Revising PELs in CA
Current Process and Results

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What are OELs and PELs?

- Our discussion is about **airborne** chemical concentrations of hazardous substances in workplaces.
- An occupational exposure limit (OEL) is a limit designed to protect **worker** health for the duration of their 45-year working life. Units are typically given in units of ppm or mg/m^3 for an 8-hour shift, 15 minute short-term exposures, or not to exceed ceiling limits.
- A permissible exposure limit (PEL) is an OEL adopted by OSHA that is enforceable.
- The majority of chemicals in US commerce do not have PELs or OELs.
- The bottom line is that many current Federal PELs are not protective of workers.

Note: For decades, AIHA has defined the "update of occupational exposure limits" as one of the profession's top public policy issue.

Historical

- Following the 1970 OSHA Act, federal PELs were based on the 1968 ACGIH TLVs. Note that the ACGIH TLVs were *not* intended for use as regulatory limits.
- California started revising / updating federal PELs early on, since the mid-1970s.
- Wholesale revisions to the PELs were passed by federal OSHA in 1989. This action was designed to keep pace with toxicology research and with ACGIH TLV changes.
- Lawsuits by Labor precipitated a decision by the 11th US Court of Appeals which vacated the new PELs in 1992. Federal PEL values reverted back to the 1968 TLVs.

US Court of Appeals for the Eleventh Circuit: AFL:CIO v. OSHA (CA 1 No. 89-7185) 965 F. 2nd 962 July 7, 1992)

Historical

- Most States still use the 1968 TLV values established under the original Federal OSHA Act – i.e. federal PELs.
- California is the only state that routinely reviews and revises their PEL values; theoretically on a biannual basis.
- Due to the review process, PELs in California have **generally** kept pace with toxicology research & literature, and other bodies that set OELs: NIOSH RELs, OARS/TERA WEELs, and ACGIH TLVs.
- Hence, many PELs in California (and Oregon), are lower than federal OSHA PELs and in some cases they are lower then the ACGIH TLVs

California History

- In 1973 California implemented a state OSHA plan:
  - this was and continues to be the largest state plan
  - in 1983, Governor Deukmejian eliminated the state OSHA Plan, fired everyone at Cal OSHA, and turned CA OSHA back to feds
  - in 1986, a public referendum was passed to reinstate Cal OSHA

- Since 1986, an advisory committee structure was adopted to recommend to Cal/OSHA whether a specific potential airborne occupational hazard should be regulated and advise on the structure and content of such a regulation.

- The Airborne Contaminants Advisory Committee has convened periodically since 1977 (except for the gap noted above) to provide recommendations for occupational airborne exposures revising section 5155 of the CAC.

California OSHA – Section 5155 Airborne Advisory Committee Process

- A voluntary science advisory committee was to be assembled ~ every 2 years to make recommendations to the State OSHA Standards Board regarding PEL revisions.
- Membership is comprised of industry, academic, medical, and consultants. Meetings were public. Teams of 2 members took on substances and wrote summaries for review for the whole committee. Votes established whether a recommendation was given to the Division.
- 54 chemicals were under consideration by the 2001-2004 Advisory Committee. This is ~ 7% of the 750 PELs in the California Code of Regulations 5155.
- The PELs from the 2004 committee were basically adopted in December 2009.

This process went along from the mid 1970s until 2004 except for the return to Fed OSHA

