LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

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IRWIN Engineers, Inc.

WITH GRATEFUL ACKNOWLEDGEMENT TO

MATTHEW A TAYLOR, PH.D., DABT

DUPONT ELECTRONICS & INDUSTRIAL

Prior to 1976, the USA had few restrictions on the manufacture or use of chemical substances

The Toxic Substances Control Act (TSCA) of 1976 gave the US EPA authority to regulate chemicals

All chemicals used in the USA must be either listed on the TSCA inventory or exempt from listing (such as food, drugs, or tobacco)

Manufacturers/importers submit an application for new chemicals to the EPA, which the EPA must review and either approve or deny

TSCA TO LCSA

TSCA was revolutionary in 1976, but the world moved on

EU REACH and other global chemical regulations came into force, while TSCA was still using a framework from the 1970's

NGOs demanded that TSCA be modernized, and industry worked to influence the modernization process

The bipartisan Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA) was signed into law on June 22, 2016, and took immediate effect

Implementation of the new law has been evolving over the past few years

WHAT CHANGED (AND IS STILL ACCELERATING)?

TSCA

Chemicals are generally considered safe to use unless evidence to the contrary is found

EPA must show a danger to take action

LCSA

Chemicals are generally considered dangerous until they can be shown to be safe to use

Applicants must demonstrate safety to be approved

WHAT ARE PRIORITY RE-EVALUATIONS?

Congress decided that existing chemicals hadn't been thoroughly evaluated for safety and told the EPA to fix that gap.

EPA was directed to pick 10 chemicals to start the re-evaluation process and expand from there.

EPA is required to have at least 20 ongoing risk evaluations of existing chemicals at all times.

Existing manufacturers/importers are required to pay for a portion of the re-evaluation work.

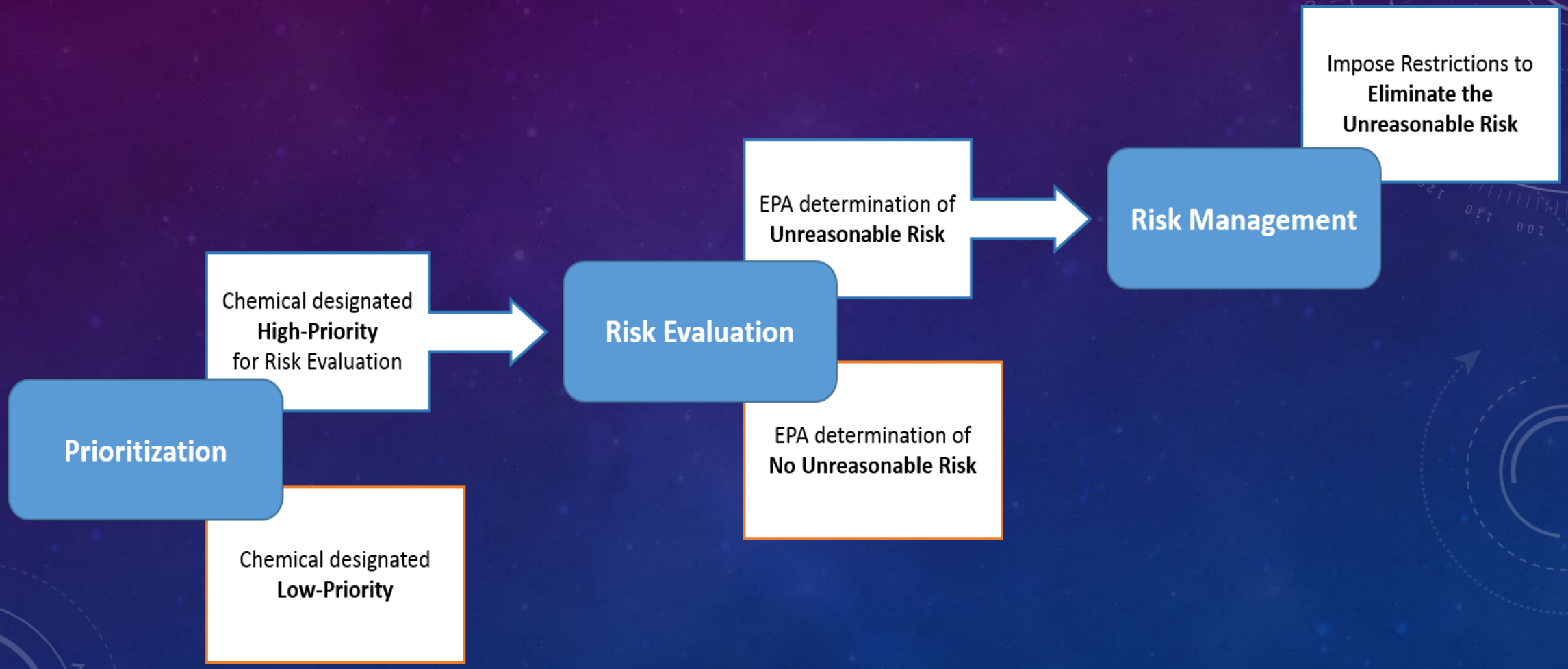
EPA is charged with determining if any use of a chemical poses an "unreasonable risk" and to take action if it does.

THE FIRST 10

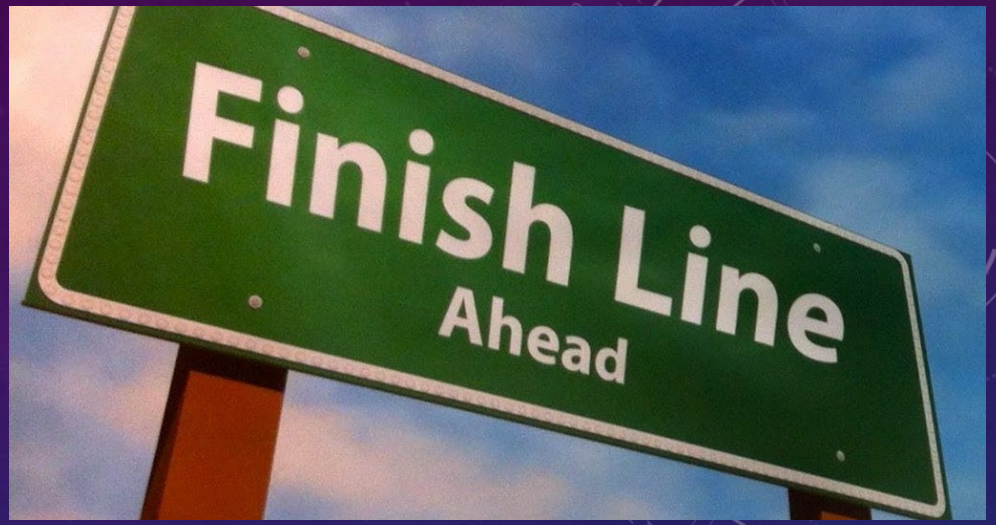
Chemical Name	CASRN	Chemical Group
Asbestos	1332-21-4	N/A
1-Bromopropane	106-94-5	Solvents
Carbon Tetrachloride	56-23-5	Solvents
C.I. Pigment Violet 29 (PV29)	81-33-4	Pigments
Cyclic Aliphatic Bromide Cluster (HBCD)	25637-99-4; 3194-55-6; 3194-57-8	Flame retardants
1,4-dioxane	123-91-1	Solvents
Methylene Chloride	75-09-2	Solvents
N-Methylpyrrolidone (NMP)	872-50-4	Solvents
Perchloroethylene	127-18-4	Solvents
Trichlorethylene (TCE)	79-01-6	Solvents

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca

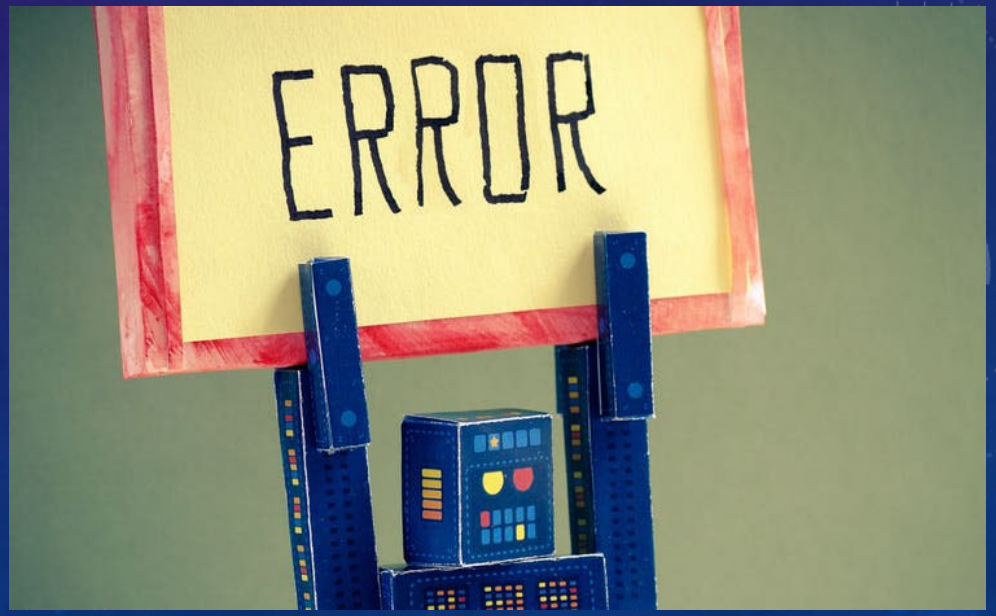
EPA PROCESS FLOW



STATUS REPORT



- The first 10 reviews are finished.
- Except they’re not.



RE-OPENING THE FIRST 10

- Under the previous administration, the first 10 risk evaluations **did not assess air, water or disposal exposures to the general population** because these exposure pathways were already regulated, or could be regulated, under other EPA-administered statutes such as the Clean Air Act, Safe Drinking Water Act, or Clean Water Act. The approach to exclude certain exposure pathways also resulted in a **failure to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations**, including fenceline communities (i.e., communities near industrial facilities).

https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

MORE CHANGES SINCE 2020

- In the final risk evaluations for the first 10 chemicals, the previous administration generally assumed that workers were always provided, and used, personal protective equipment (PPE) appropriately. However, **data on violations of PPE use suggest that assumptions that PPE is always provided to workers, and worn properly, are not justified**. Continued use of this assumption could result in risk evaluations that underestimate the risk, and in turn, risk management rules may not provide the needed protections.

https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

MORE CHANGES SINCE 2020

- EPA is therefore **revisiting the assumption that PPE is always used in occupational settings** when making risk determinations for a chemical. Instead, the agency plans to consider information on use of PPE, or other ways industry protects its workers, as a **potential way to address unreasonable risk** during the risk management process.

https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

WHAT'S NEXT?

- EPA's likely to make "unreasonable risk" findings about at least some uses for most of the first 10 re-evaluation chemicals
- Unreasonable risks will not be allowed to continue
- EPA has many tools
  - New restrictions on handling, PPE, engineering controls, and environmental releases, which can be prohibitively expensive
  - Outright bans on certain uses
  - Complete bans on using a chemical

THE NEXT GENERATION

Chemical Name	CASRN	Chemical Name	CASRN
p-Dichlorobenzene	106-46-7	Di-isodecyl phthalate (DIDP) – (1,2-benzenedicarboxylic acid 1,2-diisodecyl ester)	26761-40-0, 68515-49-1
1,2-Dichloroethane	107-06-2	Di-isononyl phthalate (DINP) – (1,2-benzenedicarboxylic acid, 1,2-diisononyl ester)	28553-12-0; 68515-48-0
trans-1,2- Dichloroethylene	156-60-5	4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)	79-94-7
o-Dichlorobenzene	95-50-1	Tris(2-chloroethyl) phosphate (TCEP)	115-96-8
1,1,2-Trichloroethane	79-00-5	Phosphoric acid, triphenyl ester (TPP)	115-86-6
1,2-Dichloropropane	78-87-5	Ethylene dibromide	106-93-4
1,1-Dichloroethane	75-34-3	1,3-Butadiene	106-99-0
Dibutyl phthalate (1,2-Benzene- dicarboxylic acid, 1,2-dibutyl ester)	84-74-2	1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5
Butyl benzyl phthalate - 1,2-Benzene- dicarboxylic acid, 1-butyl 2(phenylmethyl) ester	85-68-7	Formaldehyde	50-00-0
Di-ethylhexyl phthalate - (1,2-Benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester)	117-81-7	Phthalic anhydride	85-44-9
Di-isobutyl phthalate - (1,2-Benzene- dicarboxylic acid, 1,2- bis-(2methylpropyl) ester)	84-69-5	Octamethylcyclotetra- siloxane (D4)	556-67-2
Dicyclohexyl phthalate	84-61-7		

How Ready Are We for LCSA regulations? A case study - TCE Vapor Degreasing

J. Andrew Irwin, PE, LSP, TURP

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Introduction

- Regulatory History for TCE
- Exposure/Risk Evaluation Exercise
- TUR Planning
  - "Low Hanging Fruit"
  - TURI Cleaning Lab Trials
  - In-house R&D
  - Replacement Vapor Degreaser

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Regulatory History for TCE Use in Degreasing

EPA RCRA Regulations (1980)

F001-Listed Hazardous Waste

Regulatory History for TCE Use in Degreasing

EPA Halogenated Solvent Cleaning – Clean Air Act - MACT (1994)

Alternative Standards: As an alternative to complying with the equipment standards option, each owner or operator of batch vapor or in-line cleaning machines may elect to comply by demonstrating that each solvent cleaning machine emits less than the overall solvent emissions limit specified in the standards. No alternative emission standards are proposed for batch cold cleaning machines.

The overall solvent emissions limits are as follows:

-- For batch vapor solvent cleaning machines, 150 kg/square meter-month.

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TUR Higher Hazard Substance Designation

- Science Advisory Board (SAB) votes to list Trichloroethylene as a Higher Hazard Substance in 2008.
  - Reporting threshold 1,000 lb/YR (M/P/OU)

EPA Authority under TSCA

Section 6(a) of the Toxic Substances Control Act (TSCA) provides authority for EPA to ban or restrict the manufacture (including import), processing, distribution in commerce, and use of chemical substances, as well as any manner or method of disposal.

(EPA Unified Agenda Spring 2020 - RIN: 2070-AK03)

[Underline emphasis added.]

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Regulatory Future

Section 26(l)(4) of TSCA authorizes EPA to issue rules under TSCA Section 6 for chemicals listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which EPA published completed risk assessments prior to June 22, 2016, consistent with the scope of the completed risk assessment.

(EPA Unified Agenda Spring 2020 - RIN: 2070-AK03)

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Regulatory Future - Focus on Uses of TCE

TCE was selected as one of the first 10 chemicals for risk re-evaluation under section 6 of TSCA.

In the June 2014 TSCA Work Plan Chemical Risk Assessment for TCE, EPA characterized risks from the use of TCE in commercial degreasing and in some consumer uses. EPA has preliminarily determined that these risks are unreasonable risks.

