

Supplementary Appendix: Exposure Assessment Methods

The exposure assessment and reconstruction focused on the years before 1974. The promulgation of the OSHA PEL of 1 ppm as an 8-hour time-weighted average (TWA) in 1974 (from 500 ppm as a ceiling concentration) provided a catalyst for technological innovation to control exposures in the PVC manufacturing industry. By the mid- to late 1970s, the PVC industry had broadly adopted a closed loop process to minimize worker exposure during polymerization of vinyl chloride [1]. VC exposures over the past 40 years are generally assumed to be strictly controlled and not representative of the polymerization process for the years prior to 1974. As a result, industrial hygiene data generated since 1974 cannot validly be used to extrapolate to earlier polymerization process operations and an alternative approach was applied.

The approach used to derive individual exposure estimates followed a five step process: 1) literature review; 2) preparation of an industry-wide “default” job-exposure matrix; 3) preparation of facility profiles; 4) development of facility-specific job-exposure matrices; and 5) calculation of individual exposure estimates. This approach combined all available industrial hygiene measurements from the early 1970s with expert judgment informed by a synthesis of quantitative and qualitative information on workplace characteristics, work practices, and process and workplace changes over time. The industry-wide matrix was customized for each facility, based on the facility profiles and information specific to each factory, but relied on industrywide estimates where factory-specific information was not available.

Literature Review

The following sources were searched to identify potentially relevant historical VC exposure information: PubMed; the Occupational Safety and Health Administration (OSHA) Rule Making for the Vinyl Chloride Standard (Docket OSHA-H036)¹; in-house company documents provided by former and current producers of VC monomer and PVC; internet searches; and various documents and monographs produced by government agencies (e.g., NIOSH, OSHA, EPA) or other authoritative bodies (e.g., IARC). A public domain database created by the Environmental Working Group (EWG)² for documents relevant to PVC production facilities was also searched.

Two major characteristics differentiated exposures in PVC manufacturing from VC monomer manufacturing facilities from the 1940s through the early 1970s: process operations and ventilation systems. Polymerization operations used a batch process that required periodic manual entry of the reactors to remove caked polymer. PVC resins (both homopolymers and PVC copolymers) were manufactured using one of four production processes: suspension, emulsion, bulk, and solution [2]. By 1974, approximately 80% of PVC resins and copolymers were produced using the suspension process [2]. The polymerization process was closely linked to the monomer recovery process, as well as to characteristics of the resin particle (e.g., porosity). Polymerization facilities were spread geographically across the South, Midwest, and Northeast. Process units for polymerization operations were usually contained in enclosed structures and

¹ Docket ID OSHA-H036-2006-0910 (Available at <http://regulations.gov>).

² Available at: www.chemicalindustryarchives.org. This database contains more than 10,000 documents produced in response to toxic tort litigation against the chemical industry.

relied on mechanical, forced ventilation. Prior to 1975, general ventilation was considered adequate for the management of VC exposures. In 1956, the recommended standard for general room ventilation for PVC facilities was a minimum of 6 air exchanges per hour [3].

Vinyl chloride monomer was produced historically using one of three processes: 1) an acetylene process; 2) direct chlorination of ethylene to produce ethylene dichloride (EDC), followed by pyrolysis of EDC to make vinyl chloride; or 3) a balanced process based on ethylene oxychlorination [4]. By 1974, most monomer facilities were using the balanced oxychlorination process. For facilities that solely produced monomer, the finished product was transferred from storage vessels directly to rail tank cars and transported as a liquid under pressure. Few opportunities for exposure existed in monomer production, which was a closed loop process. Monomer production facilities were typically located in open air structures that used natural ventilation to disperse vinyl chloride vapors. Many of the monomer facilities were located along the Gulf Coast of Texas and Louisiana, where sea breezes provided additional ventilation.

