



NATURAL RESOURCES DEFENSE COUNCIL
THE EARTH'S BEST DEFENSE

NRDC Comments at The
EPA Workshop on Alternatives and Risk Reduction Approaches to
Trichloroethylene (TCE) Use as a Degreaser

July 29–30, 2014, Washington, DC

These comments are being submitted on behalf of the Natural Resources Defense Council (NRDC). NRDC uses law, science, and the support of more than 1.2 million members and on-line activists nationwide to protect the planet's wildlife and wild places and to ensure a safe and healthy environment for people and all living things. NRDC has no direct or indirect financial or fiduciary interest in the deliberations of this committee.

General Comments

We are pleased that EPA issued its final TSCA Work Plan Chemical Risk Assessment for Trichloroethylene (TCE), and not surprised that the science provided that there were unacceptably high health risks from TCE exposure when used as a degreasing agent, a spot removal agent in dry-cleaning and as a spray arts fixative.¹ EPA found that the greatest risks are for developmental effects (fetal cardiac malformations), followed by kidney effects and then immunotoxicity (EPA at 69).

The risk assessment clearly supports immediate protective action by EPA to implement risk reduction strategies to address the serious potential health effects that are associated with TCE use in the assessed exposure scenarios. NRDC believes that an EPA ban of TCE use in small commercial degreasing facilities and in consumer aerosol degreasers and protective coating sprays is the most effective risk

¹ http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf

reduction strategy. The use of ventilation (general and local exhaust) in commercial degreasing facilities is inadequate and does not eliminate the risks of developmental toxicity, cancer, and other TCE-induced health effects. The use of consumer general purpose degreaser products that contain TCE are already banned in California and safer substitutes are in use. Instead, water-based cleaning systems are effective, safe, and economical alternatives for vapor degreasing, cold cleaning, and acetone and soy provide safer alternatives for aerosol uses. Water-based cleaners are used extensively in Southern California instead of TCE-based vapor degreasing, due to regulations that limit the use of solvents that are VOCs.

The non-user risk estimates are an important aspect of the TCE risk assessment. EPA's assessment documents serious and largely unexpected potential health problems that are not addressed by required preventive measures like the Hazard Communication Standard and precautionary labeling that are directed at users of toxic chemicals and consumer products. Cancer and the other potential chronic health effects that are identified as risks for bystanders in commercial facilities, and developmental toxicity potentially caused by exposure of pregnant non-users in both commercial and residential settings to TCE used as a degreaser, would be difficult to detect and would have substantial and costly adverse public health impacts.

Therefore, only a full ban will protect the public. EPA must not capitulate to industry arguments that voluntary initiatives will be good enough. They won't. EPA spent twenty-three years trying to finalize its hazard assessment of TCE. FDA banned TCE from food uses in 1977, almost four decades ago. Ten years later, in 1987, EPA determined that TCE "probably causes cancer". Since then, EPA has been delayed by TCE manufacturers, its lobbying group the American Chemistry Council (ACC), and its allies in Congress. Nonetheless, many forward-thinking companies that use TCE in their operations sought out safer alternatives, and have since moved completely away from TCE-based cleaners. Safer alternatives are readily available and in common use. The hold-out companies that still use TCE have proved by their inaction that they will not move away from TCE unless regulation forces them. EPA has already let decades of harmful exposures occur. Now that EPA has issued this risk assessment, it needs to cross the finish line with enforceable rules. It is decades too late for EPA to claim it is leading the effort to protect people from TCE-induced cancer, developmental malformations, and chronic disease, but it can bring up the rear by pushing the last 'bad actor' companies towards safer substitutes.

EPA must be mindful of not allowing 'regrettable substitutes' to TCE onto the market. For example, n-hexane is a very hazardous substitute for TCE, used in auto cleaners after the California Air Resources Board (CARB) banned TCE, methylene chloride, and perchloroethylene from vehicle repair cleaners. Another regrettable substitute is 1-bromopropane, which replaced TCE and other ozone-depleting solvents. It is linked to severe debilitating nerve damage, reproductive harm, and cancer. EPA must take measures to prevent highly hazardous substitutes from coming onto the market.

