EPA Proposes to Ban TCE

The U.S. Environmental Protection Agency (EPA) proposed on October 31, 2023, to ban all uses of trichloroethylene (TCE) after determining that it presents an unreasonable risk of injury to human health under its conditions of use as documented in EPA’s November 2020 risk evaluation (2020 TCE RE) and January 2023 revised risk determination (2023 Revised RD) pursuant to the Toxic Substances Control Act (TSCA). According to EPA’s October 23, 2023, press release, TCE is used in cleaning and furniture care products, degreasers, brake cleaners, and tire repair sealants, and safer alternatives are readily available for many uses. The proposed rule would ban the manufacture, processing, and distribution of TCE for all uses. It would take effect in one year for consumer products and most commercial uses and would implement stringent worker protections on the limited remaining commercial and industrial uses that would be phased down over a longer period. Comments are due December 15, 2023. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of the comments on or before November 30, 2023.

The proposed rule states that pursuant to Section 6(b) of TSCA, EPA determined that TCE presents an unreasonable risk of injury to health, without consideration of costs or other nonrisk factors, including an
unreasonable risk to potentially exposed or susceptible subpopulations (PESS) identified as relevant to the 2020 TCE RE by EPA, under the conditions of use. EPA states that the term “conditions of use” is defined at TSCA Section 3(4) to mean the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. EPA notes that all TSCA conditions of use of TCE are subject to the proposed rule. Accordingly, to address the unreasonable risk, EPA proposes, under TSCA Section 6(a), to:

- Prohibit the manufacture (including import), processing, and distribution in commerce of TCE for all uses (including all consumer uses), with longer compliance timeframes for manufacture and processing related to certain uses;

- Prohibit the industrial and commercial use of TCE, with longer compliance timeframes for certain uses;

- Prohibit the manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon134a (HFC-134a), following an 8.5-year phaseout;

- Prohibit the industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production by federal agencies and their contractors, following a ten-year phaseout;

- For Department of Defense (DOD) naval vessels and their systems, and in the maintenance, fabrication, and sustainment for and of such vessels and systems, prohibit the industrial and commercial use of TCE as potting compounds for naval electronic systems and equipment; sealing compounds for high and ultra-high vacuum systems; bonding compounds for materials testing and maintenance of underwater systems and bonding of
nonmetallic materials; and cleaning requirements (which includes degreasing using wipes, sprays, solvents, and vapor degreasing) for: materials and components required for military ordinance testing; temporary resin repairs in vessel spaces where welding is not authorized; ensuring polyurethane adhesion for electronic systems and equipment repair and installation of elastomeric materials; various naval combat systems, radars, and sensors equipment; fabrication and prototyping processes to remove coolant and other residue from machine parts; machined part fabrications for naval systems; installation of topside rubber tile material aboard vessels; and vapor degreasing required for substrate surface preparation prior to electroplating processes, following a ten-year TSCA Section 6(g) exemption;

- Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for battery separator manufacturing, following a ten-year TSCA Section 6(g) exemption;

- Prohibit the manufacture (including import), processing, distribution in commerce, and use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities, following a 50-year TSCA Section 6(g) exemption;

- Prohibit the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by the National Aeronautics and Space Administration (NASA) and its contractors, following a seven-year TSCA Section 6(g) exemption;

- Prohibit the emergency industrial and commercial use of TCE in furtherance of the NASA mission for specific conditions that are critical or essential and for which no technically and economically
feasible safer alternative is available, following a ten-year TSCA Section 6(g) exemption;

- Require strict workplace controls, including compliance with a TCE workplace chemical protection program (WCPP), which would include requirements for an inhalation exposure limit and dermal protection to limit exposure to TCE, for conditions of use with long-term phaseouts or time-limited exemptions under TSCA Section 6(g);

- Prohibit, due to worker risks, the disposal of TCE to industrial pretreatment, industrial treatment, or publicly owned treatment works, with a 50-year TSCA Section 6(g) exemption for cleanup projects; and

- Establish recordkeeping and downstream notification requirements.

EPA states that in addition, it proposes to amend the general provisions of 40 C.F.R. Part 751, Subpart A, to define the following terms so that these definitions may be commonly applied to this and other rules under TSCA Section 6 that would be codified under 40 C.F.R. Part 751: “authorized person,” “ECEL,” “exposure group,” “owner or operator,” “potentially exposed person,” “regulated area,” and “retailer.” EPA seeks public comment on all aspects of this proposed rule.

