

- Proposed rule addresses vapor degreasing with TCE.
- Will be in first round of rulemaking under TSCA § 6 since 1989, among first rules to interpret “unreasonable risk” under revised TSCA.
- SBAR meeting held June 15, 2016; EPA disclosed intent to take over regulation of TCE in workplace from OSHA.
- Clearly raises novel legal or policy issues arising out of legal mandates for purposes of E.O 12866.

TSCA § 6 Requirements Applicable to Completed Risk Assessments

- TSCA § 26(l)(4) – where risk assessment completed prior to date of enactment, § 6(a) rule must be consistent with “the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of § 6.”
- Scope of TCE Work Plan Assessment is “small commercial degreasing facilities,” but the term is undefined. “EPA/OPPT has determined that more research will be required to determine which factors will best define small shops for the industries that do vapor degreasing.” How can EPA conduct an assessment without knowing the exposure cohort?
- Also § 6(c)(2)(C) – in adopting a specific condition of use EPA must consider whether “technically and economically feasible alternatives” that benefit health or the environment, compared to use to be restricted, will be “reasonably available as a substitute.”

- Precision Machined Products Association (240 shops) commented at SBAR:
 - Cost to replace existing degreasing equipment ranges from \$350,000-500,000, workplace modifications often required to accommodate larger systems.
 - Cost estimates range from 25% of net revenue to total annual profit for some of the shops consulted.
 - Expenditure of \$350,000-500,000 is equivalent to 2-3 years of planned capital investments and would leave US shops far behind South Asian competitors.
 - Such expenditure would starve PMPA members of capital to upgrade their current processes, purchase new equipment, and make needed improvements.
 - Smaller companies (12-75 employees) report that a mandate to replace cleaning equipment requiring \$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 and destroy millions in owner's equity as the business assets would be liquidated.
 - One shop said that \$500,000 cost for new cleaning technology would consume its total planned 5-year capital investment budget.

- Where TCE is used it is generally sole means of parts cleaning -100% of shop output.
- Shops investigating alternatives found no comparable cleanliness except using NPB, which is not a viable alternative as it is toxic for worker exposure above TLV (0.1 ppm).
- Aerospace, defense, medical and automotive contracts lock in cleaning methods as part of the approval process. Customers typically demand that critical machined parts be free from oil.
- Failure to remove oil completely can affect reliability of automatic optical and electronic gauging systems in place to assure 100% verification on safety-critical automotive and aerospace parts.
- Compatibility of replacement cleaners an issue as TCE is accepted for compatibility with polymers, especially important in defense applications (e.g., many shops in Europe have received derogations due to requirements of BAE, Airbus, and others for parts to be cleaned with TCE).
- One shop making airbag, braking, and other engine mount parts estimated that approval of a new cleaning process by automotive customers would entail 5-10 man-years to test, document results, prepare automotive FMEA/PPAP documentation, submit, and follow up with customers for approval.

- Under TSCA § 6(b)(4)(F) the risk evaluation must:
 - “integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment . . .;”
 - “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance;” and
 - “describe the weight of the scientific evidence for the identified hazard and exposure.”

§ 26(h): “In carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

- (1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- (2) the extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture;
- (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.”

§ 26(i): “The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence.”

- Characterization of TCE as “carcinogenic to humans” based entirely on IRIS Assessment, but no discussion of concerns raised by HSIA and other commenters, including:
 - Inconsistency of such classification with National Academy of Sciences report “Contaminated Water Supplies at Camp Lejeune” (2009) which concluded the same human data provided only “limited or suggestive evidence of an association.”
 - IRIS Assessment, like the IARC classification, used a “strength of the evidence” approach; TSCA § 26(i) requires “decisions under sections 4, 5, and 6 [to be] based on the weight of the scientific evidence.”