Industry-wide JEM

By modifying standardized job classification schemes reported in the literature [5, 6], five similar exposure groups (SEGs) were identified for an industry-wide JEM. A separate JEM was created for PVC and VC monomer facilities (Table 3). The PVC SEGs were close-contact polymer operations (including autoclave cleaners and those working in close proximity, such as monomer stripping and recovery); resin finishing operations

(including drying and packing/warehouse operations); maintenance and support operations; laboratory and quality control; and administration and supervisory jobs. We used as few job classifications as necessary to categorize jobs with likely similar exposures based on actual exposure measurements and estimates reported in the various data sources. Although fewer than identified in earlier job classification schemes [5, 6], there was relatively high confidence among the industrial hygienists that these SEGs would provide adequate discrimination between jobs with different exposure potential (low, moderate, and high). In addition, calendar intervals for the industry-wide JEM were based on reports of estimated exposures for polymerization workers that were cited often in the literature as representative of average exposure [7, 8]. For polymerization workers, these exposure levels were: 1000 ppm for the years between 1945 and 1955; 500 ppm for 1956-1960; 400 ppm for 1961-1970; 150 ppm for 1971-1973; 5 ppm for 1974. For purposes of the industry-wide JEM, we assumed that finishing operations (including drying and materials handling) were about one half of the close-contact polymer operations (including reactor cleaning, stripping, and monomer recovery).

For monomer operations, we relied upon a survey conducted by NIOSH investigators in August 1975 [4] as well as information reported in a publication [9] and by a major producer of monomer throughout the 1940s, 1950s, and 1960s [10,11]. Based on these documents, the highest exposures were likely encountered by tank car loaders and operators, and workers engaged in sampling the liquid monomer product. These surveys reports reported lower VC concentrations in monomer facilities than polymer facilities.

For both monomer and polymer operations, we assumed that industry average exposure levels declined over time due to technological advancements, especially related to changes in reactor technology and increases in production efficiency (reducing unreacted monomer), improvements in work practices (for example, increased ventilation, adoption of high water pressure and solvent cleaning reactor methods), and increased awareness regarding the hazards of vinyl chloride exposure. Ultimately, the industry-wide default JEM for the monomer and the PVC manufacturing sectors each included exposure estimates for 25 SEG-calendar interval cells (table SA.1).

Table SA.1 Job Exposure Matrix: Estimated Time-Weighted Average Exposure to VC by Similar Exposure Group (SEG) and Calendar Intervals for VC Monomer and PVC Sectors

| Similar Exposure Group | Calendar Period | | | | |
|---|-----------------|-----------|-----------|-----------|------|
| | 1940-1955 | 1956-1960 | 1961-1970 | 1971-1973 | 1974 |
| VC Monomer Sector (exposures in parts per million) | | | | | |
| Supervisory/Admin | 50 | 10 | 5 | 2 | 1 |
| Operations | 100 | 25 | 5 | 2 | 1 |
| Maintenance/Support | 50 | 50 | 10 | 5 | 5 |
| Lab QA/QC | 350 | 300 | 90 | 10 | 5 |
| Rail Car Operations (Loading/ Unloading/ Cleaning) | 400 | 400 | 100 | 25 | 10 |
| PVC Sector (exposure in parts per million) | | | | | |
| Supervisory/Admin | 50 | 50 | 10 | 5 | 3 |
| Maintenance/ Support | 50 | 50 | 25 | 5 | 5 |
| Polymer finishing operations | 100 | 100 | 50 | 10 | 5 |
| Lab QA/QC | 400 | 300 | 150 | 25 | 10 |
| Close contact polymer operations* | 800 | 500 | 400 | 50 | 25 |

* Based approximately on the average estimates reported by Barnes et al. [7]. Nicholson et al. [12] reported peak exposures of 1000 ppm and ACGIH had recommended a 500 ppm maximum allowable concentration by the early 1950s. Therefore, we arbitrarily selected 800 ppm as the default industrywide average value for polymerization in the early years.

