Welcome to

Product Quality Cleaning Workshop webinar

EPA Regulatory Happenings & Your Critical Cleaning Process

February 8, 2022

We will begin soon…

1

BFK Solutions
Critical Cleaning Consultants, est. 1994

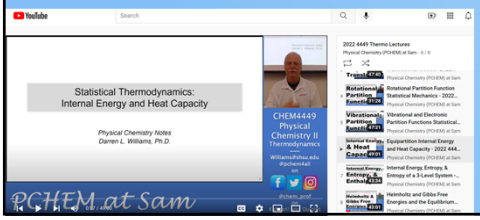
- As the industry leaders, we provide
  - Process improvement, not product sales
  - Experience, expertise, common sense
  - Industry involvement: JS3 (military), IPC, ASTM, U.S. ISO expert, EPA, FDA
- Barbara Kanegsberg, "*The Cleaning Lady*"
  - Biochemist, clinical chemist, manufacturing process
- Ed Kanegsberg, "*The Rocket Scientist*"
  - Physicist, engineer, process evaluation

2

Darren Williams and the Cleaning Research Group

Professor of Physical Chemistry

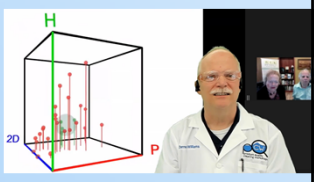
- Pressure, temperature, volume, energy, heat, work,
- Spectroscopy, molecular structure, reactivity, kinetics
- Behavior of fluids and mixtures, distillation, refrigeration, azeotropes, boiling, freezing, phase separation, precipitation, viscosity, density, surface tension, cavitation methods



Leader: Cleaning Research Group

- Solvent blend formulations, distillation, phase separation, solubility parameters
- Materials compatibility (gloves, polymers, gaskets, surfaces)
- Flashpoint determinations
- Cleaning verifications (fluorescence, contact angle, gravimetric, spectroscopic, NVR)
- Cleaning methods (solvent, aqueous, dry steam, ultrasonic, vapor degreasing)
- CNC Machining
- Aluminum anodizing
- Composite 3D printing

NEW in 2022!



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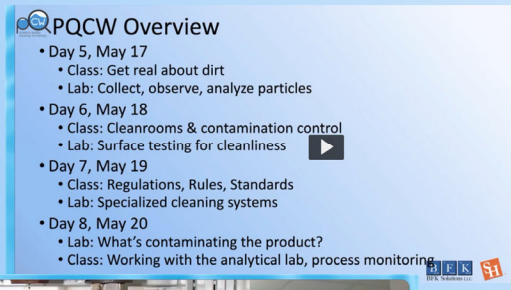

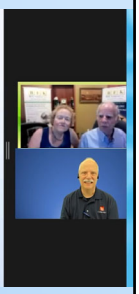

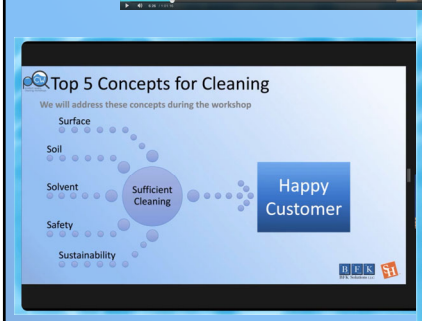

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Overview: EPA Regulatory Happenings and Your Critical Cleaning Process

- **News and rumors**
- EPA amended TSCA
- Risks, regulatory options
- Strategies for manufacturers

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Prediction: You are nearly certain to spend more on cleaning within the next 3 to 5 years

- Small parts, components
- New materials
- Higher performance demands
  - Medical
  - Advanced automotive
- Overall manufacturing costs
- Worker safety & environmental issues (local, national, global)
  - **U.S. EPA TSCA**, EU Regulations
  - Climate change
  - Water as a valuable resource

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What are your cleaning requirements? Where are you on the supply chain? What does it take to change the cleaning process?

