BEFORE THE ENVIRONMENTAL PROTECTION AGENCY

Comments on Carbon Tetrachloride; Regulation Under
the Toxic Substances Control Act
(TSCA)
88 Fed. Reg. 49180 (July 28, 2023)
EPA-HQ-OPPT-2020-0592

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The Halogenated Solvents Industry Alliance, Inc. (HSIA) represents manufacturers and users of chlorinated solvents, including carbon tetrachloride (CTC). A list of HSIA's members is attached (Attachment A). We appreciate the opportunity to provide these comments in response to the proposed rule governing the manufacture, processing, and use of CTC under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 49180 (July 28, 2023). The proposed rule would impose limits on worker exposure which are much more restrictive than those imposed by the Occupational Health & Safety Administration (OSHA) or in effect elsewhere in the world. We address in turn below a number of significant deficiencies in the proposed rule that show it is not based on best available science or supported by substantial evidence, as required by TSCA.

As will be discussed more fully below, the proposed rule breaks down into (i) 7 conditions of CTC use where EPA found unreasonable risk to workers and proposes to ban the use[1] and (ii) specific requirements for 9 conditions of use not prohibited. The 9 allowed uses would be subject to Workplace Chemical Protection Program (WCPP) requirements to be implemented by employers.[2] Most notably, these include an Existing Chemical Exposure Limit (ECEL) of 0.03 parts per million (ppm) (8-hour time weighted average (TWA)). EPA's proposed 0.03 ppm ECEL value is intended to address unreasonable risk for cancer as well as for non-cancer effects. These cancer endpoints are addressed in Section II(B) below including:

- CTC is a liver tumorigen with a threshold mode of action (MOA) involving toxicity to liver cells (cell death) with a resulting compensatory proliferation (hyperplasia). An ECEL value based on liver tumors using the best available science is 1.5 ppm as an 8-hour TWA.
- Mouse pheochromocytomas should not be used to evaluate human cancer risk to CTC as these tumors occur under conditions that are not relevant to humans.

Section III then includes several recommendations specific to the proposed rule and WCPP implementation, including:

- Additional time is needed for WCPP development and ECEL implementation requirements to accommodate any new occupational exposure limit (OEL), especially one as low as the proposed ECEL.
- Monitoring technologies must be identified and lab methodologies verified for the proposed ECEL.

[1] 88 Fed. Reg. at 49202.

[2] *Id.* at 49194.

- Industrial hygiene professionals will need time to plan for revised risk assessments at each facility to accommodate the new ECEL and account for the much lower limits of detection (LODs).
- The WCPP should clarify that values may be evaluated for tasks as well as full shifts.

While many of the WCPP concerns listed above are cross-cutting issues applicable to many of the initial ten risk management rule proposals, a couple of issues unique to CTC are presented in these comments for EPA's consideration:

- EPA should clarify that recovery of tail gas, as well as elimination of nitrogen trichloride, both part of chlorine and caustic soda production, are allowed conditions of use (COUs) subject to WCPP requirements.
- EPA should recognize that use of recycled CTC as feedstock in the manufacture of perchloroethylene is also an allowed COU.

Importantly, both of these are ongoing COUs allowed under the Montreal Protocol.

The extremely low ECEL proposed by EPA is at least an order of magnitude lower than workplace limits in effect in other countries.[3] If adopted, this would obviously have major implications for the competitiveness of American manufacturing. We submit that this divergence from every other country in the world also indicates that something is profoundly wrong with EPA's "unreasonable risk" findings, of which CTC appears, on the evidence of Attachment B, to be representative. As described in detail in § II below, Gradient has derived an ECEL value of 1.5 ppm, 50 times higher than the ECEL proposed by EPA.[4] Significantly, Gradient's derivation, based on benchmark dose and physiologically-based pharmacokinetic (PBPK) modeling, aligns with the dose-response approach used by EPA in an earlier assessment of CTC under a different Agency program.[5]

In a case of similar overreach by OSHA, involving comparable language in the Occupational Safety and Health Act ("OSH Act") defining an occupational safety and health standard as one "reasonably necessary or appropriate to provide safe or healthful employment,"

[3] The table at Attachment B compares the ECEL for CTC (and those proposed/expected for a number of other compounds) to workplace limits in effect in France, Germany, Canada, and Mexico, as well as the OSHA limits.

[4] Gradient, Comments on the US EPA's carbon tetrachloride existing chemical exposure levels (ECELs) and ambient air pathway evaluation for fenceline communities – as incorporated into the proposed risk management rule under TSCA (2023) (Attachment C).

[5] EPA, Toxicological Review of Carbon Tetrachloride (CAS 56-23-5) in Support of Summary Information on the Integrated Risk Information System (IRIS), EPA/635/R-08/005F (2010) (hereafter "IRIS Assessment").

the Supreme Court found a duty on OSHA's part to make a finding that a workplace exposure was unsafe before adopting a workplace standard.[6] OSHA must quantify a "certain" level of risk and conclude that it is "significant" before regulating.[7] These findings must be supported by substantial evidence. The comments that follow show how EPA, in implementing a statute of similar vintage and wording (the OSH Act was enacted in 1970; TSCA in 1976) has departed from the TSCA statutory directive.[8]

EPA selected CTC as one of the initial ten substances to be evaluated under TSCA as amended in 2016. CTC is an industrial chemical that was once in widespread use but is now tightly regulated under the Montreal Protocol on Substances That Deplete the Ozone Layer and Title VI of the Clean Air Act (CAA). Because of its ozone depletion potential, this regulatory program phased out the manufacture and import of CTC over 20 years ago, subject to limited exceptions for use as a process agent or feedstock, where by definition it is "used and entirely consumed (except for trace quantities)."[9] Furthermore, facilities that manufacture CTC and use it as an intermediate are covered by National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI),[10] which require closed systems where exposure is tightly controlled. And such facilities must meet OSHA workplace limits.

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[6] *Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al.,* 448 U.S. 607 (1980) (*"Benzene"*).

[7] "By empowering the Secretary to promulgate standards that are 'reasonably necessary or appropriate to provide safe or healthful employment and places of employment,' the Act implies that, before promulgating any standard, the Secretary must make a finding that the workplaces in question are not safe. But 'safe' is not the equivalent of 'risk-free.' There are many activities that we engage in every day -- such as driving a car or even breathing city air -- that entail some risk of accident or material health impairment; nevertheless, few people would consider these activities 'unsafe.' Similarly, a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm." *Id.* at 642.

[8] By raising the *Benzene* decision, HSIA does not mean to imply that the risks of perc are in any way comparable to those of benzene. Benzene is a known human leukemogen. The driver for the CTC Risk Evaluation is potential carcinogenicity. Unlike benzene, however, CTC is not a known human carcinogen. Yet the ECEL proposed for perc is only a tiny fraction of the 1 ppm limit for benzene overturned by the Supreme Court. The concerns expressed by the Court in *Benzene* apply many times over to the regulation of CTC.

[9] Title VI of the Clean Air Act (implementing the Montreal Protocol on Substances That Deplete the Ozone Layer) restricts the production and consumption of carbon tetrachloride. "The manufacture of a substance that is used and entirely consumed (except for trace quantities) in the manufacture of other chemicals" is excluded from the definition of production, as is "the reuse or recycling of a substance." 42 U.S.C. § 7671(11). *See also* the implementing regulations at 40 C.F.R. Part 82, Subpart A.

[10] 40 C.F.R. 63 Subparts F, G, H, I (hereafter "the NESHAP").

EPA's proposed 0.03 ppm ECEL value is intended to address unreasonable risk for cancer as well as for non-cancer effects. These endpoints are addressed in Section II below. Thereafter, § III provides recommendations to modify the proposed rule's implementation of WCPPs. The remainder of the comment addresses additional concerns relating to specific COUs, *de minimis*, distribution, and export as discussed in the preamble and the proposed rule.

I. SUMMARY LEGAL FRAMEWORK

TSCA provides EPA authority to regulate the use of chemical substances, to impose reporting, record-keeping and testing requirements, and to limit conditions of use. Section 6(a), relevant here, requires EPA to promulgate regulations to restrict the use of chemical substances where they "present[] an unreasonable risk of injury to health or the environment." Section 6(a) permits EPA to limit, condition, and prohibit the use of any chemical substance where it presents an unreasonable risk. As noted above, Section 6(a) further states that EPA should apply requirements for addressing unreasonable risks "to the extent necessary so that the chemical substance or mixture no longer presents such risk."

TSCA § 6(c) provides that "In selecting among ... restrictions," EPA "shall factor in, to the extent practicable," considerations such as "the effects of the chemical ... on the environment," "the benefits of the chemical substance or mixture for various uses," and "the reasonably ascertainable economic consequences of the rule. The assessment of economic consequences must include the "costs and benefits" and the "cost effectiveness" of the "proposed and final regulatory action" as well as of at least one alternative. EPA must publish a statement discussing those factors.. If a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."

The 2016 Lautenberg Act also added substantive requirements that appear in TSCA § 26. TSCA § 26(h): "In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information. . .employed in a manner consistent with the best available science. . . and shall consider as applicable—(5) the extent of independent verification or peer review of the information. . . ." TSCA § 26(i): "The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence."

Finally, TSCA § 17(c) makes clear that both the final rule and the associated determination of unreasonable risk shall be held unlawful and set aside "if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole."

II. THE RISK EVALUATION DOES NOT REFLECT BEST AVAILABLE SCIENCE OR THE WEIGHT OF THE SCIENTIFIC EVIDENCE

The OSHA Permissible Exposure Limit (PEL) for CTC, adopted in 1971, is 10 ppm.[11] The Threshold Limit Value (TLV©) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) is 5 ppm as an 8-hour TWA. Compliance with the TLVs has long been recommended by HSIA members.

EPA's Office of Pollution Prevention & Toxics (OPPT) in the CTC Risk Evaluation, on the other hand, asserts that CTC is a probable human carcinogen to justify a much, much lower proposed limit, without regard to HSIA's extensive comments as described below. Notably, the Revised Risk Determination does not even mention the carcinogenicity issue.[12] Yet it is well-established that "[a]n agency must consider and respond to significant comments received during the period for public comment."[13] In summary, OPPT's Risk Evaluation mischaracterized the findings from the epidemiology studies that investigated cancer in CTC-exposed workers and the general population.[14]

A. EPA's assessments of CTC cancer risk are scientifically unsound and do not reflect either the "best available science" or the "weight of the scientific evidence" as required by TSCA

The proposed ECEL of 0.03 ppm (30 ppb) as an 8-hour TWA is intended to address unreasonable risk for cancer and chronic toxicity for non-cancer effects. The Risk Evaluation used two different approaches to assess cancer risk, both based on the findings from the two-year

[11] 29 C.F.R. part 1910, subpart Z.

[12] EPA, Carbon Tetrachloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination (December 2022) (hereafter "Revised Risk Determination"), EPA-HQ-OPPT-2016-0733-0120; *see also* Carbon Tetrachloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination, Response to Public Comments (December 2022), EPA–HQ–OPPT–2016–0733-0119.

[13] *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015).

[14] Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-); EPA-740-R1-8014 (November 2020) (hereafter "Risk Evaluation"); EPA-HQ-OPPT-2019-0499-0047.

rat and mouse inhalation study by Nagano *et al.* (2007).[15] One was derived from the increased incidence of mouse liver tumors assuming a mode-of-action (MOA) with a threshold dose-response, as recommended by EPA's Science Advisory Committee on Chemicals (SACC) in its peer review of the draft CTC Risk Evaluation. The other approach is based on mouse pheochromocytomas (adrenal gland tumors) and assumes a linear, no-threshold MOA. Both approaches used by OPPT to assess the human cancer risk of CTC are scientifically unsound and do not reflect the "best available science" as required by TSCA.

1. The increase in female mouse liver tumors at the lowest exposure level (5 ppm) in Nagano *et al.* (2007) is not treatment-related.

Nagano *et al.* (2007) exposed male and female F344 rats and BDF1 mice to 0, 5, 25, or 125 ppm CTC for 6 hours/day, 5 days/week for 104 weeks. In rats, the incidence of liver carcinomas and adenomas was significantly increased in both sexes at 125 ppm, but not at 5 or 25 ppm. Chronic liver toxicity was also seen in the male and female rats at 25 and 125 ppm, but not at 5 ppm. In mice, there was a significant increase in liver tumors (adenomas and carcinomas) in both males and female at 25 and 125 ppm. At 5 ppm, Nagano *et al.* (2007) reported a significant increase in liver adenomas in the female mice, but not for adenomas and carcinomas combined.

The CTC Risk Evaluation concludes "that the low dose female adenoma result is likely compound related" and thus 5 ppm is the Lowest-Observed-Adverse-Effect-Concentration (LOAEC) for liver tumors in Nagano *et al.* (2007).[16] This conclusion is scientifically flawed in several ways.[17] First, OPPT relied upon limited information on the historical spontaneous liver tumor incidence of BDF1 mice at the Japan Bioassay Research Center (JBRC) where the CTC bioassay was conducted. More comprehensive historical control data from this laboratory shows that the incidence of liver tumors (adenomas, carcinomas, and combined adenomas plus

[15] Nagano, K *et al.*, Inhalation carcinogenicity and chronic toxicity of carbon tetrachloride in rats and mice, *Inhal. Toxicol.* 19: 1089-1103 (2007).

