Appendix A: Materials EPA shared with Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix A1. Materials EPA shared with potential SERs before the Pre-Panel outreach meeting, March 17, 2016

- Agenda for Pre-Panel Outreach Meeting, March 17, 2016
- Power Point Presentation: An Overview of the Small Business Advocacy Review Panel Process
- PowerPoint Presentation: Rulemaking for TCE under the Toxic Substances Control Act (TSCA) March 17, 2016
- SBAR Pre-Panel Discussion Questions
- Estimated incremental costs for TCE vapor degreasing options

EPA's SBAR Pre-Panel Outreach Meeting with

Potential Small Entity Representatives on Proposed Rulemaking for

Trichloroethylene in Vapor Degreasing Under TSCA Section 6(a)

Thursday, March 17, 2016

10:00 am – 12:30 pm, Eastern time zone

10:00 **Welcome and Introductions** (Office of Policy)

10:15 **SBAR Panel Process Overview** (Office of Policy)

10:30 **Presentation on Proposed Rulemaking for Trichloroethylene in Vapor Degreasing Under TSCA Section 6(a)** (Office of Chemical Safety and Pollution Prevention)

11:30 **Questions and Discussion** (All participants)

12:20 **Summary and Closing** (Office of Policy)

An Overview of the Small Business Advocacy Review Panel Process

William Nickerson, Acting Small Business Advocacy Review Chair (SBAC)
Pre-Panel Outreach Meeting, March 17, 2016

Office of the Administrator
Office of Policy
Office of Regulatory Policy and Management
http://www.epa.gov/op/orpm.html

Today, I'll answer these questions…

- What is a Small Business Advocacy Review (SBAR) Panel?
- How does a Panel fit into the rulemaking process?
- How do Small Entity Representatives (SERs) participate in the Panel process?
- What is the difference between this Pre-Panel meeting and the future Panel meeting?
- What does the Panel do with SER recommendations?

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- What does the Panel do with SER recommendations?

What is an SBAR Panel? (cont'd.)

- SBREFA amended the 1980 Regulatory Flexibility Act (RFA), which requires agencies to:

  "assure that small entities have been given an opportunity to participate in the rulemaking process"[1] for any rule "which will have a significant economic impact on a substantial number of small entities."[2]

[1] 5 USC 609(a)
[2] 5 USC 602(a)(1)

Panel within the rulemaking process?

"the panel shall review **any material the agency has prepared**..., including any draft proposed rule, **collect advice and recommendations** of each individual small entity representative identified by the agency after consultation with the Chief Counsel [for Advocacy of the Small Business Administration], on issues related to"[1] the following:

- Who are the small entities to which the proposed rule will apply? [2]
- What are the anticipated compliance requirements of the upcoming proposed rule? [3]
- Are there any existing federal rules that may overlap or conflict with the regulation? [4]
- Are there any significant regulatory alternatives that could minimize the impact on small entities? [5]

[1] 5 USC 609(b)(4)
[2] 5 USC 603(b)(3)
[3] 5 USC 603(b)(4)
[4] 5 USC 603(b)(5)
[5] 5 USC 603(c)

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Panel within the rulemaking process?
(cont'd.)

Let's focus on "any material the agency has prepared"

- For this Panel, EPA will not provide a proposed rule, though we expect to discuss regulatory alternatives in as great a detail as we can.
- It is EPA's policy to host SBAR Panels like this one well before a proposed rule is written so we have adequate time to incorporate your advice and recommendations into senior management decision-making about the proposed rule.
- Participation in the Panel outreach meeting does not preclude or take the place of participation in the normal public comment period at the time the rule is proposed.

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How do SERs participate?

...Let's focus on "collect advice and recommendations"

- This is how SERs help the Panel members.
  - You're invited to provide advice and recommendations on the materials shared today and at the future Panel outreach meeting.
  - You will have an opportunity to submit written comments as well as the verbal comments you provide in the meetings.
- Those of you joining this meeting to assist the potential SERs are asked not to speak to allow the potential SERs ample time to talk.

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How do SERs participate? (cont'd.)

- As potential SERS, you are in a unique position during the Pre-Panel outreach and Panel outreach meetings
- You have the opportunity, because of your status as a small entity expected to be regulated by this rule, to influence the decisions senior EPA officials make about the forthcoming regulation

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Pre-Panel vs. Panel Outreach Mtg.?

- Pre-Panel Outreach Meeting
  - Conducted by EPA with SBA and OMB as invitees
  - Overview of the RFA, how the Panel process works, and the role of SERs
  - Background and overview of proposed rulemaking
- Panel Outreach Meeting
  - Chaired by SBAC, but all Panel members have active role
  - Bulk of meeting spent discussing regulatory alternatives and input of SERs

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What does the Panel do with your recommendations?

- EPA, OMB, and SBA prepare a joint Panel report:
  - Submitted to the EPA Administrator
  - Considered during senior-management decision-making prior to the issuance of the proposed rule
  - Placed in the rule's docket when the proposed rule is published

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Contact Information

- Contact my staff:
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    Jutras.Nathaniel@epa.gov
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    EPA Office of Policy
    202-566-2372
    Wiggins.Lanelle@epa.gov

Rulemaking under the Toxic Substances Control Act (TSCA) for Use of Trichloroethylene (TCE) in Vapor Degreasing

Pre-Panel Outreach

March 17, 2016

1

Today's Discussion

- Background:
  - Consultation with Small Entity Representatives
  - TSCA Work Plan for Chemical Assessments
- Trichloroethylene (TCE)
  - Overview & Risk Assessment
  - Uses Considered for Regulation
- Toxic Substances Control Act (TSCA) Section 6(a)
  - Background
  - Developing the Regulations
- Affected entities and potential compliance costs
- Contact information
- Your feedback
- Appendix A: Regulatory History and International Action
- Appendix B: Estimated Incremental Costs for TCE Vapor Degreasing Options

2

Background: Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the proposed regulation
- Key elements in this analysis:
  - Number of small entities to which the proposed rule would apply
  - Projected compliance requirements of the proposed rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule
  - Any significant alternatives to the proposed rule which accomplish the stated objectives and which minimize significant economic impact of the proposed rule on small entities

3

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data on their costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory Federal regulations you are aware of

4

Background: TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment
- 2012-2013:
  - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized.
  - Performed problem formulation for five of the Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.

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Background: TSCA Work Plan for Chemical Assessments

- 2014-2015:
  - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB)
    - No risks found for uses assessed for antimony trioxide and HHCB.
    - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
  - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals
- 2015-2016:
  - Problem formulation and data needs assessment issued for several flame retardant clusters
  - Problem formulation issued for 1,4-Dioxane
  - Draft risk assessment for 1-bromopropane (planned release) for public comment

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Overview: TCE

- EPA assessed several TCE uses as part of the TSCA Work Plan for Chemical Assessments
- Volatile organic compound (VOC) classified as a human carcinogen.
- Widely used in industrial and commercial processes; has some limited uses in consumer products.
- More than 255 million lbs per year used in the U.S.
  - Majority of TCE (~84%) used as an intermediate for manufacturing refrigerant chemicals.
  - Much of the remainder used as a solvent for metal degreasing (~15%).
  - A small percentage (~1%) used in other applications, including dry cleaning and consumer uses.
  - EPA assessed degreasing and other uses, because refrigerant uses take place in enclosed systems where exposures are expected to be low.

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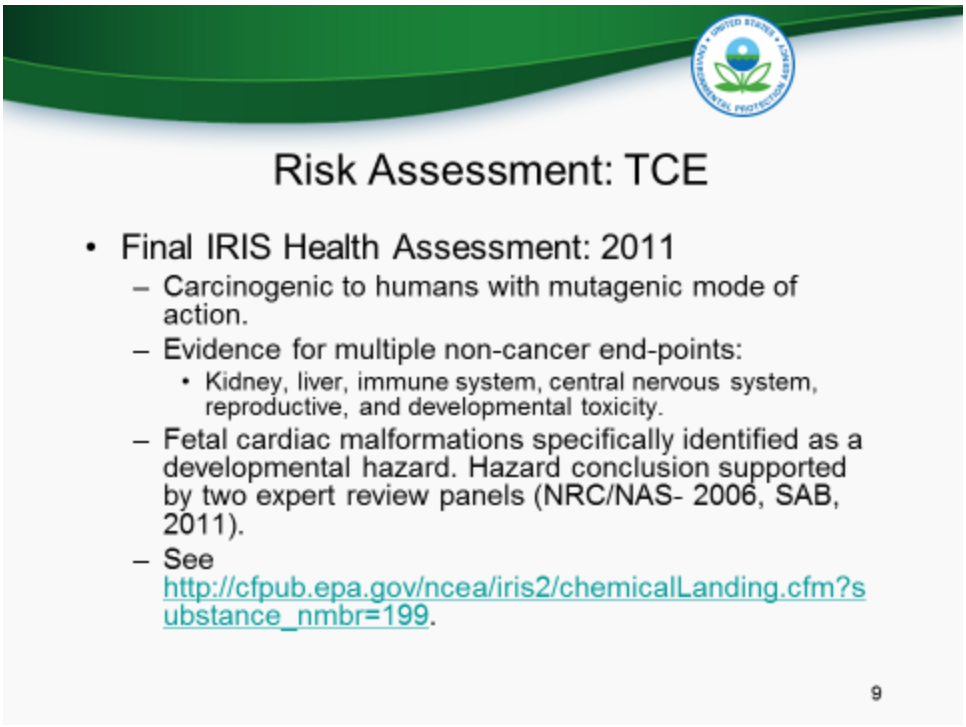
Key information: TCE

Use in vapor degreasing	TCE is boiled to produce a hot vapor. Components are suspended just above the bath, where the condensation of hot vapors cleans them. Vapor degreasing can be conducted with several types of machines, generally described as in-line (conveyor), closed, or open-top.
Manufacturers & Users	Manufacturers: Approximately 9 manufacturers (including importers) Distributors: Numerous distributors Vapor degreasing users: Approximately 2,600 – 6,200 machines (estimated 150 in-line, 120 closed, and 2,400 – 6,000 open top) with approximately 5 – 12 workers per machine.
Health Effects and Risks of Concern	Acute exposure can potentially affect the developing fetus (cardiac malformation to fetal death). High acute concentrations of TCE vapors can irritate the respiratory system and skin and induce central nervous system (CNS) effects such as light-headedness, drowsiness, and headaches. Repeated (chronic) or prolonged exposure is associated with adverse effects in the liver, kidneys, immune system, reproductive system, and CNS; there are also concerns for effects in the developing fetus. Chronic TCE exposure is carcinogenic to humans by all routes of exposure. Risks for bystanders due to inhalation exposures.
Substitutes	Substitutes (drop-in solvents): methylene chloride; perchloroethylene; 1-bromopropane. These have significant risk trade-offs. Substitutes (non-drop in solvents): Hydrofluorocarbons; hydrofluoroethers; hydrofluoroolefin. Substitutes (non-drop-in alternatives): alkaline water-based solvents; volatile methyl siloxanes; citrus terpene-based cleaners; parachlorobenotrifluoride; hydrocarbon solvents; soy-based cleaners; water-based cleaners. Alternative methods: Cold-cleaning (presents risks) or aqueous cleaning. **Aside from the drop-in solvents, generally the hazards associated with substitutes are of less concern than for TCE.**
Notable Regulations	Already subject to a permissible exposure limit (PEL) of 100 ppm time-weighted average (TWA) set by the Occupational Safety and Health Administration (OSHA) or state agencies. TCE is banned in the EU except for authorized uses (which do not include vapor degreasing).



