Honorable Michael Regan
Administrator
US Environmental Protection Agency Mail Code 1101A
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: TSCA Risk Evaluation for Trichloroethylene

Dear Administrator Regan:

We are writing to reiterate our February 26, 2021 request that that the Environmental Protection Agency (EPA) revise its November 2020 final risk evaluation for trichloroethylene (TCE) under the Toxic Substances Control Act (TSCA) in light of evidence that White House staff in the prior Administration directed EPA career scientists to alter its central findings of unreasonable risk. We would welcome the opportunity to discuss this request.

As reported by Reveal/Center for Investigative Journalism,[1] because of intervention by the White House during the Trump Administration, EPA scientists were compelled to rewrite the draft TSCA evaluation so that the most sensitive endpoint – fetal heart malformations– was no longer used to determine whether TCE presents unreasonable risks to health. This reversed the longstanding position of the Agency that these effects provide a sound and reliable basis for public health protection. EPA Assistant Administrator Freedhoff has stated publicly that this political interference was a serious violation of the Biden Administration's scientific integrity principles.

As discussed below, EPA's commitment to scientific integrity demands that it withdraw findings in the final TCE evaluation that resulted from political influence and reconsider those findings on their scientific merits. This is essential not only to restore public confidence in the Agency's science but to assure that all parts of EPA speak with one voice on the critical endpoints for a widespread chemical of concern that touches numerous state and federal programs. Equally important, restoring the fetal heart defects as a basis for the unreasonable risk determination will assure that EPA's risk management requirements for TCE are fully protective of public health.

EPA's 2011 IRIS assessment concluded that the weight of the scientific evidence supports the link between TCE and fetal heart malformations and that, as the most sensitive endpoint, these effects should drive the TCE reference concentration (RfC).[2] The IRIS assessment underwent peer review by EPA's Science Advisory Board (SAB) in 2002, the National Academy of Sciences (NAS) in 2006,[3] and the

[1] Elizabeth Shogren, *EPA scientists found a toxic chemical damages fetal hearts. The Trump White House rewrote their assessment,* Reveal/Center for Investigative Reporting, February 28, 2020 (Reveal Report) https://www.revealnews.org/article/epa-scientists-found-a-toxic-chemical-damages-fetal-hearts-the- trump-white-house-rewrote-their-assessment/.

[2] EPA, Toxicological review of trichloroethylene (CASRN 79-01-6) in support of summary information on the Integrated Risk Information System (IRIS) (IRIS Report]. (EPA/635/R- 09/011F), September 2011 https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0199tr/0199tr.pdf

[3] NAS report, "Assessing the human health risks of trichloroethylene: Key scientific issues (2006)": http://www.nap.edu/catalog.php?record_id=11707.

SAB again in January 2011. [4] The IRIS scientific determinations were affirmed in OSCPP's 2014 Work Plan Risk Assessment for TCE, which was also peer reviewed.[5] In 2016, several EPA scientists published an updated weight of evidence (WOE) review of the available scientific literature confirming earlier EPA findings that TCE-related developmental heart defects were linked to TCE exposure (Makris et al 2016).[6] These conclusions formed the basis for EPA's proposals (still not finalized) in late 2016 and early 2017 to ban vapor and aerosol degreasing and spot removal uses of TCE under section 6 of TSCA.[7]

EPA again relied on the evidence of fetal heart defects in the draft TSCA risk evaluation it submitted to the White House for OMB review in December 2019. According to Reveal, the draft described the heart defects as the "most sensitive" effect and identified them "as the driver end point for the conditions of use that EPA has preliminarily determined present unreasonable risk." However, when the draft evaluation was released publicly on February 21, 2020, it no longer contained these findings. Instead, it claimed that "there are uncertainties which decrease EPA's confidence in this endpoint" and therefore EPA will now use "immunosuppression and autoimmunity as the key endpoints for determining whether or not a condition of use presents unreasonable risks."[8] Despite the concerns of our groups and others, the final TCE risk evaluation released in November 2020 continued to dismiss the relevance of the heart defects. [9]

As Reveal reported, this reversal of EPA's longstanding position occurred at the express direction of the White House Executive Office of the President, which instructed EPA career scientists to rewrite the draft to cast doubt on the evidence of heart defects and to shift the basis of its risk determinations to less sensitive endpoints.

Even with the changes demanded by the White House, the final TCE evaluation presents a strong case for the sufficiency of the evidence of TCE-related heart effects for TSCA risk determinations. Both the body of the risk evaluation and Appendix F provide a detailed analysis of the weight of evidence for congenital heart defects which concludes that: "Overall, the database is both reliable and relevant and provides positive overall evidence that TCE may produce heart defects in humans (based on positive evidence from epidemiology studies, ambiguous evidence from animal toxicity studies, and stronger positive evidence from mechanistic studies)." [10] Thus, the scientific basis for EPA's original draft risk

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[4] EPA's SAB peer review report for the 2009 EPA's Draft Assessment entitled "Toxicological Review of Trichloroethylene": http://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f648525742400690127/B73D5D39A8F184BD85257817004A1988/$File/EPA-SAB-11-002-unsigned.pdf.

[5] EPA, TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, June 2014 (Work Plan Assessment), https://www.epa.gov/sites/production/files/2015-09/documents/tce_opptworkplanchemra_final_062414.pdf

[6] 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.