TCE poses unacceptably high risks to workers, consumers, and bystanders in vapor degreasing, cold cleaning, and aerosols. All of these uses have safer alternatives available and in widespread use. EPA should ban TCE, using enforceable regulations, so that no more people have to suffer from predicted and preventable disease or death from TCE.

Specific Technical Comments

The final assessment had a number of significant improvements over the earlier draft, consistent with scientific understanding of TCE toxicity and EPA risk assessment approaches. We support these improvements and discuss them below.

EPA included developmental risks from TCE exposures during fetal development for both acute and chronic exposure scenarios. The draft had considered only acute scenarios. This is important because the window of developmental vulnerability may occur at any time during child-bearing years – often without warning – for an exposed adult.

In another improvement, EPA based its Point of Departure (POD) for developmental toxicity on fetal cardiac abnormalities in rodents. The study – Johnson et al 2003 - reported a statistically significant increase in severe heart malformations associated with fetal exposure to TCE in the drinking water of the pregnant dams. The study findings are supported by similar findings in chick embryos, data supporting a possible mode of action, and some weakly positive epidemiologic data (EPA page 97, Section 2.6). Fetal cardiac effects – including deformities in the septum and heart valves – are very serious and may cause lifelong impairments or death. EPA used this endpoint because it is the most sensitive – and, therefore will support the most health-protective assessment – and is consistent with its

long-standing policy that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects ([EPA, 1991](#)).²

EPA included exposures for spot dry cleaners in its final assessment. These exposures were determined to pose unacceptably high risks for both commercial users and for bystanders, based on fetal cardiac abnormalities. Spotting chemical formulations that contain high concentrations of TCE are commonly used by drycleaners to remove spots from fabrics. Concomitant exposures to tetrachloroethylene (perchloroethylene) could result in cumulative adverse health impacts because both chemicals produce the same potentially toxic metabolites. Under its Consumer Products Regulation, the California Air Resources Board (CARB) banned dry cleaning uses of TCE-containing spot removers in California effective December 31, 2012. Safer substitutes to TCE-based spot removers are available, and include water-based cleaners, soy based cleaners and acetone based cleaners. The [cost analysis](#) indicates that the alternatives are less costly than the spotting agents used today.³

Response to Congress

This is the first time EPA has issued an assessment under TSCA since 1986, when it identified the human health hazards of asbestos (see blog by Dr. [Richard Denison, EDF](#)). EPA's successful efforts to use its existing statutory authorities to inform the public about this hazardous and common chemical did not go unnoticed by industrial chemical manufacturers and the chemical-friendly Members of Congress. Senator Vitter (R-La.), top Republican on the Environment and Public Works Committee, along with Senators Mike Crapo (R-Idaho) and Jim Inhofe (R-Okla.), has since [requested the raw data](#) on TCE research that supported the EPA TCE assessment, as well as impugning the EPA researcher that co-authored the study. From Senator Vitter's [webpage](#): "On June 16, 2014, Senator [Vitter sent a letter](#) to Dr. Francesca Grifo, the Science Integrity Official for EPA requesting their research data, suggesting there may be some data-related misconduct." The letter raises three concerns, for which I offer my perspective:

1. the Johnson et al (2003) study of cardiac malformations is fundamentally flawed;

² Guidelines for Developmental Toxicity Risk Assessment. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC, EPA/600/FR-91/001, 1991.

³ <http://www.irta.us/reports.htm>

2. the EPA scientist, Dr. Stan Barone, that drafted the external charge to peer reviewers had undue influence on the outcome of the peer review; and
3. Dr. Barone may have committed scientific misconduct.⁴

Senators Vitter, Crapo, and Inhofe will be pleased to know that these concerns are unwarranted.

First, the Johnson et al (2003)⁵ study has undergone extremely rigorous scientific review, including by EPA and external experts, public scrutiny and comment, and the peer review that comes with publication in a reputable scientific journal. Although it can reasonably be accused of being imperfect, an expert consensus to use it for this assessment should be respected. Moreover, the findings in the Johnson et al (2003) rodent study are supported by findings in other rodent studies, studies in other species, some epidemiologic data, and a plausible mode of action, making EPA's overall assessment very strong.

