Occupational Health Standard-Setting and Worker Risks

Permissible Exposure Limits (PELs)
Managing Risks of Chemical Hazards

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Presentation Overview

- Occupational Exposure Limits
  - ◆Cal/OSHA PELs ◆NIOSH RELs ◆ACGIH TLVs
- CAL/OSHA PELs–Mandated Responsibilities
  - ◆HESIS ◆Cal/OSHA ◆OSH Standards Board
- Quantitative Risk Assessment (QRA) and PELs
  - ◆Benzene Decision (1980) ◆OEHHA Report (2007)
- QRA-Based Cal/OSHA PELs–Examples
- VOC-Exempt Chemicals– Worker Health Risks
  - ◆tert-Butyl Acetate ◆Dimethyl Carbonate ◆Solstice

Occupational Exposure Limits (OELS)

- Set to prevent airborne chemical contaminants from harming health
- Three major types of OELs in U.S.
  - Permissible Exposure Limits (PELs)
  - Recommended Exposure Limits (RELs)
  - Threshold Limit Values (TLVs)

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Permissible Exposure Limits–PELs

- Set by OSHA and Cal/OSHA
- Prevent material impairment of health over a working lifetime
- Legally enforceable limits— based on health & feasibility
- Most PELs are based on ACGIH Threshold Limit Values (TLVs)
- Most OSHA PELs not updated since 1971
- Cal/OSHA PELs updated on regular basis

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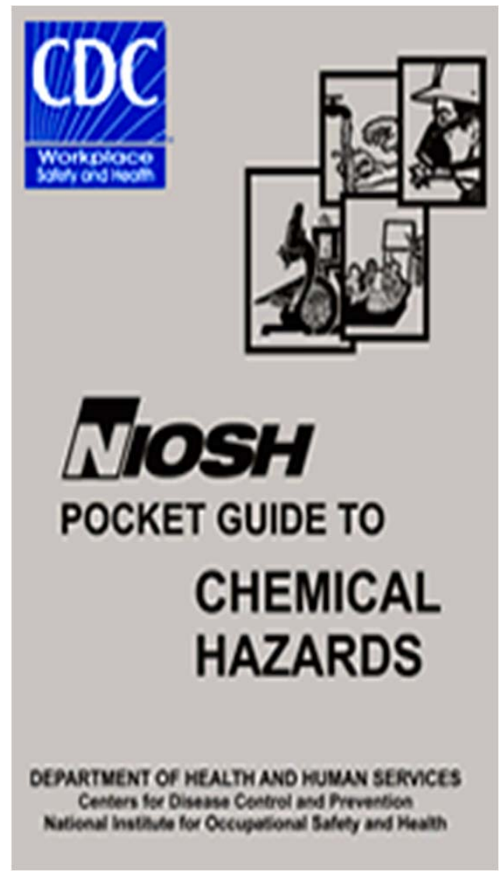
Recommended Exposure Limits-RELs

- Set by NIOSH
- Based primarily on health effects
- Most not QRA-based
- Carcinogens = “Ca”

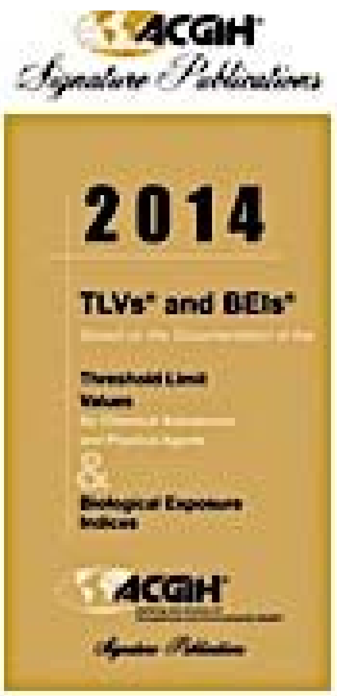
  No safe exposure level
- Recommendations made to OSHA



2005

Threshold Limit Values—TLVs

- Set by the American Conference of Governmental Industrial Hygienists (ACGIH)
- ACGIH is a private org.
- Updated on regular basis
- TLV bases are published
- Cancer in animals–relevance to humans is unknown
- TLVs are not QRA-based



Cal/OSHA PELS–
Responsible Entities & Their Roles

Hazard Evaluation System & Information Service (HESIS), Occupational Health Branch, CDPH

- Identifies and evaluates workplace chemical hazards
- Recommends PELs & provides technical assistance