Risk Assessment: TCE

- Final IRIS Health Assessment: 2011
  - Carcinogenic to humans with mutagenic mode of action.
  - Evidence for multiple non-cancer end-points:
    - Kidney, liver, immune system, central nervous system, reproductive, and developmental toxicity.
  - Fetal cardiac malformations specifically identified as a developmental hazard. Hazard conclusion supported by two expert review panels (NRC/NAS- 2006, SAB, 2011).
  - See http://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=199.

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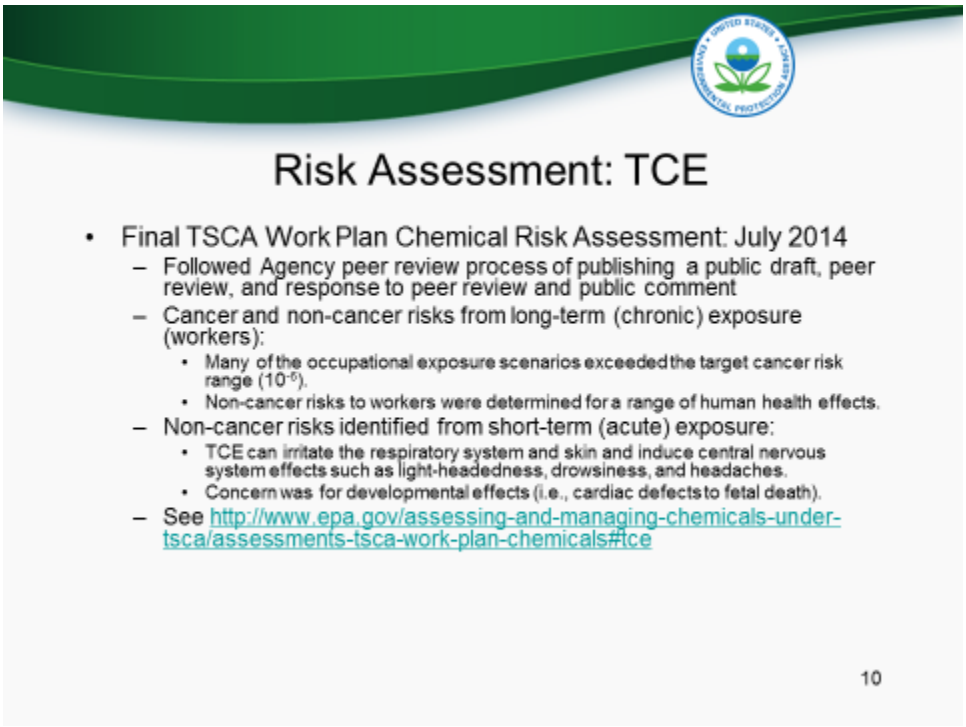

Risk Assessment: TCE

- Final TSCA Work Plan Chemical Risk Assessment: July 2014
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
  - Cancer and non-cancer risks from long-term (chronic) exposure (workers):
    - Many of the occupational exposure scenarios exceeded the target cancer risk range (10^{-5}).
    - Non-cancer risks to workers were determined for a range of human health effects.
  - Non-cancer risks identified from short-term (acute) exposure:
    - TCE can irritate the respiratory system and skin and induce central nervous system effects such as light-headedness, drowsiness, and headaches.
    - Concern was for developmental effects (i.e., cardiac defects to fetal death).
  - See http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#tce

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Risk Assessment: TCE

- For **non-cancer risks** a **margin of exposure** (MOE) method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
  - The benchmark MOE used for fetal cardiac defects in the TCE risk assessment is 10.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3x residual uncertainty for variability in humans
  - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.
  - MOEs and risks calculations for non-cancer effects are explained on the next slide
- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
  - The excess cancer risk is the product of the exposure concentration and the IUR
  - Protecting against non-cancer risks protects against these cancer risks
  - Risk calculations for cancer are explained on the next slide

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Risk Calculation (Non-Cancer)

Non-Cancer MOE compared to benchmark MOE (uncertainty factors, or UFs)

$$\text{MOE (acute or chronic)} = \frac{\text{Non-Cancer Hazard Value (Point of Departure)}}{\text{Human Exposure (ppm)}}$$

Where: Hazard Value

POD = Human equivalent dose (ppm)

MOE = Margin of exposure (unitless)

- **The lower the exposure the higher the MOE.**
- **The *lower* the calculated MOE value, the higher the risk**
- **Cause for concern increases the lower the scenario's risk value (MOE) is below the benchmark MOE**

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Risk Calculation (Cancer)

Cancer

Risk = Human Exposure X IUR

Where:

- Risk = Cancer risk (unitless)
- Human exposure = Exposure estimate (LADC in ppm) from occupational exposure assessment
- IUR = inhalation unit risk (a x 10* ppm)

*** The *higher* the calculated risk value, the higher the risk**

*** Cause for concern increases the more the scenario's cancer risk value is above the cancer benchmark**

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Baseline Risk Estimates for Workers and Adjacent Workers (non-users) at Vapor Degreasing Facilities: Non-Cancer Risks

Exposure Scenario and Toxicological Endpoint	Benchmark MOE	Worker MOE	Adjacent Worker MOE
Acute exposure, congenital defects	10	0.0000584	0.0000766
Chronic exposure, congenital defects	10	0.0000819	0.000108

The lower this number is below 10, the greater the risk (numbers above 10 indicate no non-cancer risks of concern)

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Baseline Risk Estimates for Workers and Adjacent Workers (non-users) at Vapor Degreasing Facilities: Cancer Risks

Exposure Scenario and Toxicological Endpoint	Benchmark Cancer Risk	Worker Risk	Adjacent Worker Risk
Chronic exposure, cancer	1 in 1,000,000	5.16 in 10	3.93 in 10

The larger this number is, the greater the risk

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Acceptable Exposure Limit (AEL): TCE

Existing chemical acceptable exposure limit (AEL) is:

- Derived from the lowest risk estimate and appropriate uncertainty factors to provide a margin of safety
- Calculated for acute and chronic exposures and non-cancer and cancer effects
- Selected to be protective of all risks

Non-cancer

$$\mathrm{AEL}_{non-cancer\ 8\mathrm{hrTWA}} = \frac{POD(acute\ or\ chronic)}{MOE_{benchmark}(acute\ or\ chronic)} * Duration\ Adjustment$$

$\mathrm{AEL}_{\text{non-cancer 8 hr TWA}}$ for acute exposures = 1 ppb

$\mathrm{AEL}_{\text{non-cancer 8 hr TWA}}$ for chronic exposures = 2 ppb

Cancer

$$\mathrm{AEL}_{cancer\ 8\mathrm{hrTWA}} = \frac{Cancer\ benchmark(10^{-6})}{IUR} * \frac{Lifetime(24hrs\ X\ 365days\ X\ 70\ yrs)}{Working\ Career(8hrsX\ 250days\ X\ 40\ yrs)} = \mathbf{0.4\ ppb}$$

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Exposure Estimates: TCE at Vapor Degreasing Facilities

Exposure Scenario	Acceptable exposure limit (8 hr TWA, ppm)	Estimated exposure (8 hr TWA, ppm)
Workers	**0.0004**	190
Adjacent Workers (non-users)	**0.0004**	145

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TCE Vapor Degreasing Systems

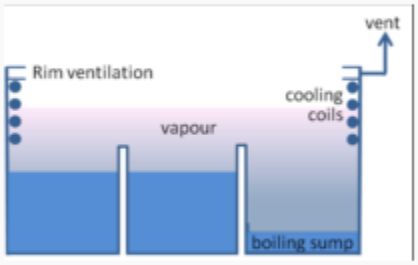

Diagram: Open top vapor degreasing (OTVD) (*Image: European Chlorinated Solvent Association*)

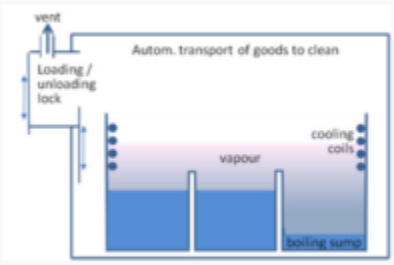

Diagram: Enclosed vapor degreasing (*Image: European Chlorinated Solvent Association*)

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Additional Analysis of Vapor Degreasing Systems

- EPA conducted additional analyses to identify what emissions and exposure reductions could be achieved by switching from open-top to closed vapor degreasing systems
  - The EPA exposure model assumed a 98% reduction in indoor-air emissions for a closed-loop vapor degreaser
  - This is based on a 98% reduction in solvent purchases noted in an analysis by Northeast Waste Management Officials' Association (NEWMOA).
- EPA also conducted additional analyses on emissions and exposures from inline or conveyorized systems
  - Modeling estimates indicate potential for high baseline exposures (higher than OTVDs) of workers engaged in conveyorized vapor degreasing.
  - Single data point from on-site area monitoring by the National Institute for Occupational Safety and Health (NIOSH) provides an air-concentration value of 2.3 ppm as an 8-hour time weighted average (TWA) from TCE use in a conveyorized vapor degreaser.

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TCE Vapor Degreasing Systems (continued)

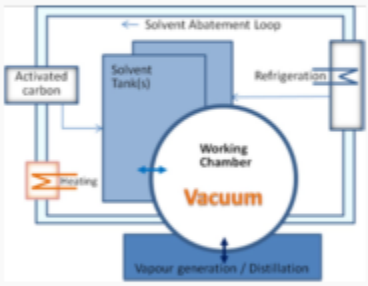

Diagram: Closed vapor degreasing under vacuum (*Image: European Chlorinated Solvent Association*)

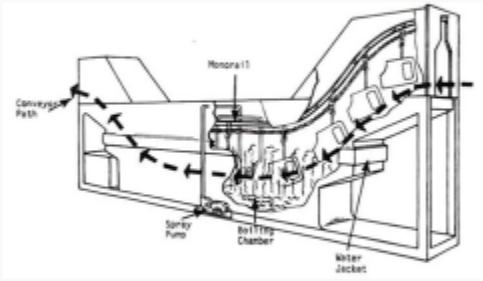

Diagram: Inline/ Conveyorized vapor degreasing system (monorail) (*Image: EPA*)

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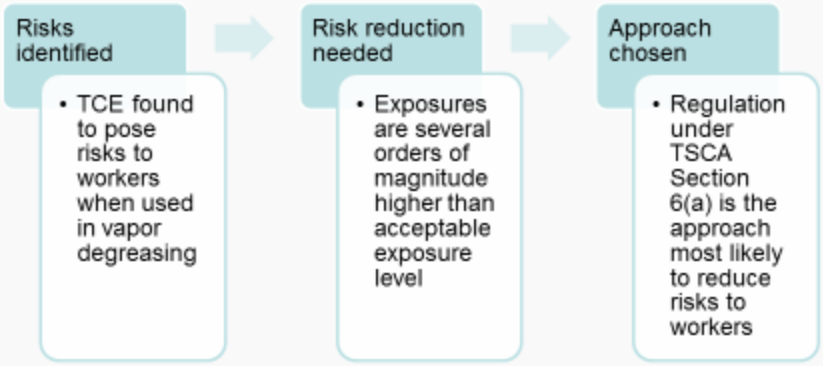
From Risk Assessment to Risk Reduction



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Background: TSCA Section 6(a)

- Provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
- EPA must make certain findings before a section 6(a) rule may be finalized:
  - There is a reasonable basis to conclude that a chemical substance or mixture "presents or will present an unreasonable risk of injury to health or the environment."
  - The regulatory option chosen is the least burdensome option that adequately protects against such risk.

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Options Under TSCA Section 6(a)

- Prohibit or limit manufacture, processing or distribution in commerce.
- Prohibit or limit for particular use or above a set concentration.
- Require warnings and instructions.
- Require recordkeeping and testing.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of risk to distributers and users and replace or repurchase.

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Uses Under Consideration

- Uses considered for regulation under this proposed rule under TSCA Section 6(a) are commercial use of TCE in all types of vapor degreasing

- Examples of small business uses:
  - Vapor degreasing of small parts
  - Fabrication of metal products
  - Instruments and related products
  - Machinery
  - Electrical and electronic equipment
  - Miscellaneous manufacturing industries

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Potentially Impacted Sectors

- TCE manufacturers/processors/blenders
- Plate work manufacturing
- Metal can manufacturing
- Metal coating, engraving
- Electroplating, plating, polishing, and coloring
- Industrial mold manufacturing

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Developing Potential Regulatory Options

- Many options analyzed, including:
  - Material substitution (MS): Reducing the concentration of TCE in the degreasing formulation, with concentrations varying from 5 to 95 weight percent.
  - Equipment substitution (ES): Replacing open-top vapor degreasing units with an enclosed system to reduce the escape of TCE vapors into the air, which achieves a 98 percent reduction effectiveness.
  - Engineering controls (EC): Using local exhaust ventilation (LEV) to improve ventilation near the worker activity, which achieves 90 percent reduction effectiveness.
  - Personal protective equipment (PPE): Workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000.

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Potential Regulatory Options

- Two options would mitigate the risk of TCE exposure for the vapor degreasing use:

  1. Prohibit manufacturing, distribution, and use of TCE in vapor degreasing
     - Risks eliminated; complete risk reduction

  2. Allow use of TCE with appropriate personal protective equipment (supplied air respirator of APF 10,000) in certain closed vapor degreasing systems
     - APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees. For example, APF 10,000 reduces the exposure concentration by 10,000 times.
     - Risks eliminated under perfect conditions
     - Risks are reduced so that MOEs are above target benchmarks and cancer is above a risk level of 10^{-4} (see table on next slide)
       - This is at the 99th percentile human equivalent concentration (HEC) and exposure concentration.

- Other options do not provide sufficient risk reduction (see next slide)

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Vapor Degreasing Risk Management Options

Risk Management Option	Acceptable exposure limit, 8 hr TWA ppm)	Worker Exposures (8 hr TWA, ppm)	Adjacent Worker Exposures (8 hr TWA, ppm)
Material substitution (MS) 5% TCE	0.0004	**9.5**	**7.2**
Equipment substitution (ES) Encl. eff. 98%	0.0004	**3.8**	**2.9**
Engineering controls (EC) LEV eff. 90%	0.0004	**19**	**14**
Personal protective equipment (PPE) APF 10,000	0.0004	**0.02**	**0.014**
Material substitution (MS) and personal protective equipment (PPE)	0.0004	**0.00095**	**0.00072**
Material substitution (MS) + Engineering controls (EC)	0.0004	**0.95**	**0.72**
Material substitution (MS) + Equipment substitution (ES)	0.0004	**0.19**	**0.14**
Personal protective equipment (PPE) + Engineering controls (EC)	0.0004	**0.0019**	**0.0014**
Personal protective equipment (PPE) + Equipment substitution (ES)	0.0004	0.00038	0.00029
Prohibition on manufacture, distribution, and use of TCE in vapor degreasing	0.0004	0	0

Costs: TCE Vapor Degreasing Prohibition

- **First Year Costs per System**
  - Inline System: $34,000-$340,000; $123,000 if switching to aqueous
  - Closed-systems: $6,000 - $58,000
  - Open-top Vapor Degreaser (switching to alternatives): ($4,800) - $279,000; $48,000 if switching to aqueous; $18,000-$51,000 if switching to cold cleaning
- **Annualized Costs (3%) per System**
  - Inline System: $5,000 - $291,000; ($10,000) if switching to aqueous
  - Closed-systems: $1,700 - $49,000
  - Open-top Vapor Degreaser (switching to alternatives): ($7,000) - $59,000; $18,000-$51,000 if switching to cold cleaning; up to ($26,000) if switching to aqueous

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Substitute Chemicals or Methods

- Estimated incremental costs for substitute chemicals or alternative methods are presented in the appendix document
  - Costs vary by type of system and risk management option
- Substitutes
  - Drop-in solvents: methylene chloride; perchloroethylene; 1-bromopropane.
  - Non-drop in solvents: Hydrofluorocarbons; hydrofluoroethers; hydrofluoroolefin.
  - Non-drop-in alternatives: Alkaline water-based solvents; volatile methyl siloxanes; citrus. terpene-based cleaners; parachlorobenotrifluoride; hydrocarbon solvents; soy-based cleaners; water-based cleaners.
- Alternative methods:
  - Cold-cleaning
  - Aqueous cleaning

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Costs: PPE & Closed Systems

- Though this option is different from a prohibition, the costs are projected to be the same as a prohibition if the workplace switches to an alternative solvent rather than using TCE with the PPE and closed system.
  - There are different costs expected when a workplace chooses to continue to use TCE in a closed system with PPE (APF 10,000).
- **First Year Costs per System**
  - Inline System: $34,000-$340,000; $123,000 if switching to aqueous
  - Closed-systems: $6,000 - $58,000 if switching solvent; **$149,000 if maintaining closed-system and adding PPE**
  - Open-top Vapor Degreaser (switching to alternatives): ($4,800) - $279,000; $48,000 if switching to aqueous; $18,000-$51,000 if switching to cold cleaning
- **Annualized Costs (3%) per System**
  - Inline System: $5,000 - $291,000; ($10,000) if switching to aqueous
  - Closed-systems: $1,700 - $49,000; **$26,000 if maintaining closed system and adding PPE**
  - Open-top Vapor Degreaser (switching to alternatives): ($7,000) - $59,000; $18,000-$51,000 if switching to cold cleaning; up to ($26,000) if switching to aqueous
- There are many limitations to successful implementation of PPE with APF of 10,000
  - Worker limitations: Not all workers can wear respirators (e.g., impaired lung function, selection fit); respirators may also present communication problems, vision problems, increased fatigue and reduced work efficiency.
  - Not just the devices: Current standard (used by OSHA) contains requirements for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; and other provisions

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Contact Information

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  - Joel Wolf, 202-564-0432, wolf.joel@epa.gov
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    Jutras.Nathaniel@epa.gov
- All risk assessments:
  http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

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APPENDIX A

Regulatory History and International Action

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Regulatory History of TCE at EPA (1 of 3)

- Subject to 25 final rules and notices issued by the Agency from 1979 to 2009.
  - These 25 rules and notices were promulgated by EPA's Office of Air and Radiation (OAR), the Office of Land and Emergency Management (OLEM), the Office of Water (OW) and the Office of Pollution Prevention and Toxics (OPPT).
- Office of Air and Radiation
  - Listed TCE as a hazardous air pollutant (HAP) from several different industrial emission sources in multiple rules, including solvent cleaning operations as well as a "probable or possible human carcinogen" from operations including printing, coating, and dyeing of fabrics and other textiles.
  - Classified TCE as a group I chemical for emission standards for equipment leaks in the synthetic organic chemical manufacturing industry.
- Office of Land and Emergency Management
  - One of the more common groundwater contaminants and is found at more than at 700 NPL sites.
  - Listed as a hazardous waste as toxicity characteristic contaminant and as a spent solvent waste (F001, F002).
  - Set a reportable quantity of 100 lbs (45.4 kg) for releases of TCE from vessels or facilities in 1989.
  - Determined to be ineligible for the conditional exclusion in the solvent-contaminated wipes rule.

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Regulatory History of TCE at EPA (2 of 3)

- Office of Water
  - 1979: OW initially identified TCE as a "toxic pollutant."
  - 1982: Classified TCE as a "priority pollutant" in and no discharges of TCE were allowed from steam electric power generating point sources.
  - 1987: Published the current National Primary Drinking Water Regulation (NPDWR) for TCE on July 8, 1987 (52 FR 25690).
    - The NPDWR established a non-enforceable maximum contaminant level goal (MCLG) of zero mg/L based on a cancer classification of B2, probable human carcinogen.
    - The NPDWR also established an enforceable maximum contaminant level (MCL) of 0.005 mg/L based on analytical feasibility.
  - 1993: Set an effluent limitation of 69 µg/L maximum daily average and 26 µg/L maximum monthly average for new and existing sources discharging to publicly owned treatment works (POTWs) from the organic chemicals, plastics, and synthetic fibers industrial category.
  - 1994: Prohibited injection of TCE into class I underground injection wells.

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Regulatory History of TCE at EPA (3 of 3)

- Office of Water (continued)
  - 1995: Under the Clean Water Act, in EPA's final regulation Water Quality Guidance for the Great Lakes System, TCE was identified by OW as a non-bioaccumulative pollutant of initial focus.
    - This regulation included water quality criteria for TCE for protection of human health, a human cancer value (HCV) of 29 µg/L for drinking water and 370 µg/L for non-drinking water, for the Great Lakes System.
    - Each of the Great Lakes states were required to adopt water quality standards and implementation procedures as protective as the regulation.
    - All states have complied with this requirement for TCE.
  - 1998: OW identified TCE's major sources in drinking water originating from "discharge from metal degreasing sites and other factories."
    - OW is currently evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.

