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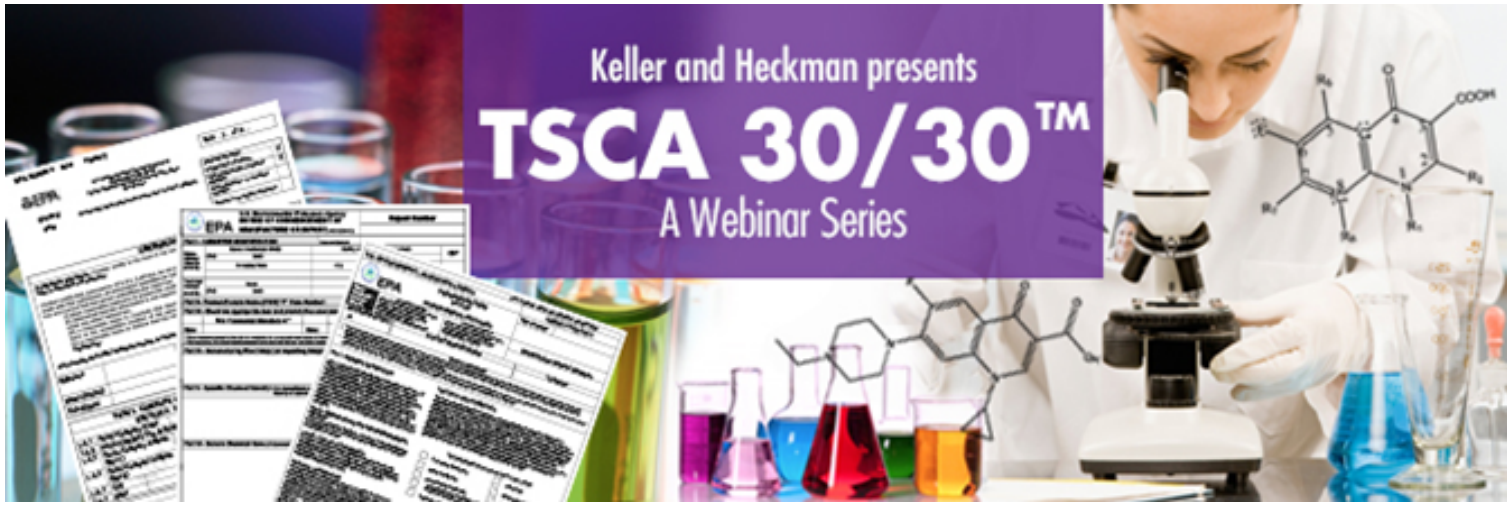
# Occupational Exposure Under the Biden EPA

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# Herb Estreicher

- Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his US law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few US-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.
- Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.
- Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

 

# Lawrence P. Halprin

- Lawrence Halprin is nationally recognized for his work in the areas of occupational safety and health and chemical regulation, representing companies and trade associations at the federal and state levels. His hands-on familiarity with the manufacturing and construction environments, and his engineering and financial background have been invaluable to his clients in handling enforcement actions, in providing compliance counseling, and in evaluating and critiquing rulemaking proposals and policy initiatives before the Occupational Safety and Health Administration (OSHA), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the Chemical Safety Board, the Department of Treasury (TTB licensing and formula approval, and ethanol and Superfund excise taxes), and corresponding state agencies.
- Lawrence is a strong advocate of measures to enhance the effectiveness of regulatory agencies and ensure they do not overreach their authority. This is demonstrated by his testimony before Congress, his participation in agency rulemakings and policy initiatives, as well as litigation he has brought on behalf of clients. Lawrence is a prolific writer and is frequently invited to speak on a broad range of environmental, product stewardship, and health and safety management issues.

 

# OSHA vs EPA – WHO IS BETTER POSITIONED TO ADDRESS OCCUPATIONAL EXPOSURE TO TOXIC CHEMICALS?

 

# OSHA Regulation of Chemical Exposures (1)

- Current Situation
  - OSHA: “workers suffer more than 190,000 illnesses and 50,000 deaths annually related to chemical exposures.” https://www.osha.gov/safer-chemicals. All other workplace deaths ~ 5,000/yr
    - Most not captured by OSHA Injury & Illness Recordkeeping System
  - 60,000 substances +/- in TSCA inventory: not all pose an airborne inhalation hazard, but many do
- OSHA Tools to Regulate Airborne Chemical Exposures
  - OSHA Permissible Exposure Limits (PELs): substance-specific
    - Approx. 425 adopted in 1972, OSHA indicates most are outdated, 30 updated in last 50 years
    - OSHA gave up on amending the other 395 PELs after AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992)
  - Respiratory Protection Standard – provide when necessary to protect the health of an employee
  - General Duty Clause – “recognized hazards” -- resource intensive – rarely used

