



HSIA

halogenated
solvents
industry
alliance, inc.

September 18, 2017

Stephanie Jarmul
US Environmental Protection Agency
Docket Center
1301 Constitutional Avenue, N.W.
Washington DC 20004

Re: Carbon Tetrachloride – EPA – HQ-OPPT-2016-0733

Dear Ms. Jarmul:

Pursuant to an EPA memorandum posted to the above referenced docket on June 19, 2017, HSIA is submitting additional information to support the use of scientifically appropriate occupational exposure levels to be used by EPA when conducting risk evaluations for chemicals used in the manufacturing setting. We encourage EPA to state in the problem formulation for carbon tetrachloride that occupational exposure levels will be used in the risk evaluation. There are strong reasons to support this determination for carbon tetrachloride in the problem formulation document:

1. Worker exposures to carbon tetrachloride are regulated under the Occupational Safety and Health Act (OSH Act) which is designed to regulate risk to worker populations through exposure monitoring, controls, and personal protective equipment (PPE).
2. As required by the Clean Air Act and implementing EPA regulations, the use of carbon tetrachloride is limited to feedstock use where the carbon tetrachloride is transformed into other products in chemical processes, and other essential uses as approved by EPA.¹

To efficiently carry out the Congressional mandate to review all chemicals in commerce, EPA must maintain the flexibility to issue a decision on specific conditions of use in stages. 40 CFR 702.41(a)(9); *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, Final Rule*, 82 Fed Reg 33729/2 (July 20, 2017). The Occupational Safety & Health Administration (OSHA) standards and protections already in place, together with the heavily regulated nature of carbon tetrachloride, support making a no unreasonable risk determination for occupational exposures early in the risk evaluation process.

HSIA #0013 lists the primary uses of carbon tetrachloride: 1) feedstock in manufacturing processes, including for next generation, low global warming potential (GWP) refrigerants; 2) processing agent for industrial production; and 3) limited uses in laboratories. Other uses would be subject to regulatory restrictions/prohibition and thus are not reasonably foreseen. Employee activities with potential exposure

¹ Additional sources and information regarding the regulations already imposed upon carbon tetrachloride were submitted in the HSIA Executive Summary submittal (EPA-HQ-OPPT-2016-0733-0013 (HSIA #0013)); HSIA Comment on Carbon Tetrachloride (EPA-HQ-OPPT-2016-0733-0007 (HSIA #0007)) and supplement letter for Carbon Tetrachloride (EPA-HQ-OPPT-2016-0733-0008 (HSIA #0008)).

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to carbon tetrachloride in the workplace are involved in generally short-term and time-limited, including conducting filter changes, transferring waste, loading/unloading tank cars and sample collection activities, all while wearing appropriate PPE.² The limited conditions of use of carbon tetrachloride in the manufacturing and industrial sectors also support making a no unreasonable risk determination for carbon tetrachloride early in the risk evaluation process.

OSHA PEL Values and Evaluating Risks to Workers

As originally enacted and as updated by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), TSCA requires EPA to consult and coordinate with other federal agencies "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."³ Worker safety falls under the jurisdiction of OSHA. The use of carbon tetrachloride is already adequately regulated under the OSH Act.

The Lautenberg Act eliminated the requirement in TSCA § 6(a) that EPA protect "against [unreasonable] risk using the least burdensome requirements," but did not materially change the existing framework that requires unreasonable risks to be addressed under statutory authority other than TSCA wherever possible. EPA's longstanding interpretation of this framework is as follows:

"Under section 9(a)(1) of TSCA, the Administrator is required to submit a report to another Federal agency when two determinations are made. The first determination is that the Administrator has reasonable basis to conclude that a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The second determination is that the unreasonable risk may be prevented or reduced to a sufficient extent by action taken by another Federal agency under a Federal law not administered by EPA. Section 9(a)(1) provides that where the Administrator makes these two determinations, EPA must provide an opportunity to the other Federal agency to assess the risk described in the report, to interpret its own statutory authorities, and to initiate an action under the Federal laws that it administers.

"Accordingly, section 9(a)(1) requires a report requesting the other agency: (1) To determine if the risk may be prevented or reduced to a sufficient extent by action taken under its authority, and (2) if so, to issue an order declaring whether or not the activities described in the report present the risk described in the report.