Facility profiles

To evaluate potential changes in exposure over time (from the 1940s to the early 1970s), two industrial hygienists assessed reports of changes in technology, processes, work activities, and exposure conditions over time. This information came from testimony and documents submitted to the OSHA docket in 1974. In addition, industrial hygienists reviewed existing monitoring data, either reported in the literature or submitted to the OSHA docket by companies. Based on this information, the industrial hygienists identified factors that likely varied across facilities that would potentially impact VC exposure potential over time (table SA.2).

Table SA.2 Knowledge of Technologies, Work Practices, and Processes over Time that Potentially Impacted VC Exposure Potential

| Factors / indicator of exposure | Before mid-1950's | Mid-1950's to late 1960's | Late 1960's to 1974 |
|---------------------------------|--|--|---|
| Factory layouts | Little separation of equipment; control rooms in close proximity to process areas | Increasing separation of process units Centrifugal compressors begin to replace reciprocal compressors | Control rooms remote from processing equipment |
| Reactor technology | Small steel reactors, 1100 – 3000 gallon capacities Top entering baffles and agitators Many pump seals, valves, flanged connections – accidental leaks and spills were common, exposures poorly controlled | Glass lined reactors, 2000 – 5000 gallons Reactor design refinements: Bottom entering baffles and agitators (1964-1968) | Large reactors (18,000+ gallons) Improvements in pumps and seals Use of portable gas chromatographs to actively survey for leaks and fugitive emissions |

Estimating Historical Vinyl Chloride Exposures

| Factors / indicator of exposure | Before mid-1950's | Mid-1950's to late 1960's | Late 1960's to 1974 |
|---------------------------------|--|--|--|
| Reactor cleaning practices | <p>Manual entry and cleaning after each batch</p> <p>Air purging common</p> <p>Entry determined by minimal lapse of time (20 min/ 30 min) or by absence of VC odors</p> <p>Vapors discharged to reactor floor area</p> | <p>Purging with CO₂ or other inert gas, monitoring of reactor air concentrations to ensure VC exposures were below a company imposed maximum air concentration before entry</p> <p>Negative reading on flammable vapor tester - most sensitive reading is 400 – 720 ppm (1-2% of lower explosive limit)</p> | <p>Automated cleaning systems introduced, e.g., solvent and/or high pressure water wash</p> <p>Manual entry after 5 to 20 batches</p> <p>Vapors discharged to roof</p> |
| Stripping and monomer recovery | <p>Early stripping technology and monomer recovery – Depressurization and monomer recovery in reactor</p> <p>Reciprocating compressors</p> <p>Residual monomer levels are relatively high</p> | <p>Improved stripping technology</p> <p>Blowdown tanks in stripping operations</p> <p>Vacuum steam jets</p> <p>Improvements in efficiency of unreacted monomer</p> | <p>Vacuum pumps</p> <p>Rotary compressors</p> <p>Vacuum steam jets</p> <p>Continued improvements in efficiency of unreacted monomer</p> |
| Ventilation | <p>General ventilation considered adequate</p> <p>Recommendation of 6 or more air changes per hour</p> <p>Reactors vented to reactor room</p> | <p>Improvements in general ventilation; 12-20 air changes per hour</p> <p>Blowers and air movers added (reactors still vented to reactor room)</p> | <p>Local exhaust ventilation</p> <p>Vapors discharged to roof</p> |
| Personal Protective Equipment | <p>Typically not used, despite recommendation of respiratory protection in event of accidental leaks, spills or excessive vapor concentrations</p> <p>Safety goggles rarely used</p> | <p>Corporate standards dictate use of PPE. PPE was rarely used or intermittently used.</p> | <p>Greater use of respirators in VC areas</p> <p>Fresh air breathing device worn for reactor cleaning and protective clothing (not before 1974)</p> |
| Laboratory / Quality control | <p>Manual sampling of product, vented to work space</p> | <p>Manual sampling of product, vented to work space</p> | <p>Closed loop sampling of product (VC monomer)</p> |