(EPA Unified Agenda Spring 2020 - RIN: 2070-AK03)

[Underline emphasis added.]

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2017 Proposed Prohibition of TCE Use in Vapor Degreasing

"EPA is proposing under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; …"

Proposed Rule 82 FR 7432 (January 19, 2017)

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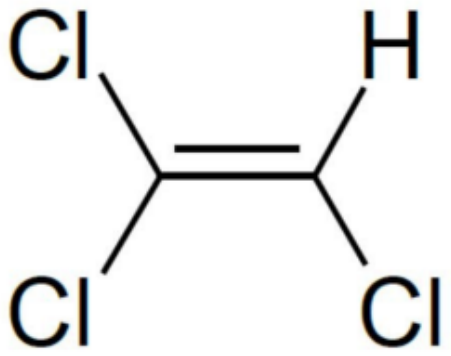
2020 TSCA Risk Evaluation

United States
Environmental Protection Agency

EPA Document #740R18008
November 2020
Office of Chemical Safety and
Pollution Prevention

Nontechnical Summary of the Risk Evaluation for Trichloroethylene

CASRN: 79-01-6



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EPA - Key Risk Points

- **After evaluating 54 conditions of use of TCE, EPA determined that TCE presents an unreasonable risk under 52 conditions of use.**
- This includes unreasonable risks to health of workers and occupational non-users (ONUs) during occupational exposures, and to consumers and bystanders during exposures to consumer uses.
- These unreasonable risks include potential immunosuppression from acute exposures, and autoimmunity and cancer from chronic exposures.

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TCE Risk Summary 2020

EPA has determined that the following conditions of use of TCE present an unreasonable risk of injury. EPA will initiate TSCA section 6(a) risk management actions on these conditions of use as required under TSCA section 6(c)(1). Pursuant to TSCA section 6(i)(2), the unreasonable risk determinations for these conditions of use are not considered final agency action.

Industrial and Commercial Uses that Present an Unreasonable Risk
• Industrial and commercial use as a solvent for open-top batch vapor degreasing • Industrial and commercial use as a solvent for closed-loop batch vapor degreasing • Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing • Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing • Industrial and commercial use as a solvent for cold cleaning • Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release • Industrial and commercial use as a lubricant and grease in tap and die fluid • Industrial and commercial use as a lubricant and grease in penetrating lubricant • Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant

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EPA Significant New Alternatives Policy (SNAP)

End Uses

- Metals Cleaning
  Metals cleaning is removing contaminants such as cutting oils, grease, or metal filings from metal parts.
- Electronics Cleaning
  Electronics cleaning is removing contaminants, primarily solder flux residues, from electronics or circuit boards.
- Precision Cleaning
  Precision cleaning is cleaning to a specific grade of cleanliness in order for products to maintain their value.

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SNAP Decisions

To arrive at determinations on the acceptability of substitutes, the Agency performs a cross-media analysis of risks to human health and the environment from the use of various substitutes in different industrial and consumer uses that have historically used ODS. EPA reviews characteristics, including the following, when evaluating each proposed substitute:

- Ozone depletion potential (ODP),
- Global warming potential (GWP),
- Toxicity,
- Flammability,
- Occupational and consumer health/safety,
- Local air quality, and
- Ecosystem effects.

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SNAP Toxicity Criteria

Toxicity data is used to assess the possible health and environmental effects for exposure to substitutes. The Occupational Safety and Health Administration (OSHA) or EPA approve wide health-based criteria that are available for a substitute such as:

- Permissible exposure limits **(PELs for occupational exposure)**
- Inhalation reference concentrations **(RfCs for non-carcinogenic effects on the general population)**
- Cancer slope factors **(for carcinogenic risk to members of the general population)**

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Metal, Electronics, and Precision Cleaning SNAP

"Substitutes are reviewed on the basis of ozone depletion potential, global warming potential, toxicity, flammability, exposure potential. Lists of and substitutes are updated several times each year. The list of acceptable substitutes are shown below."
(February 2022)

Show All entries Search all columns: trichlor

Substitute	Trade Name(s)	ODP	GWP	Flammable	SNAP Listing Date	Listing Status	Further Information
Trichloroethylene		0.00037	N/A	yes	March 18, 1994	**Acceptable**	OSHA and RCRA standards must be met. EPA issued Maximum Achievable Control Technology requirements under the Clean Air Act for vapor degreasing in November 1994.

Showing 1 to 1 of 1 entries (filtered from 35 total entries) Previous 1 Next

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Lautenberg Shift

Under the LCSA, operations inside of your plant are now under the jurisdiction of EPA; and EPA is not limited to OSHA standards.

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TCE Regulatory Values

UNITS	OSHA PEL	ACGIH TWA	MCP Imminent Hazard (1)
ppm	100 8-Hr TWA	10	0.004
ug/m3	535,000 8-Hr TWA	53,500	24

Notes:
(1) Involving exposure to women of childbearing age.

Odor Threshold Range (Non-Regulatory): 1 ppm (NJDOH); 28 ppm (EPA); 100 ppm (ATSDR)

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LCSA IS CLOSER TO MCP THAN OSHA

- EPA risk characterization will be similar to characterizations used in state programs such as the Massachusetts contingency plan (MCP).

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Case Study Introduction

Case study of how a small manufacturing operation realizes the potential impact of LCSA updated health risk assessments on their operations.

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Electronic Component Manufacturing

- Manufacturer of electronic components for applications in communications, defense and healthcare.
- 75 Employees
- Operations:
  - Shaping of metal and ceramics
  - Screen Printing – Ceramic Pastes
  - Heat Treating
  - Plating
  - Assembly
  - Solvent Cleaning

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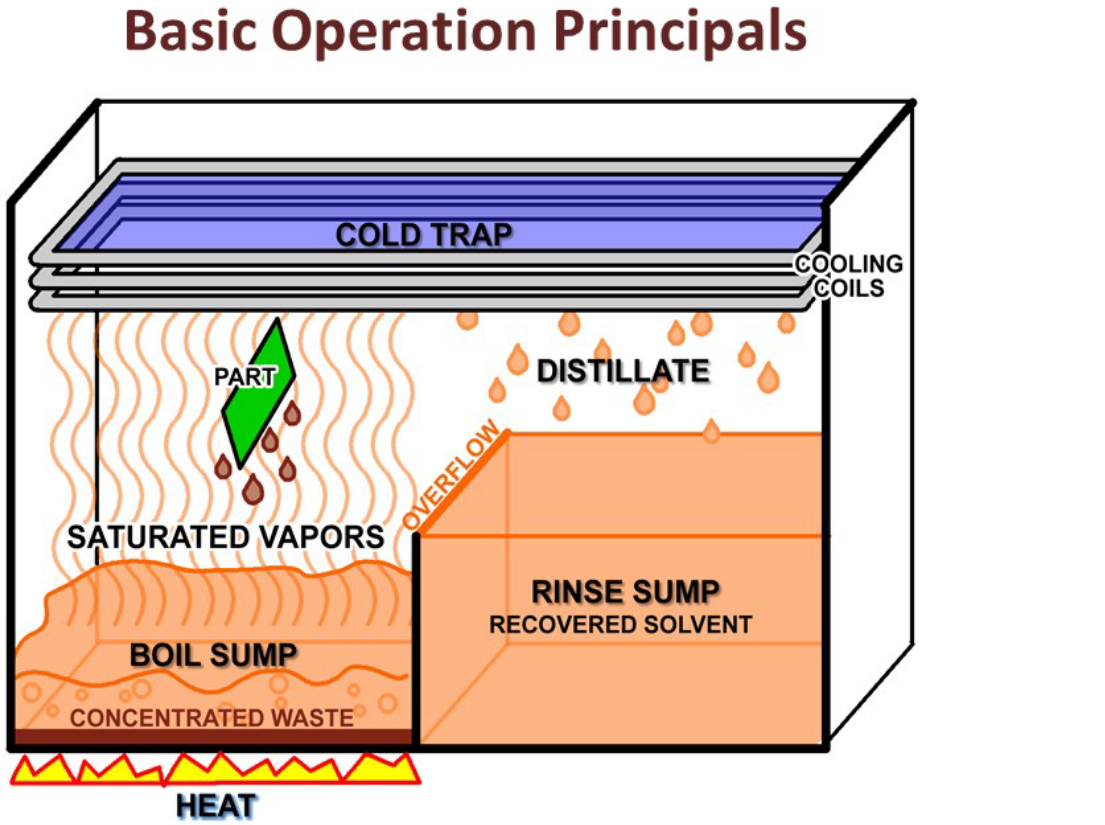
TCE Vapor Degreasing



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What we don’t know…

We have a very small degreaser, what is the exposure?

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TCE Exposure Estimate Calculation Exercise

1. Calculate the estimated mass emission from the degreaser.
2. Calculate the concentration of TCE in the local ventilation exhaust for the room.
3. Calculate the average concentration of TCE in the building.

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TCE Exposure Estimate Calculation Exercise

- Batch vapor degreaser – 6 ft^2 opening
- MACT Alternative Compliance - 150 $kg/mo/m^2$
- Local exhaust 600 cfm
- Local capture 95%
- Building Footprint 200 ft x 80 ft
- HVAC Building Ventilation Turnover Rate

  1 $ft^3/min/sq\text{-}ft$
- HVAC Fresh Air Makeup 25%

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- Helpful conversions:
  - 1 foot = 0.3048 meter
  - 1 lb = 454 gm
  - 1 kg = 1000 gm
  - 1 gm = 10^6 ug
  - 5,350 ug TCE/m^3 = ppm TCE (based on MW)

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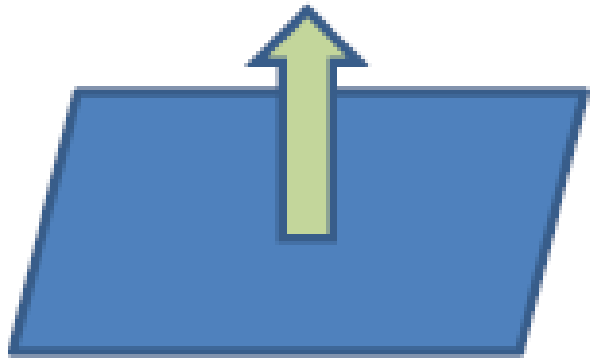
1. Mass emission from the degreaser



