April 4, 2017

Wendy Cleland-Hamnett
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington DC 20460

Re: *Extension of Comment Period for Rulemaking on TCE Vapor Degreasing under Section 6(a) of TSCA: Docket No. EPA-HQ-OPPT-2016-0387*

Dear Ms. Cleland-Hamnett,

On March 17, 2017, the Halogenated Solvents Industry Association (HSIA) requested an additional 120-day extension of the comment period on EPA's proposed rule banning the use of trichloroethylene (TCE) in vapor degreasing under section 6(a) of the amended Toxic Substances Control Act (TSCA). [1] If granted, this extension would come on top of a 30 day extension already granted by the Agency and would provide industry with an unprecedented 7 months to comment on the TCE proposal.

Our organizations strongly oppose the HSIA extension request. Together with EPA's separate proposal targeting TCE use in aerosol degreasing and dry cleaning spot removal,[2] the proposed rule is essential to protect tens of thousands of workers and consumers against serious and widespread risks of adverse health effects. Any delay in completing the two rulemakings would jeopardize public health and violate the requirements of TSCA. HSIA's rationale for this delay is spurious and without merit and has the apparent goal of blocking long-overdue EPA action to eliminate a well-documented chemical threat in order to benefit TCE's producers.

HSIA's earlier extension request sought additional time to complete a new animal toxicity study initiated to ascertain if the results of a developmental study showing fetal heart malformations by Johnson et al. (2003) can be replicated. However, HSIA now reveals that the study has been aborted because of protocol deviations that compromised the validity of the study. These "methodological issues" are still being investigated and, once they are resolved and laboratory schedules permitting, HSIA claims that the study will be "rerun." HSIA asserts that the "target" for making results available is August 17 but provides no information to indicate that this schedule is realistic. In fact, given HSIA's acknowledgement that the now-aborted study was initiated nearly 6 months ago, the most likely scenario is that **the new study will not be finalized by August 17 and HSIA will ask for a further extension.**

Even more breathtaking is HSIA's demand that EPA indulge its last-ditch effort to discredit evidence of TCE's developmental toxicity that has repeatedly been affirmed by agency scientists and external peer reviewers over a lengthy 15 year process of evaluating TCE's risks to health.

EPA's IRIS program began assessing TCE's health effects in 2001, issuing multiple drafts that were reviewed by the National Academy of Sciences (NAS) and then by EPA's Science Advisory Board (SAB) before a final IRIS assessment was published in 2011. Industry had multiple opportunities to be heard

[1] 82 Fed. Reg. 7432 (January 19, 2017).
[2] 81 Fed. Reg. 91592 (December 16, 2016)

during this process. OCSPP followed the IRIS assessment in 2012 with its own risk evaluation of specific TCE uses. The draft assessment was subject to peer review and public comment and was finalized in 2014.

At every point in this process, the sufficiency of the evidence (including the Johnson study) demonstrating fetal heart malformations was examined and deemed acceptable. Agency scientists and eternal reviewers repeatedly found that numerous studies, both animal and human, confirmed these effects. Industry arguments against this finding were presented on numerous occasions and rejected.

Despite ample opportunity to conduct additional studies at any time over the last 15 years, HSIA failed to do so until well after the IRIS and TSCA assessments were finalized. Only when EPA was poised to begin rulemaking under TSCA did HSIA take any action and even now, three months after EPA's proposal, its study is still not underway. EPA would lack all credibility if it rewarded this shameful history of foot-dragging and obstructionism with a generous extension of time.

At this late stage, the priority of the Agency should be completing the TCE rulemakings as soon as possible so that, after years of delay, unacceptable risks to human health can be eliminated.

TCE's hazards to health are unusually serious and well-documented in animal and human studies. The voluminous evidence of these hazards is presented in great detail in the record for EPA's two TCE proposals and summarized in the comments of SCHF and other interested parties on the initial proposal. In addition to a suite of developmental effects, they include several forms of cancer, immunotoxicity, kidney toxicity, neurotoxicity, reproductive and endocrine effects and liver effects. The consumer and worker populations exposed to TCE through the uses targeted by the two proposals number in the tens of thousands and include hundreds of men and women of childbearing age at risk of effects on fertility and reproduction. Exposure during these uses is largely uncontrolled and risk levels significantly exceed EPA's established benchmarks for unsafe chemical exposure. The targeted uses have already been banned by states and other countries.

Section 26(l)(4) of amended TSCA expressly authorizes section 6(a) rules on chemicals (like TCE) for which EPA has completed risk assessments under the old law. Nothing in this provision allows these risk assessments to be reopened based on after-the-fact studies that could have been conducted while the risk assessment process was underway. In addition, section 26(l)(4) provides that rules based on pre-enactment risk assessments must be "consistent with other applicable requirements of section 6." One such requirement under section 6(a) is that where – as here – EPA determines that uses of a chemical "present an unreasonable risk of injury," the Agency "shall by rule" apply requirements to the chemical "necessary so that [it] no longer presents such risk." A related requirement under section 6(c)(1) is that upon making a determination of unreasonable risk for a chemical, EPA must propose a rule restricting the chemical within one year and finalize that rule one year thereafter.

In sum, any further delays in the TCE rulemakings -- or an indefinite failure to finalize them at all -- would violate TSCA requirements as well as deny protection to exposed workers and consumers from serious and unacceptable health risks.

For these reasons, we urge EPA to deny HSIA's request to extend the comment period for the TCE vapor degreasing rulemaking.

If you have any questions, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net or 202-716-0118.

Sincerely yours,

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