
Health-Based Occupational Exposure Limits

- Does the need still exist?

Larry Gibbs
Associate Vice Provost
Stanford University



Questions to ask ourselves

- Are Occupational Exposure Limits (OELs) ***useful*** for Industrial Hygienists to fulfill their professional obligations?
- Are OELs ***necessary*** for Industrial Hygienists to fulfill their professional obligations?
- What is the ***value*** of traditional science derived OELs versus newer approaches to occupational health protection?



OELs – History and Approach

- Health-based OELs established for airborne workplace chemicals by regulatory and authoritative organizations world-wide for over 60 years.
- OELs broadly defined as a limit on magnitude and duration of individual's exposure to airborne chemical
- Most OELs set as TWA concentrations for 8 hour workday, 40 hour workweek, to which nearly all workers may be repeatedly exposed without adverse effect



OELs - types

- Functional types of OELs
 - Daily exposure limits (TWA-8/10 hour)
 - Short-term exposure limits (15 min)
 - Ceiling exposure limits (C-)
 - Emergency chemical exposure limits (IDLH, ERPG)
- Categories from legal perspective
 - Recommendations/professional guidance only – no legal duties
 - Mandatory – legally binding



Health-Based OEL Development–Traditional Approach

- OELs are generally established by committees consisting of toxicologists, IHS, Occ. Physicians and other health professionals
- Committees tend to use same general framework for OEL development
 - Gather and review all available health hazard data
 - Select a critical health endpoint and associated dose descriptor (NOAEL, LOAEL, etc)
 - Modify the dose descriptor, as necessary
 - Account for uncertainties using an appropriate safety/uncertainty factor

OELs have been one of most important cornerstones of ensuring worker health and safety for many years



OELs - Purpose

- OEL is a means to an end; not an end in itself. The end here is prevention of work-related injury and illness. OEL is used to:
 - convey information about health risks of exposures
 - Provide guidance to occ. health professionals
 - Aid in determination of control selection
 - For statutory OELs, serve as legally enforceable requirement for regulatory agencies
- As Risk assessment and risk management tool
 - Served as primary tools in workplace disease prevention for over 50 years.
 - Essential part of any firm's risk management framework.



OELs-Challenges for the Profession

- Limited number of OELs
 - Only small number of substances for which OELs have been developed
- OEL-setting process is inefficient
 - Few OELs produced or updated each year
- Are OELs necessary/useful for professional practice?



OELs – Number of Hazardous Substances

- USA – per TSCA reporting (1990, 1994 & 1998)
 - ~70,000 chemicals in commerce
 - ~2,800 are High Production Volume (HPV) Chemicals (>1 million pounds/year) - excluding polymers
- Organisation for Economic Co-operation and Development (OECD)
 - 4638 HPV chemicals compiled in 2007
 - Includes chemicals with annual production volume > 1,000 metric tonnes (2.2 million pds) in more than one economically developed country

http://www.oecd.org/document/9/0,3343,en_2649_34379_35211849_1_1_1_1,00.html



U.S. Based OEL Standards/Guidelines

- Standards
 - OSHA PELs - 447
 - State specific PELs
 - California - 747
 - Minnesota
 - Michigan
 - Washington
 - Other?
- Guidelines
 - 2008 TLVs[®]/BEIs[®] – 696
 - 2008 WEELs - 113
- Other
 - Foreign standards
 - Company standards
 - Association Guidelines



Regulatory OELs by Country

List of countries with an Internet link to a table or database containing the exposure limit values

Argentina
Australia
Austria
Belgium
Brazil
Bulgaria
Canada
Chile
Cyprus
Denmark
Estonia
European Union
Finland
France
Germany

<http://www.ilo.org/public/english/protection/safework/cis/products/explim.htm>



OEL Setting: U.S. Experience

- PELs - OSHA and state OSHAs
- RELs – NIOSH
- TLVs – ACGIH
- WEELs – AIHA
- OELs – company and trade association developed



Mandatory OEL Setting: European Union

- EU and affiliated countries – common processes and data, sometimes with different numeric outcomes
- Many original OELs based on ACGIH TLVs; now a move to integrated EU approach not solely based on OELs
- Opportunity for stakeholder participation; often government, industry and labor with independent expertise. Insurance associations often play role.



Mandatory OEL Setting: European Union

- Often two stage process; science/health based issues defined by experts-followed by process in which economic/technical feasibility are considered.
- Indicative Occupational Exposure Limit (IOEL) is legally binding as a minimum level in EU countries
- OELs play a limited role in chemical risk management in most of EU
 - Limited number of OELs
 - Limited number of Professional Industrial Hygienists
 - Occupational Physician influence
 - Focus on required controls
 - Bans on substances
 - Little air monitoring used
- Question of overall effectiveness of controls approach



New Paradigms for Controlling Workplace Risk

- Traditional risk assessment and risk management approaches in developed countries may not translate to developing countries or to medium sized employers in developed countries
 - Only large firms have technical resources to assess risk quantitatively
 - List of potentially harmful agents needing an OEL is very large
 - Governmental enforcement of OELs is often limited.



