PMPA
PRECISION MACHINED PRODUCTS ASSOCIATION

Helping Precision Machine Shops Be More Productive and Profitable

15 June 2016

Nathaniel Jutras
U.S. Environmental Protection Agency
Regulatory Management Division

Re: Trichloroethylene Small Business Advocacy Review Panel Comments from PMPA

Dear Nathaniel:

PMPA is pleased to have been able to participate via web conference in the June 15, 2016 Small Business Advocacy and Review Panel to help EPA gain additional facts regarding the essential nature of TCE as a vapor degreaser for critical products manufactured by our small business member companies in the precision machining industry. We also appreciated the opportunity to share some issues of concern as well to our small manufacturing businesses. Thank you for considering our verbal and written comments as you consider the regulatory approach to TCE.

Questions of Reasonable Risk

Frankly, our first concern is of what constitutes "authoritative science" when looking at the potential impact of the regulations built on "Baseline Risk Estimates"- that claim authority at fractions of a part per billion level - while the National Academies of Science - when reviewing actual data from exposures resulting from TCE contamination at Camp Lejeune - were unable to find "Sufficient Evidence of a Causal Relationship," or "Sufficient Evidence of an Association." The National Academies' report found "Limited / Suggestive Evidence of an Association" for PCE or Solvent Mixtures, in 14 health outcomes, and found "Inadequate / Insufficient Evidence to Determine Whether an Association Exists on 44 Health Outcomes - only 4 of which were characterized as potentially thought to be connected to TCE.

It is hard for us to understand how EPA analysis can be so certain in its condemnation of TCE while the National Academies, working with actual exposure data was unable to find evidence of even a causal relationship. That our small manufacturing businesses should face existential impacts as a result of a regulation on TCE when the National Academies were unable to find a causal relationship for negative health outcomes while the EPA can confidently determine risk to a fraction of a part per billion is unfounded, ill-considered, unjust, and calls loudly for a referee of the actual risks. "No Evidence of a Causal Relationship" cannot be simultaneously held to be true with "AEL cancer 8hr TWA= 0.4ppb." We are not sure how these mutually exclusive declarations can coexist, nor how regulatory policies can be held to be valid given the divergence of these values and the authorities claimed.

Link to National Academies report: http://www.nationalacademies.org/includes/clfinal.pdf

Substitute Chemicals- Impropriety of EPA offering 1-bromopropane (n-Propyl Bromide (nPB)) as a "Drop-in Substitute" for TCE

Frankly, we were shocked to find nPB offered by EPA as a drop in substitute for TCE, given the wide knowledge of nPB neurological damage resulting from workplace exposures. (EPA Slide 32)

We'll let the New York Times reporting on nPB from March 30, 2013 stand in for our comments on this. The prescription of nPB as a "drop-in substitute" for TCE by EPA seems to be misfeasance at best.

"Medical researchers, government officials and even chemical companies that once manufactured nPB have warned for over a decade that it causes neurological damage and infertility when inhaled at low levels over long periods, but its use has grown 15-fold in the past six years."

"But the story of the rise of nPB ...is a parable about the law of unintended consequences. "

"It shows how an Environmental Protection Agency program meant to prevent the use of harmful chemicals fostered the proliferation of one, and how a hard-fought victory by OSHA in controlling one source of deadly fumes led workers to be exposed to something worse — a phenomenon familiar enough to be lamented in government parlance as "regrettable substitution.""

Link to NY times Story on NPB: http://www.nytimes.com/2013/03/31/us/osha-emphasizes-safety-health-risks-fester.html?pagewanted=all&_r=1

As manufacturers committed to having safe and compliant workplaces and to protecting the health and lives of our employees, we must ask if anyone at EPA did any kind of risk analysis before pasting "1-bromopropane" into the slide for this SBAR Panel as a *"drop-in substitute for TCE." (Note, on slide 7 of the same EPA presentation EPA states that "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.") How can EPA prescribe nPB as a "drop-in replacement" for TCE knowing these risks?*

We would ask why, and on what basis, EPA suggests that we replace an undocumented hazard (TCE-National Academies) with a demonstrated one (nPB- NYTIMES). Surely EPA understands its authority and implied credibility in these matters; how are we to take fraction of parts per billion estimates of risk seriously when EPA suggests nPB as a "drop-in replacement" despite demonstrated and widely reported workplace epidemiological consequences? The provision of the list of "drop-in substitutes" seriously damages the credibility of EPA in this area, especially given EPA's admission of hazards for nPB on slide 7.

