a chemical because its use has declined in a particular sector. The only justification for such a ban is that it would present an "unreasonable risk," which EPA has determined is not present where the user is in compliance with a WCPP.

Perhaps in recognition of the concern with peremptorily shutting down thousands of small businesses, EPA offers an alternative regulatory option:

> "EPA acknowledges that, for some of the occupational conditions of use that it is proposing to prohibit, there may be some activities or facilities that could conceivably implement requirements under a PCE WCPP to ensure that exposure remain below an ECEL and prevent direct dermal contact with PCE. In some cases, they may be able to undertake more extensive risk reduction measures than EPA currently anticipates. Therefore, as a primary alternative regulatory action, described in Unit IV.B., EPA is

[64] 88 Fed. Reg. at 39691-92.

> considering and requesting comment on a PCE WCPP -- including requirements to ensure exposures remain below an ECEL and prevent direct dermal contact -- for some conditions of use of PCE that would be prohibited under the proposed regulatory action. For those conditions of use that would be subject to a PCE WCPP under the primary alternative regulatory action but not the proposed regulatory action, EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could mitigate identified unreasonable risk through a PCE WCPP. Due to this uncertainty, EPA is requesting comment on the primary alternative regulatory action and in particular the likelihood of successful compliance with a PCE WCPP, as described in Unit IV.A., for the conditions of use listed for the primary alternative regulatory action of PCE WCPP in Unit IV.B."[65]

HSIA supports this option, but there is no rationale for it to be limited to the five uses specified in Table 2: Industrial and commercial use as a processing aid in pesticide, fertilizer, and other agricultural chemical manufacturing; Industrial and commercial use in specialty DOD uses (oil analysis and water pipe repair); Industrial and commercial use in solvent-based paints and coatings; Industrial and commercial use as solvent for aerosol spray degreaser/cleaner; and Processing into formulation, mixture or reaction product in other chemical products and preparations.

EPA's rationale for excluding the dozens of other perc uses, for many of which small businesses predominate, appears to be based upon a lack of knowledge of both the business operations and whether the ECEL can be achieved: "the value of EPA's exposure limit is almost three orders of magnitude lower than the OSHA. . . This creates a degree of uncertainty as to whether facilities engaging in most conditions of use could meet the ECEL (and associated action level) and whether they could do so without relying primarily on the use of PPE. . . ."[66] Given EPA's uncertainty regarding whether most users will be able to achieve the ECEL, it is unclear why EPA chose to implement a default prohibition. Likewise, this uncertainty also prevented EPA from following the TSCA § 6(c) mandate 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." As discussed in the following section, this alternatives analysis requirement has not been met.

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[65] *Id.* at 39696-97.

[66] *Id.* at 39694.

Where other options are available to regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk," it is inconsistent with TSCA to allow only regulated entities that may have fewer challenges implementing requirements to meet an ECEL because work activities may occur in sophisticated facilities or take place in a closed system. Yet this is precisely the import of the following limitation on the availability of WCPP compliance as an alternative for smaller businesses:

> As described in Unit V.A., uncertainties regarding (i) the feasibility of implementing workplace safety control measures in open-systems or when worker activities require manual application or removal of PCE or PCE-containing products, (ii) availability of alternatives, or (iii) whether the use is ongoing or phased out led EPA to propose that most of these conditions of use be prohibited. EPA does not have sufficient information to confidently conclude that these conditions of use can meet requirements of a WCPP for PCE. Therefore, EPA requests comment on the ways in which PCE may be used in these conditions of use, including whether activities may take place in a closed system and the degree to which users of PCE in these sectors could successfully implement an ECEL, DDCC, and ancillary requirements described in Unit IV.A.[67]

It is quite unrealistic for EPA to expect the small businesses that predominate in these and the other sectors where it proposes to ban perc use would be able to provide in two months the kind of information requested, when many years after declaring regulation of perc to be a priority "EPA was not able to identify reasonably available information such as monitoring data or detailed activity descriptions to indicate with certainty that relevant regulated entities for these conditions of use could mitigate identified unreasonable risk through a PCE WCPP."[68]

Finally, in passing the Regulatory Flexibility Act, subsequently amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), Congress stated:

> ''(a) The Congress finds and declares that—
>
> ''(1) when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public;
>
> ''(2) laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental

[67] *Id.* at 39683-84.

[68] *Id.* at 39697.

jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities;

''(3) uniform Federal regulatory and reporting requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting and consulting costs upon small businesses, small organizations, and small governmental jurisdictions with limited resources;

''(4) the failure to recognize differences in the scale and resources of regulated entities has in numerous instances adversely affected competition in the marketplace, discouraged innovation and restricted improvements in productivity;

''(5) unnecessary regulations create entry barriers in many industries and discourage potential entrepreneurs from introducing beneficial products and processes;

''(6) the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems, and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation;

''(7) alternative regulatory approaches which do not conflict with the stated objectives of applicable statutes may be available which minimize the significant economic impact of rules on small businesses, small organizations, and small governmental jurisdictions;

''(8) the process by which Federal regulations are developed and adopted should be reformed to require agencies to solicit the ideas and comments of small businesses, small organizations, and small governmental jurisdictions to examine the impact of proposed and existing rules on such entities, and to review the continued need for existing rules.

''(b) It is the purpose of this Act [enacting this chapter] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.''[69]

The instant proposal appears to have completely ignored this law. The docket includes 40 pages describing concerns raised by small businesses representing several use sectors.[70]

[69] Regulatory Flexibility Act, Pub. L. 96-351, as amended by Small Business Regulatory Enforcement Fairness Act (SBREFA), Pub. L. 96–354, Section 2; see note following 5 USC § 601.

[70] 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). EPA-HQ-OPPT-2020-0720-0066. EPA's proposed

Nowhere in the docket or the preamble to the proposed rule is there substantive discussion of these comments. Additionally, although SBREFA clearly encourages implementation of alternatives to minimize the impact upon small businesses, the proposal instead prohibits several small business uses. At the very least, the final rule should allow small businesses the opportunity to implement a WCPP as an alternative.

