Comments to

EPA TSCA Science Advisory Committee on Chemicals (SACC)

Review of EPA Draft Risk Evaluation of Trichloroethylene

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Department of Environmental and Occupational Health Milken Institute School of Public Health The George Washington University 950 New Hampshire Ave NW Washington, DC 20052 dmm@gwu.edu My name is David Michaels. I am an epidemiologist and Professor of Environmental and Occupational Health at the Milken Institute School of Public Health of George Washington University. The views expressed in these comments are my own and do not represent the views of George Washington University.

From 2009 until January 2017, I served as Assistant Secretary of Labor for the Occupational Safety and Health Administration, the longest serving Assistant Secretary in OSHA's history. From 1998 to 2001, I was Assistant Secretary for Environment, Safety and Health in the U.S. Department of Energy, charged with protecting the workers, community residents and environment in and around the nation's nuclear weapons complex. I am a currently a member of the Board of Scientific Counselors of the National Toxicology Program. From 2011 through January 2017, I served as the chairman of the NTP's Executive Committee.

In this statement, I want to address an important issue in which aspects of this Draft Risk Evaluation are fundamentally, fatally flawed.

The hierarchy of controls represents decades of OSHA policy and practice. OSHA is very clear that it is unacceptable to use personal protective equipment (PPE) as the primary means to protect workers. The most effective way to control respiratory hazards in the workplace environment is through engineering controls. The "hierarchy of controls" is a widely-recognized and long-standing industrial hygiene principle, applied in all of OSHA's comprehensive workplace exposure standards. The basic approach can be summarized as: "fix the workplace, not the worker."

In the draft risk evaluation, EPA's basis for much of the estimation of hazard facing workers is the draft's assertion that workers will be protected from the effects of exposure because of recommendations that they wear personal protective equipment, in this case respirators. Underlying this assertion are numerous unfounded assumptions:

- that workers will be given proper PPE by their employer;
- that they will be able to use that PPE, that they be trained to use it correctly, that they have no medical conditions that will preclude that use; and
- that it will be effective in protecting them.

There is no reason to believe any of those assumptions are true, even most of the time.

EPA seems to think that a recommendation for providing respiratory protection in a Safety Data Sheet (SDS) means that every employer will do that. In fact, OSHA does not require employers to follow recommendations in SDSs. Under the Hazard Communication Standard, OSHA's only requirement is that employers maintain those SDSs. The worker protection recommendations in the SDSs are only that: recommendations. In many cases, employers, especially small ones, don't even read the SDSs.

And anyone who has spent time in worker protection knows that many employers often do not follow recommendations. They don't even comply with OSHA legal requirements. The authors of this EPA draft do not seem to understand that.

I call your attention to the statement on page 377 of the draft:

EPA expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE consistent with the applicable SDSs.

That statement is simply and demonstrably false: existing OSHA regulations for worker protection and hazard communication will NOT result in use of appropriate PPE consistent with the applicable SDSs.

In conversations with high level personnel at OSHA and NIOSH, I have been told that both the agencies have repeatedly informed the EPA that the reliance on PPE in these risk evaluations is deeply flawed. Yet EPA continues to produce risk evaluations that ignore the experts at the agencies and the long-standing worker protection policies of these agencies.

I suggest the SACC request the EPA provide for SACC review all the materials and communications from OSHA and NIOSH to the EPA on this TCE risk evaluation and all the other risk evaluations, dating back to the first risk evaluation for PV 29. Everything I have said to this point applies to chemical exposures in general and the flaws in EPA's method for developing risk evaluations. When you focus on TCE, it gets worse.

The OSHA Permissible Exposure Limit (PEL) for TCE dates from the 1968 ACGIH TLV list, adopted by OSHA in 1972. It was probably out of date then, and it has never been updated. OSHA's current standard is 100 ppm averaged over an 8-hour day, with a ceiling of 200 ppm. In contrast, California has an OEL of 25 ppm and the ACGIH has lowered theirs to 10 ppm. The draft risk assessment correctly notes that OSHA recommends the NIOSH REL of 2 ppm (as a 60-minute ceiling) during the usage of TCE as an anesthetic agent and 25 ppm (as a 10-hour TWA) during all other exposures.

The chasm between OSHA's current standards and the levels that would actually protect workers led me when I ran OSHA to recommend that employers should look to standards other than the PELs listed on OSHA's Z Table to protect workers. To document this chasm and encourage employers to better protect workers, OSHA produced annotated Z-Tables.¹

The OSHA standard for TCE consists only of the PEL; in addition to being far too high, it is not a comprehensive standard, the only type of chemical exposure standard OSHA has been issuing for several decades. OSHA's TCE standard does not require application of the hierarchy of controls, or the use of PPE, or any sort of training or education, or medical monitoring.

This situation actually incentivizes employers NOT to provide PPE to their employees, the opposite of what the EPA draft assumes. This requires some explanation:

The OSHA PEL for TCE, as I have stated, is weak and antiquated. The authors of the draft apparently think that employers will not care that the OSHA standard asks little of them, and that when exposures are below the outdated OSHA standard, employers will voluntarily offer PPE anyway. This will occur, the draft suggests, even when exposures are far too high, above NIOSH's recommendation but below the OSHA legal limit.

But if employers do as the EPA assumes they will, and provide workers with appropriate PPE (in particular, respirators), under the general OSHA respiratory protection standard the employer must also provide medical monitoring, fit testing and much more.²

This is a very big deal, and involves far more than simply giving out some respirators. And it is expensive.

I can assure you there are many employers who will not do this voluntarily. Yet in its analysis, EPA assumes the use of PPE, which leads to incorrect estimates of exposure, drastically underestimating risks by orders of magnitude.

To get this right, EPA must go back and make determinations of unreasonable risk assuming that many workers will not be using appropriate PPE.

Thank you for considering my comments and thank you for your service to the country.

¹ https://www.osha.gov/dsg/annotated-pels/index.html

² https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards