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Strategies for refinement of occupational inhalation exposure evaluation in the EPA TSCA risk evaluation process

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Abstract

The focus on occupational exposures in the first published risk evaluations of existing chemicals by the Environmental Protection Agency (EPA) under the amended Toxic Substances Control Act (TSCA) puts a welcome spotlight on protecting the health of workers in the United States. Because new, fit-for-purpose occupational exposure assessment methodologies were developed by EPA, the objective of this analysis was to evaluate these methodologies in light of other existing occupational risk assessment frameworks. We focused our analysis on three chlorinated chemicals (methylene chloride, carbon tetrachloride, perchloroethylene). The EPA's methods were evaluated relative to peer-reviewed and professional organizations' guidelines for conducting site- and facility-based exposure assessment. Analyses of several key phases in the EPA approach were conducted to evaluate the effect of alternative approaches on exposure estimates. The revised exposure estimates using these alternative approaches yielded substantially different exposure estimates from those in the TSCA risk evaluations for these chemicals. The results also demonstrated the importance of utilizing a tiered approach to exposure estimation that includes collecting qualitative data, defining similar exposure groups, and integrating well-parameterized models with empirical data. These approaches aid in preventing mischaracterization of exposures and generating exposure estimates representative of current industrial practices. Collaboration among industry, EPA, and other government agencies to develop a harmonized approach to exposure assessment would improve the methodological rigor of, and increase stakeholder confidence in, the results of TSCA risk evaluations.

Keywords

Toxic Substances Control Act, industrial hygiene, exposure assessment

Introduction

Exposure assessment is a critical step in characterizing and managing the potential health risks faced by workers in the occupational environment (Dankovic et al., 2015; Jahn et al., 2015; Stewart and Stenzel, 2000). In the United States (US), the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) work in unison to develop and maintain "safe and healthful working conditions for the labor force" (NIOSH, 2018, OSHA, 2021). OSHA promulgates regulations and provides technical guidance and education, while NIOSH develops research that supports and advises OSHA and employers. These agencies have developed and implemented strategies for occupational exposure assessment, which are described extensively in the published literature and complemented by guidance from professional societies such as the American Industrial Hygiene Association (AIHA), among others (Stewart and Stenzel, 2000; Anna, 2011; Jahn et al., 2015). Comprehensive industrial hygiene and chemical safety programs incorporate guidance from numerous sources and use

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systematic approaches to assess, develop, and implement strategies for managing existing and emerging health risks in the workplace. Because measuring personal exposures for all workers on a daily basis is impractical, standard strategies exist that occupational health professionals routinely employ to efficiently and effectively characterize exposure potential (Mulhausen et al., 2015; Waters et al., 2015; Spear, 2004).

Occupational exposure assessments are incorporated into a wide range of product registration and stewardship activities (Dankovic et al., 2015). For example, occupational risk assessments are conducted for acute and long-term inhalation and dermal exposures for substances registered under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation in the European Union (EU) (ECHA, 2016). Occupational use scenarios are also included in EPA's pesticide risk assessments and, to a limited degree, new chemical assessments. Assessing health risks in workers has received increased attention following its recent inclusion in TSCA risk evaluations for existing chemicals. Occupational risk assessments are mandated under the Frank R. Lautenberg Chemical Safety for the 21st Century Act ["Lautenberg Act"], which amended TSCA in 2016. TSCA risk evaluations are intended to determine whether there is unreasonable risk to human health and the environment for any condition of use (COU, i.e., the circumstances under which a chemical is manufactured, processed, distributed in commerce, used, or disposed of (EPA, 1982)). If there is unreasonable risk for any COU, EPA must take action to mitigate that risk, including in the workplace. Occupational exposure assessments are therefore an essential component of these risk assessments.

Since the amended TSCA was enacted in 2016, EPA has completed risk evaluations for the first group of ten high-priority existing chemicals, thus providing an opportune time to compare EPA occupational exposure assessment methodologies with occupational exposure science best practices employed for site or facility-level assessments. This analysis focuses on the occupational exposure assessments of three chlorinated chemicals (methylene chloride [DCM], carbon tetrachloride [CTC], perchloroethylene [PCE]) in this first group of high-priority chemicals (EPA, 2020a, b, c). These chemicals are volatile liquids (vapor pressures ranging from 2.5 to 58.4 kPa) that have been in use for many years. EPA determined that occupational exposure to these chlorinated chemicals may pose unreasonable risk of health effects. However, in an initial review of the risk evaluations for the chlorinated chemicals (including trichloroethylene, not discussed in this paper), we identified several methodological questions regarding how the occupational exposure data were evaluated, including: (1) aggregation of historical data; (2) aggregation of workplace scenarios; and (3) exposure estimation of occupational non-users (ONUs, defined in the TSCA risk evaluations as employees at a facility who neither directly perform activities near the area of the source of chemical nor regularly handle the chemical). Therefore, the objective of this analysis was to evaluate EPA's occupational exposure assessment methodologies in light of other existing occupational risk assessment frameworks.

Methods

We conducted a review of the methods used for occupational inhalation scenarios for several COUs in the EPA TSCA risk evaluations for the three chlorinated chemicals. Specifically, the EPA approaches were summarized and then assessed by direct comparison to existing peer-reviewed and professional practice guidelines for conducting exposure assessments including, but not limited to, those of the AIHA, National Institute for Occupational Safety and Health (NIOSH), and the European Chemicals Agency (ECHA) (ECHA, 2016). Second, for a subset of the steps included in the EPA risk evaluation process, qualitative and quantitative assessments of EPA methodologies for three chlorinated chemicals were conducted to evaluate the effect of alternative assumptions and methodologies on estimates of exposure. This included evaluations of the use of DCM in manufacturing, including import and repackaging, and spray degreasing scenarios; PCE manufacturing; and CTC loading and unloading. Specifically, we addressed treatment of historical data, identification and refinement of similar exposure groups (SEGs), combining empirical and modeled exposure estimates, consideration of routine and non-routine tasks, and use of modeling to estimate ONU exposure potential.