B. EPA's consideration of alternatives is inadequate

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."[71] EPA's failure to meet its obligation adequately to consider alternatives cannot, however, justify its exclusion of thousands of users from the opportunity to implement a WCPP. TSCA contains no authorization for EPA to consider "uncertainties regarding. . . the feasibility of implementing workplace safety control measures"[72] to prohibit a use. Just the opposite: it affirmatively requires EPA to consider "whether technically and economically feasible alternatives . . . will be reasonably available."

TSCA § 6(c) provides that if a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must 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." Here EPA proposes to eliminate uses constituting a significant amount of the perc market, including uses such as vapor degreasing and aerosol brake cleaning that originated decades ago and continue to be important. EPA's economic analysis, however, completely fails to consider the impact on American manufacturing competitiveness of eliminating such uses by adopting a workplace limit much lower than those of other countries.

EPA's Alternatives Assessment fails to identify technically and economically feasible alternatives because it does not consider whether any particular alternative will work effectively

bans are predicated on its conclusion that there are viable alternatives to perc in most of these applications. Several small entity representatives (SERs) provided compelling arguments as to why the available alternatives are not technically or economically feasible. In sum, given the information EPA has received from small businesses, the alternatives on the market constitute neither technically nor economically feasible alternatives.

[71] 88 Fed. Reg. at 39697.

[72] *Id.*

in a given use. Rather, the Alternatives Assessment simply 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, and the environmental fate and toxicity, as well as certain chemical and physical properties (global warming potential, ozone depletion, and flammability) of each chemical for each product in each product category."[73] Thus, EPA's Alternatives Assessment does not address the fundamental question of whether the alternatives identified are "reasonably available" "technically and economically feasible alternatives." Indeed, it 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, as described in more detail in Appendix C. 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."[74]

Rather, the analysis is intended "to enable EPA to compare the human health hazards, environmental hazards, potential persistence, and bioaccumulative properties of each chemical for each product in each product category," an exercise of no practical utility for any specific condition of use if the alternatives considered do not perform the functions for which perc is used.

Such alternatives analysis as there is appears in the Economic Analysis:

> "This analysis compares the hazard endpoints and fate characteristics of PCE (the subject of this TSCA section 6(a) risk management proposed rulemaking) to chemical ingredients in alternative products known to be reasonably available. Consideration of whether there are technically and economically feasible alternatives, when compared with PCE for the uses proposed to be prohibited or restricted, is discussed in the Economic Analysis of the Proposed Regulation of PCE Under TSCA section 6(a)."[75]

The Economic Analysis, however, does not remedy the shortcomings of the Alternatives Assessment. It notes at the outset:

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[73] Alternatives Assessment, at 7-8.

[74] *Id*. at 7.

[75] *Id.*

> "This economic analysis does not include quantified cost estimates for all costs under the options. Although certain costs cannot be quantified, this does not mean that they are less important than the quantified costs. Additional unquantified costs are discussed in more detail in section 7.12, but 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."[76]

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 certain physical and chemical characteristics, human health/ecological toxicity, and environmental fate of potential alternatives, and even customer satisfaction, but does not consider the physical/chemical properties of perc that make it *uniquely* suited to many uses. Given the limitations of the analysis, it is hardly surprising that the analysis concludes that the proposed rule will have minimal cost impacts on small businesses. Again, nowhere does EPA address the myriad reasons that small businesses told it in the Small Business Advocacy Review (SBAR) that alternatives are not suitable.[77]

Indeed, the Economic Analysis recognizes that it does not adequately consider costs with regard to alternatives:

> "Except for liquid and batch spray cold cleaning and dry cleaning machines, no cost impacts are estimated for users of products that contain PCE who will need to switch to alternative products that do not contain PCE (e.g., PCE aerosol spray cleaners and degreasers). As noted in Chapter 5, alternative products with similar costs and efficacy are generally available. However, in some cases some effort might be required by firms using PCE products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products. The information to estimate how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred is not available. Therefore, EPA is unable to consider these costs quantitatively in the Economic Analysis." [78]

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[76] Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a) (June 2023), EPA-HQ-OPPT 2020-0720-0125 (hereafter "Economic Analysis"), at ES-10.

[77] 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). EPA-HQ-OPPT-2020-0720-0066.

[78] Economic Analysis at ES-25.

The Agency's proposed rule also fails to meet the requirements of TSCA § 6(c)(2)(A), which requires that EPA consider fully the benefits of chemical products it seeks to prohibit in one or more conditions of use. EPA's analysis is flawed because it assumes benefits based on tenuous evidence and ignores nearly certain costs. EPA may not assume benefits while ignoring costs. *Michigan v. EPA*, 576 U.S. 743, 757 (2015). Many small business participants at the SBAR submitted information demonstrating that perc-based formulations are the most efficient products available. Equally, they submitted information demonstrating that the alternatives available do not work effectively. Only by ignoring these submissions was EPA able to conclude, incorrectly, that alternative products are technically and economically feasible.

While EPA included flammability properties of replacement chemicals in its Alternatives Assessment, EPA did not further assess the comparative fire risks of perc-based products and alternatives, nor has it addressed concerns about fire risk and overall safety of the available alternatives. For example, one participant noted that during testing of alternatives employees experienced contact dermatitis, rashes, and allergic reactions, several of which were severe. Other representative comments include:

- One SER described how when using water as a degreasing solvent, mold and termites can become issues if the building has a wooden roof, as many warehouses do. Additionally, because this SER is located on the West Coast, limited water availability and its high cost of use, due to disruptions in the water supply and drought restrictions/regulations, make water undesirable as a potential alternative to PCE.
- One SER described how they would need a new shop place, as well as new restrictions in place (including from fire departments) on the amount of chemicals that can be in a building; the SER described how some alternatives would mean they would be over that amount.
- As an example, a SER stated that a new vapor degreasing machine that uses modified alcohol needs to be filled with 1,000 gallons of alcohol, which is restricted by California fire/the California EPA.
- A vapor degreasing SER stated that some of the modified alcohol machines are 30 feet long and don't fit in the SER's existing warehouses.
- Additionally, one SER described how there is a limit on how close alcohol-based vapor degreasing equipment can be to residential buildings (500-feet for a house and 1000 feet from a school).
- A SER in aerospace has done some testing on other hydrocarbons but found them inadequate.

