PERCHLOROETHYLENE (PCE); REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

Office of Pollution Prevention and Toxics
Environmental Protection Agency

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS COMMENTS

Attention: EPA–HQ–OPPT–2020–0720; FRL–8329–03–OCSPP

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I. Introduction

The American Fuel & Petrochemical Manufacturers ("AFPM") respectfully submits these comments on the Environmental Protection Agency's ("EPA" or "the Agency") Federal Register notice titled, "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)" ("Rule Reconsideration"). In its Federal Register notice, EPA is seeking comment on its risk management rule promulgated in December 2024.[1] AFPM's comments reiterate previous concerns raised with the proposed risk management rule that it:[2]

- Imposes burdens on the workplace beyond the owner/operator's control,
- Proposes standards and Personal Protective Equipment ("PPE") selection criteria that are duplicative or contradictory to other regulatory agencies,
- Proposes an entirely new workplace exposure limit that is intended to supplant the current exposure limits established by other federal and state agencies, and,
- Includes overly detailed planning requirements that will overwhelm workers.

II. AFPM Interest in the Proposed Rule

AFPM is the leading trade association representing the manufacturers of the fuels that keep America moving and base petrochemicals that are the essential building blocks for organic chemistry, including plastic products that improve the health, safety, and living conditions of humankind and make modern life possible. AFPM members are committed to sustainably manufacturing safe, high-performing fuels and the petrochemicals and derivatives for plastics that growing global populations and economies need to thrive. AFPM members use PCE as a chloriding agent to regenerate catalysts used to make EPA-compliant fuels.

III. "Conditions of Use" for PCE in Refining Processes

PCE is used as a catalyst regenerator in isomerization and catalytic reforming processes at petroleum refineries. The resulting products from these processes, called isomerate and reformate, go into gasoline blends that make up approximately 45% of the gasoline pool in the United States.[3] The catalyst is critical to process safety because it allows the processes to run at lower reaction temperatures, which is an engineering control to lower the overall safety risk and reduce carbon dioxide emissions from the process.

PCE is the safest catalyst activator and regenerator for spent catalyst during normal operating conditions. The alternatives, such as trichloroethylene, chlorine gas, methylene chloride, and carbon tetrachloride, are either more hazardous or being phased out by EPA due to the Agency's findings of unreasonable risk. One particular alternative catalyst regenerator, chlorine, is regulated under Department of Homeland Security and United States Coast Guard security regulations and switching to that substance would increase the overall security risk of facilities.

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[1] See *90 Fed. Reg. 35858,* "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-0720; FRL-8329-03-OCSPP, published July 30, 2023.

[2] See AFPM comments on the proposed risk management rule, submitted August 15, 2023.

[3] From Honeywell UOP (UOP) technical presentation to EPA on isomerization and reforming processes, and the use of PCE as a catalyst regenerator.

PCE must be replenished on a periodic basis and is transported to the facility by suppliers who take responsibility for their own employees, especially in the areas of training and personal protection. Certain transfer operations are also coved by the United States Department of Transportation ("US DOT") regulations.[4] The predominant transportation method is by tote or tank truck. If delivered by tank truck, the PCE is transferred from the truck into a storage tank that is directly hooked up to the processing unit for direct injection in a closed system. If by tote, then the tote is directly hooked up for direct injection in a closed system. The totes and tank trucks are returned to the supplier and are maintained by the supplier. Refinery workers do not clean or service the totes and tank trucks. Cleaning and servicing are performed by the supplier, and those conditions of use are accounted for in other sections of the risk evaluation.

PCE is used in continuous, closed processes, subject to multiple engineering controls to prevent exposures. As mentioned above, PCE is directly injected from a tote or storage tank into the closed processing unit. The tanks and totes are clearly labelled in accordance with Occupational Safety and Health Administration ("OSHA") hazard communications standards.[5] Transfers of PCE from tank trucks to storage tanks and changeout of totes are performed pursuant to comprehensive written procedures under strict PPE guidelines that include hardhats, gloves, goggles and/or face shields, and when appropriate, respirators.[6] Both OSHA and DOT prescribe material handling requirements, including the requirement to wear PPE and train employees on the safe handling of hazardous substances/materials. Those requirements are typically fulfilled by owner/operators for refinery personnel and by employers (e.g., contractors, vendors, etc.) for those who are not direct employees of the owner/operator. These regulations function effectively to mitigate the risks of exposure from conditions of use applicable to PCE in refineries.

