ACGIH®: Dedicated to Development of Exposure Guidelines for the Professional

Presented at AIHce
May 15, 2006
Chicago
RT 203
Forum Overview

• Bob Soule – Welcome and Opening Comments
• Dennis Casserly – TLV®-CS Committee
• Tom Bernard – TLV®-PA Committee
• Larry Lowry – BEI® Committee
• Jim Price – ACGIH® TLV®/BEI® Development Process
Opening Comments & Overview of the Organization

Robert D. Soule
Chair, ACGIH®
Indiana University of Pennsylvania
State of the Organization

• Roll out of Marketing Plan
  ✓ Chair’s Letter
  ✓ Brand Promise
  ✓ Tag Line

• New/Expanded Educational Services
  ✓ Webinars
  ✓ Symposia
  ✓ Workshops

• Strategic Plan
Chair’s Letter

• Investment in market research
• Market strategy based on results
• Development of brand promise & tag line
• Defined position to drive everything we do
• Roll out in conjunction with AIHce
• Goal: Confirm that ACGIH® has been trusted source since 1938 and will continue to be connection to timely, objective scientific information
Brand Promise

ACGIH® advances worker protection by providing timely, objective scientific information to occupational and environmental health professionals.
New Tag Line

ACGIH®: Defining the Science of Occupational and Environmental Health
Webinars

• Four webinars planned for 2006
  ✓ Heat Stress and Strain – conducted April 27, 2006
  ✓ Endotoxins – August
  ✓ PAH Exposure – September
  ✓ TLV®-CS: Definitions, Notations and Appendices - November
Symposia

• “Health Effects of Occupational Exposure to Emissions from Asphalt/Bitumen”
• June 7-8, 2006
• Dresden, Germany
• Purpose: Provide opportunity to share key research regarding emissions from asphalt/bitumen, emphasizing evaluation of exposure and carcinogenic risk
2006 Workshops

• Fundamentals in Industrial Ventilation – March and September
• Practical Applications of Useful Equations – March and September
• Mold, Moisture and Remediation – April and November
• Indoor Environmental Quality – June and October
Continuing Interaction with AIHA

• Proven joint/cooperative efforts
  ✓ AIHce
  ✓ JOEH
  ✓ Interaction Committee
• Exploring issues of common interest, e.g., ethics, credentialing
• Examining means by which together we can better serve the industrial hygiene profession
Threshold Limit Values for Chemical Substances (TLV®-CS) 2006

Dennis Casserly
TLV®-CS Committee
University of Houston at Clear Lake
This presentation will focus on the following:

- TLV® and *Documentation* revisions for 2006
- Particles Not Otherwise Specified (PNOS)
- Minimal Oxygen Content
- Inhalable Fraction and Vapor Endnote
- TLV® development process using Toluene Diisocyanate (TDI)
Revisions or Additions for 2006

- 677 TLV®-TWAs or TLV-Ceilings in the TLV®-CS section
- Under Study List
  - 104 substances
  - Group Guidance Values for Refined C₅ - C₁₅ Aliphatic and Aromatic Petroleum Hydrocarbons
  - Reciprocal Calculation Procedure
- 15 Documentation and associated TLVs® adopted in 2006
- 15 Documentation and associated TLVs® withdrawn due to insufficient data or replaced by new entries in 2006
- Notice of Intended Changes (NIC) for 2006
  - 3 new substances
  - 28 updated
  - Proposed withdraw of 1 Documentation and associated TLV®
  - Appendix F: Minimal Oxygen Content
  - Appendix G: Substances Whose Documentation and Adopted TLVs® Have Been Withdrawn
TLVs® Adopted in 2006

- Calcium sulfate
- Carbon disulfide
- Coumaphos
- Fenamiphos
- Fenthion
- Fonofos
- Iron oxide
- 2-Methoxyethanol
- 2-Methoxyethyl acetate
- Monochloroacetic acid
- Propylene
- Propylene dichloride
- Ronnel
- Silica, Crystalline
  - α-Quartz
  - Cristobalite
- 1,1,2,2-Tetrabromomethane
Documentation & Associated TLVs® withdrawn in 2006

Due to insufficient data
- Magnesite
- Perlite
- Silica, Amorphous - Diatomaceous earth (uncalcined)
- Silica, Amorphous
  ✓ Precipitated silica
  ✓ Silica gel
- Silica, Amorphous
  ✓ Silica fume
- Silica, Amorphous
  ✓ Silica fused
- Silica, Crystalline - Tripoli
- Silicon
- Tetrasodium pyrophosphate
- Vegetable oil mist