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State Regulations: TCE

- Listed on California's Safer Consumer Products regulations candidate chemicals list and the Proposition 65 list of chemicals.
- Minnesota classifies TCE as a chemical of high concern, while other states, like Washington and Maine, have considered TCE for similar chemical listings.
- Several additional states have various regulatory actions that range from reporting requirements to contamination limits and use reduction efforts.

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State Regulations for TCE in Products

State	Prohibited Chlorinated Solvents: TCE and Methylene Chloride
New Hampshire, Virginia	Aerosol Adhesives
Connecticut, Delaware, District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, Rhode Island	The above plus: Contact Adhesives, Electrical Cleaners, Electronic Cleaners, Footwear/Leather Care Products, Adhesive, Removers, General Purpose Degreasers, and Graffiti Removers
New Jersey	The above plus: Brake Cleaners, Engine Degreasers, and Carburetor/Fuel-injection Air Intake Cleaners
California	All of the above plus: Bathroom and Tile Cleaners, Construction, Panel, and Floor Covering Adhesives; Carpet/Upholstery Cleaner, General Purpose Cleaners, Fabric Protectant, Multi-Purpose Lubricant, Penetrant, Metal Polish or Cleanser, Multi-Purpose Solvent, Oven Cleaners, Paint Thinner, Pressurized Gas Duster, Sealant or Caulking Compound, Spot Remover, and Silicone-based Multi-Purpose Lubricant

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EU Regulations: TCE

- TCE is listed in the European Union Authorization List owing to its classification as carcinogen(category 1B), with a sunset date of April 21, 2016.
- Continued-use authorizations for substances that would otherwise be banned can be granted under REACH if applicants can show that no alternatives are available and that the risks posed by substances can be controlled, or that there is a socioeconomic case for continued use of the substance.
- Companies were required to submit their requests for authorizations by January 7, 2015. All applications for authorizations of use of TCE as a degreaser were use in closed systems only (no open top uses).

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Other TCE Regulations

- Canada
  - Canada assessed TCE in 1993 and considered it as a "toxic" under section 11 of the 1988 Canadian Environmental Protection Act (CEPA 1988).
- Japan
  - Considered a Class II substance (substances that may pose a risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment).
  - Japan also controls air emissions and water dischargers containing TCE, as well as aerosol products for household use and household cleaners containing TCE.
- Australia
  - Listed in the Australian National Pollutant Inventory (NPI), a programme run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Reporting obligations may apply to this chemical.
  - Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.

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TCE in Vapor Degreasing SBAR Pre-Panel Discussion Questions for Potential SERs

These are informal questions that aim to guide discussion on your work practices and your experiences with this chemical. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives.

If you are interested in providing this or other information in writing, please see the contact information at the end.

<u>For all vapor degreasers:</u>

1) Your business:
    a. What items do you degrease with vapor degreasing?
    b. What type of system do you use (open-top, closed vacuum, etc)?
    c. What size system do you use?
    d. How significant is vapor degreasing to your business overall?
    e. Do any particular items or soils present special challenges?
2) Current work practices related to vapor degreasing:
    a. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
    b. Do the types of vapor degreasers we are considering (open-top, enclosed vacuum, continuous strip, and inline belt vapor degreasers) seem representative of those currently in use for small businesses?
    c. How many hours per day do you operate your vapor degreaser? How many days per year? Is there any difference for the different types of vapor degreasers?
    d. Regarding the operation of various degreasing systems in small businesses, do you think the following is a reasonable range of solvent use?
        i. Between 452 and 1,120 gallons of TCE per year for all open-top vapor degreasing units
        ii. Average annual use of 1,500-1,600 gallons per year for conveyorized vapor degreasing units
        iii. Average annual use of 400-500 gallons per year for enclosed vacuum vapor degreasing units
    e. When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc)? What prompted this update?
    f. How large is your facility that uses vapor degreaser? (ie., dimensions of the room that the degreaser units is used and overall size of facility)
    g. How many employees perform degreasing operations? How frequently?
    h. How many employees are located in the same room with the degreaser unit but not necessarily operating the machine?
    i. What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?
3) Using TCE in your business:

a. If TCE were not available for degreasing, how would you adjust and what would the impacts be on your business?
b. What are your current and best practices to protect workers from exposure to TCE? For example, do you or your colleagues use ventilation or engineering controls, personal protective equipment, worker training, or other methods?
c. What are the benefits to your business of TCE?

4) Exposure reduction for vapor degreasing
   a. What are your experiences with:
      i. Installing or updating ventilation and local exhaust
      ii. Installing or operating other engineering controls
      iii. Equipment changes to reduce exposures
      iv. Monitoring worker exposures to chemicals in the air
      v. Air-supplied respirators
      vi. Other personal protective equipment
   b. If you have changed or updated your exposure reduction technology or methods, how long did that process take?
   c. What do you do to comply with OSHA standards for TCE?
5) Substitutes and alternatives:
   a. How do you know which chemicals are in the products you are using?
   b. What are the trusted sources of information for you about chemicals you use?
   c. Have you tried using alternative chemicals or methods for degreasing? What were the results?
      i. Please discuss alternative methods to vapor degreasing as well as alternative solvents or equipment in your vapor degreasing process
      ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?
      iii. If you have tried or switched to alternative chemicals or methods, how long did that process take? Did it require equipment modifications or new equipment purchases?
   d. If TCE could no longer be used for vapor degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
6) Regulatory options
   a. Which of the regulatory options presented today would you recommend?
   b. Cost estimates: In your experience, are the cost estimates reasonably representative for both options presented?
   c. Can you think of ways to add flexibility to this rulemaking for your small businesses?
   d. How do you learn about EPA regulations and what you should do to comply?
   e. What is the best way to reach out to members of your industry?

Contact information:

7) Nathaniel Jutras, RFA/SBREFA staff contact EPA
Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov

Appendix C: Estimated Incremental Costs for TCE Vapor Degreasing Options

First Year and Annualized by System and Compliance Choice

Incremental Cost Estimates: Ban on Open Top Vapor Degreasing with TCE		
Compliance Strategy	**Cost per System**	
	1st Year	**Annualized (3% discount rate)**
Open Top Vapor Degreasers		
Drop-in: Perchloroethylene	$4,000-$11,000	$4,000-$11,000
Drop-in: Methylene Chloride	($4,800)-($1,000)	($4,800)-($1,000)
Drop-in: 1-bromopropane	$8,900-$24,000	$8,900-$24,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$155,000-$279,000	$28,000-$59,000
Aqueous Cleaning System	$46,000-$48,000	($26,000)-($7,000)
Not-In-Kind Non-Water Alternatives (e.g., glycol ethers, siloxanes, terpenes, soy-based)	($1,500)-($600)	($7,214)-($5,000)
Cold Cleaning with TCE	$18,000-$51,000	$18,000-$51,000
Closed Systems		
Drop-in: Perchloroethylene	$11,000	$1,700
Drop-in: 1-bromopropane	$5,700	$5,700
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$57,000	$49,000
Hydrocarbon	$58,000	$1,700
Inline/Continuous Systems		
Continuous Strip Cleaner		
Drop-in: Perchloroethylene	$43,000	$7,900
Drop-in: 1-bromopropane	$40,000	$40,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$383,000	$344,000
Aqueous Cleaning	$134,000	-$11,000
Inline Belt Cleaner		
Drop-in: Perchloroethylene	$27,000	$3,800
Drop-in: 1-bromopropane	$10,800	$10,800
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$116,000	$93,000
Aqueous Cleaning	$80,000	-$6,000

Incremental Cost Estimates: Ban on TCE in Vapor Degreasing Unless Using Specified Closed System with PPE		
Compliance Strategy	**Cost per System**	
	1st Year	**Annualized (3% discount rate)**
Open-Top Vapor Degreasers		
Drop-in: Perchloroethylene	$4,000-$11,000	$4,000-$11,000
Drop-in: Methylene Chloride	($4,800)-($1,000)	($4,800)-($1,000)
Drop-in: 1-bromopropane	$8,900-$24,000	$8,900-$24,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$155,000-$279,000	$28,000-$59,000
Aqueous Cleaning	$46,000-$48,000	($26,000)-($7,000)
Not-In-Kind Non-Water Alternatives (e.g., glycol ethers, siloxanes, terpenes, soy-based)	($1,500)-($600)	($7,214)-($5,000)
Cold Cleaning with TCE	$18,000-$51,000	$18,000-$51,000
Closed Systems – Including Respirators		
Closed with TCE and Respirator 10,000 APF	$149,000	$26,000
Continuous/Inline Systems		
Continuous Strip Cleaner		
Drop-in: Perchloroethylene	$43,000	$7,900
Drop-in: 1-bromopropane	$40,000	$40,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$383,000	$344,000
Aqueous Cleaning	$134,000	-$11,000
Inline Belt Cleaner		
Drop-in: Perchloroethylene	$27,000	$3,800
Drop-in: 1-bromopropane	$10,800	$10,800
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$116,000	$93,000
Aqueous Cleaning	$80,000	-$6,000

Appendix A: Materials EPA shared with Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix A2. Materials EPA shared with SERs before the Panel outreach meeting, June 15, 2016

- Agenda for Panel Outreach meeting, June 15, 2016
- Power Point Presentation: Small Business Advocacy Review Panel Process Recap, June 15, 2016
- Power Point Presentation: Rulemaking under the Toxic Substances Control Act (TSCA) for Use of trichloroethylene (TCE) in Vapor Degreasing, June 15, 2016.
- Panel questions for Small Entity Representatives (SERs)
- Regulatory history and international actions for TCE
- U.S. Department of Labor Letter to EPA in support of rulemaking
- Additional cost information - Cost of substitute materials
- OSHA assigned protection factors for the revised respiratory standard

EPA's SBAR Panel Outreach Meeting with
Small Entity Representatives on Proposed Rulemaking for
Trichloroethylene in Vapor Degreasing Under TSCA Section 6(a)

Wednesday, June 15, 2016
10:00 am – 12:30 pm, Eastern time zone

10:00 **Welcome and Introductions** (Office of Policy)

10:15 **SBAR Panel Process Overview** (Office of Policy)

10:25 **Presentation on Proposed Rulemaking for Trichloroethylene in Vapor Degreasing Under TSCA Section 6(a)** (Office of Chemical Safety and Pollution Prevention)

11:20 **Questions and Discussion** (All participants)

12:20 **Summary and Closing** (Office of Policy)

An Overview of the Small Business Advocacy Review Panel Process

William Nickerson, Acting Small Business Advocacy Review Chair (SBAC)
Panel Outreach Meeting, June 15, 2016

Office of the Administrator
Office of Policy
Office of Regulatory Policy and Management
http://www.epa.gov/op/orpm.html

Today's Topics

- What is a Small Business Advocacy Review (SBAR) Panel?
- Your role as a Small Entity Representative (SER)
- The difference between an SBAR Panel and a proposed regulation

What is an SBAR Panel?

