

EPN Comments on Trichloroethylene: Regulation under the Toxic Substances Control Act Docket No.: EPA-HQ-OPPT-2020-0642 December 12, 2023

The Environmental Protection Network (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

Trichloroethylene (TCE) is one of the most dangerous chemicals in use today. It has been found to cause liver cancer, kidney cancer, and non-Hodgkin's lymphoma. TCE also causes damage to the central nervous system, liver, kidneys, immune system, reproductive organs, and is dangerous for fetal development. These risks are present even at very low concentrations of TCE. EPA's fenceline community screening analysis has also indicated that people living near facilities where TCE is made and used can be at higher risk for developing these health conditions. As a result, EPA has the statutory obligation to protect consumers, workers, occupational non-users, and bystanders from TCE's harmful health effects. Prohibitions on TCE are long overdue, and EPA should resist industry's efforts to further delay or weaken them.

EPN commends EPA for proposing to ban the manufacture (including import), processing, and distribution in commerce of TCE for all uses. We further commend EPA for proposing that this ban take effect one year after final rule publication for all consumer products and most commercial uses. We also support the requirement that stringent worker protection programs be implemented for the commercial and industrial uses of TCE that are phased down over a longer period.

EPN finds that this proposed rule will spur development and use of safer substitutes, advance the Biden administration's Cancer Moonshot and Environmental Justice commitments, and satisfy the Toxic Substances Control Act's (TSCA) requirement to ensure the elimination of TCE's unreasonable risks. We urge EPA to ensure that all programs within the agency update their TCE toxicity endpoints to reflect those developed for this risk management rule.

EPA appropriately bans TCE for all consumer products and most commercial uses within one year of final rule publication.

We support the proposed rule's ban for all consumer uses and most commercial uses within one year because: 1) EPA's risk evaluation found unreasonable risks for all but one of the 24 consumer uses of TCE and 2) EPA found manufacturing, importing, and processing of TCE for consumer uses result in unreasonable risks for workers and occupational non-users. We support this ban because consumers are not protected by workplace exposure limits, and consumer risks are known to persist even when labels on a product warn of a chemical's toxicity. We also support the ban on manufacturing and importing of TCE for consumer uses in three months, on processing of TCE for consumer uses in six months, and on distribution of TCE in commerce in six months after publication of the final rule.

In defining the rule's scope, EPA proposes to prohibit all uses of TCE aside from those carved out of EPA's definition of "chemical substance." We find the language on page 74733 very unclear regarding TCE uses carved out of the definition. It appears EPA is proposing to exclude from the definition the processing of TCE into any type of formulation, mixture, or reaction product used in other chemical products not regulated under TSCA, such as pesticides, drugs, and cosmetics. We know that raw materials, intermediates, and inert ingredients (in this case TCE) produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA (unless they happen to be pesticides themselves). Without more clarity on what EPA is excluding from the definition, we can only comment that we are concerned that the continued distribution in commerce of TCE for these excluded purposes will pose a public health risk during its transport.

EPN supports EPA's decision not to propose a de minimis exemption from bans of TCE to account for impurities. Even if EPA could identify a safe concentration of TCE in a particular product, consumers and workers are often exposed to multiple products and pathways. Allowing ongoing sale and use of products with de minimis TCE concentrations would leave exposed populations subject to unreasonable risk from their total exposure.

EPA appropriately allows longer compliance periods for certain uses.

EPN supports EPA's application of section 6(g) exemption criteria to allow longer phase-down times for certain Department of Defense and NASA uses as well as for battery separator manufacturing and essential laboratory activities. We also support the longer compliance times for two uses that are not based on section 6(g) criteria: the manufacturing and processing of TCE in producing hydrofluorocarbon 134a and the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing of rocket booster nozzles.

This support comes with some degree of hesitancy. While we understand why the agency chose to allow some uses to continue past the one-year period and to impose certain workplace protections in the interim, we are concerned about whether the agency has sufficient staff to enforce these provisions.