Hoses to transfer PCE from the tank truck to the storage tank are sealed, creating a closed system for the transfer. The storage tank has a sealed pipe or hose that directly injects the PCE into the processing unit. Likewise, hoses that transfer PCE from totes to processing units are sealed, creating a closed system. The only way a worker could be exposed to PCE during transfer is from an accidental spill or leak from a hose, which is very unlikely and not considered a normal condition of use. Accidental spills and leaks should not be considered in a risk evaluation under TSCA § 6, nor should they form the basis of risk management actions under that section.

Data on PCE changeout confirms that the risk evaluation's exposure estimates are clearly erroneous. For example, the risk evaluation assumes that changeout occurs 250 times per year and that each changeout lasts a full work shift of 8 hours; however, real world changeouts and potential exposure opportunities are significantly different. Consider, per AFPM members that use PCE, on average, the frequency that totes are switched out is 10 to 35 times per year. The duration of each changeout is approximately 15 minutes. The frequency of tank truck changeouts is anywhere from 2 to 12 times per year, with an average duration between 30 and 60 minutes each time. The variability in frequencies is due to each refinery being different in design, layout, and processing capacity. The actual frequency of PCE replenishment shows how unrealistic the risk evaluation's use and exposure assumptions are for PCE as a catalyst regenerator at petroleum refineries. Simply

[4] See 49 CFR Parts 100 – 185.
[5] See OSHA standard for hazard communications.
[6] In addition to company policies and guidelines, NIOSH has specific guidelines for PCE.

put, the exposure assessment upon which the risk management regulation for petroleum refineries is based is flawed; therefore, PCE use as a catalyst regenerator in refining operations has not been demonstrated to present an unreasonable risk of injury to health or the environment and should never have been regulated in the first place.

IV. TSCA Risk Evaluations of PCE and AFPM Engagement on the Issue

The final risk evaluation for PCE did not take into account the unique conditions of use in petroleum refineries; rather, it generalized the use as a processing aid and not specifically as a catalyst regenerator. The exposure models used for the risk evaluation assumed that spills from hoses resulting in splashes to the skin occur 250 days per year (with one exposure event per workday). In risk evaluation modeling scenarios, that means a spill occurs every day that PCE is used, and the exposed workers just leave it on their skin without washing it off. The risk evaluation's assumptions ignore fundamental industrial hygiene practices and procedures required by OSHA to protect workers. They are hypothetical scenarios that have no basis in reality and are arbitrary and capricious.

On July 29, 2021, AFPM member companies met with EPA staff and discussed process engineering for isomerization and catalytic reforming, as well as details on the frequency and duration of PCE use as a catalyst regenerator, including safety practices and PPE. AFPM members requested that since EPA was reopening the risk evaluation to incorporate its newly announced whole chemical approach and an assumption that no PPE is used (contrary to regulatory requirements), the Agency should incorporate the actual frequency and duration of transfers from storage containers to processing units and rerun the exposure models.

On May 5, 2022, AFPM members subsequently met with Assistant Administrator Freedhoff, and recapped the previous comments and discussions. Petroleum refiners again requested that EPA reopen the risk evaluation to incorporate the actual frequency and duration under the conditions of use and rerun the exposure models. The Agency refused to rerun the exposure models and use the correct information in the exposure assessment portion of the risk evaluation. In essence, the risk evaluation does not use the best available science, which is required under TSCA § 26.

V. AFPM Concerns with the Risk Management Rule

A. The Workplace Chemical Protection Program ("WPCC") Requirements Impose Burdens on the Workplace Beyond the Owner/Operator's Control; Alternative Requirements are Warranted

The risk management rule incorrectly failed to distinguish between employers and owners/operators. These are not always the same entity. The risk management rule places too much of the burden on the owner/operator. Sometimes, owners/operators are involved in, and understand, the employer's (i.e., contractor's) business, in which case they may require that the contractor (the actual employer) adhere to basic employee protection measures. In other situations, the owner/operator may not be involved in the details of the contractor's business. In fact, the owner/operator may not even possess the specific knowledge to appreciate the details involved in

the contractor's business. One of the main reasons an owner/operator retains a contractor is because the contractor will have knowledge or skills that the owner/operator does not possess.