Second, the peer review charge questions were developed and reviewed by numerous EPA staff, and then vetted for public comment prior to being finalized. I am somewhat sympathetic to the general claim in the Senators' letter that wording of charge questions can limit or constrain the peer review feedback, and thereby the outcome of a peer review. However, in this case, the charge questions to the peer reviewers resulted from internal discussions among numerous EPA staff, review and comment by the public, and then further EPA review to address the public comments. It is reasonable, therefore, that Dr. Barone was one among many people – within and outside EPA – that developed the final charge questions.

Third, the suggestion that Dr. Barone may have committed scientific misconduct is simply unfounded. In fact, in the situation to which the Senators' letter refers, he co-published with other authors a paper over a decade ago on a completely unrelated chemical – a fungicide – which subsequently underwent

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http://www.epw.senate.gov/public/index.cfm?FuseAction=PressRoom.PressReleases&ContentRecord_id=7D861308-98D6-51CA-08FA-85F6CEFB2E95

⁵ Johnson PD, Goldberg SJ, Mays MZ, Dawson BV. Threshold of trichloroethylene contamination in maternal drinking waters affecting fetal heart development in the rat. *Environ Health Perspect.* 2003 Mar;111(3):289-92. Erratum in: *Environ Health Perspect.* 2014 Apr;122(4):A94.

some re-analysis of the pathology findings that did not change the conclusions of the paper. Both the paper and re-analysis were published in a scientific journal.⁶

The Halogenated Solvents Industry Alliance (HSIA) recently sponsored a review of epidemiologic studies examining the association between congenital heart defects and TCE exposure, concluding that overall the “literature provides no substantive or consistent evidence linking TCE to CHD [coronary heart disease]”.⁷ The study found that some studies didn’t find a link, some studies did, and all the ones that did had design and analytic flaws making them unusable. Although the author spent a good deal more effort identifying flaws with the studies that found links (the positive studies), he did include a short section of “limitations” with the ones that didn’t (the negative studies). He reported that the “negative” studies were based on small numbers so increases might have been missed due to low statistical power, and “each study had substantial potential for non-differential misclassification that might have biased toward the null”. In plain-speak, this means that the “negative” studies had flaws that made it more likely that they would fail to detect a link between TCE and CHD, and they did fail. Ironically, so did the review article. Nonetheless, the conclusions are not inconsistent with EPA’s own review, which also determined that the epidemiologic evidence overall was “weakly suggestive” (EPA at 97). However, in combination with the animal and mechanistic studies, the science supports the risk assessment.

Conclusion and Recommendations

We commend EPA on its assessment, which identified some significant high health risks for both workers and consumers. Since in many cases there are safer alternative materials available, EPA should immediately establish more health-protective exposure limits for these unsafe uses, and ban TCE use in small commercial degreasing facilities and in consumer aerosol degreasers and protective coating sprays.

⁶ Barone S Jr, Moser VC. The effects of perinatal tebuconazole exposure on adult neurological, immunological, and reproductive function in rats. *Toxicol Sci.* 2004 Jan;77(1):183.

Moser VC, Barone S Jr, Smialowicz RJ, Harris MW, Davis BJ, Overstreet D, Mauney M, Chapin RE. The effects of perinatal tebuconazole exposure on adult neurological, immunological, and reproductive function in rats. *Toxicol Sci.* 2001 Aug;62(2):339-52.

⁷ Bukowski, John (06/05/2014). "Critical review of the epidemiologic literature regarding the association between congenital heart defects and exposure to trichloroethylene". *Critical reviews in toxicology* (1040-8444), 44 (7), 1.

In a [statement](#) that accompanied the release of its TCE assessment, EPA called on Congress to enact legislation that strengthens our current federal toxics law, TSCA. NRDC agrees that it is long past time that hazardous chemicals were assessed and regulated so as to prevent unsafe human exposures and releases to the environment. Using TSCA to identify unsafe exposures to chemicals already in widespread commercial and residential use is too little, too late.

Respectfully,

A handwritten signature in black ink that reads "Jennifer B. Sass". The signature is written in a cursive, flowing style.

Jennifer B. Sass, Ph.D.

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