- A Panel consists of representatives from the:
  - Agency authoring the regulation (i.e., EPA)
  - OMB's Office of Information and Regulatory Affairs (OIRA)
  - SBA's Office of Advocacy
- The Regulatory Flexibility Act (RFA) instructs the Panel to:
  - Review "any material the agency has prepared" related to the development of the regulation
  - Collect advice and recommendations from SERs
  - Prepare a report within 60 days of the Panel convening

See Title 5, section 609(b)(3)-(5), of the *United States Code* (USC). This is also known as section 609(b)(3)-(5) of the Regulatory Flexibility Act (RFA).

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What is an SBAR Panel? (cont'd.)

- The types of materials the Panel will review and on which you, the SERs, will provide advice and recommendations are specified by law
- Section 609(b)(4) of the RFA states that "the panel shall review any material the agency has prepared…on issues related to":
  - "a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply" (Sec. 603(b)(3))
  - "a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record" (Sec. 603(b)(4))
  - "an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule" (Sec. 603(b)(5))
  - "a description of any significant alternatives to the proposed rule which accomplish the stated objective of applicable statutes and which minimize any significant economic impact …on small entities" (Sec. 603(c))

4

Your role as a SER

- EPA values this SBAR Panel process because it provides us with important small entity perspectives and information
- Your verbal and written input is considered and valued by the Panel as the Panel develops the Panel report
- Copies of your written comments will be appended to the Panel Report and a chapter in the Panel report will summarize them.
- The Panel will consider the comments you provide to us, but the findings that ultimately appear in the report are those of the Panel members: EPA, OMB, and SBA
- The Administrator will carefully consider the input we gather from the SERs and the Panel members, but is not legally bound to adopt the recommendations of the Panel

5

The difference between an SBAR Panel and a proposed regulation

- SBAR Panel
  - Reviews materials related to:
    - the impacts of the regulation on small entities
    - Federal rules which may intersect with this proposed regulation
    - Alternatives to the regulation that may minimize small entity impacts
  - EPA uses the Panel report to inform our decision-making about the forthcoming proposed regulation
- Proposed regulation
  - Fully formed regulatory proposal or set of regulatory alternatives
  - You will have an opportunity to comment on the proposal, just like any other public citizen

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Thank You

- Participation is voluntary and we appreciate the time and energy you put towards this rulemaking.
- Thank you - we know it is, and has been, an intense resource commitment.
- Contact my staff:
  - Nathaniel Jutras, RFA/SBREFA staff contact
    EPA Office of Policy
    202-564-0301
    Jutras.Nathaniel@epa.gov
  - Lanelle Wiggins, RFA/SBREFA Team Leader
    EPA Office of Policy
    202-566-2372
    Wiggins.Lanelle@epa.gov

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Rulemaking under the Toxic Substances Control Act (TSCA) for Use of Trichloroethylene (TCE) in Vapor Degreasing

Panel Outreach

June 15, 2016

1

Today's Discussion

- Background:
  - Consultation with Small Entity Representatives
  - TSCA Work Plan for Chemical Assessments
- Trichloroethylene (TCE)
  - Overview & Risk Assessment
  - Uses Considered for Regulation
- Toxic Substances Control Act (TSCA) Section 6(a)
  - Background
  - Developing the Regulations
- Affected entities and potential compliance costs
- Contact information
- Appendix A: Descriptions of Respirators
- Appendix B: Regulatory History and International Action
- Appendix C: Estimated Incremental Costs for TCE Vapor Degreasing Options (separate document)

2

Background: Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation
- Key elements in this analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives and which minimize significant economic impact of the potential rule on small entities

3

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data on their costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory Federal regulations you are aware of

4

SERs and the Regulatory Process

- On March 17, 2016, EPA held a pre-panel meeting with SERs to discuss the rulemaking process and how the regulatory options may impact their businesses
- In response to your comments, we:
  - Provided requested follow-up information
  - Added clarifying information to this presentation
  - Added your feedback to this presentation

5

Background: TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment
- 2012-2013:
  - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized.
  - Performed problem formulation for five of the Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.

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Background: TSCA Work Plan for Chemical Assessments

- 2014-2015:
  - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB)
    - No risks found for uses assessed for antimony trioxide and HHCB.
    - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
  - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals
- 2015-2016:
  - Problem formulation and data needs assessment issued for several flame retardant clusters
  - Problem formulation issued for 1,4-Dioxane
  - Draft risk assessment for 1-bromopropane released for public comment and peer review
    - Draft risk assessment found cancer and non-cancer risks (developmental toxicity, reproductive toxicity, and neurotoxicity) for occupational users and bystanders to degreasing and other uses
    - Peer review meeting May 24-25, 2016

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Overview: TCE

- EPA assessed several TCE uses as part of the TSCA Work Plan for Chemical Assessments
- Volatile organic compound (VOC) classified as a human carcinogen.
- Widely used in industrial and commercial processes; has some limited uses in consumer products.
- More than 255 million lbs. per year used in the U.S.
  - Majority of TCE (~84%) used as an intermediate for manufacturing refrigerant chemicals.
  - Much of the remainder used as a solvent for metal degreasing (~15%).
  - A small percentage (~1%) used in other applications, including dry cleaning and consumer uses.
  - EPA assessed degreasing and other uses, because refrigerant uses take place in enclosed systems where exposures are expected to be low.

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Key information: TCE

Use in vapor degreasing	TCE is boiled to produce a hot vapor. Components are suspended just above the bath, where the condensation of hot vapors cleans them. Vapor degreasing can be conducted with several types of machines, generally described as in-line (conveyor), closed, or open-top.
Manufacturers & Users	Manufacturers: Approximately 9 manufacturers (including importers) Distributors: Numerous distributors Vapor degreasing users: Approximately 2,600 – 6,200 machines (estimated 150 in-line, 120 closed, and 2,400 – 6,000 open top) with approximately 5 – 12 workers per machine.
Health Effects and Risks of Concern	Acute exposure can potentially affect the developing fetus (cardiac malformation to fetal death). High acute concentrations of TCE vapors can irritate the respiratory system and skin and induce central nervous system (CNS) effects such as light-headedness, drowsiness, and headaches. Repeated (chronic) or prolonged exposure is associated with adverse effects in the liver, kidneys, immune system, reproductive system, and CNS; there are also concerns for effects in the developing fetus. Chronic TCE exposure is carcinogenic to humans by all routes of exposure. Risks for bystanders due to inhalation exposures.
Substitutes	Substitutes (drop-in solvents): methylene chloride; perchloroethylene; 1-bromopropane. These have significant risk trade-offs. Substitutes (non-drop in solvents): Hydrofluorocarbons; hydrofluoroethers; hydrofluoroolefin. Substitutes (non-drop-in alternatives): alkaline water-based solvents; volatile methyl siloxanes; citrus. terpene-based cleaners; parachlorobenotrifluoride; hydrocarbon solvents; soy-based cleaners; water-based cleaners. Alternative methods: Cold-cleaning (presents risks) or aqueous cleaning. **Aside from the drop-in solvents, generally the hazards associated with substitutes are of less concern than for TCE.**
Notable Regulations	Already subject to a permissible exposure limit (PEL) of 100 ppm time-weighted average (TWA) set by the Occupational Safety and Health Administration (OSHA) or state agencies. TCE is banned in the EU except for authorized uses (which do not include vapor degreasing).

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Risk Assessment: TCE

- Final IRIS Health Assessment: 2011
  - Carcinogenic to humans with mutagenic mode of action.
  - Evidence for multiple non-cancer end-points:
    - Kidney, liver, immune system, central nervous system, reproductive, and developmental toxicity.
  - Fetal cardiac malformations specifically identified as a developmental hazard. Hazard conclusion supported by two expert review panels (NRC/NAS- 2006, SAB, 2011).
  - See http://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=199.

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Risk Assessment: TCE

- Final TSCA Work Plan Chemical Risk Assessment: July 2014
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
  - Cancer and non-cancer risks from long-term (chronic) exposure (workers):
    - Many of the occupational exposure scenarios exceeded the target cancer risk range (10^{-6}).
    - Non-cancer risks to workers were determined for a range of human health effects.
  - Non-cancer risks identified from short-term (acute) exposure:
    - TCE can irritate the respiratory system and skin and induce central nervous system effects such as light-headedness, drowsiness, and headaches.
    - Concern was for developmental effects (i.e., cardiac defects to fetal death).
  - See http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#tce

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Risk Assessment: TCE

- For **non-cancer risks** a **margin of exposure** (MOE) method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
  - The benchmark MOE used for fetal cardiac defects in the TCE risk assessment is 10.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3x residual uncertainty for variability in humans
  - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.
  - MOEs and risks calculations for non-cancer effects are explained on the next slide
- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
  - The excess cancer risk is the product of the exposure concentration and the IUR
  - Risk calculations for cancer are explained on the following slide

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Risk Calculation (Non-Cancer)

Non-Cancer MOE compared to benchmark MOE (uncertainty factors, or UFs)

MOE (acute or chronic) = Non-Cancer Hazard Value (Point of Departure)
Human Exposure (ppm)

Where: Hazard Value
POD = Human equivalent dose (ppm)
MOE = Margin of exposure (unitless)

- **The lower the exposure the higher the MOE.**
- **The *lower* the calculated MOE value, the higher the risk**
- **Cause for concern increases the lower the scenario's risk value (MOE) is below the benchmark MOE**

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Risk Calculation (Cancer)

Cancer

Risk = Human Exposure X IUR

Where:

- Risk = Cancer risk (unitless)
- Human exposure = Exposure estimate (LADC in ppm) from occupational exposure assessment
- IUR = inhalation unit risk (a x 10* ppm)

*** The *higher* the calculated risk value, the higher the risk**

*** Cause for concern increases the more the scenarios cancer risk value is above the cancer benchmark**

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Baseline Risk Estimates for Workers and Adjacent Workers (non-users) at Vapor Degreasing Facilities: Non-Cancer Risks

Exposure Scenario and Toxicological Endpoint	Benchmark MOE	Worker MOE	Adjacent Worker MOE
Acute exposure, congenital defects	10	0.0000584	0.0000766
Chronic exposure, congenital defects	10	0.0000819	0.000108

The lower this number is below 10, the greater the risk (numbers above 10 indicate no non-cancer risks of concern)

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Baseline Risk Estimates for Workers and Adjacent Workers (non-users) at Vapor Degreasing Facilities: Cancer Risks

Exposure Scenario and Toxicological Endpoint	Benchmark Cancer Risk	Worker Risk	Adjacent Worker Risk
Chronic exposure, cancer	1 in 1,000,000	5.16 in 10	3.93 in 10

The larger this number is, the greater the risk

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Acceptable Exposure Limit (AEL): TCE

Existing chemical acceptable exposure limit (AEL) is:

- Derived from the lowest risk estimate and appropriate uncertainty factors to provide a margin of safety
- Calculated for acute and chronic exposures and non-cancer and cancer effects
- Selected to be protective of all risks

Non-cancer

$$\text{AEL}_{non-cancer\ 8\text{hrTWA}} = \frac{POD(acute\ or\ chronic)}{MOE_{benchmark}(acute\ or\ chronic)} * Duration\ Adjustment$$

$\text{AEL}_{\text{non-cancer 8 hr TWA}}$ for acute exposures = 1 ppb
$\text{AEL}_{\text{non-cancer 8 hr TWA}}$ for chronic exposures = 2 ppb

Cancer

$$\text{AEL}_{cancer\ 8\text{hrTWA}} = \frac{Cancer\ benchmark}{IUR} * \frac{Lifetime(24hrs\ X\ 365days\ X\ 70\ yrs)}{Working\ Career(8hrsX\ 250days\ X\ 40\ yrs)} = 0.4\ \text{ppb}$$

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Exposure Estimates: TCE at Vapor Degreasing Facilities

Exposure Scenario	Acceptable exposure limit for cancer (8 hr TWA, ppm)	Estimated exposure (8 hr TWA, ppm)
Workers	**0.0004**	190
Adjacent Workers (non-users)	**0.0004**	145

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TCE Vapor Degreasing Systems

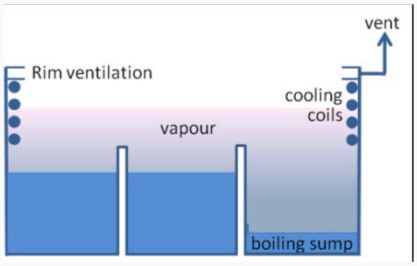

Diagram: Open top vapor degreasing (OTVD) (*Image: European Chlorinated Solvent Association*)

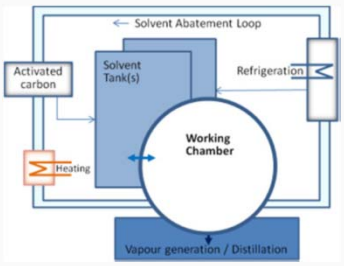

Diagram: Enclosed vapor degreasing (*Image: European Chlorinated Solvent Association*)

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TCE Vapor Degreasing Systems (continued)

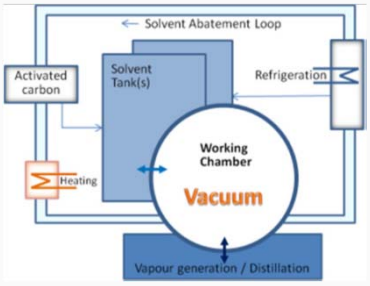

Diagram: Closed vapor degreasing under vacuum (*Image: European Chlorinated Solvent Association*)

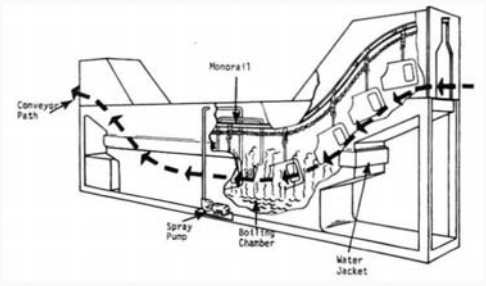

Diagram: Inline/ Conveyorized vapor degreasing system (monorail) (*Image: EPA*)

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Additional Analysis of Vapor Degreasing Systems

- EPA conducted additional analyses to identify what emissions and exposure reductions could be achieved by switching from open-top to closed vapor degreasing systems
  - The EPA exposure model assumed a 98% reduction in indoor-air emissions for a closed-loop vapor degreaser
    - This does not distinguish between types of closed systems such as enclosed vapor cleaning machines and vacuum-to-vacuum vapor cleaning machines
  - This is based on a 98% reduction in solvent purchases noted in an analysis by Northeast Waste Management Officials' Association (NEWMOA).
- EPA also conducted additional analyses on emissions and exposures from inline or conveyorized systems
  - Modeling estimates indicate potential for high baseline exposures (higher than OTVDs) of workers engaged in conveyorized vapor degreasing.
  - Single data point from on-site area monitoring by the National Institute for Occupational Safety and Health (NIOSH) provides an air-concentration value of 2.3 ppm as an 8-hour time weighted average (TWA) from TCE use in a conveyorized vapor degreaser.

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From Risk Assessment to Risk Reduction

Risks identified
- TCE found to pose risks to workers when used in vapor degreasing

Risk reduction needed
- Exposures are several orders of magnitude higher than acceptable exposure level

Approach chosen
- Regulation under TSCA Section 6(a) is the approach most likely to reduce risks

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Background: TSCA Section 6(a)

- Provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
- EPA must make certain findings before a section 6(a) rule may be finalized:
  - There is a reasonable basis to conclude that a chemical substance or mixture "presents or will present an unreasonable risk of injury to health or the environment."
  - The regulatory option chosen is the least burdensome option that adequately protects against such risk.

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Options Under TSCA Section 6(a)

- Prohibit or limit manufacture, processing or distribution in commerce.
- Prohibit or limit for particular use or above a set concentration.
- Require warnings and instructions.
- Require recordkeeping and testing.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of risk to distributers and users and replace or repurchase.

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EPA's Authority to Regulate Occupational Risks

- SERs were interested in more information about EPA's authority to regulate occupational hazards and risks, compared to OSHA
- OSHA authority extends only to private sector employers
  - Public sector employees using vapor degreasing are not subject to OSHA, this would likely occur in repair shops associated with public (including school) transportation and possibly electronics repair shops.
- OSHA has no plans to revise its PEL for TCE in vapor degreasing or other uses where EPA identified risks
  - TSCA restrictions are consistent with OSHA hierarchy of hazard control (eliminate/substitute hazard; engineering controls; best practices administrative controls; personal protective equipment)
- TSCA authority can address TCE uses that cut across worker, public sector and consumer settings
- EPA is working closely with OSHA; both agencies feel TSCA is the appropriate authority to address the risks that EPA has identified, including those that occur in workplaces
  - See letter of support from Department of Labor in Appendix C

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Uses Under Consideration

- Uses considered for regulation under this proposed rule under TSCA Section 6(a) are commercial use of TCE in all types of vapor degreasing

- Examples of small business uses:
  - Vapor degreasing of small parts
  - Fabrication of metal products
  - Instruments and related products
  - Machinery
  - Electrical and electronic equipment
  - Miscellaneous manufacturing industries

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Potentially Impacted Sectors

- TCE manufacturers/processors/blenders
- Plate work manufacturing
- Metal can manufacturing
- Metal coating, engraving
- Electroplating, plating, polishing, and coloring
- Industrial mold manufacturing

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Developing Potential Regulatory Options

- Many options analyzed, including:
  - Material substitution (MS): Reducing the concentration of TCE in the degreasing formulation, with concentrations varying from 5 to 95 weight percent.
  - Equipment substitution (ES): Replacing open-top vapor degreasing units with an enclosed system to reduce the escape of TCE vapors into the air, which achieves a 98 percent reduction effectiveness.
  - Engineering controls (EC): Using local exhaust ventilation (LEV) to improve ventilation near the worker activity, which achieves 90 percent reduction effectiveness.
  - Personal protective equipment (PPE): Workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000.
- Combinations of options were analyzed when needed
  - Some are mutually exclusive, such as EC and ES, and so were not evaluated together

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Vapor Degreasing Risk Management Options

- This table shows some potential risk management options
- Options that reduce worker exposures to acceptable levels are highlighted

Risk Management Option	Acceptable exposure limit (8 hr TWA, ppm)	Worker Exposures (8 hr TWA, ppm)	Adjacent Worker Exposures (8 hr TWA, ppm)
Material substitution (MS) 5% TCE	0.0004	**9.5**	**7.2**
Equipment substitution (ES) Encl. eff. 98%	0.0004	**3.8**	**2.9**
Engineering controls (EC) LEV eff. 90%	0.0004	**19**	**14**
Personal protective equipment (PPE) APF 10,000	0.0004	**0.02**	**0.014**
Material substitution (MS) and personal protective equipment (PPE)	0.0004	**0.00095**	**0.00072**
Material substitution (MS) + Engineering controls (EC)	0.0004	**0.95**	**0.72**
Material substitution (MS) + Equipment substitution (ES)	0.0004	**0.19**	**0.14**
Personal protective equipment (PPE) + Engineering controls (EC)	0.0004	**0.0019**	**0.0014**
Personal protective equipment (PPE) + Equipment substitution (ES)	0.0004	0.00038	0.00029
Prohibition on manufacture, distribution, and use of TCE in vapor degreasing	0.0004	0	0

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Developing Potential Regulatory Options

- Two options would mitigate the risk of TCE exposure for the vapor degreasing use:

1. Prohibit the manufacturing, processing, distribution in commerce, and use of TCE in vapor degreasing and require downstream notification
   - Risks eliminated; complete risk reduction

2. Allow use of TCE with appropriate personal protective equipment (supplied air respirator of APF 10,000) in certain closed vapor degreasing systems
   - APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees. For example, APF 10,000 reduces the exposure concentration by 10,000 times.
   - Risks eliminated under perfect conditions
   - Risks are reduced so that MOEs are above target benchmarks and cancer is above a risk level of 10^{-6}
     - This is at the 99th percentile human equivalent concentration (HEC) and exposure concentration.

