HSIA
halogenated
solvents
industry
alliance, inc.

March 17, 2017

Office of Pollution Prevention & Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Att'n: Cindy Wheeler and Niva Kramek

Re: Docket No. EPA-HQ-OPPT-2016-0231
Docket No. EPA-HQ-OPPT-2016-0387

Dear Ms. Wheeler and Ms. Kramek:

I write on behalf of the Halogenated Solvents Industry Alliance, Inc. (HSIA) to seek an extension of the comment deadline for a proposed rule on use of trichloroethylene (TCE) and a proposed rule on use of methylene chloride (dichloromethane or DCM) that are the subjects of the captioned dockets. HSIA represents producers and users of TCE and DCM and has been actively involved in EPA's programs to assess and regulate TCE and DCM since its formation in 1980.

Comments on the proposed ban on TCE in vapor degreasing, 82 Fed. Reg. 7432 (January 19, 2017), as extended at 82 Fed. Reg. 10732 (Feb. 15, 2017), are due April 19, 2017. Comments on the proposed ban on DCM in paint stripping, 82 Fed. Reg. 7464 (January 19, 2017) are also due April 19, 2017. We respectfully request that the comment deadline for both proposals be extended by 120 days to August 17, 2017.

The two regulatory proposals are both based on risk assessments completed in 2014 that we submit are not "consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of § 6," as required by Toxic Substances Control Act (TSCA) § 26(l)(4). They also raise many common legal and policy issues (*e.g.*, what constitutes "unreasonable risk," EPA's authority to regulate the workplace).

With regard to TCE, moving the comment deadline to August 17 will allow for the submission within the comment period of significant new scientific information directly relevant to the rulemakings. The TCE proposal is driven by a toxicological value derived from a developmental study by Johnson *et al.* (2003). For both acute and chronic (non-cancer) risks, EPA determined that "the greatest risk is for developmental effects (*i.e.*, fetal cardiac defects)" as derived using Johnson *et al.* (2003). *See* 82 Fed. Reg. 7432, 7438-39. As EPA is aware, HSIA has sponsored a study at Charles River

Laboratories.[1] This study was intended specifically to try to replicate the cardiovascular effects seen by Johnson *et al.* (2003), which no laboratory to date has been able to reproduce, in an EPA Guideline study that meets Good Laboratory Practices. The Protocol was signed on October 6, 2016 and the in-life portion of the study was conducted during October and November 2016. Unfortunately, we were recently notified by the laboratory that the concentrations of TCE measured in the drinking water solutions were found to be below the acceptable target range of 100% ± 10%, invalidating the study. The laboratory has conducted additional studies to identify the source of the deviation and the study will be rerun as soon as dosing methodological issues are resolved and scheduling permits, with a target of having results available by August 17. As opposed to EPA's proposed reliance on the so far unreproducible Johnson *et al.* study, the results of this study will provide a record for EPA decision-making consistent with the requirements of TSCA § 26(h) that § 6 rulemaking be based on the "best available science."

With regard to DCM, we are aware that commenters are working with a number of outside technical experts who will assist in addressing various elements of the EPA proposal, including EPA's economic assessment, its hazard and exposure assessments, and its alternatives. These analyses are time-intensive and require collaboration with paint removal product manufacturers and users. Our goal is to prepare comments that will provide the Agency with accurate and up-to-date information on the latest scientific and economic developments with regard to both DCM-based and alternative paint removal products so that the Agency can reach an informed decision. This extension request in no way prejudices the Agency or its deliberation as we understand, based on the language in the preamble to the proposed rule, that the Agency does not intend to issue a final rule on paint stripper uses until EPA has also proposed and solicited comments on a forthcoming rulemaking addressing use of these and similar products in commercial furniture refinishing application. See 82 Fed. Reg. at 7465.

I note that this request is supported by EPA's recent action to extend by 120 days the comment period on a draft notice of the rationale for granting petitions to add n-propyl bromide (nPB), also known as 1-bromopropane (1-BP) (Chemical Abstract Service No. 106–94–5), to the list of hazardous air pollutants contained in section 112(b)(1) of the Clean Air Act. 82 Fed. Reg. 12589 (Mar. 6, 2017). EPA made this interim extension as an initial response to allow adequate consideration of a request to extend the comment period by more than six months. The rationale for the extension was: "According to EPA's [Toxics Release Inventory, or TRI] website, the preliminary dataset for the July 1, 2017 TRI data will be available to the public in July, 2017. . . Extending the comment period to October 1, 2017, will insure that the TRI database for nPB is part of this rulemaking, and will also provide the public with an opportunity to review the TRI dataset for nPB usage, sources and emissions, and use that data to prepare meaningful comments on the draft notice." We believe that our request provides an even more compelling case for extension.

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[1] Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats.

We ask that you let us know as soon as possible whether EPA will grant the requested extensions.

Very truly yours,

Faye Graul /WCN

Faye Graul
Executive Director