**Commentary**

Bergeson & Campbell, P.C. (B&C®) was not surprised by the Office of Pollution Prevention and Toxics’ (OPPT) proposal to ban all uses of TCE. This proposal is comparable to OPPT’s proposal to ban most uses of methylene chloride. For discussion, see our [memorandum](#) dated April 25, 2023. We recognize that regulated entities that use TCE
as part of their supply chain will find OPPT’s proposal alarming, yet the most impactful aspect of this proposal goes far beyond banning one chemical.

As we discussed in our memorandum dated January 19, 2023, the Biden-Harris Administration characterized scientific decisions made by the Trump-Pence Administration in the 2020 TCE RE as “political interference” in science. The underlying issue for this characterization was the Trump-Pence Administration’s decision not to rely on a controversial study that reported fetal cardiac defects in rats administered TCE (i.e., Johnson et al., 2003). We previously expressed concern that this characterization, although popular as click bait in the media, failed to “appreciate the legitimate differences of opinion that exist on this topic.” For additional details, see our memorandum dated January 19, 2023, but we note that the effects reported by Johnson et al. (2003) were not reproducible in subsequent studies and that there were disagreements among members of the TSCA Science Advisory Committee on Chemicals (SACC) on the credibility of Johnson et al. (2003).

In the 2020 TCE RE, OPPT did not rely on Johnson et al. (2003) for quantifying risks. Instead, OPPT concluded under Section 3.2.5.4.1 “Best Overall Non-Cancer Endpoints for Risk Conclusions” that:

On January 9, 2023, OPPT released its final revision to the risk determination for the 2020 TCE RE (the 2023 Revised RD) that included policy changes it announced on June 30, 2021 (e.g., the Whole Chemical Approach). OPPT stated in the 2023 Revised RD that it “views the peer reviewed hazard and exposure assessments and associated risk characterization [in the 2020 TCE RE] as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).” [Emphasis added.] That is, less than eight months ago, the Biden-
Harris Administration agreed with the Trump-Pence Administration’s exclusion of Johnson et al. (2023) as a basis for evaluating unreasonable risks.

On the other hand, also on January 9, 2023, OPPT simultaneously issued a press release stating that it will develop “existing chemical exposure limits [ECELs] based on both the immune endpoint [i.e., a generally agreed upon effect] and the CHD endpoint [i.e., fetal cardiac defects] in support of risk management.” OPPT clarified this decision by stating that the fetal cardiac defects endpoint “was not relied on to determine whether there is unreasonable risk from TCE [in the 2020 Final RE] because of direction not to do so that was provided by the previous political leadership.”

OPPT cannot have it both ways, either the Johnson et al. (2003) study is the best available science (i.e., for purposes of calculating the ECEL) or it is not (for purposes of evaluating risk). Our view is that a study result that cannot be reproduced in subsequent studies does not pass the test as the “best available science.” These conflicting conclusions call into question whether the Biden-Harris Administration is “following the science and the law.”

Regrettably, if EPA insists on proceeding with basing its ECEL on Johnson et al. (2003), it will likely lead to litigation on the promulgated risk management rule and will delay protecting against unreasonable risks that were identified on the more justifiable point of departure (as reflected in the 2023 Revised RD).

EPA’s pivot on the basis for the ECEL is especially troubling given OPPT’s proposed changes to the framework rule for risk evaluations, in which OPPT proposed lowering the scientific standard from the current regulations. For discussion, see our memorandum dated October 30, 2023.

Beyond the above issues, we note that OPPT’s proposed ban on TCE
is inconsistent with TSCA Section 6(a), which states that EPA shall:

Given that OPPT concluded that compliance with the WCPP, which includes compliance with the ECEL for fetal cardiac defects, will mitigate the unreasonable risk concerns it identified, it is difficult to understand how EPA justifies a ban. OPPT has solicited comments on this very point by stating that:

This has been OPPT’s default in all of its proposed Section 6 risk management actions. It will ban or subject uses to phase-outs even when OPPT concludes that a WCPP is sufficiently protective. Regulated entities must pay careful attention to EPA’s risk management actions even if the subject substance is not in your supply chain. The ramifications of EPA’s decision to use a lower quality study as its basis for an ECEL and to impose bans even when a WCPP is sufficiently protective are far reaching and will, if unchallenged, empower OPPT to disregard recommendations from the SACC and public commenters in support of decisions that may in fact be driven by motives other than seeking the best available science on which to base public health decisions. Allowing OPPT to select an endpoint based on its preferred regulatory outcome rather than sound science should concern all stakeholders, regardless of your point of view.