

- Proposed rule addresses spot cleaning and aerosol spray degreasing products.
- In other contexts EPA has disclosed intent to take over regulation of toxic chemicals in workplace from OSHA and regulation of consumer products from CPSC, equally of concern here.
- More generally, will be first rulemaking under TSCA § 6 in 27 years, will be first rulemaking interpreting “unreasonable risk” under revised TSCA.
- Clearly raises novel legal or policy issues arising out of legal mandates for purposes of E.O 12866.

- OSHA regulates occupational exposure to TCE. The permissible exposure limits (PELs) are 100 ppm as an eight-hour TWA, 200 ppm as an acceptable ceiling concentration, and 300 ppm as an acceptable maximum peak (five minutes in any two-hour period) above the acceptable ceiling concentration for an eight-hour shift.
- TCE producers recommend compliance with TLVs developed by the American Conference of Governmental Industrial Hygienists. For TCE, the current TLVs are 10 ppm as an eight-hour TWA and 25 ppm as a Short-Term Exposure Limit.
- As to consumer exposure, EPA appears prepared to act without reference to the Federal Hazardous Substances Act (FHSA), which grants jurisdiction over household products containing hazardous substances to the CPSC.

- § 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. . . .”

- TSCA § 26(l) – 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.”
- 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.”

# Spot Cleaning

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- Draft TCE Assessment entitled “Degreaser and Arts/Crafts Uses”
- “EPA focused the assessment on uses of TCE as a degreaser (i.e., both in small commercial settings and by consumers or hobbyists) and on consumer use of TCE in products used by individuals in the arts and crafts field.” (p. 14)
- Spot cleaning mentioned only in fn. 8: “there were several spot cleaners for fabrics marketed to consumers, but none contained TCE; lists of ingredients were not available for a few of the spot cleaners.”
- No reference at all to spot cleaning in the workplace.
- With no explanation, final TCE Assessment is entitled “Degreasing, *Spot Cleaning* and Arts & Crafts Uses” and includes “Commercial use of TCE as a spotting agent at dry cleaning facilities.” (p. 26)
- EPA relied solely on a 2007 California study, which it recognized may not be representative of US dry cleaning facilities. It also based estimates of workers/bystanders on census data “not adjusted to exclude job categories that likely would not be present at dry cleaning facilities. Thus, EPA/OPPT’s estimate likely overestimates the size of the population exposed.” (p. 116)

- No public comment on spot cleaning, no participation by dry cleaning industry representatives, no peer review of spot cleaning assessment
- No Small Business Advocacy Review, even though spot cleaning is done by retail dry cleaners which are almost all small entities
  - How certify the rule would not have a significant economic impact on a substantial number of small entities (SISNOSE)?
  - Estimated impact of 4-5 % of gross revenues for over 14,000 small entities.

- EPA identified only two aerosol degreasing products containing TCE in the marketplace and found no emissions or monitoring data for either product – thus these are hypothetical exposures.
- Used E-FAST2/CEM modeling to develop “high-end acute inhalation exposure estimates” based solely on professional judgment (demonstrates, as draft assessment acknowledges, that this is a screening level assessment).
- Risks/hazards to consumers evaluated based solely on developmental toxicity endpoint from Johnson et al. (2003) study.
- Highest uncertainties associated with mass of product used per event, duration of event and number of events per year as values selected are hypothetical, leading to lack of confidence in assessment.

- EPA acknowledged in the draft that “*EPA used a screening level modeling approach to assess consumer 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**

The TCE Assessment relies on hazard values derived directly from a single academic study 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;
- The academic study has been heavily criticized in the published literature;
- Other regulatory agencies have expressly declined to rely on the academic study citing data quality concerns;
- The authors of the study have published repeated corrections that fail to address the data quality concerns;
- A majority of EPA's own staff scientists expressed "low" confidence in its results.

- Developmental Toxicity Evaluated Using Contentious Study

Johnson, P. D., S. J. Goldberg, M. Z. Mays, and B. V. Dawson. 2003. *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*. Environmental Health Perspectives, 111(3), 289-292.

## Critique (Summary of Issues)

- Non-GLP study conducted at university laboratory
- Inappropriate controls not run at same time as treated animals
- Nonstandard technique to evaluate cardiac malformations
- Two dosing periods some eight years apart
- High background rate of cardiac defects in control animals
- Data evaluated by EPA comprised a spreadsheet with no dates
- Inappropriate pooling of control animals from other studies
- GLP gavage and inhalation studies revealed no cardiac defects

- In 2014, EPA conducted a staff review of the evidence linking TCE with cardiac defects and posted it to docket after TCE Assessment was released. The review indicates serious concerns of scientific staff regarding their confidence in the data.
- “The rodent developmental toxicology studies conducted by Dawson et al. (1993), Johnson et al. (2003), and Johnson et al. (1998) that have reported cardiac defects resulting from TCE (and metabolite) drinking water exposures have study design and reporting limitations. . . . . These limitations and uncertainties 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”).”

## EPA's Position on Johnson et al. (2003)

- “In conclusion, 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.”
- “[T]here is insufficient reason to dismiss their findings, especially when the findings are analyzed in combination with human, animal and mechanistic evidence.”

## HSIA Response

- Guideline GLP studies found no cardiac defects. § 26(i) requires § 6 regulation be based on weight of scientific evidence. HSIA is sponsoring a guideline developmental drinking water study, to be completed in January 2017, to verify findings of Johnson et al. (2003) or add to weight of evidence against association of TCE and cardiac defects. Happy to share draft protocol with EPA/OMB.

- 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

OMB should not clear proposed rule:

- Spot cleaning not part of draft assessment, no peer review, no SBAR even though spot cleaning has significant economic impact on thousands of small businesses
- Only two aerosol cleaning products identified and exposures are hypothetical
- Exposure, hazard, and risk assessments for both uses lack scientific rigor; such screening level assessments not appropriate to support regulation
- Assessments do not comply with TSCA §§ 6, 26