Comments from Academics, Scientists and Clinicians on Trichloroethylene (TCE): Regulation of Use in Vapor Degreasing Under TSCA Section 6(a)

EPA-HQ-OPPT-2016-0387

Comments submitted to EPA-HQ-OPPT-2016-0387 on April 19, 2017

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians from universities and non-governmental organizations (NGO) located within the United States and worldwide. We declare that we have no direct or indirect financial or fiduciary interest in the manufacture or sale of any chemical under the consideration of this proposed regulation. The co-signers' institutional affiliations are included for identification purposes only and do not necessarily imply any institutional endorsement or support, unless indicated otherwise.

We appreciate this opportunity to provide comments to the Environmental Protection Agency (EPA) on its proposal to promulgate a section 6 rule under the Toxic Substances Control Act (TSCA) that would prohibit manufacture, processing, and distribution in commerce or commercial use of trichloroethylene (TCE) for use in vapor degreasing. As this proposed rule would be one of the first to apply EPA's strengthened authority under Section 6 of the Lautenberg Amendments to TSCA, we believe that this is a critical and appropriate opportunity to fully exercise the Agency's newly established authority. We respectfully submit these comments in strong support of EPA's proposed rule.

In summary, our comments address the following main points:

1. **Agreement that there are clear, unreasonable risks to human health posed by the use of TCE in vapor degreasing;**

2. **Support for the scientific rigor of EPA's evaluation of TCE risk for the proposed TSCA section 6 rule;**

3. **Support for EPA's consideration of risk to potential susceptible subpopulations;**

4. **Support for EPA's correct application of risk evaluation and management in the case of TCE use for vapor degreasing and its utilization of authority to expeditiously move forward on finalizing this regulation on TCE for use in vapor degreasing.**

Thank you for the opportunity to provide comments and nominations. Please let us know if we can provide any additional information or be of further help.

Respectfully,

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Background

We appreciate the opportunity to provide comments on EPA's proposed actions under section 6 of TSCA to address the potential risks to human health posed by the use of TCE in vapor degreasing. The Lautenberg Amendments to TSCA were the first major overhaul to the 1976 TSCA law and an important step forward to granting EPA the necessary authority to act on reducing the risks of harmful chemical exposures to the public. Although scientific evidence continues to build demonstrating the harmful effects resulting from exposures to environmental chemicals, under the old TSCA law only a handful of existing chemicals were addressed under section 6. Even chemicals known to be harmful, such as asbestos and lead, could not successfully be phased out or regulated under the old law. We hope the Lautenberg Amendments has now removed barriers to allow for swift and appropriate action by the EPA to remove exposures to harmful chemical substances towards fulfilling its mission of protecting human health and the environment.

EPA initiated an Integrated Risk Information System (IRIS) assessment for TCE sixteen years ago in 2001, which produced the 2011 IRIS Toxicological Review of Trichloroethylene. This IRIS assessment, along with EPA's 2014 work plan risk assessment of TCE and several supplemental technical reports, reflects the extensive evaluation and integration of the best available science to date along with input during the process of finalizing these documents from numerous and extensive peer reviews. Although EPA's TCE assessment was completed prior to the Lautenberg Amendments' passage, section 26(l)(4) of these amendments expressly authorizes EPA to use its expanded section 6 rulemaking powers to protect against the risks identified within this completed assessment. Therefore, as the evaluation of risk has already been completed with the conclusion that uses of TCE "present an unreasonable risk of injury," under the Lautenberg Amendments the Agency "shall by rule" apply necessary restrictions to the chemical so that it "no longer presents such a risk." Therefore, it is essential that EPA take action to reduce the health risks that have been identified. Furthermore, under section 6(c)(1), upon making this determination of "unreasonable risk" for a chemical, EPA must propose a rule restricting the chemical use within one year and finalize that rule within a year thereafter. Thus, it is imperative that the Agency acts in a timely manner to ensure that these deadlines are met.