- One SER described how their hygienists say to make sure that any alternative goes through the same strenuous testing, especially modified alcohol (risk of explosion and combustion among other hazards).[79]

In sum, TSCA § 6(c) provides that "in selecting among . . . restrictions," EPA "shall factor in, to the extent practicable," considerations such as "the effects of the chemical ... on the environment," "the benefits of the chemical substance or mixture for various uses," and "the reasonably ascertainable economic consequences" of the rule. The assessment of economic consequences must include the "costs and benefits" and the "cost effectiveness" of the "proposed and final regulatory action" as well as of at least one alternative. EPA must publish a statement discussing those factors. If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must 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." Having failed to conduct a meaningful alternatives analysis, EPA should reevaluate the proposed ban on perc in these use sectors in the final rule and allow the implementation of a WCPP.[80]

V. DISTRIBUTION IN COMMERCE

EPA should confirm the no unreasonable risk determination and order under TSCA § 6(i)(l) for distribution of perc in commerce.[81] Because distribution in commerce does not pose an unreasonable risk, risk management regulation is not necessary to prevent such unreasonable risk. Additionally, the proposed rule requires a WCPP to prevent unreasonable risk in any

[79] 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) (February 1, 2023), at 29; EPA-HQ-OPPT-2020-0720-0066.

[80] Some of the foregoing discussion is acknowledged in the preamble: "The most notable unquantified costs include possible costs from prohibition of use of PCE as a processing aid outside of the petrochemical industry; EPA's analysis was unable to quantify these costs, as described more fully in section 7.11 in the Economic Analysis (Ref. 3). The economic impact on users of PCE for chemical milling and vapor degreasing is also unclear because there are no clear alternatives to PCE; these users might have to use PPE to meet the requirements of a WCPP for PCE." 88 Fed. Reg. at 39655.

[81] Risk Evaluation at 562. For some reason, distribution is missing from the list of allowable conditions of use in the proposed rule. As noted, it was deemed to present "no unreasonable risk" in the 2020 Risk Evaluation. Although the response to comments on the draft Revised Risk Determination (at 41) states: "[b]ased on the limited emissions from the transportation of chemicals, EPA has determined that distribution in commerce of PCE does not drive the unreasonable risk determination for PCE," it was not included in the Revised Risk Determination under the whole chemical approach.

upstream or downstream use following distribution in commerce, therefore negating any need to regulate distribution in commerce to address upstream or downstream activities.[82] EPA should clarify that distribution in commerce in compliance with regulations for transportation of perc does not pose an unreasonable risk so that additional regulation is not necessary.

EPA could clarify the applicability of the regulation of distribution to the COUs allowed under the rule by inserting the following language (based upon the Risk Evaluation Condition of Use description):

> Distribution in Commerce. For the purpose of use conditions listed in 40 CFR § 751.607 or use conditions not otherwise prohibited in this subpart, distribution in commerce of PCE, the transportation associated with the moving of PCE in commerce, is an allowed use condition. Loading and unloading activities are not included in the Distribution in Commerce use condition.

VI. ALLOWED USES

A. Having determined that its ECEL eliminates unreasonable risk, any use that can meet the ECEL should be allowed to continue subject to WCPP requirements

EPA proposes that 16 current uses of perc would be allowed to continue subject to WCPP requirements to be implemented by employers (referred to by EPA as "owners or operators"). WCPPs would apply to the following conditions of use identified in the proposed rule:

(1) Manufacturing (domestic manufacture);

(2) Manufacturing (import);

(3) Processing as a reactant/intermediate;

(4) Processing into formulation, mixture or reaction product in paint and coating products;

(5) Processing into formulation, mixture or reaction product in cleaning and degreasing products;

(6) Processing into formulation, mixture or reaction product in adhesive and sealant products;

(7) Repackaging;

(8) Industrial and commercial use as solvent for open-top batch vapor degreasing;

(9) Industrial and commercial use as solvent for closed-loop batch vapor degreasing;

[82] Of course, this is not to concede that either the upstream or downstream uses pose an unreasonable risk, or that EPA has the authority to regulate upstream activities which do not pose an unreasonable risk.

(10) Industrial and commercial use as solvent for in-line conveyorized vapor degreasing;

(11) Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;

(12) Industrial and commercial use in maskant for chemical milling;

(13) Industrial and commercial use in solvent-based adhesives and sealants;

(14) Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing;

(15) Recycling; and

(16) Disposal.

TSCA § 6(a) directs EPA to regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk." A facility in compliance with its WCPP has acted, by EPA's definition, to "ensure that unreasonable risks are addressed." The statute does not ask or empower EPA further to make judgments regarding the use and it is unclear why EPA justifies allowing certain conditions of use on the basis of EPA's own assessment of the societal importance of these uses:

> "In addition to EPA's confidence that facilities engaging in these conditions of use could meet the WCPP requirements and thus address the unreasonable risk, EPA found compelling reasons to allow continued use of PCE for these conditions of use because they may complement the Agency's efforts to address climate-damaging HFCs under the AIM Act or have national security or other significance for critical sectors."[83]

Once it establishes the regulatory requirements, EPA has no further authorization to determine that there are "compelling reasons" to allow continued use of perc. No such reasons are needed as long as the workplace is able to comply with a WCPP.

