

Draft Revision to Toxic Substances Control Act (TSCA)
Risk Determination Perchloroethylene (Docket ID
EPA-HQ-OPPT-2016-0732)

Comment of the American Fuels & Petrochemical
Manufacturers and the American Petroleum Institute

August 1, 2022

1.0 Introduction

The American Fuel & Petrochemical Manufacturers (“AFPM”) and American Petroleum Institute (“API”) submit these comments on the Environmental Protection Agency’s (“EPA” or “the Agency”) *Federal Register* notice titled, “Perchloroethylene (PCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment” (“the proposed rule”).¹ Specifically, EPA is seeking comments on two main distinctions between the original final risk evaluation of PCE and the reevaluation: (1) use of the “whole chemical approach”² and (2) the assumption that workers do not wear personal protective equipment (“PPE”) even when required by regulation.

AFPM and API have significant concerns with both the whole chemical approach and the assumption about PPE not being used at refining operations. In addition, AFPM and API believe that the Agency must correct known deficiencies in the exposure assessment of the original risk evaluation. The Agency’s refusal to correct the science is arbitrary and capricious.

2.0 AFPM and API Interest in the Risk Evaluation for PCE

Combined, AFPM and API represent the entire petroleum supply chain from upstream exploration and production to midstream processing and transportation, to downstream refining. AFPM and API members make the fuels that keep America moving and are keenly interested in policies that impact the fuel and petrochemical supply chains.

Petroleum refineries employ two processes that use PCE as a chloriding agent to regenerate catalysts. The processes, isomerization and catalytic reforming, are essential to make fuels compliant with environmental regulations. Isomerization reduces the amount of benzene in fuels and catalytic reforming generates hydrogen that is used to remove sulfur compounds. The catalyst used in those processes contains platinum, alumina and chloride in a molecular matrix where the chloride degrades and is required to be regenerated on a constant basis. The catalyst is a key component of these processes because it enhances safety while promoting the formation of desirable products. The PCE activates the catalyst and regenerates the spent catalyst by providing chloride.

EPA identified the use of PCE as a catalyst regenerator in petroleum refineries to be within the scope of its risk evaluation. Unfortunately, the Agency generalized the use of PCE and made unrealistic assumptions about the frequency and duration of use, which adversely affected the output of the exposure models and led to an erroneous finding of unreasonable risk for that condition of use (COU).

¹ See 87 *Fed. Reg.* 39085, “Perchloroethylene (PCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment,” EPA-HQ-2016-0732, published June 20, 2022, at <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0732-0112>.

² Historically, EPA made separate unreasonable risk determinations for every condition of use of a chemical. EPA has recently decided to modify this approach when conducting risk assessments under TSCA. Per the EPA “[f]or the first 10 chemicals under TSCA and for any similar chemical that presents significant risks across many uses, EPA will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination.” EPA is referring to this as the “whole chemical approach” See also, <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

3.0 Conditions of Use for PCE

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 risk of the process 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 less efficient, which require larger amounts of hazardous materials onsite and leads to increased exposure possibilities, or the alternatives are more hazardous. Furthermore, most of the other chloriding agents are restricted by EPA or undergoing risk management due to findings of unreasonable risk. One particular alternative catalyst regenerator, chlorine, is regulated under DHS and USCG security regulations and switching to that substance would increase the overall security risk of the facility.

PCE must be replenished on a periodic basis and is transported to the facility by suppliers. The preferred 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 OSHA hazardous communications standards. 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.

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 from a hose, which is very unlikely and not considered a normal condition of use. Accidental spills should not be considered in a risk evaluation under TSCA § 6.

Data on PCE changeout confirms that EPA's exposure estimates are clearly erroneous. For example, EPA assumes that changeout occurs 250 times per year; 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

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

frequencies is due to each refinery being different in design, layout, and processing capacity. The actual frequency of PCE replenishment shows how unrealistic EPA's exposure assumptions are for this use.

