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



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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

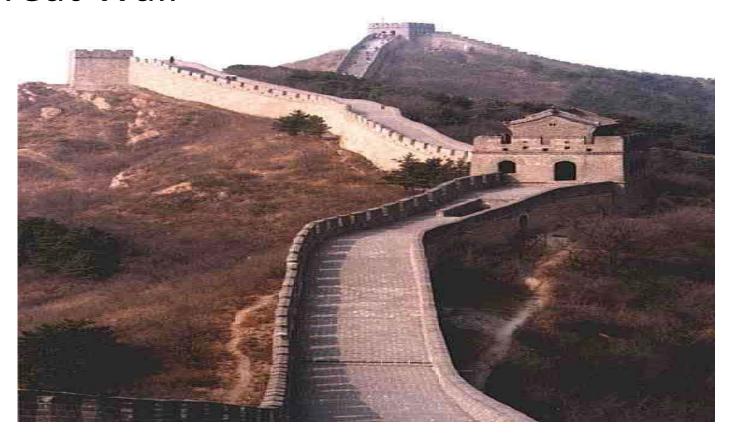
- ACGIH TLVs a starting point
- SCOEL (Scientific Committee on OELs)
- Individual country efforts...eg UK
  - Control of Substances Hazardous to Health Regulations (COSHH) from 1988
  - 1980-2005, annual update, ~ 500 WELs
  - Since 2005, new WELS-implement IOELVs
- -2007 REACh

#### **REACh**

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

# China's OEL Development

Great Wall



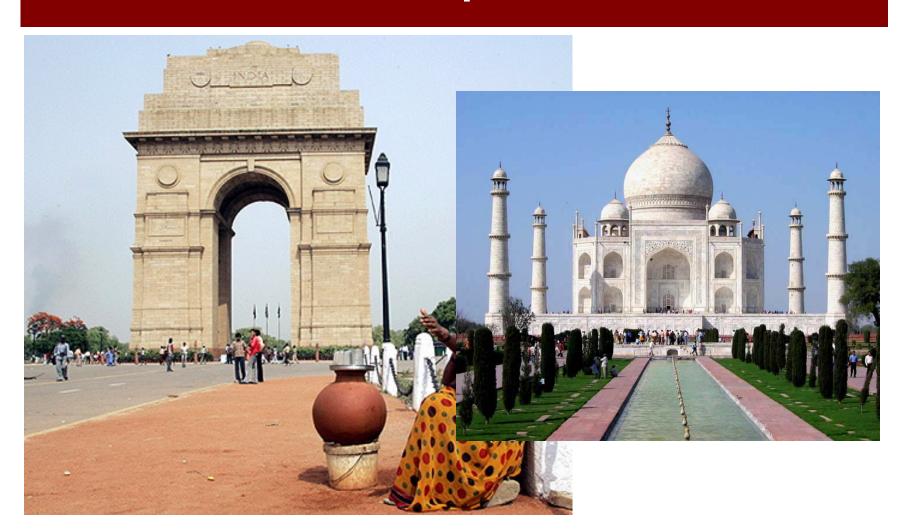
#### China's OEL Process

- **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 O PC-TW (mg/m³	A	ACGIHTLY TWA (mg/m³)	UK OEL TWA (mg/m³)
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
	I 0%≤free SiO <sub>2</sub> ≤50%	0.7		
Crystalline Silica/ Quartz (respirable)	50% <free SiO<sub>2</sub>≤80%</free 	0.3	0.025	0.1
	free ${ m SiO_2}{ m >}$	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

Substance (mg/m3)	ACGIH	UK OEL	INDIA
Asbestos	0.1 f/cc	0.1 f/cc	0.1 f/cc
Benzene	1.6	3.25	1.5
Beryllium	0.002	0.002	0.002
Carbon Monoxide	28	35	55
Hexavalent Cr (Sol)	0.05	0.05	0.05
Hexavalent Cr (Insol)	0.01		0.05
Manganese fume	0.2	0.5	1.0
Total Dust	10	10	10
Vinyl Chloride	2.5	7.8	10

## Latin America Overview



#### Latin America General Information

Official Language: Spanish and Portuguese most spoken

**Number of Countries: 43** 

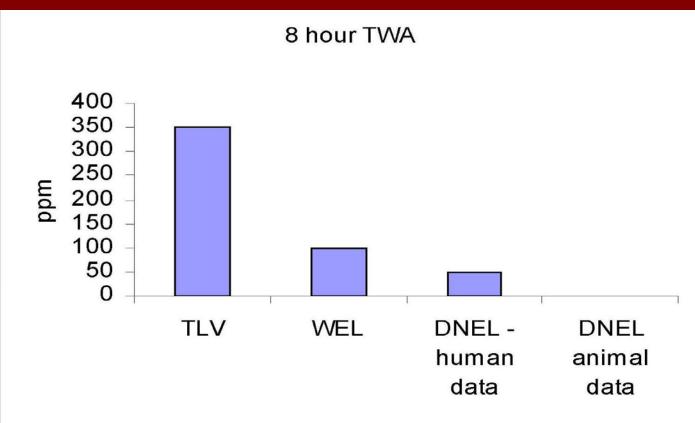
Social Inequality is a major roadblock. 25% of the population lives with less than \$2 / day.