 

# OSHA Regulation of Chemical Exposures (2)

- Current Situation
  - Other Generic OSHA standards Regulating Exposure to Toxic Chemicals
    - PPE Other Than Respirators – provide when necessary
    - Hazard Communication Standard and Laboratory Standard -- generic, communication and training, recommendations in SDS and label not enforceable. Requires listing of internal OELs in SDS. Relatively few do
    - Chemical Process Safety Management Standard – only covers about 110 toxic and highly reactive chemicals and all flammable liquids and gases
    - Chemical Emergency Response Standard – generic
  - Scope of OSH Act: No coverage of sole proprietors or military, no coverage of state and local employees in approximately 22 states without state plans
  - Hierarchy of Controls
    - PELs: Feasible engineering or administrative controls must be implemented. When those controls do not achieve compliance with the PEL, respirators must be used to close the gap
    - Respiratory Protection Standard: Prevent atmospheric contamination to the extent feasible with engineering controls and fill in any gaps in protection with respirators
    - OSHA: “Respiratory protection is relegated to the bottom of the compliance priority list because it is an ineffective, unreliable, and unsafe method of reducing employee exposure.” 1978 Lead Standard Preamble

 

# OSHA Regulation of Chemical Exposures (3)

- Requirements to establish PEL
  - Measures most adequately assure, to the extent feasible, based on the best available evidence, that no employee will suffer material impairment of health or functional capacity from regular exposure for entire working life (45 years)
    - Significant risk: Supreme Court (Benzene) held OSHA must first establish "significant risk" and suggested significant incremental lifetime risk of death from cancer was between 1/1000 & 1/billion
      - OSHA chose 1/1,000 assuming regular exposure over 45-year working lifetime. Why 1/1,000? NIOSH Cancer Policy 2017: 1 in 10,000 ($10^{-4}$) excess working lifetime risk
    - Significant reduction in risk
    - Proposed measures are technically and economically feasible for each affected industrial sector
      - OSHA: widespread use of respirators is not feasible
    - Proposed measures are most cost-effective approach (?)
- OSHA lacks tools and resources under current scheme to set new PELs, and OSH Act reform efforts on this issue never progressed
- Along came the Lautenberg Chemical Safety Act

 

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (1)

| Required Submission of Data and Mandatory Agency Action | TSCA | OSH Act |
|---|---|---|
| Authority to require submission of health and safety studies | Yes per § 8(d) rule | No |
| Notify agency of new info that chemical poses substantial risk to health | Yes per § 8(e) | No counterpart as to animal or in vitro studies<br><br>29 CFR 1904 Injury & Illness Recordkeeping Rule<br>Current: report of work-related injury or illness resulting in overnight hospitalization or death within 30 days<br>Proposed: annual reports of work-related injury/illness to worker requiring more than first aid by higher risk industry sectors |
| Authority to require testing of chemicals | Yes per § 4(a) rule if the chemical<br>• may present an unreasonable risk of injury to health or the environment, OR<br>• will be produced in substantial quantities and insufficient info available; AND<br>• testing is needed to develop data | No |
| Requirement for agency to take action based on test data | Yes per § 4(f) if test data provides reasonable basis to conclude that a chemical presents significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects. EPA must initiate action within 180 to 270 days to prevent or sufficiently reduce risk made without consideration of costs or other non-risk factors | No counterpart, no mandate, no deadline |

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (2)

| Regulation of New Chemicals or Significant New Uses | TSCA | OSH Act |
|---|---|---|
| PMN or other filing required before proceeding with commercial production or use | Yes, per TSCA § 5. EPA must issue an order to prohibit or limit activity to the extent necessary to protect against an unreasonable risk of injury to health, without consideration of costs or other non-risk factors if:<br>• chemical presents an unreasonable risk of injury to health; OR<br>• info insufficient to permit evaluation and<br>• chemical may present unreasonable risk; OR<br>• substance either may reasonably be anticipated to enter the environment in substantial quantities or there may be significant human exposure to the substance<br>Order may also mandate testing | No. OSHA may not issue a PEL without demonstrating:<br>(1) Significant risk of material impairment of health exists at the current levels of exposure<br>(2) Proposed rule is technically and economically feasible for each affected industry sector<br>OSHA acts only after there is epidemiological evidence of a serious problem. Would almost never act on new chemical<br>OSHA has generally limited itself to adopting comprehensive substance-specific standards for carcinogens, which may pose additional hazards |

