

**-OEL Setting  
Processes –  
North America**

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# ~1,500 OELs in North America

- Only a modest number of OELs available compared to total list of chemicals
  - More than **80,000** products in North American commerce

# North American OELs

- United States
  - ACGIH TLVs<sup>®</sup>
  - NIOSH RELs
  - OSHA PELs
  - AIHA WEELs
  - Manufacturer IHGs
  - EPA (NCELs)
  - Green Chemistry
- Canada
- Mexico

# North America OEL Criteria for “Durations”

- **TWA 8-hour** – Protects against chronic endpoints as well as prevents irritation
  
- **STEL** – Set when a substance is irritating to the workers to prevent peak exposures during the 8-hr workday
  1. any irritation
  2. chronic or irreversible tissue damage,
  3. dose-rate-dependent toxic effects, or
  4. narcosis of sufficient degree to increase the likelihood of accidental injury, impaired self-rescue, or materially reduced work efficiency.
  
- **Ceiling** – Set to protect against lethality or quick-acting point of contact toxins (e.g. asphyxiants, CNS depressants, or those that have steep dose-response profiles of toxicity)

# North American Skin Notations

- Skin Notation considered:
- when material is “DOT Corrosive”
  - when materials having a relatively low dermal LD<sub>50</sub> (i.e., 1000 mg/kg of body weight or less) would
  - when chemicals penetrate the skin easily (i.e., higher octanol–water partition coefficients), and
  - where extrapolations of systemic effects from other routes of exposure suggest dermal absorption may be important in the expressed toxicity

# United States

- OEL-Setting falls within six frameworks:
  - Occupational Safety & Health Administration (OSHA)
  - National Institutes of Safety and Health (NIOSH)
  - American Conference of Governmental Hygienists (ACGIH)
  - American Industrial Hygiene Association (AIHA)
  - State OSHA PELs
  - Environmental Protection Agency (EPA)
  - Some manufacturers and employers set limits in the absence of regulations

# OEL-Challenges in United States

- Regulatory OELs (with socio-political influence by regulation) is a level of “**acceptable risk**” and not true “threshold of toxic risk”
- **Litigation** in USA precludes development of additional PELs and TLVs and has slowed the WEELs
- Lack of Political Support
  - Various political administrations do not support adding government regulations such as PELs
  - USA budget to NIOSH has slowed the NIOSH REL development
- REACH – new default OELs in North America?
  - It will definitely force sharing of data globally

# ACGIH TLVs®

- ACGIH published its first list of 148 “Maximum Allowable Concentrations” (MACs) of air contaminants (MACs) in 1946.
- MACs became known as “Threshold Limit Values” (TLVs®) in 1950
  - Published in the “A.M.A. Archives of Industrial Hygiene and Occupational Medicine.”
- The first “*Documentation of the Threshold Limit Values*” was published in 1962 and is now into its seventh edition.
- The ACGIH TLV Committee continues to generate exposure limits for chemical substances with the total today approximating 700 TLVs®.

# ACGIH TLVs®

- No adjustment for socio-political impacts – true “threshold of toxic risk”
  - May not have an exposure monitoring method
  - Does not consider technical or economic feasibility to attain controls
  - Does not consider economic impact on employers
  - Does not require consideration to the value or appropriateness of setting an OEL
- Health-based OELs based on “Weight of Evidence”
  - NOAEL-basis with proper adjustments from data evidence
  - All Points of Departure considered
- Set
  - TWAs (full-shift), Ceiling (peak) and STEL (15-min task)
  - Notations: Skin and **SEN**sitizer
- Cancer designation by ‘classification’ (A1 – A5)

# ACGIH TLVs®

- TLVs are considered “guideline” OELs in the USA
- TLVs “are not developed for use as legal standards, nor are they intended to be fine lines between safe and hazardous concentrations.”
- However the TLV® process is:
  - the largest ongoing process for the revision and setting of chemical exposure limits,
  - is recognized internationally, and
  - often provides the starting place for other bodies setting OELs.