- Developmental product
  - Research, prototype
  - Cleaning process must be "scalable"
- General cleaning
  - Preliminary cleaning
  - Gross soil removal
  - Visual inspection sufficient
  - Little to no testing required
- High precision cleaning
  - Failure costs money
  - Consistency required
  - Cleaning validation required
- Safety/critical cleaning
  - Failure is not an option
  - Examples of product failure: airplanes drop out of the sky and people's tushes fall off
  - Extensive testing, validation, verification required
  - Retesting needed for process change

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Assertions, claims, rumors (many are false or uncertain) – regulatory tsunami?

- All chlorinated and brominated solvents will be banned within two years
- Aqueous processes are more effective and cost less
- Aqueous processes can work for almost all applications
- You have to switch to ….
  - (followed by a product or process being offered)
- Vapor degreasing is dead
- Send us your samples, we'll take care of it
- There will be lots of exemptions
- The military won't have to do this
- Only the little guys will have to comply

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8

9

TANSTAAFL ("There ain't no such thing as a free lunch")

Robert Heinlein, "*The Moon is a Harsh Mistress*"

- Cleaner is better
  - We want cleaner surfaces
- More cleaning, more problems
  - High temperature, more adherent soils
  - Surface damage (materials compatibility)
  - May remove "beneficial contamination"
- Better solvency
  - If it dissolves the soil, it MAY damage the product
  - Everyone wants a universal solvent
    - How would you store it?
- Safety, low environmental impact
  - If a cleaning agent dissolves the soil
    - it can impact you
      - Our products depend on organic chemicals (metalworking fluids)
      - We're made of organic chemicals
    - It can impact the environment

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10

Overview: EPA Regulatory Happenings and Your Critical Cleaning Process

- News and rumors
- **EPA amended TSCA**
- Risks, regulatory options
- Strategies for manufacturers
- (updated February 7, 2022)

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11

Why are we concerned with EPA TSCA?

- EPA actions can impact our clients in the manufacturing community
  - Cleaning agents, cleaning equipment, costs, evaluation, performance, etc.
- BFK Solutions is a subcontractor to the EPA
  - Provide technical information, risk management
  - Evaluate risks/benefits of alternative chemicals & processes
  - We are NOT involved in risk assessment for chemicals under review

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12

EPA TSCA

Will solvents be banned?

TSCA may result in drama but it's not an opera!

13

EPA TSCA reform, existing chemicals

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals

- U.S. Environmental Protection Agency
  - United States, not just California
- Toxic Substances Control Act (TSCA)
  - Provides direction to EPA
- TSCA Amended 2016 by Frank R. Lautenberg Chemical Safety for the 21st Century Act
  - Broad bi-partisan Congressional support
    - Co-sponsors: 8 Democrats and 8 Republicans
    - *A miracle happened!*
  - Requires EPA to evaluate **safety** of existing chemicals

14

How EPA evaluates safety of existing chemicals (linear approach, one at a time, no feedback loop)

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals

15

Highlights, EPA activities with Existing Chemicals, Lautenberg (Amended TSCA)

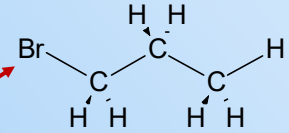
https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/highlights-key-provisions-frank-r-lautenberg-chemical

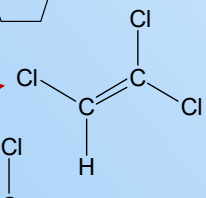
- Set priorities
- Evaluate risks to environment and human health
- Set new risk-based safety standard
  - Scientific Advisory Committee on Chemicals
    - https://www.epa.gov/tsca-peer-review/science-advisory-committee-chemicals-basic-information
  - Determine if chemical poses an "unreasonable risk"
    - Must consider susceptible and highly-exposed populations
  - Excludes costs and non-risk factors
- Take action to address unreasonable risks (EPA has to do something)
  - Manage the risks
  - Consider if alternatives are available
  - Consider costs
  - Action (including bans and phaseouts) ASAP no later than 5 years after regulation
    - Observation: timelines may not be met

