SQUIRE PATTON BOGGS

OCTC Ohio Chemistry Technology Council

TSCA § 6 Regulation Case Study

W. Caffey Norman
Partner
Squire Patton Boggs

Trichloroethylene in Vapor Degreasing

- Draft Work Plan Assessment released January 2013
- Comment period/Peer Review March-June 2013
- Peer Review report issued September 2013
- Final Work Plan Assessment issued June 2014
- SBAR held June 2016
- Proposed rule expected late 2016

TSCA § 6(a)

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  - If EPA determines that manufacture or use of a chemical *presents* an "unreasonable risk of injury to health or the environment" it shall apply one or more of the requirements shown next so that the chemical no longer presents such risk.

Options Under TSCA § 6(a)

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

Judicial Interpretation

- *Corrosion Proof Fittings*
- Language requiring that EPA protect "against such risk using the least burdensome requirements" has been dropped, so part is no longer relevant
- "Unreasonable risk" discussion still relevant
  - Term not defined in statute
  - In evaluating what is unreasonable, EPA must "consider the environmental, economic, and social impact." TSCA § 2(c) (unchanged)
  - "Balancing test" – regulation may issue if severity of injury that may result from product, factored by likelihood of injury, offsets the harm the regulation itself imposes on manufacturers and consumers

TSCA § 6(a) Rulemaking

- Most importantly, TSCA § 6(c) still requires EPA to consider cost in rulemaking:
  - "(iv) the reasonably ascertainable economic consequences of the rule, after including consideration of—
  - (I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
  - (II) the costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
  - (III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator."

TSCA § 6(a) Rulemaking, cont.

- § 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"
- § 6(c)(2)(D) – EPA "shall exempt replacement parts for complex durable goods and complex consumer goods" designed prior to the date of publication of the rule, unless "such replacement parts contribute significantly to the risk"
- § 26(l) – where risk assessment completed prior to date of enactment, rules must be consistent with "the scope of the completed risk assessment for the chemical substance"

Risk Evaluation

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 and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;"
- "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."

Risk Evaluation, cont.

Under § 26(h) “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.”

Background: 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.

Background: 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 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
    - Peer review meeting May 24-25, 2016

Risk Assessment: TCE

- 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.

Risk Assessment: TCE

- 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}).
    - 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.
    - Concern was for 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

Existing EPA Regulation

- 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 fenceline emissions
- Work Plan assessment relies on data collected before the May 2010 compliance deadline for NESHAP, meaning that the baseline exposures are all wrong
  - Probably fewer machines in operation, lower exposures, etc.
  - No need to speculate: under the NESHAP EPA has records showing location, date of installation, solvent consumption, and emissions for every covered degreaser

TSCA Requirement/TCE Assessment

- 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

- Assessment based on pre-NESHAP use conditions/exceedance of PEL
- 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

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

$\mathrm{AEL}_{\text{non-cancer 8 hr TWA}}$ for acute exposures = 1 ppb

$\mathrm{AEL}_{\text{non-cancer 8 hr TWA}}$ for chronic exposures = 2 ppb

Cancer

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

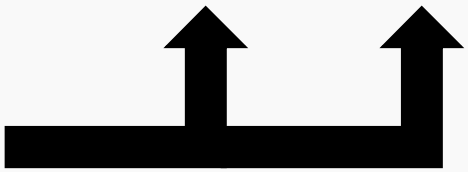
Exposure Estimates: TCE at Vapor Degreasing Facilities

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

TSCA § 9

- § 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.

Legislative History

- 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.”
- Also 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.”
- But *cf.* June 7 Democratic Senators statement: ”TSCA as the Primary Statute for the Regulation of Toxic Substances . . . . EPA's authorities and duties under § 6 of TSCA have been significantly expanded . . . .The interagency referral process and the intra-agency consideration process established under § 9 of existing TSCA must now be regarded in a different light since TSCA can no longer be construed as a ``gap-filler'' statutory authority of last resort.

Legislative History, cont.

- 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 since its own existing regulatory framework already appropriately addresses risk to human health. New § 9(b)(2) will force the Agency to do just that.

OSHA Letter

- “Given certain limitations imposed on OSHA's authority under the OSH Act, this agency believes TSCA provides the EPA with a means of eliminating or reducing the risks associated with these chemical uses in a more coordinated fashion across both consumer and occupational settings.”
- “OSHA lacks direct jurisdiction over state and local government workers.”

OSHA Letter, cont.

- “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.”