# ACGIH TLVs<sup>®</sup> Influence Globally

- For the last 65 years, multiple countries have adopted ACGIH TLVs either without change, or as their basis for national exposure limits.
  - Canada Provincial Regulations
  - Mexico
  - USA (only in Walsh-Healy-OSH Act 1970)
    - Required to be included for communication of hazards on SDSs
    - Rarely enforced in the USA

# Original OSHA PELs

## ■ 1970

- OSHA Act authorized the Secretary of Labor to adopt (within 2 years) any existing federal standards and national consensus standards

## ■ 1971

- OSHA adopted the 1969 Walsh-Healy Act Standards including the 1968 TLVs® as PELs

# PELs Today

- After 1971, OSHA must follow onerous rulemaking which must be:
  - Health-based using weight-of-evidence
  - Technical ability of employers to comply with the regulation
  - Economic and Social impacts must be considered
  - Public notice and comment
  - Justification for promulgating standards (benefit to the public versus the cost of compliance)
- 1989: ~1,500 PELs set in one regulation
- 1992: AFL-CIO won a lawsuit against OSHA for one PEL and the court reversed all 1989 PELs since they were not individually reviewed in the USA for all of the rulemaking requirements

# OSHA PEL-Setting Limitations

- OSHA's limited PEL-setting for 16 agents and 13 carcinogens since 1971 limited by:
  - 1992 ruling which requires individual substance reviewed singly according to the onerous rulemaking procedures
  - Political reservation by various administrations on impacts to industry and the economy →
    - Onerous process to ensure lack of over-regulation by government and allow for free capital system
- Litigation potential stifles initiatives to set PELs

# NIOSH RELs

## Recommended Exposure Limits

- NIOSH established within the Department of Health & Human Services (DHHS) by OSHA Act.
- In theory OSHA considers them in the regulatory process, although they have largely been ignored by OSHA.
- No regulations were issued based on the Criteria Documents
- During the 1988-89 period when OSHA undertook its PEL Project NIOSH derived RELs for a large number of substances for use in the new OSHA list
  - Was eventually overturned following lawsuits filed by both labor and industry
- Now focuses on National Occupational Research Agenda (NORA) in 1996,
  - NIOSH began focusing on non-REL partnership activities to apply research findings to exposure and risk minimization strategies.

# State OSHA PELs

- State OSHA organizations adopt Federal OSHA PELs or . . . . .

. . . set more current and stringent PELs for substances where new data exists

# AIHA WEELs

## Workplace Environmental Exposure Levels

- In 1984, the **AIHA** began development of WEELs when:
  - there was potential for significant worker exposure to substances that were not sold in large quantities & thus, not targeted by other OEL setting bodies
- The AIHA WEEL-setting process is consistent with those of other non-government OEL-setting bodies (e.g., TLV, MAK, etc.).
- There are currently about 120 WEELs for agents that otherwise would not have OELs.
- WEEL process uses the Hazard Banding Process (validated on ~700 TLVs and ~100 WEELs) to guide the data categorization for initial discussions by the Committee

# EPA NCELs

## New Chemical Exposure Limits

- EPA TSCA Section 5(e)
  - Pre-manufacturing Notices (PMN) often require hazard communication and worker protection in the facilities in a ‘Significant New Use Rule’ (SNUR)
    - Set a 8-hour TWA limit
    - “Sunset” provision for required toxicology data upon which a more robust OEL can be set (usually <5 years)
- Not helpful for the thousands of chemicals already in commerce which don’t have the required data!

# Canada OELs

## Each Province Sets OELs

- Alberta
  - Occupational Health & Safety Code, Schedule 1, Table 2, July 2009
  - 882 Substances
  
- New Brunswick, Nova Scotia, Manitoba
  - ACGIH TLVs with the exception that carcinogens are given a zero exposure level “so far as is reasonably practicable”
  
- Saskatchewan
  - Occupational Health and Safety Regulations, 1996, Table 21, as amended through May 6, 2009
  - 742 Substances
  
- Quebec
  - Based on TLVs: Règlement sur la santé et la sécurité du travail, v. S-2.1, r.19.01, as amended through December 12, 2008
  - 724 Substances
  
- Ontario
  - Reg. 833, Control of Exposure to Biological or Chemical Agents, as amended to Reg. 491/09; Reg. 490, Designated Substances, effective July 1, 2010
  - 816 Substances
  
- British Columbia
  - Workers Compensation Board, Exposure Limits for Chemical Biological Substances, October 23, 2009
  - Based on current list of ACGIH TLVs®
  - 871 Substances

# Mexico OELs

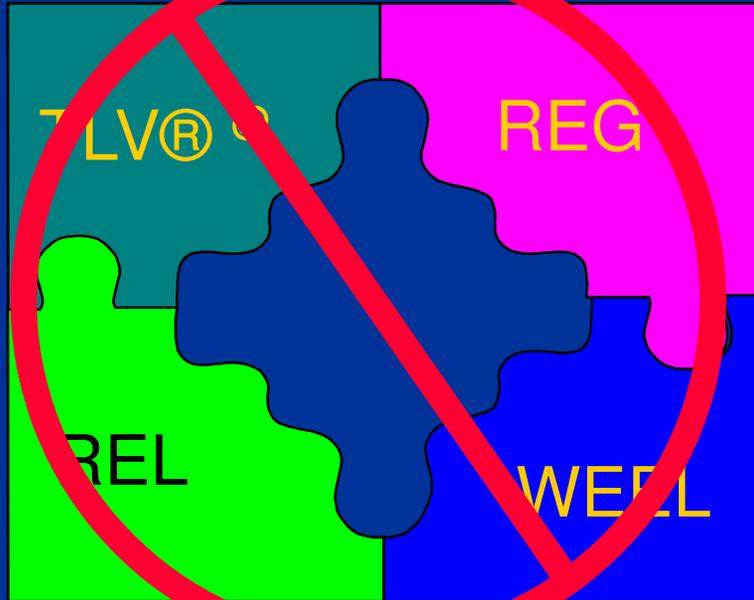
- NOM-010-STPS-1999, Safety and Health Conditions in the Workplace. Official Journal of the Federation, March 13, 2000
  - 623 OELs based on ACGIH TLVs®
    - Updated as TLVs are revised
  - TWA, STEL and Ceiling
  - Notations: Skin and Asphyxiants

# Status in the USA

- Given the lack of updated or new OELs available in the United States:
  - Health professionals have sought other means to meet the need for health-based OELs in the risk assessment process.
  - Control Banding approach popular in the United Kingdom,
  - Some have based “safe” exposure levels on structurally-equivalent chemical structures for which health-based OELs do exist, some have used OEL values available from other countries, some have employed medical surveillance to calibrate decline in health and performance with exposure improvements, and others have simply focused on good housekeeping and other risk reducing strategies without the ability to know whether the contaminant reduction in exposure is significant.

# Manufacturer OELs

## Industrial Hygiene Guidelines



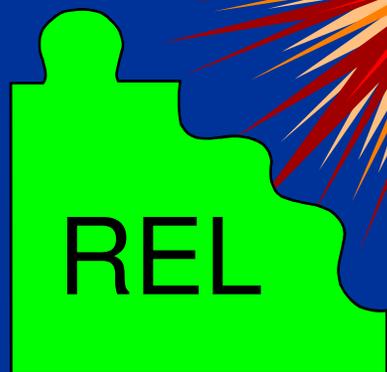
-  No regulation
-  No TLV®
-  No WEEL
-  No REL

# *Completing the USA Puzzle:*

ACGIH



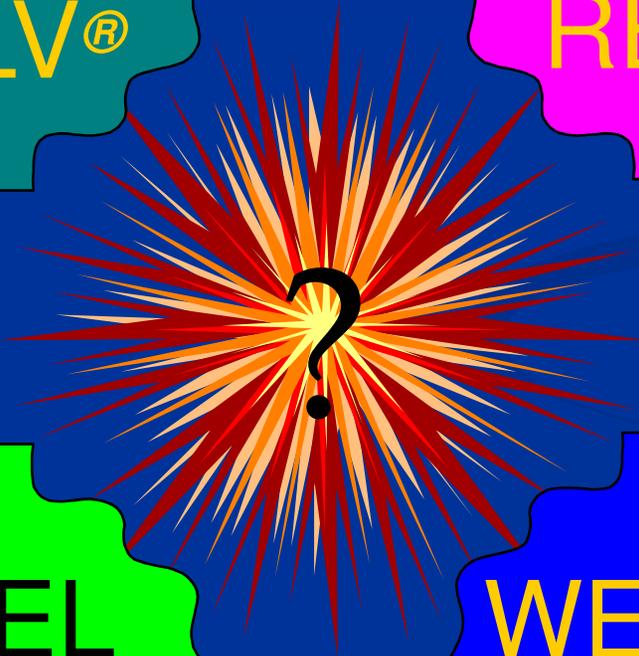
Government



Vendor  
Recommended  
Guides



AIHA



# Manufacturer's "Industrial Hygiene Guidelines"



# North American OEL Issues

- Lack of regulatory OELs does not provide the same ‘standard of care’ for USA workers
- Litigation and political constraints “paralyze” or limit the setting or update of TLVs or RELs as well as regulatory OELs in the USA, Canada and Mexico