Specific Comments

1. **Agreement that there are clear, unreasonable risks to human health posed by the use of TCE in vapor degreasing.**

The health effects of TCE are extremely well-characterized and has been extensively reviewed in assessments completed by EPA and other authoritative bodies. Once in the blood stream, TCE can travel throughout the entire body and access all organs, cross the placenta to access the developing fetus, and pass through the blood-brain barrier. It is a dangerous chemical that has numerous acute and chronic health effects, as has been documented in numerous human, animal, and mechanistic studies. It is classified as a known human carcinogen by EPA IRIS, the National Toxicology Program in its Report on Carcinogens, the World Health Organization's International Agency for Research on Cancer, and California's Proposition 65 list of carcinogens. Its non-cancer health effects include:

- Skin irritation and rashes
- Kidney toxicity
- Liver toxicity
- Cardiac effects
- Immunotoxicity

- Neurotoxicity
- Reproductive toxicity
- Developmental toxicity

The number and variability of consumer and worker populations exposed to TCE through its vapor degreasing use are extensive and concerning. Exposure during these uses is largely uncontrolled and as a result, the subsequent risks are anticipated to be unsafe according to EPA's established exposure benchmarks. As such, we agree with EPA's determination that there are clear, unreasonable risks posed by TCE in its use as a vapor degreaser.

2. **Support for the scientific rigor of EPA's evaluation of TCE risk for the proposed TSCA section 6 rule.**

EPA's IRIS program began assessing TCE's health effects in 2001, issuing multiple draft assessments that have undergone review within the Agency, by other federal agencies, at the Executive Office of the President, and through public comment as well as by the National Academy of Sciences (NAS), the EPA's Science Advisory Board (SAB), and final internal agency review and EPA-led science discussion on the final draft before it was released in 2011. The EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) subsequently published its own risk evaluation in 2012 reviewing specific uses of TCE, which was subjected to peer review and public comment prior to its finalization in 2014. Thus, EPA's transparent and fully documented risk assessment, based on peer-reviewed scientific data, and the assessment itself having undergone extensive peer-review, clearly meets section 26(h) of the Lautenberg-amended TSCA's general principles regarding use of science in decision-making.

3. **Support for EPA's consideration of risk to potential susceptible subpopulations.**

In addition to risks to the general worker and consumer population, TCE in vapor degreasing poses unique risks to women of childbearing age and developing fetuses. These groups meet the definition in section 3(12) of TSCA regarding "potentially exposed or susceptible subpopulations." Under section 6(a) and 6(c), EPA has an obligation to determine whether the risks experiences by these subpopulation are unreasonable, as a separate consideration from the level of risk posed to the general population. EPA is also required to protect these subpopulations from such unreasonable risk, again separate from any restrictions imposed to protect the general population. Consideration of these susceptible populations is clearly appropriate in this situation and we fully support EPA's identification of this potentially exposed or susceptible subpopulation. We also strongly agree that a ban on TCE's use in vapor degreasers would be an appropriate and sufficient action to protect these subpopulations so that TCE no longer presents these unreasonable risks through these uses.

4. **Support for EPA's correct application of risk evaluation and management in the case of TCE use for vapor degreasing and its utilization of authority to expeditiously move forward on finalizing this regulation on TCE for use in vapor degreasing.**

The Lautenberg Amendments clearly lays out new section 6 requirements for EPA to determine whether a chemical presents unreasonable risk of injury to health or the environment and to take action to mitigate such risks. In the case of TCE for the use of vapor degreasing, EPA has correctly made the determination that there exists unreasonable risk, as assessed through consideration of strictly health-based factors (and not, for instance, considerations of cost) and the restrictions imposed under section 6(a) are sufficient to provide full protection, including for vulnerable populations, against the unreasonable risk. Furthermore, we concur with the rejection of label warnings and instructions or required use of personal protective equipment under TSCA section 6(a)(3) on the grounds that this alone could not mitigate the risks to the

extent necessary to ensure that TCE no longer presents the identified unreasonable risks to users. Labels are not uniformly read, comprehended, used or followed and thus provides limited protection, particularly in small businesses with high employee turnover and to consumer uses of vapor degreasers. We also believe this placing this onerous burden on workers and the consumer is unfair and is does not ensure full protection of the population, including susceptible populations, from the potential risks from exposures. Thus, we are fully supportive of EPA's proposal to ban the use of TCE in vapor degreasers and strongly encourage the Agency to move forward in a timely manner to effectively implement the final regulation. There is a large population currently at risk of adverse health effects from exposure to TCE in vapor degreasing and so we strongly encourage no delay in acting to protect the health of the public.

Thank you for taking the time to review our comments and please do not hesitate to contact us if you would like further clarification or elaboration on anything we have addressed in our comments.