An example is when an operator hires a contractor to perform specialty work. In these cases, it is the contractor (acting as the employer) who possesses the training and knowledge to protect their employees. Requiring the owner/operator to implement the WCPP on behalf of the contractor is misplaced. The primary duty to protect employees from adverse workplace exposures rests with the employer; they have the knowledge and sophistication to ensure employee protection. This duty cannot be transferred to the owner/operator with an expectation that the owner/operator understands how to run the contractor's business.

AFPM is further concerned that issues of co-employment are created when owners/operators are required to dictate how a contractor runs their business, for example, by being responsible for implementing the WCPP for the employer. Contractors are hired because they possess skills and knowledge that are outside the owner/operator's abilities or capabilities. The employer (contractor), not the owner/operator, is clearly in the best position to direct work so as to ensure employees are protected.

More broadly, the expansive and burdensome requirements of the WCPP are closely connected to the stringency of the ECEL. Changes to the ECEL, as outlined below, should prompt a commensurate change in the scope and breadth of the WCPP, reflecting a significant reduction in monitoring, reporting, and administrative duplication with OSHA requirements. This includes elements such as:

- Removing the obligation to determine each potentially exposed person's exposure, *without regard to respiratory protection*, by collecting breathing zone air for analysis against the ECEL. Assessing exposures by pretending that existing mitigation measures and mandated PPE obligations do not exist only serves to create a false sense of justification for the WCPP.
- Re-monitoring within 15 working days after receipt of any exposure monitoring when results indicate a non-detect, unless officially certified otherwise. EPA's presumption that non-detect readings are inherently suspect and require extra authentication is meritless.
- Notice of monitoring results availability in dual languages. Proper management of safety, both administratively and as executed in the field, requires a common form of communication. Requiring multiple language documents runs counter to this effectiveness and jeopardizes safe operations.
- Identification of exposure controls in the Exposure Control Plan that were considered, *including those that were used or not used*. Identification of controls considered but not implemented only serves as a reflection of EPA's position that industry's implementation of exposure mitigation is suspect. The subtext in this requirement is that effective controls will be sidelined due to costs, while ineffective control will be implemented. EPA neither has the basis to support such a position, nor does it have the authority to craft obligations that require "reporting the negative".

AFPM recommends that a revised final rule allow for greater flexibility in compliance by allowing either specific controls outlined in the rule or a specific WCPP for industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing. The added provision would specify dermal PPE and respiratory protection for transferring concentrated PCE at petroleum refineries. The current final rule for PCE already has this type of specific dermal and respiratory PPE provisions for energized electrical cleaning, and the provisions could be similar for the petroleum refinery conditions of use. The owner and operator should have the option to either implement the specified dermal and respiratory protection or comply with the WCPP.

B. Many of the Proposed Requirements are Overly Burdensome and Duplicative of or In Conflict with Other Agencies

The Proposed Rule duplicates requirements imposed by OSHA, US DOT, and the National Institute for Occupational Safety and Health ("NIOSH"), and in some cases conflicts. For example, EPA proposes to require very specific respiratory protection. NIOSH is charged with making recommendations on respiratory protection, which are already in place for PCE, and OSHA is the regulatory authority for ensuring respiratory protection, which it already does for PCE. This could lead to confusion as to which regulatory standards and requirements to follow, especially if EPA's recommendations differ, like they do for the exposure limits.

40 CFR § 751.607(f) is duplicative of OSHA requirements found in 29 CFR Parts 1910.132, 1910.133, and 1910.134. Furthermore, noncompliance of the EPA regulations could result in double-jeopardy because owner/operators are already subject to OSHA regulations and penalties explicitly authorized by Congress. Therefore, EPA should delete the entire section and just reference the appropriate OSHA requirements so as not to infringe on OSHA's Congressionally authorized jurisdiction.[7,8]

The WCPP requirements present a significant burden, not just in terms of recordkeeping and compliance, but also in terms of practicality in day-to-day operations. A significant concern among AFPM members is having to comply with multiple WCPPs and ECELs, where few options, other than supplied-air respirators and Level A chemical protective suits would ensure compliance.

AFPM recommends that EPA refer to existing regulations and standards as appropriate and not try to recreate these within its own rule. Additionally, in isolation one rule may not create a significant burden, but if a WCPP is required for every high-priority chemical that is found to have an unreasonable risk (most have so far), AFPM recommends significant streamlining of these requirements and allowing companies to choose how to demonstrate compliance within their own established recordkeeping practices.

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[7] *Id.* at 103611 – 103613.
[8] See 29 CFR 1910.134.

