National Institute of Environmental Health Sciences
Worker Training Program

Paint strippers containing methylene chloride have been associated with 13 fatalities to bathtub refinishers since 2000. *©2016 Earl Dotter*

How will the changes to the Toxic Substances Control Act (TSCA) impact workplace chemical safety and health?

What is TSCA?

TSCA is the "Toxic Substances Control Act" of 1976 that gave the US Environmental Protection Agency (EPA) the authority:

> "to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment".[1]

TSCA provides EPA with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.

Why was TSCA amended and updated?

People concerned with chemical safety and the EPA itself have long considered TSCA outdated and ineffective in protecting people from dangerous chemicals. Even asbestos, with its record of killing more than 10,000 Americans every year, could not be restricted under TSCA. In 1991 the federal courts ruled that TSCA did not give EPA the power to ban asbestos. Subsequently, EPA stopped using the law to restrict chemicals.

On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which updates and amends the TSCA, including its impact on workplace chemical safety and health.

85,000 different chemicals have been produced and used since TSCA became law in 1976.[4]

62,000 of these chemicals were grandfathered in when TSCA became law with no requirement they be tested.

In the **40 years** that TSCA has been in place, EPA has required testing on just 200 chemicals.

When the federal court stopped EPA from banning asbestos in 1991, **EPA halted all such efforts.**

What is the current state of chemical regulation in the workplace?

Under the Occupational Safety & Health Act, OSHA is the federal agency responsible for establishing and enforcing national safety & health standards. However, OSHA has acknowledged that limitations on its authority are preventing it from using the most current evidenced based chemical exposure limits in regulating workplace chemical exposures. From the OSHA website[2]:

> "OSHA recognizes that many of its permissible exposure limits[3] (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. Section 6(a) of the OSH Act granted the Agency the authority to adopt existing Federal standards or national consensus standards as enforceable OSHA standards."

Most of the current PELs were based on the 1968 Threshold Limit Values (TLVs®) of the American Conference of Governmental Industrial Hygienists (ACGIH®). These outdated standards include about 450 chemicals. OSHA has promulgated only about 30 new chemical standards in its 46-year history.

OSHA attempted to update its outdated chemical standards in 1989 in a single rulemaking. However, the rule was vacated by the federal court, finding that OSHA had not proven that each new PEL would eliminate significant risk and be feasible in each effected industry. OSHA has addressed this dilemma, in part, by posting more current exposure limits on its website including 1) NIOSH recommended exposure limits (RELs), 2) ACGIH® Threshold Limit Values (TLVs®), and 3) California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs). Links to the tables are located at: *https://www.osha.gov/dsg/annotated-pels/index.html*. However, these more protective limits are not enforceable OSHA standards.

In a letter to EPA Assistant Administrator James J. Jones, OSHA Director, David Michaels stated his view that given limitations imposed on OSHA, TSCA gives EPA a means of regulating risk associated with methylene chloride and N-methyl pyrrolidone in paint removers and trichloroethylene in a more coordinated fashion in both consumer and occupational settings.

EPA is planning to complete work on the rules for these three chemicals by October and December of 2017.

Why is this important?

There are more than 85,000 chemical substances on the EPA's TSCA Inventory of Chemical Substances. More than 7,600 of these chemicals were reported in volumes of 25,000 pounds or more as part of the 2012 Chemical Data Reporting (CDR) effort.[4]

The estimated number of occupational diseases in 2007 was 53,000 deaths and 463,000 non-fatal cases at a cost of $46 billion.[5] More on-the-job deaths are due to occupational diseases than injuries. About a third of the disease deaths are occupational cancers. Workers' compensation covers less than 25 percent of these costs, so all members of society share the burden.

President Obama remarked during the bill signing in explaining the need for TSCA reform,

> "The system was so complex, it was so burdensome that our country hasn't even been able to uphold a ban on asbestos, a known carcinogen that kills as many as 10,000 Americans every year."[6]

What are the important reforms in the revised TSCA?

Under the new law:

1. EPA has a mandatory duty to evaluate chemicals with clear and enforceable deadlines.
2. Chemicals must be assessed against risk-based safety standard.
3. EPA must consider susceptible and highly exposed populations including workers.
4. EPA must move to regulatory action on chemicals. Unreasonable risks must be eliminated/reduced.
5. EPA will require that the OSHA hierarchy of controls is used.
6. EPA is authorized to move quickly to ensure development of chemical risk assessments when needed.

53,000 deaths due to occupational diseases annually[5]

463,000 non-fatal illnesses

Cost = **$46 billion**

Asbestos Tearout Worker

The summaries below address key provisions in the updated TSCA that should impact worker safety and health.

Section 3, Susceptible populations

EPA must identify populations that are disproportionately at risk either due to greater exposure or greater susceptibility to injury from a chemical. The new law identifies workers as one of the potentially exposed or susceptible populations that may be at greater risk. An exposure to a susceptible population is considered in setting priorities and in risk assessments.

Populations with Greater Susceptibility or Exposure

- Infants
- Children
- Workers
- The Elderly
- Pregnant Women

Section 5, New Chemicals

There is a new requirement that EPA must make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace. EPA can still take a range of actions to address potential concerns including restrictions, additional testing of the chemical, or a ban for one or more use. EPA is also updating its regulations to coincide with changes to the OSHA Hazard Communication Standard (29 CFR 1910.1200) to conform with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), changes to the OSHA Respiratory Protection Standard (29 CFR 1910.134), and changes to the NIOSH respirator certification requirements (42 CFR Part 84).

