

**Alaska Community Action on Toxics -- BlueGreen Alliance -- Defend Our Health -- Earthjustice
Natural Resources Defense Council -- Safer Chemicals Healthy Families
Union of Concerned Scientists**

February 26, 2021

Honorable Jane Nishida
Acting Administrator
US Environmental Protection Agency Mail Code 1101A
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Political Interference in the TSCA TCE Risk Evaluation by the Prior Administration

Dear Acting Administrator Nishida:

We are writing to ask the Environmental Protection Agency (EPA) to address the prior Administration's political interference with the final risk evaluation for trichloroethylene (TCE) under the Toxic Substances Control Act (TSCA). White House staff directed EPA career scientists to alter the draft evaluation so that the most sensitive endpoint – fetal heart malformations – was no longer used to determine TCE's risks to health. This reversed the longstanding judgement of EPA scientists that these effects provide a sound and reliable basis for public health protection. The actions of the Trump White House to alter the TCE evaluation were in clear violation of the scientific integrity principles announced by President Biden and previously adopted by EPA itself. EPA recently withdrew a toxicity assessment for perfluorobutanesulfonic acid (PFBS) under identical circumstances.

Prohibition on Improper Political Interference in the Work of Federal Scientists

President Biden signed a Memorandum on January 27 entitled "Restoring Trust in Government through Science and Integrity and Evidence-based Policy Making."¹ The memorandum emphasizes that:

Scientific findings should never be distorted or influenced by political considerations. . . . Improper political interference in the work of Federal scientists or other scientists who support the work of the Federal Government and in the communication of scientific facts undermines the welfare of the Nation, contributes to systemic inequities and injustices, and violates the trust that the public places in government to best serve its collective interests.

The memorandum creates a Task Force charged with strengthening safeguards against political interference in agency science and calls for it to examine past instances of such interference:

The Task Force's review shall include an analysis of any instances in which existing scientific-integrity policies have not been followed or enforced, including whether such deviations from existing policies have resulted in improper political interference in the conduct of scientific research and the collection of scientific or technological data; [or] led to the suppression or

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policy-making/>.

distortion of scientific or technological findings, data, information, conclusions, or technical results.

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."² It directs that EPA employees must "[e]nsure that the Agency's scientific work is of the highest quality, free from political interference or personal motivations." The Policy states that "[t]o operate an effective science and regulatory agency like the EPA, it is . . . essential that political or other officials not suppress or alter scientific findings."

During your confirmation, you recognized that the President's January Memorandum "sends a clear message that the Biden-Harris Administration will protect scientists from political interference" and "commit[ed] to implementing this vision at EPA."³

Citing the January 27 Presidential memorandum and the EPA Scientific Integrity Policy, EPA announced on February 9 that it was withdrawing the PFBS assessment because it was "compromised by political interference as well as infringement of authorship and the scientific independence of the authors' conclusions."⁴ Jennifer Orme-Zavaleta, acting chief of EPA's Office of Research and Development (ORD) and a career scientist, said that "Issuing documents, like the PFBS Toxicity Assessment, that include conclusions purporting to reflect science when in fact they are the product of biased political interference undermines the agency's scientific integrity policy and erodes the trust that the American public has in EPA."

Compelling Evidence of White House Interference to Alter Key Scientific Findings on TCE

The evidence that the final TCE evaluation was altered at the direction of the White House is likewise compelling and requires action by EPA to undo the improper effects of political influence on the TCE evaluation.

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 risk determinations for acute and chronic TCE exposure.⁵ The IRIS assessment underwent peer review by EPA's Science Advisory Board (SAB) in 2002, the National Academy of Sciences (NAS) in 2006,⁶ and the SAB again in January 2011.⁷ The IRIS scientific determinations were affirmed in OSCPP's

² https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf.

³ https://www.eenews.net/assets/2021/02/09/document_gw_06.pdf.

⁴ <https://www.epa.gov/newsreleases/epa-takes-action-protect-scientific-integrity>.

⁵ 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

⁶ NAS report, "Assessing the human health risks of trichloroethylene: Key scientific issues (2006)":
http://www.nap.edu/catalog.php?record_id=11707.