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (3)

| Regulation of Existing Chemicals | TSCA | OSH Act |
|---|---|---|
| Rule must be technically and economically feasible | No. TSCA § 6 | Yes, for all industrial sectors without widespread use of respiratory protection |
| Rule may ban chemical if substitute available | Yes. TSCA § 6 | No |
| Acceptable incremental lifetime risk of serious disease or death due to exposure to chemical | 1/10,000<br>(adopting NIOSH 2017 position) | 1/1000<br>Subject to feasibility constraints |
| Hierarchy of Controls | All harmful exposures<br>Typical Section 5 consent order:<br>Company must implement engineering controls or administrative controls, where feasible, to prevent [ALL] exposure to the New Chemical Substance<br>Many go further, prohibiting activity that would result in inhalation or requiring use of a respirator with an APF of 1000 or 10,000 | Harmful inhalation exposures<br>OSHA generally sets the PEL above the 1/1,000 risk level where widespread use of respirators would be required on a regular basis |
| Civil penalty | $43,611.00 per violation/day | Civil penalty: $14,502 per violation |

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (4)

**Table VII-3: Selected OSHA Risk Estimates (Excess Cancers per 1000 Workers)**

| *Standard* | *Risk at prior PEL* | *Risk at new PEL* | *Federal Register date* |
|---|---|---|---|
| Ethylene Oxide | 63 - 109 per 1000 | 1.2 - 2.3 per 1000 | June 22, 1984 |
| Asbestos | 64 per 1000 | 6.7 per 1000 | June 20, 1986 |
| Benzene | 95 per 1000 | 10 per 1000 | September 11, 1987 |
| Formaldehyde | 0.43 – 18.9 per 1000* | .0056 – 2.64 per 1000* | December 4, 1987 |
| Methylenedianiline | 6 - 30 per 1000** | 0.8 per 1000 | August 10, 1992 |
| Cadmium | 58 - 157 per 1000 | 3 - 15 per 1000 | September 14, 1992 |
| 1,3-Butadiene | 11.2 - 59.4 per 1000 | 1.3 - 8.1 per 1000 | November 4, 1996 |
| Methylene Chloride | 126 per 1000 | 3.6 per 1000 | January 10, 1997 |
| Chromium VI | 101 - 351 per 1000 | 10 - 45 per 1000 | 2006 |

* range is based on maximum likelihood estimate (0.43, .0056) and upper 95% confidence limit (18.9, 2.64)

** no prior standard; reported risk is based on estimated exposures at the time of the rulemaking

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (5)

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**Table VI-1. Summary of Lifetime or Cumulative Risk Estimates for Crystalline Silica***

| Health Endpoint (Source) | Risk Associated with 45 Years of Occupational Exposure (per 1,000 Workers) Respirable Crystalline Silica Exposure ($\mu g/m^3$) | | | | |
|---|---|---|---|---|---|
| | 25 | 50 | 100 | 250 | 500 |
| **Lung Cancer Mortality (Lifetime Risk)** | | | | | |
| Pooled Analysis, ToxaChemica, Inc (2004)[a,b] | 10-21 | 16-23 | 20-26 | 24-30 | 32-33 |
| Diatomaceous Earth Worker study (Rice et al., 2001)[a,c] | 8 | 15 | 30 | 72 | 137 |
| U.S. Granite Worker study (Attfield and Costello, 2004)[a,d] | 10 | 22 | 54 | 231 | 657 |
| North American Industrial Sand Worker study (Hughes et al., 2001)[a,e] | 7 | 14 | 33 | 120 | 407 |
| British Coal Miner study (Miller and MacCalman, 2009)[a,f] | 3 | 5 | 11 | 33 | 86 |
| **Silicosis and Non-Malignant Lung Disease Mortality (Lifetime Risk)** | | | | | |
| Pooled Analysis (ToxaChemica, Inc., 2004) (silicosis)[g] | 4 | 7 | 11 | 17 | 22 |
| Diatomaceous Earth Worker study (Park et al., 2002) (NMRD)[h] | 22 | 44 | 85 | 192 | 329 |
| **Renal Disease Mortality (Lifetime Risk)** | | | | | |
| Pooled Cohort study (Steenland et al., 2002a)[i] | 25 | 32 | 39 | 52 | 63 |