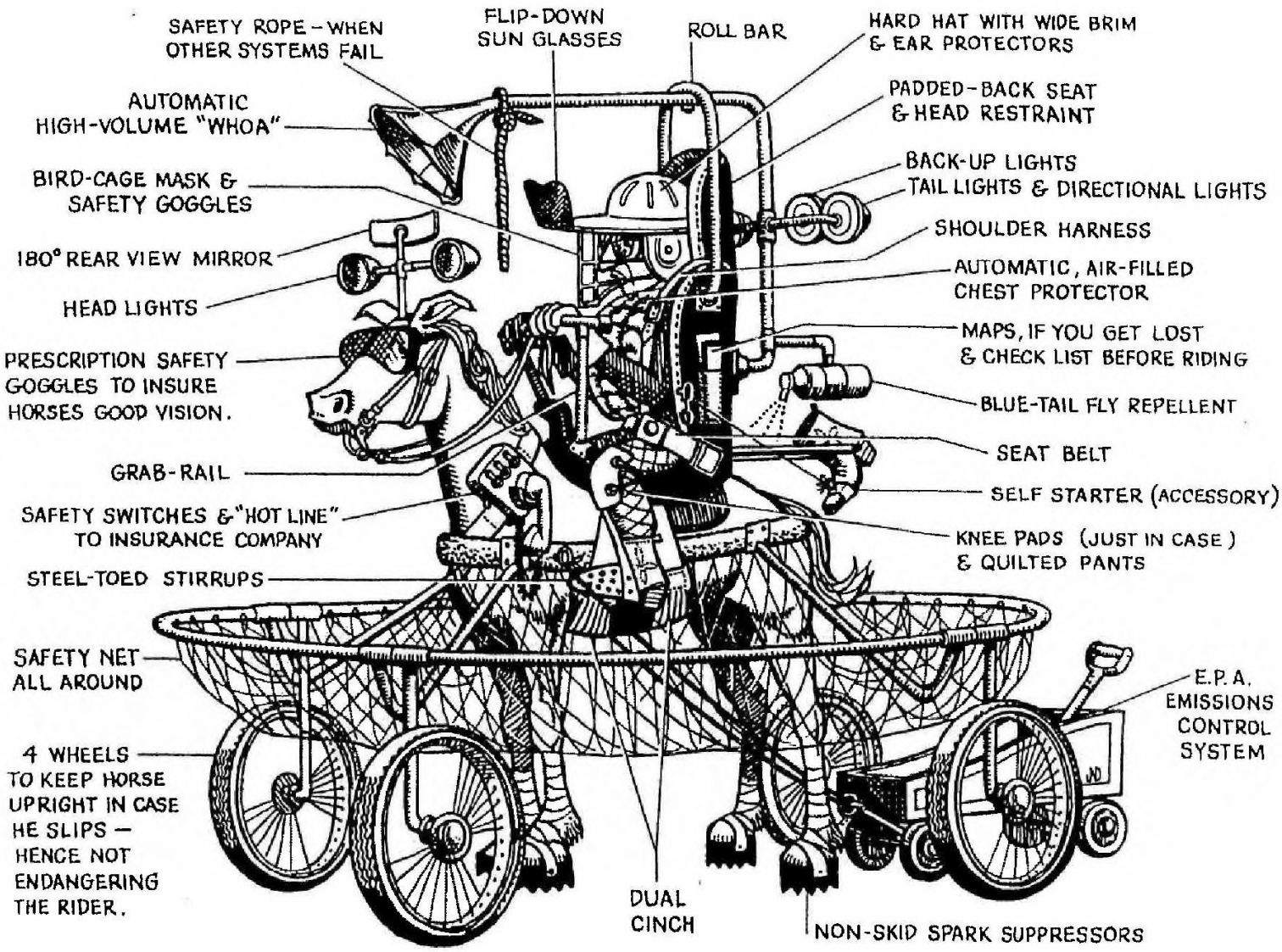
OSHA Letter, cont.

- “OSHA supports the goals of EPA to broadly address the hazards associated with these chemicals and looks forward to collaborating with you on activities that will reduce occupational risk.”

Precedent?

Chemical	Units for AELs and PELs	OSHA PEL*	Cancer AEL	PEL/Cancer AEL
Benzene	ppm	10	0.00031	32,505
Beryllium and compounds	mg/m3	0.002	0.0000032	626
Butadiene, 1,3-	ppm	1	0.00012	8,660
Formaldehyde	ppm	0.75	0.00048	1,561
Lead and Compounds	mg/m3	0.05	0.00064	78
Methylene Chloride	ppm	25	0.22	113
Trichloroethylene	ppm	100	0.00035	286,592
Vinyl Chloride	ppm	1	0.00068	1,467

** Cal PEL for 'lead and compounds'*



Cowboy after ~~O.S.H.A.~~ E.P.A.