The TCE Work Plan Assessment relies on hazard values derived directly from a single academic study (Johnson *et al.*) to estimate acute risk, even though:

- Several other studies, including two Good Laboratory Practice-compliant studies conducted under EPA guidelines, have been unable to reproduce the effect;
- Johnson *et al.* has been heavily criticized in the published literature;
- Other regulatory agencies have expressly declined to rely on Johnson *et al.* citing data quality concerns;
- The authors of the study have published repeated corrections that fail to address the data quality concerns, including:
 - Inappropriate pooling of control animals from other studies, two dosing periods were some eight years apart , and nonstandard technique was used to evaluate cardiac malformations;
- Most significantly, EPA's own peer review was highly critical of reliance on Johnson *et al.*

- In justifying reliance on Johnson *et al.*, Assessment points (p. 98) to a “recent erratum (Johnson 2014) and subsequent evaluation of the developmental toxicity data.” This evaluation shows serious concerns of EPA’s own scientists regarding the data:
 - The studies “that have reported cardiac defects resulting from TCE (and metabolite) drinking water exposures have study design and reporting limitations [which] were the basis of the single dissenting opinion of a team member regarding whether the database supports a conclusion that TCE exposures during development are likely to cause cardiac defects.”
 - “[A] majority of the team members agreed that the Johnson *et al.* (2003) study was suitable for use in deriving a point of departure. However, *confidence of team members in the dose response evaluation* of the cardiac defect data from the Johnson *et al.* (2003) study was characterized as between “low” and “medium” (with 7 of 11 team members rating confidence as “low” and four team members rating confidence as “low to medium”).”
 - Nevertheless, Johnson *et al.* was used for dose response evaluation.

- Work Plan Assessment concludes “there has not been a confirmation of the results of the Johnson *et al.* (2003) and Dawson *et al.* (1993) studies by another laboratory, but there has also not been a repeat of the exact same study design that would corroborate or refute their findings.”

HSIA Response:

- Again, TSCA § 26(i) requires § 6 regulation be based on weight of scientific evidence. Guideline GLP studies found no cardiac defects. HSIA is sponsoring a guideline developmental drinking water study, with results available in January 2017, to verify findings of Johnson *et al.* or add to weight of evidence against association of TCE and cardiac defects. Protocol shared with EPA/OMB.

- Halogenated Solvent Cleaning NESHAP, 40 C.F.R. Part 63, Subpart T
 - 59 Fed. Reg. 61800 (Dec. 2, 1994) – MACT for major and area sources
 - 72 Fed. Reg. 25138 (May 3, 2007) – 14,100 kg/year facility-wide emissions limit (“ample margin of safety to protect public health”)
- Changed work practices, reduced in-facility exposure (occupational and bystander) and fence-line emissions
- Work Plan Assessment relies on data collected before the May 2010 compliance deadline for NESHAP (primarily the NEI and TRI, and many assumptions (see pp. 34-37)) to estimate releases, exposures, and population exposed (pp. 114-15). This major source of uncertainty could be eliminated by reference to data required to be reported under the NESHAP:
 - Under the NESHAP, every facility must make initial notification and report annually to EPA for each degreaser: type of machine and controls, location, date of installation, solvent consumption, and emissions.

- More basically, to extent Work Plan Assessment references NESHAP at all, it seems to reflect misunderstanding of it:
 - “EPA’s overall emission limit for implementing [the NESHAP] is 150 kilograms (kg) per square meter (m²) per month (EPA, 2004a)” (p. 39).
 - This reference is to NESHAP for organic liquids distribution (non-gasoline), not here relevant.
 - 150 kg/m² per month limit was an alternative standard for batch machines in 1994 degreasing NESHAP (MACT).
- Current emissions limit is 14,100 kg/year facility-wide TCE emissions; not reflected at all in Assessment.

- The Assessment uses a screening level modeling approach to assess hazard and exposure.
- This does not meet OMB Information Quality Act guidelines for a “highly influential scientific assessment” to support TSCA § 6 rulemaking. Screening level assessments are considered inappropriate to support regulations intended to reduce risk because they do not accurately estimate risk or quantify exposures.
- The report of the peer reviewers highlighted this concern, but EPA has to date ignored it. In fact, EPA wrote to the Inspector General that “[i]t is notable that the external peer reviews of all the Work Plan assessments we have completed thus far supported our overall assessment methodologies and conclusions,” although a contemporaneous press report was entitled “EPA Peer Reviewers Say Trichloroethylene Analysis Not Ready for Regulatory Use.”

- Comments of P. Fenner-Crisp (Peer Review Panel Chair)
 - “The draft document fails to articulate satisfactorily that the analysis described within should be characterized as a screening level assessment.”
 - “However, I believe that the Agency acted prematurely in issuing this (screening level) assessment for public comment and in convening a formal scientific expert peer review, given the conclusions reached in it. If all of the conclusions had indicated “no problem, then that assessment should have been peer reviewed externally, to determine if there were outside expert agreement. Presumably, if so, then no further risk assessments would be needed. However, most of the exposure scenarios assessed in the present draft resulted in the conclusion of “indicates potential risks of concern.” This begs for refinement of the assessments, on both the exposure and hazard side of the equation. This is essential for any defensible regulatory actions to be undertaken.”