[16] Risk Evaluation, at 166.

[17] Cohen, SM, Bevan, C, Gollapudi, B, Klaunig, JE, Evaluation of the carcinogenicity of carbon tetrachloride. *J. Toxicol. Environ. Health, Part B* 342: 342-370 (2023) (Attachment D).

carcinomas) at 5 ppm in the CTC study was indeed within the historical range for this strain of mouse.[18]

A second reason for OPPT's mistaken conclusion that 5 ppm represents a LOAEC for liver tumors in Nagano *et al.* (2007) is its interpretation of the statistical analysis. In its response to external peer review and public comments on the draft CTC Risk Evaluation, OPPT noted "the significance of the 8/49 adenomas in the 5 ppm dose female group as compared with 2/50 in the matched controls is P = 0.05, which is statistically significant in the IRIS assessments and TSCA risk evaluations."[19] This is not entirely correct; a re-analysis of the data using the Fisher's exact test resulted in the p value = 0.05112; this may or may be considered significant at the p = 0.05 level of significance depending on whether the p value is rounded off. Nevertheless, the statistical consideration of the increase of liver adenomas in the 5 ppm-exposed females must be reconsidered from the perspective of these tumors being common. For common tumors, Haseman (1983) stated that the statistical significance for tumor incidences should be based on the probability of $p < 0.01$ rather than $p < 0.05$ because of the multiple comparisons and to avoid the high probability of false positives.[20] Certainly, liver cell hepatocellular tumors in mice are a common tumor (as defined by Haseman as tumors with spontaneous incidence of >1%). This statistical standard has been adopted by the Food and Drug Administration (FDA),[21] and was extended to have the trend test be significant only if $p < 0.005$, rather than 0.01. The Organization for Economic Co-operation and Development (OECD) has also accepted this standard of $p < 0.01$ for comparison of incidences of common tumors.[22] OPPT is departing from these standards set by corresponding organizations.

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[18] *Id.*

[19] Summary of External Peer Review and Public Comments and Disposition for Carbon Tetrachloride (Methane, Tetrachloro-) CASRN: 56-23-5 (October 2020) (hereafter "Response to Comments on Risk Evaluation"), at 102; EPA-HQ-OPPT-2019-0499-0062.

[20] Haseman, JK, A reexamination of false-positive rates for carcinogenesis studies. *Fundam. Appl. Toxicol.* 3: 334-339 (1983).

[21] FDA, Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals, Draft Guidance (2001); https://www.fda.gov/media/72296/download.

[22] OECD Guidance Document 116 on the conduct and design of chronic toxicity and carcinogenicity studies, supporting test guidelines 451, 452, and 453, 2nd Edition (2012). https://www.oecd-ilibrary.org/docserver/9789264221475-en.pdf?expires=1663207771&id=id&accname=guest&checksum=CF8F7C009CE8F2CCC366CB04F82B72A3.

Most importantly, OPPT failed to consider total liver tumor incidence (adenomas and carcinomas) in the 5 ppm-exposed female mice in its decision on a point-of-departure (POD) for its cancer risk assessment. While there may be an increase in the liver adenomas in the 5 ppm-exposed female mice, the incidence of total liver tumors (adenomas plus carcinomas) was *not significantly* increased compared to controls (9/49 vs. 4/50, respectively). It is well known that the comparison of liver tumors needs to be made on total tumor incidence, not on adenomas or carcinomas separately. Indeed, this has been recognized by EPA, as indicated in the following statements from its 2012 IRIS Assessment for perchloroethylene:

> "Because hepatic adenomas and carcinomas are considered part of the same continuum of tumor development, and adenomas may be differentiated from carcinomas only on the basis of size, this analysis emphasizes the combined incidences of these two tumor types."[23]

> "EPA generally emphasizes combining hepatocellular adenomas and carcinomas in developing cancer risk values, for three reasons: (1) hepatocellular adenomas develop from the same cell lines as carcinomas and can progress to carcinomas; (2) adenomas are often distinguished from carcinomas only on the basis of size; and (3) histopathologic decision criteria may vary between laboratories or over time."[24]

In the CTC Risk Evaluation itself (and previously by EPA in the 2010 IRIS Assessment for CTC) OPPT used total liver tumors (adenomas plus carcinomas) and not adenomas in the CTC-exposed female mice from the Nagano study for benchmark dose modeling in its cancer risk assessment. Thus, OPPT's interpretation of 5 ppm in the Nagano study as being a treatment-related effect for liver tumors is at odds with its scientific position on how liver tumors should be evaluated for cancer risk.

A LOAEC of 25 ppm and a NOAEC of 5 ppm for mouse and rat liver tumors in the two-year inhalation study by Nagano *et al.* (2007) is consistent with a mode of action (MOA) involving toxicity to liver cells (cell death) resulting in compensatory proliferation (hyperplasia).[25] For the formation of tumors, cell injury must occur to a sufficient level to result in hepatocyte cell proliferation; this occurs only from chronic exposures. Thus, the proper

[23] EPA Integrated Risk Information System (IRIS) Review of Toxicological Information on Tetrachloroethylene (Perchloroethylene) (2012), at 5-42.

[24] *Id.*, at C-1.

[25] Cohen *et al*. (Attachment D).

weight-of-the-evidence conclusion is that CTC exposures that do not initiate sufficient cytotoxicity to elicit compensatory hyperplasia do not start the cascade to tumor formation.[26]

2. EPA's derivation of an ECEL based on liver tumors is not consistent with generally accepted (including its own) methodology

For the ECEL based on liver tumors, OPPT applied a LOAEC/NOAEC approach and used 5 ppm (the lowest exposure concentration tested) in Nagano *et al.* (2007) as the LOAEC for the point-of-departure (POD). OPPT considered the increase in liver adenomas in the 5 ppm CTC-exposed female mice to be treatment-related. Excluding EPA's exposure duration adjustments to continuous exposure and then back to an occupational exposure scenario, the LOAEC value was adjusted to a human equivalent concentration (HEC) using a dosimetric adjustment factor (DAP) of 1.[27] A total uncertainty factor (UF) of 300 was then applied to derive the ECEL value: 3 for variability in response between species; 10 for variability in the human response and to protect susceptible individuals, and 10 to account for use of a LOAEC. The resulting ECEL value is 0.03 ppm.

The fundamental problem with OPPT's approach for deriving this ECEL value based on liver tumors is that it is not the "best available science" as required under TSCA. OPPT used a LOAEC/NOAEC approach for determining the POD instead of benchmark dose (BMD) modeling, which is EPA's preferred approach for dose-response assessments.[28] In addition, while CTC PBPK models are available in the rat, mouse, and humans,[29] OPPT did not use these models to derive the ECEL value, consistent with best available science. PBPK modeling

[26] Following a court decision, EPA acknowledged such an MOA for chloroform. When "adequate data on mode of action show that linearity is not the most reasonable working judgment and provide sufficient evidence to support a nonlinear mode of action," the default assumption of linearity drops out. Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. at 17,969/1." *Chlorine Chemistry Council v. E.P.A*, 206 F.3d 1286 (D.C. Cir., 2000).

[27] EPA, Advances in inhalation gas dosimetry for derivation of a reference concentration (RfC) and use in risk assessment. EPA/600/R-12/044 (2012).

[28] EPA, Benchmark Dose Technical Guidance, EPA/100/R-12/001 (2012); Davis, JA, Gift, JS, Zhao, QJ, Introduction to benchmark dose methods and U.S. EPA's benchmark dose software (BMDS) version 2.1.1. *Toxicol. Appl. Pharmacol.* 254: 181-191 (2011); Risk Evaluation, at 339.

[29] Thrall, KD *et al.*, Evaluation of a carbon tetrachloride physiologically based pharmacokinetic model using real-time breath analysis monitoring of the rat. *Inhal. Toxicol.* 8: 251-261 (2000); Fisher, J *et al.*, PBPK modeling of the metabolic interactions of carbon tetrachloride and tetrachloroethylene in B6C3F1 mice. *Environ. Toxicol. Pharmacol.* 16: 93-105 (2004); Paustenbach, DJ *et al.*, Development of a physiologically based pharmacokinetic mode for inhaled carbon tetrachloride. *Toxicol. Appl. Pharmacol.* 96: 191-211 (1988).

provides a more scientific approach to converting CTC exposures from the animal studies to human equivalent concentrations by estimating dose in the target organ of concern, in this case the liver. As noted by OPPT in the Risk Evaluation, "Because the MOA for carbon tetrachloride-induced hepatotoxicity involves metabolism to reactive metabolites in the liver, the HECs based on the mean rate of metabolism in the liver (MRAMKL) dose metric is the most proximate to the critical effect."[30] These omissions are very surprising since EPA had used both the BMD methodology and PBPK modeling in its 2010 IRIS assessment for CTC in deriving both the non-cancer Reference Concentration (RfC) and the Inhalation Unit Risk (IUR) value for assessing cancer risk using the same rat and mouse data from the Nagano *et al.* (2007) study.[31] OPPT does not explain why it departs from the methods used in the IRIS assessment.

To compare ECEL values using the two dose-response approaches, a dose-response analysis was conducted using the same BMD/PBPK modeling approach that was utilized by EPA in the CTC IRIS assessment.[32] Specifically, BMD modeling was conducted on female mice liver tumors (adenomas + carcinomas) using EPA's own software (BMDS) and technical guidance and the same two CTC PBPK models. The HECs were initially determined for continuous exposure and then converted to an occupational exposure scenario. The HECs for occupational exposure were then divided by a total UF of 30 (3 for interspecies variability; 10 for variation in sensitivity within human population) to derive an ECEL value. Based on this approach, which aligns with the dose-response approach used by EPA in the CTC IRIS Assessment, the ECEL value based on female mouse liver tumors is 1.5 ppm, a value that is 50 times higher than the ECEL value proposed by EPA in the Risk Evaluation which was derived using a LOAEC/NOAEC approach for dose-response.

The ECEL value of 1.5 ppm value, incorporating BMD and PBPK modeling of the female mouse liver tumors, aligns with current OELs of 1 ppm in the EU and France, 2 ppm in Canada, and 5 ppm in Japan.

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[30] Risk Evaluation, at 160.

[31] EPA, Toxicological Review of Carbon Tetrachloride (CAS 56-23-5) in Support of Summary Information on the Integrated Risk Information System (IRIS), EPA/635/R-08/005F (2010).

[32] Gradient, Comments on the US EPA's carbon tetrachloride existing chemical exposure levels (ECELs) and ambient air pathway evaluation for fenceline communities – as incorporated into the proposed risk management rule under TSCA (2023) (Attachment C).

EPA's flawed approach resulting in the proposed ECEL value for CTC in the proposed rule is not state-of-the science. It does not meet the TSCA § 26 requirement that EPA use "best available science" and "weight of the scientific evidence."

3. The CTC-induced mouse pheochromocytomas in Nagano *et al.* (2007) are not relevant to assessing human cancer risk.

In their two-year carcinogenicity study, Nagano *et al*. reported a statistically significant increase in the incidence of benign pheochromocytomas (tumors originating in the adrenal medulla) in the male mice exposed by inhalation to 25 and 125 ppm CTC and in the female mice at 125 ppm CTC. Benign pheochromocytomas were also observed in an oral gavage carcinogenicity study conducted in mice by the National Cancer Institute (NCI) where CTC was used as a positive control for liver tumors.[33] These tumors were not increased in CTC-exposed rats in either study.

The CTC Risk Evaluation concludes that the MOA for the mouse pheochromocytomas is unknown but biologically relevant to humans, justifying a linear extrapolation approach for assessing human cancer risk. Unlike the CTC-induced liver tumors, OPPT noted that there was no evidence for a MOA based on cytotoxicity and regenerative proliferation, primarily because there was no evidence of adrenal toxicity. Medullary hyperplasia forms a continuous histological spectrum with pheochromocytomas and thus represents a diagnostic challenge, particularly for the mouse due to the size of the adrenal medulla.[34] The criteria used by the pathologist at JBRC to distinguish between medullary hyperplasia and pheochromocytomas are unknown, however.

Pheochromocytomas are uncommon tumors in mice as well as in humans. Besides CTC, only nine chemicals have also been shown to induce mouse pheochromocytomas in animal carcinogenicity studies.[35] Several MOAs have been proposed for the induction of rodent

[33] Weisburger, EK, Carcinogenicity studies on halogenated hydrocarbons. *Environ. Health Perspect.* 21; 7-16 (1977).

[34] Endocrine glands, In: *Histopathology of Preclinical Toxicity Studies. Interpretation and Relevance in Drug Safety Evaluation* (P. Greaves, ed.), Academic Press-Elsevier, Amsterdam, The Netherlands (2012), at 725-797,

[35] Greim, H, Hartwig, A, Reuter, U, Richter-Reichhelm, A-B, Thielman, H-W, Chemically induced pheochromocytomas in rats: mechanisms and relevance for human risk assessment. *Crit. Rev. Toxicol*. 39: 695-718 (2009).

pheochromocytomas; all share a general toxic, stress-related mechanism of action. The results of the carcinogenicity studies indicate that the rodent pheochromocytomas only occurred when there were other tumors or toxic effects in other organs.[36] For eight of the nine chemicals where mouse pheochromocytomas were reported in carcinogenicity studies, there was also severe liver toxicity and liver carcinomas. The results of the CTC-exposed mice in the Nagano study follow this pattern, with pheochromocytomas occurring predominantly in combination with significant liver toxicity and liver carcinomas. It is also apparent that the pheochromocytomas in the Nagano study occurred in animals with severe body weight reduction (>30% for the ≥ 25 ppm males and 125 ppm females) and close to 100% mortality for the male and female mice at 125 ppm (see table below). Even after 52 weeks of exposure, there was a notable reduction in body weights in the 25 and 125 ppm mice (both sexes), particularly for the 125 ppm-exposed mice (>10%).

