# From PELs to ECELs

.....how did we get here and where are we going

Carter Ficklen, CIH, CSP



## Background





















# **Langley Research Center**

NASA's Langley Research Center is revolutionizing aviation, expanding our understanding of the Earth's atmosphere, and developing innovative technology for space exploration.

Hampton, Virginia

FOUNDED July 17, 1917



## in·dus·tri·al

#### /inˈdəstrēəl/ 🐠

adjective

 of, relating to, or characterized by industry. "a small industrial town" synonyms: manufacturing, factory; More

noun

1. shares in industrial companies.













#### hy∙giene /ˈhī.jēn/ -⊕

noun

conditions or practices conducive to maintaining health and preventing disease, especially through cleanliness.

"poor standards of food hygiene"

synonyms: cleanliness, sanitation, sterility, purity, disinfection; More





ndustrial nyglene is generally defined as the art and science dedicated o the anticipation, recognition, evaluation, communication and control of environmental stressors in, or arising from, the work place that may result in injury, illness, impairment, or affect the well being of workers and members of the community ...

Nhat is Industrial Hygiene? www.ors.od.nih.gov/.../technical\_branch\_ih.asp... National Institutes of Health ▼













Robert F. Furth gott



![](_page_9_Picture_0.jpeg)

![](_page_9_Picture_1.jpeg)

#### Edward Cornish National Lead Company

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![](_page_11_Picture_0.jpeg)

the tragic tale of wittenoom, western australia

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![](_page_11_Picture_3.jpeg)

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![](_page_13_Picture_0.jpeg)

Health and Safety Act 1974 Health and Safety Law Health and Safety Law

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![](_page_13_Picture_3.jpeg)

![](_page_13_Picture_4.jpeg)

"The Congress, the Administration and the public all share a profound commitment to the rescue of our natural environment, and the preservation of the Earth as a place both habitable by and hospitable to man."

#### **President Richard Nixon**

President Nixon signs the Occupational Safety and Health Ac December 29, 1970, which was enacted on April 28, 1971.

#### Environmental Protection Act Signed December 2, 1970

![](_page_14_Picture_4.jpeg)

Twins?

![](_page_14_Picture_6.jpeg)

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"Measurement requires a reference point, and in the situations, we are concerned with, this reference point should be an OEL."

Harry Ettinger, Smyth Award Lecture, 2011

## The History and Biological Basis of Occupational Exposure Limits for Chemical Agents

Dennis J. Paustenbach Ph.D., CIH, DABT, Dallas M. Cowan Ph.D., Jennifer Sahmel CIH

First published: 14 February 2011 | https://doi.org/10.1002/0471435139.hyg041.pub2

## Early Exposure Limits

- Occupational Exposure Limits (OELs) are thought to have begun with reports published in 1883 by Max Gruber of Germany
  - Studied the effects of carbon monoxide at varying air concentrations by exposing <u>both himself</u> and laboratory animals
  - His conclusions reflected the relative imprecision of then available analytical methods

![](_page_17_Picture_4.jpeg)

 The boundary of injurious action of carbon monoxide lies at a concentration in all probability of 500 parts per million, but certainly not less than 200 parts per million.....

![](_page_17_Picture_6.jpeg)

## Early Exposure Limits

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# 0

#### **Bureau of Mines - 1921**

Described odor and irritation thresholds of 33 substances frequently encountered in workplaces and mines

#### ACGIH - 1946

Included 132 specific chemicals and X-rays Initially called Maximum Allowable Concentration – updated to Threshold Limit Value in 1956

## The OG of OELs

- The first set of ACGIH Limits relied mainly on data originally compiled in 1945 by Warren Cook
  - along with a smaller number of standards established by the Z-37 committee of the American Standards Association (now known as ANSI)
- Cook's list, which included 132 specific chemicals plus X-rays
  - derived from exposure limits that had been earlier recommended by the American Standards Association, U.S. Public Health Service and six states (California, Connecticut, Massachusetts, New York, Oregon, and Utah).

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![](_page_20_Picture_0.jpeg)

OSHA PELs, or Permissible Exposure Limits, are regulations that establish the acceptable amount or concentration of a substance in the air in the workplace. They are intended to protect workers from adverse health effects related to hazardous chemical exposure.

![](_page_20_Picture_2.jpeg)

Of the thousands of chemicals used in workplaces, OSHA has PELs for less than 500.

 $\Theta$ 

Many of the PELs have not been updated since 1971, and current scientific data suggests that, in many instances, the outdated PELs are not sufficiently protective of worker health.

![](_page_20_Picture_6.jpeg)

In 1989, OSHA attempted to update or set new PELS for more than 350 chemicals in a single rulemaking. Although OSHA presented analyses of the risks associated with these chemicals, as well as the feasibility and economic impacts, the analyses were not as detailed as those for individual rulemakings. The entire rulemaking was ultimately vacated by the Court.

![](_page_20_Picture_8.jpeg)

Workers are essentially covered by the same PELs as they were 40 years ago and, while OSHA has been given no new tools to control workplace exposures, it has had to conduct increasingly resource-intensive analyses that have slowed the PEL rulemaking process to a crawl. Since 1971, OSHA has been successful in establishing or updating PELs for only about 30 chemicals

![](_page_21_Picture_0.jpeg)

#### How many OSHA standards mention "Certified Industrial Hygienist"?

## Asbestos

There has been more rulemaking activity involving asbestos than any other hazard regulated by OSHA.

 Between 1971 and 1994, OSHA issued two emergency temporary standards, three major notices of proposed rulemaking, three final rules, and 31 Federal Register notices related to asbestos.

The final asbestos rule issued in June 1972 was the OSHA's first comprehensive standard.

- This regulation reduced the permissible exposure limit (PEL) to an eight-hour TWA of 2 f/cc, with a ceiling of 10 f/cc.
- The standard became fully effective in July 1976

## What is TSCA

The <u>Toxic Substances Control Act</u> (TSCA) was passed by Congress in September 1976 (House vote 319-45 and Senate vote 60-13) and signed into law by President Gerald Ford on October 11, 1976. The push to regulate toxic substances began in 1971 when the President's Council on Environmental Quality released a report on Toxic Substances and noted that there was a need for comprehensive legislation that would identify and control potentially dangerous chemicals.

#### Why TSCA?

- In the 1970s, Michigan experienced a chemical contamination crisis involving polybrominated biphenyls (PBBs):
  - In 1973, the Michigan Chemical Company accidentally shipped bags of PBB to a livestock feed plant
  - The PBB was mixed into animal feed and distributed to farmers across Michigan
  - Millions of Michiganders ate contaminated food, including beef, chicken, pork, milk, and eggs
  - The state enrolled about 6,000 people in a registry to track their health

![](_page_24_Picture_6.jpeg)

# TSCA also brought the *gift* of AHERA to the IH profession

# Message from the EPA administrator Lee Thomas (that is potentially the precursor of why you and I are here today....)

![](_page_26_Picture_1.jpeg)

I am pleased that President Reagan has today signed into law the Asbestos Hazard Emergency Response Act of 1986. The Act directs EPA to develop a regulatory framework to require schools to inspect their buildings for asbestos and take appropriate abatement actions using qualified, accredited persons for inspection and abatement.

![](_page_26_Picture_4.jpeg)

EPA believes that the Asbestos Hazard Emergency Response Act represents a positive step toward protecting the estimated 15 million students and 1.4 million employees who are potentially exposed to friable asbestos-containing material in 35,000 schools

## Growth

#### **AIHA National Membership**

- 1940 160
- 1950 620
- 1960 1,100
- 1970 1,600
- 1980 5,000
- 1990 8,500

![](_page_28_Picture_0.jpeg)

American Industrial and Environmental Health Association

AIEHA

History of AIHA from

By a mere handful of votes, a ballot initiative to change AIHA's name to the American Industrial and Environmental Health Association fails to AIHA website achieve the necessary two-thirds approval of eligible voting members.

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![](_page_28_Picture_6.jpeg)

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Occupational Health, Safety and Environment Association

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#### Name Change for AIHA Nixed

1999 EHS Today

It's little si illegal dru pool of jol Gregg LaBar	urprise thang use, and b seekers.	t 18- to 34 the manu	l-yea Ifacti	r-olds are at the heart o uring industry tradition	of a nationwide increase in ally draws heavily from this Mar 7, 1999
EMAIL	in share	y Tweet	G+I	Recommend	COMMENTS
A vote to c to gain the asked to cl Environme	hange the n two-thirds hange the n ent Associat	ame of th majority ame of the tion.	e Am vote r e orga	erican Industrial Hygier required to pass. Membe mization to the Occupati	ne Association (AIHA) failed ers of the association were ional Health, Safety and
The vote c that the Al	ame about l IHA name d	because th lid not ref	ere h lect ti	as been a growing conce ne expanding nature of t	ern among some members heir duties or education.
AIHA Pres name that our board: add service	ident Jame has served continue to es in the are	s C. Rock, us well for provide t as of safe	Ph.E near insur ty and	)., said, "Our members v rly 60 years [They] ha passed member services d the environment."	roted to retain the proud ave sent a strong message to s for industrial hygiene and