4.0 Petroleum Refining Safety Record

The petroleum refining industry strives to comply with all federal and state laws. AFPM and API member facilities are among the most regulated and audited in all of manufacturing through agencies such as EPA and OSHA.

- In 2020, the rate of job-related nonfatal injuries and illnesses for U.S. petroleum refinery workers was 0.5 per 100 full-time workers, compared to a rate of 3.1 for the entire U.S. Manufacturing sector.⁴
- The 2021 Tier 1 PSE rate was above the 5-year rolling average, which decreased 9.8% compared to the 5-year rolling average in 2017. The 2021 Tier 2 PSE rate was above the 5-year rolling average, which saw a 15.9% decrease from the 5-year rolling average in 2017.⁵
- RP-754 identifies leading and lagging process safety indicators useful for driving performance improvement. As a framework for measuring activity, status or performance, this document classifies process safety indicators into four tiers of leading and lagging indicators.⁶

API is engaged in the Voluntary Protection Programs (VPP), which recognize employers and workers in the private industry and federal agencies who have implemented effective safety and health management systems and maintain injury and illness rates below national Bureau of Labor Statistics averages for their respective industries.

In VPP, management, labor, and OSHA work cooperatively and proactively to prevent fatalities, injuries, and illnesses through a system focused on: hazard prevention and control; worksite analysis; training; and management commitment and worker involvement. VPP participants are re-evaluated every three to five years to remain in the programs. VPP participants are exempt from OSHA programmed inspections while they maintain their VPP status.

5.0 EPA Risk Evaluation of PCE

EPA's 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. In its exposure models, EPA assumed that spills from hoses resulting in splashes to the skin occur 250 days per year (with one exposure event per workday). In EPA's modeling scenario 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.

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

⁴ <https://www.api.org/-/media/Files/Publications/API-Workplace-Safety-Report-2020.pdf>

⁵ <https://www.api.org/-/media/Files/Oil-and-Natural-Gas/Refining/Process%20Safety/2021-RP-754-PSE-Public-Reporting-2017-2021-Data.pdf?la=en&hash=2EAA97BEDB423929B49B4412F254F2892C6702B0>

⁶ <https://www.api.org/oil-and-natural-gas/health-and-safety/refinery-and-plant-safety/process-safety/process-safety-standards/rp-754#:~:text=RP%2D754%20identifies%20leading%20and,of%20leading%20and%20lagging%20indicators>

assumption that no PPE is used, the Agency should incorporate the actual frequency and duration of transfers from storage containers to processing units.

On May 5, 2022, AFPM members subsequently met with Assistant Administrator Freedhoff, and recapped the previous comments and discussions. Petroleum refiners expressed a commitment to work constructively with EPA during the risk management phase and 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. EPA has thus far expressed resistance to reopening the exposure assessment portion of the risk evaluation.

In *Chemical Manufacturers Association, et al. v. U.S. Environmental Protection Agency*, the court found that EPA could not use hypothetical exposures to justify a test rule under TSCA § 4.⁷ Section 4 contains a standard that requires the agency to identify scenarios that "may present" a potential for likely exposures, while § 6 has a more exacting standard for risk evaluation, ratcheting up the "may present" standard in § 4 to a "will present" in § 6. EPA's hypothetical use scenario for PCE at petroleum refineries would never occur in the real world, has no relation to actual risk, and ignores existing OSHA regulations, standard industrial hygiene practices, and standard operating procedures at refineries. EPA must modify its underlying assumptions before using the finalized risk evaluation as justification for new risk management measures.

6.0 EPA Re-evaluation of PCE

6.1 Whole Chemical Approach

Under the newly introduced whole chemical approach, if EPA finds that there are unreasonable risks for a "substantial" number of uses, then the Agency will communicate that the chemical substance as a whole presents an unreasonable risk, even when other uses do not present an unreasonable risk.⁸ In effect, EPA will not acknowledge the conditions of use that do not present an unreasonable risk, which distorts the actual risk profile of the chemical by ignoring the uses where the level of risk is acceptable.