Terminal body weights (Percent of Controls) of Mice Exposed to CTC for Two Years in Nagano *et al.* (2007)

	CTC Exposure Concentrations		
	5 ppm	25 ppm	125 ppm
Male Mice	106%	68%	61%*
Female Mice	109%	78%	69%*

*Only one animal survived to the end of the study

A similar pattern is seen in the NCI studies where mice were given high oral doses of CTC (1,250 or 2,500 mg/kg-day 5 days/week for 78 weeks and then maintained without treatment for an additional 32 weeks) as a positive control for liver tumors.[37] Liver carcinomas were found in practically all CTC-dosed mice. Pheochromocytomas were increased in both male and female mice in both dose groups.[38] In both dose groups there was high mortality: survival was about 20% in low-dose groups and <10% in high-dose groups at 78 weeks (versus 70% in

[36] *Id.*

[37] NCI, Report on the carcinogenesis of chloroform, CAS No. 67-66-3, U.S. Department of Health, Education and Welfare (1976); NCI, Report on the carcinogenesis of trichloroethylene, CAS No. 79-01-6, NCI-CG-TR-2, U.S. Department of Health, Education and Welfare (1976); NCI, Report on the carcinogenesis of 1,1,1-trichloroethane, CAS No. 7155-6, NCI-CG-TR-3, U.S. Department of Health, Education and Welfare (1977).

[38] Weisburger, EK, Carcinogenicity studies on halogenated hydrocarbons. *Environ. Health Perspect.* 21; 7-16 (1977).

control males and 90% in control females), and only one treated mouse survived to study termination at 92 weeks (versus 50% in control males and 80% in control females).[39] While the NCI reports did not also provide data on body weights or on non-neoplastic lesions (*i.e.,* liver toxicity), the high mortality and high incidence of liver carcinomas in the CTC-dosed mice strongly suggest a moribund condition for the mice.

In both Nagano *et al.* (2007) and the NCI studies, pheochromocytomas occurred in mice only under conditions of severe toxicity and liver carcinomas. Give the extreme poor health of the treated mice under these conditions, it cannot be determined whether the pheochromocytomas were a direct result of CTC toxicity or a secondary effect from the severe toxicity of the animal (*i.e*., stress-related). Therefore, the mouse pheochromocytomas should not be considered in the assessment of human cancer risk.

4. Epidemiology studies do not support an association between neuroblastomas and CTC exposure

OPPT has highly inflated the significance of the epidemiology study by Heck *et al.* (2013) in its assessment of human cancer risk from CTC exposure.[40] OPPT claims that "a strong association between neuroblastoma and CTC in a single well-conducted epidemiological study in the same organ [as mouse pheochromocytomas] raises concern for potential carcinogenic effects in humans."[41] The study in question is a case-control study that links neuroblastoma cases identified from the California Cancer Registry and air pollution monitors of the California Air Resources Board's Air Toxic Program; birth certificates were used to identify controls and determine addresses. There were 75 neuroblastoma cases and 14,602 controls from an air pollution monitor, and 12 neuroblastoma cases that lived 2.5 km for an air pollution monitor.

This study was reviewed by Dr. Carol Burns, an epidemiologist, who concluded "The evidence from Heck *et. al.* (2013) is inconclusive due to small number of exposed cases, poor

[39] NCI, Report on the carcinogenesis of trichloroethylene. CAS No. 79-01-6, NCI-CG-TR-2, U.S. Department of Health, Education and Welfare (1976).

[40] Heck, JE, Park, AS, Qiu, J, Cockburn, M, Ritz, B, An exploratory study of ambient air toxics exposure in pregnancy and the risk of neuroblastoma in offspring. *Environ. Res.* 127: 1-6 (2013).

[41] 88 Fed. Reg. at 49209.

precision in risk estimates, and low-quality exposure assessment."[42] A significant limitation to this study is the exposure assessment; this was recognized by OPPT in the "low" quality rating given in its systematic review for the CTC Risk Evaluation. The following is from Dr. Burn's evaluation of the exposure assessment in the Heck *et al.* (2013) study:

> "Exposure to an air pollutant was inferred based only upon residence at birth. The authors used data from the 39 statewide monitors of the California Air Resources Board's Air Toxics Program, available for the study period 1990 to 2007. These locations were linked to addresses provided on the birth certificate. It is notable that for the period 1990 – 1998, only zip code was available. This exposure assessment makes several assumptions:
>
> - The mother lived at the same address during the entire pregnancy. [note the authors cite research that 9 – 30% of families may move during pregnancy]
> - The mother did not spend time away from the address (i.e., the site monitor) such as for school or employment.
> - Exposure levels were constant throughout the measurement period.
>
> Building on the limited assumption of residence and exposure, the authors' methods for calculating the mean concentrations were vague. The authors used at least one reading for each full month of the pregnancy, but it is not clear how a summary concentration was computed. No information was provided for the actual concentrations of carbon tetrachloride (and other pollutants) over time or by location."

There were also only 12 exposed neuroblastoma cases in the residence group that were 2.5 km away from an air monitor. The following table from Dr. Burns's report provides the neuroblastoma risk estimates from CTC exposure in the Heck *et al.* (2013) study. While the risk estimates were statistically significant and higher for residences closer to the monitor and in the highest quartile, the results are imprecise as indicated by the wide range in the confidence interval (CI):

Exposure	N exposed cases	Risk estimate	95% confidence interval (CI)	CI ratio
Residence 5 km from monitor (Model 2)*	40	OR = 2.65	1.07 – 6.53	6.10
Residence 2.5 km from monitor (Model 2)*	12	OR = 7.87	1.37 –45.34	33.09
Highest quartile compared to lowest	NR	OR = 8.85	1.19 – 66.0	55.46

[42] Burns, C, Summary of carbon tetrachloride epidemiology studies of adult brain cancer and childhood neuroblastoma (2020), submitted as Appendix A to HSIA Comments on draft Risk Evaluation, EPA-HQ-OPPT-2019-0499-0039; and resubmitted as Attachment E due to formatting issue in initial submission.

*Model adjusts for birth year, mother's age, mother's race/ethnicity, and method of payment for prenatal care.

Dr. Burns points out "small studies of rare diseases such as [neuroblastoma], and uncommon exposures, such as chlorinated solvents, are subject to random variability resulting in artificially high-risk estimates. . . . These outcomes, while statistically significant, are often imprecise with very wide confidence intervals." Precision is defined as "the degree of certainty surrounding an effect estimate with respect to a given effect." The lack of precision in low powered studies can be quantified by calculating the ratio of the upper and lower confidence limit,[43] which is the method used by the National Toxicology Program (NTP) Office of Health Assessment and Translation (OHAT) in its systematic reviews.[44] OHAT considers the data imprecise for CI ratios of $\geq$10. Other reviewers have considered the measures to be precise if the CI ratio is below 4."[45]

In other studies, there was no increased risk of neuroblastomas from parental occupational exposures to CTC (OR = 0.4; 95% CI 0.2-1.2). [46] A nonsignificant odds ratio of 1.2 (95% CI 0.8-1.6) was reported for hazardous air pollutants (HAPs) and neuroblastomas in a study investigating HAPs and childhood cancers.[47] Thus, OPPT's assertion of a strong association between neuroblastomas and CTC exposure in a "single well-conducted epidemiological study" is overstated; it is also not supported by the epidemiology literature.

[43] Poole, C, Low P-values or narrow confidence intervals: which are more durable? *Epidemiology* 12: 291-294 (2001).

[44] National Toxicology Program (NTP) Office of Health Assessment and Translation (OHAT), Handbook for conducting a literature-based health assessment using OHAT approach for systematic review and evidence integration, at 59 (2019).

[45] Schinasi, L, Leon, ME, Non-Hodgkin lymphoma and occupational exposure to agricultural pesticide chemical groups and active ingredients: a systematic review and meta-analysis. *Int. J. Environ. Res. Public Health* 11: 4449-4527 (2014).

[46] De Roos *et al.*, Parental occupational exposures to chemicals and incidence of neuroblastoma in offspring. *Am. J. Epidemiol.* 154: 106-114 (2001).

[47] Thompson, JA, Carozza, SE, Zhu, L, Geographic risk modeling of childhood cancer relative to county-level crops, hazardous air pollutants and population density characteristics in Texas. *Environ. Health* 7: 45 (2008).

5. There is no association between CTC exposure and increased risk of brain cancer

OPPT concluded in the Risk Evaluation that "The available epidemiologic studies provide evidence of an association between carbon tetrachloride and increased risk of brain cancer." The five epidemiology studies on which OPPT based its conclusion were reviewed by Dr. Carol Burns (Attachment E). Considering the risk of bias, lack of consistency, and high contribution of chance and confounding, Dr. Burns concluded that these five studies do not show an increased risk of brain and nervous system tumors and CTC exposure. It is important to note that, in these small epidemiology studies of rare diseases and uncommon exposures, artificially high risk estimates can occur from random variability, resulting in a phenomenon of effect size magnification.[48] The results may be statistically significant but with very wide confidence intervals that indicate imprecision. This imprecision is seen in all five of the epidemiology studies, with the exception of the case-control study by Ruder *et al.* (2013)[49] which showed no association between brain tumors and CTC exposures.

B. EPA's derivation of an ECEL value for chronic, non-cancer effects based on fatty liver in chronically exposed rats is not the best available science

While EPA did not propose an ECEL value for CTC in the proposed rule based on chronic non-cancer effects, an ECEL value was derived in a draft memorandum based on the approach used in the Risk Evaluation for the risk characterization.[50] The basis for the proposed chronic non-cancer ECEL value is the fatty changes in the liver seen in rats exposed by inhalation to 25 and 125 ppm CTC for two years in the study by Nagano *et al.* (2007). Using BMD and PBPK modeling, and exposure duration adjustments to convert the exposures from the laboratory animal study to continuous exposures and then back to an occupational exposure scenario, EPA calculated a human equivalent concentration (HEC) of 31.1 mg/m^3 (~5 ppm) for a 40-hour work week. A total UF of 30 was applied (3 for variability in response between species;

[48] EPA, Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides, Office of Pesticide Programs (2016).

[49] Ruder AM, Yin JH, Waters MA, *et al*., The Upper Midwest Health Study: Gliomas and Occupational Exposure to Chlorinated Solvents, *Occup. Environ. Med.* 70: 73-80 (2013).

[50] EPA-HQ-OPPT-2020-0592-0113.

10 for variability in the human response and to protect susceptible individuals), resulting in an ECEL value of 0.2 ppm for an 8-hour time-weighted average (TWA).

EPA's methodology to derive the chronic non-cancer ECEL value for CTC has been reviewed by Gradient and an alternative approach has been proposed based on the same endpoint (fatty liver effects in chronically exposed rats) (Attachment C). The key differences between the two approaches are: PBPK modeling approach; exposure duration adjustments from continuous exposure to an occupational exposure of a 40-hour work week; and the application of UFs. As noted in § II.A.2 above, PBPK models are used to predict the internal dose metric in the target organ (in this case the liver). While EPA utilized two PBPK models to predict the internal dose metric for CTC,[51] Gradient found that only the PBPK model by Paustenbach *et al.* (1988) with further refinement was needed to more accurately predict the behavior of CTC and its metabolites. Regarding the exposure duration adjustments from continuous exposure to an occupational exposure, Gradient concluded that the use of the ten Berg *et al.* (1986)[52] equation used by EPA was not scientifically sound and that EPA should use the methodology that is included in the Risk Evaluation for exposure duration adjustments. Finally, Gradient proposes that, instead of 30, a total UF of 7.5 should be used (1.5 to account for pharmacodynamic differences between animals and humans; 5 to account for variation within the human worker population), which would result in a chronic, non-cancer ECEL value of 1.6 ppm. This value is 8-fold higher than EPA's derived ECEL value of 0.2 ppm.

C. The exposure assessment in the CTC Risk Evaluation is neither best available science nor supported by substantial evidence

The Risk Evaluation concludes that CTC presents unreasonable risks to workers under 13 of 15 conditions of use (COUs) with or without Personal Protective Equipment (PPE), as well as to occupational non-users (ONUs) without PPE.[53] For dermal exposure, although unsupported

[51] Gargas, ML, Andersen, ME, Clewell, HJ, III, A physiologically based simulation approach for determining metabolic constants from gas uptake data. Toxicol. Appl. Pharmacol. 86: 341-352 (1986); Paustenbach, DJ *et al.*, Development of a physiologically based pharmacokinetic mode for inhaled carbon tetrachloride. *Toxicol. Appl. Pharmacol.* 96: 191-211 (1988).