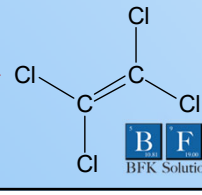
16

Initial 10 Chemicals - EPA Amended TSCA

- EPA list for risk evaluation (posted Dec. 19, 2016)
- Let's call them "The naughty 10"
  - 1,4-dioxane
  - **1-bromopropane (n-propyl bromide) (1BP, nPB)***
  - Asbestos
  - Carbon tetrachloride
  - Cyclic aliphatic bromide cluster (HBCD)
  - **Methylene chloride (MC, DCM)***
  - **N-methyl pyrrolidone (NMP)***
  - Pigment violet 29
  - **Trichloroethylene (TCE)***
  - **Tetrachloroethylene, perchloroethylene (PCE, PERC)***







* Cleaning Solvents

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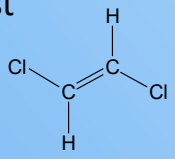
17

17

EPA Amended TSCA impacts entire category of cleaning agents

Halogenated Solvents

- N-propyl bromide
- Methylene chloride
- Trichloroethylene
- Perchloroethylene
- What about *trans*-1,2-dichloroethylene? – it's not on the first list



Properties

- Broad solvency range
- Favorable wetting properties
- Self-rinsing
- Rapid drying
- Negligible residue
- Can be contained to meet *current* worker exposure limits (including Cal/OSHA, ACGIH,etc.)

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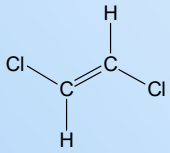
trans-1,2-dichloroethylene? –It's on the second TSCA list



- *trans*-DCE a component of many "replacement" blends
  - Note: Boiling point of *trans*-DCE is 48 °C (considerably lower than 1-BP, TCE, or PCE)
  - Implications for cleaning efficiency
- *trans*-DCE designed a high priority chemical, Dec. 2019
- Currently undergoing risk evaluation
- Based on history of 1-BP, TCE, PCE, MC, risk evaluation could take 2 ½-3 years
- Other chemicals may be on the 3rd, or higher list
  - When one risk evaluation is done, EPA must start another, and another

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What does safety mean? - Sweeping EPA authority with amended TSCA

- Environment
- Workers using the chemical
- Workers in vicinity
  - ONU – Occupational Non-Users
- "Fenceline" communities
  - Added January 2022
    - Not included in 2017-2020 risk assessments
    - Public comment through March 22, 2022
  - Potentially exposed or susceptible subpopulations near industrial facilities
    - May be disproportionately exposed to chemicals over long periods of time
  - **Air pathway, up to 10 km (6.2 miles)**
  - https://www.epa.gov/newsreleases/epa-releases-screening-methodology-evaluate-chemical-exposures-and-risks-fenceline

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20

Risk evaluations completed* Halogenated cleaning solvents

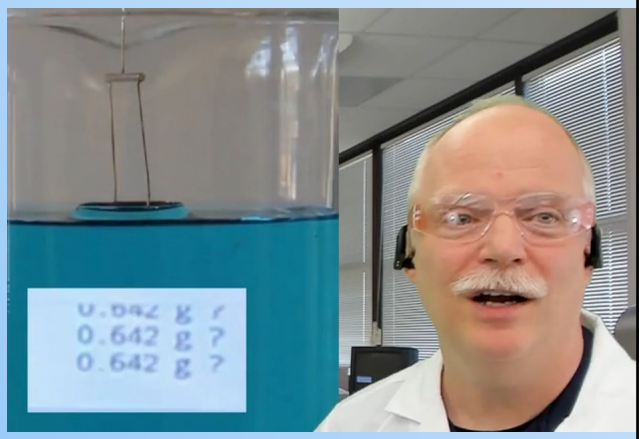
Chemical name	Status	Date posted
1-BP (nPB)	Final risk evaluation	August 2020
Methylene chloride (MC, DCM)	Final risk evaluation	June 2020
Perchloroethylene (PCE)	Final risk evaluation	December 2020
Trichlorethylene (TCE)	Final risk evaluation	November 2020

