

Memoranda

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December 28, 2022

EPA Finds Carbon Tetrachloride, as a Whole Chemical Substance, Poses an Unreasonable Risk to Human Health

Bergeson & Campbell, P.C.

The U.S. Environmental Protection Agency (EPA) announced on December 27, 2022, the availability of the final revision to the risk determination for the carbon tetrachloride risk evaluation issued under the Toxic Substances Control Act (TSCA). [87 Fed. Reg. 79303](#). EPA determined that carbon tetrachloride, as a whole chemical substance, presents an unreasonable risk of injury to human health when evaluated under its conditions of use (COU). EPA states that the revision to the risk determination reflects its announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law.

In its December 27, 2022, [press release](#), EPA states that carbon tetrachloride is used in commercial settings as a raw material for producing other chemicals such as refrigerants, chlorinated compounds, and agricultural products. EPA notes that the Consumer Product Safety Commission (CPSC) banned the use of carbon tetrachloride in consumer products (excluding unavoidable residues not exceeding ten parts per million (ppm) atmospheric concentration) in 1970, so EPA did not evaluate risks to consumers in its risk evaluation.

In its revised risk determination, EPA found that carbon tetrachloride presents unreasonable risk to the health of workers and occupational non-users (ONU) (workers nearby but not in direct contact with this chemical). EPA identified risks for adverse human health effects, including cancer and chronic liver toxicity from long-term inhalation and dermal exposure to the chemical and liver toxicity from short-term dermal exposure to carbon tetrachloride.

EPA states that it used the whole chemical risk determination approach for carbon tetrachloride in part because there are benchmark exceedances for multiple COUs spanning across most aspects of the chemical's life cycle, from manufacturing (including import), processing, commercial use, and disposal. EPA is taking this approach for health of workers and ONUs, and because the health effects associated with carbon tetrachloride exposures are severe (specifically cancer and liver toxicity).

EPA determined that 13 of the 15 COUs evaluated drive the unreasonable risk determination. Two out of 15 COUs do not drive the unreasonable risk: processing as a reactant/intermediate in reactive ion etching, and distribution in commerce. The revised risk determination supersedes the COU-specific no unreasonable risk determinations that were previously issued by order under TSCA Section 6(i) in the 2020 carbon tetrachloride risk evaluation.

EPA notes that the revised risk determination does not reflect an assumption that workers always and appropriately wear personal protective equipment (PPE), even though some facilities might be using PPE as one means to reduce workers' exposure. EPA states that this decision "should not be viewed as an indication that EPA believes there is widespread non-compliance with applicable Occupational Safety and Health Administration (OSHA) standards." In fact, according to EPA, it received public comments from industry respondents about occupational safety practices currently in use at their facilities and will consider these comments, as well as other information on

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use of PPE, engineering controls, and other ways industry protects its workers, as potential ways to address unreasonable risk during the risk management process.

EPA acknowledges that there could be occupational safety protections in place at some workplace locations. Not assuming use of PPE in its baseline exposure scenarios, however, reflects EPA's recognition that certain subpopulations of workers exist that may be highly exposed because:

- They are not covered by OSHA standards (*e.g.*, self-employed individuals and public sector workers who are not covered by a state plan);
- Their employers are out of compliance with OSHA standards;
- OSHA's chemical-specific permissible exposure limits (PEL) (largely adopted in the 1970s) are described by OSHA as being "outdated and inadequate for ensuring protection of worker health"; or
- The OSHA PEL alone may be inadequate for ensuring protection of worker health, as is the case for carbon tetrachloride, according to EPA.

EPA states that as it moves forward with a risk management rulemaking for carbon tetrachloride, it will "strive for consistency with existing OSHA requirements or best industry practices when those measures would address the identified unreasonable risk." EPA will propose occupational safety measures in the risk management process that would meet TSCA's statutory requirement to eliminate unreasonable risk of injury to health and the environment.

Next Steps

EPA states that it is now moving forward on risk management to address the unreasonable risk presented by carbon tetrachloride. EPA notes that in revising the risk determinations, it has not conducted new scientific analysis and the risk evaluation continue to characterize risks associated with individual COUs in the risk evaluations of carbon tetrachloride to inform risk management.

Separately, EPA is conducting a screening-level approach to assess potential risks from the air and water pathways for several of the "first 10" chemicals, including carbon tetrachloride. The goal of the screening-level approach is to evaluate the surface water, drinking water, and ambient air pathways for carbon tetrachloride that were excluded from the 2020 risk evaluation, and to determine if there are risks that were unaccounted for in the risk evaluation. EPA states that it expects to describe its findings regarding the chemical-specific application of this screening-level approach in its proposed risk management rule for carbon tetrachloride.