Results

Analysis of key phases in EPA TSCA occupational exposure assessment

Occupational exposure assessment involves some or all of several basic steps in a varying sequence, including identifying hazard(s), collecting qualitative data, forming SEGs, selecting appropriate exposure metrics, collecting quantitative exposure data, and estimating exposures (Stewart and Stenzel, 2000; Dankovic et al., 2015). While some steps may be iterative once initiated (e.g., data collection), the overall approach should be step-wise with emphasis on the early phases of qualitative data collection, followed by modeling or prioritized collection of quantitative exposure data (Pettersson-Stromback et al., 2006; Dankovic et al., 2015; EPA 2019).

Exposure assessment for the purpose of a regulatory risk assessment should therefore also follow these best practices, which are built around an integrated, tiered strategy that begins with a robust data collection phase, including identifying and evaluating existing industry data. TSCA Section 6, however, does not detail or require specific exposure assessment strategies, beyond use of "best available science." For each of the first ten high-priority chemical TSCA risk evaluations, EPA provided a supplemental document entitled "Releases and Occupational Exposure Assessment" (see, for example, EPA, 2020d, Supplemental File for PCE). Within these documents, the same general approach and methodology for occupational exposure assessment is provided. Figure 1 presents a flow diagram with each step in the TSCA exposure evaluation process, described in further detail below.

In the sections that follow, we provide the results of our analysis of several of these critical phases, specifically: phase 3 (the identification of existing data), phase 4 (identification of scenarios for which exposure modeling may be amenable), phase 6 (selection process for data/approaches used as the basis for quantitative exposure estimates), phase 7 (exposure estimate calculation), and phase 8 (ONU exposure estimation). Where data were amenable, alternative exposure assessment results were provided. Specifically, we provide results of alternative analyses addressing the use of historical data and combination of measured and modeled exposure estimates in the DCM risk evaluation, identification and refinement of SEGs in the PCE risk evaluation, and use of modeling to estimate ONU exposure potential in the CTC risk evaluation.

Phase 3: Identify existing data for occupational exposures and assess quality. During the risk evaluation process, EPA utilized various approaches to obtain exposure data, including requests to industry during the problem formulation and scoping phases, through issuance of test orders, systematic literature review, and/or search of governmental agency databases (e.g., NIOSH, OSHA) (CRC Industries, 2018). Readily available data sets found in published literature or from publicly available databases (e.g., OSHA incident reporting) may represent exposures associated with upset conditions, or may be inconsistent with current industry practices. Additionally, key information may be missing from these historical data sets, including

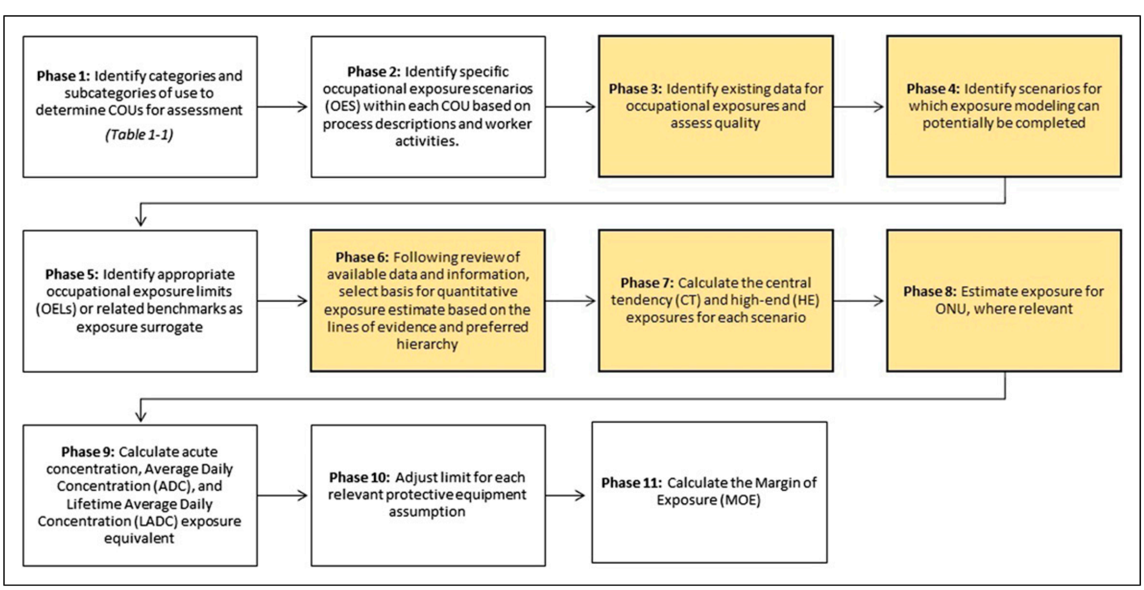

Figure 1. Phases of the risk evaluation process for TSCA occupational exposure scenarios. Boxes in orange are discussed in this paper.

information on the reason for sampling and the presence of exposure controls (Jahn et al., 2015, p. 158). As such, historical data sets may not always be appropriately representative of current industrial practices that utilize modern operating equipment and/or ventilation controls. Reductions in airborne concentrations in industry have been shown to mirror changes in the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLVs) or the OSHA Permissible Exposure Limits (PEL) (Paustenbach et al., 2011, p. 869). Many of the empirical data sets relied upon for the first ten TSCA risk evaluations have small sample sizes and are limited in their descriptions of the conditions under which the samples were collected.