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Environment, Health and Safety Conference and Exposition - EHSce

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![](_page_30_Picture_3.jpeg)

![](_page_30_Picture_4.jpeg)

![](_page_30_Picture_5.jpeg)

The abyss of "environmental" and "workplace" exposures

Led to a lot of distraction, but a lot of growth in the profession and some amazing cocktail parties

![](_page_31_Figure_2.jpeg)

Pause. Let's talk We are just warming up;-)

## REACH and GHS.....2007

#### REACH

- The Registration, Evaluation, Authorization, and Restriction of Chemicals regulation is a European Union (EU) law that requires manufacturers and importers of chemicals to register with the European Chemicals Agency (ECHA)
  - REACH's goal is to improve the identification of chemical substances' properties to better protect the environment and human health.

#### GHS

- The Globally Harmonized System of Classification and Labeling of Chemicals is a United Nations (UN) regulation that aims to reduce the regulatory burden for businesses that handle, store, and use hazardous chemicals.
- GHS was fully implemented in the EU, USA, and other countries in 2015.
  - The goal of GHS is to avoid using different symbols and labels for the same hazards around the world.

![](_page_34_Picture_0.jpeg)

Who is Lautenburg?

![](_page_34_Picture_2.jpeg)

June 22, 2016

![](_page_35_Picture_0.jpeg)

Are you aware that the 2016 updates to TSCA are significant in how chemicals are used in the workplace?

![](_page_35_Picture_2.jpeg)

If so, when did you become aware of this?

![](_page_36_Picture_0.jpeg)

C Play Again

**Played Today** 

On June 26, 2024, B&C, along with the Environmental Law Institute and the George Washington University Milken Institute of Public Health, sponsored the all-day virtual conference, TSCA Reform — Eight Years Later. The quality of the

# Lautenburg - 2016

- Frank R. Lautenberg Chemical Safety for the 21st Century Act
  - This bill amends the Toxic Substances Control Act (TSCA) to revise the process and requirements
  - Evaluating and determining whether regulatory control is warranted for manufacturing, distributing, processing, using, and disposing of chemicals.
  - Revises several provisions in TSCA, including those relating to:
    - chemical testing
    - review and regulation of new chemicals, <u>new uses of</u> <u>existing chemicals</u>, and existing chemicals
    - information reporting
    - confidential business information (CBI)
    - preemption of state regulations
    - fees

What is EPA's authority for taking this action?

- Under TSCA section 6(a) (<u>15 U.S.C. 2605(a)</u>), if the EPA determines through a TSCA section 6(b) risk evaluation that a chemical substance 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 to the risk evaluation, under the conditions of use
- EPA *must* by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

OSHA	EPA (TSCA)
Mission is "to assure safe and healthful working conditions for <b>working men</b> and <b>women</b> "	Mission is to "protect human health and the environment". Includes susceptible and highly exposed populations.
Risk evaluation is based on " <b>the extent</b> <b>feasible</b> " (economic and technical)	"determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other non-risk factors"
"Significant risk" – 1 in 1,000. <b>Defined</b> by the U.S Supreme Court	"Unreasonable risk" – <b>Not Defined</b> by TSCA
Some exposure limits have residual risk (may be significant)	Goal is for exposure limits to eliminate "unreasonable risk"

## TSCA Changes (Section 6) Under Lautenburg

Directs EPA to "eliminate unreasonable risk" to health and environment from existing chemicals

- Designates hazardous chemicals as "high-priority" – list of >50 chemicals is growing over time
- Evaluates risks to human health and environment, including risks to workers
- Develops risk management rule to eliminate any identified unreasonable risks

EPA has several options for risk management, including the following potential obsolescence drivers:

- Prohibit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit or otherwise restrict for particular use or above a specific concentration in products
- Set exposure limits
  - Existing Chemical Exposure Limits ECELs
    - Drastically lower than OSHA PELs and ACGIH TLVs
      - Producers and users may find difficult to meet

