

April 16, 2019

Francesca T. Grifo, Ph.D.  
Scientific Integrity Official  
U.S. Environmental Protection Agency  
1301 Constitution Ave. NW  
Washington, D.C. 20460

Dear Dr. Francesca Grifo:

On behalf of our organizations, we ask you to investigate under the EPA Scientific Integrity Policy whether there have been losses of scientific integrity surrounding the Integrated Risk Information System (IRIS) risk assessment on formaldehyde. Significant evidence that is already public—combined with information recently obtained by the Union of Concerned Scientists through the Freedom of Information Act—suggests that significant and sustained political interference in the risk assessment process is harming public health by preventing communities throughout the United States from reducing exposure to the chemical.

Chronic exposure to formaldehyde has been linked to cancer in humans, including cancers of the nose and throat, lymphomas, and leukemia. In 2004, the International Agency for Research on Cancer concluded that formaldehyde is a human carcinogen, and the U.S. Department of Health and Human Services listed it as a known human carcinogen in 2011.<sup>1</sup> The completion and release of the IRIS assessment on formaldehyde would help inform science-based EPA regulations to better protect public health from this chemical. Conversely, permitting the suppression of this study to persist unchecked normalizes political interference at the agency and sends a message to career staff that their knowledge and expertise is not valued.

A recent Government Accountability Office (GAO) report revealed that senior officials at EPA interfered with the ability of IRIS career staff to continue work on or issue critical scientific assessments on the health risks associated with exposures to environmental contaminants, including formaldehyde. The GAO report does not identify any individual(s) who directly stalled the assessment releases, only mentioning that they were in leadership positions.<sup>2</sup> EPA's scientific integrity policy "prohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific information."<sup>3</sup>

According to current and former EPA employees, the IRIS formaldehyde assessment was completed and ready for peer review since at least fall 2017 and has been actively suppressed by EPA officials during this administration.<sup>4</sup> The GAO report provides further evidence of this suppression by specifying that the formaldehyde assessment is "ready to be released for public comment and external peer review."

In an EPA ORD report to Congress in January 2018, the agency wrote that it expected the draft formaldehyde assessment to be released for public comment and peer review in fiscal year 2018.<sup>5</sup> Not only did that not occur, but the assessment has since been suspended by the agency. According to the

GAO report, EPA leadership asked program offices to prioritize chemical assessments needed from IRIS without giving adequate information on the criteria on which to prioritize these assessments or why they were being asked to do so. Responses from just two program offices (the Office of Water and the Office of Land and Emergency Management) were included in the December 2018 priority list issued by EPA. Notably absent is the Office of Air and Radiation, the program that should have prioritized formaldehyde, due to formaldehyde's role as one of the three air pollutants responsible for over 90 percent of the cancer risk related to air pollution in over a hundred census tracts that have pollution above the 100 per million threshold.<sup>6</sup>

Documents recently obtained by the Union of Concerned Scientists through the Freedom of Information Act demonstrate that the IRIS formaldehyde assessment was indeed prioritized by the Office of Air and Radiation (OAR) staff. In November 2017, Erika Sasser, the director of the Health and Environmental Impacts Division at the Office of Air Quality Planning and Standards (OAQPS), wrote to Jennifer Orme-Zavaleta at the Office of Research and Development (ORD). "As you know, we have a strong interest in this review and are **anxious to see it completed**," she wrote (our emphasis added). "OAR regularly provides input to ORD on which hazardous air pollutants (HAP) the program office believes may be critical in shaping its regulations, and **we have consistently identified formaldehyde as a priority**. Having a current cancer unit risk estimate for formaldehyde is critical for the agency's air toxics program for use in 1) the National Air Toxics Assessment (NATA), 2) the Clean Air Act (CAA) Section 112 Risk and Technology Review (RTR) rulemakings, 3) evaluation of potential risks from on-road and nonroad mobile sources regulated under relevant sections of the CAA and 4) regional and local-scale risk assessment." This email chain was also brought to the attention of former ORD chief, Richard Yamada.<sup>7</sup> Since senior EPA staff knew of the air program's keen interest in the status of the formaldehyde assessment, its exclusion from the list of prioritized chemicals appears to be political. EPA must conduct an investigation to find out why the scientific opinions of staff at OAR were not considered when prioritizing IRIS assessments to release.

An investigation is warranted to understand whether the IRIS formaldehyde assessment has been suppressed and set aside by any staff at the agency, or if any other losses of scientific integrity occurred. The undersigned organizations do not have any financial conflicts of interest with any of the potential individuals involved in this allegation.

Sincerely,

Dr. Andrew Rosenberg  
Director, Center for Science and Democracy  
Union of Concerned Scientists

Dr. Jennifer McPartland  
Senior Scientist  
Environmental Defense Fund

Dr. Jennifer Sass  
Senior Scientist  
Natural Resources Defense Council

Michelle Roos  
Executive Director  
Environmental Protection Network

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<sup>1</sup> National Institute of Environmental Health Sciences. 2011. New Substances Added to HHS Report on Carcinogens. News Release, June 10. Online at <https://www.niehs.nih.gov/news/newsroom/releases/2011/june10/>;

International Agency for Research on Cancer (IARC). 2018. Chemical Agents and Related Occupations: Volume 100F, A Review of Human Carcinogens. Lyon, France: IARC. Online at <https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100F-29.pdf>.

<sup>2</sup> U.S. Government Accountability Office. 2019. Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act, Report to the Ranking Member, Committee on Environment and Public Works, U.S. Senate. Washington, DC: GAO. Online at <https://www.gao.gov/assets/700/697212.pdf>.

<sup>3</sup> U.S. Environmental Protection Agency. 2012. Scientific Integrity Policy. Online at [https://www.epa.gov/sites/production/files/2014-02/documents/scientific\\_integrity\\_policy\\_2012.pdf](https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf)

<sup>4</sup> Markey, E. J., Whitehouse, S., and Carper, T.R. 2018. Letter to EPA Administrator Scott Pruitt, May 18. Online at <https://www.markey.senate.gov/imo/media/doc/Pruitt%20Letter%20formaldehyde%20assessment.pdf>.

<sup>5</sup> U.S. Environmental Protection Agency, Office of Research and Development. 2018. EPA's Integrated Risk Information System (IRIS) Program: Report to Congress. Online at [https://www.epa.gov/sites/production/files/2018-02/documents/iris\\_report\\_to\\_congress\\_2018.pdf](https://www.epa.gov/sites/production/files/2018-02/documents/iris_report_to_congress_2018.pdf).

<sup>6</sup> Lerner, S. 2019. A Tale of Two Cities: The EPA's Bungled Response to an Air Pollution Crisis Exposes a Toxic Racial Divide. *The Intercept*, February 24. Online at <https://theintercept.com/2019/02/24/epa-response-air-pollution-crisis-toxic-racial-divide/>.

<sup>7</sup> Sasser, E.N, EPA. 2017. Email to J. Orme-Zavaleta [Subject: Formaldehyde IRIS Review], November 7. (Obtained by the Union of Concerned Scientists under the Freedom of Information Act Request No. EPA-HQ-2018-007949 from EPA; Requested July 2018, Received January 2019. Online at <https://s3.amazonaws.com/ucs-documents/science-and-democracy/epa-formaldehyde-email.pdf>.