The WCPPs to be implemented would have to achieve a far lower exposure limit than those adopted by OSHA. Specifically, EPA is proposing an 8-Hour Time-Weighted Average (TWA) ECEL of 0.14 ppm, representing a reduction from the OSHA limit of over 99%. EPA is also proposing an ECEL action level of 0.07 ppm. For implementing a WCPP, EPA proposes a 9-month period after the final rule is published for compliance with the ECEL and to establish and maintain regulated areas. EPA acknowledges that a WCPP is in addition to, and not a substitute for, OSHA requirements. Having two regulators responsible for the same workplace obviously will raise serious compliance issues for employers which now find themselves subject

[83] 88 Fed. Reg. at 39695.

to both sets of regulations. Compliance issues relating to uses allowed with WCPPs are addressed in § III above.

Regarding the industrial and commercial use in solvent-based adhesives and sealants COU, EPA proposes:

> "For the industrial and commercial use in solvent-based adhesives and sealants, EPA identified several products available on the market at concentrations of PCE between 0.1% and 1% by weight (Ref. 1). As part of the primary alternative regulatory action, EPA would set a concentration limit of PCE in adhesive and sealant products for industrial and commercial use to1%.[84]

EPA also requests comment on "a combination of the 1% concentration limit for adhesives and sealants with specific engineering controls, administrative controls, or respiratory protection that would reduce inhalation exposures to PCE at or below the ECEL of 0.14 ppm as an 8-hour TWA" as well as on "a combination of a concentration limit with WCPP requirements."[85] HSIA supports the concentration limit approach, and believes that no further requirements are needed for products that are below this limit.

B. Having determined that its ECEL eliminates unreasonable risk, there is no justification for a time limit on uses that meet this limit

For the important maskant and vapor degreasing uses allowed pursuant to WCPPs, EPA proposes as a second alternative action a prohibition with a 10-year time-limited exemption and interim WCPP. For the reasons stated below, we do not believe such a prohibition is warranted and urge EPA to allow this sector to continue operating subject to a WCPP. Having determined that compliance with WCPPs eliminates unreasonable risk, there is no justification for a time limit on such compliant use.

EPA's rationale for a time limit for these uses follows:

> "Under TSCA section 6(g)(1), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if EPA makes one of three findings required by the statute, as outlined in Unit IV.A.5. TSCA section 6(g)(2) requires EPA to analyze the need for the exemption, and to make public the analysis and a statement on how the analysis was taken into account when proposing an exemption under TSCA section 6(g). Based on discussions with and information provided by industry stakeholders, consultation with the DOD and NASA,

[84] *Id.* at 39698.

[85] *Id.* at 39707.

and Panel recommendations in the SBAR Panel Report (Ref. 33), EPA has analyzed the need for three different exemptions and would grant two if the second alternative regulatory action described in this document is adopted in the final rule."[86]

1. Maskant use

The Preamble indicates that EPA understands that PCE-based maskant is used in commercial and defense aerospace programs that are essential for national security and critical infrastructure, for the following reasons:

- PCE-based maskant is required to meet certain performance requirements that other alternatives are unable to meet. For example, PCE-based maskant meets several Boeing Aircraft process specifications which are mandatory for suppliers as part of the quality system that aircraft production certificate holders are required to establish under 14 CFR 21.137.
- PCE-based maskant meets other industry performance requirements such as
- Stretch Forming, Laser Scribe Compatible, and General Parts Protection.
- Efforts to develop new maskants have been ongoing for over 30 years but have not resulted in a substitute that meets all of the necessary performance requirements.
- PCE-based maskant allows for solvent capture and recycling.
- Substitute chemicals for maskant for chemical milling may not meet the performance requirements of maskant needed for chemical milling of aluminum aircraft skins for commercial and defense purposes and thus may not be technically feasible as alternatives.[87]

2. Vapor degreasing

EPA proposes to allow ongoing use of perc in vapor degreasing generally, subject to compliance with a WCPP. Vapor degreasing is a very important perc application. Due to its physical and chemical properties, perc is in many cases the only technically and/or economically viable option for achieving the desired cleaning results. This is especially true for industries with extremely high cleaning quality requirements such as aviation and automotive, or in cases where there are very complex part geometries and/or high contamination intake..

[86] *Id.* at 39686. An exemption for dry cleaning, which EPA indicated it is not inclined to grant in any event, is not further discussed here; a better alternative is presented in the following section on dry cleaning.

[87] *Id.* at 39687.

More specifically, the preamble indicates that "EPA received a request for a section 6(g) exemption from prohibition for the use of PCE in vapor degreasing of aerospace parts from a manufacturer of commercial jetliners and defense, space, and security systems (Refs. 57, 58). The aerospace parts have commercial, DOD, and NASA uses (Ref. 59); as the requester describes, they manufacture and procure these parts and have identified that PCE vapor degreasing is necessary due to technical challenges with other alternative substitute chemicals or methods. Factors in support of this request include:

- The requester has spent many years developing, qualifying, and implementing alternative materials and processes to replace PCE vapor degreasing with aqueous cleaning where technically viable; while the transition to aqueous cleaning has been successful for many detail parts, there are technical challenges with alternative substitute chemicals and processes for the vast majority of complex aerospace machining parts and actuation systems, such as structural components, gears, and other parts that make up drive units and control mechanisms.
- PCE vapor degreasing is the best cleaning method to pre-clean most complex machining parts and actuation systems because it does not allow the transfer of contaminates from one part to another. Parts approved for aqueous cleaning, the parts so cleaned must be carefully segregated to avoid cross-contamination, which substantially increases the required processing time.
- Conversion from vapor degreasing to aqueous cleaning is a capital-intensive investment that would require several years to plan, permit, construct, and install.
- Aerospace parts meet DOD and other Federal Aviation Administration (FAA) specifications to ensure safety of flight.
- Any PCE alternative, must meet technical requirements derived from FAA mandated standards for a typical part used in a commercial aircraft, such as specifications for specific gravity (ASTM D 792), Water Absorption (ASTM D 750), and other test requirements, and certification can take at least nine months for individual parts of components or up to several years for major subsystems or complete aircraft.
- PCE has been used in vapor degreasing to meet required levels of cleanliness of certain supplied parts by long-standing design specifications that are incorporated into contracts of a complex supply chain. Suppliers are not required to notify of the process they use to clean parts, so the requester may not know which solvent supplier has selected for vapor degreasing or what factors were considered when selecting cleaning systems.
- Material declarations and auditing processes to validate usage may be burdensome, considering that a large portion of the requester's supply chain includes small suppliers.

