

# **Hierarchy of OELs: Where Have We Been? Where Do We Go?**



**Chris Laszcz-Davis, MS, CIH, FAIHA, REPA**  
The Environmental Quality Organization, LLC

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# Presentation Highlights

- Historical Evolution
- OEL Setting Processes Today
  - Traditional, threshold approach
  - Newer ideas
    - Risk based
    - Band based

# Global Evolution

- Pre 1900
- Early 1900s
- 1940s-1970s
- Post 1970s



# Today's OEL Processes

- **US Environment (1920s start)**
  - 1927 Walsh Healey Act
  - 1946 ACGIH
  - 1971 OSHA
  - 1971 NIOSH
  - 1984 AIHA
  - State Level Efforts

# Today's OEL Processes

- **European Union**

- ACGIH TLVs a starting point
- SCOEL (Scientific Committee on OELs)
- Individual country efforts...eg UK
  - Control of Substances Hazardous to Health Regulations (COSHH) from 1988
  - 1980-2005, annual update, ~ 500 WELs
  - Since 2005, new WELs-implement IOELVs
- 2007 REACH

# REACH

- EU effort
- 2007 Regulation on Registration Evaluation & Control of Chemicals (REACH)
- Prescribed DNEs
- Include EH&S risks
- Lower than traditional OELs

# China's OEL Development

- Great Wall



# China's OEL Process

- **1950s**, Republic of China published first exposure standards.
- **1990s**, Emphasis on Occupational Disease Prevention
- **Today**, 339 Conservative Compulsory OELs
- **Today**, Health is Primary Consideration
- **Today**, Strive for Economic & Technological Feasibility



# Comparison: China's OELs, TLVs and WELs

Hazardous Agents	China's OEL PC-TWA (mg/m <sup>3</sup> )		ACGIH TLV TWA (mg/m <sup>3</sup> )	UK OEL TWA (mg/m <sup>3</sup> )
Methanol	25		262	266
Lead, fume & dust	0.03, fume 0.05, dust		0.05	0.15
n-Hexane	100		176	72
Dimethylformamide	20		29.9	15
Crystalline Silica/ Quartz (respirable)	10%≤free SiO <sub>2</sub> ≤50%	0.7	0.025	0.1
	50%<free SiO <sub>2</sub> ≤80%	0.3		
	free SiO <sub>2</sub> > 80%	0.2		
Noise (8hr per day)	85dbA		85dbA	85dbA

# Democratic Republic of India



# India's OEL Processes

- Safety Focus and Huge Unorganized Workforce
- Lack of Occupational Disease Data
- Meager Spending on Public Health
- No Coherent National Policy
- **1948** Factories Act, Permissible Limits of Exposure of Chemical and Toxic Substance

# India's Permissible Limits of Exposure

<b>Substance (mg/m<sup>3</sup>)</b>	<b>ACGIH</b>	<b>UK OEL</b>	<b>INDIA</b>
<b>Asbestos</b>	<b>0.1 f/cc</b>	<b>0.1 f/cc</b>	<b>0.1 f/cc</b>
<b>Benzene</b>	<b>1.6</b>	<b>3.25</b>	<b>1.5</b>
<b>Beryllium</b>	<b>0.002</b>	<b>0.002</b>	<b>0.002</b>
<b>Carbon Monoxide</b>	<b>28</b>	<b>35</b>	<b>55</b>
<b>Hexavalent Cr (Sol)</b>	<b>0.05</b>	<b>0.05</b>	<b>0.05</b>
<b>Hexavalent Cr (Insol)</b>	<b>0.01</b>		<b>0.05</b>
<b>Manganese fume</b>	<b>0.2</b>	<b>0.5</b>	<b>1.0</b>
<b>Total Dust</b>	<b>10</b>	<b>10</b>	<b>10</b>
<b>Vinyl Chloride</b>	<b>2.5</b>	<b>7.8</b>	<b>10</b>



# Latin America Overview



# Latin America General Information

**Official Language: Spanish and Portuguese most spoken**

**Number of Countries: 43**

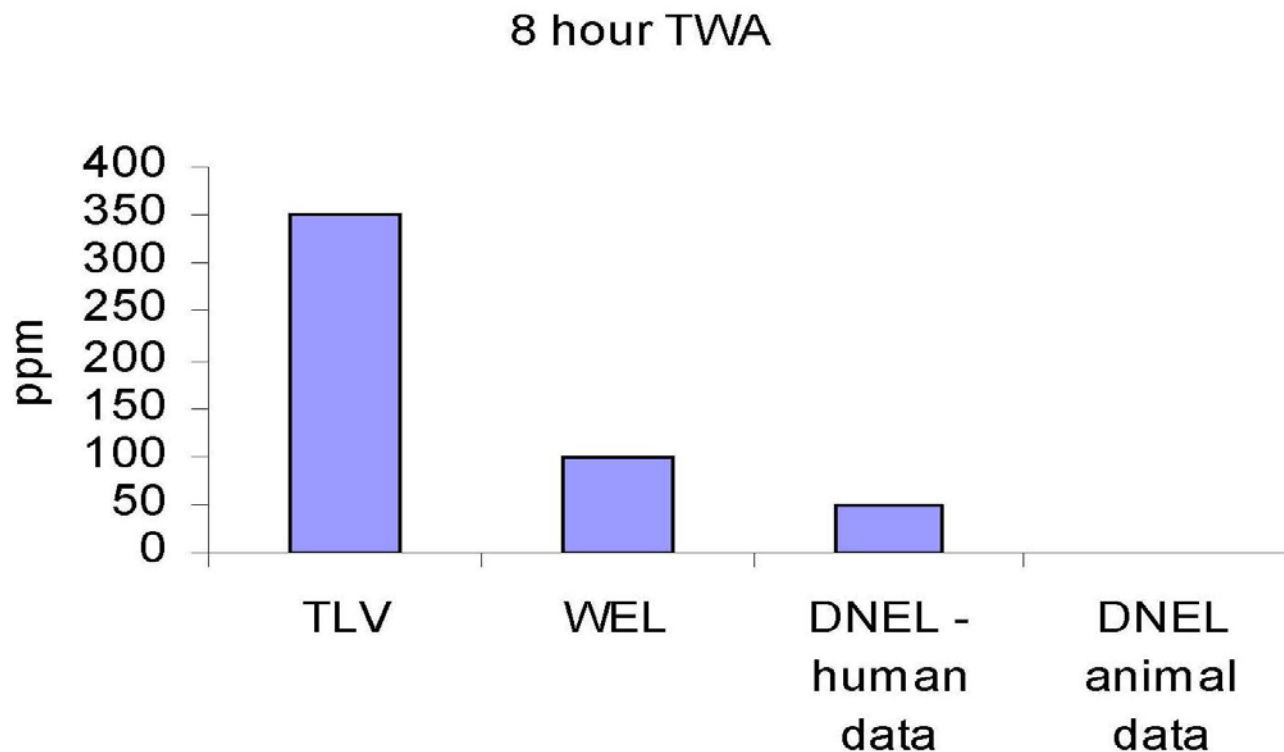
**Social Inequality is a major roadblock.  
25% of the population lives with less than \$2 / day.**

**Brazil leading country economically,  
followed by Mexico, Argentina and Colombia**

# Latin American Countries

COUNTRY	EXPOSURE LIMITS	DATE
BRAZIL	ACGIH	ACTUAL
ARGENTINA	ACGIH	ACTUAL
CHILE	ACGIH	ACTUAL
COLOMBIA	ACGIH	ACTUAL
MEXICO	ACGIH	1998
VENEZUELA	ACGIH	2001 (Under review)