Replaced by New Entries with New TLVs®
- Acetylene tetrabromide
- Iron (Fe₂O₃) dust & fume, as Fe
- Rouge
- Silica, Crystalline – Cristobalite
- Silica, Crystalline – Quartz
2006 NOTICE OF INTENDED CHANGES (NIC)

- Alachlor
- Aldrin
- Arsine
- Beryllium and compounds
- Carbaryl
- Copper and inorganic compounds
- Diglycidyl ether [DGE]
- Dimethyl carbamoyl chloride
- Dimethyl disulfide
- 3,5-Dinitro-o-toluamide
- Ethyl amyl ketone
- Hexafluoropropylene
- Hydrogen sulfide
- Hydroquinone
- Methyl demeton
- 1-Methyl naphthalene and 2-Methyl naphthalene
- Methyl propyl ketone
- α-Methyl styrene
- Mineral oil
- 5-Nitro-o-toluidine
- Portland cement
- N-Propanol
- Sulprofos
- 1,1,1,2-Tetrachloro-2,2-difluoroethane
- 1,1,2,2-Tetrachloro-1,2-difluoroethane
- Tetraethyl pyrophosphate [TEPP]
- Thiram
- Toluene
- Toluene-2,4- or 2,6-diisocyanate
- Trichloroethylene
- Vanadium pentoxide
2006 NIC TLVs® to be Withdrawn

- Calcium carbonate – Insufficient data
- Copper, fume, dust, mist – Name change and new TLVs®
- Dinitolmide – Name change and new TLV®
- Oil mist, mineral – Name change and new TLV®
Appendix F: Minimal Oxygen Content
2006 NIC

- Sensitive tissues:
  - Brain and myocardium

- Initial symptoms:
  - Increased respiration and cardiac output

- Ensuing symptoms:
  - Headache
  - Impaired attention and thought processes
  - Decreased coordination
  - Impaired vision
  - Nausea
  - Unconsciousness, convulsions and death
Increased Respiration and Increased Cardiac Output Occur When the:

- Hemoglobin oxygen saturation is reduced below 90%.
- Partial pressure of oxygen ($\rho O_2$) in pulmonary capillaries drops below 60 torr.
- Corresponds to 120 torr $\rho O_2$ in the ambient air, due to anatomic dead space, CO$_2$ and H$_2$O vapor
Expressing Oxygen Requirements in Percent can be Problematic

- %O₂ does not change with altitude
- It is the ρO₂ in the lung that is important and therefore the ambient ρO₂ not the percent O₂
- ρO₂ of the atmosphere:
  - decreases with increasing altitude
  - decreases with the passage of low pressure weather events
  - decreases with increasing water vapor
19.5% $\text{O}_2$ Equivalent at Sea Level

- Corresponds to 148 torr $\rho\text{O}_2$, dry air
- Provides an adequate amount of oxygen for most work assignments
- Includes a margin of safety for altitudes less than @ 8000 ft
- Represents a concentration of 7.5% (75,000 ppm) of displacing gases
- Some displacing gases may have flammable properties or may produce physiological effects, so that their identity and source should be thoroughly investigated.
2006 ACGIH® Recommendation

- Oxygen deficiency: ambient $\rho O_2 < 132$ torr
- Recommends additional work practices when the ambient oxygen partial pressure is less than 132 torr
- Considers the use of 19.5% $O_2$ equivalent at sea level (148 torr) a useful guide that is protective against inert displacing gases and oxygen-consuming processes for altitudes up to 5000 feet and is protective for most weather conditions up to approximately 8000 feet
When the Ambient Oxygen Partial Pressure is Less than 132 torr, Additional Work Practices are Recommended:

- Thorough evaluation of confined spaces
- Use of continuous monitors integrated with warning devices
- Use workers acclimatized to altitude of work
- Use of rest-work cycles with reduced work rates and increased rest periods
- Training, observation and monitoring of workers
- Easy and rapid access to properly maintained oxygen supplying respirators
Nuisance Dust → PNOC → PNOS