- Substitute chemicals for vapor degreasing of aerospace parts may not be technically feasible at this time for meeting the cleanliness standards of certain parts as required by DOD and FAA specifications or other specifications included in existing contracts within the supply chain.
- A prohibition on the use of PCE for vapor degreasing of aerospace parts could negatively affect DOD's capability and readiness, and could also negatively affect the maintenance of civilian aircraft and potentially have impacts on the safety of civilian flight."[88]

3. Discussion

There can be no doubt that the foregoing uses would qualify for critical use exemptions.[89] It appears, however, that these facilities may be able to adopt and comply with WCPPs if EPA promulgates a reasonable ECEL. Accordingly, we urge EPA to allow these sectors to continue operating subject to a WCPP. Having determined that compliance with WCPPs eliminates unreasonable risk, there is no justification for a time limit on such compliant use: once such a WCPP is implemented, the unreasonable risk asserted by EPA is eliminated.

As in the case of the 24 commercial uses EPA proposes to eliminate outright discussed in § IV, the problem may be EPA's expectation that it will be provided by the end of the comment period "information on the extent to which this industry could meet the requirements of the proposed WCPP."[90] That is an entirely unrealistic expectation, and it represents a misunderstanding of the statutory directive. TSCA § 6(a) directs EPA to regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk." A facility in compliance with its WCPP has acted, by EPA's definition, to "ensure that unreasonable risks are addressed." The statute does not ask or empower EPA to gather any further information (although EPA of course maintains its enforcement mechanisms). Once it establishes the

[88] *Id*.

[89] Regarding the § 6(g) essential use exemption generally, it is important to note that various chlorinated solvents are produced as coproducts in the same production process. Unintended consequences in the production and availability of critical building block chemicals will occur if sufficient time is not provided to evaluate any necessary changes to IH procedures, monitoring protocols, or manufacturing processes across a manufacturing unit. Perc obviously has critical uses, but production of commodity chemicals such as perc may be curtailed if the only markets are a handful of essential uses. A minimum baseload volume is necessary to achieve economically acceptable operating rates. Elimination of the majority of current COUs, as proposed, may well result in closure of chlorocarbon production facilities with significant economic impact that is not addressed in the Economic Analysis.

[90] 88 Fed. Reg. at 39687 (maskant); 88 Fed. Reg..at 39688 (vapor degreasing).

regulatory requirements, EPA has no further authorization to distinguish between facilities that would be able to meet the WCPP and those that would not.

VII. DRY CLEANING

For dry cleaning, EPA proposes a phaseout of perc use, as follows:

"EPA is proposing to prohibit the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE for dry cleaning and spot cleaning, including in 3rd generation (dry-to-dry machines with refrigerated condenser) and 4th/5th generation (dry-to-dry machines with refrigerated condenser and carbon adsorber process controls) machines.

As discussed in Units III.B.3. and V.A., based on a consideration of alternatives under TSCA section 6(c)(2)(C), uncertainty relative to the feasibility of exposure reduction to sufficiently address the unreasonable risk across the broad range of work environments and activities, and the irreversible health effects associated with PCE exposures, EPA has determined that prohibition is the best way to address the unreasonable risk. A prohibition on the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE in dry cleaning and spot cleaning would address the unreasonable risk for the following conditions of use evaluated in the 2020 Risk Evaluation and described further in Unit III.B.1:

- Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning;
- Industrial and commercial use in dry cleaning and spot cleaning 4th/5th generation only dry cleaning; and
- Consumer use in dry cleaning solvent (*i.e.,* exposure to clothing or articles recently dry cleaned with PCE).

EPA recognizes that the transition to an alternative dry cleaning process or solvent could require significant time and investment from dry cleaning facilities; therefore, EPA is proposing a phaseout period to take place following the publication date of the final rule. The phaseout would start with a prohibition on the use of PCE in any dry cleaning machine acquired 6 months or later after the publication date of the rule, followed by a prohibition on the use of PCE in 3rd generation machines 3 years after the publication date of the rule. Full implementation of the phaseout would be achieved with a prohibition on the use of PCE in all dry cleaning and spot cleaning, including in 4th and 5th generation machines, 10 years after the publication date of the final rule and a prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent 10 years after the publication date of the final rule."[91]

[91] 88 Fed. Reg. at 39670-71.

Such a prohibition is unnecessary; as documented by the exposure information submitted by New York State, dry cleaning operations using 4th or 5th generation machines achieve remarkably low perc concentration levels over an 8-hour averaging period. HSIA supports the proposed requirement that PCE be used in dry cleaning only in 4th and 5th generation machines. This requirement should be in place for 15 years after the publication date of the final rule to ensure consistency with the National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities (the "Dry Cleaning NESHAP"),[92] which recognized a useful life of 15 years for such equipment.[93]

At the end of 15 years, dry cleaners that can monitor and comply with the ECEL should be able to continue to use perc in compliance with a WCPP. Having determined that compliance with WCPPs eliminates unreasonable risk, there is no justification for a time limit on such compliant use: once such a WCPP is implemented, the unreasonable risk asserted by EPA has been eliminated.

