ACGIH’s TLV Committee – How We Handle Exposure Mixtures

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Overview

• Importance of TLVs
  – Short history of TLV Committee

• TLVs for combined exposures

• Challenges for a TLV for Diesel Exhaust
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®
Core Principles for Setting a TLV

✓ Focus on airborne exposures in occupational settings
✓ Utilize the “threshold” concept
✓ Primary users are industrial hygienists/safety professionals
✓ Goal is toward protection of “nearly all” workers
✓ Technical, economic, and analytic feasibility are NOT considered
TLV Subcommittees

• D&I, MISCO, and HOC
• Up to 10 members on each
  ✓ 28 current members/candidates
  ✓ 4 are Canadian; 2 Australian
• Membership from academia, government, labor, industry within 4 key disciplines:
  ✓ Industrial hygiene
  ✓ Toxicology
  ✓ Occupational Medicine
  ✓ Occupational Epidemiology
• Committee expenses (travel and literature searches) are supported by ACGIH
• Time is donated by the volunteer members
Changes Over Time:

- 1941 - TLV Committee Created
  - Subcommittee on Threshold Limits
- 1946 - First published list of 150 “MACs”
  - renamed TLVs in 1948
- 1955 – Added written documentations
- 1961 - Skin Notation
- 1962 - Carcinogens Appendix
- 1963 - Excursion factors
- 1964 - Notice of Intended Changes
- 1972 - Cancer classifications defined
- 1981 - List of Substances Under Study
The TLV Committee and its processes change over time!

- Some things change more slowly than others
  - ~700 substances w/ ~20 substances approved per year
    - So, 30+ years *if* no new substances added
- Carefully deal with bias and COI
  - Started pre-law suit
- We have a prioritization scheme for developing TLVs for new and old substances, but the committee welcomes suggestions
TLV Development Process
Process from Under Study to Adopted takes a minimum of 3 years
Why So Long?

Contents of *Documentation*

- Recommendation Section
- Chemical and Physical Properties
- Major Sources of Exposure
- Animal Studies
- Absorption, Distribution, Metabolism
- Human Studies
- TLV Basis
- TLV Chronology
- References
General Approach to Setting an OEL

• Identify a reference point, e.g., a no observed adverse effect level (NOAEL)
  - Human studies are best but often must rely on animal studies
• Set the OEL below the reference point (threshold)
• Margin between the reference point and exposure level = uncertainty factor
  - Also called a safety, extrapolation, or assessment factor
• Sometimes use a modifying factor for “infusion of professional judgment”
• However – there is not a lot of guidance for selecting or using uncertainty factors in developing OELs
Who Uses This General Approach to Setting OELs?

- TLV Committee
- MAK Commission
- EU’s SCOEL
- Scandanavian Working Group
- WEEL/OARS
- OSHA
- NIOSH
How Does This Approach Handle Mixtures in the Mining Environment?

• Mixture formula
• Diesel exhaust problems
The Problems of Mixtures

• Most TLVs/PELs are developed for a single chemical substance

• Workplace exposures to mixtures of agents are common
Toxicity of Chemical Combinations

- Synergistic
- Potentiation
- Antagonistic
- Additive
  - Only place where mixtures formula can apply
If Additive then use:
Additive Mixture Formula

• Applies when exposure to 2 or more substances causes similar adverse effects on the same target organ or system.
• The combined effect, rather than that of either individually, should be addressed.
• Absent contrary information, different substances are usually considered as additive where the health effect and target organ are the same.
Additive Mixture Formula

\[
\frac{C_1}{T_1} + \frac{C_2}{T_2} + \cdots + \frac{C_n}{T_n}, \text{ where}
\]

\(C_n = \) atmospheric concentration, and 
\(T_n = \) corresponding TLV\(^\circ\) of \(n\)th compound

If this expression exceeds unity, the TLV of the mixture should be regarded as exceeded.
Diesel Exhaust

- Contains several toxic components
- Needs an OEL value for protecting workers
- So...
  - Can a mixtures formula be applied to diesel exhaust?
  - Can a separate TLV/OEL be developed for diesel exhaust?
Can a mixtures formula be applied to diesel exhaust?

• Several potential chemicals or substances to consider
  – airborne PM
  – PAHs
  – CO
  – Elemental Carbon
  – Organic Carbon
Can a mixtures formula be applied to diesel exhaust?

• Emissions of DEP and DEP-associated genotoxic compounds of new technology diesel engines are significantly lower than those of older technology diesel engines
  – What are used in mining operations?
Diesel Exhaust in Mining Operations

![Graph showing emissions over time for different Euro standards](image)
Can a mixtures formula be applied to diesel exhaust?

• Mixture formula applies to substances in the same phase
  – PM - particle
  – PAHs - particle or gas
  – CO - gas
  – Elemental Carbon - particle
  – Organic Carbon - particle or gas
Can a mixtures formula be applied to diesel exhaust?

• Not a good approach
Develop A Diesel Exhaust-Specific TLV?

• Plenty of dose-response data in the peer-reviewed literature (mostly old tech engines)
  – acute and chronic animal studies
  – epi studies
  – human clinical exposure studies

• While technical and economic factors are not considered in developing a TLV, we need:
  – Critical effect: Pulmonary effects including cancer
  – Enough data: To choose a TWA, STEL, or Ceiling
  – A chemical or substance to reliably measure
Develop A Diesel Exhaust-Specific TLV?

- A chemical or substance to reliably measure:
  - PM?
  - Respirable PM?
  - Elemental Carbon?
  - CO?
  - NO₂?
Diesel Exhaust in Mining Operations

• Mining operations produce non-diesel exhaust particles, so is it suitable to use:
  – PM or Respirable PM?
  – Elemental Carbon (EC)?
• What about:
  – Respirable EC (4 µm)?
  – Ultrafine EC (<100 nm)?
Proposed Diesel Exhaust OELs

• **Extractable mass** (Hammond, 1988).

• **Respirable EC** (Birch and Cary, 1996).
  - EC typically constitutes around 75% of the DEP mass of older technology heavy-duty diesel engines (USEPA, 2002).

• 350 µg/m³ EC (MSHA, 2007)

• Newer Proposal: **Both Respirable EC and NO₂**
  - Taxell and Santonen, 2017
History of A Diesel Exhaust-Specific TLV

• 1995/1996 - Diesel exhaust was placed on ACGIH's Notice of Intended Changes (NIC)
  – 0.15 mg/m³ TWA and A2, suspected human carcinogen

• 2002 - 0.02 mg/m³ TWA as elemental carbon, A2

• 2003 – Withdrawn

• 2016 – Placed on Understudy List
Diesel Exhaust-Specific TLV

• 2016 – Placed on Understudy List
  – Key issues
    • Old vs. New engines
    • Old vs. New fuels
    • Level
    • Measurement parameter
      – Chemical
      – Size-selection
TLVs and ACGIH
What will ACGIH be in the Future?

• A 501(c)(3) science organization that will NOT be a professional society.
  – ACGIH has never sought to directly represent the profession
  – Many different professions – in addition to industrial hygiene - utilize the organization’s scientific products

• Continue to focus on the development of scientific products that support the practice of occupational and environmental health
The Future

Undertaking fundraising activities that attract support from a wider variety of individuals and organizations

Can you imagine a world without the ACGIH TLVs® and BEIs®?
Confusion, uncertainty, and workers at risk

Help ensure their continued existence — SUPPORT THE SUSTAINABLE TLV/BEI FUND TODAY!