- Response to Comments (Summary of External Peer Review and Public Comments and Disposition [Version 06/24/14])
 - Peer Review Comment 28:

“Panelists and the general public suggested describing the consumer exposure assessment as screening level.”
 - EPA/OPPT Response:

“The exposure assessment is not a theoretical bounding assessment or a worst case assessment. Collection of new data or measurements is outside the scope of the workplan assessment process.”
- **Not an adequate response to clear peer review criticism**

- Take into account exposure under the conditions of use
- Describe weight of the scientific evidence for identified hazard and exposure
- Use of scientific information, employed in a manner consistent with the best available science
- Consider variability and uncertainty in the information
- Consider extent of independent verification or peer review of the information
- Screening level assessment
- Assessment based on “strength of evidence” as opposed to “weight of evidence”
- Noncancer assessment based on unreproducible academic study v. negative guideline GLP studies
- No formal or informal uncertainty analysis
- Highly unfavorable peer review ignored or characterized as favorable



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

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

$AEL_{non-cancer\ 8\ hr\ TWA}$ for acute exposures = 1 ppb

$AEL_{non-cancer\ 8\ hr\ TWA}$ for chronic exposures = 2 ppb

Cancer

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



Exposure Estimates: TCE at Vapor Degreasing Facilities

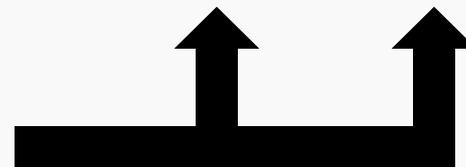
Exposure Scenario	Acceptable exposure limit for cancer (8 hr TWA, ppm)	Estimated exposure (8 hr TWA, ppm)
Workers	0.0004	190
Adjacent Workers (non-users)	0.0004	145



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





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

- “OSHA lacks direct jurisdiction over state and local government workers.”
- “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.”
- “[S]ince 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.”

- § 9(a) – Laws not administered by EPA:
 - If unreasonable risk can be sufficiently reduced under a law not administered by EPA, EPA shall publish and submit to the other agency a report and request it to determine if it can reduce the risk under such other law. The other agency must respond to EPA and publish its response.
 - Other agency must either decide that there is no such risk or initiate rulemaking within 90 days of its response
- § 9(b) – Laws administered by EPA:
 - If risk can be sufficiently reduced under another law administered by EPA, then EPA must use that other authority unless it determines that it is in the public interest to proceed under TSCA.
 - In making public interest determination, EPA must compare the estimated costs and efficiencies of the actions to be taken under TSCA and action to be taken under such other law.

- Original history is clear: “it was the intent of the conferees that the Toxic Substance Act not be used, when another act is sufficient to regulate a particular risk.”
- Recent House report: “TSCA's original purpose [is] filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals,” and “the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety.” Colloquy:
 - “Mrs. BLACKBURN. It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under § 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA. Would the chairman please confirm my understanding of § 9?”
 - “Mr. SHIMKUS. The gentlewoman is correct in her understanding.
 - “Mrs. BLACKBURN. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA § 6 illustrate, they are also timely. EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary. . . .”

- As already noted, under the Clean Air Act EPA has adopted regulations for TCE in vapor degreasing that protect public health with an ample margin of safety.
- Strangely, the Assessment appears to have been conducted without reference to the NESHAP, resulting in great uncertainty in its estimates of TCE releases, exposures, and population exposed, all of which could be eliminated by using data required to be reported to EPA under the NESHAP:
 - type of machine and controls, location, date of installation, solvent consumption, and emissions
- Has EPA compared the estimated costs and efficiencies of the actions to be taken under TSCA against the NESHAP or any action that might be taken to strengthen the NESHAP?

OMB should not clear proposed rule:

- Assessment does not comply with TSCA §§ 6, 26:
 - Not best available science or based on weight of scientific evidence
 - Noncancer toxicological value not reproducible
 - Screening level hazard/exposure assessments
 - Harshly criticized by peer reviewers
- No justification for usurping OSHA authority over workplace or ignoring existing EPA regulation of same sources