VIII. THE PROHIBITION ON SALES BY RETAILERS, IF NOT CHANGED, WILL DESTROY THE SUPPLY CHAIN FOR SMALL COMMERCIAL USERS

As if the prohibitions/restrictions described above were not onerous enough, EPA also proposes essentially to ban distribution of perc in commerce by retail establishments:

> "Regarding industrial, commercial, and consumer uses of PCE, TSCA section 6(a)(2) provides EPA with the authority to prohibit or otherwise restrict the manufacture (including import), processing, or distribution in commerce of a substance or mixture ''for a particular use'' to ensure that a chemical substance no longer presents unreasonable risk. For this rule, EPA proposes that ''for a particular use'' includes consumer use more broadly, as well as industrial and commercial use, which encompasses all known, intended, and reasonably foreseen uses of PCE. Given the severity and ubiquitous nature of the risks identified in the 2020 Risk Evaluation for PCE for all industrial, commercial, and consumer uses evaluated, and noting that those conditions of use evaluated in the Risk Evaluation encompass all known, intended, and reasonably foreseen uses of PCE, EPA proposes that prohibiting manufacture (including import), processing, and distribution in commerce of PCE for most industrial and commercial use and all consumer use is reasonable and necessary to eliminate the unreasonable risk of PCE, including by precluding retailers from selling PCE and PCE-containing products to consumers."[94]

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[92] 40 C.F.R. Part 63, Subpart M.

[93] *See* 70 Fed. Reg. 75884, 75897 (December 21, 2005).

[94] *Id.* at 39692.

The remarkably overbroad restriction on commerce reflected in the final clause above is based on a similar requirement adopted by EPA in connection with the consumer use of methylene chloride paint stripping products.[95] In effect, if a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer (40 CFR § 751.103). For a distributor not to be considered a retailer, the distributor must distribute or make available products *solely* to commercial or industrial end-users or businesses. In its proposed regulation of methylene chloride, EPA noted that "during litigation on the 2019 final rule petitioners argued that EPA's definition of 'retailer' was so broad as to cover all commercial entities, creating supply chain issues for commercial users seeking to attain and use the chemical for commercial activities (*Lab. Council for Latin Am. Advancement* v. *United States Env't Prot. Agency,* 12 F.4th 234 (2d Cir. 2021)). EPA has not found this to be the case; small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR process for this rulemaking."[96]

HSIA does not support elimination of consumer use of perc. Our concern here, however, is the ongoing ability of small businesses to purchase the perc-based products they need in order to continue to provide services efficiently. It is true, as referenced in the quote above, that the definition of "retailer" is so broad that it eliminates virtually all supply outside of one or two "non-retail distributors. . . that participated as small entity representatives consulted as part of the SBAR process." These companies provide a valuable service by making methylene chloride available in bulk to large commercial users. They are able legally to do so because they do not sell to the public. It should be obvious, however, that one or two bulk distributors (of perc or methylene chloride) cannot serve a geographically dispersed nation of tens of thousands of small businesses desiring to purchase small containers for allowed uses. In the absence of availability

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[95] "Previously, in the 2019 methylene chloride TSCA section 6(a) risk management rule addressing consumer use of methylene chloride in paint and coating removal (40 CFR part 751, subpart B), EPA prohibited retailers from distributing in commerce paint and coating removers containing methylene chloride (see 40 CFR 751.105(b) and (c)). To meet the same goal of protecting consumers from accessing PCE-containing products that could pose unreasonable risk, for a broader range of consumer conditions of use, EPA considered and is proposing a similar provision to ensure that retailers will not be able to purchase PCE for sale or distribution to consumers and will not be able to sell or distribute PCE to consumers, including making available to consumers products containing PCE. For these reasons, as described in Unit IV.A., EPA's proposal to address unreasonable risk from PCE includes prohibition on the distribution in commerce of PCE to and by retailers." *Id.* at 39692-93.

[96] 88 Fed. Reg. 28284 (May 3, 2023) at 28308.

at hardware and home improvement stores, these small businesses will be unable to access a supply. In this as in other ways, the definition of retailer in the proposed rule discriminates unlawfully against small businesses.

The remarkably broad definition of "retailer" would solve a problem that exists only in EPA's imagination: there is no evidence of any consumer attempting to purchase from a bulk seller. The solution is for EPA to eliminate the overbroad definition of "retailer," while leaving in place the prohibition on selling to consumers. Thus, sales of perc-based products for consumer use will be unlawful, and formulators and distributors would have to provide notice of that prohibition down the distribution chain. Sales could be restricted to individuals with commercial accounts or those who can show tax IDs or other verification methods to establish that they are businesses. This would also be administratively straight-forward, requiring only the elimination of the prohibition on distributing to retailers and limiting the prohibition on retailers from distributing perc-containing products "for any use" to distributing to "consumers." A definition of "consumer" could also be provided to replace that of "retailers." Laws in all states prevent sales by retailers of alcohol or tobacco products to minors, and limit sale of drugs to customers who have a prescription. Clearly a limitation on sales of perc-based products to commercial users could be effective.

IX. EPA HAS NOT MET THE REQUIREMENTS OF TSCA § 9

TSCA § 9, as originally enacted and as updated by the Lautenberg Act, requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes." Worker health and safety falls under the jurisdiction of federal OSHA, and use of perc is already regulated under the OSH Act. Taking steps that would lead to the removal of products from the marketplace where the existing OSHA requirements are met is not consistent with TSCA either as initially enacted or as revised.

A. From its inception, TSCA has been intended to fill gaps in regulation, not to supplant existing regulatory frameworks

TSCA § 9, as amended, provides:

> "(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any

combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

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

"Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

"(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk."

> "(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.
>
> "(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the actions to be taken under this title and an action to be taken under such other law to protect against such risk."

If this statutory language were not sufficient to express the limitations on EPA's authority, the legislative history leaves no doubt. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety."[97]

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk."[98] EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or

[97] H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

[98] 122 Cong. Rec. H11344 (Sept. 28, 1976).

reduced to a significant extent under the Occupational Safety and Health Act, and referring the matter for action by OSHA.[99] And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that "Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them."[100]

Indeed, TSCA § 9 was strengthened by the Lautenberg Act, as evidenced by two colloquies on the floor of the House of Representatives. First:

> "Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. *Blackburn*), the vice chair of the full committee.
>
> Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.
>
> Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).
>
> It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.
>
> Would the chairman please confirm my understanding of section 9?
>
> Mr. SHIMKUS. Will the gentlewoman yield?
>
> Mrs. BLACKBURN. I yield to the gentleman from Illinois.
>
> Mr. SHIMKUS. The gentlewoman is correct in her understanding.