Additionally, EPA expects to focus its risk management action on the COUs that drive the unreasonable risk. EPA notes that it is not limited to regulating the specific activities found to drive unreasonable risk, however, and may select from among the range of risk management requirements included in TSCA Section 6(a). EPA states that as a general example, it may regulate upstream activities (*e.g.*, processing, distribution in commerce) to address downstream activities (*e.g.*, consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

Commentary

Bergeson & Campbell, P.C. (B&C[®]) notes that EPA has now released in final seven of the eight revised risk determinations issued since March 2022. The first six final revised risk determinations are available at: 1-Bromopropane (**1-BP**), Colour Index Pigment Violet 29 (**PV29**), Cyclic Aliphatic Bromide Cluster (**HBCD**), Methylene Chloride (**MC**), N-Methylpyrrolidone (**NMP**), and Perchloroethylene (**PCE**). B&C anticipates that EPA will release the final revised risk determination for Trichloroethylene (**TCE**) in the forthcoming weeks. Each of these documents incorporates EPA's new policy directions for making unreasonable risk determinations for the whole chemical substance and assuming that PPE is not always appropriately worn. EPA incorporated these same policy directions in the final revised risk determination for carbon tetrachloride. We refer readers to the Commentary in our November 11, 2022, [memorandum](#) that summarizes the issues with EPA's new policy directions and other issues that permeate each of EPA's final risk evaluations and final revised risk determinations. Below, we focus our discussion on issues that relate to the final risk evaluation on carbon tetrachloride, including EPA's proposed existing chemical exposure limits (ECEL), consumer exposures, and EPA's discrepant practices for new and existing chemical substances.

As we noted in our August 30, 2022, [memorandum](#), B&C anticipates that the carcinogenic mode-of-action conclusion in the *Final Risk Evaluation for Carbon*

Tetrachloride will be strongly contested by the regulated community. We recognize that there are advocates on both sides of the question whether a threshold (non-linear) or linear (non-threshold) approach should be used. We note, however, as we did in our August 30, 2022, [memorandum](#) that the TSCA Science Advisory Committee on Chemicals (SACC) [recommended](#) that “EPA should apply a non-linear model in estimating cancer risks, in light of the preponderance of evidence that [cellular toxicity, not mutagenicity is] the origins of tumors of the liver and adrenal gland.” EPA ended up doing so, in part, when calculating the ECEs for carbon tetrachloride. For example, EPA calculated [a chronic non-cancer ECEL](#) of 0.2 ppm from rat data on fatty changes in the liver and [a chronic cancer ECEL](#) of 0.03 ppm from female mouse data on [liver](#) adenomas using a threshold (non-linear) approach, which EPA considered protective of adrenal tumors that it [evaluated](#) using a linear (non-threshold) approach. EPA did not address these points in its updated risk evaluation.

As we mentioned in our August 30, 2022, [memorandum](#), EPA [stated](#) in the *Federal Register* notice for the draft revised risk determination that it “expects that consumer use of [products that contain carbon tetrachloride as an impurity] present only negligible exposure to carbon tetrachloride...”, based on CPSC’s ban on “...the use of carbon tetrachloride in consumer products (excluding unavoidable residues not exceeding 10 ppm atmospheric concentration) in 1970.” EPA reiterated this information in its [press release](#) dated December 27, 2022, for the final revised risk determination as the basis for not “...evaluat[ing] risks to consumers.” Interestingly, the formal *Federal Register* notice for the final revised risk determination on carbon tetrachloride was silent on the CPSC ban and EPA’s decision not to quantify potential unreasonable risks to consumers.

Another point we raised in our August 30, 2022, [memorandum](#) was the dichotomy EPA created for new and existing chemical substances. For new chemicals, EPA discontinued the use of “negligible” exposure modeling thresholds (for further discussion on this issue, see our [memorandum](#) dated August 22, 2022), yet for existing chemicals, EPA excluded specific exposure pathways based upon a conclusion of “negligible” exposures, including in [the Final Risk Evaluation for Carbon Tetrachloride](#). We remind readers that EPA [concluded](#) that “the peer reviewed hazard and exposure assessments and associated risk characterization [in the *Final Risk Evaluation for Carbon Tetrachloride* were] robust and uph[eld] the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).” We further remind readers that the distinction between new and existing chemical substances is a legal one, not a scientific one. While we generally support conclusions of negligible exposures, discrepant practices of this type should include robust scientific justifications, not mere statements that its conclusions uphold the scientific standards under TSCA Section 26 just because EPA says so.

B&C encourages readers to consider the above issues, as well as those referenced herein, as EPA moves forward with its draft risk management rules. It is imperative that scientific and legal issues be raised repeatedly during the public comment periods for EPA’s draft risk evaluations and its forthcoming draft risk management rules. We expect that doing so will not alter EPA’s final decisions. Doing so, however, builds the requisite administrative record for challenging EPA’s final risk management rules in court, should that become the only tenable option for establishing scientifically and legally sound regulations moving forward.

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