| Factors / indicator of exposure | Before mid-1950's | Mid-1950's to late 1960's | Late 1960's to 1974 |
|--|---|--|--|
| Rail car operations (Monomer operations) | Manual gauging of rail cars | Manual gauging of rail cars | Remote sensors for rail car gauging |
| Vinyl chloride odors | Odors detected frequently or occasionally during work shift Odor threshold reported by industry to be around 250 - 400 ppm | Odors detected occasionally during work shift | Odors detected rarely Odor threshold reported to be much higher than industry believed (>1200 ppm – 3000 ppm) [13,14] |
| Monitoring devices | MSA explosimeter to monitor gross exposure levels | Installation of area monitors and continuous conductivity monitoring (earliest in 1959) Occasional “grab” samples | Continuous area monitoring Occasional personal air samples (breathing zones, time-weighted averages) |
| Occupational exposure limits | 500 ppm maximum allowable concentration recommended by ACGIH (early 1950s) | Corporate OEL (50 ppm) implemented by Dow (1959) ACGIH adopts ceiling value of 500 ppm (1963) | 200 ppm recommended by ACGIH [15] OSHA ETS of 50 ppm and permanent standard of 1 ppm (1974) |

Facility profiles were developed based on information abstracted from existing publications and archival materials (i.e., submitted to the OSHA docket in 1974). An example facility profile is presented in table SA.3.

Table SA.3 Example facility profile

| Indicator/factor potentially impacting exposure | Description for facility |
|---|---|
| Products ^a | PVC resins; 36 different product lines in 5 major categories; plastisol grade resins, suspension PVC resins and copolymer resins; solution-grade resins; and styrene-butadiene latex At any time, 7 different resins – 4 suspension types, 3 plastisol types |
| Year operations began ^b | 1946 |
| Process ^c | Suspension and emulsion, Spray and rotary drying |
| Capacity (million pounds/yr) ^d | 140 (as of mid-19972) 190 (as of 1974) |

| Indicator/factor potentially impacting exposure | Description for facility |
|---|--|
| Number and size of reactors ^c | <ul style="list-style-type: none"> • 10 (as of 1947) • 30 (as of 1954) • 53 (as of 1964) • 65 (61 for PVC, 4 for SBR, as of 1974) • Size: < 3500 gallons |
| Additional workplace characteristics ^f | <ul style="list-style-type: none"> • Enclosed process area; 3 floors with a vertical process flow • 2 poly buildings, 1 with 23 reactors, 1 with 42 reactors (1974) • Ventilation rate set at 10 air exchanges per hour (1974: Increased ventilation to 10 to 20 air exchanges per hour) • Air is exhausted from sides of poly building and may be introduced in another area of facility • Polymerization, maintenance, lab, office, drying and warehousing are located under single discontinuous roof system with hazardous areas separated only by firewalls. • Improved ventilation (early 1970s); all reactors have converted to drop line ventilation and emissions pulled out through a compressor; formerly to reactor room atmosphere. • Monomer recovery system improved in mid 1960s – polymerized PVC moved through closed piping system to degassing vessel. Unreacted VC removed by vacuum and sent through a closed system for recovery. • Suspension product is pumped to large blend tanks outside and moved through closed system to solid bowl centrifuge to remove water; wet cake is gravity fed to rotary dryers. • Emulsion product is pumped from blend tanks and spray dried. |
| Work practices ^g | <ul style="list-style-type: none"> • Reaction time: 6-20 hrs; reactors cleaned periodically, 2 cleaners per reactor; cleaned once every 1-2 batches (once per day) reduced to once every 100 batches or one a month over time; high pressure water cleaning • VC levels checked before entry for cleaning; • Reactors ventilated with fresh air before and during cleaning • Blows air in over manholes • Ventilation rate increases to 20 air exchanges per hour when gas alarm goes off • PPE presumed not used before 1973 or 1974 |
| Industrial hygiene monitoring data ^h | <ul style="list-style-type: none"> • No air monitoring before 1974; equipment to continuously monitor ordered in 1974 • IH monitoring began in March 1974 (60 10-min samples collected per day) • Emergency ventilation system activated when gas alarm system goes off |
| Odors / Acute events ⁱ | <ul style="list-style-type: none"> • Odors not mentioned in reports • Reports of dizziness, lightheadedness, passing out, headaches |
| Exposure score ^j (Tabershaw and Gaffey) [16] | <ul style="list-style-type: none"> • Low: <50 ppm • Moderate: 50–199 ppm • High: ≥200 ppm |
| Job Titles ^k | <ul style="list-style-type: none"> • High exposures: Reactor operators, Stripper operator, Relief operator, High pressure water cleaners, Semi-works technicians, Development technicians, Recovery technicians, Tank farm attendant (D93) • Medium exposure: Centrifuge operator, Utility and service, Utility technician, Supervisors, Chemicals engineers and |