Cal/OSHA

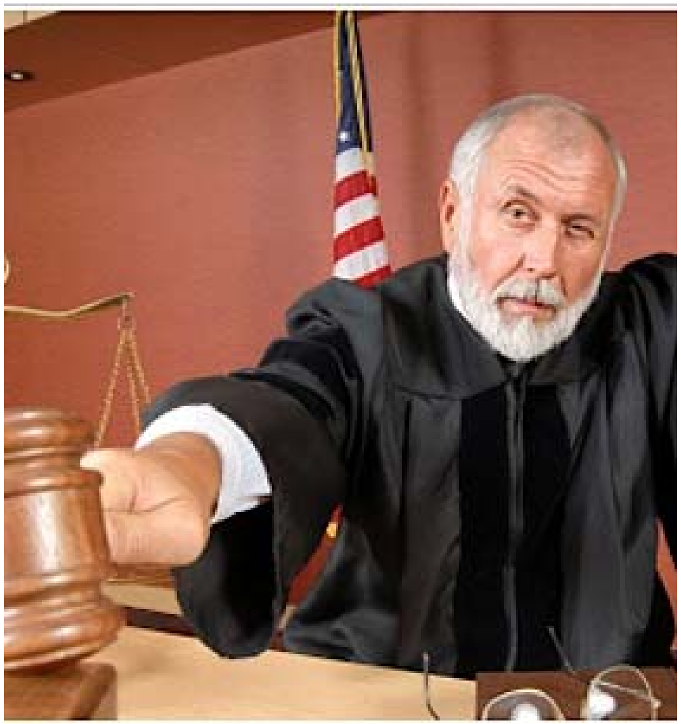
- Develops PEL proposals based on Health Experts and Feasibility Advisory Committees' recommendations

Occupational Safety and Health Standards Board

- Decides PELs based on proposals and public input

Quantitative Risk Assessment (QRA) Use in PEL Development

- Benzene Court Decision (1980)
- OSHA responsible for demonstrating significance of risk when developing PELs
- Significant cancer risk is between 1/billion and 1/1000 (Judge)



Selected OSHA Cancer Risk Estimates (Excess Cancers per 1,000 Workers)

Federal Register V. 71, No. 39, 2006

Standard	Risk at Prior PEL	Risk at New PEL	Date
Ethylene oxide	63-109	1.2-2.3	1984
Asbestos	64	6.7	1986
Benzene	95	10	1987
Formaldehyde	0.43-18.9*	0.0056-2.64*	1987
Methylenediani-line	6-30**	0.8	1992
Cadmium	58-157	3-15	1992
1,3-Butadiene	11.2-59.4	1.3-8.1	1996
Methylene Cl	126	3.6	1997
Chromium VI	101-351	10-45	2006

*Range is based on maximum likelihood estimate (0.43, 0.0056) and upper 95% confidence limit (18.9, 2.64). **Estimated exposure, no prior standard.

1997 Cal OSHA Airborne Contaminants Advisory Committee —PEL Recommendations

- Acetaldehyde
- Carbon tetrachloride
- Cobalt, elemental and inorganic compounds, as Co
- Cr VI compounds
- p-Dichlorobenzene
- 1,1 –Dimethylhydrazine
- Glass, fibrous
- Heptachlor
- Hexachlorobenzene
- Hydrazine
- Perchloroethylene
- Phenyl glycidyl ether
- Trichloroethylene
- Vinyl acetate
- 4-Vinyl cyclohexene
- Vinyl cyclohexene dioxide

The Cal OSHA Airborne Contaminants Advisory Committee Carcinogen Position Statement (1997)

These substances have been identified by IARC as a carcinogen (Group 2B or higher).

The recommended exposure limits are based on other types of toxic results, damage or interference with organ systems, irritation, respiratory problems, etc.

Quantitative risk assessments can be used to estimate risks of cancer at various exposure levels in order to set a PEL.

<u>No such risk assessments have been conducted by this committee.</u>

<u>Neither Cal OSHA nor the Occupational Safety and Health Standards Board have standard methods for performing these assessments or a useful criterion against which limits might be set.</u>

Cal OSHA should reconsider the proposed PELs if a carcinogen guideline policy is adopted & appropriate resources allocated.

Occupational Health Hazard Risk Assessment Project for California

HESIS conceived project and contracted with OEHHA to:

- Conduct a systematic analysis of whether existing QRAs could be used to develop protective PELs
- Screen Proposition 65 List for workplace chemicals of concern (unregulated or under-regulated chemicals)
- Describe and apply methods for calculating health protective air concentrations
- Discuss scientific issues related to dose-response assessment for the occupational setting

CA Occupational Health Hazard Risk Assessment Project – Some Key Findings

- **44** workplace chemicals listed as "known to cause **cancer**" on the Prop 65 List* did not have PELs
- **5** chemicals listed as "known to cause **reproductive/developmental toxicity**" listed under Prop 65 did not have PELs
- **62** listed **carcinogens** had PELs that were not based on cancer (no QRAs conducted)
- **14** listed **reproductive/developmental toxicants** had PELs that were not explicitly based on this endpoint, or the PEL bases were unclear