[7] 81 Fed. Reg. 91592 (Dec. 16, 2016) (proposed TSCA ban on TCE aerosol degreasing and spot removal uses); 82 FR 7432 (Jan. 19, 2017) (proposed TSCA ban on TCE use for vapor degreasing).

[8] TCE Draft Evaluation at 377.

[9] Risk Evaluation for Trichloroethylene, November 2020, https://www.epa.gov/sites/production/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf (Final Risk Evaluation. .

[10] Final Risk Evaluation at 654.

determinations was unchanged even though the White House directed career EPA scientists to reject the evidence of heart defects as too "uncertain" to inform these determinations.

The actions of the Trump White House were in clear violation of the scientific integrity principles embraced by this Administration and previously adopted by EPA. The President's January 27, 2021 Memorandum *Restoring Trust in Government through Science and Integrity and Evidence-based Policy Making* emphasizes that "[s]cientific findings should never be distorted or influenced by political considerations. . . Improper political interference in the work of Federal scientists. . . undermines the welfare of the Nation." [11] EPA's 2012 Scientific Integrity Policy likewise seeks to "protect[] the EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference" and emphasizes that "it is . . . essential that political or other officials not suppress or alter scientific findings."[12]

Consistent with this Administration's commitment to scientific integrity, on February 9, 2021, EPA announced that it was withdrawing its perfluorobutane sulfonic acid (PFBS) toxicity assessment because it was "compromised by political interference as well as infringement of authorship and the scientific independence of the authors' conclusions."[13] Jennifer Orme-Zavaleta, acting chief of EPA's Office of Research and Development (ORD), said that "documents, like the PFBS Toxicity Assessment, that include conclusions purporting to reflect science when in fact they are the product of biased political interference undermine the agency's scientific integrity policy." On April 8, 2021, EPA issued a revised version of the PFBS assessment after a rigorous and independent scientific review.

In a March 20, 2021 email to OCSPP staff, then Acting Administrator Freedhoff correctly cited the TCE case as another example of political interference compromising the integrity of EPA science:

> White House staff directed OCSPP career staff to alter the draft TCE risk evaluation to change the point of departure used for making determinations of risk to a less sensitive endpoint. While the risk evaluation included a description of the more sensitive endpoint (fetal heart malformations), it was no longer used to determine whether there is unreasonable risk from TCE. Unreasonable risks were nevertheless identified for most uses of TCE, but the magnitude of the risk from exposures to TCE would have been greater had EPA relied upon the fetal cardiac defect endpoint that had been used in previous EPA peer-reviewed assessments.

Despite this recognition, nearly a year after this email, the TCE risk evaluation has not been corrected and remains in conflict with the TCE IRIS assessment. The IRIS assessment is relied on by other EPA program offices as well as the states. While the TSCA Risk Evaluation may be specific to TSCA, the science used to address chemical risks under TSCA should be identical to the science relied on by other EPA programs to address the same chemicals. For this reason, there is no justification for continued confusion surrounding EPA's current position on the hazards of TCE. You should ensure that the TSCA TCE risk evaluation relies on the best available science as reflected in the IRIS assessment. Given the multiple, extensive peer reviews of the assessments of TCE, including specifically fetal heart malformations, and the political interference by the Trump Administration, it should be relatively straightforward to make the change without further peer review.

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[11] https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/.
[12] https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.
[13] https://www.epa.gov/newsreleases/epa-takes-action-protect-scientific-integrity.

Failure to rely on the fetal heart malformations to determine unreasonable risk will weaken the health protections in EPA's TSCA risk management rule for TCE. EPA's dose response analysis of acute exposure scenarios shows that the HEC_{99} for immune system effects is 470 times higher than the HEC_{99} for heart malformations.[14] Accordingly, for consumers and workers, the Margins of Exposure (MOEs) for acute exposure are over two orders of magnitude lower for heart defects than immune effects. This means that exposure limits based on the immune effects would be unprotective for women of childbearing age and their offspring, for whom heart defects can cause serious health impairments and death in utero, during childhood and later in life. If applied across the Agency, the TSCA approach would undermine the use of this endpoint by other EPA programs, thus weakening their ability to sufficiently mitigate risks, including risks to vulnerable populations. Finally, failure of the TSCA program to rely on fetal heart malformations may have adverse impacts on the standing of IRIS, which is generally viewed as the gold standard for EPA assessments of chemical hazards.

We recognize the need to move forward with risk management for TCE under TSCA. EPA has already announced that it plans to reopen its TCE evaluation to incorporate a whole chemical approach and potentially to make risk determinations for "fenceline" air and water releases. Having previously analyzed the risks of fetal heart defects in its final risk evaluation, EPA's revision of its risk determinations to rely on this endpoint can be accomplished quickly and should not prolong the revisions to EPA's risk determinations already underway or delay risk management.

In sum, we ask you to ensure the use of consistent robust science across the agency by removing the effects of the last Administration's political interference in the TCE risk evaluation and, consistent with the IRIS assessment, restoring the fetal heart malformations as a basis for EPA's determinations of unreasonable risk. We would welcome the opportunity to discuss this important issue with you.

Please contact Bob Sussman, counsel for Safer Chemicals Healthy Families, at bobsussman1@comcast.net with any questions about this letter.

Respectfully submitted,

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[14] Final Risk Evaluation, at 252.

cc: Assistant Administrator Michal Freedhoff (OCSPP)
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