[52] ten Berge, WF, Zwart, A, Appelman, LM, Concentration-time mortality response relationship of irritant and systematically acting vapours and gases, *J. Hazard Materials* 13: 301-309 (1986)

[53] To be clear, while the focus of this section is dermal exposure, the flawed approach to the assessment of cancer risk underlies the unreasonable risk determinations for other COUs based on inhalation exposure as well..

by actual data, EPA finds unreasonable cancer risks to workers under all 13 of these COUs even with the most protective glove use (Protection Factor of 20). In the absence of dermal exposure data for CTC, OPPT relied on models to estimate the amount of CTC that is retained by workers from dermal contact. These "worst-case scenarios" assume unrealistic dermal exposure durations and fail to recognize basic industrial hygiene (IH) practices, as well as engineering controls required by the NESHAP. Thus, they are clearly inapplicable to facilities that manufacture CTC or use CTC as a process reactant or intermediate.

The manufacture of CTC and its use as in the production of other chemicals (*i.e.*, perchloroethylene, HFOs) are COUs that occur in closed system process units where potential dermal contact is limited to short-term tasks in the operation of unit activities. The typical tasks that could potentially involve contact with liquid phase CTC are handling of transfer lines for vessel charging/uncharging and collecting samples from process points for laboratory analysis. In general, these tasks would involve limited direct contact with liquid, and the duration of any potential contact with the liquid is very short (*i.e.*, minutes).

1. Dermal exposure assessment

In both the Risk Evaluation and the Revised Risk Determination, OPPT found unreasonable risks to workers from acute and chronic dermal exposure in the manufacture of CTC and its use in the production of other chemicals (feedstock or intermediate use), even with the most protective glove use (Protection Factor of 20). Although OPPT assumed glove use in the Risk Evaluation for dermal protection, the models OPPT used to estimate the amount of CTC that is retained by workers from dermal contact was not based on any supporting information and overestimated any potential exposure. These "worst-case scenarios" assumed unrealistic dermal exposure durations and fail to recognize basic industrial hygiene (IH) practices, including implementation of OSHA-compliant standard operating procedures (SOPs), as well as engineering controls required by the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Synthetic Organic Chemical Manufacturing Industry (SOCMI)[54] and Miscellaneous Organic Chemical Manufacturing (MON),[55] which require closed systems where

[54] 40 C.F.R. Part 63 Subparts F, G, H, I.

[55] 40 C.F.R. Part 63, Subpart FFFF.

exposure is tightly controlled. Thus, they are clearly inapplicable to facilities that manufacture CTC or use CTC as a process reactant or intermediate.

The manufacture of CTC and its use in the production of other chemicals (*e.g.*, refrigerants) are COUs that occur in closed system process units where potential dermal contact is limited to short-term tasks in the operation of unit activities. "Closed systems (including rigorous containment by technical means) generally relate to high integrity plant/machinery where the opportunity for exposure is negligible, both in terms of frequency and magnitude."[56] Following several meetings with OPPT staff, HSIA submitted to the docket two documents that provide comprehensive details on the typical tasks involved in the manufacturing of CTC and the Standard Operating Procedures (SOPs) for these tasks including personal protection equipment (PPE) use.[57] HSIA emphasized repeatedly to OPPT staff that these comments apply equally to CTC use as an intermediate in manufacturing fluorochemicals. The typical short-term (5-30 minutes) tasks that could potentially involve contact with liquid phase CTC are loading transport equipment, conducting minor maintenance and line openings, packaging wastes, and collecting process samples. Although not expected, should accidental contact with CTC occur during the performance of these tasks, concentrations and amounts are minimal. Incidental, intermittent, or splash contact may only occur if there is an accidental spill, overspray conditions, or unexpected failure of a control device.

Despite the SOPs in place to prevent any exposure and potential for exposure limited to the short-term tasks described above, OPPT estimated dermal exposure to CTC for workers using Kasting and Miller (2006)[58] with the following assumptions: (1) one dermal contact with undiluted CTC which coats fully one or both hands per work shift; (2) workers do not wash their hands at any point during the 8-hour work shift if gloves are not worn; and (3) a worker wears the same pair of gloves for the entire 8-hour work shift without stopping to wash their hands

[56] European Chemicals Agency (ECHA), Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.14: Occupational Exposure Assessment, Version 3.0 (2016).

[57] SOPs for Personal Protection at CTC Manufacturing Sites; HSIA Response to EPA's Questions on Standard Operating Procedures (SOPs) at Carbon Tetrachloride and Other Solvent Manufacturing Facilities (September 27, 2021). EPA-HQ-OPPT-2020-0592-0003.

[58] 40 C.F.R. 63 Subparts F, G, H, I (hereafter "the NESHAP").

and/or change their gloves.[59] OPPT also fails to account for the volatility of CTC, which will compete with absorption to limit the potential body burden by dermal exposure. Incredibly, OPPT provides no documentation or justification for these assumptions other than the intent to establish a theoretical "worst-case scenario." As a result of these assumptions, OPPT very substantially overestimated worker exposure to CTC from dermal contact in facilities that manufacture and use CTC as a reactant or intermediate.

According to EPA, risk evaluations under TSCA § 6(b) are not screening level risk assessments, but are intended to "use scientific information, technical procedures, measures, protocols, methodologies and models consistent with the best available science." Therefore, OPPT should use in its dermal exposure models data and assumptions that are relevant and appropriate to actual workplace practices for the COUs being evaluated, information which OPPT has had now for several years.[60] Unfortunately, the Risk Evaluation fails to acknowledge basic IH practices and engineering controls in preference for worst-case assumptions.

As noted in the information provided to OPPT on use of PPE at chlorinated solvent production facilities with closed systems, any potential dermal exposures are for short durations and, combined with the industry standards for good IH practices at these facilities which require removal and disposal of potentially contaminated gloves and hand washing after each task completion, do not justify an 8-hour period for absorption of CTC through skin. Moreover, CTC will evaporate from the skin and gloves between exposure periods.

Lynch *et al*.[61] reviewed the methodology in the Risk Evaluation for estimating dermal exposures of workers to several chlorinated chemicals for the COUs involving manufacturing and feedstock use. They also provided best practice recommendations which can be broadly

[59] Risk Evaluation, Supplemental Information on Releases and Occupational Exposure Assessment.

[60] In this regard, the SACC concluded that "the worker exposures characterized in the draft risk evaluation are best described as a screening-level assessment. Due to the lack of readily available monitoring data and low confidence in the data sources, this assessment should not be used to decide whether health risks are reasonable or unreasonable. The results of a screening-level assessment can be used to determine if further refinement and more data are needed." See Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE): Response to Support Risk Evaluation (epa.gov) at 217. In spite of having had very reliable monitoring data for these COUs for years, EPA has continued to ignore this input.

[61] Lynch, HN, Gloekler, LE, Allen, LH, Maskrey, JR, Bevan, C, Maier, Analysis of dermal exposure assessment in the US Environmental Protection Agency Toxic Substances Control Act risk evaluations of chemical manufacturing, *Toxicol Ind Health* 39: 49-65 (2023b) (Attachment F).

applied to any of the exposure scenarios used in the Risk Evaluation. The authors recommended a "tiered, integrated approach to dermal exposure assessment that emphasizes collecting qualitative data; employing validated, peer-reviewed models that align with current industrial practices; and gathering empirical sampling data when needed." They also recommended that a more realistic approach to estimating the dermal dose in workers in closed system facilities (manufacturing and process reactant/intermediate use) be obtained by using the IH Skin Perm model. [62] This tool is commonly used by practitioners of IH and exposure assessment to produce reliable estimates of dermal exposure. And, as noted in the Risk Evaluation, "this model takes into account losses to evaporation and estimates the mass that is absorbed." In addition, IH Skin Perm can be used to evaluate the impacts of differing patterns of exposure on fractional and total dose of absorption (*i.e.*, it allows for the incorporation of realistic exposure patterns). The IH Skin Perm model is reasonably available information and is a peer-reviewed tool that is demonstrably a higher quality source than worst-case assumptions with no basis in fact.

Recognition of standard work practices and reliance on reasonable and realistic exposure data are critical to meet the statutory requirements of TSCA, as well as the "objectivity" criterion of the Information Quality Act. EPA's reliance on hypothetical assumptions for modeling of the amount of CTC that is absorbed by workers from dermal contact cannot be justified, especially in the face of a peer-reviewed model as an alternative. Assumptions used for estimating worker exposures should be as relevant as possible for the COUs being evaluated. EPA's use of unrealistic dermal exposure assumptions has led to erroneous conclusions regarding the health risks to workers using CTC in closed systems. Because the Risk Evaluation is intended to determine whether CTC presents an unreasonable risk of injury to workers under TSCA § 6(b), which requires rulemaking to mitigate risks found to be unreasonable, it is imperative that it be revised to reflect the "best available science" in advance of any risk management rulemaking.

2. Flawed assumptions regarding use of PPE in Revised Risk Determinations

In its justification for the Revised Risk Determination for all COUs of CTC, OPPT states that this change "reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such

[62] IH Skin Perm is a peer-reviewed exposure assessment tool published by the American Industrial Hygiene Association (AIHA) Exposure Assessment Strategies Committee.

as self-employed individuals and public sector workers who are not covered by an OSHA State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements."[63]

OPPT has generalized this concern to all COUs for CTC, yet it is not pertinent at all to the manufacture of CTC, or its use as a fluorochemicals feedstock, based on the information provided by HSIA to OPPT on industry best practices for industrial hygiene. The CTC manufacturers, of which there are only two in the United States, submitted to OPPT two documents that provide comprehensive details on the typical tasks involved in the manufacture of CTC (and more generally, chlorinated solvent manufacturing), and the SOPs for these tasks including PPE use.[64] These documents also provide a summary of the extensive training that are in place for employees (new and seasoned) to ensure SOP requirements are followed. There are no exceptions – the SOPs and training apply to all workers. OPPT has no rational basis to assume that any worker that is potentially exposed to CTC would be a public sector employee or self-employed individual. Furthermore, OPPT's assumption that existing OSHA requirements are not met by employers of covered workers would be misuse, in contravention of Congress's understanding, when it amended TSCA, that the term "conditions of use" is "*not intended to include 'intentional misuse' of chemicals*."[65]

For the manufacture and feedstock COUs for CTC, OPPT must assess in the Risk Evaluation the circumstances under which CTC is intended, known, or reasonably foreseen to be manufactured/used. Where PPE use is required by all U.S. manufacturers and that information has been "clearly articulated" to EPA, OPPT must take that information into account in its Risk Evaluation.

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[63] 88 Fed. Reg. at 49186.

[64] SOPs for Personal Protection at CTC Manufacturing Sites; HSIA Response to EPA's Questions on Standard Operating Procedures (SOPs) at Carbon Tetrachloride and Other Solvent Manufacturing Facilities (September 27, 2021); EPA-HQ-OPPT-2020-0592-0003.

[65] *See* U.S. Congress (2015), *Frank R. Lautenberg Chemical Safety for the 21stCentury Act, Report together with Minority Views,* 114th Congress, 1st Session, Report 114-67, at 7 (emphasis added), available at https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.

3. EPA did not use best available science in its systematic review

The preamble states "EPA considers the CTC ECEL to represent the best available science under TSCA section 26(h) because it was derived from information in the 2020 Risk Evaluation for Carbon Tetrachloride, which was subject to peer review, and which is the result of a systematic review process that investigated the reasonably available information in order to identify relevant adverse health effects."[66] This was not the view of the outside peer reviewers, who have been generally critical of the systematic review process EPA employed in the Risk Evaluation.

TSCA §§ 6 and 26 require EPA to use the best available science and weight of the scientific evidence when considering study quality and relevance for multiple lines of evidence. EPA developed its fit-for-purpose systematic review approach because other existing approaches did not satisfy these TSCA statutory requirements. However, the TSCA systematic review approach used for the Risk Evaluation does not include sufficiently detailed guidance for evidence integration and weight of evidence methodology, and EPA did not consistently apply a weight of evidence approach in the Risk Evaluation.

EPA's Scientific Advisory Committee on Chemicals (SACC) recommended a number of improvements in the systematic review process, as did many commenters on the draft Risk Evaluation.[67] More specifically, the Committee to Review EPA's TSCA Systematic Review Guidance Document convened by the Board on Environmental Studies and Toxicology of the National Academy of Sciences was unable to conclude that the TSCA systematic review process is comprehensive, workable, objective, and transparent.[68] Given the significant criticisms from both SACC and the National Academy, for EPA to continue to rely upon the 2018 systematic review process undermines EPA's position that its risk evaluation has met TSCA § 26 requirements.

[66] 88 Fed. Reg. at 49186.

[67] *E.g.,* Response to Comments on Risk Evaluation, at 178, 186, 188, 198.

[68] The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations, National Academy Press (2021).

III. ECEL AND WCPP IMPLEMENTATION CONCERNS

Monitoring methodologies, laboratory availability, monitoring protocols and control development, training and implementation all require time to implement a new ECEL, particularly one significantly lower and more conservative than the PEL currently in effect. EPA should extend the time in § 751.707 to implement the WCPPs required under the regulations.

