Bullets for OMB Meeting on Carbon Tetrachloride (CTC)

The primary point today is the concern that the CTC Risk Evaluation was not conducted pursuant to, or in a manner that satisfies, the risk evaluation requirements in TSCA § 26(h), Scientific Standards for Section 6 Risk Evaluations and Risk Management Rules. As a result, the Risk Evaluation resulted in an overly conservative Existing Chemical Exposure Limit (ECEL) due to the exaggerated health risks of CTC. It may also have resulted in a proposed risk management rule that goes beyond TSCA's mandate to regulate unreasonable risks.

CTC is the feedstock for all the low-global warming potential (GWP) alternatives that will enable compliance with the Kigali Amendment and the AIM Act, including the refrigerant HFO-1234yf.

As the transition to low-GWP refrigerants will take over a decade, eliminating the manufacture or use of CTC as a feedstock would cause severe disruptions in the transition to low-GWP refrigerants.

<u>Dermal and Inhalation Risks Overstated</u>

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

<u>Inhalation/ECEL-Based Limit</u>

- EPA published the CTC Risk Evaluation in 2020, but only released the ECEL to the public in May 2022.

- The CTC ECEL is 0.03 ppm as an 8-hour TWA, 333 times lower than the OSHA PEL of 10 ppm and 166 times lower than the ACGIH TLV of 5 ppm. This much lower ECEL cannot be justified based on EPA's unsupported conclusions in the Risk Evaluation.

- The CTC Risk Evaluation did not utilize best available science in at least 3 ways.

    1. EPA selectively used the increase in the incidence of liver adenomas in female mice exposed to 5 ppm CTC (the lowest exposure concentration tested in a two-year Japanese inhalation study by Nagano *et al*) to estimate human cancer risks, as well as to derive an ECEL value. The generally accepted methodology for evaluating liver tumor data, as well as the one used by EPA for other chemicals, is to consider all liver tumors (adenomas + carcinomas), not just adenomas. A more complete analysis of the data in the Nagano study indicates that there was no treatment-related increase in liver tumors in the 5 ppm-exposed female mice. **EPA's approach to selectively consider only the liver adenomas and not total liver tumors in the 5 ppm-exposed mice results has resulted in a scientifically flawed risk assessment.**

    2. When reviewing a complete analysis of the liver data in the Nagano study, EPA's science advisors generally supported a non-linear mode of action (MOA) for the liver tumors. A just-published paper by two well-regarded experts in liver pathology concluded that the increase in liver tumors in the female mice exposed to 5 ppm CTC was not treatment-related and therefore was a No-Observed-Adverse-Effect-Concentration (NOAEC). This is consistent with a 2019 CTC REACH assessment which also resulted in a NOAEC of 5 ppm for CTC. **EPA should at least revise its cancer risk assessment to reflect a NOAEC of 5 ppm for CTC.**

    3. To determine the ECEL, the use of the NOAEC/Lowest Observed Adverse Effect Concentration (LOAEC) to estimate the dose response is not best available science. Physiologically-based pharmacokinetic (PBPK) and benchmark dose (BMD) modeling to determine the point of departure is best available science based upon EPA's own guidance

and its practice in the perchloroethylene Risk Evaluation. **When PBPK and a BMD analysis are used in the dose-response assessment using total liver tumors in female mice from the two-year study, the chronic cancer ECEL is revised from 0.03 to 1.5 ppm, an increase of 50-fold.**

Dermal

- EPA's dermal risk assessment for the CTC 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 CTC and use CTC 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 CTC 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 CTC 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 moves forward with the proposed ECEL, 5 years is needed to evaluate the technical feasibility of CTC monitoring methods reliably to measure down to 0.03 ppm.

- 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

- In the interest of time, 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.

- CTC was phased out of manufacture/import under the Montreal Protocol and the Clean Air Act, except for feedstock use (the current primary condition of use). Feedstock use is allowed because the CTC is "used and entirely consumed (except for trace quantities)." Exposure so *de minimis* that it is excluded from regulation for ozone depletion seems an unlikely candidate for posing unreasonable risk.

- Foreign country PELs for CTC range from 1 to 5 ppm, also suggesting that something is very wrong with EPA's determination that it poses a risk to workers even at levels 33 to 167 times lower.

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