6 ft2 opening

150 kg
month-m2

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1. Mass emission from the degreaser

150 kg
month-m2

In Metric Units

$$M\ (gm/min) = 150\ \frac{kg}{month\text{-}\ m2} * 6\ ft2 * 0.3048\text{^}2\ \frac{m2}{ft2} * \frac{1\ month}{28\ days} * \frac{1\ day}{1440\ min} * \frac{1000\ gm}{kg}$$

$$M\ (gm/min) = 2.07\ \frac{gm}{min}$$

In English Units

$$M\ (lb/min) = 150\ \frac{kg}{month\text{-}\ m2} * 6\ ft2 * 0.3048\text{^}2\ \frac{m2}{ft2} * \frac{1\ month}{28\ days} * \frac{1\ day}{1440\ min} * \frac{2.2\ lb}{kg}$$

$$M\ (lb/min) = 0.00457\ \frac{lb}{min}$$

1.2 Tons per Year

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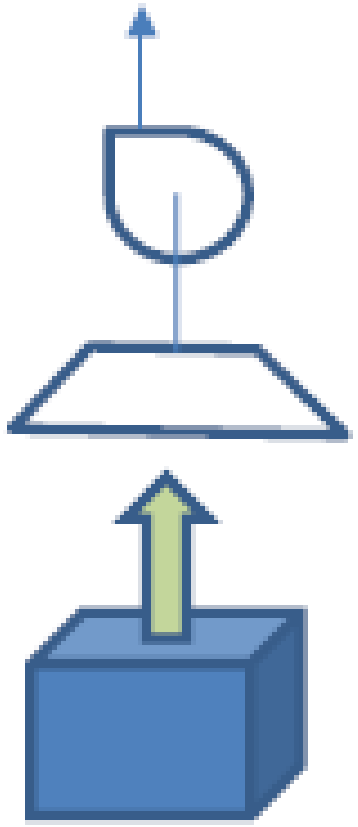
2. Concentration of TCE in local ventilation exhaust



600 ft3
min

95% capture

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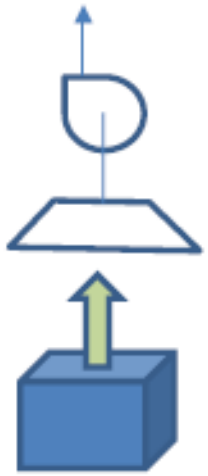
2. Concentration of TCE in local ventilation exhaust



600 ft3 / min

95% capture

Cvent = Mvent / Qvent

$$\text{Cvent (ug/m3)} = \frac{2.07\ \frac{\text{gm}}{\text{min}} * 1E{+}06\ \frac{\text{ug}}{\text{gm}} * \text{Capture } 95\%}{17.0\ \frac{\text{m3}}{\text{min}}}$$

Cvent (ug/m3) = 115,952 ug/m3

$$\text{Cvent (ug/m3)} = \frac{0.00457\ \frac{\text{lb}}{\text{min}} * 454\ \frac{\text{gm}}{\text{lb}} * 1E{+}06\ \frac{\text{ug}}{\text{gm}} * 95\%}{600\ \frac{\text{ft3}}{\text{min}} * 0.3048\ \frac{\text{m}}{\text{ft}}}$$

$$\text{Cvent (ug/m3)} = 115{,}952\ \frac{\text{ug}}{\text{m3}}$$

$$\text{Cvent (ppm)} = 115{,}952\ \frac{\text{ug}}{\text{m3}} * \frac{1\ \text{ppm TCE}}{5350\ \frac{\text{ug}}{\text{m3}}}$$