A. Time is needed for monitoring methodology validation and lab availability

Implementing a monitoring methodology for the new ECEL will not be seamless. Time will be required for method validation by a lab for measurement of the proposed ECEL and action limit. NIOSH 1003 is a validated method that meets OSHA's accuracy standards and analytical methods. NIOSH 1003 is the most commonly utilized method for IH sampling in the workplace for CTC. However, the NIOSH 1003 method as currently validated will not achieve the LODs required for evaluating the proposed ECEL or action limit. Time will be required to coordinate with a lab for method validation at 10% of the proposed ECEL, as recommended by NIOSH for OEL sampling. NIOSH Manual of Analytical Methods (NMAM), 5th Edition, Section 2 (December 11, 2017).[69] It is also currently technically infeasible to use the NIOSH 1003 sampling methodology for measuring the ECEL for short-term (*e.g.,* < 1 hour) tasks.

EPA's ECEL document lists EPA method 325 b as a potential air sampling analytical method. This method, also known as TO-17, can measure full shift and task, but there are several implementation issues associated with its implementation:

> **New technology for implementation by IH professionals would require training.** The EPA TO-17 method allows the use of sampling media with which facilities have little experience – either with the Tenax tube or the SKU Ultra Diffusive sampler.
>
> **Lack of available labs for SKU Ultra Diffusive sampler:** One member company contacted 5 AIHA accredited laboratories to determine their ability to analyze IH samples using SKC Ultra Diffusive media with TO-17 method analysis. Contact information could not be found for one lab. For the remaining labs contacted, three did not have the media for the analysis; a fourth had the media but could not measure to the manufacturer's stated limit of detection.
>
> **Shelf life of Tenax tubes is limited.** Tenax tubes require conditioning and if not used within a short window (months) need to be sent back to the lab for re-conditioning. This

[69] https://www.cdc.gov/niosh/nmam/pdfs/nmam_5thed_ebook.pdf

stability limitation could delay results and introduce additional errors that could give biased data.

Sample volume limitation requires multiple tube change outs for one shift. Due to sample volume limitations for the CTC validated method, each sample tube could only be used for a small portion of the full-shift exposure (*e.g.*, approximately 2 hours). For full shifts, this would potentially require 4 individual and consecutive sampling periods in an 8-hour shift.

Although not mentioned in the CTC ECEL document or the proposed rule, NIOSH 3900 and TO-15, the two methods mentioned in the perc ECEL documentation, are both area sampling methods that use specially prepared canisters. NIOSH 3900 is not validated for CTC so only TO-15 will be addressed here. For TO-15, it is unclear whether this method could measure at the ECEL but, regardless, it is worth reiterating that TO-15 cannot be used for personal breathing zone (PBZ) sampling. The PBZ sampling is "personal" because it evaluates an individual's exposure to a chemical as opposed to ambient area sampling (*e.g.*, as described in EPA's TO-15 method) that measures the concentration of a substance in a given area. Area sampling conducted with the TO-15 method would not meet the personal breathing zone air sample required by the proposed rule.

The EPA TO-15 method requires the use of bulky canisters to collect ambient air samples which are not appropriate for PBZ sampling. Industrial hygiene applications for canister sampling are limited to monitoring short-duration peak exposures and source emissions as described in two NIOSH Health Hazard Evaluations of coffee roasting facilities, not for sampling full-shift employee exposures to compare to full-shift exposure levels (*e.g.*, ECELs and PELs).[70] Although certain inferences can be made about exposure through area sampling by considering the length of time an employee is in the area, the best indicator of a person's actual exposure comes from PBZ sampling since the sample is collected by equipment that is worn by the employee during the workday.

The proposed requirement of Good Laboratory Practices (GLP) is inconsistent with current workplace monitoring that is analyzed to AIHA Industrial Hygiene Laboratory Accreditation Program (AIHA-IHLAP) standards, which most IH labs follow. CTC samples could not be analyzed at AIHA-IHLAP labs and would need to be sent to EPA or the handful of commercial labs that follow GLP. As most IH professionals are not familiar with GLP

[70] https://www.cdc.gov/niosh/hhe/reports/pdfs/2016-0067-3313.pdf.

requirements, additional time would also be required to train IH personnel and consultants regarding IH requirements. The required training and implementation of GLP requirements could cause an unnecessary implementation delay. Additionally, the likely backlog at the available -- but limited -- GLP labs could result in samples not being analyzed before their hold time expires.

EPA's expectation of GLP testing for workplaces is also inconsistent with EPA's TSCA § 5(e) order template, which states: "Compliance with TSCA GLP[s], however, is not required under this New Chemical Exposure Limit Section where the analytical method is verified by a laboratory accredited by either: the American Industrial Hygiene Association ("AIHA") Industrial Hygiene Laboratory Accreditation Program ("IHLAP") or another comparable program approved in advance in writing by EPA." A similar provision should be considered in the instant rulemaking.

B. 18 months is needed for personal monitoring assessment, implementation, and training

To allow proper implementation of the steps and time taken to assess or reassess an IH program for a new ECEL, at a minimum EPA should revise § 751.707(b)(3)(ii) to allow 18 months for the initial CTC exposure monitoring requirement. A typical IH reassessment at a facility, as described below in this subsection, takes approximately 12 months. OSHA also allowed 12 months for the initial exposure assessment in the beryllium standard (29 CFR § 1910.1024(d), (o)). But particularly for CTC, at least 18 months is needed for the exposure reassessment and the method revalidation as described above as well as to address the specific implementation and technical feasibility challenges of measuring the CTC ECEL for both the full shift and task measurements. Additionally, corporate and facility IH resources, and third party labs, may also be conducting a reassessment and analysis for other risk management rules (IH assessments associated with methylene chloride or perchloroethylene, for example), which may lead to additional time delays. With these resource constraints, particularly for a new CTC OEL that is 333 times lower than the existing PEL at a level where monitoring will require new lab validations and/or monitoring methodologies, each facility will likely need more time to reassess its corporate exposure assessment strategy for the new ECEL evaluation.

A typical exposure assessment/reassessment strategy would include identifying and involving stakeholders in the re-evaluation, such as operations management, process engineers,

PSM engineers, and HESS personnel. An exposure assessment/reassessment strategy may include confirming and/or reassessing the following exposure assessment goals and written plans for the ECEL evaluation:

1. Methods for systematic information gathering;
2. Confirming similar exposure groups (SEG) for the new ECEL;
3. Identify decision statistics and number of random samples that will be used to determine whether the exposure profile for a SEG is acceptable, unacceptable, or uncertain;
4. Identify exposure thresholds and appropriate exposure monitoring methods to meet thresholds;
5. Develop new monitoring procedures for new monitoring methodologies; and
6. Train to the new monitoring technology and/or methodology to ensure the proper execution of an exposure assessment strategy.

To proceed with an exposure reassessment against a new ECEL, each representative air sample that will be evaluated will be subject to a Qualitative Exposure Assessment to help determine the expected exposure category before attempting to perform exposure monitoring. The Qualitative Exposure Assessment includes identifying the following:

1. All tasks
2. The frequency/duration of each task
3. Estimate of quantity of stressor per task
4. Exposure controls in place for each task exposure

Once the Qualitative Exposure Assessment is complete, the Quantitative Exposure Assessment (personal exposure monitoring) takes place. This step includes:

1. Obtain and train to any new monitoring equipment or methodologies
2. Collecting the appropriate number of random samples (full-shift and tasks)
3. Performing statistical analysis on sample set, as appropriate
4. Comparing to exposure level
5. Decisions related to exposure profile

In addition to the reassessment strategy and implementation steps listed above, monitoring at the proposed ECEL of 0.03 ppm and the proposed action level of 0.02 ppm likely will require laboratory analysis (rather than direct measurement) that will delay the availability of results and make meeting a 6-month time frame challenging.

To allow proper implementation of the steps and time taken to assess or reassess an IH program for a new CTC ECEL, given the potential resource constraints together with the new validations and methodologies that may need to be considered, at a minimum EPA should revise proposed § 751.707(b)(3)(ii) to allow 18 months for the initial exposure monitoring requirement. It is important to note that during the reassessment the existing facility requirements will remain in place to protect workers as required by OSHA-mandated standard operating procedures and hazard assessments as well as facility-specific administrative, engineering, and personal protection controls, including respiratory protection requirements and permitting requirements.

C. Adequate time is needed to evaluate monitoring data, plan for, and implement a performance-based WCPP

24-36 months is needed by facilities to evaluate and implement a WCPP. This is consistent with the OSHA beryllium standard that provided 36 months for evaluating and implementing engineering control requirements in a written exposure control plan (29 CFR § 1019.1024(f), (o)). An appropriate compliance deadline for evaluating the hierarchy of controls will allow entities adequately to plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers.

As described above, requiring that initial monitoring be completed within 6 months of the effective date of the rule provides insufficient time to revalidate monitoring technology and assess/reassess an IH strategy and conduct monitoring for a new ECEL. Likewise, additional time is required to allow owner/operators to document their efforts to implement the NIOSH hierarchy of controls – elimination, substitution, engineering controls, and administrative controls – to reduce exposures to the ECEL.

The proposal would require a detailed description of efforts to implement the control hierarchy in the exposure control plan. 40 CFR § 751.707(d)(2). Importantly, manufacturing and processing facilities rely upon layers of protection rather than a single engineering or administrative control. Each of these layers would need to be reassessed upon completion of the initial exposure monitoring. The proposal indicates that respirator use would be permitted to supplement the exposure controls only after other feasible controls are determined to be insufficient to achieve the ECEL. This does not recognize that currently respirator use is often required as an additional or secondary layer of protection on top of engineering controls (*e.g.,* inline sampling for sampling events). The discussion of the exposure control plan suggests a

rigid consideration of each of the steps in the control hierarchy, requiring that each step in the hierarchy be fully considered before moving to the next step. EPA should give greater flexibility to facilities when applying the hierarchy of controls to recognize there are often multiple layers of protection and the evaluation does not stop at a step when, for example, an inline sample mechanism is installed for routine samples. To allow for the multi-layer evaluation with complex chemical facilities, we recommend that the time required to develop the plan (§ 751.707(b)(4)) be extended to 2 years from the completion of initial exposure monitoring, for a total of 24-36 months from the effective date, to provide adequate time to evaluate and implement appropriate compliance approaches that are the least burdensome and most effective for workers. During the implementation time protections would remain in place for workers through the existing OSHA requirements implemented by facilities such as hazard assessments, including dermal and respiratory protection requirements, and administrative controls such as SOPs and permit requirements.

To allow adequate time to plan for and implement the controls, which will thus help to ensure that adequate protection is provided for workers, EPA should allow 24-36 months after the effective date for full implementation of the exposure control plan in proposed § 751.707(b)(4). Adequate time would also allow for full implementation of any necessary engineering, administrative or other controls for compliance with the new ECEL.

D. Exposure control plan documentation

The exposure control plan requires a significant amount of information for this new regulatory requirement. The following comments include recommendations for streamlining the reporting requirements, removing some requirements regarding actions "not" taken which impose analysis of all potential actions, without a threshold for significance, that could dilute the documentation resources dedicated towards the controls that are identified for implementation and lead to regulatory uncertainty regarding when an item "not" listed becomes a violation.

The following lists comments associated with the exposure control plan (ECP) requirements in § 751.707(2) by subsection:

> § 751.707(2)(i): Many industrial facilities have robust hazard assessments and standard operating procedures describing the potential hazard and controls required, including PPE and actions that should be taken to prevent exposure to the hazards. For the exposure control plan documentation requested by this subsection, EPA should allow industrial facilities to reference existing

documentation relating to controls selected and in place. Additionally, the ECP should have the ability to describe how manufacturing and processing facilities rely upon layers of protection rather than a single engineering or administrative control.

§ 751.707(2)(ii): This section should be removed as the provisions provide no additional value to the evaluation required in subsection (i) above. Requiring an entity to list every control *not* implemented and why the control not implemented does *not* work, without even a threshold for such an evaluation, creates administrative overwork that does not serve the purpose of documenting and implementing an ECP that meets the ECEL. This prong should be removed as a requirement.

§ 751.707(2)(v): For the attestation, EPA should clarify that ambient air outside the workplace means outside the fenceline of the subject facility. Additionally, the second phrase "whether additional equipment was installed to capture or otherwise prevent increased emissions of CTC to ambient air" should be removed from this subsection for two reasons: 1) the phrase does not seem to be information required for the primary purpose of the attestation relating to ambient air outside the workplace; and 2) the requested information seems duplicative of subsection (i) above that requires the identification of controls installed at the facility.

§ 751.707(2)(vii): This requirement for documentation relating to "any change" without a threshold for evaluation is vague and overly broad. As provided in the WCPP, periodic monitoring would capture any increase caused by a significant change that potentially impacts exposure and therefore removes the necessity of this additional documentation requirement. If EPA chooses to keep this prong, a threshold such as a *significant change that could create a regulated area based upon process knowledge* or other experience should be considered as a threshold for this documentation requirement. Finally, this subsection should remove the words "or not" as that would not be a significant change and is not required to demonstrate compliance with the ECEL, the primary purpose of the WCPP.

EPA is encouraged to evaluate the ECP requirement to remove duplicative documentation requirements. Additionally, multiple references to documentation of actions that are *not* taken and actions that are *no*t expected to result in exposures over the ECEL not only divert administrative resources away from the primary purpose of the ECP -- to document the exposure strategy, implementation of, and compliance with the WCPP -- but also counter the TSCA § 6(a) requirement that EPA regulate unreasonable risk to the extent necessary so that the chemical substance no longer presents such risk. A requirement to document the plan to achieve the ECEL may be seen as necessary; a requirement to document all actions not taken and/or actions or changes not anticipated to exceed the ECEL goes beyond the statutory mandate.