- Other options do not provide sufficient risk reduction (see previous slide)

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Costs: TCE Vapor Degreasing Prohibition

- **First Year Costs per System**
  - Inline System: $34,000-$340,000; $123,000 if switching to aqueous
  - Closed-systems: $6,000 - $58,000
  - Open-top Vapor Degreaser (switching to alternatives): ($4,800) - $279,000; $48,000 if switching to aqueous; $18,000-$51,000 if switching to cold cleaning

- **Annualized Costs (3%) per System**
  - Inline System: $5,000 - $291,000; ($10,000) if switching to aqueous
  - Closed-systems: $1,700 - $49,000
  - Open-top Vapor Degreaser (switching to alternatives): ($7,000) - $59,000; $18,000-$51,000 if switching to cold cleaning; up to ($26,000) if switching to aqueous

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Substitute Chemicals or Methods

- Estimated incremental costs for substitute chemicals or alternative methods are presented in the appendix document
  - Costs vary by type of system and risk management option
- Substitutes
  - Drop-in solvents: methylene chloride; perchloroethylene; 1-bromopropane.
  - Non-drop in solvents: Hydrofluorocarbons; hydrofluoroethers; hydrofluoroolefin.
  - Non-drop-in alternatives: Alkaline water-based solvents; volatile methyl siloxanes; citrus. terpene-based cleaners; parachlorobenotrifluoride; hydrocarbon solvents; soy-based cleaners; water-based cleaners.
- Alternative methods:
  - Cold-cleaning
  - Aqueous cleaning

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Costs: PPE & Closed Systems

- Though this option is different from a prohibition, the costs are projected to be the same as a prohibition if the workplace switches to an alternative solvent rather than using TCE with the PPE and closed system.
  - There are different costs expected when a workplace chooses to continue to use TCE in a closed system with PPE (APF 10,000).
- **First Year Costs per System**
  - Inline System: $34,000-$340,000; $123,000 if switching to aqueous
  - Closed-systems: $6,000 - $58,000 if switching solvent**; $149,000 if maintaining closed-system and adding PPE**
  - Open-top Vapor Degreaser (switching to alternatives): ($4,800) - $279,000; $48,000 if switching to aqueous; $18,000-$51,000 if switching to cold cleaning
- **Annualized Costs (3%) per System**
  - Inline System: $5,000 - $291,000; ($10,000) if switching to aqueous
  - Closed-systems: $1,700 - $49,000; **$26,000 if maintaining closed system and adding PPE**
  - Open-top Vapor Degreaser (switching to alternatives): ($7,000) - $59,000; $18,000-$51,000 if switching to cold cleaning; up to ($26,000) if switching to aqueous
- There are many limitations to successful implementation of PPE with APF of 10,000
  - Worker limitations: Not all workers can wear respirators (e.g., impaired lung function, selection fit); respirators may also present communication problems, vision problems, increased fatigue and reduced work efficiency.
  - Not just the devices: Current standard (used by OSHA) contains requirements for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; and other provisions

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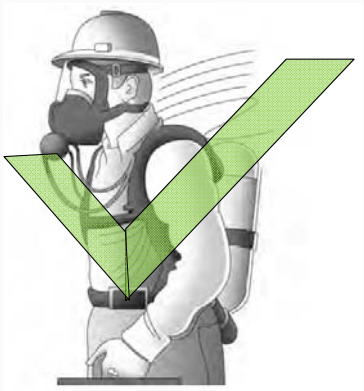
Examples of Respirator APF 10,000

Half mask (Elastomeric)
APF=10
Needs to be fit tested



Full Facepiece Self-Contained Breathing Apparatus (SCBA)
Pressure demand mode is APF=10,000
Needs to be fit tested

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https://www.osha.gov/Publications/3352-APF-respirators.pdf

Questions & Your Thoughts

- We would like to hear more about:
  - TCE and your business
  - Exposure reduction for workers
  - Experiences with alternatives
  - The types of vapor degreasing systems you use e.g. conveyorized, enclosed vapor cleaning machines, vacuum-to-vacuum vapor cleaning machines
- Do you have any advice for EPA?

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Contact Information

- For TCE rulemaking:
  - Cindy Wheeler, 202-566-0480, wheeler.cindy@epa.gov
  - Toni Krasnic, 202-564-0984, krasnic.toni@epa.gov
  - Joel Wolf, 202-564-0432, wolf.joel@epa.gov
- For SBAR:
  - Nathaniel Jutras, RFA/SBREFA staff contact
    EPA Office of Policy
    202-564-0301
    Jutras.Nathaniel@epa.gov
- All risk assessments: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

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Appendices

A. Panel Questions for SERs
B. Regulatory History and International Actions on TCE
C. U.S. Department of Labor Letter in Support of Rulemaking
D. Additional Cost Information
E. OSHA Assigned Protection Factors for the Revised Respiratory Standard

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TSCA Section 6 Proposed Rule: TCE in Vapor Degreasing

Panel Outreach SER Questions for Discussion

These are informal questions that aim to guide discussion on your work practices and your experiences with this chemical. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives.

To provide this or other information in writing, please see the contact information at the end.

<u>For all vapor degreasers:</u>

1) Your business:
    a. What items do you degrease with vapor degreasing?
    b. What type of system do you use (open-top, closed, closed with vacuum, etc)? Can you provide a brief description of your system and how it works?
    c. What size system do you use?
    d. How significant is vapor degreasing to your business overall?
    e. Do any particular items or soils present special challenges?
2) Current work practices related to vapor degreasing:
    a. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
    b. Do the types of vapor degreasers we are considering (open-top, enclosed vacuum, continuous strip, and inline belt vapor degreasers) seem representative of those currently in use for small businesses?
    c. How many hours per day do you operate your vapor degreaser? How many days per year? Is there any difference for the different types of vapor degreasers?
    d. Regarding the operation of various degreasing systems in small businesses, do you think the following is a reasonable range of solvent use?
        i. Between 452 and 1,120 gallons of TCE per year for all open-top vapor degreasing units
        ii. Average annual use of 1,500-1,600 gallons per year for conveyorized vapor degreasing units
        iii. Average annual use of 400-500 gallons per year for enclosed vacuum vapor degreasing units
    e. When did you last update your system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc)? What prompted this update?
    f. How large is your facility that uses vapor degreaser? (ie., dimensions of the room that the degreaser units is used and overall size of facility)
    g. How many employees perform degreasing operations? How frequently?
    h. How many employees are located in the same room with the degreaser unit but not necessarily operating the machine?
    i. What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?
3) Using TCE in your business:

a. If TCE were not available for degreasing, how would you adjust and what would the impacts be on your business?
b. What are your current and best practices to protect workers from exposure to TCE? For example, do you or your colleagues use ventilation or engineering controls, personal protective equipment, worker training, or other methods?
c. What are the benefits to your business of TCE?

4) Exposure reduction for vapor degreasing
   a. What are your experiences with:
      i. Installing or updating ventilation and local exhaust
      ii. Installing or operating other engineering controls
      iii. Equipment changes to reduce exposures
      iv. Monitoring worker exposures to chemicals in the air
      v. Air-supplied respirators
      vi. Other personal protective equipment
   b. If you have changed or updated your exposure reduction technology or methods, how long did that process take?
   c. What do you do to comply with OSHA standards for TCE?
5) Substitutes and alternatives:
   a. How do you know which chemicals are in the products you are using?
   b. What are the trusted sources of information for you about chemicals you use?
   c. Have you tried using alternative chemicals or methods for degreasing? What were the results?
      i. Please discuss alternative methods to vapor degreasing as well as alternative solvents or equipment in your vapor degreasing process
      ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?
      iii. If you have tried or switched to alternative chemicals or methods, how long did that process take? Did it require equipment modifications or new equipment purchases?
   d. If TCE could no longer be used for vapor degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
   e. If TCE could no longer be used for vapor degreasing and you were to choose another solvent, would you have to make specific changes to your system to meet emission requirements?
      i. What would those changes be?
      ii. What would it cost to make those changes in order to be compliant with emissions requirements? [Please note that these would be the changes associated with meeting emission requirements and not those associated with converting or otherwise updating systems to operate using the new solvent.]

6) Regulatory options
   a. Which of the regulatory options presented today would you recommend?
   b. Cost estimates: In your experience, are the cost estimates reasonably representative for both options presented?

c. Can you think of ways to add flexibility to this rulemaking for your small businesses?
d. How do you learn about EPA regulations and what you should do to comply?
e. What is the best way to reach out to members of your industry?

Contact information:

7) **Nathaniel Jutras, RFA/SBREFA staff contact**
EPA Office of Policy
202-564-0301
Jutras.Nathaniel@epa.gov

Regulatory History of TCE at EPA (1 of 3)

- Subject to 25 final rules and notices issued by the Agency from 1979 to 2009.
  - These 25 rules and notices were promulgated by EPA's Office of Air and Radiation (OAR), the Office of Land and Emergency Management (OLEM), the Office of Water (OW) and the Office of Pollution Prevention and Toxics (OPPT).
- Office of Air and Radiation
  - Listed TCE as a hazardous air pollutant (HAP) from several different industrial emission sources in multiple rules, including solvent cleaning operations as well as a "probable or possible human carcinogen" from operations including printing, coating, and dyeing of fabrics and other textiles.
  - Classified TCE as a group I chemical for emission standards for equipment leaks in the synthetic organic chemical manufacturing industry.
- Office of Land and Emergency Management
  - One of the more common groundwater contaminants and is found at more than at 700 NPL sites.
  - Listed as a hazardous waste as toxicity characteristic contaminant and as a spent solvent waste (F001, F002).
  - Set a reportable quantity of 100 lbs (45.4 kg) for releases of TCE from vessels or facilities in 1989.
  - Determined to be ineligible for the conditional exclusion in the solvent-contaminated wipes rule.

Regulatory History of TCE at EPA (2 of 3)

- Office of Water
  - 1979: OW initially identified TCE as a "toxic pollutant."
  - 1982: Classified TCE as a "priority pollutant" in and no discharges of TCE were allowed from steam electric power generating point sources.
  - 1987: Published the current National Primary Drinking Water Regulation (NPDWR) for TCE on July 8, 1987 (52 FR 25690).
    - The NPDWR established a non-enforceable maximum contaminant level goal (MCLG) of zero mg/L based on a cancer classification of B2, probable human carcinogen.
    - The NPDWR also established an enforceable maximum contaminant level (MCL) of 0.005 mg/L based on analytical feasibility.
  - 1993: Set an effluent limitation of 69 µg/L maximum daily average and 26 µg/L maximum monthly average for new and existing sources discharging to publicly owned treatment works (POTWs) from the organic chemicals, plastics, and synthetic fibers industrial category.
  - 1994: Prohibited injection of TCE into class I underground injection wells.

Regulatory History of TCE at EPA (3 of 3)

- Office of Water (continued)
  - 1995: Under the Clean Water Act, in EPA's final regulation Water Quality Guidance for the Great Lakes System, TCE was identified by OW as a non-bioaccumulative pollutant of initial focus.
    - This regulation included water quality criteria for TCE for protection of human health, a human cancer value (HCV) of 29 µg/L for drinking water and 370 µg/L for non-drinking water, for the Great Lakes System.
    - Each of the Great Lakes states were required to adopt water quality standards and implementation procedures as protective as the regulation.
    - All states have complied with this requirement for TCE.
  - 1998: OW identified TCE's major sources in drinking water originating from "discharge from metal degreasing sites and other factories."
    - OW is currently evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.

State Regulations: TCE

- Listed on California's Safer Consumer Products regulations candidate chemicals list and the Proposition 65 list of chemicals.
- Minnesota classifies TCE as a chemical of high concern, while other states, like Washington and Maine, have considered TCE for similar chemical listings.
- Several additional states have various regulatory actions that range from reporting requirements to contamination limits and use reduction efforts.