In chemical risk assessment, scientists compare the hazards of a chemical substance with potential exposures (estimated from the conditions of use) and generate a margin of exposure, by which one can estimate the risk posed by that substance. Congress understood this approach when it created the original TSCA statute and reiterated that understanding when it enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016.

The statutory language is quite clear in its expectation of comparing hazard and exposure for each condition of use to determine risk.⁹ There is no mention of the phrase "whole chemical approach" anywhere in either statute. There is also no mention of the phrase in the scientific literature of professional societies. The Agency's own risk evaluation process rule is also explicit in its direction to

⁷ See *Chemical Manufacturers Association, v. U.S. Environmental Protection Agency*, 859 F.2d 977 (D.C. Cir. 1988) at <https://law.justia.com/cases/federal/appellate-courts/F2/859/977/126560/>.

⁸ See 87 *Fed. Reg.* 39088, Section II(B), published June 30, 2022.

⁹ TSCA § 6(b)(4) says in general EPA "shall conduct risk evaluations...to determine whether a chemical substance presents an unreasonable risk...under the conditions of use," and § 6(b)(4)(F) says EPA "shall...assess available information on hazards and exposures for the conditions of use," and "take into account...duration, intensity, frequency...under the conditions of use." Additionally, § 6(c) says if EPA finds an unreasonable risk in accordance with § 6(b)(4)(A), the Agency must propose a risk management rule, which affirms that Congress intended for EPA to use the conditions of use as a basis for specific risk management actions.

address each condition of use.¹⁰ It is only recently that this whole chemical approach modification to EPA's methodology was introduced into a regulatory context, with no opportunity for public comment and presented during the regulatory reevaluation of the first 10 high priority chemicals.

The concept of a whole chemical approach contradicts TSCA's long-standing risk-based approach to chemicals management. EPA has traditionally generated and communicated a margin of exposure for each use of a chemical substance, to ensure a transparent, risk-based system for chemicals management. This is a departure from EPA's own risk evaluation process rule, where § 702.49(d) explicitly states if EPA determines that a chemical substance does not present an unreasonable risk "under one or more conditions of use," the Agency will communicate that finding by issuing an order.

6.2 EPA's Assumption That PPE is Not Used

Petroleum refining is regulated under Section 313 of the Emergency Planning and Community Right-to-Know Act, Hazardous Air Pollutant provisions under the Clean Air Act, Comprehensive Environmental Response Compensation and Liability Act, National Primary Drinking Water Regulations under the Safe Drinking Water Act, Occupational Safety and Health Act, Chemical Facility Anti-Terrorism Act, and Marine Transportation Security Act, just to name a few. Petroleum refineries are subject to inspections by EPA, OSHA, DOT, DHS, USCG, and state regulatory authorities, in addition to their own internal or third-party audits as part of continuous improvement programs.

AFPM and API work cooperatively and have a renowned safety program recognized as a gold standard in the manufacturing sector.¹¹ OSHA safety statistics continually demonstrate that the refining industry is among the safest of all manufacturing sectors. PPE is worn to protect refinery workers from other chemical exposures present in the refinery process and is readily available. Refineries as a result tend to have mature industrial hygiene monitoring programs and robust employee exposure reduction processes. Petroleum refineries have well-defined and explicit operating procedures that very often exceed regulatory standards.

It is beyond reason that a chemical risk evaluation under TSCA would assume that workers in petroleum refineries would ignore other agencies' regulations, especially those under OSHA. To assume workers are not wearing PPE is to assume they are not complying with the law, which is an arbitrary and unreasonable assumption.¹² Illegal actions are not normal conditions of use and have never been part of risk evaluations under TSCA § 6.

As mentioned previously, during the initial risk evaluation for PCE, EPA used models with faulty assumptions (i.e., accidental spills and splashes to skin) and default values to estimate exposures. Accidental releases are not normal conditions of use and, therefore, are not appropriate scenarios for risk evaluations under TSCA § 6. Risk assessment for accidental releases and spills requires a different methodology that relies on probability factors based on frequency of occurrence, similar to process

¹⁰ § 702.41(a)(8) states EPA will determine risk under "all conditions of use within the scope" and "identify the individual conditions of use...that are responsible" for risk determinations. § 702.47 states EPA will determine risk "under each condition of use."