E. IH measurement and WCPP implementation should allow for use of the assigned protection factor (APF) for tasks to comply with the ECEL in a full shift

With the low levels of the ECEL as an 8-hour TWA, the proposed respiratory protection language in 40 CFR § 751.707(f)(5) should be clarified so that an exceedance of the ECEL does not automatically default to a required use of the APF for the full shift. Employers should be allowed to implement IH assessments to compare to the ECEL TWA that separately measure i) a task where potential exposure may occur (*i.e.,* 30 minutes for a sampling event); and ii) the "rest of day" exposure (*i.e.,* 7.5 hours), where such tasks are not anticipated to have potential CTC exposure.

Effectively, this approach allows control banding to be focused on task-based scenarios that occur in well-characterized similar exposure groups (SEGs) instead of the full 8-hour data ("Control Band by Task Approach"). This approach of specifying controls for specific product uses is also included for compliance under European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (ECHA 2020). Furthermore, task-based control strategies are common in many industrial operations, particularly in chemical manufacturing. This is because the nature of many of the tasks with potential exposure are of short duration or of intermittent frequency. There are many guidance documents and reviews that reinforce the importance of task-based exposure controls and application of control banding concepts.[71] For this reason, it is very rare for a worker in chemical manufacturing to wear respiratory protection devices for the full shift.

In the Control Band by Task Approach, the use of the APF for a required respirator can be considered in evaluating compliance against the ECEL for a short-term task. For example, to compare to an 8-hr TWA ECEL, one would collect a short-term air sample (*e.g.*, 30 minutes) while a task is being performed, and apply the APF associated with the respiratory protection that is required and used for that task. An additional and separate air sample would be collected for the remainder of the shift to calculate an 8-hr TWA.

[71] *E.g.*, National Institute for Occupational Safety and Health (NIOSH). Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding (CB) (2009); available online at: https://www.cdc.gov/niosh/docs/2009-152/default.html; Zalk, D.M. Control Banding; A Simplified, Qualitative Strategy for the Assessment of Risks and Selection of Solutions, 210. Delft, The Netherlands: TU Delft Publisher (2010).

The following narrative illustrates how the Control Band by Task Approach could be implemented:

1. The IH risk assessment creates a similar exposure group (SEG) for employees that conduct sampling once a day;
2. A 30 min. "task" PBZ sample is taken on an employee conducting in-line sampling, during which time the employee is wearing a respirator with a specific APF that has been selected in compliance with the maximum use concentration (MUC) appropriate for the sampling period and as required by the facility's Standard Operating Procedure and Hazard Assessment and/or the WCPP;
3. After the PBZ task sampling period, for the "rest of the day" tasks over the remaining 7.5 hours, the same employee will take a separate PBZ "rest of day" sample;
4. The APF associated with the respiratory protection used for the PBZ "task" PBZ sample will apply to the 30 min task sample taken, and then added to the PBZ rest-of-the day 7.5 hour sample to calculate an 8-hour TWA:

[(PBZ task value x .5)/APF] + (PBZ rest-of-day value x 7.5) /8 = 8 hour TWA

This approach would be effective in confirming that controls are in place for the short-term tasks and that the respirator use is sufficient (meets the MUC requirements) to cover any potential risk of exposure for that SEG task. The rest-of-the-day PBZ sample separates tasks where potential exposure is not expected and confirms that engineering controls are in place.

To allow for the Control Band by Task approach, 40 CFR § 751.707(f)(5)(ii) could be modified to read as follows *(new language in italics)*:

> For the purpose of this paragraph (f), the maximum use concentration (MUC) as used in 29 CFR 1910.134 must be calculated by multiplying the assigned protection factor (APF) specified for a respirator by the ECEL. *An employer may also utilize the MUC to evaluate a specific task measured separately within a full shift for comparison to the ECEL.*

The proposed language provides that MUCs could be used for short-duration exposure, as described in the example above for the CBT approach. The task-based exposure average is then combined with the exposure estimate for the remaining portion of the shift.

It is recommended that at least six samples are collected to demonstrate the MUC of the APF is appropriate for a SEG and evaluate compliance with the ECEL. This is based on AIHA guidance for assessing and managing occupational exposures, which states that according to statistical sampling theory, there is a point of diminishing returns above approximately six to ten measurements (AIHA 2015). Given the repetitive task exposure scenarios at PCE manufacturing facilities a "rolling average" could be calculated based on the prior six measurements.

Statistical methods for evaluation against an OEL are also utilized by OSHA. OSHA recognizes that statistical methods should be utilized to account for error factors in the sample results.[72]

1. Direct-read instruments must be validated for the new limits

Direct-reading field instruments are currently utilized for maintenance activities, such as a line break, to confirm the air concentrations are safe for downgrading PPE. For example, it is common practice for maintenance tasks involving opening chemical distribution lines to start with employees in full PPE (namely a full chemical resistant suit, chemical resistant gloves and boots, a full face supplied air respirator, and a hardhat). A direct reading instrument is then used to show that the airborne concentration is below the exposure limit and permit a downgrade of PPE and/or respiratory protection.

Currently, manufacturing facilities utilize instruments such as a Photo Ionization Detector (PID) as a portable vapor and gas detector for direct reading in the field for a variety of organic compounds, including CTC. PIDs are available in portable hand-held models and in a number of lamp configurations. Results are almost immediate; however, specific lamps and correction factors have to be applied and there are many limitations and concerns for continuing their use with the new lower EPA ECELs. PIDs are not technically capable of measuring CTC at the ECEL level. To our knowledge, the minimum instrument detection for CTC is 0.17 ppm; but measurements would be unstable, with widely fluctuating readings, at such a low level due to the interferences from other volatile organic compounds, humidity, and other factors. In the absence of being able to measure air concentration consistently and accurately below the ECEL, an employee will have to remain in full PPE for the entire duration of the task, creating other physiological concerns such as heat stress. Absence of direct-read monitoring equipment also impacts inspection and maintenance of CTC-containing equipment when confined space entry is required. Monitoring that is currently required by OSHA to be conducted before confined space entry by 29 CFR § 1910.146 is not technically feasible to evaluate against the proposed CTC ECEL with current direct-read monitoring technologies. Confined space entry is a critical task for inspecting and maintaining equipment in the field which requires real-time measurements to

[72] OSHA Technical Manual, Chapter 1, https://www.osha.gov/otm/section-2-health-hazards/chapter-1 (last viewed on August 14, 2023).

assess conditions. New direct-read technologies will be required to measure levels as low as the CTC ECEL in the field for inspection and maintenance of CTC-containing equipment when confined space entry is required.

Consistent with the need for up to 36 months to implement the WCPP, time is needed to evaluate the feasibility and implementation of alternate direct-reading monitoring capabilities in the field.

2. Requirements to resample when results indicate a non-detect are unnecessary

The requirement in § 751.707(b)(3)(i)(E) to re-monitor within 15 working days when results indicate non-detect is unnecessary. Facilities use accredited labs to perform IH sampling analysis and the results are reviewed by IH professionals prior to communicating the results to the employee. Requiring an environmental or IH professional to make a determination that re-monitoring is not necessary is an unneeded step that adds no value and creates the potential for enforcement, as it is not clear what will suffice as justification for this determination and how it is documented.

3. Requirements for direct dermal contact are vague

The regulations generally reference "direct dermal contact." The regulations should clarify in § 751.707(f)(6)(iii) that, based upon a hazard assessment, a facility could determine that gloves are sufficient for dermal PPE on a task-by-task basis, such as sampling and loading/ unloading tasks. The dermal control reference in the proposal is very broad and should be qualified to allow a facility to evaluate potential dermal exposure based upon the task.

Additionally, neither carbon charcoal pads (CCP) nor activated charcoal cloth (ACC) have been validated for CTC dermal hand wipe sampling, or, to our knowledge, for any volatile organic compounds. A validated dermal sampling method appropriate for characterizing worker exposure to CTC must first be developed and tested before it can be determined if such methods are effective or feasible.

F. Regulated Areas

The final rule should confirm that an entity may mark an area as a regulated area limited to certain processes or tasks. Even though, for example, the proposed definition of regulated area states that the regulated area must be established and "maintained," the use of the word

"maintain" does not override the ability to use methods of demarcation of a regulated area that are most appropriate for identifying potential risks or the specific tasks or process conditions where concentrations of CTC may exceed or reasonably be expected to exceed the ECEL.

It appears that this is the Agency's intent in § 751.707(b)(4)(v), which provides that where an owner or operator "has established a regulated area as required by paragraph (b)(4)(i) of this section where carbon tetrachloride exposure can be reliably predicted to exceed the ECEL only on certain days (for example, because of work or process schedule) [it] must have persons use respirators in that regulated area on those days." In keeping with the performance-based orientation of the WCPP, the owner/operator will consider several factors to determine how to demarcate a potential regulated area, including the configuration of the area, whether the regulated area is a result of certain tasks or processes, the airborne carbon tetrachloride concentration, the number and proximity of employees in adjacent areas, and the period of time the area is expected to have or potentially have exposure levels above the ECEL.

Separately, employers often need to establish temporary regulated areas during hazardous operation involving a line break, a confined space entry, and/or an emergency response activity just to name of few. There should be no confusion in the rule that just because a specific hazardous operation requires establishment of a temporary regulated area for a line break or an emergency response it must remain a permanent regulated area. Allowing employers to demarcate and limit access to regulated areas as appropriate for the potential risk is consistent with OSHA's three most recent substance-specific health standards, addressing occupational exposure to methylene chloride (29 CFR § 1910.1052(e)); 1,3-butadiene (29 CFR § 1910.1051(e)) and hexavalent chrome (29 CFR § 1910.1026 (e)).

IV. ALLOWED USES

A. EPA should clarify that both recovery of tail gas and elimination of nitrogen trichloride in the production of chlorine and caustic soda are COUs subject to WCPP requirements

EPA proposes that 9 current uses of CTC would be allowed to continue subject to WCPP requirements to be implemented by employers (referred to by EPA as "owners or operators"). WCPPs would apply to the following conditions of use identified in the proposed rule:

- Domestic manufacture
- Import;

- Processing as a reactant in the production of HCFCs, HFCs, HFOs, and perchloroethylene (PCE);
- Incorporation into formulation, mixture or reaction products in agricultural products manufacturing and other basic organic and inorganic chemical manufacturing;
- Repackaging for use as a laboratory chemical;
- Recycling;
- Industrial and commercial use as an industrial processing aid in the manufacture of agricultural products;
- Industrial and commercial use in the elimination of nitrogen trichloride in the production of chlorine and caustic soda; and
- Disposal.[73]

The final rule should be clarified to make clear that that the following two distinct CTC COUs each continue to be allowed under the Montreal Protocol: 1) elimination of nitrogen trichloride in the production of chlorine and caustic soda, and 2) recovery of chlorine in tail gas from the production of chlorine. Both are recognized uses of CTC as a process agent.[74]

The preamble describes both uses by referencing CTC's use as a process agent in "the elimination of nitrogen trichloride in the production of chlorine and caustic soda" and "the recovery of chlorine in tail gas from the production of chlorine."[75] However, the proposed rule does not include "recovery of chlorine in tail gas from production of chlorine" among the listed allowed uses. To clarify that this is an allowed use, § 751.707(a)(8) should be amended to read as follows: "Industrial and commercial use in the elimination of nitrogen trichloride in the production of chlorine and caustic soda *and the recovery of chlorine in tail gas from the production of chlorine*." Alternatively, "Industrial and commercial use in the recovery of chlorine in tail gas from the production of chlorine" could be added as a new subsection.

The italicized language below should also be included in § 751.711(c) **Downstream Notification**:

> After [DATE 180 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE Federal Register], this chemical is and may only be distributed in commerce or processed for the following purposes: Processing as a reactant/intermediate; Repackaging for use as a laboratory chemical; Recycling; Incorporation into formulation, mixture or reaction products in agricultural products manufacturing and other basic organic and inorganic chemical manufacturing; Industrial and commercial use as an industrial processing aid in the

[73] 88 Fed. Reg. at 49181.

[74] Risk Evaluation, at 103, Table 2-16; List of Approved Uses of Carbon Tetrachloride as a Process Agent in Decision of the Parties X/14: Process Agents.

[75] *Id.*, at 49191.

manufacture of agricultural products; Industrial and commercial use in the elimination of nitrogen trichloride in the production of chlorine and caustic soda; *recovery of tail gas from production of chlorine*; Industrial and commercial use as a laboratory chemical; Industrial and commercial specialty uses by the U.S. Department of Defense until [DATE 365 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE Federal Register]; and Disposal.

B. Recycled CTC as feedstock in perchloroethylene (PCE) production

EPA requests comment on the presence or use of CTC when recycled in the chlorinated organics process to manufacture PCE.[76] This occurs in a manufacturing facility with the same protections in place as the current manufacturing process, *e.g.*, compliance with OSHA hazard assessment and industrial hygiene requirements, implementation of facility-specific permitting, and engineering, administrative, and control requirements.