C. The Existing Chemical Exposure Limit ("ECEL") is Not Based on the Best Available Science

The risk management rule established an entirely new workplace exposure limit that is intended to supplant the current exposure limits established by other federal and state agencies. The proposed risk management rule for PCE discussed workplace exposure thresholds established by OSHA, NIOSH, the American Conference of Government Industrial Hygienists ("ACGIH"), and the California Division of Occupational Safety and Health, all of which, with the exception of OSHA, recommend a 25 parts per million ("ppm") workplace exposure threshold.[9] OSHA's standard is 100-ppm. The 25-ppm threshold established by the other agencies incorporates the standard 4-fold margin of safety employed by every agency except EPA. The proposed risk management rule dismissed the use of the 4-fold threshold standard because it does not conform to EPA's own guidance, which uses anywhere from a 30-fold to 100-fold margin of safety.[10] The risk management rule established an ECEL of 0.14 ppm, which is 700-fold below OSHA's workplace exposure limit and almost 200-fold lower than the other established standards that already incorporate a margin of safety.[11]

The proposed risk management rule stated that the ECEL for PCE (0.14 ppm) is based primarily on two studies, Cavalerri et al., 1994, and Echeverria et al., 1995, both of which are epidemiological studies with very small sample sizes and subjective endpoints, such as "color confusion, impaired pattern recognition, and reaction time in pattern memory."[12] Neither study quantified the actual level of PCE in the study subjects; rather, both used air sampling to guess at what the dose values could be. There are myriad toxicological studies on PCE of varying quality. The proposed risk management rule did not adequately compare the study designs or weight the studies, as instructed by Congress in TSCA Sec. 26, [13] to provide an indication of why the Agency chose those two as the primary drivers for such a dramatic shift in workplace exposure thresholds.

AFPM does not support the ECEL because its establishment did not include a variety of stakeholder scientists who are experts in toxicology and/or industrial hygiene. AFPM recommends that EPA adopt the 25-ppm threshold used by all other agencies, as those thresholds were established through normal scientific review bodies. If EPA insists on its own threshold, it will likely confuse the regulated community as to which threshold should be followed. In light of this, AFPM members could operate under an alternate threshold value such as the one proposed by the American Chemistry Council ("ACC"), a value of 2.1 ppm. The derivation of this value, shown in ACC's analysis, has a stronger scientific foundation than the current 0.14 ppm or proposed 0.5 ppm threshold.

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[9] See *88 Fed. Reg.* 39652. "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-0720; FRL-8329-02-OCSPP, published June 16, 2023. p. 39660.
[10] *Id.*
[11] See *89 Fed. Reg.* 103560. "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-720; FRL-8329-01-OCSPP, published December 19, 2024. p. 103583.
[12] See *88 Fed. Reg.* 39652. "Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-0720; FRL-8329-02-OCSPP, published June 16, 2023. p. 39655 and 39659.
[13] See U.S. Code 15 § 2625(h).

D. ECEL and Direct Dermal Contact Control ("DDCC") Records Should be Combined

40 CFR § 751.615 has separate requirements for ECEL and DDCC records and many of those elements are redundant.[14]

ECEL record-keeping requirements include:

- Exposure control plan as described in § 751.607(d)(2)
- Notifications of exposure monitoring results
- The name, workplace address, work shift, job classification, work area and respiratory protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f), including fit-testing and training
- Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential exposure to perchloroethylene and any re-training as required in § 751.607(e)

DDCC record-keeping requirements include:

- Exposure control plan as described in § 751.607(d)(2)
- Dermal protection used by each potentially exposed person and PPE program implementation as described in § 751.607(f)(3), including the name, workplace address, work shift, job classification, and work area of each person reasonably likely to directly handle perchloroethylene or handle equipment or materials on which perchloroethylene may present and the type of PPE selected to be worn by each of these persons
- The basis for specific PPE selection
- Appropriately sized PPE and training
- Occurrence and duration of any direct dermal contact with perchloroethylene Training in accordance with § 751.607(f)(3)
- Information and training provided by the regulated entity to each person prior to or at the time of initial assignment to a job involving potential direct dermal contact with perchloroethylene and any re-training as required in § 751.607(e)

AFPM recommends that the records be combined to reduce duplicative records.

