Bullets for OMB Meeting on Trichloroethylene (TCE)

As with the three preceding TSCA proposals, the TCE Risk Evaluation was not conducted in accordance with the risk evaluation requirements in TSCA §§ 6, 26. As a result, the Risk Evaluation resulted in an overly conservative Existing Chemical Exposure Limit (ECEL) due to the exaggerated health risks of TCE. A risk management rule based on this ECEL would go far beyond TSCA's mandate to regulate unreasonable risks.

Inhalation and Dermal Risks Overstated

For all conditions of use (COUs), the toxicological assessments do not reflect best available science. For the manufacture and feedstock COUs, the exposure assessments are not realistic and do not reflect current industrial hygiene (IH) practices

Inhalation/ECEL-Based Limit

- EPA published the TCE Risk Evaluation in November 2020, but only released the ECEL to the public in May 2022. The TCE ECEL is 4 ppb as an 8-hour TWA, based on immune system effects.

- More recently, EPA posted a second ECEL for TCE of 1.1 ppb, based on developmental toxicity.

- These ECELs would be 25,000 or 100,000 times lower than the OSHA PEL of 100 ppm and would amount to a *de facto* ban. Neither ECEL can be justified based on EPA's unsupported conclusions in the Risk Evaluation.

- The TCE Risk Evaluation did not utilize best available science in at least three ways:

    - EPA derived an ECEL value based on serum DNA autoantibody responses in a study by Keil *et al.* (2009). This study has significant scientific validity problems. First, Keil *et al.* is a drinking water study, and is seriously deficient is that the investigators did not provide any analytical data on the levels of TCE in the drinking water. This is a huge problem because TCE volatilizes rapidly from drinking water, which makes drinking water studies very impractical for investigating the health effects of TCE. Second, there was no dose-response in the serum DNA autoantibody responses and there was no convincing evidence of an adverse effect of TCE on the immune system. Importantly, there is no agreement in the scientific community that an increase in these autoantibodies is an adverse effect; studies have been conducted where increases in specific autoantibodies from environmental exposure can occur without any evidence of a specific autoimmune disease. The exposure level that EPA considers protective for TCE-induced autoimmunity in the workplace is at least >10,000-fold lower than the levels reported historically for the metal degreasing industry (not taking dermal exposure into account). While there is limited epidemiological evidence for scleroderma (an autoimmune disease), given the historically high TCE exposures one would expect this health concern to have been more apparent.

    - EPA continues to use results from the fetal heart defect study by Johnson *et al.* (2003). The lengths to which EPA has gone to support the Johnson study at the expense of a balanced scientific review is not only inconsistent with the requirements of the Lautenberg Act but violates the fundamental principles of science. In its peer-review of the draft TCE Risk Evaluation, the Science Advisory Committee on Chemicals (SACC) cautioned that the limited evidence for heart malformation should not be used for the purposes of quantifying risks. EPA's treatment of the Johnson study was also cited in the National Academy of Sciences review of the TSCA systematic review process as a primary illustration for the conclusion that overall confidence in the results of the TCE hazard review was "critically low" and that the review "should not be relied on to provide an accurate and comprehensive summary of the available studies." It is therefore not only irresponsible for EPA to propose an ECEL value based on the cardiac malformation effects from the Johnson study, but shows a flagrant disregard for "the best available science" that is required by TSCA.

- EPA concluded that TCE is "carcinogenic to humans" based on updated meta-analyses on epidemiologic studies of kidney cancer, non-Hodgkin lymphoma (NHL), and liver cancer. There are substantial objectivity concerns regarding the systematic review of the epidemiology studies. EPA's conclusions do not account for some serious methodological limitations of individual studies (exposure measurement error and confounding). Use of the Charbotel study for quantitative risk assessment is contrary to recommendations of the National Academy of Sciences review.

Dermal

- EPA's dermal risk assessment for the TCE Risk Evaluation 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 TCE and use TCE 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, the Risk Evaluation shows 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 TCE 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. 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 TCE as a reactant and intermediate to prevent exposure during the short term tasks.

- HSIA has repeatedly made EPA aware of its unrealistic dermal exposure assessments, yet the mistake was not corrected (or even addressed) in the Revised Risk Determination.

Implementation

- If EPA were to move forward with either proposed ECEL, at least 5 years would be needed to evaluate the technical feasibility of TCE monitoring methods reliably to measure down to 0.004 ppm. As 0.001 ppm is at or near background concentrations, compliance would not be feasible.

- NIOSH 1003 is the primary methodology utilized to measure against existing PELs; therefore, existing IH measurements i) mostly have limits of detection (LODs) above the proposed ECEL for full-shift durations, and ii) all LODs are above the ECEL for short task durations.

    1. 5 years is needed to:

        - Evaluate a new monitoring technology for IH evaluation to sample at such levels;

        - Revise sampling methodology and procedures to accommodate the new technology;

        - Allow labs time to build up capacity to analyze such samples;

        - Create and conduct an exposure assessment strategy, including both a qualitative and quantitative assessment utilizing the new ECEL value using new monitoring technology for different work groups and tasks.

Summary Points

- We do not repeat today how TSCA and EPA's regulations compel EPA to make COU-specific risk determinations instead of following a "whole chemical" approach. These points were covered in our December meeting on methylene chloride.

- Foreign country PELs for TCE range from 5 to 10 ppm, also suggesting that something is very wrong with EPA's determination that it poses a risk to workers at levels many thousands of times lower.

- In sum, the TCE Risk Evaluation does not utilize best available science, including EPA's own technical and methodological guidance, when determining unreasonable risk and setting the ECEL.