ToxStrategies

The TSCA-fication of OSHA

Potential Impacts on the Chemical Industry

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Sound Science

TSCA Amendment added workers as a focus

§2602. Definitions

The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, ***workers****, or the elderly.*

TSCA risk evaluations now include a focus on workers

Amended TSCA can trump OSHA

TSCA Section 9 – Relationship to Other Federal Laws

Section 9 directs that if the Administrator determines that a risk to health or the environment associated with a chemical substance could be eliminated or reduced to a sufficient extent by actions taken under those other federal laws, the Administrator shall use those other laws unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under TSCA.

Outcome 1: If that agency finds there is no risk, or responds to EPA and takes action within 90 days to address such risk, EPA cannot regulate

Outcome 2: If that agency does not respond within the specified time, or does not take action within 90 days to address such risk, EPA shall regulate

Do not expect OSHA to be a roadblock to EPA regulating worker protection under TSCA

EPA must evaluate worker risks for New Chemicals

In EPA TSCA Safety Determinations for New Chemicals

§2604. Manufacturing and processing notices

The Administrator shall review PMNs and SNUNs and determine—

If the chemical substance or significant new use 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 identified as relevant by the Administrator under the conditions of use

EPA Sets Inhalation Exposure Limits for New Chemicals

- If EPA determines that a PMN substance may present an unreasonable risk of injury to human health via inhalation exposure,
- EPA may require, among other things, that potentially exposed employees of the Company must wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health.
- EPA generally extends these requirements to other manufacturers and processors of the same chemical substance.

EPA must evaluate worker risks for existing high-priority chemicals

In EPA TSCA Risk Evaluations for Existing Chemicals

§2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

- *In conducting a risk evaluation of an existing high-priority chemical substance, the Administrator shall—*

- *Assess 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 (workers)*

All of this has created the potential for "The TSCA-fication of OSHA"

Because EPA TSCA looks at risk differently than OSHA
(and OSHA may defer to EPA)

Approach to worker risk estimation

EPA Risk Evaluation (Existing Chemicals)	EPA NCEL (New Chemicals)	OSHA PELs
• Respirator Assigned Protection Factors (APFs) of 0, 10, 25, and 50	• No respirator	• No respirator
• With and without local exhaust ventilation (LEV) – assume to be 90% effective	• No local exhaust ventilation assumed	• No local exhaust ventilation assumed
• Worker Exposure: 8 hours/day, 125 days/year and 250 days/year, 20 years and 40 years	• Worker exposure: 8 hours/day, 250 days/year, 40 years	• Worker exposure: 8 hours/day, 250 days/year, 45 years
• Hazard Index Goal = 1	• Hazard Index Goal = 1	• Hazard Index Goal = 1
• Cancer Risk Goal = 10^{-4} to 10^{-6}	• Cancer Risk Goal = 10^{-4}	• Cancer Risk Goal = 10^{-3}

Approach to dose-response in risk assessments

EPA

- Upper confidence limit of dose-response curve
- Interspecies scaling using ¾-power scaling factor

OSHA

- MLE of dose-response curve
- Interspecies scaling based on body weight

Statutory Context Comparison

EPA TSCA	OSHA
• Determine if a chemical substance is likely to present an unreasonable risk of injury to health, including workers as a potentially exposed or susceptible subpopulation	• Determine if significant risk exists from workplace exposure
• Set prohibitions and restrictions	• Set a standard to reduce significant risk

• With consideration of:
  • Economic consequences on national economy, small business, technological innovation
  • Availability of technically and economically feasible alternatives to a use being prevented
	• Tempered by technological and economic feasibility and cost effectiveness

Statutory Context Comparison

EPA TSCA

- Based on reasonably available information, best available science, and weight of scientific evidence
- Amended TSCA required policies and procedures for risk evaluations to be issued, including guidance for risk evaluations by external parties (both issued in 2017)

OSHA

- Based on “best available evidence” considering “latest scientific data”
- No formal written internal or external guidance on risk assessment procedures

OSHA PEL → EPA Cancer Risk

	units	EPA RSL	EPA Risk	OSHA PEL	OSHA Risk
Asbestos	fiber/m3	NA	NA	0.1	3.4E-03
Acrylomide	µg/m3	0.12	1.0E-06	300	2.5E-03
Acrylonitrile	µg/m3	0.18	1.0E-06	4300	2.4E-02
Trichloroethylene	µg/m3	3	1.0E-06	537000	1.8E-01
Carbon Tetrachloride	µg/m3	2	1.0E-06	63000	3.2E-02
Methylene Chloride	µg/m3	1200	1.0E-06	87500	7.3E-05
Perchloroethylene	µg/m3	47	1.0E-06	690000	1.5E-02

Example – EPA 2016 Risk Assessment of methylene chloride (being redone now)

EPA recommended a ban based on the following worker inhalation risks:

Cancer Risk: Estimated cancer risks from 10^{-5} to almost 10^{-3} were viewed as being high enough for a ban.

Non-Cancer Risk: Non-cancer risks based on 250 days/year for 40 years of exposure with no respirator also supported a proposed ban

In developing restrictions to manage worker risks, EPA considered:

Workers being exposed may not be in a position to … ensure that their employer provides appropriate PPE and an adequate respiratory protection program.

Effective personal protection resulting in risk reduction would require … the appropriate use of a supplied-air respirator. (based on the risk assessment)

Union position

- The USW and AFL-CIO labor unions argue that OSHA regulations are outdated and inadequate to protect workers and that the agency also lacks resources for enforcement.
- USW says that 400 OSHA chemical exposure limits are based on science from the 1960s or earlier.
- "Where a new chemical poses an unreasonable risk to workers, EPA must act to impose and codify worker protections when the new chemical is introduced into commerce," AFL-CIO says.

20 Chemical Companies speak

New Chemicals Coalition

- December 11, 2017 letter to EPA

- Urged agency to craft a process for consulting with OSHA under the revised TSCA, arguing that OSHA rules adequately protect workers in most cases, making EPA restrictions unnecessary.

Business Implications

- Possibility of higher level of respiratory protection and/or venting
- Reformulation to lower exposure and risk levels
- Possible worker hazard communication issues
- Litigation for past exposures?