Cvent (ppm) = 21.7 ppm

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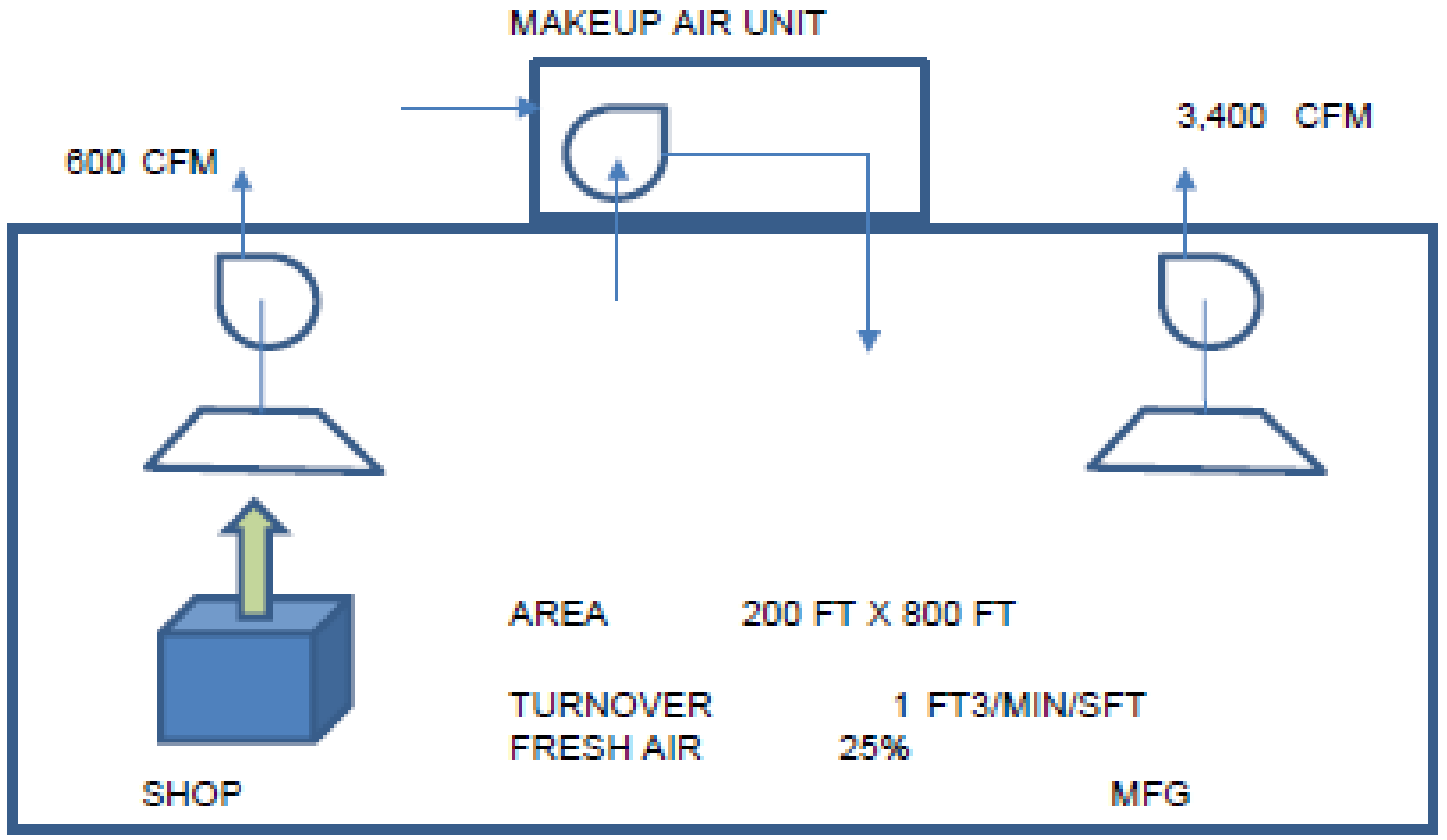
3. Average concentration of TCE in the building



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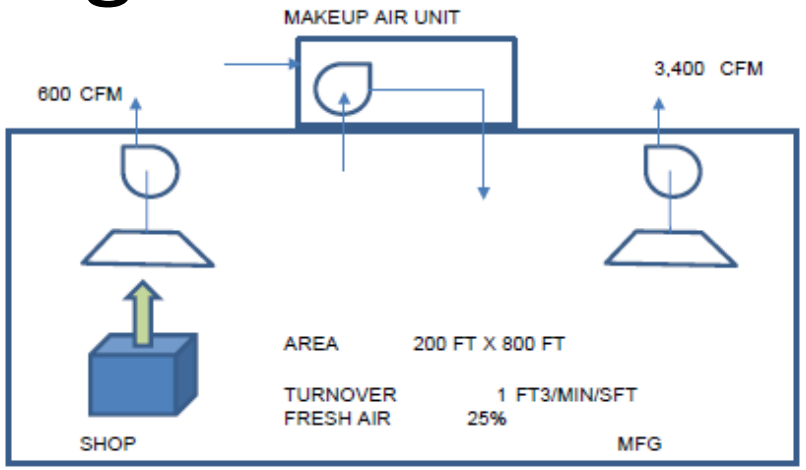
3. Average concentration of TCE in the building



$$C_{air}\ (ug/m3) = \frac{2.07\ \frac{gm}{min} * 5\% * 10^6\ \frac{ug}{gm}}{\left(113 - 17\right)\ \frac{m3}{min}}$$

Cair (ug/m3) = 1,077 ug/m3

Exceeds MassDEP 24 ug/m3
MCP Site Imminent Hazard
Level for Commercial Worker

$$C_{air}\ (ppmv) = \frac{0.0045677\ \frac{lb}{min} * 5\% * 454\ \frac{gm}{lb} * 10^6\ \frac{ug}{gm} * 1\ ppmv\ TCE}{\left(4000 - 600\right)\ \frac{ft3}{min} * 0.3048^3\ \frac{m3}{ft3} * 5350\ \frac{ug}{m3}}$$