[99] 50 Fed. Reg. 27674 (July 5, 1985).

[100] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2. *See also* TSCA § 2(c): "INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided to take under this Act."

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work."[101]

Second:

"Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:

Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and that authority sufficiently protects against a risk of injury to human health or the environment; or

Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.

Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue."[102]

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[101] 162 Cong. Rec. H3028 (May 24, 2016).

[102] *Id.*

These colloquies make clear the ongoing Congressional intent that TSCA not be used when either EPA or another agency has taken steps to address the risks identified.

B. The instant proposal fails to take into account existing regulation of perc, as required by TSCA § 9

As noted above, OSHA has regulated occupational exposure to perc for many years. OSHA should be given an opportunity to consider whether a lower workplace limit would be appropriate. Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA's existing limits would remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the OSH Act, even if the EPA regulation afforded greater protection, as long as an OSHA standard on the same substance is in effect.

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.[103] EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.,* by controlling the amount of substance used in a product or prohibiting a particular use of the substance under § 6. This is potentially much more burdensome economically than ambient standards, which permit each employer subject to the standards to achieve the necessary reduction in exposure in the most cost-effective manner. Yet TSCA § 6(c)(2) requires EPA carefully to consider the cost-effectiveness of a proposed regulatory action against at least one alternative, and Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[104] Here, the most cost-effective alternatives have not been chosen.

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[103] H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act*, at 441 (1976).

[104] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

> "This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential

In light of the foregoing, considerations of avoiding unnecessary duplication and utilizing established expertise weigh in favor of invoking the Administrator's referral authority under TSCA § 9(a) even if EPA were to proceed under TSCA. If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.[105] Yet there is no evidence that EPA has submitted to OSHA "a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk." The non-existent report obviously did not "include a detailed statement of the information on which it is based" and was not "published in the Federal Register," as required.

Had the required report been issued, in the case of OSHA it presumably would have identified how OSHA's authority over the workplace was insufficient to address the risks posed by perc. A letter from the Assistant Secretary of Labor for Occupational Safety and Health (undated but apparently issued on April 4, 2016) identifying limits on OSHA's authority to regulate hazardous substances was issued in connection with a previous unrelated rulemaking, but it does not come close to meeting the requirements of TSCA for EPA action in this case. The April 2016 letter identifies no such gap specific to use of perc in any particular workplace, rather it simply recites how OSHA's authority does not extend to self-employed workers, military personnel, and consumer uses. But those are limitations that were imposed by Congress and have existed since the Occupational Safety and Health Act was enacted. Those limitations apply

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economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

[105] As noted above, § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

to every use of every toxic substance. Congress cannot have meant, in enacting "gap-filling" legislation, to open the door to EPA assuming all authority over the use of hazardous substances in the workplace.

Finally, EPA has not taken into account its own extensive regulation of perc uses under the Clean Air Act, as required under TSCA § 9(b). EPA has adopted a number of emission standards that limit emissions of perc, which is a hazardous air pollutant (HAP) listed in Clean Air Act (CAA) § 112. These include, notably, National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities (the "Dry Cleaning NESHAP"),[106] which sharply limits emissions of perc from dry cleaning facilities large and small.[107] As another example, National Emission Standards for Halogenated Solvent Cleaning (the "Degreasing NESHAP")[108] require batch vapor solvent cleaning machines and inline solvent cleaning machines to meet emission standards reflecting the application of maximum achievable control technology (MACT) and generally available control technology (GACT) for major and area sources, respectively. The rule imposes specific caps on emissions of several halogenated solvents, including perc.

Under CAA § 112, these standards must ensure an "ample margin of safety to protect public health." Thus, if the risk of concern was significant, EPA would have to adopt more protective standards under the Clean Air Act. Thus, regulations that were adopted during a process that properly took into account small business considerations and that by definition provide an "ample margin of safety to protect public health" are already in effect for major use sectors where EPA now proposes further to restrict or to eliminate perc use.

The existence of a comprehensive regulatory framework for perc uses under the Clean Air Act has two important implications for any consideration of TSCA § 6 rulemaking for the same sectors. First, it means that regulation under TSCA § 6 is precluded under TSCA § 9(b) unless EPA can make a determination "that it is in the public interest to protect against such risk

[106] 40 C.F.R. Part 63, Subpart M.

[107] EPA refers to these as either major or area sources. An area source is defined in CAA § 112(a) as any stationary source of HAP that is not a major source, and a major source is defined as any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, considering controls, in the aggregate, 10 tons per year (tpy) or more of any single HAP or 25 tpy or more of any combination of HAP.

[108] 40 C.F.R. Part 63, Subpart T.

by actions taken under this Act," where sponsors of the Lautenberg Act have stated the view that EPA's "own existing regulatory framework already appropriately addresses risk to human health."[109] Second, it is remarkable that EPA has not drawn on use and exposure information from these regulated uses to inform the instant proposal. Analyses conducted by the EPA Air Office and data collected under the various NESHAPs applicable to perc would provide information that is missing from the meager Alternatives Analysis in the record.

