Proposed Regulation of Trichloroethylene (TCE) under Toxic Substances Control Act (TSCA) for Use in Vapor Degreasing, Aerosol Degreasing, and Spot Cleaning at Dry Cleaning Facilities

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TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment.
- 2012-2013:
  - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized.
  - Performed problem formulation for five of the Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.

TSCA Work Plan for Chemical Assessments

- 2014-2015:
  - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB):
    - No risks found for uses assessed for antimony trioxide and HHCB.
    - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
  - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals.
- 2015-2016:
  - Problem formulation and data needs assessment issued for several flame retardant clusters.
  - Problem formulation issued for 1,4-Dioxane.
  - Draft risk assessment for 1-bromopropane released for public comment
- June 22, 2016:
  - TSCA amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Toxic Substances Control Act (TSCA)

- TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to move ahead with ongoing efforts to issue section 6(a) rules for TSCA Work Plan chemicals with completed risk assessments published prior to enactment.
- TSCA section 6(a) provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
  - EPA must:
    - Determine after risk evaluation whether a chemical substance or mixture "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation….under the conditions of use."
    - Apply one or more of the regulatory options to the extent necessary so that the chemical substance no longer presents such risk.

TCE: Proposed Regulation

- EPA is proposing a regulation under TSCA § 6(a) to reduce or eliminate risks posed by TCE for the following three uses:
  - Use of TCE in all types of vapor degreasing:
    - Examples:
      - Vapor degreasing of small parts.
      - Fabrication of metal products.
      - Instruments and related products.
      - Machinery.
      - Electrical and electronic equipment.
      - Miscellaneous manufacturing industries.
  - Use of TCE in aerosol degreasing:
    - Consumer and commercial use of TCE in aerosol degreasing.
    - Examples:
      - Repair shops: shops that repair automobiles, motorcycles, bicycles, or electronics.
      - Fabrication shops: shops that fabricate metals, glass, or plastic components onto a final product (e.g., facilities that produce automobiles, aircraft, appliances, motor vehicle parts, machine parts, and jewelry).
      - Metal plating shops: shops that plate, or coat, metal onto a surface.
      - Electronics assembly shops: shops that assemble a wide variety of electronic devices onto circuit boards.
  - Use of TCE for spot cleaning in dry cleaning facilities:
    - Pre-spotting to remove stains or spots before cleaning the garment in the machine

TCE: Overview

- Volatile organic compound (VOC) and hazardous air pollutant (HAP) classified as a human carcinogen.
- Widely used in industrial and commercial processes; has some limited uses in consumer products.
- More than 255 million lbs per year used in the United States:
  - Majority of TCE (~84%) used as an intermediate for manufacturing refrigerant chemicals.
  - Much of the remainder used as a solvent for metal degreasing (~15%).
  - A small percentage (~1%) used in other applications, including dry cleaning and consumer uses.
  - EPA prioritized assessment of degreasing and other uses, because refrigerant uses take place in enclosed systems where exposures are expected to be comparatively low.

TCE: Risk Assessment

- Final IRIS Health Assessment: 2011
  - Carcinogenic to humans with mutagenic mode of action.
  - Evidence for multiple non-cancer end-points:
    - Kidney, liver, immune system, central nervous system, reproductive, and developmental toxicity.
  - Fetal cardiac malformations specifically identified as a developmental hazard. Hazard conclusion supported by two expert review panels (NRC/NAS- 2006, SAB, 2011).
  - See http://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=199.

TCE: Risk Assessment

- Final TSCA Work Plan Chemical Risk Assessment: July 2014
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment .
  - Cancer and non-cancer risks from long-term (chronic) exposure (workers):
    - Many of the occupational exposure scenarios exceeded the target cancer risk range (10^{-6} to 10^{-4}).
    - Non-cancer risks to workers were determined for a range of human health effects.
  - Non-cancer risks identified from short-term (acute) exposure:
    - TCE can irritate the respiratory system and skin and induce central nervous system effects such as light-headedness, drowsiness, and headaches.
    - Developmental effects (i.e., cardiac defects to fetal death).
  - See http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#tce

TCE: Risk Assessment

- For **non-cancer risks** a **margin of exposure** (MOE) method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
  - The benchmark MOE used for fetal cardiac defects in the TCE risk assessment is 10.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3x residual uncertainty for variability in humans.
  - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.

- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
  - The excess cancer risk is the product of the exposure concentration and the IUR.
  - Exposure reductions that protect against non-cancer risks also protect against these cancer risks.

From Risk Assessment to Risk Reduction

Risks identified

- TCE found to pose risks to workers when used in vapor and aerosol degreasing and spot cleaning in dry cleaning facilities

Risk reduction needed

- Exposures are several orders of magnitude higher than acceptable exposure level

Approach chosen

- Regulation under TSCA Section 6(a) is the approach most likely to reduce risks

Options Under TSCA Section 6(a)

- Prohibit or restrict manufacture, processing or distribution in commerce.
- Prohibit or restrict for particular use or above a set concentration.
- Require minimum warnings and instructions.
- Require recordkeeping or testing by manufacturers and processors.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of the determination of risk to distributers and users and replace or repurchase.

EPA's Authority to Regulate Occupational Risks

- OSHA authority extends only to private sector employers; CPSC authority extends only to consumer products

- EPA is working closely with OSHA and CPSC; both agencies agree that TSCA is the appropriate authority to address the risks that EPA has identified, including those that occur in workplace, because TSCA authority can address risks that cut across worker, public sector and consumer settings

- TSCA restrictions are consistent with OSHA hierarchy of hazard control (eliminate/substitute hazard; engineering controls; best practices administrative controls; personal protective equipment)

Developing Potential Regulatory Options

- Many options analyzed, including:
  - Material substitution (MS): Reducing the concentration of TCE in the degreasing formulation, with concentrations varying from 5 to 95 weight percent.
  - Equipment substitution (ES): Replacing open-top vapor degreasing units with an enclosed system to reduce the escape of TCE vapors into the air, which achieves a 98 percent reduction effectiveness.
  - Engineering controls (EC): Using local exhaust ventilation (LEV) to improve ventilation near the worker activity, which achieves 90 percent reduction effectiveness.
  - Personal protective equipment (PPE): Workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000.
  - Bans and restrictions.
  - Other options under TSCA section 6(a).

- Combinations of options were also analyzed.

Next Steps and Your Feedback

- Planning to publish the proposed rule later this year.
- We would like to hear more about:
  - TCE and your business for these three uses.
  - Exposure reduction for workers.
  - Experiences with alternatives.

Contact Information

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- All Work Plan Chemical risk assessments: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

- Changes to TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act