Chemical-specific example: Analysis of historical data in the DCM risk evaluation. In the final risk evaluation for DCM, a small data set consisting of five full-shift and four short-term inhalation exposure samples collected in 1986 was used to assess exposure to DCM for the repackaging COU (EPA, 2020a, p. 139). Using the TSCA data quality evaluation framework, the data set was rated medium quality, despite receiving low scores for methodology, temporal representativeness, and variability and uncertainty (EPA, 2020e). While EPA considers data age (i.e., temporal representativeness) as a data quality evaluation criterion, older data are not necessarily considered unacceptable if the data source is otherwise of medium or high quality for other metrics (EPA, 2018 [systematic review guidance used for the first ten risk evaluations]; EPA, 2021a [new systematic review protocol]). If no metrics are unacceptable, ratings on each individual metric are effectively "averaged" to arrive at the final rating. To receive an "unacceptable" rating in the temporal representative metric and to exclude the data set from use, EPA provides the following guidance: "Known factors (e.g., new and completely different process or equipment) are so different as to make outdated information unacceptable" (EPA, 2018, p. 75). It is unclear why data that were collected around 35 years ago prior to a change in PEL, which would have substantively altered potential exposures, were not rated as unacceptable. Understanding the purpose for collection and potential limitations of historical data sets, particularly as they pertain to current handling practices, is critical to appropriate risk characterization.

For the processing as a reactant COU, EPA relied on two data sources to characterize full-shift worker exposures to DCM, one of which consisted of measurements collected prior to the 1997 revision of the OSHA PEL. This data source, submitted to EPA in 2017, was accompanied by a letter and analysis intended to support the conclusion that exposure concentrations collected prior to the revision of the OSHA regulation were not significantly different than concentrations expected for modern exposures (Finkel, 2017). The analysis consisted of a comparison of OSHA data collected before and after the revised PEL and concluded that "the full data set … shows that while the cumulative distribution of exposures has shifted slightly downward since the standard was promulgated, the pre-1999 and post-1999 distributions are more similar than different" (Finkel, 2017, p. 3). There were numerous limitations to this analysis – most notably, the conclusions did not include a supporting statistical analysis. There are numerous methods, both parametric and non-parametric, that are appropriate for comparing means or distributions of two groups between treatments, whether pre- or post-implementation of a regulation or a time point at which industry best practices changed.

We conducted a secondary analysis of 13,436 exposure measurements for DCM, abstracted from the OSHA Chemical Exposure Health Database, to assess whether the central tendency (CT) and high-end (HE) full-shift inhalation exposure concentrations of DCM changed over time following the 1997 PEL revision (OSHA, 2021). Using the search function for the OSHA database, all entries for the substance "Methylene Chloride" were downloaded. The data set was prepared for analysis by exclusion of all non-personal samples (i.e., wipe, area, and bulk samples) and those samples that were not reported in units of parts per million (ppm) (because the annotation was not sufficiently clear to convert units). Data exclusion resulted in 10,143 exposure measurements for further analysis. A "datecut" variable was used to specify samples collected prior to the issuance of the new PEL (up to 1998), the transition period for implementing the new PEL (1998–1999), and samples collected after the new standard was promulgated (post 1999). Each group was found to resemble a log-normal distribution, as is anticipated for occupational exposure data. A least-squares mean approach with a Tukey–Kramer adjustment for multiple comparisons (SAS Version. 9.4, SAS Institute Inc., Cary, NC) was used to examine differences between the geometric mean of the distribution for each period. Statistically significant differences ($p < 0.0001$) were found between pre-implementation and post-implementation (geometric means of 2.04 and 2.31 ppm, respectively), as well as between pre-implementation and the transition period (geometric means of 2.04 and 2.51 ppm, respectively). This initial analysis identified differences in concentrations before and after implementation of the new PEL; however, exposure medians were marginally higher in the post-implementation phase, consistent with the conclusions of Finkel (Finkel, 2017). However, based on occupational hygiene experience, this trend was not expected, and suggested that grouping of dissimilar scenarios was causing the increase in median estimates that did not capture sector-specific trends in exposure reduction, as evidenced by the variability demonstrated through high geometric standard deviations.

Refinement of exposure groups. As a second step in the OSHA data set analysis, DCM exposure monitoring data were evaluated by industry code to determine if there were measurable differences in exposure profiles between industry groups overall, as well as pre- and post-implementation of the PEL. Ten industry categories, separated by North American Industry Classification System (NAICS) and Standard Industrial Classification (SIC) codes, were identified in the OSHA data set (Table S1). Comparison of the natural log-transformed concentrations by NAICS/SIC code revealed differences in concentration that were less readily identifiable in the aggregated data set (Figure 2).

The industry groups were further evaluated for differences in DCM concentrations pre- and post-OSHA PEL implementation, demonstrating substantial reduction in concentration. The geometric mean DCM airborne concentration for the Reupholstery and Furniture Repair industry (NAICS Code 811420), for example, was reduced by more than 72%, from 212 ppm to 59 ppm following implementation of the OSHA PEL, (Table 1). Further, the medians of the pre- and post-implementation distributions for the Reupholstery and Furniture Repair industry were significantly different from on another ($p < 0.0001$; $\alpha = 0.05$). Another notable trend seen across all industry groups was a reduction in the GSD from pre-implementation to post-implementation, suggesting a decrease in data variability over time (Table 1). This reduction may be the result of standardizing industry practices over time, modernizing exposure controls, or a reflection of the smaller sample size for pre-implementation data. Regardless of the cause, the differences observed in this simplified analysis illustrate the importance of proper data sub-setting when analyzing the appropriateness of empirical data for exposure estimation. Further refinement of exposure profiles, particularly in the reupholstery and furniture repair industry, should be performed to ensure potential worker exposures to DCM are properly characterized (EPA, 2020a).