⁷ 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](http://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f648525742400690127/B73D5D39A8F184BD85257817004A1988/$File/EPA-SAB-11-002-unsigned.pdf).

2014 Work Plan Risk Assessment for TCE, which was also peer reviewed.⁸ In 2016, several EPA scientists published an updated weight of evidence (WOE) review of the available scientific literature on TCE-related developmental cardiac defects, confirming earlier EPA findings that these defects were linked to TCE exposure (Makris et al 2016).⁹ These conclusions formed the basis for EPA's proposals in late 2016 and early 2017 to ban vapor and aerosol degreasing and spot removal uses of TCE under section 6 of TSCA.¹⁰

EPA again relied on the evidence of fetal heart defects in the draft TSCA risk evaluation it submitted to the White House for interagency review in December 2019. According to a report by the Center for Investigative Reporting, this draft stated as follows:¹¹

“EPA identifies developmental cardiac malformations as the driver end point for the conditions of use that EPA has preliminarily determined present unreasonable risk. This is the effect that is most sensitive, and it is expected that addressing risks for this effect would address identified risks.”

However, the draft that EPA released for public comment and peer review on February 21, 2020 omitted this statement and no longer based EPA's determination of unreasonable risk on fetal heart defects. 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.”¹² Despite the concerns of our groups and other commenters, including an allegation of a violation of scientific integrity submitted by the Union of Concerned Scientists, the final TCE risk evaluation released in November 2020 continued to dismiss the relevance of cardiac defects as instructed by the White House.¹³

As the Center for Investigative Reporting found, 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 cardiac 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 cardiac effects for TSCA risk determinations. Both the

⁸ 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

⁹ 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.

¹⁰ 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).

¹¹ 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, 2010 (Reveal Report) <https://www.revealnews.org/article/epa-scientists-found-a-toxic-chemical-damages-fetal-hearts-the-trump-white-house-rewrote-their-assessment/>.

¹² TCE Draft Evaluation at 377.

¹³ 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.

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 cardiac defects in humans (based on positive evidence from epidemiology studies, ambiguous evidence from animal toxicity studies, and stronger positive evidence from mechanistic studies).”¹⁴ As dictated by the White House, however, the overall conclusions of the evaluation negate these findings of career EPA scientists by rejecting the evidence of heart defects as too “uncertain” to inform TCE risk determinations.

While immune-related effects are a serious health concern, they occur at significantly higher dose levels than the heart malformations. Thus, an unreasonable risk may still exist if EPA bases risk management requirements on immune endpoints. For example, EPA’s dose response analysis of acute exposure scenarios shows that the HEC₉₉ for immune system effects is 470 times higher than the HEC₉₉ for heart malformations.¹⁵ Accordingly, for consumers and workers, the Margins of Exposure (MOEs) 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.

Necessary Action

In sum, political interference by White House officials in the prior Administration compelled EPA career scientists to exclude evidence of fetal heart malformations from unreasonable risk determinations for TCE despite their repeated conclusion that this evidence was “reliable and relevant” and provides “positive overall evidence” of risks to human health. The result of this interference was to dismiss a serious end-point that EPA had relied on in previous peer reviewed assessments and replace it with risk estimates that failed to protect pregnant women and fetuses from significant harm. As with PFBS, this egregious political interference in the TCE risk evaluation violated scientific integrity principles of the Biden Administration and EPA.

We believe EPA scientists should reconsider the treatment of fetal heart malformations in the final TCE evaluation in light of the political interference that occurred during the Trump Administration and advise EPA leadership on the need for revisions to correctly reflect the findings of EPA career experts. For those conditions of use in the risk evaluation where EPA found unreasonable risks based on the less protective endpoints, EPA should proceed with the risk management rules, but expressly take into account the risks posed by fetal heart malformations when crafting the risk management rules in accordance with Section 6(c)(2)(A)(i) of TSCA. For the remaining conditions of use, EPA should withdraw its determinations of no unreasonable risk, issue new risk determinations based on the analyses of fetal heart malformations contained in the final evaluation, and immediately commence the risk management process for all conditions of use that present unreasonable risk for that endpoint.

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

Respectfully submitted,

¹⁴ Final Risk Evaluation at 654.

¹⁵ TCE Draft Evaluation, at 252.

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