"Under section 9(a)(2), EPA is prohibited from taking any action under section 6 or 7 with respect to the risk reported to another Federal agency pending a response to the report from the other Federal agency. There would be no similar restriction on EPA for any risks associated with a chemical substance or mixture that is not within the section 9(a)(1) determinations and therefore not part of the report submitted by EPA to the other Federal agency."⁴

² HSIA #0013 also provides information on regulations applicable to carbon tetrachloride, and a summary of the halogenated manufacturing process, which includes carbon tetrachloride.

³ TSCA § 9(d).

⁴ 4,4'-Methylenedianiline; Decision to Report to the Occupational Safety and Health Administration, 50 Fed. Reg. 27674 (July 5, 1985). EPA also has acted under § 9(a) to refer 1,3-butadiene and glycol ethers to OSHA, 50 Fed. Reg. 41393 (Oct. 10, 1985) and 51 Fed. Reg. 18488 (May 20, 1986), respectively, and to refer dioxins in bleached wood pulp and paper products to the Food and Drug Administration, 55 Fed. Reg. 53047 (Dec. 26, 1990).

It was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. When TSCA was enacted in 1976, Representative James Broyhill of North Carolina indicated that “it was the intent of the conferees that the Toxic Substance Act not be used, when another Act is sufficient to regulate a particular risk.”⁵ TSCA § 9(a) is substantively unchanged by the Lautenberg Act. The House Energy and Commerce Committee Report states: “H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals,” and further clarifies that “while § 5 makes no amendment to TSCA § 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety.”⁶

Indeed, TSCA § 9 was strengthened by the Lautenberg Act, and it was clear from the outset that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks. Representative James Broyhill of North Carolina indicated that “it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk.”⁷ EPA applied this statutory directive in determining that the risk from 4,4' methylenedianiline (MDA) could be prevented or reduced to a significant extent under the OSH Act, and referring the matter for action by OSHA.⁸ And in an analysis of TSCA § 9, EPA's Acting General Counsel concluded that “Congress expected EPA – particularly where the Occupational Safety and Health Act was concerned – to err on the side of making referrals rather than withholding them.”⁹

If EPA were to identify a category of exposure deemed to present a risk that is unreasonable, these considerations indicate that referral under § 9(a) would be the appropriate course.¹⁰ It is clear from Section 9(a) that TSCA is to be used only when other statutes fail to provide a remedy for unreasonable risks.

EPA codified this principle in the Risk Evaluation Rule. 40 C.F.R. §702.39. EPA should adopt the OSHA permissible exposure limits (PELs) as the appropriate screening levels for potential risks to

⁵ 122 Cong. Rec. H11344 (Sept. 28, 1976).

⁶ H. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28.

⁷ 122 Cong. Rec. H11344 (Sept. 28, 1976).

⁸ 50 Fed. Reg. 27674 (July 5, 1985).

⁹ Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2.

¹⁰ As noted above, TSCA § 9(a) provides that if the Administrator has reasonable basis to conclude that an unreasonable risk of injury is presented, and he determines, in his discretion, that the risk may be prevented or sufficiently reduced by action under another federal statute not administered by EPA, then the Administrator shall submit a report to that agency describing the risk. In the report, the Administrator shall request that the agency determine if the risk can be prevented or sufficiently reduced by action under the law administered by that agency; if so, the other agency is to issue an order declaring whether the risk described in the Administrator's report is presented, and is to respond to the Administrator regarding its prevention or reduction. The Administrator may set a time (of not less than 90 days) within which the response is to be made. The other agency must publish its response in the Federal Register. If the other agency decides that the risk described is not presented, or within 90 days of publication in the Federal Register initiates action to protect against the risk, EPA may not take any action under § 6 of TSCA.

workers. If the 90th percentile estimates from the 8-hour time-weighted average (TWA) exposure concentrations are at or below the OSHA PELs, EPA should conclude a condition of no significant risk for worker exposures. However, it is possible that EPA could, if scientifically appropriate, decide to apply more recent American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) to evaluate potential risks to workers.

Occupational exposure limits, such as OSHA PELs and ACGIH TLVs, are derived to be protective for occupational exposures. The values are typically based on occupational epidemiology studies and, therefore, are especially relevant for worker populations. For example, occupational studies by their very nature include consideration of the healthy worker effect.¹¹ Occupational exposure limits also consider other factors unique to the workplace, such as technical feasibility. In general, occupational exposure limits should be considered protective for worker exposures. Such limits and their bases should be part of worker risk evaluations under the new TSCA.

