Occupational Health
Standard-Setting and Worker Risks

Permissible Exposure Limits (PELs)
Managing Risks of Chemical Hazards

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(Retired)
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

► 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)
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
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
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

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

*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.

No such risk assessments have been conducted by this committee.

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.

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

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

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

*Lifetime cancer risk/1000 workers calculated using OEHHA unit risk values adjusted for occupational exposure [10 m³/20 m³ x 250 days/365 days x 40 years/70 years]
## Cal/OSHA QRA-Based PELs—Examples

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Prior PEL/Cancer Risk</th>
<th>QRA-Based PEL</th>
<th>Cancer Risk/Health Endpoint</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,4-Dioxane</td>
<td>25 ppm 135/1000</td>
<td>0.28 ppm</td>
<td>1.4/1000</td>
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<tr>
<td>Cyclonite (RDX)</td>
<td>0.5 mg/m³</td>
<td>0.075 mg/m³</td>
<td>Liver damage</td>
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<tr>
<td>1-Bromopropane</td>
<td>None</td>
<td>5 ppm</td>
<td>Reproductive &amp; Developmental</td>
</tr>
<tr>
<td>N-Methylpyrrolidone</td>
<td>None</td>
<td>1 ppm</td>
<td>Developmental</td>
</tr>
<tr>
<td>Toluene</td>
<td>50 ppm</td>
<td>10 ppm</td>
<td>Neurotoxicity; Developmental</td>
</tr>
<tr>
<td>Ethylbenzene</td>
<td>100 ppm 210/1000</td>
<td>5 ppm</td>
<td>10/1000</td>
</tr>
<tr>
<td>Methyl-n-butyl ketone</td>
<td>5 ppm</td>
<td>1 ppm</td>
<td>Peripheral Neuropathy</td>
</tr>
<tr>
<td>Sulfuric acid</td>
<td>1 mg/m³</td>
<td>0.1 mg/m³</td>
<td>Pulmonary function</td>
</tr>
</tbody>
</table>
### Summary of NMP-Derived PELs (HEAC, 2009)

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

*6 = interspecies (OEHHA 2008); 10 = developmental toxicity (OSHA 1993)
**10 = interspecies (OSHA 1993); 10 = developmental toxicity (OSHA 1993)
# VOC-Exempt Chemicals—Worker Risks

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Existing PEL (ppm)/ Cancer Risk*</th>
<th>Existing PEL Basis</th>
<th>Derived PEL (ppm)/ Cancer Risk*</th>
<th>Derived PEL Basis</th>
<th>Data/Information Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethyl Carbonate (DMC)</td>
<td>None</td>
<td>NA</td>
<td>5 (Acute-1hr) 5 (Chronic)</td>
<td>Developmental Toxicity</td>
<td>Cal/EPA OEHHA DMC Interim Acute and Chronic RELs 12/8/2009</td>
</tr>
<tr>
<td>Solstice Trans-1-chloro-3,3,3-trifluoropropene</td>
<td>None</td>
<td>NA</td>
<td>2</td>
<td>Cardiovascular Toxicity</td>
<td>Cal/EPA OEHHA Solstice Interim Chronic REL March 2014</td>
</tr>
</tbody>
</table>
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.