| Indicator/factor potentially impacting exposure | Description for facility |
|---|--|
| | assistants; Senior op (D93); Maintenance/support (D831): mechanic, electrician, pipefitter, instrument serviceman, oiler Salaried: foreman, process control coordinator, production manager, staff engineer <ul style="list-style-type: none"> • Low exposure: Bagger, Truckers, Janitors, Material handling technicians, Semi-works dryer technician, Oven room technician; Calender (D93), Dryer op (D93), Coagulator op (D93), Stabilizer op (D93), Pump attendant D93 Maintenance/support (D831): Welder, Laborer-cement mixer, Painter, Sheet metal worker; Salaried workers: Lab technician, Chemists, Technical assistance, Draftsman (low); |
| Other notes ^l | <ul style="list-style-type: none"> • Manufactures complex, low volume specialty product line - more difficult to manufacture with low residual VC levels. • Residual monomer levels in plastisols/emulsions before drying is 7-10 times higher than in suspension resins; controlling exposures more difficult with plastisols than suspension resins |

^a Assumed VC monomer facilities had lower exposures than PVC facilities, because monomer produced in closed continuous process; PVC manufactured in batch process. Also assumed manufacture of complex, low volume specialty PVC resins was associated with high workplace ambient exposures because these resins were more difficult to manufacture with low residual monomer levels.

^b Assumed older facilities were more likely to have smaller reactors, older equipment, and more potential opportunities for fugitive emissions from accidental releases than new facilities.

^c Assumed production of plastisol resins and dispersion resins was associated with increased exposure in spray dryer areas and laboratory/quality control because product quality was critical and more frequent quality control screening was required.

^d Approximate indicator of when and whether production increased/decreased over time and size of production area.

^e Assumed smaller capacity reactors require more frequent cleaning, more frequent purging. More pipes, pumps, seals, flanged connections provided more opportunities for accidental releases.

^f Assumed vertical process flow over 3 level facilities (rather than 2 or same level facilities) was associated with higher exposures over more areas. Vinyl chloride vapor is heavier than air and disperses down from top floors, polymerization and stripping operations more likely located on different floors, more frequent travel between floors. Assumed general ventilation only (no local exhaust ventilation) was associated with higher exposures. Assumed separation of polymerization process from other areas results in better controlled exposures elsewhere.

^g Description of procedures for reactor entry. Introduction of high water pressure jets and solvent cleaning methods for reactors reduced exposures by significantly decreasing the frequency of reactor entry and reactor venting. Frequency of audible alarms indicate higher exposures because alarms typically set to 25% of lower explosive limit (9,000 ppm).

^h Industrial monitoring data existed for a few facilities before 1974 and when time-weighted averages according to job categories were available, the industrial hygienists used these data to populate the JEMs. More often, industrial hygiene data of limited quality were available (for example, grab samples, or short-term duration samples). These data were used in conjunction with qualitative information from the facility profile, to adjust the industry-wide default estimates and create facility-specific JEMs by applying expert judgment.