State Regulations for TCE in Products

State	Prohibited Chlorinated Solvents: TCE and Methylene Chloride
New Hampshire, Virginia	Aerosol Adhesives
Connecticut, Delaware, District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, Rhode Island	The above plus: Contact Adhesives, Electrical Cleaners, Electronic Cleaners, Footwear/Leather Care Products, Adhesive, Removers, General Purpose Degreasers, and Graffiti Removers
New Jersey	The above plus: Brake Cleaners, Engine Degreasers, and Carburetor/Fuel-injection Air Intake Cleaners
California	All of the above plus: Bathroom and Tile Cleaners, Construction, Panel, and Floor Covering Adhesives; Carpet/Upholstery Cleaner, General Purpose Cleaners, Fabric Protectant, Multi-Purpose Lubricant, Penetrant, Metal Polish or Cleanser, Multi-Purpose Solvent, Oven Cleaners, Paint Thinner, Pressurized Gas Duster, Sealant or Caulking Compound, Spot Remover, and Silicone-based Multi-Purpose Lubricant

EU Regulations: TCE

- TCE is listed in the European Union Authorization List owing to its classification as carcinogen(category 1B), with a sunset date of April 21, 2016.
- Continued-use authorizations for substances that would otherwise be banned can be granted under REACH if applicants can show that no alternatives are available and that the risks posed by substances can be controlled, or that there is a socioeconomic case for continued use of the substance.
- Companies were required to submit their requests for authorizations by January 7, 2015. All applications for authorizations of use of TCE as a degreaser were use in closed systems only (no open top uses).

Other TCE Regulations

- Canada
  - Canada assessed TCE in 1993 and considered it as a “toxic” under section 11 of the 1988 Canadian Environmental Protection Act (CEPA 1988).
- Japan
  - Considered a Class II substance (substances that may pose a risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment).
  - Japan also controls air emissions and water dischargers containing TCE, as well as aerosol products for household use and household cleaners containing TCE.
- Australia
  - Listed in the Australian National Pollutant Inventory (NPI), a programme run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Reporting obligations may apply to this chemical.
  - Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the National Occupational Health and Safety Commission (NOHSC) Approved Criteria for Classifying Hazardous Substances.

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210

James J. Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460

Jim —

Dear Mr. Jones:

This letter follows our discussion with your office related to the risks associated with methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers and trichloroethylene (TCE) in aerosol degreasing, spot cleaning in dry cleaning, and vapor degreasing under the Toxic Substances Control Act (TSCA). More specifically, you are inquiring whether the risks from occupational exposure are more appropriately handled by actions taken under the Occupational Safety and Health (OSH) Act. Given certain limitations imposed on OSHA's authority under the OSH Act, this agency believes TSCA provides the Environmental Protection Agency (EPA) with a means of eliminating or reducing the risks associated with these chemical uses in a more coordinated fashion across both consumer and occupational settings.

There are limits on OSHA's authority to regulate exposures to hazardous chemicals such as MC, NMP, and TCE. The OSH Act grants OSHA the authority to promulgate and enforce occupational safety and health standards to address exposure to unsafe levels of hazardous chemicals in the private sector and in most federal workplaces. *See* 29 U.S.C. §§ 652(5), 655(b)(5), 653(a), 668. OSHA lacks direct jurisdiction over state and local government workers, and they are covered only if they work in those states that have an OSHA-approved state safety and health program. *See* 29 U.S.C. § 652(5); 29 C.F.R. § 1902.4(d). In such cases, they are subject to the state's safety and health standards, which must be at least as effective as OSHA's requirements. *See* 29 U.S.C. § 667(c)(2). Currently, 28 states have OSHA-approved programs.

Moreover, OSHA does not cover self-employed workers, military personnel and uniquely military equipment, systems, and operations, and workers whose occupational safety and health hazards are regulated by another federal agency (for example, the Mine Safety and Health Administration, the Department of Energy, or the Coast Guard). In addition, since 1976, there has been an annual rider to OSHA's appropriation that prohibits the agency from expending appropriated funds to issue standards for or conduct enforcement activities against certain small farming operations. See, e.g., Consolidated Appropriations Act, 2014, Pub. L. No. 113-76 (2014). Finally, OSHA's jurisdiction is limited to the workplace, and the agency does not have authority to address exposures outside that scope, such as purely consumer uses of hazardous chemicals.

OSHA has issued standards which set permissible exposure limits (PELs) for MC and TCE in the workplace. OSHA's MC standard, 29 C.F.R. § 1910.1052, was issued in 1997 through a rigorous notice and comment process and applies to general industry, construction, and shipyard employment. It sets the PEL for airborne MC to an eight-hour time-weighted-average (TWA) of 25 parts per million (ppm). This standard also includes provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, and personal protective equipment.

OSHA's PEL for occupational exposure to TCE is found at Table Z-2 of 29 C.F.R. § 1910.1000. Under Table Z-2, each employee's cumulative exposure to TCE during an eight-hour work shift may not exceed an eight-hour TWA of 100 ppm. Moreover, each employee's exposure to TCE may not exceed 200 ppm at any time during an eight-hour work shift (except that each employee's exposure to TCE may reach 300 ppm for five minutes every two hours). The PEL for TCE was adopted at the formation of OSHA in 1971 and is based on an outdated ACGIH occupational exposure limit. The ACGIH has since reduced its TCE exposure limit to a 10 ppm eight-hour TWA and a 15 minute short-term limit of 25 ppm to reflect updated scientific evidence.

OSHA does not have a PEL for NMP. However, the agency may issue citations and penalties to employers under the general duty provisions of the OSH Act, 29 U.S.C. § 654(a)(1), in instances where that substance presents a recognized hazard that is causing or is likely to cause death or serious physical harm to employees.

OSHA's current regulatory agenda does not include updates to the agency's MC and TCE requirements or the issuance of a new standard for NMP, and at this time OSHA does not anticipate such regulatory activity in the near future. However, OSHA supports the goals of EPA to broadly address the hazards associated with these chemicals and looks forward to collaborating with you on activities that will reduce occupational risk.

Sincerely,

David Michaels, PhD, MPH

☐ CONGRESSIONAL

OSHA's Controlled Correspondence Unit

Room: N 3626 – *Phone:* 3 - 2050

DATE: 3/31/16 **CONTROL #:** 800965

FOR CCU USE ONLY

DIRECTORATE/OFFICE: DSG

CONGRESSMAN(WOMAN)/SENATOR:

NON-CONGRESSIONAL ORIGINATOR:

ORGINATOR ORGANIZATION:

SUBJECT/ISSUE: Risks associated w/ Methylene Chloride (MC) and N-Methylpyrolidone (NMP) in paint removers (TCE)

COMMENTS

DESTINATION *(Check Box)*

- ☒ A/S
- ☐ SOL/OSH
- ☐ SOL/FLS
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FROM (Initial): K.I. ***DATE:*** 4/4/16

CIRCLE: A/S SOL OCIA DIR CCU

TO (Circle): A/S SOL OCIA DIR CCU

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Correspondence Details

Correspondence ID: **OSHA-L2016-800965** Record Status: **Closed**

Originator: **Michaels, David**

Addressed To: **Jones, James**

Organization: **DSG**

Constituent:

Subject: **Risk associated with Methylene Cloride (MC) and N-Methylprrolidone (NMP) in pain**

Letter Type: **Agency Generated Letter**

Signature Level: **Assistant Secretary**

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Date Entered: **3/31/2016**

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Due Date: **4/13/2016**

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Date: **3/31/2016**

Office: **DSG - Directorate of Standards & Guidance**

Action: **Action**

Front Office Review

Assistant Secretary:

CCU:

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Final Signed By: **Michaels, David**

Final Signed Date: **4/4/2016**

Close Out Date: **4/4/2016**

Estimated Incremental Costs for TCE Vapor Degreasing Options

First Year and Annualized by System and Compliance Choice

Incremental Cost Estimates: Ban on Vapor Degreasing with TCE		
Compliance Strategy	**Cost per System**	
	1st Year	**Annualized (3% discount rate)**
Vapor Degreasers		
Drop-in: Perchloroethylene	$4,000-$11,000	$4,000-$11,000
Drop-in: Methylene Chloride	($4,800)-($1,000)	($4,800)-($1,000)
Drop-in: 1-bromopropane	$8,900-$24,000	$8,900-$24,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$155,000-$279,000	$28,000-$59,000
Aqueous Cleaning System	$46,000-$48,000	($26,000)-($7,000)
Not-In-Kind Non-Water Alternatives (e.g., glycol ethers, siloxanes, terpenes, soy-based)	($1,500)-($600)	($7,214)-($5,000)
Cold Cleaning with TCE	$18,000-$51,000	$18,000-$51,000
Closed Systems		
Drop-in: Perchloroethylene	$11,000	$1,700
Drop-in: 1-bromopropane	$5,700	$5,700
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$57,000	$49,000
Hydrocarbon	$58,000	$1,700
Inline/Continuous Systems		
Continuous Strip Cleaner		
Drop-in: Perchloroethylene	$43,000	$7,900
Drop-in: 1-bromopropane	$40,000	$40,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$383,000	$344,000
Aqueous Cleaning	$134,000	-$11,000
Inline Belt Cleaner		
Drop-in: Perchloroethylene	$27,000	$3,800
Drop-in: 1-bromopropane	$10,800	$10,800
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrofluoroolefins, hydrofluoroethers)	$116,000	$93,000
Aqueous Cleaning	$80,000	-$6,000

Incremental Cost Estimates: Ban on TCE in Vapor Degreasing Unless Using Specified Closed System with PPE		
Compliance Strategy	**Cost per System**	
	1st Year	**Annualized (3% discount rate)**
Vapor Degreasers		
Drop-in: Perchloroethylene	$4,000-$11,000	$4,000-$11,000
Drop-in: Methylene Chloride	($4,800)-($1,000)	($4,800)-($1,000)
Drop-in: 1-bromopropane	$8,900-$24,000	$8,900-$24,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$155,000-$279,000	$28,000-$59,000
Aqueous Cleaning	$46,000-$48,000	($26,000)-($7,000)
Not-In-Kind Non-Water Alternatives (e.g., glycol ethers, siloxanes, terpenes, soy-based)	($1,500)-($600)	($7,214)-($5,000)
Cold Cleaning with TCE	$18,000-$51,000	$18,000-$51,000
Closed Systems – Including Respirators		
Closed with TCE and Respirator 10,000 APF	$149,000	$26,000
Continuous/Inline Systems		
Continuous Strip Cleaner		
Drop-in: Perchloroethylene	$43,000	$7,900
Drop-in: 1-bromopropane	$40,000	$40,000
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$383,000	$344,000
Aqueous Cleaning	$134,000	-$11,000
Inline Belt Cleaner		
Drop-in: Perchloroethylene	$27,000	$3,800
Drop-in: 1-bromopropane	$10,800	$10,800
Non-Drop-In Alternatives (i.e., designer solvents – includes hydrofluorocarbons, hydrochlorofluorocarbons, hydrofluoroethers)	$116,000	$93,000
Aqueous Cleaning	$80,000	-$6,000

OSHA Assigned Protection Factors for the Revised Respiratory Protection Standard

for EPA's Planned Proposed Rule under
the Toxic Substances Control Act (TSCA) Section 6(a)
for Trichloroethylene in Vapor Degreasing

Find source at https://www.osha.gov/Publications/3352-APF-respirators.pdf