- 1964: Nuisance dust introduced
  15 mg/m³ or 50 mppcf, whichever less
- 1968: Nuisance Particulate Appendix added
- 1972: 10 mg/m³, total dust, or 30 mppcf
- 1976: 5 mg/m³, respirable added
- 1988: Appendix dropped, substances listed
- 1989: Changed to Particles Not Otherwise Classified (PNOC)
- 1995: 10 mg/m³, inhalable and 3 mg/m³, respirable (insoluble)
- 2001: Changed to Particles Not Otherwise Specified (PNOS)
Nuisance Dust Rationale

- Excessive concentrations may...
  - Seriously reduce visibility
  - Cause unpleasant deposits in eyes, ears, & nasal passages
  - Cause injury to the skin or mucous membranes by chemical or mechanical action or rigorous skin cleaning

(Also states that there is no particulate that does not provoke some response when inhaled in sufficient amounts)
Misuse of the “Inert” or “Nuisance Particulates” or “PNOC” TLV®

- Ignoring toxic constituents with TLVs
- Use for toxic materials which do not yet have a TLV®
- Inappropriate use on MSDSs
- Adoption by regulatory agencies
Appendix B: PNOS

- Do not have an applicable TLV®
- Insoluble or poorly soluble
- Low toxicity (i.e. not cytotoxic, genotoxic, or otherwise chemically reactive with lung tissue, not radioactive or a sensitizer, or toxic other than by inflammation or the mechanism of “lung overload”)

- 3 mg/m³, respirable
- 10 mg/m³, inhalable
Inhalable Fraction and Vapor (IV Endnote)

- Material present in both particle and vapor phases
- Saturated Vapor Concentration (SVC)/TLV-TWA
- Also, consider both particle and vapor phases:
  - For spraying operations
  - For processes involving temperature changes
  - When a significant fraction of the vapor may be dissolved into or adsorbed onto particles of another substance (such as water-soluble compounds in high humidity environments)
  - In selecting sampling techniques to collect both states of matter
Toluene Diisocyanate (TDI)
$\text{CH}_3\text{C}_6\text{H}_3(\text{NCO})_2$

- 2,4- and 2,6-TDI (mixtures also)
- Generally liquid, but may be solid
- Volatile, with acrid odor
- Chemically reactive, heat and light-sensitive
- Used in polyurethane plastics, coatings, elastomers

Current TLV-TWA 0.005 ppm
Current TLV-STEL 0.02 ppm
Some Important Issues in the Discussion of TDI

• Dose - response relationship for a sensitizer

• Evidence of sensitization

• Time-weighted average (TWA) vs. peak exposures

• Sensitized or susceptible individuals
ACGIH® TDI Symposium

• Held: April 22, 2002 (Cincinnati, OH)

• Presenters/Authors: Brown (and Burkert), Collins, Conner, Cummings (and Booth), Diller, Ott, Levine, Tarlo

• Published:
TDI Effect Levels

- 10 ppm: LC$_{50}$ values
- 1 ppm: Delayed death
- 0.1 ppm: Inflammation, fibrosis, NOEL for reproductive effects
- 0.05 ppm: Sensory irritation
- 0.005 ppm: Cell adhesion, protein conjugation
- 0.002 ppm: FEV$_1$ reductions
- ???: OA
Ott (2002): Table 1

TDI Production Units

<table>
<thead>
<tr>
<th>Study</th>
<th>Period</th>
<th>% OA*</th>
<th>TDI (TWA, ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams, 1975</td>
<td>1961-70</td>
<td>5.6</td>
<td>decline % samples &gt;0.02</td>
</tr>
<tr>
<td>(N=565)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Porter, 1975</td>
<td>1956-59</td>
<td>1.6</td>
<td>0.06 mean area</td>
</tr>
<tr>
<td>(N=300)</td>
<td>1960-69</td>
<td>0.8</td>
<td>steady decline</td>
</tr>
<tr>
<td></td>
<td>1970-74</td>
<td>0.3</td>
<td>&lt;0.004 mean area</td>
</tr>
<tr>
<td>Weill, 1981</td>
<td>1973-78</td>
<td>1.0</td>
<td>0.0016-0.0068**</td>
</tr>
<tr>
<td>(N=277)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ott, 2000</td>
<td>1967-79</td>
<td>1.8</td>
<td>0.0034-0.0101**</td>
</tr>
<tr>
<td>(N=297)</td>
<td>1980-96</td>
<td>0.7</td>
<td>0.0003-0.0027**</td>
</tr>
</tbody>
</table>