*Prop 65 List=12/2006. Final Project Report=12/2007

CA Occupational Health Hazard Risk Assessment Project –Findings/Conclusions

- Adjusted OEHHA & EPA QRAs can be applied to the workplace, which leverages resources
- Using existing QRAs to develop PELs requires appropriate expertise
- Lifetime cancer risks at existing PELs are high for many workplace chemicals
- Science-based PELs can be developed using a transparent & risk-based approach.
- NIOSH reviewed the report & agreed with the methods
- Risk managers can still take technical feasibility into account to set limits

CA Occupational Health Hazard Risk Assessment Project – High Cancer Risks

Chemical	PEL Basis	Cal/OSHA Risk at PEL*	OSHA Risk at PEL*
Acetaldehyde	Irritation	24	210
Naphthalene	Irritation; blood effects	310	310
Perchloroethylene	CNS impairment	200	744
Trichloroethylene	CNS impairment; renal toxicity	53	196
Ethylbenzene	Irritation; CNS impairment	210	210
1,4-Dioxane	Liver damage	135	558
p-Dichlorobenzene	Kidney damage	129	959

*Lifetime cancer risk/1000 workers calculated using OEHHA unit risk values adjusted for occupational exposure [10 m^3/20 m^3 x 250 days/365 days x 40 years/70 years]

Cal/OSHA QRA-Based PELs–Examples

Chemical	Prior PEL/ Cancer Risk	QRA-Based PEL	Cancer Risk/Health Endpoint
1,4-Dioxane	25 ppm **135/1000**	0.28 ppm	1.4/1000
Cyclonite (RDX)	0.5 mg/m^3	0.075 mg/m^3	Liver damage
1-Bromopropane	None	5 ppm	Reproductive & Developmental
N-Methylpyrrolidone	None	1 ppm	Developmental
Toluene	50 ppm	10 ppm	Neurotoxicity; Developmental
Ethylbenzene	100 ppm **210/1000**	5 ppm	10/1000
Methyl-n-butyl ketone	5 ppm	1 ppm	Peripheral Neuropathy
Sulfuric acid	1 mg/m^3	0.1 mg/m^3 Carcinogen Designation	Pulmonary function

Summary of NMP-Derived PELs (HEAC, 2009)

Study/ Proposal	NOAEL (ppm)	UF (Total)	BMCLSD (ppm)	UF (Total)	BMCL (ppm)	UF (Total)	PEL (ppm)
Saillenfait et al., 2003	60	60*					1
HEAC	60	100**					0.6
Saillenfait et al., 2003			102	60*			1.7
Industry			102	100**			1
Saillenfait et al., 2003					74	60*	1.2
OEHHA					74	100**	0.7
Staples, 1990	50	60*					0.8
HEAC	50	100*					0.5
Staples, 1990					50	60**	0.8
OEHHA					50	100**	0.5

*6 = interspecies (OEHHA 2008); 10 = developmental toxicity (OSHA 1993)
**10 = interspecies (OSHA 1993); 10 = developmental toxicity (OSHA 1993)

VOC-Exempt Chemicals—Worker Risks

Chemical	Existing PEL (ppm)/ Cancer Risk*	Existing PEL Basis	Derived PEL (ppm)/ Cancer Risk*	Derived PEL Basis	Data/Information Source
tert-Butyl Acetate	200/ 74/1000	Irritation (eye; respiratory tract)	3/ 1/1000	Cancer	Budroe et al. 2004. Regul Toxicol Pharmacol 40(2):168-176
Dimethyl Carbonate (DMC)	None	NA	5 (Acute-1hr) 5 (Chronic)	Develop-mental Toxicity	Cal/EPA OEHHA DMC Interim Acute and Chronic RELs 12/8/2009
Solstice Trans-1-chloro-3,3,3-trifluoropropene	None	NA	2	Cardiovas-cular Toxicity	Cal/EPA OEHHA Solstice Interim Chronic REL March 2014

Managing Worker Risks to Alternative VOC Compounds—Guidelines to Protect Health

- Consider toxicity and workers directly exposed in the emitting source to prevent transfer of risks
- Understand that worker risks can be high due to more extensive exposure, lack of protective PELs, other factors
- Derive protective QRA-based OELs to assess exposures that could be harmful to workers
- Avoid exempting chemicals with known toxicity to protect health & to prevent regrettable substitutions
- Continue to identify and promote the use of safer alternative chemicals consistent with IH principles and California's commitment to Green Chemistry