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Review of VI comments on EPA TSCA risk management rule for TCE

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As presented to OIRA and EPA

Agenda

1. Opening remarks
2. Regulating EDC production does not meet the legal standard for Section 6 risk management
3. TCE as a byproduct
4. Improvement to ECEL development and implementation
5. Establishment of a De Minimis Threshold
6. Economic impact of TCE rule
7. Open forum for agency questions
8. Closing remarks

Regulating EDC Production Does Not Meet the Legal Standard for Section 6 Risk Management

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1. **EPA should clarify that EDC manufacturing was not intended to be covered by the rule**
2. **The "Domestic Manufacture" Condition of Use Excludes Byproduct TCE**

- In the preamble to the proposed rule, EPA summarized the COUs it evaluated during the risk evaluation and confirms that the Agency defered the evaluation of byproduct TCE to the EDC risk evaluation. Because EPA made no unreasonable risk finding with respect to TCE produced as a byproduct during the EDC manufacturing process, EPA lacks authority to regulate the condition of use in this rulemaking.
- EPA did not make the limits of its unreasonable risk determination and resultant risk management rule clear in the regulatory text of the proposed rule. VI understands from meeting with EPA that the TCE risk management rule is not intended to apply to the manufacture of TCE during the EDC production process.
- VI comments provided suggested language that would memorialize this exclusion in the definition of manufacturing covered by the rule.

Improvement of ECEL Development

- Reliance on certain animal studies suggesting fetal cardiac defects and autoimmunity, which lack broader scientific support
- These studies have not been replicated by other laboratories
- EPA's own scientific advisors have recommended against using these studies as a basis for regulatory decisions
- We urge reconsideration in favor of more robust data to ground the regulation in the best available science

ECEL Implementation and Consideration of Actual Task Duration

- Proposed ECELs of 1.1 ppb and 4 ppb are far lower than current occupational exposure limits and below the detection limits of existing analytical methods
- Compliance would be nearly impossible to demonstrate, making the regulation impractical and unenforceable
- EPA should consider the actual time spent completing tasks with potential TCE exposure, rather than assuming full-shift exposure. This approach would lead to a more accurate assessment of risk

Implementation Amendments

- Extending compliance timelines for initial exposure assessment and the implementation of the performance-based WCPP
- Allowing refinement of the ECEL based on actual tasks and potential occupational exposure
- Allowing for control-banding approaches during short-term tasks and averaging samples from repetitive tasks to remove the need for resampling

ECEL takes Non-Risk Factors into Account

- The revised Risk Evaluation Framework Rule acknowledges that the ECEL for risk management purposes may differ from an Occupational Exposure Value (OEV) calculated during risk evaluation

- If the risk evaluation OEV did not consider actual exposures, the risk management ECEL should

- At the risk management step, non-risk factors are considered consistent with 6(c) of TSCA

Establishment of a De Minimis Threshold

- Set a de minimis threshold as early in the risk management process as possible

- While a TCE de minimis level would address several feedstock streams that contain TCE as an impurity, there are some feedstock streams that contain TCE levels higher than 0.1 percent due to reuse or recycling within the process. For these streams, it is critical that in addition to the de minimis level, the final rule allow that TCE unintentionally produced as a byproduct/impurity be allowed to continue in compliance with a WCPP.

Economic Impact of TCE Rule

- Prohibiting feedstock streams that include low levels of TCE byproducts would have significant economic impacts on a variety of industries
- EDC cannot be manufactured by the oxychlorination process without creating mixed chlorinated organics, which includes TCE as a byproduct
- TCE as a byproduct will be covered in the EDC risk evaluation (rather than this rule) but EPA must get the approach right in this rule
- EPA not allowing the continued processing/recycling of streams containing TCE as a byproduct in EDC could have significant downstream effects, particularly in industries dependent on the vinyl chemistries, such as automotive, aerospace, and electronics

Economic Impact of TCE Rule (cont.)

- The prohibition of low-level TCE byproducts in feedstock streams would lead to a substantial increase in waste generation, as these byproducts are currently being reused or recycled efficiently

- Existing VI member facilities do not have capacity for onsite destruction of these large volume streams

- Requiring incineration of these streams would increase emissions and add economic burdens to companies due to higher disposal costs and potential environmental liabilities

Economic Impact of TCE Rule (cont.)

- To replace the lost volume from the increased waste disposal of TCE-containing streams, additional make-up volume of raw material, such as chlorine and ethylene, would need to be produced from virgin feedstocks. This would require an increase in current production capacity of these raw materials, corresponding with an increase in overall production costs.