EPA's Ozone Depleting Substance (ODS) Regulations provide a production exemption for the reuse or recycling of CTC. This approved used of CTC includes recycling CTC that is not transformed as feedstock in other manufacturing processes to be used as feedstock in the PCE production process. Recycling CTC is in lieu of sending the material to destruction by approved technologies.[77] This recycling use is expected to continue and would be appropriately regulated under the WCPP regulatory option with an ECEL and DDCC requirement for these uses.

C. Having determined that its ECEL eliminates unreasonable risk, any use that can meet the ECEL should be allowed to continue subject to WCPP requirements

EPA proposes prohibition, rather than compliance with a WCPP, of the following industrial and commercial uses of CTC because it "has not found any ongoing users of CTC for these conditions of use [and] expects that this is a result of the phaseout of CTC manufacturing in the United States for most non-feedstock domestic uses due to the Montreal Protocol and Title VI of the CAA, and EPA believes it is reasonable to assume that industry has found alternatives for these uses."[78]

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[76] *Id.*, at 49194.

[77] 40 CFR § 82.3. As noted elsewhere, "the reuse or recycling of a substance" is excluded from the definition of "production" and therefore is not subject to restrictions under the Montreal Protocol. 42 U.S.C. § 7671(11).

[78] 88 Fed. Reg. at 49191, 49202. The preamble states "EPA is proposing under TSCA section 6(a) to. . .(3) Prohibit certain processing, industrial, and commercial conditions of use and the manufacture, processing, and distribution for those uses, which the Agency understands have already been phased out." *Id*., at 49193. As noted above and

- Industrial and commercial use as a processing aid in the manufacture of petrochemical-derived products;
- Industrial and commercial use in the manufacture of other basic chemicals (including chlorinated compounds used in solvents, adhesives, asphalt, and paints and coatings), except for use in the elimination of nitrogen trichloride in the production of chlorine and caustic soda (for which EPA is proposing a WCPP);
- Industrial and commercial use in metal recovery; and
- Industrial and commercial use as an additive.
- Processing: Incorporation into formulation, mixture or reaction products in petrochemical-derived manufacturing (the upstream processing condition of use for the industrial and commercial use of CTC as a processing aid in the manufacture of petrochemicals-derived products); and
- Industrial and commercial use in specialty uses by the U.S. Department of Defense (DoD).

Importantly, however, the preamble states that "if EPA receives information indicating the continued use of CTC for these conditions of use, the Agency may consider regulating these uses rather than prohibiting them. Therefore, the primary alternative regulatory action considered by EPA would require the implementation of a WCPP, including an ECEL and DDCC requirements."[79] HSIA strongly supports this primary alternative regulatory action, for two reasons.

First, TSCA § 6(a) directs EPA to regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk." A facility in compliance with its WCPP has acted, by EPA's definition, to "ensure that unreasonable risks are addressed." The statute does not ask or empower EPA further to make judgments regarding the use. Once it establishes the regulatory requirements, EPA has no additional authorization to prohibit a COU as long as the workplace is able to comply with a WCPP. Second, as EPA implicitly recognizes, it would be redundant and unnecessary to prohibit any of these uses under TSCA. Any use (other than recycling) that falls outside the definition of "feedstock" or "process agent" is already effectively

recognized by EPA, uses that are not feedstock or process agent have already been phased out under CAA Title VI and the Montreal Protocol, making such a prohibition unnecessary. Moreover, the only justification for such a ban is that it would present an "unreasonable risk," which EPA has determined is not present where the user is in compliance with a WCPP: "EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL would eliminate the contribution to the unreasonable risk of injury to health for CTC resulting from inhalation exposures in an occupational setting." *Id.,* at 49194.

[79] 88 Fed. Reg. at 49205.

banned, as manufacture/import for such use is prohibited under the Montreal Protocol and the Clean Air Act.

Finally, EPA acknowledges that a WCPP is in addition to, and not a substitute for, OSHA requirements. Having two regulators responsible for the same workplace obviously will raise serious compliance issues for employers which now find themselves subject to both sets of regulations. Compliance issues relating to uses allowed with WCPPs are addressed in § III above.

V. DISTRIBUTION IN COMMERCE

EPA should confirm the no unreasonable risk determination and order under TSCA § 6(i)(l) for distribution of CTC in commerce.[80] Because distribution in commerce does not pose an unreasonable risk, risk management regulation is not necessary to prevent such unreasonable risk. Additionally, the proposed rule requires a WCPP to prevent unreasonable risk in any upstream or downstream use following distribution in commerce, therefore negating any need to regulate distribution in commerce to address upstream or downstream activities.[81] EPA should clarify that distribution in commerce in compliance with regulations for transportation of CTC does not pose an unreasonable risk so that additional regulation is not necessary.

EPA could clarify the applicability of the regulation of distribution to the COUs allowed under the rule by inserting the following language (based upon the Risk Evaluation Condition of Use description):

> Distribution in Commerce. For the purpose of use conditions listed in 40 CFR § 751.707(a) or use conditions not otherwise prohibited in this subpart, distribution in commerce of CTC, the transportation associated with the moving of CTC in commerce, is an allowed use condition. Loading and unloading activities are not included in the Distribution in Commerce use condition.

In addition, Section 751.707(a) should be amended to add the following:

> *(10) Distribution in commerce to (1) through (9) in this paragraph and for export.*

[80] Risk Evaluation at 242. For some reason, distribution is missing from the list of allowable conditions of use in the proposed rule. As noted, it was deemed to present "no unreasonable risk" in the 2020 Risk Evaluation. Although the Revised Unreasonable Risk Determination (EPA-HQ-OPPT-2016-0733-0120, at 2) states that distribution in commerce does "not drive the unreasonable risk determination for carbon tetrachloride," it was not included in the Revised Risk Determination under the whole chemical approach.

[81] Of course, this is not to concede that either the upstream or downstream uses pose an unreasonable risk, or that EPA has the authority to regulate upstream activities which do not pose an unreasonable risk.

VI. EPA HAS NOT MET THE REQUIREMENTS OF TSCA § 9

TSCA § 9, as originally enacted and as updated by the Lautenberg Act, 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." Worker health and safety falls under the jurisdiction of the federal OSHA, and use of CTC is already regulated under the OSH Act. Taking steps that would lead to the removal of products from the marketplace where the existing OSHA requirements are met is not consistent with TSCA either as initially enacted or as revised.

A. From its inception, TSCA has been intended to fill gaps in regulation, not to supplant existing regulatory frameworks.

TSCA § 9, as amended, provides:

> "(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—
>
> > (A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and
> > (ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and
> > (B) to respond to the Administrator with respect to the matters described in subparagraph (A).
>
> "Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested

determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

"(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk."

"(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

"(2) In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk described in paragraph (1) and a comparison of the estimated costs and efficiencies of the actions to be taken under this title and an action to be taken under such other law to protect against such risk."

If this statutory language were not sufficient to express the limitations on EPA's authority, the legislative history leaves no doubt. 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 section 5 makes no amendment to TSCA section 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."[82]

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."[83] 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 Occupational Safety and Health Act, and referring the matter for action by OSHA.[84] 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."[85]

Indeed, TSCA § 9 was strengthened by the Lautenberg Act, as evidenced by two colloquies on the floor of the House of Representatives. First:

> "Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentlewoman from Tennessee (Mrs. *Blackburn*), the vice chair of the full committee.
>
> Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done. Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.
>
> Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).

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

[83] 122 Cong. Rec. H11344 (Sept. 28, 1976).

[84] 50 Fed. Reg. 27674 (July 5, 1985).

[85] Memorandum to Lee M. Thomas from Gerald H. Yamada, June 7, 1985, p. 2. *See also* TSCA § 2(c): "INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided to take under this Act."

It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.

Would the chairman please confirm my understanding of section 9?

Mr. SHIMKUS. Will the gentlewoman yield?

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

I thank the chairman for his good work."[86]

Second:

"Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

[86] 162 Cong. Rec. H3028 (May 24, 2016).

> As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:
>
> Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and that authority sufficiently protects against a risk of injury to human health or the environment; or
>
> Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.
>
> Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue."[87]

These colloquies make clear the ongoing Congressional intent that TSCA not be used when either EPA or another agency has taken steps to address the risks identified.

B. The instant proposal fails to take into account existing regulation of CTC, as required by TSCA § 9

As noted above, OSHA has regulated occupational exposure to CTC for many years. OSHA should be given an opportunity to consider whether a lower workplace limit would be appropriate. Otherwise, if EPA were to go forward with regulation under TSCA, there would be a potential for conflicting and overlapping regulation. OSHA's existing limits would remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory (subject to prosecutorial discretion). OSHA may not, however, enforce an EPA regulation under the general duty clause of the OSH Act, even if the EPA regulation afforded greater protection, as long as an OSHA standard on the same substance is in effect.

It is also significant that EPA is not authorized to establish ambient concentration limits under TSCA § 6.[88] EPA thus cannot limit employee exposure directly, but could only do so indirectly, *e.g.,* by controlling the amount of substance used in a product or prohibiting a

[87] *Id.*

[88] H. Rep. No. 1341, 94th Cong., 2d Sess. 34 (1976), *reprinted in* House Committee on Interstate and Foreign Commerce, *Legislative History of the Toxic Substances Control Act*, at 441 (1976).

particular use of the substance under § 6. This is potentially much more burdensome economically than ambient standards, which permit each employer subject to the standards to achieve the necessary reduction in exposure in the most cost-effective manner. Yet TSCA § 6(c)(2) requires EPA carefully to consider the cost-effectiveness of a proposed regulatory action against at least one alternative, and Executive Order 13563 requires agencies to achieve their objectives by using the least costly regulatory alternative.[89] Here, the most cost-effective alternatives have not been chosen.

In light of the foregoing, considerations of avoiding unnecessary duplication and utilizing established expertise weigh in favor of invoking the Administrator's referral authority under TSCA § 9(a) even if EPA were to proceed under TSCA. 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.[90] Yet there is no evidence that EPA has submitted to OSHA "a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk and includes in such description a specification of the activity or combination

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[89] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821-3823 (January 21, 2011). In pertinent part, E.O. 13563 states:

> "This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

[90] As noted above, § 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.

of activities which the Administrator has reason to believe so presents such risk." The non-existent report obviously did not "include a detailed statement of the information on which it is based" and was not "published in the Federal Register," as required.

Had the required report been issued, in the case of OSHA it presumably would have identified how OSHA's authority over the workplace was insufficient to address the risks posed by CTC. A letter from the Assistant Secretary of Labor for Occupational Safety and Health (undated but apparently issued on April 4, 2016) identifying limits on OSHA's authority to regulate hazardous substances was issued in connection with a previous unrelated rulemaking, but it does not come close to meeting the requirements of TSCA for EPA action in this case. The April 2016 letter identifies no such gap specific to use of CTC in any particular workplace, rather it simply recites how OSHA's authority does not extend to self-employed workers, military personnel, and consumer uses. But those are limitations that were imposed by Congress and have existed since the Occupational Safety and Health Act was enacted. Those limitations apply to every use of every toxic substance. Congress cannot have meant, in enacting "gap-filling" legislation, to open the door to EPA assuming all authority over the use of hazardous substances in the workplace.

Finally, EPA has not taken into account its own extensive regulation of CTC use under the Clean Air Act (CAA), as required under TSCA § 9(b). As noted above, in the 1990 CAA Amendments and the more recent AIM Act, Congress expressly excluded feedstock uses from production restrictions on the basis that the chemical is "used and entirely consumed (except for trace quantities),"[91] in essence a judgment that such uses are *de minimis.* Thus, production or import of CTC, which depletes stratospheric ozone, was prohibited as of 2010 under CAA Title VI but with limited exceptions for feedstock or process agent uses. It is illogical that uses so trivial they have been excluded from regulation to address the overriding global environmental concerns of stratospheric ozone depletion and climate change would now be causing unreasonable risk to workers.

Elsewhere in the 1990 CAA Amendments, Congress also created a comprehensive program to regulate sources of HAPs such as CTC. CAA § 112(d) provides that EPA shall "promulgate standards . . . to provide an ample margin of safety to protect public health in accordance with this section." Further, CAA § 112(f)(2) provides "if standards promulgated

[91] 42 U.S.C. § 7671(11).

pursuant to subsection (d) and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million, the Administrator shall promulgate standards under this subsection for such source category." Pursuant to these authorities EPA has already adopted standards applicable to fluorinated gas manufacturing that specifically regulate the risk now identified in the proposed rule.

Clearly, § 112 is the authority that Congress provided to address any risk from manufacturing fluorinated gasses. The principal such program is the National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry ("HON Rule"), 40 CFR part 63, subparts F, G, H, and I, which covers facilities manufacturing fluorochemicals using chlorinated solvents as feedstocks. In 2006, EPA's Risk and Technology Review determined that no changes to the existing CAA § 112(d) rule were required under CAA § 112(f) because the current level of control both (i) reduced HAP emissions to levels that present an acceptable level of risk and (ii) protects public health with an ample margin of safety. The finding regarding an ''ample margin of safety'' was based on a consideration of the additional costs of further control and the relatively small reductions in health risks that would be achieved by an alternative. The level of risk from the HON Rule was found acceptable because the maximum individual lifetime cancer risk was estimated to be 100-in-1 million, and this level of risk occurred at only two facilities. There were no people with estimated cancer risks greater than 100-in-1 million (the presumptively acceptable level of maximum individual lifetime cancer risk under applicable law) resulting from exposure to HON HAP emissions.[92]

Under CAA § 112, these standards must ensure an "ample margin of safety to protect public health." If the risk of concern was significant, EPA would have to adopt more protective standards under the Clean Air Act. Thus, regulations that were adopted during a process that by definition provide an "ample margin of safety to protect public health" are already in effect for the major ongoing CTC use sectors.