* % OA (annual incidence)
** Range by job
Proposed TLV® for TDI

- **TLV–TWA:** 0.001 ppm (0.007 mg/m³), Inhalable fraction and vapor
- **TLV–STEL:** 0.003 ppm (0.021 mg/m³), Inhalable fraction and vapor
- Skin
- Sensitizer (SEN)
- A3 — Confirmed Animal Carcinogen with Unknown Relevance to Humans
TLVs®

• More than just “THE NUMBER”

• *TLV® Documentation:*
  ✓ Critical health effects
  ✓ NOAELs and LOAELs
  ✓ Quality of the data relied upon and areas of uncertainty
  ✓ Possible sensitive subgroups
  ✓ Type of TLV® (TWA, STEL, C) and reason for selection
  ✓ Notations
    • SKIN
    • SEN
    • Carcinogenicity
Threshold Limit Values for Physical Agents (TLV®-PA) Committee

Thomas E. Bernard
Chair, TLV®-PA Committee
University of South Florida
Updates for 2006

• RF&MW: Note on Ultra-wide bandwidth

• Sub-RF Magnetic Fields: Note on Contact Currents

• Sub-RF Static Fields: Note on Contact Currents

• Noise: Note on Ototoxicity

• Note on carcinogenicity
NICs for 2006

• Visible and Near Infrared Radiation

• Heat Stress and Strain
Visible and Near Infrared Radiation

Thermal Effects Hazard Function
Overestimated Risk

- The risk of thermal effects between 380 and 500 nm was higher than necessary.

- The hazard function \([R(\lambda)]\) in this range was reduced accordingly.
Graphically Speaking

![Graph showing Hazard Function](image-url)

- **Wave Length [nm]**
- **Hazard Function**

- **R(\lamda) - New**
- **R(\lamda) - Old**
Heat Stress and Strain

Major Changes
Action Limit

• Action Limit
  ✓ Replaces the Unacclimatized TLV®

• Work below the Action Limit is presumptively low stress for any healthy worker.
TLV® for Heat Stress

Metabolic Rate [W] vs. WBGTeff [°C]

- TLV®
- Action Limit
Accounting for Clothing

- Clothing makes an environmental condition seem worse. It reduces both evaporative and dry heat exchange.

- Intuitively, there should be a factor that adjusts the environmental measures to an equivalent condition in work clothes.
### Changed and Expanded for 2006

### Clothing Adjustment Factors [°C-WBGT]

<table>
<thead>
<tr>
<th>Clothing Type</th>
<th>Previous</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work Clothes (Baseline)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cloth Coveralls</td>
<td>3.5</td>
<td>0</td>
</tr>
<tr>
<td>Double Layer Cloth Clothing</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>SMS Coveralls</td>
<td>---</td>
<td>0.5</td>
</tr>
<tr>
<td>Polyolefin Coveralls</td>
<td>---</td>
<td>1</td>
</tr>
<tr>
<td>Limited-use Vapor-Barrier Coveralls</td>
<td>---</td>
<td>11</td>
</tr>
</tbody>
</table>
Environment Plus Clothing

Effective WBGT (WBGT_{eff}) =

Measured WBGT + Clothing Adjustment Factor (CAF)
Heat Stress and Strain

TLV®

Process Flow

(See TLV® Decision Flow Chart)
Screening

- **Clothing Adjustment Factors Available?**
  - **NO**
  - **YES**

- **Are Screening Criteria for Action Limit Exceeded?**
  - **NO**
  - **YES**

- **Are Screening Criteria for TLV® Exceeded?**
  - **NO**
  - **YES**

- **Continue Work**
- **Maintain Controls**
- **Monitor Conditions**
- **Implement General Controls**
- **Low Risk**
- **Continue Work Monitor Conditions**
Table Changes for 2006

• Assigned metabolic rate in each category has a lower value.
  ✓ Better reflects work physiology principles and other standards.
  ✓ Means higher WBGT values.