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)

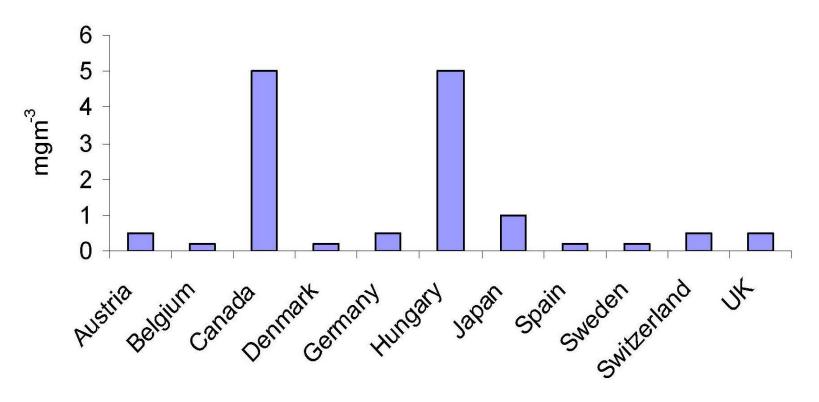
# Derivation of DNELs: 1,1,1 Trichloroethane



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.

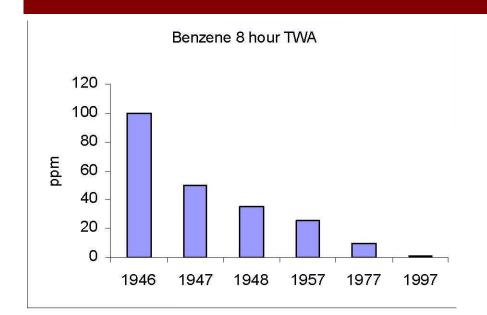
## Various OELs for Manganese

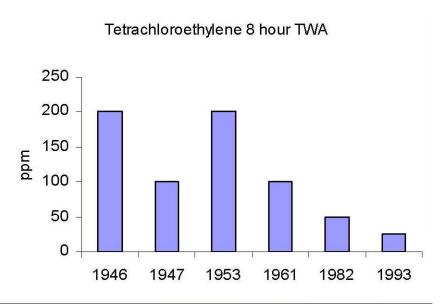
#### Manganese 8 hour TWA



**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?

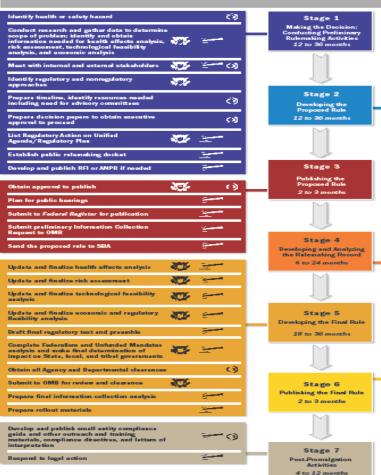
### Do OELS Have Value?

- 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



Dovelop health effects analysis	AL.	مسي
Conduct preliminary risk assessment	<b>17</b>	-
Dovelop profiminary technological feasibility analysis	47F	<del></del>
Develop preliminary ecosonic and regulatory flexibility analysis	N.	=
Braft proposed regulatory text and preamble		-
Initiate Federalism and Unfunded Mandates analysis and make preliminary determination of impact on State, local, and tribal governments	₩.	<del></del>
Prepara preliminary information collection analysis		
Continue discussion with stakeholders	AEK.	÷,©
Consult with ACCSH if rule affects the construction industry		<del></del>
Consult with MACOSH if rule affects maritime industry		(3)
Conduct review process required by SBREFA		-
Conduct review process required by SBREFA  Conduct peer reviews of health effects analysis, preliminary risk assessment, and preliminary economic analysis	40k	-
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Conduct peer reviews of health effects analysis, preliminary risk assessment, and preliminary economic analysis	\$C\$ \$C\$	
Conduct past reviews of health effects asalysis, prelimitary risk assessment, and prelimitary economic analysis Obtain all Agency and Departmental clearances		
Conduct peer reviews of health effects analysis, preliminary risk assessment, and preliminary economic analysis  Obtain all Agency and Departmental clearances  Submit to OMB for review and clearance		9
Conduct peer reviews of health effects analysis, prolininary risk assessment, and preferrinary economic analysis  Obtain all Agency and Departmental clearances  Submit to OMB for review and clearance  Receive public comments; prepare for and hold public hearings; close the public record  Review and analyse all written comments.		9
Conduct pear reviews of health effects analysis, prolininary risk assessment, and preliminary secondic analysis  Obtain all Agency and Departmental clearances  Submit to OMB for review and clearance  Receive public comments; prepare for and hold public hearings; close the public record  Review and analyse all written comments, exhibits, and testimory		9
Conduct pear reviews of health effects analysis, preliminary risk assessment, and preliminary section can share control of the		- O



#### SOURCE OF REQUIREMENT: O = Executive Order = Legal Requirements < a) = Internal Procedures

Acronyre Definition ACCSH Advisory Committee on Construction Safety and Health Advance Notice of Proposed Rulemaking MACOSH Martime Advisory Committee for Occupational Safety and Health OMB Office of Management and Evident Office of Management and Budget Request for Information Small Business Administration SBREFA Small Business Regulatory Enforcement Fairness Act

Directorate of Standards and Guidance | Revised: October 15, 2012.

# 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**

Quantitative
Health Based
OELs

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

#### **Most Extensive Data Requirements**

(human epidemiology studies) > quality, > certainty

#### **Health Based OELs**

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

#### **Moderate Data Requirements**

*in vitro* and animal studies and anecdotal reports on numan 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.