*Not completed: risks to fenceline communities

21

Solvents have advantages

- Low surface tension, low viscosity
  - Solvents can penetrate small gaps
- High solvency for soils
- Low energy use for cleaning, drying
  - Water and energy becoming more expensive resources
- Short cleaning cycles
- Airless/airtight systems minimize exposure to workers and environment



22

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Risk Evaluation, Perchloroethylene

- No unreasonable risk to environment
- Unreasonable risk to workers
  - Open top vapor degreasing
  - "Closed loop" vapor degreasing
  - Cold cleaning (cold is defined as lower than the boiling point)
  - Disposal and many other conditions
- **Costs not considered in risk evaluation**
- **Impacts of replacement chemicals or processes not considered**
- Similar determinations for MC, TCE and nPB

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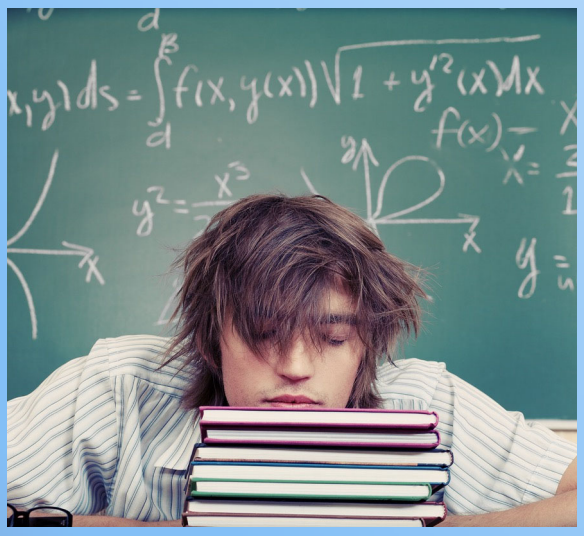
24

Understanding PCE risk evaluation



- Draft Risk Evaluation for Perchloroethylene– EPA-740 R1-8011
  - April 2020
  - 636 pages
  - 60 day comment period
- Final Risk Evaluation for Perchloroethylene--EPA-740 R1-8011
  - December 2020
  - 714 pages
- Barb has attempted to read both documents
  - Determined: Difficult to follow rationale and approach

25

Clarification would help – PCE risk evaluation

- What's the basis of the "determination of unreasonable risk?"
  - Calculated? Extrapolated? Measured?
- How were the cited studies used to support determination of "unreasonable risk"
  - Which specific studies were weighted more highly?
  - Barbara has valiantly attempted to follow the studies!
  - Do not see a definitive "smoking gun"
- What's reasonable? Where's the dividing line?
  - No equivalent of PEL or TLV
    - PEL Permissible exposure level (OSHA)
    - TLV Threshold limit value (ACGIH)

26

Not stated in EPA Reports: what levels of PCE do workers experience?

- Levels of exposure actually achieved under various conditions
- Definition of airless (or vacuum or closed loop) versus open top degreaser
  - Not yet clearly defined (or perhaps fully understood) by EPA
  - Our working definition for an airless system
    - You open the cleaning chamber, the chamber is empty, there is no solvent
      - No liquid-air interface
    - You put the parts in the empty chamber, then close the lid
    - You run the process with solvent, at reduced pressure
    - The solvent is contained and recaptured
    - You open the cleaning chamber to take out the parts; there is no solvent
- TBD: worker exposure levels actually observed with airless
  - Preliminary observations – very low

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What happens next?

- Bottom line—no one knows
  - Probably not even the EPA
- Timeline is changing for Risk Mitigation Phase
  - Amended TSCA: propose rule within 1 year of final risk evaluation
  - Adopt rule within 2 years
  - Re-evaluation of risks to fenceline communities affects start date
    - Will this result in even lower limits?
- Will chlorinated/brominated solvents be banned by end of 2022, or even 2024?
  - **Unlikely**
- More likely – rule(s) with a timeline for process change, controls

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Possible EPA actions to address "unreasonable risk"

- **Ban manufacture, sale or use**
- Set an occupational air exposure limit (ECEL)
- Regulate manner of use
- Require recordkeeping, monitoring, or testing by manufacturers and processors
- Prohibit or regulate manner or method of disposal

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Risk Mitigation, stage where EPA considers

- Costs of process change
  - Equipment
  - Chemicals,
  - Facilities
  - Process development
  - Insurance
  - Product performance
- Impacts on small business

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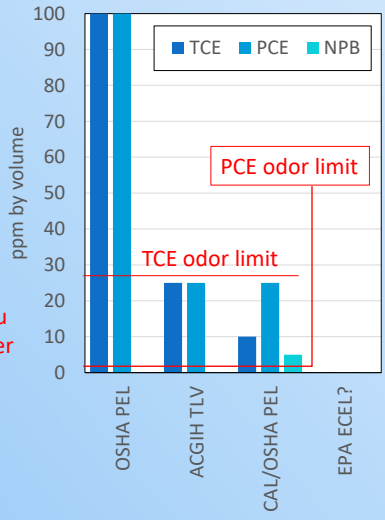
Current and possible Exposure Limits (ppm)

Solvent	OSHA PEL	ACGIH TLV	CAL/OSHA PEL	What if EPA ECEL were?
TCE	100	25	10	0.001*
nPB (1-BP)	NA	0.1	5	0.1 > ? > 0.01**
PCE	100	25	25	1 > ? > 0.1**

If you ever smell it, you are WAY over the limit.



PEL: Permissible Exposure Limit. (Enforceable)
TLV: Threshold Limit Value (Recommended, not enforceable)
ECEL (Rhymes with freckle): Existing Chemical Exposure Limit

*Proposed by EPA in 2015, EPA TCE Docket # EPA-HQ-OPPT-2016-0387-0120, https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0387-0120

** Semi educated guesses

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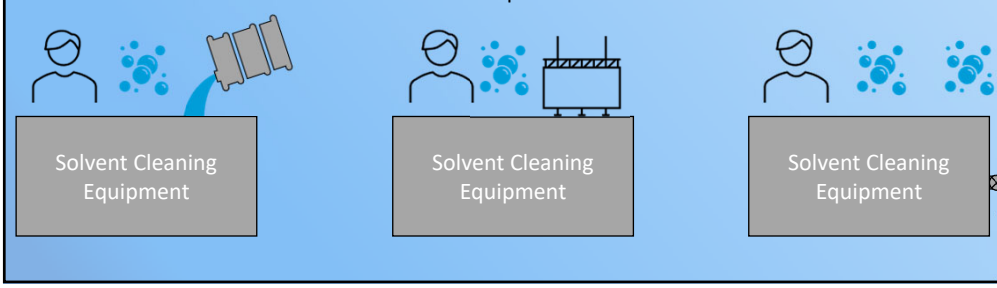
Clarifying Question:
Is there ever a time in your process where **air** is the only barrier between your nose and the solvent?

- If so, then exposure above the limits is likely.

System Maintenance
filling, charging, testing, monitoring the solvent

System Usage
introducing, cleaning, removing, monitoring the parts

System Turnaround
removing spent solvent, particle filters, grease traps, separated water



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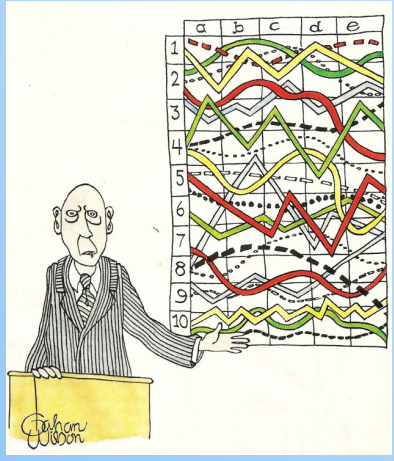
Predicted Impact of nPB listing as a HAP versus Impact of Amended TSCA

- HAP (Hazardous Air Pollutant) listing is a **rip-current**
  - Containment, work practices (must meet NESHAP requirements)
  - Record keeping
  - Reporting
- Amended TSCA activities are an impending **Tsunami**
  - Possible very low enforceable worker exposure limit
    - Unlikely that open-top degreasers can meet these limits
  - Possible requirement to use airless/airtight system
    - May still not provide sufficient containment
  - Possible ban

"I'll pause for a moment so you can let the information sink in."



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BFK Solutions view (but we are not the EPA)

- Solvent bans don't fix things
- Solvent "personifications" (witch hunt)
- Substitutes often have safety/environmental issues
- Most chemicals can be managed safely
  - It's not just the chemical, it's the process
- Bans, phaseouts not a sustainable approach
  - Disruption
  - Loss of efficiency
  - Costs
  - Product performance concerns

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Overview: EPA Regulatory Happenings and Your Critical Cleaning Process

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- Risks, regulatory options
- **Strategies for manufacturers**

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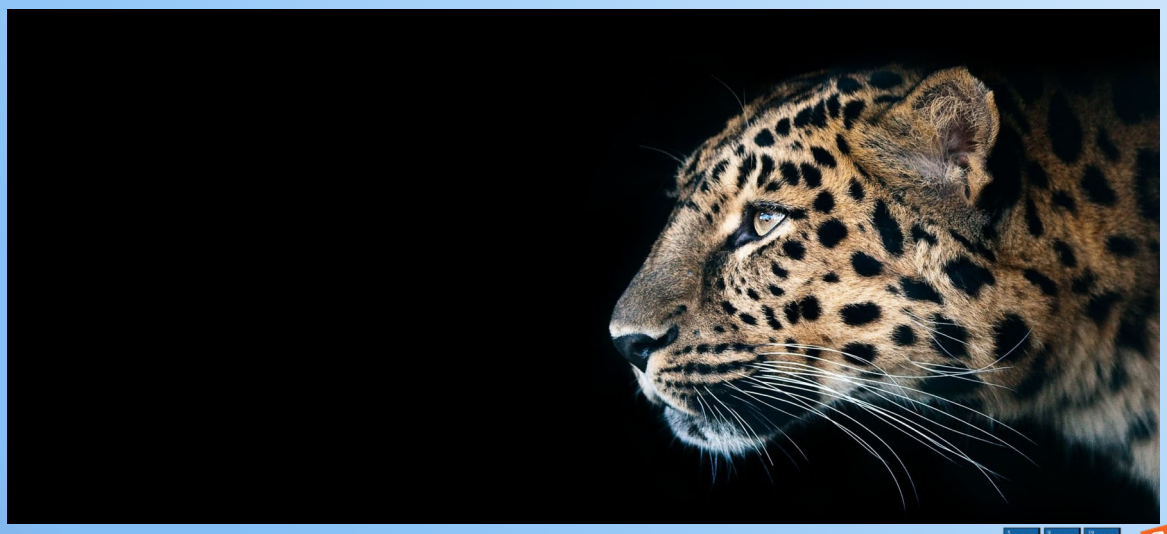
35

What should you do? Focus. Don't be linear. Encompass the whole picture.



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Will solvents be available?

- TCE shortage
  - Happening now in U.S.
  - One chemical manufacturer has ceased U.S. production
  - "Quick fix" – move to n-propyl bromide (it's what's available!)
    - Probably a short-term solution at best

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Assertions, claims, rumors (many are false or uncertain) *& our educated guesses & opinions Part 1*

- All *chlorinated and brominated solvents will be banned within two years*
  - *Guess- some may be banned, probably longer than 2 years*
- Aqueous processes are more effective and cost less
  - *Opinion based on experience: not always, depends on the application, many cost more*
- Aqueous processes can work for almost all applications
  - *Opinion based on experience: not always, depends on the application*
- You have to switch to ….(followed by a product or process being offered)
  - *Opinion: No, you don't! Be suspicious of claims like this*

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Assertions, claims, rumors (many are false or uncertain) *& our educated guesses & opinions Part 2*

- Vapor degreasing is dead
  - *Guess: with low ECEL, may be true for open-top degreasers using TCE, nPB, MC, PCE*
  - *Guess: Trans-DCE (with designer solvents) – depends on EPA risk evaluation*
- Send us your samples, we'll take care of it
  - *Opinion: this is often a sales pitch, be skeptical, make up your own mind*
- There will be lots of exemptions
  - *Guess: Based on CFC phaseout, there could possibly be a few exemptions*
    - *Solvent availability likely to decrease; solvent cost increase*
- The military won't have to do this
  - *Guess: Based on CFC phaseout, there could possibly be a few exemptions*
    - *Solvent availability likely to decrease*
- Only the little guys will have to comply
  - *Guess: highly unlikely*

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Why can't we just repeat what we did during the CFC Phaseout (mid-1980s – 1990s)

- 1990s people could use other chlorinated/brominated solvents, or interim substitutes
- Freon & 1,1,1-trichloroethane phaseout not related to worker exposure
- Production bans, not usage bans
- There were Freon banks
  - Could there be TCE banks? Maybe
  - There would still be the worker exposure, possible liability issues
- We don't know what chemical suppliers will do
  - Cost? Availability?

"This isn't going to do the old ozone layer any good, that's for sure."

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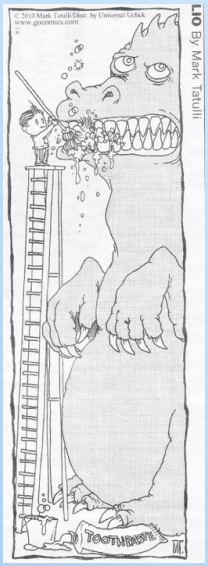
Challenges: Product requirements have increased since the "Great Freon Festival"

- Products smaller, more complex, more "stuff" packed into a tiny space
- Process fluids more complex, adherent
  - Water soluble lubricants often leave very adherent residue after machining
- Higher performance requirements
  - We tolerate lower levels of thin film residue, sub-micron particles
- Additive manufacturing
  - Porous surfaces, the product is all surface
- Growth of medical device market, autonomous vehicles
- What worked then won't work now!
  - Eg: we now clean "no-clean" fluxes



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41

How might you be impacted by solvent restrictions or bans? It depends

- Developmental (designing a new product)
  - You want to grow or sell your company
  - Select a relatively bullet-proof process
  - Don't relegate cleaning process development to the "maybe later" stage
- Precision cleaning (or even general cleaning)
  - Your customer uses components for safety/critical
  - You use nPB, PCE, TCE, MC
    - Start planning for contingency
- Safety/critical
  - You use job shops for upstream product
  - Do your job shops use nPB, TCE, PCE, MC?
  - Find out!

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42

Questions to ask yourself

- Is the cleaning step necessary
- What are the actual constraints?
- What step comes before the cleaning step?
- What step comes after the cleaning step?
- How much do I depend on cleaning by job shops?
- What do my customers say they require?
  - What do they actually require?

43

Whether or not you use halogenated solvents, look at the supply chain!

- Find out what suppliers use
  - We see n-propyl bromide EVERYWHERE
- Partner, communicate
- Undesirable scenario
  - Large companies push process change onto smaller companies
  - "Make it work or else"
  - Leads to unsafe, ineffective processes

44

As a manufacturer – don't panic, plan!

- Verify what's happening
- Don't settle for a "quick fix"
- Don't let your customer force you into an undesirable or unsafe cleaning process
- Start to consider your options
- Today's solution may be tomorrow's problem
  - Chemical by chemical approach!
- Make change an opportunity for greater productivity

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45

What if your company/customer says: change right now!

- Requirement to use "approved," safe, ineffective chemical
- Requirement to stop using effective cleaning process
- Unrealistic corporate policy
- Approaches
  - Present data
  - Don't whine!
  - Try the alternative(s) – might be successful!
  - Not successful?
    - Document
    - Show data
    - Show costs

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46

Consider the ramifications of any process change

It's also unwise for a number of reasons

Your product, your responsibility

- Review your cleaning processes
- Do you have to clean?
- What other options might you have
- What your suppliers are doing?
- What do they plan to do?
- **Amended TSCA is linear**
- **YOU DON'T HAVE TO BE LINEAR**
  - **Begin with the end in mind**

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47

CONTACT US

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product quality cleaning workshops

The PQCW offers practical, hands-on and independent, training in cleaning.

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48

PQCW – Workshops for Terrific Products

- "While I would prefer to have been at in-person laboratories so I could have hands-on experiences with cleaning processes, **I really liked the two-week virtual PQCW**.
- "People with different functions within our company, including Strategic **Sourcing**, Project **Management**, and **Manufacturing Engineering**, attended.
- "We learned a lot; and we have made changes. We are **refining our own cleaning** requirements and putting together training programs.
- "For example, we used the workshop to develop **black light testing and fixtures;** and we have already set up a one-hour **"Parts Washing 101"** training course.
- "The section about **EPA amended TSCA had useful, timely information."**
  - Christian Johnson, Engineer, Yaskawa, participant, PQCW21

49

Appendix: Lautenberg highlights 1
Full text – information-rich, difficult to follow

https://www.congress.gov/bill/114th-congress/house-bill/2576

- "This bill amends the Toxic Substances Control Act (TSCA) to revise the process and requirements for evaluating and determining whether regulatory control is warranted for manufacturing, distributing, processing, using, and disposing of chemicals."
- "The bill revises several provisions in TSCA, including those relating to: (1) chemical testing; (2) review and regulation of new chemicals, new uses of existing chemicals, and existing chemicals; (3) information reporting; (4) confidential business information (CBI); (5) preemption of state regulations; and (6) fees."
- "The bill revises TSCA requirements on testing chemicals and gives the Environmental Protection Agency (EPA) additional testing authority, including by giving the EPA the authority to develop new information for: (1) evaluating unreasonable risks to human health and the environment, (2) prioritizing the risk evaluations, and (3) implementing risk management control actions. The bill also allows the EPA to require the development of information through a consent agreement or an order as well."

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50

Appendix: Lautenberg highlights 2

https://www.congress.gov/bill/114th-congress/house-bill/2576

- "The bill: (1) revokes the requirement that the EPA must apply the least burdensome regulatory option to restrict a chemical that warrants regulation, (2) establishes a process for conducting and prioritizing risk evaluations for chemicals, and (3) revises requirements concerning risk management control actions."
- "Within a year after enactment of this bill, the EPA must establish a risk-based screening process and criteria for designating chemicals as high priority chemicals for risk evaluations or low priority chemicals for which risk evaluations are not warranted at the time. The process must include consideration of chemicals': (1) hazard and exposure potential (including persistence and bioaccumulation, potentially exposed or susceptible subpopulations, and storage near significant sources of drinking water); (2) conditions of use; and (3) volume. The conditions of use means the circumstances under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed, or disposed of, or used."
- "The EPA must: (1) continue to designate priority chemicals in accordance with the deadlines established by the bill; and (2) conduct the evaluations to determine whether a chemical presents an unreasonable risk of injury to human health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation. Costs or other nonrisk factors may not be considered in the evaluations."

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51