Section 5, Action to address unreasonable risks

In its proposed rule, EPA has included that worker safety requirements shall be implemented consistent with the OSHA hierarchy of controls approach, where feasible. Under that hierarchy, an employer should attempt to eliminate or substitute hazardous chemicals and use engineering and administrative controls before requiring workers to use personal protective equipment.

Several aspects of Section 6 are relevant to workers; each is described below:

Section 6, Chemicals already on the market

One of the most important reforms is to Section 6, which governs chemicals that are already on the market. The change addresses the limitations on EPA authority that prevented it from regulating asbestos and by implication, other chemicals. The new language requires EPA to regulate a chemical based solely on health and environmental factors. The new law requires EPA to develop regulations on prioritization, risk assessment, and regulation of chemical substances and mixtures.

Section 6, Priorities and risk assessments

EPA is directed to establish rules on setting priorities and conducting risk assessments. They expect these rules to be completed by mid-June 2017. Occupational exposures shall be considered in setting priorities and conducting risk assessments.

EPA is directed to initiate risk assessments on at least 10 chemicals drawn from the EPA work plan for chemical assessments within 6 months, and then within 3.5 years ensure that risk assessments are being conducted for at least 20 high priority substances. Preference in setting priorities is to be given to chemicals that have a high persistence and bioaccumulation[7] score, identified as known human carcinogens and those that have high acute or chronic toxicity.

Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an "unreasonable risk". Risk evaluation excludes consideration of costs or non-risk factors. Risk assessments will evaluate chemicals throughout their "life cycle", from manufacture to disposal. EPA will use a weight of evidence approach in determining risk. These risk assessments should also be invaluable for OSHA rulemaking.

Widow of asbestosis victim. *©2016 Earl Dotter*

On November 29th, 2016, the EPA published the first 10 chemicals to be evaluated for risk to human health and the environment:

- 1,4-Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster
- Methylene Chloride
- N-methylpyrrolidone
- Pigment Violet 29
- Tetrachloroethylene, also known as perchloroethylene
- Trichloroethylene

Section 6, Regulatory action

Once unreasonable risks to human health are identified, EPA must take final risk management action within two years, or four years if an extension is warranted. The decision to regulate or not is determined based on the risk to susceptible groups and any restrictions must protect them. The amendment also removes the requirement in the original law that EPA must choose the "least burdensome" way of addressing the risk posed by a chemical. This phrase was a major factor in the federal court ruling on the attempt by EPA to ban asbestos. The court effectively found that EPA had to prove it had analyzed every conceivable way of restricting asbestos and had chosen the one that was "least burdensome" to industry.

Under the new law, EPA must conduct both a cost/benefit and a cost/effectiveness analysis of any proposed restrictions that includes the impact on the economy. However, the bill makes clear that those analyses are to guide EPA in choosing among a limited number of regulatory options that ensure safety for the identified populations. The analytical burden on the agency is still significant, but EPA is still required to apply the needed protections.

Additional information on the EPA Work Plan for Chemicals is found at: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals*

Confidential Business Information

The update establishes new substantiation requirements for certain types of confidentiality claims from chemical manufacturers and users. EPA is required to review and make determinations on all new confidentiality claims for the identity of chemicals. EPA must review past confidentiality claims for chemical identity to determine if it is still warranted.

Source of Sustained Funding

TSCA now allows EPA to collect up to $25 million annually in user fees from chemical manufacturers and processors to defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals.

Federal-State Partnership

States can continue to act on any chemical, or particular uses or risks from a chemical, that EPA has not yet addressed. Existing state requirements (prior to April 22, 2016) are grandfathered and existing and new state requirements under state laws in effect on August 31, 2003, are preserved. The law preserves states environmental authorities related to air, water, waste disposal and treatment. It also allows States and the federal government to co-enforce identical regulations.

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Preemption of State Laws

State action on a chemical is preempted when:

- EPA finds through a risk evaluation that a chemical is safe, or
- EPA takes final action to address the risks of a chemical
- State action on a chemical is temporarily "paused" when the EPA risk evaluation of the chemical is underway, but lifted when EPA:
  - completes the risk evaluation, or
  - misses the deadline to complete the risk evaluation

Summary and Participation

The amendments and updates to TSCA potentially have a significant impact on improving standards for workplace chemical safety. It is critically important that all stakeholders engage with EPA in crafting effective processes and regulations. The first step is participating in EPA's prioritization and risk assessment process determination. Check the TSCA website frequently: *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act*

1 See 15 U.S.C. § 2601.
2 *https://www.osha.gov/dsg/annotated-pels/index.html* accessed on 8/29/16
3 The permissible exposure limit (PEL or OSHA PEL) is a legal limit expressed for exposure of an employee to a chemical substance, usually expressed in an 8-hour time weighted average concentration in parts per million or mg/m^3. Some substances also have short term exposure limits (15 minute TWA) or ceiling limits.
4 *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-assesses-chemical-safety*
https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory, Accessed on 9/8/16
5 J Paul Leigh, Economic Burden of Occupational Injury and Illness in the United States, The Milbank Quarterly, Vol. 89, No. 4, 2011 (pp. 728–772)
6 Remarks by the President at the bill signing of the Frank R. Lautenberg Chemical Safety Act for the 21st Century, The White House, Office of the Press Secretary, June 22, 2016
7 Definition: Bioaccumulation is the accumulation of a toxic chemical in various tissues of a living organism: for example, the bioaccumulation of mercury in fish.

Aerial cotton defoliation spraying. *©2016 Earl Dotter*

Let's take this opportunity to reduce occupational disease!