• Allocation of Work/Rest described as a range of % work in the cycle.
### Metabolic Rate by Category

#### Reference Metabolic Rate [W]

<table>
<thead>
<tr>
<th>Activity</th>
<th>Previous</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest (Baseline)</td>
<td>115</td>
<td>115</td>
</tr>
<tr>
<td>Light</td>
<td>230</td>
<td>180</td>
</tr>
<tr>
<td>Moderate</td>
<td>350</td>
<td>300</td>
</tr>
<tr>
<td>Heavy</td>
<td>465</td>
<td>415</td>
</tr>
<tr>
<td>Very Heavy</td>
<td>580</td>
<td>520</td>
</tr>
</tbody>
</table>
# Screening Action Limit

<table>
<thead>
<tr>
<th>%Work</th>
<th>L</th>
<th>M</th>
<th>H</th>
<th>VH</th>
</tr>
</thead>
<tbody>
<tr>
<td>75 to 100</td>
<td>28.1</td>
<td>25.0</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>50 to 75</td>
<td>28.7</td>
<td>26.0</td>
<td>24.2</td>
<td>--</td>
</tr>
<tr>
<td>25 to 50</td>
<td>29.3</td>
<td>27.2</td>
<td>25.7</td>
<td>24.6</td>
</tr>
<tr>
<td>0 to 25</td>
<td>30.0</td>
<td>28.8</td>
<td>27.8</td>
<td>27.0</td>
</tr>
</tbody>
</table>

Note: TLVs® and BEIs® Book rounds these numbers to the nearest 0.5 °C-WBGT
## Screening TLV®

<table>
<thead>
<tr>
<th>%Work</th>
<th>L</th>
<th>M</th>
<th>H</th>
<th>VH</th>
</tr>
</thead>
<tbody>
<tr>
<td>75 to 100</td>
<td>30.8</td>
<td>28.2</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>50 to 75</td>
<td>31.2</td>
<td>29.0</td>
<td>27.6</td>
<td>--</td>
</tr>
<tr>
<td>25 to 50</td>
<td>31.8</td>
<td>30.1</td>
<td>28.8</td>
<td>27.9</td>
</tr>
<tr>
<td>0 to 25</td>
<td>32.3</td>
<td>31.3</td>
<td>30.5</td>
<td>29.8</td>
</tr>
</tbody>
</table>

Note: TLVs® and BEIs® Book rounds these numbers to the nearest 0.5 °C-WBGT
Detailed Analysis

Are Data Available for Detailed Analysis?

YES

Action Limit Exceeded?

NO

Low Risk

Continue Work
Monitor Conditions

YES

TLV® Exceeded?

NO

Implement General Controls

YES

Continue Work
Maintain Controls
Monitor Conditions
Task Analysis

• Breakdown by Location

• Breakdown by Homogeneous Activities

• Time Assigned for Each Location/Activity
Metabolic Rate Categories

• Light
  ✓ 180 W
  ✓ sitting, standing, light hand/arm work

• Moderate
  ✓ 300 W
  ✓ walking, moderate lifting

• Heavy
  ✓ 415 W
  ✓ heavy materials handling

• Very Heavy
  ✓ 520 W
  ✓ pick and shovel work

Potential Error
• Broad Range
• Over-Estimation
ISO Estimation Method

Earlier Methods in NIOSH Criteria Document

Components of Metabolic Rate

✓ Basal (Base) Metabolism (B)
✓ Posture (P)
✓ Type of Work (W)
✓ Walking (D)
✓ Climbing (C)

Total Metabolic Rate (M) = B + P + W + D + C
Clothing Adjustments to WBGT

\[ \text{WBGT}_{\text{measured}} + \text{Clothing Adjustment} \]

\[ \text{WBGT}_{\text{eff}} \]
Time-Weighted Average

\[
TWA-\text{WBGT}_{\text{eff}} = \frac{\text{WBGT}_{\text{eff}1} \times t_1 + \cdots + \text{WBGT}_{\text{eff}n} \times t_n}{t_1 + \cdots + t_n}
\]

\[
TWA-M = \frac{M_1 \times t_1 + \cdots + M_n \times t_n}{t_1 + \cdots + t_n}
\]

Over one to two hour time period.
Where is the job?
Job Risk Factors

• Traditional
  ✓ Environment
  ✓ Work Demands
  ✓ Clothing Requirements

• Plus Time
Empirical Time Limits

US Navy PHEL Charts
Rational Time Limits

• ISO 7933 (2004)

• PHS: Predicted Heat Strain
Heat Strain Monitoring

When working above the TLV® or under conditions when a detailed analysis cannot be performed.
Heat Strain Monitoring

1. **TLV® Exceeded?**
   - NO: Implement General Controls
   - YES: Proceed to next step.

2. **Perform Heat Strain (Physiological) Monitoring**
   - YES: Proceed to next step.