# "including risks to workers"

### Chemicals to be regulated under Section 6

Regulation Development Ongoing	Slated for Risk Evalu	Being Considered for Rulemaking	
Rules that are finalized: Methylene Chloride – May 2024 Asbestos, Part 1 Rules have been proposed: Perchloroethylene Carbon Tetrachloride Trichloroethylene Rules soon will be proposed: N-Methyl Pyrrolidone N-Methyl Pyrrolidone N-Methyl Pyrrolidone Sisk management rules in development: Cyclic Aliphatic Bromide Cluster (HBCD) Pigment Violet 29 Revisions to final rules proposed: 2,4,6-Tris(tert-butyl) phenol (2,4,6-TTBP) Decabromodiphenyl ether (DecaBDE) Hexachlorobutadiene (HCBD) Pentachlorothiophenol (PCTP) Phenol, isopropylated phosphate (3:1), (PIP (3:1))	<ul> <li>Draft risk evaluation published:</li> <li>1,4 Dioxane</li> <li>Tris(2-chloroethyl) phosphate (TCEP)</li> <li>Draft risk evaluations expected in the short term:</li> <li>Asbestos, Part 2</li> <li>Formaldehyde</li> <li>Draft risk evaluations expected in the mid term:</li> <li>1,1-Dichloroethane</li> <li>1,2-Dichloroethane</li> <li>1,3-Butadiene</li> <li>Butyl benzyl phthalate (BBP)</li> <li>Dibutyl phthalate (DBP)</li> <li>Dicyclohexyl phthalate</li> <li>Diisobutyl phthalate (DIBP)</li> <li>Diisodecyl phthalate (DIDP)</li> <li>Diisononyl phthalate (DINP)</li> <li>Octamethylcyclotetra-siloxane (D4)</li> <li>trans-1,2-Dichloroethylene</li> </ul>	<ul> <li>Draft risk evaluations expected in the longer term:</li> <li>Ethylene dibromide</li> <li>o-Dichlorobenzene</li> <li>Octahydro-tetramethyl-naphthalenylethanone chemical category (OTNE)</li> <li>Phosphoric acid, triphenyl ester (TPP)</li> <li>Phthalic anhydride</li> <li>1,1,2-Trichloroethane</li> <li>1,2-Dichloropropane</li> <li>1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)</li> <li>4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)</li> <li>p-Dichlorobenzene</li> <li>EPA currently collecting information on uses of:</li> <li>Acetaldehyde</li> <li>Acrylonitrile</li> <li>Benzenamine</li> <li>Vinyl chloride</li> <li>4,4'-Methylene bis(2-chloroaniline)</li> </ul>	<ul> <li>4-tert-Octylphenol(4-(1,1,3,3-tetramethylbutyl)-phenol</li> <li>Benzene</li> <li>Bisphenol A</li> <li>Ethybenzene</li> <li>Hydrogen fluoride</li> <li>N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine (6-PPD)</li> <li>Naphthalene</li> <li>Styrene</li> <li>Tribromomethane</li> <li>Triglycidyl isocyanurate</li> </ul>

## 8 years since Lautenburg was signed

#### First final rules summer 2024?

#### Why the slow progress?

- 2016.....
- 2020.....
- 2024.....

### Round One

Chemical	<b>OSHA PEL</b>	Proposed ECEL
Asbestos	0.1 fibers/cc	0.005 fibers/cc (alternative option proposed to a ban)
Methylene Chloride	25 ppm	2 ppm
Perchloroethylene (PCE)	100 ppm	0.14 ppm
Carbon Tetrachloride (CTC)	10 ppm	0.03 ppm
TCE	100 ppm	0.0011 ppm

## Compliance

Generally regulating any product/article that contains greater than 0.1% of the TSCA chemical

#### Applies to "Owners or Operators" defined as:

• "Any person who owns, leases, operates, controls, or supervises a workplace covered by this part."

