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 under Section 6(a) of TSCA*
Docket No. EPA-HQ-OPPT-2016-0163; Docket No. EPA-HQ-OPPT-2016-0387

Dear Acting Assistant Administrator Cleland-Hamnett:

Our organizations are deeply concerned about industry requests to extend the comment period for EPA's two proposed rules for trichloroethylene (TCE) under section 6(a) of the amended Toxic Substances Control Act (TSCA). These rules would ban TCE use in aerosol degreasing, dry cleaning spot removal and vapor degreasing and are essential to protect consumers and workers 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.[1]

The extension request was filed by the Halogenated Solvents Industry Association (HSIA) on January 19 ("HSIA Request"). It urges EPA to align the comment deadlines for the two rulemakings, which were proposed a few weeks apart but have certain elements in common, including the risk assessment EPA developed to support both proposed rules. Our organizations do not object to a 30-day extension of the comment period for the first TCE proposal so that it coincides with the comment period for the second. However, HSIA seeks an extension of 60 days, apparently in order to facilitate its efforts to reopen the TCE risk assessment and derail EPA's rulemakings. We do not believe that an extension of this length serves a legitimate purpose and oppose granting it.

HSIA's rationale for the 60-day extension is the claimed need "to allow for the submission within the comment period of significant new scientific information directly relevant to the rulemakings." HSIA Request at 2. The "significant new scientific information" is data from an as yet unfinished animal toxicity study that HSIA is conducting. This study seeks to "try to reproduce" a developmental study showing fetal heart malformations by Johnson et al. (2003). *Id*. HSIA apparently hopes the results of this unfinished study will bolster its upcoming request to reconsider EPA's denial of its Request for Correction (ROC) of the TCE risk assessment under the Data Quality Act (DQA), which HSIA plans to submit by April 20. [2]

HSIA's maneuvers represent a 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 has

[1] Comments on the proposed ban on TCE in spot cleaning and aerosol degreasing, 81 Fed. Reg. 91592 (December 16, 2016), are due February 14, 2017. Comments on the proposed ban on TCE in vapor degreasing, 82 Fed. Reg. 7432 (January 19, 2017) are due March 20, 2017.
[2] EPA has designated April 20 as the deadline for filing HSIA's request for reconsideration.
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had numerous opportunities to be heard 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 et al study[3]) demonstrating fetal heart malformations was examined and deemed acceptable. Agency scientists and external reviewers repeatedly found that multiple lines of evidence, including both animal and epidemiologic studies, confirmed these effects (Makris et al 2016).[4] 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 after the IRIS and TSCA assessments were finalized. Even now, with the TSCA rulemaking process underway, the HSIA study is still not complete and it is not known whether it will in fact reveal the "significant new scientific information" claimed by HSIA.

At this late stage, EPA should reject HSIA's untimely and obstructionist 11th hour attempts to yet again challenge the Agency's risk findings. We think it would set an unfortunate precedent for EPA to extend comment periods on proposed rules that are needed to protect against unreasonable risks merely because a *possibly relevant* study is underway that could have been conducted years earlier. Such delaying tactics are routinely employed by industry and do not serve the public interest in timely decisionmaking. The priority of the Agency should be completing the two 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. 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. 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 some states and countries due to excessive risks.

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.

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[3] Johnson PD, Goldberg SJ, Mays MZ, Dawson BV. Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. Environ Health Perspect. 2003 Mar;111(3):289-92. Erratum in: Environ Health Perspect. 2014 Apr;122(4):A94.

[4] Makris SL, Scott CS, Fox J, Knudsen TB, Hotchkiss AK, Arzuaga X, Euling SY, Powers CM, Jinot J, Hogan KA, Abbott BD, Hunter ES 3rd, Narotsky MG. A systematic evaluation of the potential effects of trichloroethylene exposure on cardiac development. Reprod Toxicol. 2016 Oct;65:321-358. doi:10.1016/j.reprotox.2016.08.014. Review. PubMed PMID: 27575429

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

For these reasons, we urge EPA to extend the comment period for the first TCE proposal to no later than March 20 and to deny all further requests for extensions of the comment deadlines for the two rulemakings.

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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