# Derivation of DNELs: 1,1,1 Trichloroethane

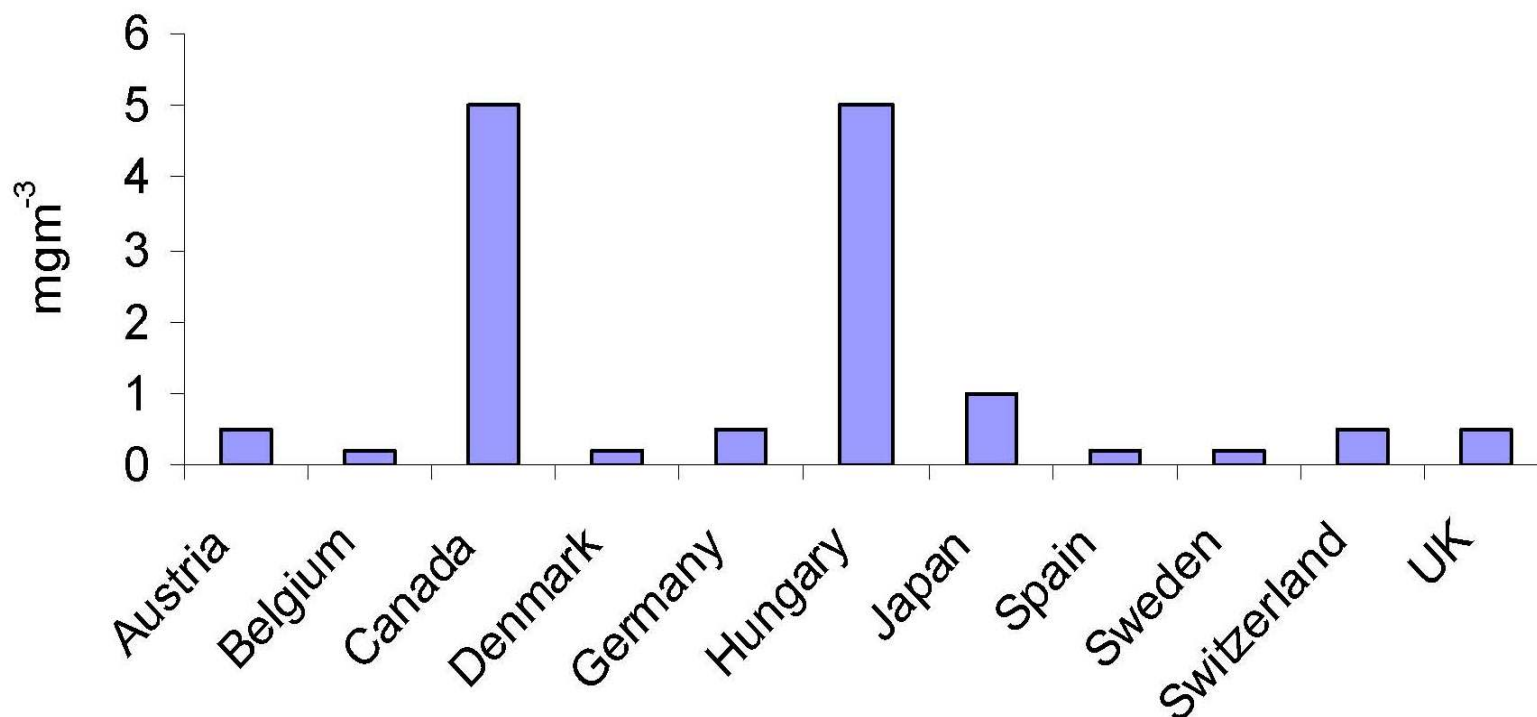


Source: Alison Searl, PhD, Director of Analytical Services, IOM Consulting, *Some Current Approaches to OEL Setting in the EU*, BOHS, Occupational Hygiene Conference, Thistle Hotel, Bristol, 2008.



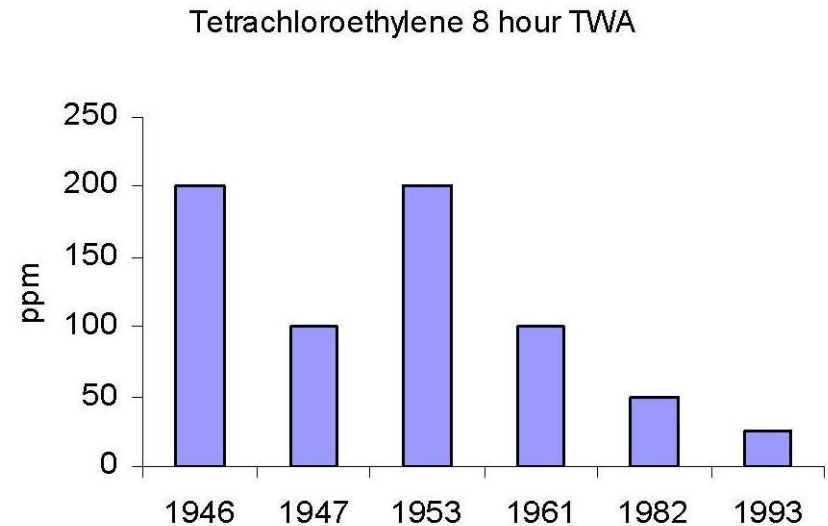
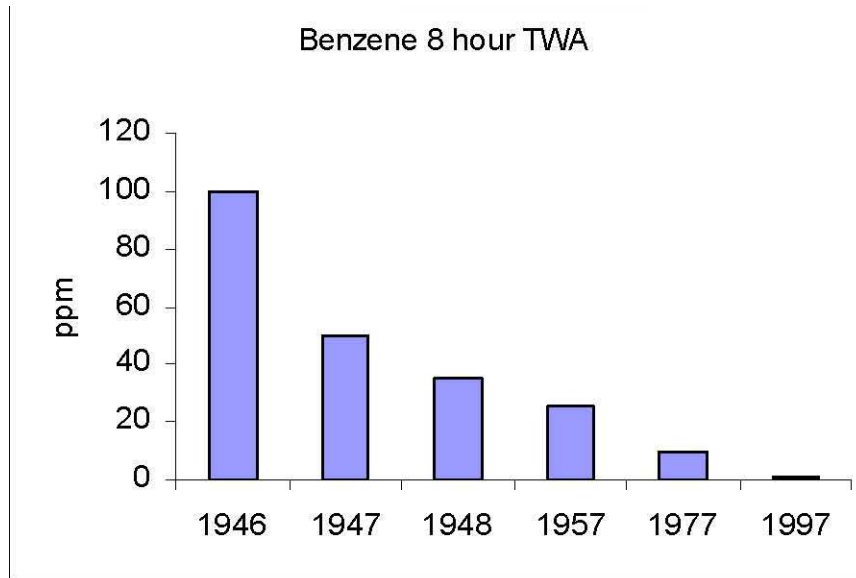
# Various OELs for Manganese

Manganese 8 hour TWA



**Source:** Alison Searl, PhD, Director of Analytical Services, IOM Consulting, *Some Current Approaches to OEL Setting in the EU*, BOHS, Occupational Hygiene Conference, Thistle Hotel, Bristol, 2008.

# ACGIH Threshold Limit Values



**Source:** Alison Searl, PhD, Director of Analytical Services, IOM Consulting, *Some Current Approaches to OEL Setting in the EU*, BOHS, Occupational Hygiene Conference, Thistle Hotel, Bristol, 2008.

# OEL Global Challenges

- # of chemicals in commerce
- OELs not well understood
- New emphasis--full cycle risks
- Not everyone values OELs
- Basic data--quality & reliability
- Resources and expertise

# OEL Global Challenges

- Varied risk determination processes...varied protection levels
- Measurement method issues
- REACh--new playing field
- OELs not set at zero risk, but *acceptable* risk.

# Critical Questions

- Do OELs have value today?
- Who should participate in OEL setting processes?
- Are there alternatives to traditional OELs?

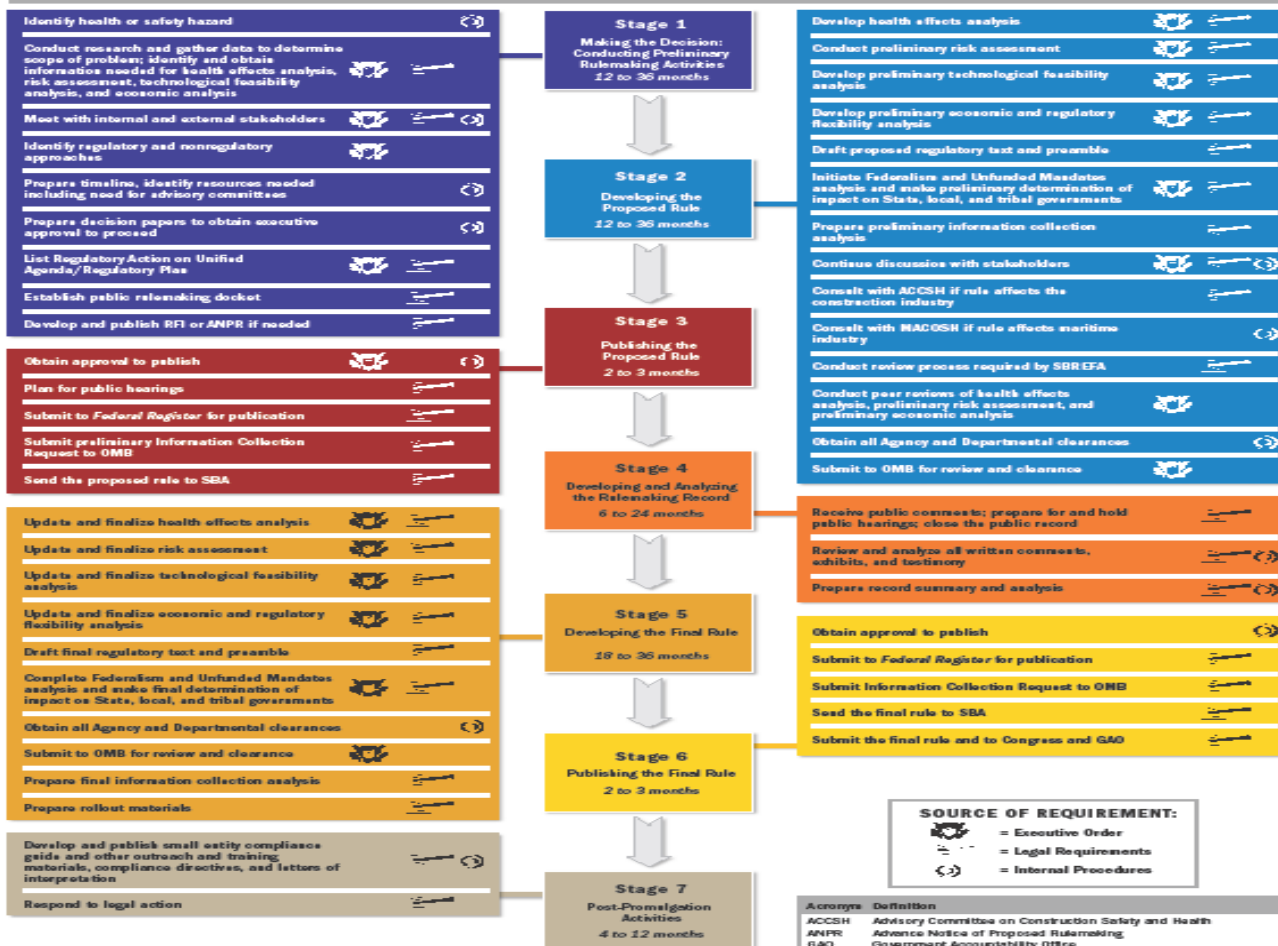
# Do OELS Have Value?

- Risk assessments
- Respirator selection
- Exposure priority setting
- Purchase decisions
- Control recommendations for product consumers

# Who Should Participate?

- Neutral 3rd party?
- International body?
- Role of U.S. organizations, federal agencies, state agencies or professional organizations?

# THE OSHA RULEMAKING PROCESS





# Federal Process Rulemaking Steps

- Step # 1: Conduct Preliminary Rulemaking Activities (12-36 months)
- Step # 2: Develop Proposed Rule (12-36 months)
- Step # 3: Publish Rule (2-3 months)
- Step # 4: Develop & Analyze Rulemaking Record (6-24 months)
- Step # 5: Develop Final Rule (18 -36 months)
- Step # 6: Publish Final Rule (2-3 months)
- Step # 7: Post-Promulgation Activities (4-12 months)
- **Timeline: 4.5 - 12. 5 years**

# Alternatives: to Traditionally-Derived OELs?

- Occupational Exposure Bands
- Quantitative or Risk Based OELs
- Risk Based Environmental Limits

# Hierarchy of OELs

**Most Extensive Data Requirements**  
(human epidemiology studies) > quality, > certainty

**Quantitative  
Health Based  
OELs**

## Health Based OELs

- Regulatory, Authoritative
- Traditional (TLVs, MAKs, WEELs, PELs, MACs, RELs)

As more toxicological & epidemiological data is available, one moves up the OEL Hierarchy.

## Moderate Data Requirements

(*in vitro* and animal studies and anecdotal reports of human health effects) > quality, > certainty

## Working Provisional OELs

- internal company
- trade association
- vendor limits

## Prescriptive Process Based OELs

(REACH DNELs/DMELs)

**Least Data Requirements**  
(*in vitro* and animal studies)

## Hazard Banding Strategies

- Pharmaceutical banding
- Occupational exposure banding

# National Poll--Learnings

- Most Chemicals Not Have OELs
- Today, **Suite of OEL Setting Tools** Exist Globally
- **“Hierarchy of OEL”** Processes May Bridge Risk Assessment and Management Gaps

# National AIHA Engagement

- National AIHA-PEL Advisory Group formed 2.0 years ago.
- AIHA input to Federal-OSHA request.
- Support of NIOSH's Occupational Hazard Banding initiative.
- Upgrade of Hierarchy of OEL Tools.