X. THE ELEMENTS ADDED BY EPA IN ITS REVISED RISK DETERMINATION ARE INCONSISTENT WITH TSCA

EPA published a draft Revised Risk Determination for perc in 2022,[110] in which it announced its intent to implement two changes to the approach taken in the 2020 Risk Evaluation: (i) EPA stated it would make a revised risk determination of unreasonable risk for perc as a whole chemical, instead of making risk determinations for each of perc's conditions of use; and (ii) EPA stated it would no longer assume that all workers wear PPE when conducting risk evaluations. HSIA commented that the proposed whole chemical approach and decision no longer to assume the use of PPE are inconsistent with the requirements of TSCA and EPA's implementing regulations, are not within the scope of EPA's discretion, and fail to provide the public with an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use. HSIA urged EPA to withdraw its proposed revision to the perc risk determination, to continue to make condition-of-use specific risk determinations for perc and other chemical substances, and to continue to include reasonable assumptions regarding the use of PPE for each condition of use.[111]

Those comments are all relevant and in the docket. In light of EPA's justification of its unreasonable risk findings by unrealistic exposure scenarios, it warrants repeating that TSCA § 3(4) defines the term "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to

[109] 162 Cong. Rec. H3028 (May 24, 2016).

[110] 87 Fed. Reg. 39085 (June 30, 2022).

[111] EPA-HQ-OPPT-2016-0732-0128. A companion comment addressing legal issues in connection with the proposed revisions was submitted to the same docket at the same time but does not appear to have been posted. It is included here as Attachment G.

be manufactured, processed, distributed in commerce, used, or disposed of." The structure of the definition makes clear that "circumstances" includes aspects of the context in which a chemical substance is manufactured, imported, processed, distributed in commerce, used, or disposed of, including whether workers wear PPE. EPA's proposal no longer to assume the use of PPE is contrary to TSCA because it effectively eliminates "circumstances" from the definition of conditions of use. The use of PPE is a circumstance that "is intended, known, or reasonably foreseen." PPE use therefore belongs as a component of the conditions of use that EPA must consider in its risk evaluations.

As noted above, in the 2020 Risk Evaluation "EPA generally assume[d] compliance with OSHA requirements for protection of workers."[112] EPA explained that "existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE," and that reasonable evidence supported the assumption that workers were complying with OSHA's requirements. EPA also acknowledged that it could not presume, "in the absence of supporting information," a lack of compliance with OSHA's existing regulatory programs. Nevertheless, EPA based its decisions on unreasonable risk to workers on "high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE." Even with these estimates, the Risk Evaluation found no unreasonable risk from either domestic manufacture or feedstock use.[113] EPA's Revised Risk Determination does not explain why the prior findings that OSHA requirements will result in appropriate PPE use are no longer supported. Without supporting record evidence or analysis, EPA's decision no longer to assume the use of PPE is clearly inconsistent with TSCA requirements. EPA has also not explained why some conditions of use that did not require PPE for the no unreasonable risk determination still require a WCPP for compliance.

XI. EXPORT

In general, TSCA imposes import certification and export notification requirements which will be triggered by the rule. Those who import perc would be required to certify

[112] *See* Risk Evaluation, EPA-HQ-OPPT-2019-0437-0107, at 38.

[113] *Id*. at 517-518.

compliance that the chemical shipment complies with all applicable rules and orders under TSCA by filing with Customs and Border Protection a statement to that effect.

Exporters of perc must first 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. "Domestic manufacture," defined as "refer[ing] to the making or producing of a chemical substance within the United States (including manufacturing for export),"[114] is allowed pursuant to a WCPP, and as noted above compliance with a WCPP means that unreasonable risk has been eliminated. On the other hand, the preamble states "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)."[115] EPA should clarifify that perc is only restricted from export if the manufacturing condition of use is not in accordance with a WCPP.

Such clarification is important and the following factors should be considered:

1. EPA's memorandum *Existing Chemical Exposure Limit (ECEL) for Occupational Use of Perchloroethylene,* EPA-HQ-OPPT-2020-0720-0023 (April 15, 2021), "determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for perchloroethylene (U.S. EPA, 2020) under TSCA."

2. By "including manufacturing for export" in the preamble's "domestic manufacture" description,[116] proposed § 751.607 that allows for "manufacturing (domestic manufacture)" if exposure is at or below the ECEL should also allow for export under those same conditions.

3. If TSCA § 12(a)(2) is read as an automatic blanket export prohibition, then EPA's "whole chemical" unreasonable risk determinations would squash international trade.

4. The Economic Analysis does not address the loss of the export market. As noted above, the U.S. Census Bureau website shows > 34,500 MT of perc exported in 2022, valued at approximately $44,000,000.

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[114] 88 Fed. Reg. at 39663.

[115] 88 Fed. Reg. at 39668-39669. TSCA § 12(a)(2) states that the exclusion in (1) "shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article presents an unreasonable risk of injury to health within the United States."

[116] *Id., at* 39663.

EPA should clarify throughout the preamble and as appropriate in the proposed rule that domestic manufacturing in accordance with the WCPP includes export. If EPA does intend to prohibit export of perc, it should reconsider for the reasons set forth above. Perc exports are substantial, and there is no basis for banning such exports where (i) no other country has adopted or even considered a limit within a thousand-fold of the proposed ECEL, and (ii) perc manufacture in the United States is in compliance with a WCPP. Moreover, the Economic Analysis is totally silent on the economic impact of such a ban. In this and other ways, the proposal is a self-inflicted wound on U.S. manufacturing competitiveness.

We recommend that the proposed regulatory language at § 751.611(c) be modified to add the italicized language so that the final clause reads: "Industrial and commercial use in all dry cleaning and related spot cleaning until [DATE 10 YEARS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]; *Distribution in commerce for export*; and Disposal."

XII. *DE MINIMIS*

EPA proposes that products containing perc at concentrations less than 0.1% by weight not be subject to the rule:

> "To aid the regulated community with implementing the prohibitions, and to account for de minimis levels of PCE as an impurity in products, EPA is proposing that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions described in this unit. EPA has determined that the prohibitions are only necessary for products containing PCE at levels equal to or greater than 0.1% by weight in order to eliminate the unreasonable risk of injury resulting from inhalation and dermal exposures from PCE-containing products during occupational and consumer conditions of use."[117]

HSIA does not have information available on the universe of products, if any, that might fall within this exception. Clearly, however, any formulated products that do contain such *de minimis* concentrations would not pose a risk and should not be covered.

[117] 88 Fed. Reg. at 39671.