Environmental Protection Network

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December 9, 2020

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Re: Trichloroethylene Final Risk Evaluation

Dear Administrator Wheeler:

The Environmental Protection Network (EPN) is an organization comprised of over 500 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of the EPA, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current administration efforts to undermine public health and environmental protections.

We wrote you a letter on March 12, 2020, expressing our deep concern about the serious health risks described in EPA's Notices of Proposed Rulemaking (NPRM) and draft risk evaluation for Trichlorethylene (TCE) under the Toxic Substances Control Act (TSCA) and EPA's failure to take regulatory action in a timely manner.

Some of the concerns that we noted in our March 12 letter are still valid today.

1. The management of the risks of TCE is taking an inordinate amount of time.

On December 16, 2016, EPA issued an NPRM under TSCA section 6(a) to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in aerosol degreasing and spot cleaning in dry-cleaning facilities. And on January 19, 2017, EPA issued an NPRM under TSCA section 6(a) to prohibit the manufacture (including import), processing, and distribution in commerce and commercial use of TCE in vapor degreasing. Both of these actions proposed to require manufacturers, processors, and distributors of TCE (except for retailers) to provide downstream notification of these prohibitions throughout the supply chain, and to require limited recordkeeping.

EPA issued these NPRMs based upon EPA's determination that the use of TCE for vapor degreasing, aerosol degreasing, and spot dry cleaning presents an unreasonable risk to human health from significant non-cancer risks under both acute and chronic exposure scenarios, and significant cancer risks from chronic exposures. The adverse health effects noted include those resulting from developmental toxicity (e.g., cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases, e.g., scleroderma and severe hypersensitivity skin disorder), non-Hodgkin's lymphoma, reproductive and endocrine effects (e.g., decreased libido and potency), neurotoxicity (e.g., trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer).

Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated drinking water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association of TCE exposure with central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function, and attention deficit disorder. These effects are alarming not only because of their serious nature, but also due to the low dose levels at which they have been observed in the animal studies and the fact that a single exposure during a critical window of fetal development may produce adverse developmental effects.

EPA identified these effects many years ago in the Integrated Risk Information System (IRIS) toxicological review in 2011 and the 2014 TSCA Work Plan Chemical Assessment. **Yet, despite knowing for many years of these serious health effects and the unreasonable risks posed by TCE, EPA has taken no final regulatory action to protect human health. Given the seriousness of these findings, why did EPA propose a rule but not follow up by issuing a final rule for these activities?** EPA did not even have to wait to issue a final rule, as it could have used its authority under TSCA Section 6(d) to declare a proposed rule under section 6(a) immediately effective when a chemical is "likely to result in an unreasonable risk of serious or widespread injury to health" before completion of the rulemaking process. TCE meets this criterion.

The draft risk evaluation issued on February 21, 2020, identifies the same adverse health effects as did the two NPRMs. However, it goes beyond the scope of the NPRMs in that it also finds that TCE presents an unreasonable risk of both acute and chronic exposure for workers in virtually all aspects of manufacturing, processing, use, and disposal of TCE. Consumers were also found to be subjected to unreasonable risk in nearly ALL exposure scenarios due to acute exposure to TCE.

Therefore, EPN urges EPA to do the following:

1. Finalize the two proposed rules to prohibit manufacture, processing, distribution in commerce, and use of TCE for aerosol and vapor degreasing and spot dry cleaning without further delay;

2. Prohibit all uses of TCE in consumer products;

3. Initiate a complete ban on the manufacture, processing, and use of TCE, with the possible exception of its use as a closed system intermediate with stringent exposure controls (i.e., an 8-hour exposure limit of 0.00037 ppm), because all commercial activities have been determined to pose an unreasonable risk to human health;

4. Immediately require manufacturers and processors to notify workers and downstream users of the hazards of TCE; and

5. Add TCE to the 5(b)(4) Risk List.

2. EPA is not utilizing the most sensitive endpoint in its risk evaluation.

TCE-induced heart malformations and immunotoxicity in animals have been identified in Johnson *et al.* (2003) as the most sensitive developmental toxicity endpoints for TCE. EPN is aware that the draft Risk Evaluation that was sent to the Office of Information and Regulatory Affairs (OIRA) for review considered the Johnson study to be adequate for derivation of a point of departure (POD). Although members of the EPA Scientific Advisory Committee on Chemicals had differences of opinion concerning the adequacy of Johnson *et al.* (2003), the study has been repeatedly vetted, reviewed, and discussed by EPA and external expert peer reviewers in previous assessments, including its limitations. In each case, the study was found to be sufficient for hazard identification and dose-response analysis. Its results are also wholly consistent with the findings of many other studies—including human, *in vitro*, and *in vivo* studies—that also indicate congenital heart defects resulting from TCE exposure (see Makris *et al.*, 2016; Runyan *et al.*, 2019).

EPN disagrees with EPA's decision not to use the most sensitive endpoint—cardiac malformations—as the basis for its derivation of the POD for TCE. If EPA selects a risk management option other than a ban, a rule to control human exposure that does not use fetal heart defects as the toxicity endpoint for the PODfor setting standards will not be adequately protective of human health.

Respectfully submitted,

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