E. EPA Should Allow More Flexibility in Exposure Monitoring for Conditions of Use That are Intermittent

EPA allows for a representative sample of exposures; however, the risk management rule establishes that samples "are representative of the 8-hour TWA of all potentially exposed persons in an exposure group if the samples are of at least one person's full-shift exposure who represents

[14] *Id* at 103614 – 103615.

the highest potential PCE exposures in that exposure group."[15] AFPM urges the Agency to allow for task-oriented sampling that can be extrapolated to an 8-hour exposure because PCE is only used on an intermittent basis at petroleum refineries. Otherwise, the approach established by the final rule will further exaggerate the risk and degree of exposure on top of the unduly conservative exposure limits built into the rule.

The risk management rule also requires owner/operators to "ensure that methods used to perform exposure monitoring produce results that are accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of PCE," which is far too prescriptive.[16] EPA should delete this provision or at least limit the statement to "ensure that methods used to perform exposure monitoring produce results that are accurate to a confidence level of 95 percent," which should allow owner/operators to follow recognized, validated methods (e.g., NIOSH sampling and analytical methods) for exposure monitoring.

The risk management rule calls for owner/operators to require respiratory protection in regulated areas and provide appropriate respirators. While owner/operators can, and do require respirators in appropriate situations, they rarely supply those respirators because the employers of the contractors and other non-employees provide PPE through their own safety programs.[17] 40 CFR § 751.607(b)(4) is duplicative of 29 CFR § 1910.134; therefore, EPA should just reference OSHA's Respiratory Protection Program.[18,19]

40 CFR § 751.607(d)(1) should only set out regulatory requirements. It is obvious that in cases where the requirements are not being met that the regulated entity is out of compliance. EPA should delete 40 CFR § 751.607(d)(1)(C):

> *"Where an owner or operator cannot demonstrate exposure to PCE has been reduced to or below the ECEL through the use of controls required under paragraphs (d)(1)(i)(A) and (B) of this section, and has not demonstrated that it has appropriately supplemented with respiratory protection that complies with the requirements of paragraph (f) of this section, this will constitute a failure to comply with the ECEL."*[20]

40 CFR § 751.607(d)(1)(ii)(C) contains similar language, so EPA should delete the following for the same reason:

> *"Where an owner or operator cannot demonstrate direct dermal contact to PCE is prevented through the use of controls required under paragraphs (d)(1)(ii)(A) and (B) of this section, and has not demonstrated that it has appropriately*

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[15] See *89 Fed. Reg.* 103560. "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-720; FRL-8329-01-OCSPP, published December 19, 2024. p. 103608.

[16] *Id.*
[17] *Id.* at 103609 and 103610.
[18] *Id.* at 103610.
[19] See 29 CFR 1910.34.
[20] See *89 Fed. Reg.* 103560. "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-720; FRL-8329-01-OCSPP, published December 19, 2024. p. 103610.

supplemented with dermal protection that complies with the requirements of paragraph (f) of this section, this will constitute a failure to comply with the direct dermal contact control requirements."[21]

F. Training Requirements Must Account for Contractors Outside of the Owner/Operator's Control

AFPM members support and conduct safety training on a continual basis and are renowned for their safety programs. Owner/operators should be afforded flexibility and an opportunity to verify training through a variety of means such as contractual agreements and confirmation from employers. Training should be performance-based and not prescriptive, as each condition of use is unique and may require more attention in certain areas or less attention in others. There are workers onsite (e.g., contractors and vendors) that may not be under the control of the owner/operator. In those cases, the employer is currently, and should be, responsible for safety training.

G. The Risk Management Rule Should Not Contain Requirements for Safety Data Sheets ("SDSs")

40 CFR § 751.613(c) requires companies to add a section that describes the regulatory status of PCE to their SDSs.[22] TSCA does not authorize EPA to promulgate regulations for SDSs. Congress gave OSHA explicit authority over SDSs, and any requirements should come directly from OSHA.

VI. Conclusion

AFPM appreciates the opportunity to comment on the reconsideration of the risk management rule for PCE. AFPM does not believe that the conditions of use from PCE as a catalyst regenerator pose an unreasonable risk; however, that will not preclude AFPM and its members from working constructively with the Agency to refine the risk management rule. AFPM looks forward to further dialog.

Sincerely,

James Cooper
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[21] *Id.*
[22] See *89 Fed. Reg.* 103560. "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)." EPA-HQ-OPPT-2020-720; FRL-8329-01-OCSPP, published December 19, 2024. p. 103614.