#### Non-compliance risk:

- Penalties of \$48,512 (civil) / \$50,000 (criminal) per day per violation
- Criminal enforcement for knowingly or willfully violating any provision (penalties and/or imprisonment)
- Regulations enable EPA to remove chemical use exemptions if owner or operator is non-compliant with restrictions (e.g. failure to achieve workplace exposure limits or maintain records)
  - "To be eligible for the exemptions established in this section, regulated parties must comply with all conditions promulgated"

**Compliance Guide** 

![](_page_46_Picture_1.jpeg)

A GUIDE TO COMPLYING WITH THE 2024 METHYLENE CHLORIDE REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA) (RIN 2070-AK70)

Includes:

Includes Compliance Guidance on Prohibitions, Workplace Chemical Protection Program (WCPP), and Other Requirements

# Methylene Chloride

OELs for Methylene Chloride		
Organization	TWA OEL (ppm)	
EPA ECEL	2	
EU DNEL	50.7	
EU SCOEL	100	
ACGIH TLV	50	
NIOSH REL		
OSHA PEL	25	

#### Compliance Timelines\* for the Workplace Chemical Protection Program

Initial Monitoring	Exposure Limits and Dermal Protections	Exposure Control Plan	Other Monitoring
Complete initial monitoring. Demarcate regulated area within 3 months of initial monitoring data. Provide respiratory protection within 3 months of initial monitoring data but no later than 15 months after final rule. Existing Facilities Before May 5, 2025 (360 days after final rule publication). New Facilities Within 30 days of initiating use.	Ensure methylene chloride inhalation exposures do not exceed the ECEL (2 ppm as an 8-hr TWA) and EPA STEL (16 ppm as a 15-min TWA) for all potentially exposed persons. Provide respiratory and/or dermal protection if applicable. <u>Existing Facilities</u> Before August 1, 2025 (450 days after final rule publication). <u>New Facilities</u> Within 90 days of initial exposure monitoring.	Develop and implement an exposure control plan. Notify potentially exposed persons of completion of exposure control plan within 30 days of its completion. Provide requested records by a potentially exposed person within 15 days of request. <u>Existing Facilities</u> Before October 30, 2025 (540 days after final rule publication). <u>New Facilities</u> Update as necessary, but at least every five years.	Periodic Monitoring Conduct at a minimum every 5 years, but could occur as frequently as every 3 months, dependent upon initial monitoring results. <u>As Needed Monitoring</u> Conduct additional monitoring after any change that may introduce additional sources of methylene chloride exposure or result in a change in exposure levels.

## Let's Talk

Are these changes a good or bad for the IH profession?

Did non-OSHA regulations create the 1980-2000ish growth?

For the industrial use and disposal of chrysotile asbestos-containing oilfield brake blocks, EPA found unreasonable risk to workers and ONUs from chronic inhalation exposure to chrysotile asbestos based on a published literature (Section 5.2.1 of the Risk Evaluation).

For the commercial use and disposal of aftermarket automotive chrysotile asbestos-containing brakes/linings and other vehicle friction products (except for the NASA Super Guppy Turbine aircraft use), EPA found unreasonable risk to workers from chronic inhalation exposure to chrysotile asbestos based on published literature and OSHA data (Section 2.3.1.8.1 of the Risk Evaluation). EPA determined, based on exposure data provided by NASA to EPA (Section 2.3.1.8.2 of the Risk Evaluation), that the use and disposal of chrysotile asbestos-containing brakes for NASA's Super Guppy Turbine aircraft did not present an unreasonable risk of injury to health or the environment.

![](_page_49_Picture_2.jpeg)

NASA's Super Guppy aircraft arrives at NASA's Marshall Space Flight Center in Huntsville, Alabama, Aug. 10. The specialized aircraft can carry bulky or heavy cargo that cannot fit on traditional aircraft.

Credits: NASA/Charles Beason

romopropane

# ECEL – 0.05 ppm

# ACGIH – 0.1 ppm (2013)

# CAL/OSHA – 5 ppm

# Federal OSHA – No PEL

### bromopropane

![](_page_51_Picture_1.jpeg)

(B) All measurements that may be necessary to determine the conditions (*e.g.*, work site temperatures, humidity, ventilation rates, monitoring equipment type and calibration dates) that may affect the monitoring results.

Certain entities that would be permitted to continue to manufacture, process, distribute, use, or dispose of 1-BP would be required to implement a WCPP and would have to meet the provisions of the program for continued use of 1–BP. A transition to a WCPP may require persons with specialized skills such as an engineer or health and safety profession. Instead of implementing the WCPP themselves, entities that use 1–BP may choose to contract with another entity to do so. Records would have to be maintained for compliance with a WCPP, as applicable. While this recording activity itself may not require a special skill, the information to be measured and recorded may require persons with specialized skills, such as an industrial hygienist. . . . .

![](_page_52_Picture_0.jpeg)

If you are interested in discussing this presentation or would like to have it for your organization, please email <u>carterficklen@gmail.com</u>