In the final DCM risk evaluation, EPA refined its methodology to evaluate the available historical data (EPA, 2020a). Specifically, EPA stated that it revised the OSHA data analysis to exclude non-personal samples and data with no units of measurement, and analyzed by NAICS code. EPA noted "a range of exposure reductions across most industry sectors and increases for several sectors. The largest decreases were for spot cleaning (94.5%), fabric finishing (93.4%), and use of adhesives (50.6%). On the other hand, exposures increased for plastics manufacturing (617%) and aerosol degreasing (130%)" (EPA, 2020a) EPA did not, however, exclude data collected before changes to the PEL.

Phase 4: Identify scenarios for which exposure modeling can potentially be completed. As part of the hierarchical approach for TSCA risk evaluations, empirical sampling data, if available, are used as the basis for the exposure assessment (EPA, 2020f). In the event that empirical sampling data are outdated or sparse, a more refined strategy is to integrate empirical data with high-quality modeling approaches (Tielemans et al., 2007). Supplementing empirical data with well-parameterized modeling can improve exposure estimates and increase confidence in the models (EPA, 2019).

Chemical-specific example: Combining empirical and modeled measurements for DCM. As demonstrated in the above analysis for plastic and wood product manufacturing and other occupational exposure scenarios (OESs) (Table 1), exposure characterization for many scenarios in the DCM risk evaluation relied solely on low-quality historical data sets that may not be representative of current industry practices. If data for the chemical of interest are limited and/or of low-quality, these data can be supplemented with exposure modeling. In some cases, the models can be validated using empirical data from other, similar chemicals and similar scenarios. For example, in the draft risk evaluation, EPA estimated DCM exposures for the aerosol spray degreasing scenario using a small empirical data set from OSHA ($n = 21$, including 7 pre-PEL samples). However, EPA acknowledged that the

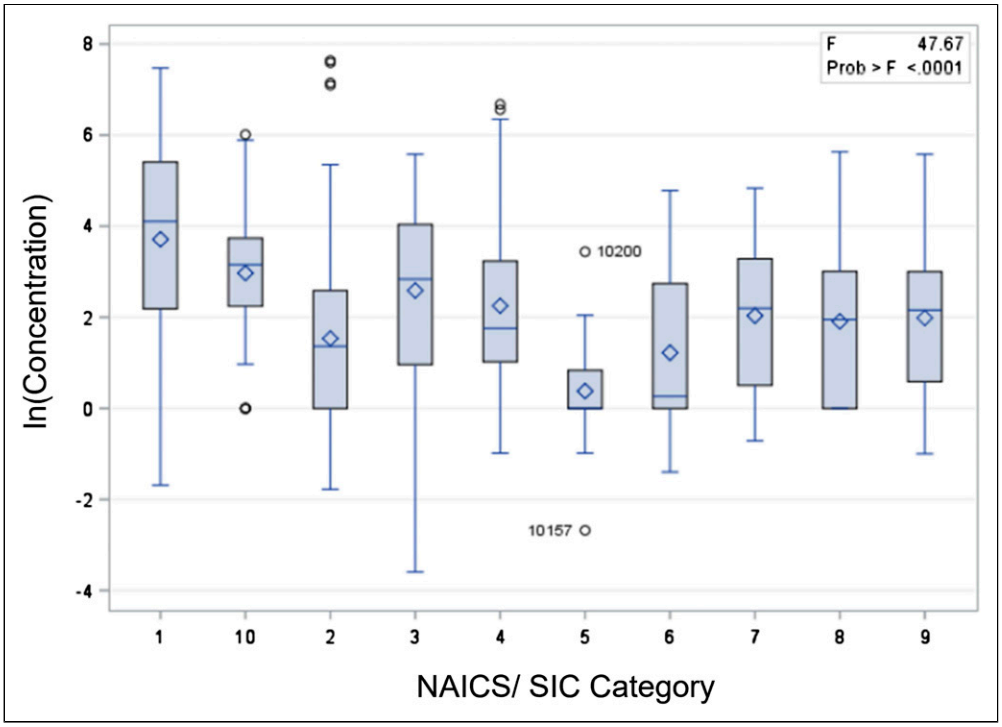

Figure 2. Distribution of natural log-transformed concentrations of DCM by NAICS/SIC Category. NAICS/SIC categories are identified in Table 3. The mean natural log-transformed concentration (ppm) is presented by the horizontal line in each interquartile range, and median indicated with a diamond. Suspected outliers are noted at the far ends of the range with circles.

data could not be specifically attributed to aerosol product applications.

We tested an alternative approach to estimate DCM exposures during aerosol degreasing utilizing a published model for toluene-based automotive spray cleaners calibrated with high-quality information on DCM usage for spray degreasing (Fries et al., 2018). The model used in Fries et al. (2018) is well validated and generalizable for this application because the use scenarios among solvents for spray cleaning are similar and the primary differences in exposure estimates across solvents stem from differing physicochemical properties that have predictable impacts on generation rates (AIHA, 2022). The toluene- and DCM-based products were used in a similar manner for a commercial part degreasing task using the same ventilation conditions; thus, the only model parameter requiring adjustment was the mass emission rate of the chemical (G). A similar brake cleaning product containing 5–20% DCM by mass was identified from the same product supplier (CRC Industries, 2018) as the toluene-based product evaluated by Fries et al. (Fries et al., 2018). Assuming 20% of the product was DCM, and 50 g of product were used per application, G was estimated as:

$$G = \frac{10\ grams}{0.6\ minutes}\ x\ \frac{1,000\ mg}{1\ g} = 16,667\ mg/min \tag{1}$$