EPN support for these longer phasedown times is contingent on the rule's requirement for stringent workplace controls during this period, including compliance with an inhalation exposure limit based on fetal cardiac effects as well as dermal protection. We also support the prohibition on distributing TCE for these longer-term situations being effective at the same time as the manufacturing/processing prohibitions.

EPN supports the prohibition, due to worker risks, of the disposal of TCE to industrial pretreatment, industrial treatment, or publicly-owned treatment works nine months after final rule publication. We also support the section 6(g) exemption to support soil and groundwater cleanup by allowing essential laboratory analyses of TCE and proper disposal of TCE waste to continue longer, but believe 30 years is a more reasonable time frame than the proposed 50 years. Years are needed to address the extensive soil and groundwater contamination caused by decades of unregulated use of TCE, but 50 years is unreasonably long.

EPA appropriately bases Existing Chemical Exposure Limit on fetal cardiac effects.

EPN supports EPA's acknowledgment of the critical role of TSCA in worker protections. Congress was well aware that worker risks persist despite the existence of the Office of Safety and Health Administration's (OSHA) permissible exposure limits (PELs), which OSHA publicly admits are often inadequate to protect health. We further agree that TSCA requires EPA to conduct risk evaluations assuming workers and non-occupational users are not covered by OSHA standards, such as self-employed and public sector employees who are not covered by a State Plan. We note, however, that even when respirators were assumed to be worn, most of the TCE conditions of use still posed unreasonable risks.

EPA requests comment on a number of issues regarding workplace controls for TCE uses continuing beyond the first year after final rule publication. EPA requests comment on whether these workplace controls should require compliance with an Existing Chemical Exposure Limit (ECEL) based on fetal cardiac effects, an ECEL based on immunotoxicity effects, or an unspecified "lowest achievable level." EPA asks for comment on whether an ECEL action level of one-half the ECEL should be used to trigger more frequent air sampling of TCE and if an interim ECEL should be required based on the limit of detection for OSHA Method 1001. EPA also asks whether it should replace prohibitions with compliance with a Workplace Chemical Protection Program (WCPP) if entities are able to consistently demonstrate compliance with an ECEL through workplace controls.

EPN urges EPA to require that entities ensure their workplace controls reduce exposures below the ECEL, rather than to the lowest achievable level. We are concerned that even if EPA could establish fool-proof criteria defining the lowest achievable level, the agency would lack the staff needed to enforce those criteria. An ECEL is also better because it will be technology forcing, leading to greater health protection, whereas the lowest achievable level than one based on chronic autoimmunity. This level of protection is needed to protect pregnant workers and occupational non-users who may be especially susceptible to TCE-induced cardiac defects in their developing fetus. We support EPA's proposal to set an ECEL action level at one-half the ECEL to trigger more frequent periodic monitoring of exposures to TCE and do not recommend setting the action level closer to the ECEL. We support EPA's requirement that this monitoring be designed to represent each potentially exposed person's full-shift exposures. We urge EPA to require monitoring using personal air sampling devices capable of detecting indoor TCE concentrations at or below the action level rather than area source monitoring.

If a WCPP cannot reduce exposures below the ECEL, EPN supports EPA's proposal to require the owner/operator to reduce TCE to the "lowest level achievable" and require respiratory and dermal protection before people are permitted to enter an area out of compliance. We also support EPA's prohibiting owners/operators from rotating work schedules of potentially exposed workers in order to comply with the ECEL.

EPN does not support allowing the use of an interim ECEL based on the limit of detection for OSHA Method 1001, which equates to an action level of 0.018 ppm and an ECEL of 0.036 ppm, an order of magnitude less stringent than health protection requires. We are certain that analytical methods capable of measuring below the action level based on fetal cardiac effects (0.00055 ppm) will be developed in time for use in WCPPs.