3. **Excessive Heat Strain Based on Monitoring?**
   - NO: Return to previous step.
   - YES: Implement Job-Specific Controls.

This flowchart outlines the steps for monitoring and managing heat strain in the workplace.
Body Core Temperature

• Acceptable Limit
  ✓ Acclimatized, Healthy, Experienced: 38.5 °C
  ✓ Unacclimatized and Unselected: 38 °C

• Oral Temperature
  ✓ No recent drinks/food, mouth closed
  ✓ Core is Oral plus 0.5 °C
Heart Rate

- Sustained heart rate greater than \((180 - \text{Age})\)

- Recovery heart rate greater than 120 bpm at one minute
Symptoms

- Sudden or severe fatigue, nausea, dizziness, or lightheadedness.

MEDICAL EMERGENCY

- Disorientation, irritability, malaise, chills, unconscious.
Patterns of Strain

- No pattern of excessive strain
- Pattern of excessive strain
Under Study*

- Ergonomics
  - Hand-Arm Vibration
  - Localized Fatigue

- Lasers

- Nonionizing Radiation
  - Light and Near Infrared
  - Radiofrequency and microwave radiation
  - Static Magnetic Fields
  - Ultraviolet Radiation

- Cold Stress

*Refer to the ACGIH® website for the up-to-date list. This list is evergreen and can change during the year.
Thank You

Thanks to the Committee members
BEI<sup>®</sup> Committee Update
Feasibility Assessments

Larry K. Lowry
Chair, BEI<sup>®</sup> Committee
The University of Texas Health Center at Tyler
Topics for discussion

• BEI® Committee Activities
• Basis of BEIs®
  ✓ TLV®-CS
  ✓ Health effects
• BEI® development process
• Feasibility assessments
• Examples
BEI® Committee Activities

• 45 substances with BEI® determinants
• 17 substances with negative feasibility assessments

2005 Actions

• 14 substances and 3 other issues Under Study (as of 4/3/06)*
• 6 NIC (2 for new substances, 4 to update BEIs®)

*Refer to the ACGIH® website for the up-to-date list. This list is evergreen and can change during the year.
BEI® Committee Activities

2005 Actions (cont.)

• 2 new Documentation updates w/o change to BEIs®

• 2 Adaptations
  ✓ 1,3-Butadiene
  ✓ 2-Propanol

• 1 new feasibility assessment – Methyl Formate
Basis of BEIs®

• Relationship between airborne exposure at TLV® and biomarker of exposure
  ✓ Most volatile organics, some metals

• Relationship between health effects and biomarker of exposure
  ✓ Lead, Cadmium, Mercury
BEI® Development Process

1. Select Chemical and place Under Study
2. Assign Author(s)
3. Review Data
4. Develop Feasibility
5. BEI®?
   - Yes: Write Negative Feasibility Assessment
   - No: Stop
6. Discuss Justification
7. Select Determinant
   - Yes: Recommend Draft to Board of Directors
   - No: Review Draft by Committee
8. Prepare Draft
9. Discuss Justification
10. Review Draft by Committee
11. Prepare Draft
12. Discuss Justification
13. Select Determinant
14. Revise
   - Yes: Return to Author(s)
   - No: Recommend Draft to Board of Directors
15. Board Approves Draft
16. Issue as NIC
17. Track Data Development

...
What are feasibility assessments?

• An initial assessment of the quantity and quality of data for a possible BEI®

• An initial written assessment
  ✓ Is there sufficient data to establish a BEI®?

• A means to manage critical Committee resources
Criteria for feasibility assessments

• Use and use trends
• Availability of data for a BEI® basis
• Data on occupational routes of exposure and the selection of determinants
• Data on metabolism and rates of excretion
• Health risks
• Analytical methods
What now?