Using the modified generation rate and assuming two 15-minute brake jobs over a 1-hour period, the resulting near field 1-hour TWA concentration estimate using a two-zone model was calculated as 50.5 mg/m^3. Assuming some portion of the worker's shift would be spent away from the immediate area of use, the equivalent full-shift DCM exposure would be even lower. As a comparison, the 8-hour OSHA PEL for DCM is 87 mg/m^3. The HE concentration used in the final risk evaluation for DCM for a 1-hour TWA exposure during aerosol product application was 230 mg/m^3, 4.5-fold higher than that estimated using a well-calibrated model (EPA, 2020a). This analysis indicates that leveraging empirical data to inform modeling may be a useful strategy; and in this example, it yielded exposure estimates lower than those generated in the DCM risk evaluation. Additionally, this analysis highlights a key limitation of modeled estimates that lack relevant contemporary exposure data. Both approaches would be strengthened with

Table 1. Geometric mean (GM), geometric standard deviation (GSD) of DCM and number of samples (*n*) for the top three NAICS/SIC industry categories, separated by time period (pre-implementation, transition, and post-implementation).

	Pre-implementation			Transition			Post-implementation				
Industry	*n*	GM (ppm)	GSD	*n*	GM (ppm)	GSD	*n*	GM (ppm)	GSD	% Difference[1]	KW Test *p*-value
All other plastics product manufacturing	22	14.90	6.28	13	3.40	0.69	155	7.13	1.19	52.14%	0.2799
Reupholstery and furniture repair	131	211.89	24.65	7	85.45	33.47	385	58.60	5.24	72.34%	<0.0001
Wood kitchen cabinet and countertop manufacturing	21	36.73	8.48	—	—	—	153	17.70	2.33	51.81%	0.0765
All other categories	2504	37.87	1.42	511	28.57	2.29	3234	17.49	0.52	53.82%	<0.0001

Notes: GM = geometric mean; GSD = geometric standard deviation; *n* = number of samples; KW = Kruskal–Wallis.
[1]Percent difference reflects the reduction in the GM from pre-implementation to post-implementation. $\alpha = 0.05$. Notably, EPA revised its statistical analysis of pre- and post-OSHA data for the final risk evaluation for DCM.[1] However, EPA continued to rely on the historical data in the final DCM risk evaluation, assigning the data a lower weight in some categories, lowering the overall confidence level in the source.

comparison to empirical measurements, leading to a better calibrated modeled representation of the exposure scenario.

Our alternative modeling approach is supported by EPA's decision to augment their methodology for this scenario in the final risk evaluation for DCM. Acknowledging the issues with the empirical data, EPA also modeled exposures using inputs from a 2000 California Air Resources Board (CARB) brake service study at 137 automotive maintenance and repair shops in California that used PCE-containing brake cleaners. These estimates were used for risk characterization (EPA, 2020d).

Phases 6 and 7: Select basis for estimation and calculate the CT and HE exposures for each scenario. A strategy routinely used in industrial hygiene programs is to designate SEGs, defined as groups of workers who experience the same general exposure profile based on the similarity of tasks they perform, the materials and processes with which they work, and the frequency and duration of the tasks they perform (Jahn et al., 2015). A similar concept of generalizing worker and ONU exposures for each COU was utilized in some of the TSCA risk evaluations that relied on empirical data; however, the broad groups selected lacked the refinement needed to adequately characterize differences in exposure profiles across the industry. In the first ten risk evaluations under the amended TSCA, exposure groups were developed within each COU for specific OESs, grouping all empirical data relevant to each COU together. This grouping, however, did not always reflect differences in processes across the industry. Figure 3 illustrates an example of a SEG array for chemical manufacturing. At present, the TSCA exposure assessments do not move beyond the first tier (e.g., process units as a whole), and typically lump all potential OESs together, rather than evaluating specific groups and activity profiles (e.g., operations and maintenance by task) separately from other groups and defining routine and non-routine tasks for each of these refined groups. Failure to distinguish between SEGs in exposure data by combining data for workers or tasks with different exposure profiles or incorporation of non-routine exposures may lead to misrepresentation of exposures and misinformed risk management decisions.

Chemical-specific example: Refinement of SEGs for the PCE Risk evaluation. In the PCE risk evaluation, EPA used a data set provided by the Halogenated Solvents Industry Alliance, Inc. (HSIA) that contained exposure measurements collected at manufacturing sites from 2006 through 2018 (HSIA, 2018). According to EPA, full-shift data were collected over 8–12 hours "during which workers engaged in a variety of activities including collecting catch samples; performing filter changes; line and equipment opening; loading and unloading; process sampling; and transferring of hazardous wastes" (EPA, 2020d). EPA calculated the

CT (50th percentile) exposure and the HE (95^{th} percentile) values for 15-minute, 30-minute, 8-hour, and 12-hour time-weighted average (TWA) exposures. Margin of exposure (MOE) comparisons were made using the 8-hour and 12-hour TWAs for acute health benchmarks and 8-hour TWAs for chronic health benchmarks (EPA, 2020c). However, the full-shift TWAs included in the HSIA data set characterized exposures for a variety of tasks, some of which likely occurred only weekly or monthly, rather than daily. As such, the 8-hour TWA estimates of "daily" exposure included in the CT and HE estimates were likely affected through the combination of exposure measurements collected on typical workdays and during non-routine tasks.

To evaluate the potential for inappropriate grouping in the PCE risk evaluation, an independent analysis of the HSIA data set was conducted to determine whether multiple exposure profiles were represented. The HSIA data set consisted of 375 individual entries, with 171 entries identified as full-shift, 195 entries specified as task-length, and 9 of unspecified type. Twenty-three of the samples (18 full-shift and 5 unspecified samples) were reported as below the detection limit (BDL) with no limit of detection (LOD) specified (HSIA, 2018). These samples were not included in subsequent analyses. A standard substitution method of LOD divided by the square root of two was utilized for samples that were reported as below an identified LOD.