^l Intensity of odors and frequency of odor detection was associated with higher exposures. Odors detected at levels 1200-4,000 ppm; reduced sensitivity of odor detection for workers consistently exposed was possible. Assumed reported incidents of loss of consciousness, dizziness, and nausea indicated higher exposures at facilities because these symptoms occur at very high concentrations (10,000 ppm). In published literature, the odor threshold for vinyl chloride has been reported as low as 260 ppm [14] and as high as 3000-4000 ppm [13]. IARC reported that vinyl chloride is detectable at about 400 to 500 ppm [6]. Some PVC manufacturers believed the odor threshold to be around 250 ppm at the time of the OSHA hearings.

^j Tabershaw and Gaffey [16] created an exposure score for each exposed job that corresponded to low, moderate, or high exposure. Although the authors noted limitations with this approach, they also concluded that for epidemiological purposes, individuals with “high” exposures can be expected to have the greatest exposure on average and individuals with “low” exposures can be expected to have the least exposure. At many of the facilities, company personnel assigned estimated exposure in parts per million to these categories at the time of the initial study. These were subjective estimates that were not used by Tabershaw and Gaffey [16]; in this exposure assessment, these estimates were used to inform the assessment of the facility by the industrial hygienists.

^k Job titles were identified as jobs with low, medium or high exposure by company personnel at the time of the initial study.

^l Miscellaneous comments reported by company personnel.

Facility-specific JEMs

Using the information from each facility profile, the industrial hygienists reviewed the source documents and modified the exposure estimates from the “default” industry-wide JEM to create a facility-specific. For each facility-specific JEM, the rationale and specific assumptions used to inform the exposure estimates were documented. JEMs were developed for each of the 35 facilities included in this study (facility-specific JEMs are not presented).

The facility-specific JEMs reflected expected variation from industry-wide exposures. For example, one company imposed a corporate occupational exposure limit of 50 ppm (8 hr TWA) in 1959 following results of toxicological testing on vinyl chloride exposure [10]. The company installed continuous air monitors in its polymer facilities in 1959 and reported reducing workroom VC concentrations dramatically.

After we compiled the JEMs, we made comparisons to the values reported in the facility JEMs for the European industrywide study. The approach used by the European investigators appears to be extremely similar to our approach [6, 17]. Although the JEMs had been developed in different ways for different factories, most had used job titles as

the basis for assessing exposure.³ The distribution of summary exposure estimates for JEMs were within ranges reported for the European study, and cumulative exposure estimates for study subjects were of a similar magnitude [6, 17].

Calculation of individual estimates of exposure

Job titles and dates of assignment for study subjects had been collected at the time that the cohort was constructed (end of 1972) by the initial investigators. These job titles were linked to the SEG and calendar interval in the facility-specific JEM. Cumulative exposure of VC in parts per million-years (ppm-yrs) was calculated by multiplying time in each job by the estimated average exposure and summing across all job assignments for each study subject.

³ See Ward, E., et al. [17]: “Calendar period-specific JEMs were provided by industrial hygienists for 13 of the 19 factories. Jobs were grouped into 22 broad categories. We estimated typical exposures for each job category on the basis of a number of sources. In most factories, up until the mid-1970s, only limited air measurement data were available. These data were supplemented by knowledge of exposure conditions, processes, and changes over time. For several factories, interviews with those who worked in earlier time periods provided information on how often workers could smell VC, which is detectable at about 400 or 500 ppm. These interviews and knowledge of industrial hygienists who worked at the time revealed that use of protective equipment, such as respirators, was rare. Since the mid-1970s, air measurements have been systematically collected and provide the basis for the more recent exposure assessments. The JEMs produced for each factory were validated by two independent industrial hygienists who had several years of experience in the VC industry. There were six factories for which JEMs were not developed. For four of these, JEMs were estimated on the basis of those developed for factories in the same country. For the remaining two plants, which have together had only one death from liver cancer, no JEM was available. Quantitative estimates of exposure were available for 9,775 members (82%) of the cohort.” [17, p. 711-712].

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