• Positive feasibility assessment
  ✓ Proceed with the development of a BEI®

• Negative feasibility assessment
  ✓ Listed in the TLVs® and BEIs® book – chemical considered
  ✓ Stimulate interest and new data for possible future BEIs®
Negative Feasibility Assessments

- Acrylonitrile (1994)
- Antimony (1996)
- Beryllium (2002)
- Chlorpyrifos (1996)
- 1,4-Dichlorobenzene (1994)
- 2,4-Dichlorophenoxyacetic acid (1994)
- 2-Ethyl hexanoic acid (2001)
- Hydrazines (1994)
More negative FAs

- Inorganic borates (1995)
- Manganese (1995)
- Methyl t-butyl ether (1993)
- Methyl n-butyl ketone (1995)
- Methyl formate (2005)
- Nickel (1996)
- Selenium (1995)
- Trimethylbenzene (1999)
- Vinyl chloride (2002)
Format for BEI® Feasibility Assessment Document

- Occupational exposure and use
- Health risks
- Toxicokinetics
- Biological sampling and methods
- Relationship to TLV® or health risks
- Summary
- References
Methyl Formate (2005)

• Use and occupational exposure
  ✓ Increasing use as catalyst, binding agent
  ✓ Traditional use: fumigant, solvent, intermediate
  ✓ Vapor pressure 476 torr, inhalation risk
  ✓ Standards/guidelines
    • OSHA PEL 100 ppm
    • ACGIH® and NIOSH TLV®/REL TWA: 100 ppm, STEL: 150 ppm
    • German MAK 50 ppm, no BAT
Methyl Formate-Health risks

• Animals
  ✓ Narcotic and pulmonary irritant, LD$_{50}$ 1600 mg/kg, rabbit
  ✓ Variety of acute studies, most with no serious effects below 1500 ppm

• Humans
  ✓ One study (1958) visual disturbances, narcosis, irritation at 1500 ppm
Methyl Formate, Toxicokinetics

- No skin notation, but dermal exposure expected
- Metabolized to methanol and formate resulting in 2 formate molecules
- Metabolism not linear
- Elimination expected to be passive
- Kinetics: elimination complete 16 hrs after end of exposure
Methyl Formate
Biological sampling issues

• End of shift sampling indicated
• Both metabolites (methanol and formate) produced endogenously, a background level or “B” notation
• Formate elevated in smokers, and after eating high protein and carbohydrate meals
Methyl Formate and TLV®

- Berode et al. study of 2000
  - Two foundries
    - Foundry 1, n=9, median exposures 58 ppm
    - Foundry 2, n=19, median exposure 47 ppm
  - Volunteer study
    - N=20, median exposure 100 ppm
  - Pre-, post-shift and next morning urine samples for MeOH and Formic acid
Results

• Formic acid in urine
  ✓ Pre-shift samples higher than controls
  ✓ Post-shift samples similar in both foundries and volunteers, no dose response

• Methanol in urine
  ✓ No difference in pre-shift specimens from controls
  ✓ Post-shift specimens similar in both foundries and volunteers. No dose response
Methyl Formate and Health Risks

- No studies found
Summary

• No BEI® proposed due to:
  ✓ Insufficient data on small numbers
  ✓ Lack of a dose response
  ✓ Non-linear kinetics
  ✓ High background due to exogenous metabolism
References

• 10 references to original research
  ✓ 7 before 1985
  ✓ 3 recent but with limitations
• 3 references to NIOSH or ACGIH® documents
ACGIH®

TLV®/BEI® Development Process

James H. Price
ACGIH®, Director of Science
Agenda

• Introduction to ACGIH®
• Statement of Position
• Conflict of Interest
• TLV®/BEI® Development Process and Important Changes
• Basis and Limitations of TLVs®/BEIs®
• Providing Input to ACGIH®
• Sources of Information
ACGIH®

• New Position and Tagline for ACGIH®

✓ ACGIH® Brand Promise:
  • ACGIH® advances worker protection by providing timely, objective scientific information to occupational and environmental health professionals.

✓ ACGIH® Tagline:
  • ACGIH®: Defining the science of occupational and environmental health

• ACGIH®: Membership-based organization
• ACGIH® Committees: Provide technical expertise and knowledge fundamental to ACGIH®
ACGIH® Committees

- Committees consist of members who volunteer time toward developing scientific guidelines and publications
  - Primary goal is to serve the scientific needs of occupational and environmental health professional
  - Committee expenses (travel) are supported by ACGIH®
  - Time is donated by the members
Policies and Processes for Limiting Conflict of Interest
Conflict of Interest

• Committee members serve as individuals, not as representatives of organizations and/or interest groups

• Members are selected based on expertise, soundness of judgment, and ability to contribute
Conflict of Interest

• Annual discussion of conflict of interest in full Committee
• Annual declaration by each member
  ✓ Professional employment background
  ✓ Current professional activities
  ✓ Consulting
  ✓ Research funding
  ✓ Financial holdings
ACGIH® is not a standards setting body.