AIHA provides guidance on using descriptive statistics to understand the distribution of an exposure monitoring data set and recommends that the following statistics be calculated for all exposure monitoring data: number of samples (*n*); maximum exposure; minimum exposure; range; percent of exposures greater than the applicable OEL; mean exposure; standard deviation; mean of log-transformed exposures; standard deviation of log-transformed exposures; geometric mean; and geometric standard deviation (Jahn et al., 2015). Following these recommendations, summary statistics were calculated for the full, task-length, and unspecified samples (see Table S3 for task-length samples). When all full-shift (routine) and task-length (routine and/or non-routine) samples were grouped together within their respective sample types, the geometric standard deviations for each sample type were high, at 4.06 and 4.30, respectively. To avoid misclassifying worker exposures, AIHA recommends that, "SEGs with large geometric standard deviations (>3) should be reviewed, and if appropriate, subdivided into two or more SEGs" (Jahn et al., 2015). Utilizing the CT of the HSIA data set as a representative exposure for the average manufacturing worker likely mischaracterizes various unique SEGs that comprise the overall HSIA data set. Evaluating all SEGs together may be appropriate when comparing samples to an occupational exposure limit, such as a PEL, for compliance purposes, but typically is not sufficiently refined for risk assessment. Particularly, assessment of all SEGs at once may result in over emphasis of non-routine tasks in the overall exposure profile. Notably, some of the observed variability in the data set may arise from differences in collection practices between companies or from limited samples; these factors, among others, should be further investigated when developing SEGs on an industry-wide basis.

Figure 4 displays the average PCE concentrations by task frequency for all frequencies combined, daily, weekly, and infrequent tasks separately, and all frequencies combined with infrequent tasks removed. The average concentration for daily and weekly tasks combined (4.41 ppm) was 2.3-fold lower than the average concentration for infrequent tasks (10.19 ppm) and 1.8-fold lower than for weekly tasks alone (5.74 ppm) (Table S3). Additionally, the maximum concentration from daily (28 ppm) to infrequent tasks (200 ppm) increased approximately 7-fold (Table S3). The substantial variability in the infrequent tasks category is demonstrated in the approximate two-fold increase in the standard deviation of all task frequencies combined (SD = 16.7) as compared to all frequencies without infrequent tasks (SD = 8.2). An assessment that averages across varying task frequency and durations overestimates both the central tendency and 95th percentile PCE exposures. Finally, there also is variability within each of the frequency categories reflecting job activity differences, particularly within the infrequent task category (Figure 4).

This analysis of the task-length samples by frequency indicates the importance of understanding the representativeness of a data set before utilizing it for risk assessment or risk management decisions. Were a practitioner to include infrequent, non-routine samples in an exposure profile describing typical longer-term routine exposures, the resulting central tendency and 95th percentile would be greater than if the exposure profile included only routine work and classified infrequent tasks separately. Thus, exposure data collected during non-routine tasks to inform exposure control strategies should not be included as part of a long-term daily average used for evaluating potential

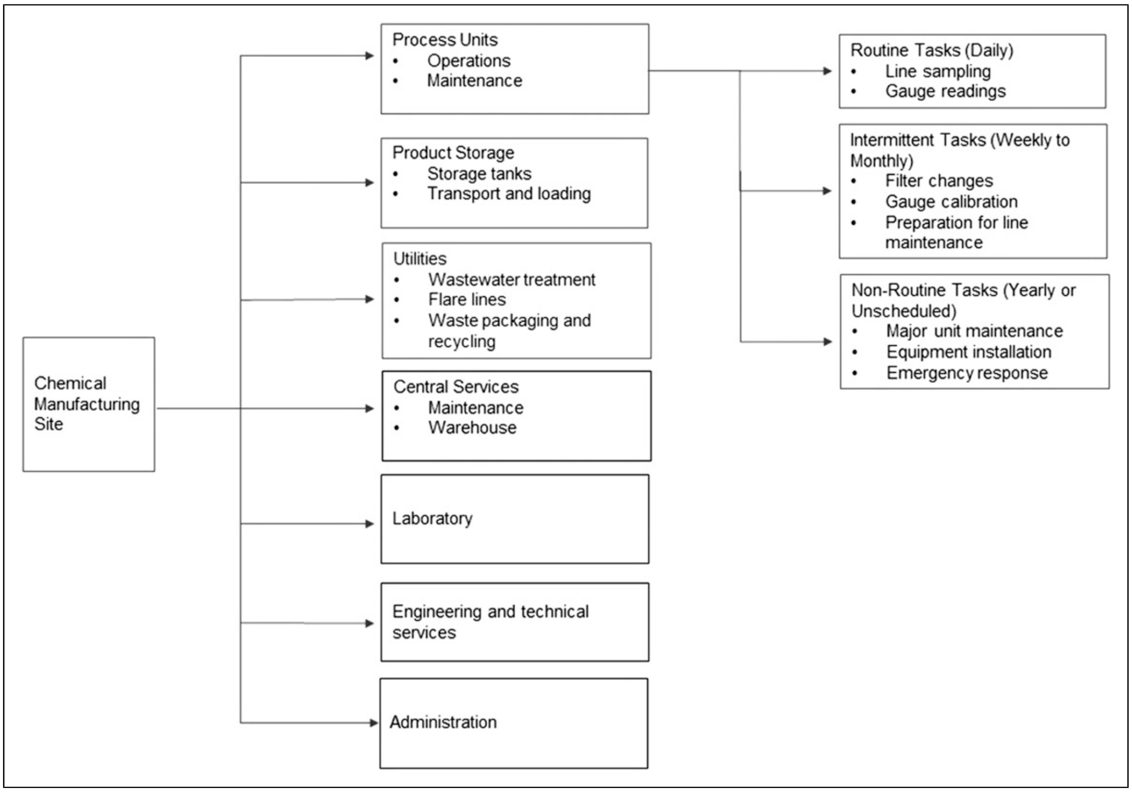

Figure 3. Example breakdown of SEGs from facility to task level. Several of these groups could be considered ONUs (e.g., administration).

health risks from chronic exposures. Furthermore, variability within task categories must be considered when developing SEGs that group workers with similar overall exposure profiles, including for non-routine tasks. We acknowledge, however, that there may be a lack of data to characterize all tasks and durations; the lack of data may spark efforts to collect additional data or may necessitate moving directly to a risk management decision. The utility of existing data is increased when there is detailed annotation and there are ongoing efforts by occupational health community of practice to enhance consistency in data annotation methods (Shockey et al., 2020).

Phase 8: Estimate exposure for ONU, where relevant. Estimating ONU exposures may also benefit from the consideration of both modeling and empirical data. In the draft risk evaluation for some of the chlorinated chemicals, the CT for workers was used as a surrogate for ONU exposure (e.g., EPA, 2020b; EPA, 2020e). In chemical manufacturing, however, workers who are not directly handling a chemical are anticipated to have limited exposure, with protections provided by the facility's engineering and administrative controls. If an ONU were present in a work area in which there was potential for exposure to a chemical at a similar level as a worker, the ONU would be subject to the same administrative controls and PPE requirements as the workers assigned to that work location. However, it should be noted that there is considerable variability in the extent of controls available across industrial sectors. Conversely, when working outside of the production area, limited exposure potential exists, and "worker" or "ONU" designations do not apply.

Chemical-specific example: estimating ONU exposure using modeling. For OESs other than manufacturing (e.g., for occupational exposures involving degreasing), there may be individuals meeting the EPA definition of ONU, but whose long-term average exposure potential is expected to differ from the CT for a worker close to an emission source. For example, in the chemical manufacturing environment, ONUs would only have periodic, passing exposures near the emission sources, and during those periods, they would be subject to the risk management strategies for operations workers exposed daily. For these scenarios,

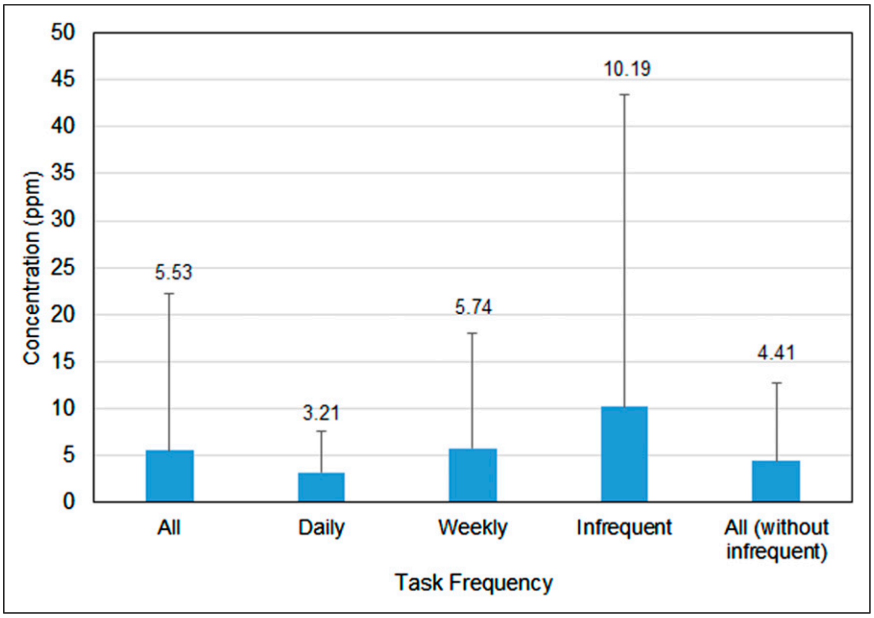

Figure 4. Average PCE concentrations (ppm) by task frequency for all frequencies combined, daily tasks, weekly tasks, infrequent tasks, and all frequencies (except infrequent) combined. Error bars indicate standard deviation.

an alternative approach to estimating ONU exposures (in the absence of adequate ONU monitoring data or paired with limited empirical data) is developing ONU-specific exposure models, such as the two-zone model (in which the ONU could be considered the far-field) or the near-field plume model, among others. Further, in some situations, area samples may be a reliable estimate of potential ONU exposure, acknowledging the limitations given their stationary nature.

In the CTC risk evaluation, the empirical CT exposure estimate for manufacturing workers was used as a surrogate for ONU exposure (EPA, 2020b, EPA, 2020f). To evaluate an alternative approach to estimating ONU exposures in CTC, a hypothetical, "worst case" evaluation of the near-field plume model (Armstrong et al., 2009) was used to estimate CTC concentrations at varying distances from a source. This model shows a large drop off in concentration with distance (Table 2). Even conservatively assuming that an ONU spent a majority of time within 2 m of a worker using CTC, the exposure reduction from the source to the ONU would be much greater than four-fold as the ONU moved further from the source. Using the same generation rate and wind velocity specified for the Tank Truck and Railcar Loading and Unloading Release and Inhalation Exposure Model in the near-field plume model results in a nearly 50-fold concentration reduction at 0.1–1 m from the source. Thus, assuming significant exposures in the absence of respiratory protection for ONUs is not consistent with industrial best practices, as any personnel authorized to work in a production area subject to high concentrations of a chemical would be included in a respiratory protection program.

Discussion

This methodology review, coupled with chemical-specific analyses of the EPA approach applied in risk evaluations of chlorinated chemicals, demonstrates that occupational exposure assessments in TSCA risk evaluations to date may not reflect current industry conditions. In some cases, the risk evaluations group workers with dissimilar exposures together, rather than following SEG methodologies, and thus alternative exposure assessment methods may be warranted. Specifically, a tiered, integrated approach to exposure assessment that emphasizes collecting qualitative data to assess general potential for exposure, conducting data quality analyses before selecting final data sets, defining similar exposure groups when analyzing the data, and integrating well-parameterized models with empirical data will help prevent mischaracterization of exposures and generate exposure estimates representative of current industrial practices.

The results of this analysis demonstrate several aspects of the TSCA exposure assessment process that may be improved with additional research, method

Table 2. Near-field plume concentration estimates for a hypothetical CTC inhalation exposure scenario for ONU at varying distances from the source.

Distance from source (m)	Hypothetical concentration (mg/m^3)[a]	Fold difference from hypothetical source concentration
0.1 (minimum in model)	29,600	—
0.25	8,090	3.7
0.5	2,260	13.1
1	631	46.9
2	176	168

[a]Hypothetical concentrations estimated using the near-field plume model with the high-end estimate for generation rate (3738 m^3/min) and wind velocity (2.23 m/s) as provided in Appendix D of the Supplemental File: Occupational Exposure estimate for CTC (EPA, 2020f).

development, data gathering, and model validation. To this end, stakeholders can work together to improve the process by:

- *Gathering more robust data and increasing information sharing.* Data owners are encouraged to provide qualitative and quantitative data at the level of granularity needed for EPA risk evaluation (e.g., including information on SEGs; task frequency and duration), as the level of specificity required for use in the TSCA process continues to be refined. EPA should develop data collection objectives and requirements in collaboration with IH professionals whose knowledge of field conditions can be utilized. Such collaboration will also facilitate consistency in the way data are provided across industries and companies, and would ensure that each data set is utilized appropriately in the risk evaluation. Additionally, improved access to contemporary exposure data may better facilitate cross comparison of modeled and measured results for specific exposure scenarios.
- *Developing occupational exposure assessment guidance to use for all TSCA risk evaluations.* First and foremost, the occupational exposure assessment process under TSCA would be substantially improved by a set of standard practices for use in all subsequent risk evaluations, drawing from existing occupational exposure resources. Industrial hygiene practitioners from across sectors could work collaboratively to develop such guidance; for example, AIHA recently hosted a workshop to facilitate information sharing and problem solving among government occupational health agencies and industrial hygiene professionals. The guidance should specify the best practices outlined above, presented in the context of a tiered approach that incorporates evidence integration techniques, SEG methodology, and comparison to empirical exposure data when possible.
- *Evaluating and incorporating occupational hygiene information and regulations from other agencies.* The process of occupational exposure assessment within the context of TSCA could be streamlined by a more thorough consideration of the information provided by: (1) existing OSHA and NIOSH chemical-specific standards and guidance, particularly concerning PPE requirements; and (2) facility permits and related emissions statutes that affect facility exposures. For example, the National Emission Standards for Hazardous Air Pollutants (NESHAP), which, by virtue of emissions controls, effectively require engineering controls that may reduce worker exposure in certain facilities (e.g., open air, closed-system production facilities). For VOCs like PCE and CTC, the hazardous organic NESHAP (HON) Subpart H (EPA, 1994) details explicit requirements for controlling purged fluids in chemical manufacturing process units. The NESHAP regulation also requires EPA inspections of facilities subject to it (EPA, 2021b). Data obtained for the purpose of the NESHAP could be used for screening purposes (at the very least) and to provide information on the processes and controls in place for groups of similar volatile substances that are subject to the same regulations.
- *Conducting new research.* Some of the health-based benchmarks derived under TSCA to evaluate health risks are lower than standards developed by occupational health agencies (e.g., ACGIH TLVs or OSHA PELs). These low benchmarks may necessitate developing new or more sensitive field sampling and analytical methods to fully characterize the potential

health risks for workers. Collaborating on method validation could be mutually beneficial for EPA and industry.
- *Cross educating* among government, industry, and other stakeholders on past, current, and novel methodologies.

Conclusions

Reviewing and analyzing occupational exposure assessment within the TSCA risk evaluation process puts a welcome spotlight on the critical need to protect the health of workers in the United States. This analysis of the current TSCA occupational exposure assessment framework compared to best practices for exposure assessment as presented by AIHA and the peer-reviewed literature indicates that there are areas in which the TSCA approach may be refined. Further, the alternative analyses conducted indicate that exposure estimates in the TSCA risk evaluations for the three chlorinated chemicals may be overestimated for certain occupational exposure scenarios, owing to grouping historical and current monitoring data; combining high-exposure, infrequent tasks with lower exposure, routine tasks; and not considering modeling strategies where empirical data are limited. A tiered, integrated approach to exposure assessment that emphasizes early qualitative data gathering and SEG definition will help avoid inappropriate grouping of data into a single OES category, misrepresenting the exposure estimates, and comparing exposure estimates to inappropriate health benchmarks. Increased cross-education and data and information sharing, and collaborative research among industry, EPA, other government agencies (NIOSH, OSHA), and other stakeholders would improve the methodological rigor, and increase stakeholder confidence in, TSCA exposure assessments.

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Authors' contributions

Conceptualization: AM, and HNL; methodology: AM, LHA, HNL; analysis: LHA, HNL, CMH; writing—original draft preparation: HNL, LHA; writing—review and editing: AM, CMH; visualization: LHA.

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