Cair (ppmv) = 0.2 ppmv TCE

Less than OSHA 100 ppmv PEL
Less than ACGIH 10 ppmv TWA

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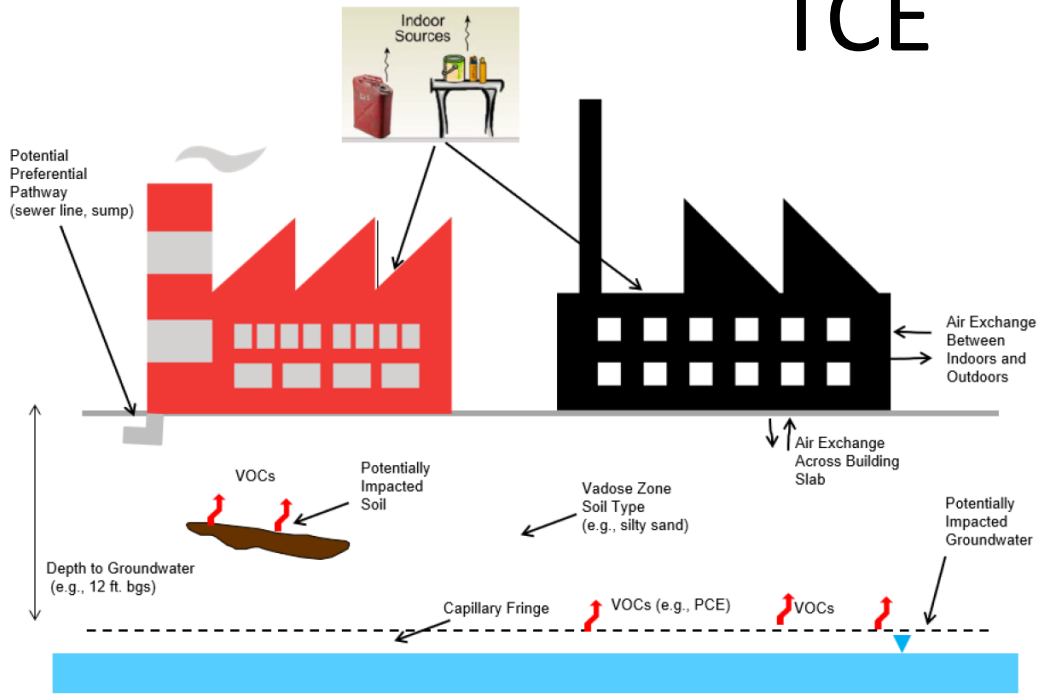
Upgradient Neighbor MCP Release of TCE



Ground water TCE/PERC plume flowing from neighbor extends under building and leads to concern for vapor intrusion.

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Indoor Air

	IA-1 MFG	IA- 2 MACH SHOP	IA-3 MFG	IA-4 MFG	Out Side	OSHA PEL	ACGIH TWA	MCP IH
TCE ppmv	0.12	3.7	0.06	0.08	0.001	100 8-Hr TWA	10	0.004
TCE ug/m3	633	19,800	336	435	5	535,000 8-Hr TWA	53,500	24

Concentrations of TCE within the building:

- Magnitude below OSHA PEL
- Below ACGIH guideline
- Exceeds MassDEP Imminent Hazard Level for Commercial Worker – MCP Site

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Is It From the MCP Release?

SOIL GAS TCE

	SG 1	SG 2	SG 3	SG 4
TCE ug/m3	44	558	2,820	405

INDOOR AIR TCE

	IA-1 MFG	IA- 2 MACHSHOP	IA-3 MFG	IA-4 MFG
TCE ug/m3	633	19,800	336	435

MCP PROVISIONS ONLY APPLY TO WORKPLACE EXPOSURES NOT RESULTING FROM A DISPOSAL SITE RELEASE.

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LCSA Changes TUR Priorities:

1. Product quality
2. Cost of TCE purchase
3. Cost of TCE waste disposal
4. Releases to Environment
5. Indoor air concentrations <OSHA PELs

1. Indoor air concentrations pose acceptable risk for workers
2. Releases to Environment
3. Product quality
4. Cost of TCE purchase
5. Cost of TCE waste disposal

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TUR Planning with LCSA Focus

- Input Substitution - Priority for Porous Parts
  - TURI Lab
    - Aqueous cleaners
    - Alternative solvents
  - In-House Research & Development
    - Alternative solvents
  - Vendors
    - HFE w/New Vapor degreaser - $$ (PFAS N.O.L.)
- Production Unit Redesign/Modernization
  - Control of Cross Draft
  - New Vapor degreaser - $$
  - Ventilation (NOT TUR)

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Takeaways

- Impact to workers has always been a TUR consideration. The measure for adequate protection is changing.
- Weighing of Options – future implications

3 COMPOSITION INFORMATION

Chemical Name	Common Name And Synonyms	CAS No. and other Unique identifiers	Concentration %
1,1,1,2,2,3,4,4,5,5,5-decafluoropentane	- NOT PFAS	138495-42-8	30-60%
trans-Dichloroethylene	- ***	156-60-5	30-60%
Pentafluorobutane	- C1-C4 NOL	406-58-6	10-30%

***** Trans 1,2 DCE:**

- SNAP approved
- Not covered by halogenated solvent NESHAP
- On LCSA next 20 list
- TURI "Substitute Of Concern"

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Thank You

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