Current developments

- Globally Harmonized System (GHS) for classification and labeling of chemicals
- Control Banding – focus on exposure controls rather than quantitative risk assessment via OEL
- R.E.A.C.h. – producer/manufacturer required to demonstrate absence or acceptability of risks associated with chemical before being marketed



New Paradigms for Controlling Workplace Risk-UK

- COSHH
 - Assess the risks to health from chemicals and decide what controls are needed
 - Use those controls and make sure workers use them
 - Make sure the controls are working properly
 - Inform workers about the risks to health
 - Train workers
- Introduced Workplace Exposure Limits (WELs)
- ALARA for substances that cause occ. asthma, cancer, or genetic damage
- Control Banding became primary focus for workplace risk mgt.



New Paradigms for Controlling Workplace Risk-EU

- REACH – Registration Evaluation and Control of Chemicals
- Creation of Derived No-Effect Levels (DNELs)
 - Level of exposure above which humans should not be exposed
 - Manufacturers and importers are required to calculate DNELs as part of their Chemical Safety Assessment for any chemicals used in quantities ≥ 10 Tons per year
- DNELs to be included in Chemical Safety Report, for Haz Comm and extended MSDS
- DNEL used in risk characterization part of CSA as benchmark to determine control for specified exposure scenarios. Risk is considered adequately controlled if exposure levels estimated do not exceed the appropriate DNEL



OEL Setting: REACH DNEL Derivation

Gather all available dose descriptors (NOAEL, LOAEL, BMDL10, T25)

Decide on the mode of action (threshold or non-threshold)

Select relevant dose descriptor(s) for the determined "critical" health effect endpoint and modify dose descriptor(s) as necessary (route-to-route extrapolation, exposure condition differences, etc.)

Apply Assessment Factors (AF) to corrected dose descriptor to get endpoint-specific DNEL for the relevant human exposure scenario

[modified] Dose Descriptor

DNEL = $\frac{\text{[modified] Dose Descriptor}}{\text{AFs}}$

Use DNEL in the calculation of the Risk Characterization Ratio;

$\text{RCR} = \frac{\text{[known or modeled] Exposure}}{\text{DNEL}}$

If Exposure < DNEL → risk is adequately controlled (RCR < 1)

If Exposure > DNEL → risk is not adequately controlled (RCR > 1)



Health-Derived OELs vrs. REACH DNEL

Comparison of Health-Based Occupational Exposure Levels (OELs) to DNELs for Two Chemical Examples (mg/m³)

Test Chemical	OSHA	ACGIH [©]	AIHA	IOEL	DNEL
Cyclohexane CAS# 110-82-7	1050	350		700	15
Isooctyl Acrylate CAS# 29590-42-9			37.5		8

Roy *et al*, "The Use of Health-Based Occupational Exposure Limits As REACH Derived No Effect Levels." Poster presented at SOT Meeting, Seattle Wa 2008



Perspective on REACH – 3M

- The ability to use any established, defensible, health-based OEL as a DNEL would considerably decrease time and effort in complying with REACH;
- Because of the process for calculating a DNEL, it is anticipated that DNELs will be lower, perhaps significantly, than the corresponding health-based OEL(s);
- DNELs could theoretically replace the need for health-based OELs established using time-tested methodology (*e.g. because* they are considered to be more appealing to some because they will tend to be stringent due to how they are calculated);
- Health-based OELs are generally derived through extensive peer review and consensus. DNELs are likely not to have that same level of scientific scrutiny;
- Having both a DNEL and a health-based OEL may cause confusion to the downstream user(s) (*e.g., they appear on Safety Data Sheets (SDSs) or Chemical Safety Report (CSR), etc.*).

Roy *et al*, "The Use of Health-Based Occupational Exposure Limits As REACH Derived No Effect Levels." Poster presented at SOT Meeting, Seattle Wa 2008



Recent “Green Paper” Perspective

- OELs are critical to IH and Risk Assessment (RA)
- RA involves integration of toxic potential and potency with exposure
- IHs measure or estimate exposure in scenarios of interest
- IHs rely on the health-based OEL to put estimated exposure into context relative to health effect
- Exposure measures have no contextual meaning without a valid toxicological benchmark for comparison

“Occupational Exposure Limits – Do They Have a Future?” Multi-author “Green Paper” available at: www.IOHA.org



Continued Challenges for OEL Development

1. Number of chemicals relative to number of OELs continues to grow
2. OELs are not true thresholds of toxic effect
3. REACH regulations may change the playing field
4. Resources and expertise needed to establish OELs
5. Possibility of bias in setting of OELs
6. Process consistencies in determining OELs
7. Decrease in OEL levels over time

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Summary

- OELs are most effective tool for performing risk assessments to determine risk management strategies for worker protection
- Need to accelerate the production of credible, respected health-based OELs
- Alternatives have not been fully evaluated to determine whether effective and efficient in worker protection
- Developments in other countries
- Belief that health-based Occupational Exposure Limits are critical for worker protection



Path Forward...

- There is a definite need to continue to develop and disseminate occupational health guidelines.
- Also, need to increase the number of **new** health-based OELs available to professionals
- Need for an independent, sustainable OEL development program with economic support base



One Solution: Sustainable TLV/OEL Program

- Alliance with AIHA/ACGIH and other professional organizations to focus on continuing ability to develop TLVs/OELs
- Will ensure on-going effort for the long-term and will result in an increase in the number of substances that can be reviewed and documented
- Goal is to add to the knowledge base of health-based risk OELs and increase the information available for professional application in the workplace environment
- Also, working on endowed program within the Foundation for Occupational Health and Safety (FOHS) specifically targeted for support of continued TLV[®] development

<http://www.fohs.org/SusTLV-BEIPrgm.htm>