EPN is opposed to EPA allowing continued use of TCE by entities that can demonstrate they consistently meet the ECEL with workplace controls. We are convinced EPA must prohibit the industrial and commercial use of TCE based on unreasonable risks to workers and occupational non-users and not depend on WCPPs to protect them because of the uncertainty about the long-term consistency of protection, the potential for accidents and process upsets, and the lack of EPA resources to enforce workplace controls. We are also concerned about the continued transport of TCE which can pose serious health risks when accidents occur.

EPA appropriately adopts a hierarchy of controls to manage occupational exposures and risks.

EPN urges EPA to afford workers and fenceline communities the same degree of protection as consumers and to phase out all non-essential uses of TCE as soon as possible. However, during the phase-out period, we support EPA's reliance on a hierarchy of controls to manage occupational risks. Consistent with long standing OSHA practice, EPA proposes relying on a hierarchy of controls ranging from the most protective and preferred to the least protective and preferred technologies. In order of preference, these controls are: elimination of the hazard; substitution with a less hazardous substance; engineering controls; administrative controls such as training or exclusion zones with warning signs; and, finally, use of Personal Protective Equipment (PPE).

EPN supports EPA's proposed compliance timelines for worker protections and urges the agency not to lengthen these timelines. EPA appropriately requires each owner/operator of a workplace subject to an ECEL to: 1) conduct initial baseline monitoring by six months after final rule publication; 2) ensure the airborne concentration of TCE does not exceed the ECEL or lowest achievable exposure level for all potentially exposed people within nine months after final rule publication; and 3) provide respiratory protection sufficient to reduce inhalation exposures below the ECEL within two weeks or three months after receipt of any exposure monitoring that indicates exposures exceeding the ECEL. EPN supports EPA's alternative of providing respiratory protection within two weeks. EPA also appropriately requires each owner/operator subject to dermal protection to establish that protection by 6 months after final rule publication.

EPA should strengthen the reporting and enforcement provisions.

To promote compliance, EPN recommends that EPA require owners/operators to provide WCPPs to EPA, and with the exception of statutorily-confined confidential business information, to share them with their workers and the public. EPN urges EPA to require owners/operators to attest in their WCPP that controls will not increase TCE emissions outside of the workplace, impacting fenceline communities. If there is a potential for emissions to the ambient air, EPA should further require that the WCPPs document equipment that will be installed to capture these TCE emissions. EPA's fenceline analysis indicates that communities are exposed to increased health risks now, and owners/operators must be required to prevent TCE emissions from increasing outside of the workplace while TCE is still in use. In addition to requiring owners/operators to notify workers who have been exposed to exceedances of an ECEL, EPA should require companies to report violations of an ECEL to EPA.

EPA should improve the Economic Analysis.

EPN notes that the Office of Management and Budget (OMB) just finalized "Circular A-4: Regulatory Analyses at 80," which recommends a default discount rate of 1.7%, much lower than the 3% and 7% discount rates EPA used in the TCE economic analysis. OMB lowered the discount rate to more appropriately discount "intergenerational" harms such as TCE's reproductive and developmental effects and long-term cancer risks. EPA should add an economic analysis for this TCE rule using the new discount rate of 1.7%, which will more accurately estimate the benefits of the rule.

Conclusion

EPN commends EPA for proposing a health-protective regulation that meets the TSCA mandate to eliminate TCE's unreasonable risks. We agree with EPA's approach to phase out all uses of TCE while permitting the time-limited continuation of critical uses pursuant to TSCA section 6(g). We are certain this proposal will spur development and use of safer substitutes and advance the Biden administration's Cancer Moonshot and Environmental Justice initiatives. We urge EPA not to weaken this proposal by adopting less protective ECELs or extending compliance periods. EPA should focus the final rule on improving enforcement by requiring public access to information on any owner/operator failures to meet prohibition deadlines for the manufacture, import, processing, or distribution of TCE. For uses with prohibitions beyond the first year, EPA should require protection of fenceline communities from any increase in TCE emissions and ensure public access to WCPPs and notice of violations of ECELs.