In particular, the OSHA PEL of 10 ppm for carbon tetrachloride is based on experiences of nausea in workers at concentrations of 25 ppm (OSHA, 1971; NIOSH 1975; ACGIH 1971). The occupational exposure limit derived by ACGIH (TLV) for carbon tetrachloride (ACGIH, 2001) (5 ppm) is based on scientific information for carbon tetrachloride that supports a cytotoxic threshold mode of action for carcinogenicity (*i.e.*, carbon tetrachloride is almost uniformly negative in genotoxicity/mutagenicity assays (Eastmond, 2008), with only a few results indicating a positive response – most of which are explained by extreme cytotoxicity/hepatotoxicity at very high doses creating reactive cellular degradation products (such as reactive oxygen species)).¹² In other words, the current occupational epidemiology studies (and animal studies) for carbon tetrachloride indicate that worker exposures to concentrations at or below 5 ppm would not result in an increased cancer risk in a worker population (ACGIH, 2001). A cytotoxic threshold mode of action for carbon tetrachloride is also supported by the Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profile for carbon tetrachloride (ATSDR, 2005). As discussed by ACGIH (2001), the 5 ppm TLV is further supported by a physiologically-based pharmacokinetic (PBPK) model for inhaled carbon tetrachloride (Paustenbach *et al.*, 1988) that predicts that occupational exposure at 5 ppm carbon tetrachloride results in a biologically effective dose to human liver tissue well below the lowest liver dose estimated to result in toxicity in animals. Therefore, both the OSHA PEL level of 10 ppm and the alternative ACGIH TLV of 5 ppm provide scientifically robust risk-based occupational exposure limit that should be considered applicable to worker risk evaluation under TSCA.

Exposure Data and PPE Reductions

The HSIA #0007 lists the primary feedstock and industrial uses of carbon tetrachloride. All tasks at the industrial facilities that manufacture, process or use carbon tetrachloride as feedstock also require the use of personal protective equipment (PPE), as described in the HSIA comment letter submitted to EPA on March 15, 2017. (HSIA #0013)

¹¹ A healthy worker effect is based on observations in occupational epidemiology studies that workers usually exhibit lower overall death rates than the general population because the severely ill and chronically disabled are ordinarily excluded from employment (Li *et al.* 1999).

¹² 'However, in light of the very weak or nonexistent genotoxicity of carbon tetrachloride, particularly in mammalian cells *in vivo*, it appears more likely that its (primarily hepatic) carcinogenicity in rodent bioassays (observed only at doses that are also associated with acute and/or chronic toxicity) was caused by increased cell proliferation in response to induced cell killing and, therefore, that noncytotoxic doses of carbon tetrachloride were not capable of increasing cancer risk.' (ACGIH, 2001).

HSIA #0013 provided a range of 330 samples collected over 11 years for Company B. The 90th percentile carbon tetrachloride concentration calculated from the 330 full-shift samples included in the sample range is 0.27 ppm, well below the ACGIH TLV and the OSHA PEL. The exposure data collected and provided by HSIA on 3/15/2017 (HSIA #0013) represent breathing zone concentrations outside of PPE; therefore, any exposure concentration is further reduced by PPE. The effective exposure concentration from all samples taken would be 10-fold less than the PEL when considering the PPE worn by the workers.¹³ At a minimum, facilities that manufacture carbon tetrachloride or use it as a feedstock require a half-mask air-purifying respirator with acid/gas organic vapor cartridges which has an APF of 10. Where a half-mask air-purifying respirator is worn, goggles are also required. If a full-face air-purifying respirator is selected, goggles are not required to be worn. Chemical protective gloves are worn for tasks involving potential for dermal contact.

Based upon the regulations already in place for carbon tetrachloride, together with the knowledge that its uses are largely limited to the manufacturing and industrial sectors, we request that EPA consider a streamlined risk evaluation for carbon tetrachloride in the draft problem formulation. We also request that such an evaluation consider appropriate and science-based occupational exposure limits when evaluating unreasonable risk. Please do not hesitate to contact Faye Graul (fgraul@hsia.org) if you have any questions or need additional information.

¹³ An assigned protection factor (APF) of 10 used with a substances that has a 10 ppm permissible exposure limit can be expected to provide the appropriate protection up to 100 ppm (10(APF) x 10 ppm (PEL)).