¹¹ See AFPM safety programs website: <https://www.afpm.org/safety-programs#:~:text=Advancing%20Process%20Safety%20Programs,to%20share%20experiences%20and%20knowledge>.

¹² Cf. *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 505-06 (D.C. Cir. 2019) (upholding EPA's decision not to require financial responsibility requirements under CERCLA for hardrock mining facilities because "existing federal and state programs and modern mining practices have obviated the need for new financial responsibility requirements").

safety analysis and security risk analysis. In fact, accidental releases are already covered under a variety of different regulatory programs, such as EPA's Risk Management Program, OSHA's Process Safety Management program, and EPA's Emergency Planning and Community Right to Know Act, among others.

To the extent that EPA believes exposures to PCE exist in other use scenarios where PPE is not mandated, the Agency is obligated to perform separate risk evaluations per § 702.41(a)(8) and § 702.47 of EPA's own risk evaluation process rule.

6.0 Using the Best Available Science

As stated previously, EPA's exposure assessment in the initial risk evaluation is significantly flawed and purely hypothetical. Petroleum refiners have provided EPA with real-world exposure frequency and duration information, in addition to procedures and PPE practices, that would produce a completely different exposure assessment output and, subsequently, risk evaluation result.

AFPM and API urge the Agency to rerun the exposure models in a conservative manner using the higher end of the frequency (35 times per year for totes and 12 times per year for tank trucks) and higher end for duration (15 minutes for totes and 60 minutes for tank trucks). This would be consistent with the requirements found in the statute (§ 6(b)(4)(F)) and EPA's own risk evaluation process rule.¹³

Furthermore, AFPM and API urge EPA to reevaluate the risk finding according to the new modeling outputs and assume a more realistic condition of use where accidental releases do not occur every time PCE is used, and that OSHA regulations and basic industrial hygiene standards are being followed.

7.0 Conclusion

AFPM and API acknowledge and appreciate the significant amount of work the Agency has performed within very tight deadlines. Furthermore, the petroleum refining industry offers to work constructively with EPA to refine the risk evaluation and reflect the highest quality science. AFPM and API are also committed to working cooperatively with the Agency during the risk management phase. AFPM and API do, however, still have significant concerns with the current risk evaluation and believe the proposed updates are not credible and will not withstand judicial scrutiny.

PCE is essential as a catalyst regenerator in key processes that reduce benzene and sulfur content in gasoline to meet EPA's own fuel standards. There are no safer alternatives that can legally be used to replace PCE. These facts should be considered moving forward.

EPA cannot use hypothetical exposures as the basis for risk management actions under TSCA § 6. Since EPA has already reopened the risk evaluation and will miss its deadlines, the Agency should use the best available science by incorporating the higher end frequencies and durations of use in the exposure models, rerun the exposure models, and incorporate the improved and more realistic outputs into the risk evaluation. This will bring the risk evaluation into conformity with the statutory obligations under § 6(b)(4)(F) and § 26(h). Furthermore, EPA should assume that OSHA and all other federal and state regulations are followed at petroleum refineries.

¹³ § 702.43(a)(4) of the risk evaluation process rule requires EPA to consider "the likely duration, intensity, frequency...under the conditions of use." The word "likely" in this context means the Agency should avoid hypothetical exposures when realistic scenarios are available.

EPA should drop the concept of the whole chemical approach, as it has no authority to depart from considering each condition of use and communicating the results of its risk findings, including the use of those findings for risk management actions under § 6(d).

AFPM and API appreciate the opportunity to submit these comments and are committed to working constructively with EPA throughout TSCA implementation. For questions or clarifications, please contact James Cooper at jcooper@afpm.org or Michael Kennedy at kennedym@api.org.



James Cooper, Senior Petrochemical Advisor
American Fuel & Petrochemical Manufacturers



Michael Kennedy, Senior Advisor
American Petroleum Institute