

Bullets for OMB Meeting on Perchloroethylene

EPA's perc risk evaluation is not consistent with the TSCA requirements. Its hazard assessment inaccurately reports the scientific literature, contains flawed analyses, and ignores conclusions from EPA's expert peer-review committee. As a result, the risk evaluation resulted in an overly conservative Existing Chemical Exposure Limit (ECEL) due to the exaggerated health risks of perc. We also have concerns that the dermal risk assessment may have resulted in a proposed risk management rule that goes beyond TSCA's mandate to regulate unreasonable risks.

Dermal and Inhalation Risks Overstated for Almost All CoUs

Dermal

- EPA's dermal risk assessment for the perc risk determination is not the best available science. As documented by HSIA in meetings with EPA in 2021, it greatly overestimates exposure.
- EPA's assessment of dermal exposure of workers at facilities that manufacture perc and use perc to produce other chemicals (*i.e.*, refrigerants) is based on a hypothetical "worst -case" scenario that does not exist in the real world. As a result, EPA found unreasonable risk to workers from acute and chronic dermal exposure at these facilities, even with the most protective glove use. This is extraordinary, particularly since EPA already regulates these closed system facilities under the NESHAPs for Synthetic Organic Chemical Manufacturing Industry (HON) and Miscellaneous Organic Chemical Manufacturing (MON), which require closed systems where exposure is tightly controlled and dermal exposure is negligible, both in terms of frequency and magnitude.
- Dermal exposure at these facilities typically involve short-term (5-30 minutes) tasks that could potentially result in contact with liquid phase perc such as loading, maintenance and the like. Instead of the short tasks with potential dermal exposures, EPA assumed daily 8-hr dermal exposure over a lifetime which EPA used in the risk evaluation. This assumption not only is an overestimate of potential exposure, it also does not take into account Standard Operating Procedures (SOPs) in place at facilities that manufacture and use perc as a reactant and intermediate to prevent exposure during the short term tasks.
- EPA has been made aware of its unrealistic dermal exposure assessments yet has made no effort to correct the mistake in the revised risk determination.

Inhalation/ECEL-Based Limit

- EPA published the final perc risk evaluation in December 2020, but only released the existing chemical exposure limit (ECEL) to the public in May 2022.
- The perc ECEL is 0.14 ppm as an 8-hour TWA. This is 714 times lower than the OSHA 8-hour PEL of 100 ppm, and 178 times lower than the ACGIH 25 ppm 8-hour TWA TLV. This much lower ECEL cannot be justified based on EPA's unsupported conclusions in the perc risk evaluation.
- Under TSCA, where EPA finds "unreasonable risk" it must regulate "to the extent necessary so that the chemical substance no longer presents such risk." If the ECEL is the basis for regulation, small businesses such as dry cleaners, which predominantly use perc, will be unable to comply with the limit.

- In the interest of time, we do not repeat today how TSCA and EPA's regulations compel EPA to make COU-specific risk determinations, not to follow a "whole chemical" approach. These points were covered in our December meeting on methylene chloride.

Risk Management Rule

Measurement

- EPA should not base its risk management rule on the unduly conservative ECEL.
- Should it do so, however, the risk management rule should provide *5 years*, as allowed by TSCA, to incorporate the ECEL into compliance procedures for manufacturing, processing, and use for the following reasons:
- Dry cleaner exposures are variable and intermittent, and measurement must rely on badges. More sophisticated monitoring is beyond the financial capability of these very small businesses. The current detection limit of these badges is 0.15 ppm for 2 hours and 1.2 ppm for 15 minutes. Half the NYC dry cleaners currently achieve non-detect over 2 hours. The other half will require time to reach this level, whether by installation of new machines, change of protocols, or the like. Equally important, this time is needed to advance the technology so that 0.15 is the mid-point of a range, not the limit of detection, thus greatly increasing accuracy.
- Dry cleaners have always been able to count on 20 years useful life after equipment changes under the NYS Part 232 regulations. The financial constraints on these small businesses are even greater in this post-pandemic era, when their business is down by some 40%. And if New York phases out natural gas, as expected, the financial situation of dry cleaning plants becomes even more dire.
- Measurement/monitoring technology also may not currently be available to measure at the low levels necessary to comply with the ECEL values (or for that matter dermal exposures). Short term measurements are used to evaluate control effectiveness. Employers subject to OSHA must comply with a ceiling/15-minute STEL, but neither the NIOSH 1003 Active or Passive Method can meet the ECEL for short term tasks. If measuring the ECEL is technically infeasible for 15-minute samples, it is unclear how compliance against the ECEL will be determined when measuring short term tasks, unless EPA provides the suggested five years for monitoring technology development.

Lab Capacity

- Even if the methodology allows for a lower sample LOD, coordination with the labs may be required to ensure they have the capacity to evaluate at the lower levels with the equipment in place or if time is needed to obtain additional equipment.
- If a new methodology (other than NIOSH 1003) is required, time will be needed to evaluate new equipment needs for the sampling methodology and in the lab, obtain the equipment, and implement training for new technologies in the lab and in the field.

Cost and Other Consequences

- Implementation costs, including increased lab fees for scarce availability, will increase if sufficient time is not provided to implement monitoring and other elements needed for compliance.
- 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 has critical uses, such as manufacture of HFC refrigerants and catalyst regenerators. Regarding the latter, AFPM has commented that there are no available alternatives to perc to reduce benzene and sulfur content in gasoline to meet EPA's fuel standards.
- Production of commodity chemicals such as perc is unlikely to continue if the only markets are limited critical uses. A minimum baseload volume is necessary to achieve economically acceptable operating rates. Elimination of the vast majority of current COUs, as would occur if the ECEL is the limit, may result in closure of chlorocarbon production facilities.

Technical Appendix

- Neither the NIOSH 1003 Active or Passive Method can meet the ECEL for short term tasks.
 - For the short term (15-min) LOD:
 - NIOSH 1003 Active Method using the highest maximum flowrate of 0.2 LPM has an LOD of 0.197 ppm for a 15-minute measurement.
 - The NIOSH 1003 Passive Method using a higher sampling rate passive 3M 3501 badge has an LOD of 0.89 ppm for a 15-minute measurement.
 - Due to the technical infeasibility of achieving the ECEL measurements for short term measurements, exposure control plans proposed by EPA can be used to identify certain tasks that require respirator protection at all times. For example, if the exposure control plan requires the use of respirators for certain tasks, then the use of that APF factor for the required respirator can be used to evaluate compliance against the ECEL.
 - The use of a respirator APF to evaluate compliance is appropriate when 1) the respirator is required for the task in the exposure control plan; 2) the ECEL is extremely conservative; 3) it is technically infeasible to monitor for the ECEL for short-term measurements; and 4) OSHA PELs and regulations which require short term measurement evaluations will also remain in place for compliance and worker safety.