Former PEL ~ 100
PEL = 50
AL =25

# TSCA Addresses Worker Exposures Where Not Adequately Addressed By Other Statutes (6)

| Substance | TSCA ECEL: 8-hr. TWA 1/10,000 Incremental Risk For Most Sensitive Condition | OSH Act PEL: 8-hr. TWA 1/1000 Incremental Risk Target (1980) | PEL/ECEL Ratio |
|---|---|---|---|
| Asbestos | 0.005 fibers/cc<br><br>1/10,000 incremental risk | 0.1 fiber/cc (1994)<br><br>6.7/1,000 incremental risk | 20 |
| Carbon tetrachloride | 30 ppb, 0.2 mg/m3 (CNS depression, liver tox; also adeq. for liver cancer) | 10 ppm (10,000 ppb) (1967) | 333 |
| Methylene chloride | 2 ppm (liver tox. and CNS depressions; also adeq. for cancer) | 25 ppm (1997) | 12.5 |
| Perchloroethylene (Tetrachloroethylene) | 0.14 ppm (0.98 mg/m3) (neurotox, also adeq. for cancer) | 100 ppm (1967) | 714 |
| Trichloroethylene | 4 ppb OR 0.021 mg/m3 (immunotox., cancer)<br><br>1.1 ppb ( 0.0059 mg/m3) (devel. tox.) | 100 ppm (100,000 ppb) (1967) | 25,000<br><br>90,909 |

 

# Potential Outcome -- Break Down the Silos

- TSCA is more proactive, reaches all employees, requires greater risk reduction (through substitution if necessary), more likely to achieve compliance, and places less emphasis on PPE
- In a letter to EPA, apparently dated April 4, 2016, then OSHA Administrator David Michaels advised EPA it was better positioned than OSHA to address the risks associated with methylene chloride, N-methylpyrrolidone and trichloroethylene in occupational settings
- OSHA has the expertise and EPA has the Regulatory Authority – The Path Forward?
  - EPA establishes PELs under TSCA with integrated OSHA participation
  - OSHA generally abandons the OSH Act PELs process
  - EPA and OSHA share enforcement of TSCA requirements per §11 of TSCA
    - Inspections and subpoenas
      - For purposes of administering this chapter, the Administrator, and any duly designated representative of the Administrator, may inspect …

 

# PPE ASSUMPTIONS IN RISK EVALUATIONS

 

# The Issue

- Trump EPA assumed the use of PPE in risk evaluations
- Biden EPA does not
- Makes a huge difference in the unreasonable risk outcomes for human health
- Industry groups have questioned the legality of the Biden EPA approach

 

# What are the Arguments?

- EPA's decision not to assume the use of PPE is inconsistent with the definition of conditions of use under Section 3(4) of TSCA
- Section 3(4) of TSCA defines conditions of use as "**the circumstances**, as determined by the Administrator, under which a chemical substance is intended, **known, or reasonably foreseen** to be manufactured, processed, distributed in commerce, used or disposed of"
- PPE use is a known and reasonably foreseen circumstance
- Reasonable to assume that workplaces comply with OSHA regulations

 

# ACC Comments on Revised HBCD Risk Eval.

- Assumption of no PPE use does not comply with TSCA's Section 26 requirements that TSCA risk evaluations be consistent with best available science and based on weight of the scientific evidence
- Assumptions are inconsistent with the Occupational Safety and Health Act's statutory and regulatory requirements
- Addressing PPE (and other OSHA requirements) only in the risk management rule, and not as part of the conditions of use in the risk evaluation, will have significant potential impacts, including the potential for duplicative and inconsistent requirements

 

# Unions and NGO Fire Back

- “Use of the [OSH Act] General Duty Clause is very rare, not preventive -- used only when workers are already sick or have died -- and leaves workers at unreasonable risk from workplace chemical exposures”
- No basis for an assumption that OSHA’s HazCom standard “compels employers to implement the recommended controls” listed on manufacturers’ safety data sheets (SDS)
- The “accuracy and consistency of SDS is questionable with studies finding that 36% or more of SDS and labels understate the danger to workers”
- “PPE is not the panacea that [Industry] would characterize it as. Equipment like respirators don’t always fit correctly”

 

# Main NGO Point

- "The **correct approach** is to **measure occupational exposures** to chemicals **without any controls** in place, and then use hazard controls to **reduce exposures**
- Control measures should follow the **hierarchy of controls** with elimination, substitution and engineering controls used first and personal protective equipment used as a last resort"

 

# FINAL THOUGHTS

 


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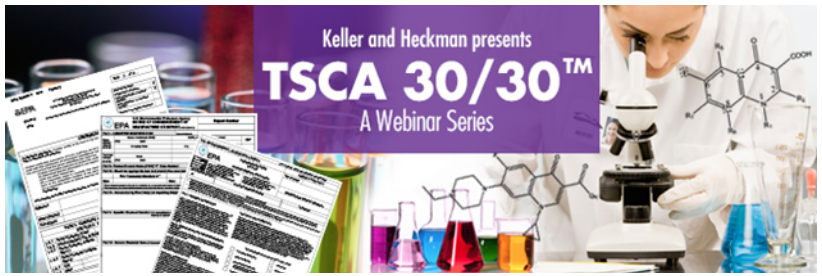


Please join us at 1:00 PM Eastern U.S.
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# Thank You


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