TLVs® and BEIs® —

• Are an expression of scientific opinion.
• Are not consensus standards.
• Are based solely on health factors; it may not be economically or technically feasible to meet established TLVs® or BEIs®.
ACGIH® Statement of Position

TLVs® and BEIs® —

• Should NOT be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions.

• Can provide valuable input into the risk characterization process. The full written Documentation for the numerical TLV® or BEI® should be reviewed.
TLV®/BEI® Development Process
1. Under Study

2. Draft Documentation
   - Not available to public

3. Notice of Intended Changes (NIC)
   - Draft TLV®/BEI® and Documentation available to public

4. TLV®/BEI® & Documentation Adopted
   - Published in yearly Supplement

Committee Selects Substance/Agent for TLV®/BEI® Review
TLV® Development Process
TLV®/BEI® Development Process

Important Changes

• **Under Study List:** Beginning 2006 provide additional information on status of substances and agents on Under Study List.

• **NIC and NIE Comment Period:** Beginning 2007 limit comment period to firm six-month period, running from February 1 to July 31 of each year.
Under Study List Change - 2006

• Continued Practice: Publish general Under Study List by February 1 of each year

• Added Practice beginning 2006: Publish updated two-tiered Under Study List by July 31 of each year
  ✓ Tier 1: Substances and agents that may move forward as an NIC or NIE in upcoming year
  ✓ Tier 2: Substances and agents that will not move forward, but will either remain on, or be removed from list in upcoming year
  ✓ Two-tier list will remain for balance of year

• Above practice: Will start over each year
  ✓ General list by February 1
  ✓ Two-tiered list by July 31
NIC and NIE Change - 2007

• Restructuring comment period to ensure receipt of comments in time for full consideration

  ✓ Comment period closes July 31 for that year’s Committee deliberations regarding outcome for possible adoption of a NIC or NIE.
  ✓ Comment period runs from February 1 to July 31.
  ✓ Draft Documentation available for review during this full six month comment period.

• Ongoing Process

  ✓ ACGIH® reviews all comments regarding substances/agents on Under Study, on NIC or NIE or currently adopted BEIs® or TLVs®
  ✓ Comments received after July 31 for a NIC or NIE will be considered in the following year.
Basis of TLVs®/BEIs®

Scientific Literature

- Published/Peer Reviewed Science (Principal Source)
- Reviewed Articles (Secondary)
- Unpublished Science (Secondary)
  - Before Use: Owner must provide ACGIH® permission to use and cite the report, and release the report to a third party
  - Consideration of TLVs® are not deferred pending completion of on-going or planned research
- Not a review of all available literature
  - Emphasis on peer-reviewed literature
  - Emphasis on literature pertinent to the issue
TLVs® Defined

• TLV® — more than just “THE NUMBER”

• Documentation describes:
  ✓ Critical health effects
  ✓ Quality of the data relied upon and areas of uncertainty
  ✓ Possible sensitive subgroups
  ✓ Type of TLV® (TWA, STEL, C) and reason for selection
  ✓ Notations
Warnings

- NOT to be used as an index of relative toxicity
- NOT for estimating toxic potential of continuous, uninterrupted exposures or other extended work periods
- NOT as proof/disproof of existing disease
- NOT to evaluate or control air pollution
- NOT legal standards
How/When Interested Parties Can Most Effectively Provide Input to the TLV®/BEI® Development Process

• Under Study stage
• NIC Stage
• Submit published, peer-reviewed science
• Unpublished works: Write an article and get it published
• Relevant unpublished studies: Submit to ACGIH® with permission to use, cite and release study
Information Sources on TLV®/BEI® Recommendations Ratified by ACGIH® Board

For Adopted and Notice of Intended Changes (NIC) Recommendations:

• ACGIH® Annual Report (January/February)*
• ACGIH® Website (January/February)*
• TLVs® and BEIs® Book (Spring)*

* Also identifies substances and agents Under Study
Online ACGIH® TLV®/BEI® Resources
www.acgih.org

• Conflict of Interest Policy
• TLV®/BEI® Policy Statement
• TLV®/BEI® Position Statement
• TLV®/BEI® Development Process
• Under Study List
• Notice of Intended Changes (NIC) List
• BEI®/TLV®-CS Committees Operations Manuals
• ACGIH® Annual Presentation at AIHce
Questions/Discussion