Concerns That Risk Data and Assumptions Do Not Reflect Current Industry Processes

We were surprised to learn that the working definition of "open top degreasing" in use by EPA officials at the meeting on the call meant to them "not under a vacuum." PMPA provided, and was supported by other small business representatives on the call, that typical processes for the use of TCE for vapor degreasing in our precision machining industry are "enclosed systems with vertical conveyor pass-through's, super-heated vapor zone to prevent vapor from rising out, operator loading station outside of enclosure, ventilation and air scrubbers. All operating in compliance with EPA permit, and best practices for worker safety including Engineering Controls, Personal Protective Equipment (face mask and elbow length gloves) and Worker Training." That EPA could consider such a typical operating system to be synonymous with "open top degreasing" begs the question of just what assumptions are at the basis of the proposed rule – outright ban or SCBA PPE. We remain skeptical that the authors of the proposal have a genuine understanding of the process, and are thus basing their thinking on conditions that are certainly not typical in our small business, precision machining, manufacturing shops today.

How TCE Is Used in Our Shops

PMPA sent a request for information to approximately 240 PMPA active member shops regarding TCE and vapor degreasing. About 5% or 12 shops responded and have provided the information which we aggregated and

used as the basis for our comments on the call, and in these written follow up comments. An additional handful (4) of these shops responded to my request for a deeper dive on their processes, practices, consumption, etc.

Typically, annual usage was reported to be in the hundreds of gallons range- 291, 110, and 145 gallons reported by three shops, one shop used ~2000 gallons last year.

All shops reported running 8 hours per day- 240-250 days per year.

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Typically, 100% of shop production is cleaned in the TCE vapor degreaser unit at these shops. One shop uses TCE only for critical items with blind holes, rigorous cleanliness requirements, and critical metal to glass seal components. Shops mentioned "Frozen practices" for automotive, defense and other customers which we will discuss further below.

Commercial, Contract, & Technical Issues If TCE Prohibited as Reported by PMPA Shops Using TCE

- Where TCE is used it is the sole means of parts cleaning-100% of shop output affected
- No comparable cleanliness using alternative methods systems has been found by shops that have been investigating alternatives. This was reported to us by several respondents.
- TCE is favored for degreasing machined metallic inserts to be used in conjunction with a number of plastics / polymers / engineered materials, as it is said to not attack them.
- Several shops have reported to me that they had replaced TCE and would no longer be participating in our ad hoc process addressing the EPA's TCE proposed rule for TCE. They have not said that they were at the same level of productivity nor cleanliness and intimated that they were struggling to get there, but they "did what they thought that they had to do."
- Failure to completely remove oil can affect the reliability of the automatic optical and electronic gaging systems in place to assure 100% verification on human safety critical automotive and aerospace parts.
- Companies that we spoke with stated that Aerospace, Defense, Medical and Automotive contracts locked in their cleaning methods as part of the approval process. ***Many end use customers demand that the critical machined parts that our shops supply be free from oil.***
- Compatibility of replacement cleaners is an issue as TCE is accepted for its compatibility and non- attack of polymers. This is especially important in defense applications, and for inserts to be molded into plastic.
- One shop (65% automotive) making airbag, braking, and other engine mount parts ***estimated that the re-approval process for a new cleaning process with their automotive customers would entail between 5 and 10 man- years of engineering level talent to do actual testing, document results, prepare automotive FMEA/PPAP documentation, submit, and then follow up with customers for approval.***
- It was noted that many shops in Europe have been exempted from any ban on TCE there due to requirements by BAE, Airbus, and others for parts to be TCE cleaned to assure polymer compatibility and oil free as received. If this is true, the proposed rule would effectively prohibit U.S. precision machining shops from supplying parts to these companies.
- One respondent noted that their orders which mandated the use of TCE in their process came from Defense Supply Logistics center in Philadelphia. Other customer companies mentioned by our respondents included Raytheon, Command, Curtiss Wright, and Electric Boat that purchase critical components that could be affected by the proposed rule.

- One respondent noted that TCE was essential in the parts that they make for metal to glass sealing and electronic connectors applications. Presence of any soil or contaminant material at all prevents the creation of the uniform oxide film needed on the metal part to assure glass adhesion. Here's what they said, "*we incorporate engineering controls to meet or exceed EPA air emissions standards and have found no better method or cleaning fluid to ensure a glass to metal seal that will meet or exceed military or commercial specifications."*

Small Business Potential Impacts of Prohibition of TCE

- Cost estimates to replace cleaning equipment ran from $350,000- to $500,000. (Most shops would have to finance purchases this large, adding cost of borrowed capital.)
- One shop that just made the switch from TCE to another method has invested over $500,000 in equipment and workplace modifications.
- These estimates ranged from 25% of net revenue to total annual profit in some of the shops consulted.
- The expenditure of $350,000 to $500,000 is equivalent to 2-3 years of planned capital investments and would leave our shops that far behind competitors in South Korea, China, Indonesia, Malaysia and India who are investing in new technologies and capabilities.
- This level of expenditure would starve our shops from capital to upgrade their current processes, purchase new equipment, and make needed improvements, putting them 2-3 years behind market competitors.
- None of the shops had estimates of costs of transition that included customer rejections and rework related to change in quality of as received parts as a consequence of the transition.
- Smaller companies (12-75 employees) felt that a mandate to replace cleaning equipment that required $350,000 or more would be a tipping point decision regarding closing or maintaining the business.
- Shop closings would put all employees out of work at these shops (roughly from 12-70 employees per shop in our sample of companies).
- Shop closings would destroy millions in owner's equity as the business assets would be sold for liquidation value only.
- One shop said that at $500,000 cost for new cleaning technology would consume their total planned 5-year capital investment budget.
- Several of our shops said that a prohibition was likely to force them to close if replacement technology costs ran as estimated.
- Replacement fluids for TCE were quoted at 10X the price of TCE. *(Kyzen M6900 was mentioned as a possible replacement by one respondent, we noted that this product is not even shown on the Kyzen website…?)*

Final Thoughts On Small Business Impacts

Our comments today and in this document are based on actual PMPA member company provided information. As mentioned earlier, our query determined that 5% of 240 PMPA companies had TCE process involvement when we first learned of this proposal. If you were to extrapolate PMPA membership to the entire industry (NAICS 332721 - Precision Machining) that 5% number would be times 3,559 establishments, so possibly impacting 178 shops. At the industry average of $5,000,000 in sales, we would expect those shops to employ 5,394 employees (using $165,000 in sales per employee to determine employee census). The lost sales from those 178 shops would be just short of $1 billion, at $890,000,000. (The Total Value of Shipments for the U.S. precision machining industry was reported to be $18.5 billion in 2014.)

The National Academies of Science could not find a causal relationship between TCE and a large number of health outcomes, yet the EPA is proposing a rule likely to shut down as many as 178 precision machining

shops nationwide, eliminating potentially over 5,000 jobs (in just our precision machining industry), while reducing U.S. Manufacturing GDP by almost a billion dollars. This will be repeated in many sub - industries across Fabricated Metals Sector as well as those noted on EPA slide 26 - Instruments and Related Products, Machinery, Electrical and Electronic Equipment and Miscellaneous manufacturing industries where TCE is also used as a vapor degreaser here in the United States.

Despite the National Academies' findings, EPA claims risk certainty to 0.4 of a part per billion of exposure, and is willing to wager the livelihood of 5000 machinists, the potential shutdown of almost 200 small manufacturers, and loss of almost $1 billion in manufacturing GDP, while suggesting that nPB and PCE are according to US EPA, "drop-in substitutes."

We find much to be confused about in this proposal starting with EPA's certainty about TCE exposure limits to the parts per billion level despite no apparent epidemiological confirmation of the etiology in workers in affected industries, and contrary findings by the National Academies of Science. We remain concerned that EPA's assumptions regarding our processes, "open top means not under a vacuum" have EPA rule makers designing solutions for problems that no longer exist. We share our concern as small business entities (according to U.S. Census the average NAICS 332721 shop has $5 million in sales) that as many as 5% of our industry could be forced out of business by the costs of compliance for the proposed rule. This is aggravated by our substantial doubts as to the credibility of EPA's risk estimates in light of the National Academies' own report on TCE and actual health outcomes in 2011. Finally, we question the standard of care used by EPA to prepare this rule, noting several flaws in the assumptions used and in the prescribed "drop-in substitutes" mentioned multiple times by EPA in their presentation.

PMPA respectfully requests that EPA reassess its assumptions regarding exposure limits, its assumptions regarding processes and exposures currently found in the industry, and its insistence that there exists a toxic connection between TCE and various cancer and non-cancer health outcomes for which the National Academies found "no causal relationship nor any associated relationship."

We respectfully suggest that EPA delay any further work on this proposed rule until we have clarity on the version of TSCA that passed the House and Senate and that will become the law of the land upon signature by the president.

We respectfully request that EPA drop its faulty and fictional notion that there exist "drop in replacements" for TCE. TCE remains an unmatched cleaner that is critical to many US high technology and advanced technology manufacturing applications. Critical modern transportation, safety, communications, computing, and defense applications require the unmatched performance provided by TCE.

Sincerely,

Miles Free
Director, Industry Research and Technology
Precision Machined Products Association

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