[92] *See* 71 Fed. Reg. 76603, 76605 (Dec. 21, 2006). The National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing ("MON") also applies to some HFC/HFO facilities. EPA recently completed the Risk and Technology Review (RTR) for the MON rule, 85 Fed. Reg. 49084 (Aug. 12, 2020).

The existence of a comprehensive regulatory framework for CTC uses under the Clean Air Act has two important implications for any consideration of TSCA § 6 rulemaking for the same sectors. First, it means that regulation under TSCA § 6 is precluded under TSCA § 9(b) unless EPA can make a determination "that it is in the public interest to protect against such risk by actions taken under this Act," where sponsors of the Lautenberg Act have stated the view that EPA's "own existing regulatory framework already appropriately addresses risk to human health."[93] Second, it is remarkable that EPA has not drawn on use and exposure information from these regulated uses to inform the instant proposal.

VII. FENCELINE ANALYSIS

The preamble includes, under the heading "TSCA Section 6(c)(2) Considerations," a detailed discussion of general population exposure to CTC from air and water pathways. It indicates that "EPA has separately conducted a screening approach to assess whether there may be potential risks to the general population from these exposure pathways. . . For CTC, the results from applying this screening approach did not allow EPA to rule out unreasonable risk to fenceline communities."[94]

The preamble notes a number of limitations to this screening analysis and additional analyses it conducted.[95] These include:

- Uncertainty if the facilities associated with a specific occupational exposure scenario were correctly cross-walked to the appropriate condition of use.

- The TRI dataset used for the single- and the multi-year fenceline analysis and land use analysis does not include actual release point locations, which can affect the estimated concentrations of the chemical at varying distances modeled.

- A discrepancy between the coordinates reported in TRI and the actual release point could result in an exposure concentration that does not represent the actual distance where fenceline communities may be exposed.

- A conservative exposure scenario that consists of a facility that operates year- round (365 days per year, 24 hours per day, 7 days per week) in a South Coastal

[93] 162 Cong. Rec. H3028 (May 24, 2016).

[94] 88 Fed. Reg., at 49209.

[95] *Id.,* at 49210-49212.

meteorologic region and a rural topography setting, meaning that the modeled exposures to receptors may be overestimated if there are fewer exposure days per year or hours per day, as is typically the case.

- The emission scenario assumed may or may not represent actual operating conditions of a given facility.

- Uncertainty in the stack parameters used and whether they represent actual stack parameters or conditions of the modeled facilities, including stack height, diameter, temperature, and other factors.

- Perhaps most importantly, the risk estimates from the fenceline analysis do not account for the background concentrations from historical emissions, which are persistent in the atmosphere.

The preamble further states:

"In the instances where efforts to reduce exposures in the workplace to levels below the ECEL could lead to adoption of engineering controls that ventilate more CTC outside, EPA believes this potential additional exposure would be limited as a result of the existing National Emission Standards for Hazardous Air Pollutants (NESHAPs) for CTC for these conditions of use under the CAA. Applicable NESHAPs include: 40 CFR part 63, subpart VVVVVV, Chemical Manufacturing Area Sources, and 40 CFR part 63, subparts F, G, H, and I, Organic HAP from the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks. In addition, as part of the proposed controls outlined in Unit IV, EPA is proposing to prohibit increased releases of CTC to outdoor air associated with the implementation of the WCPP/ECEL to avoid unintended increases in exposures to people from CTC emissions to ambient air by requiring owners and operators to attest in their WCPP/ECEL exposure control plan that engineering controls selected do not increase emissions of CTC to ambient air outside of the workplace and document in their exposure control plan whether additional equipment was installed to capture or otherwise prevent increased emissions of CTC to ambient air."[96]

EPA seeks comment on these conclusions, and the expectation that this proposed action in combination with the emissions standards resulting from existing NESHAP requirements would reduce risk sufficiently to the general population and fenceline communities. EPA also solicits comment on whether, consistent with TSCA § 9(b), any other statutory authorities administered by EPA should be used to take additional regulatory action identified as necessary to protect against such risk. HSIA submits that, as noted in § VI above, these are precisely the

[96] *Id.,* at 49212.

authorities that Congress provided should additional action be needed; TSCA is intended to fill gaps, not supplant all other environmental laws applicable to toxic chemicals.

EPA also seeks comment on whether it should require ambient air monitoring at fenceline locations or facility emissions source monitoring to demonstrate compliance with the proposed requirement that engineering controls implemented as part of a WCPP/ECEL under this rule would not result in the ventilation of more CTC outside. Specifically, the Agency "recognizes that owners and operators may have difficulty distinguishing between emission increases due to implementation of the WCPP/ECEL and emissions increases resulting from other factors such as increased manufacturing, processing, or use of CTC."[97] In addition, EPA recognizes the difficulty in distinguishing between background levels of CTC and emissions from facilities.

Whether or not EPA adopts the proposed prohibition on increased releases of CTC to ambient air outside of the workplace associated with implementation of the WCPP/ECEL, HSIA submits that ambient air monitoring at fenceline locations, or facility emissions source monitoring, is unnecessary and that its cost would exceed any benefit, particularly in light of the recognized limitations to the fenceline analysis. Given the importance of this issue, HSIA retained Stantec to provide an assessment. Stantec concluded:

> "Overall, the addition of fenceline monitoring proposed in the rule would be a burdensome and redundant regulatory requirement. Further, in consideration of long-standing agency policy for the responsible use of time and financial resources, a 'best available science' approach would be to proceed to a higher tier of risk assessment before mandating an intensive fenceline monitoring program providing no or questionable benefit to public health.
>
> "As an alternative to fenceline monitoring, site-specific screening-level fenceline modeling is a viable preliminary risk prioritization method, with subsequent advancement to further refined air dispersion modeling in the event that unreasonable risk cannot be ruled out at a screening level and additional information is desired to confirm that controls implemented as part of a WCPP would not result in discharge of additional CTC to ambient air. Air dispersion models are reliable methods for estimating air quality impacts from emissions sources and facilitate analysis of contributions of multiple sources at multiple receptor locations over averaging times of months to years. Therefore, refined modeling efforts provide a more reasonable option or next step with numerous

[97] *Id.*

advantages over fenceline monitoring for assessing potential increased risk to fenceline communities if EPA determines additional risk management efforts are necessary."[98]

In addition, the screening level analysis itself was predicated upon the assumed accuracy of EPA's benchmark toxicological values. Stantec evaluated the fenceline assessment with the benchmark concentration toxicity value of 2.7 ppm as determined by Gradient (Attachment C). In this assessment, Stantec determined that there would be no margins of exposure (MOEs) less than 15 (the Gradient recommended benchmark MOE) for any of the occupational exposure scenarios and therefore the fenceline assessment resulted in no unreasonable risk.

VIII. THE ELEMENTS ADDED BY EPA IN ITS REVISED RISK DETERMINATION ARE INCONSISTENT WITH TSCA

EPA published a draft Revised Risk Determination for CTC in 2022,[99] in which it announced its intent to implement two changes to the approach taken in the 2020 Risk Evaluation: (i) EPA stated it would make a revised risk determination of unreasonable risk for CTC as a whole chemical, instead of making risk determinations for each of CTC's conditions of use; and (ii) EPA stated it would no longer assume that all workers wear PPE when conducting risk evaluations. HSIA commented that the proposed whole chemical approach and decision no longer to assume the use of PPE are inconsistent with the requirements of TSCA and EPA's implementing regulations, are not within the scope of EPA's discretion, and fail to provide the public with an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use. HSIA urged EPA to withdraw its proposed revision to the CTC risk determination, to continue to make condition-of-use specific risk determinations for CTC and other chemical substances, and to continue to include reasonable assumptions regarding the use of PPE for each condition of use.[100]

Those comments are all relevant and in the docket. In light of EPA's justification of its unreasonable risk findings by unrealistic exposure scenarios, it warrants repeating that TSCA § 3(4) defines the term "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to

[98] Stantec, Comments on Proposed Rule for Carbon Tetrachloride Regulation under TSCA (Attachment G).

[99] 87 Fed. Reg. 52766 (August 29, 2022).

[100] EPA-HQ-OPPT-2016-0733-0102.

be manufactured, processed, distributed in commerce, used, or disposed of." The structure of the definition makes clear that "circumstances" includes aspects of the context in which a chemical substance is manufactured, imported, processed, distributed in commerce, used, or disposed of, including whether workers wear PPE. EPA's proposal no longer to assume the use of PPE is contrary to TSCA because it effectively eliminates "circumstances" from the definition of conditions of use. The use of PPE is a circumstance that "is intended, known, or reasonably foreseen." PPE use therefore belongs as a component of the conditions of use that EPA must consider in its risk evaluations.

As noted above, in the 2020 Risk Evaluation EPA generally assumed compliance with OSHA requirements for protection of workers. EPA explained that existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE, and that reasonable evidence supported the assumption that workers were complying with OSHA's requirements. EPA also acknowledged that it could not presume, in the absence of supporting information, a lack of compliance with OSHA's existing regulatory programs. Nevertheless, EPA based its decisions on unreasonable risk to workers on high-end exposure estimates, in order to account for the uncertainties related to whether or not workers are using PPE. EPA's Revised Risk Determination does not explain why the prior findings that OSHA requirements will result in appropriate PPE use are no longer supported. Without supporting record evidence or analysis, EPA's decision no longer to assume the use of PPE is clearly inconsistent with TSCA requirements. EPA has also not explained why some conditions of use that did not require PPE for the no unreasonable risk determination still require a WCPP for compliance.

IX. *DE MINIMIS*

In its most recent proposed TSCA risk management rule, EPA proposed that products containing perc at concentrations less than 0.1% by weight not be subject to the rule:

> "To aid the regulated community with implementing the prohibitions, and to account for de minimis levels of PCE as an impurity in products, EPA is proposing that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions described in this unit. EPA has determined that the prohibitions are only necessary for products containing PCE at levels equal to or greater than 0.1% by weight in order to eliminate the unreasonable risk of injury resulting from inhalation and dermal

exposures from PCE-containing products during occupational and consumer conditions of use."[101]

While HSIA does not have information available on the universe of products, if any, that might fall within this exception, any formulated products that do contain such *de minimis* concentrations of CTC likewise would not pose a risk and should not be covered. HSIA urges EPA to include a similar *de minimis* provision in the instant rule.

X. EXPORT

In general, TSCA imposes import certification and export notification requirements which will be triggered by the rule. Those who import CTC would be required to certify compliance that the chemical shipment complies with all applicable rules and orders under TSCA by filing with Customs and Border Protection a statement to that effect.

Exporters of CTC must first submit a written notice to EPA providing basic information on the exporting and importing parties, which is then forwarded to the importing party's government. "Domestic manufacture," defined as "refer[ing] to making or producing of a chemical substance within the United States (including manufacturing for export),"[102] is allowed pursuant to a WCPP, and as noted above compliance with a WCPP means that unreasonable risk has been eliminated. On the other hand, the preamble states "As the manufacture and processing of CTC presents an unreasonable risk to health in the United States, the manufacture and processing of CTC for export would also be prohibited or restricted in accordance with TSCA section 12(a)(2)."[103] EPA should clarify that CTC is only restricted from export if the manufacturing condition of use is not in accordance with a WCPP.

Such clarification is important and the following factors should be considered:

1. EPA's memorandum *Existing Chemical Exposure Limit (ECEL) for Occupational Use of Carbon Tetrachloride,* EPA-HQ-OPPT-0592-0007 (Feb. 9, 2021), "determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from occupational

[101] 88 Fed. Reg. 39652, 39671 (June 16, 2023).

[102] 88 Fed. Reg. at 49190.

[103] 88 Fed. Reg. at 49193. TSCA § 12(a)(2) states that the exclusion in (1) "shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article presents an unreasonable risk of injury to health within the United States."

inhalation exposures for conditions of use identified as presenting unreasonable risk under TSCA."

2. By "including manufacturing for export" in the preamble's "domestic manufacture" description,[104] proposed § 751.707 that allows for "manufacturing (domestic manufacture)" if exposure is at or below the ECEL should also allow for export under those same conditions.
3. If TSCA § 12(a)(2) is read as an automatic blanket export prohibition, then EPA's "whole chemical" unreasonable risk determinations would unduly burden international trade.
4. The Economic Analysis does not address the loss of the export market.

EPA should clarify throughout the preamble and as appropriate in the proposed rule that domestic manufacturing in accordance with the WCPP includes export. If EPA does intend to prohibit export of CTC, it should reconsider for the reasons set forth above. There is no basis for banning CTC exports where (i) no other country has adopted or even considered a limit within a hundred-fold of the proposed ECEL, and (ii) CTC manufacture in the United States is in compliance with a WCPP. Moreover, the Economic Analysis is totally silent on the economic impact of such a ban. In this and other ways, the proposal is a self-inflicted wound on U.S. manufacturing competitiveness.

We recommend that the proposed regulatory language at § 751.707(a) be modified to add a new subsection 10: "Distribution in commerce, including export."

[104] *Id., at* 49190.