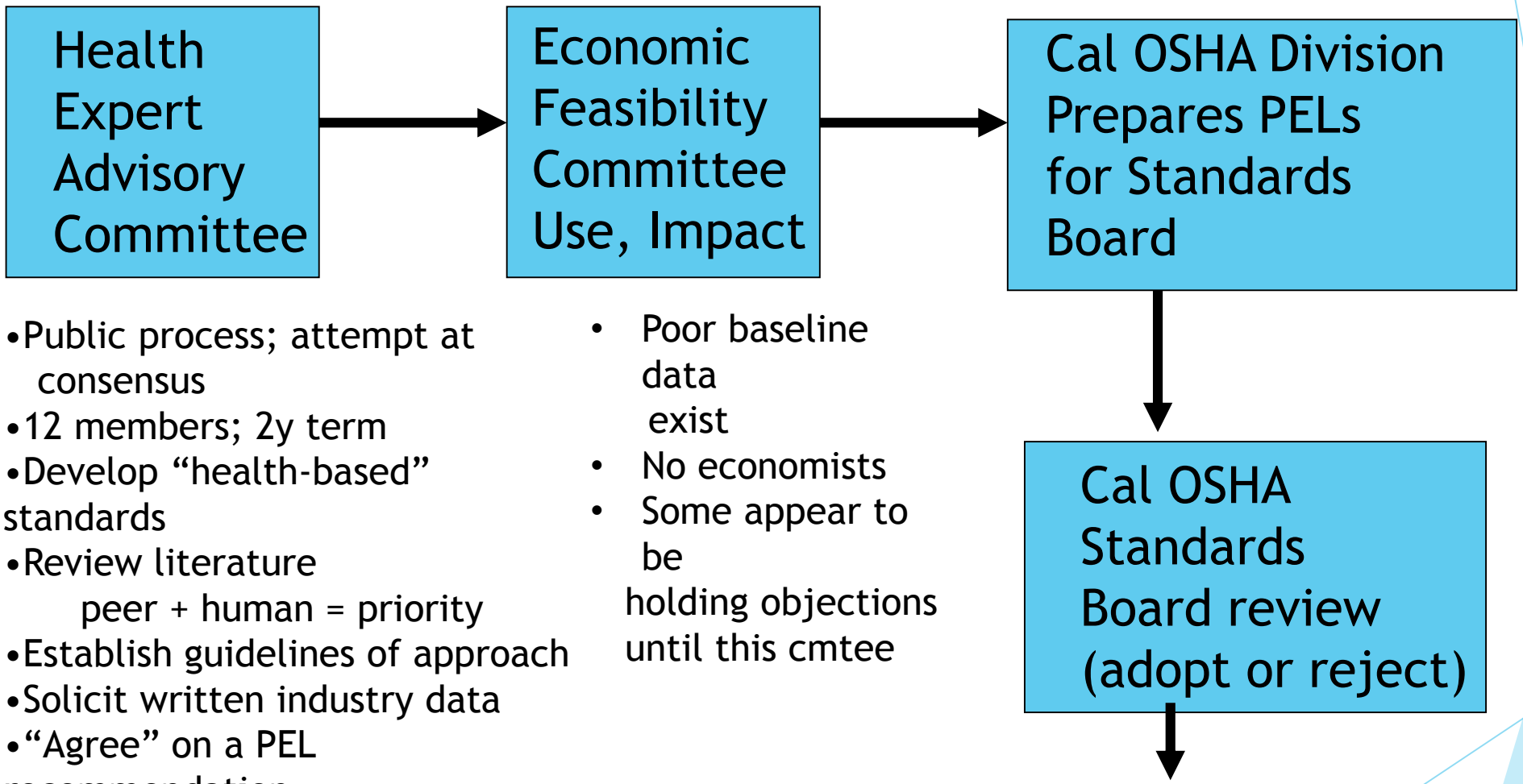
2004-2007

- In 2004, OSHA Personnel changes
  - Bruce Wallace retired;
  - No Head of Cal OSHA; Len Walsh was interim Chief
- Some PELs proposed by 5155 Committee were below the ACGIH TLVs
- After the PEL process was complete, industry complained. Meetings with lawyers ensued, law suits were threatened.
- The 5155 Committee was asked to change the science-based PELs to the ACGIH Values which they did not.
- The 5155 committee was thanked and then disbanded with a brand new CAL OSHA coffee mug.
- During 2006-7, the glutaraldehyde committee was established.
- The 5155 committee languished until 2007.

2007-2016…

- 2007 – The Division established the HEAC and FAC committees.
- The 5155 committee reconvened in 2008; the Cal OSHA Approach was revised, a priority list of ~250 chemicals was drafted based on stakeholder input.
- 2009 – PELs with no controversy from the 2004 committee were passed by Cal OSHA Standards Board.
- By 2013
  - A total of 17 HEAC meetings have been held, while the FAC has only met a few times
  - The HEAC had stopped meeting in 2012
  - Attrition caused the HEAC committee members to reduce from 12 → 6
  - B. Barish retirement; no replacement, no backfill
- The 5155 committee languished until 2016.

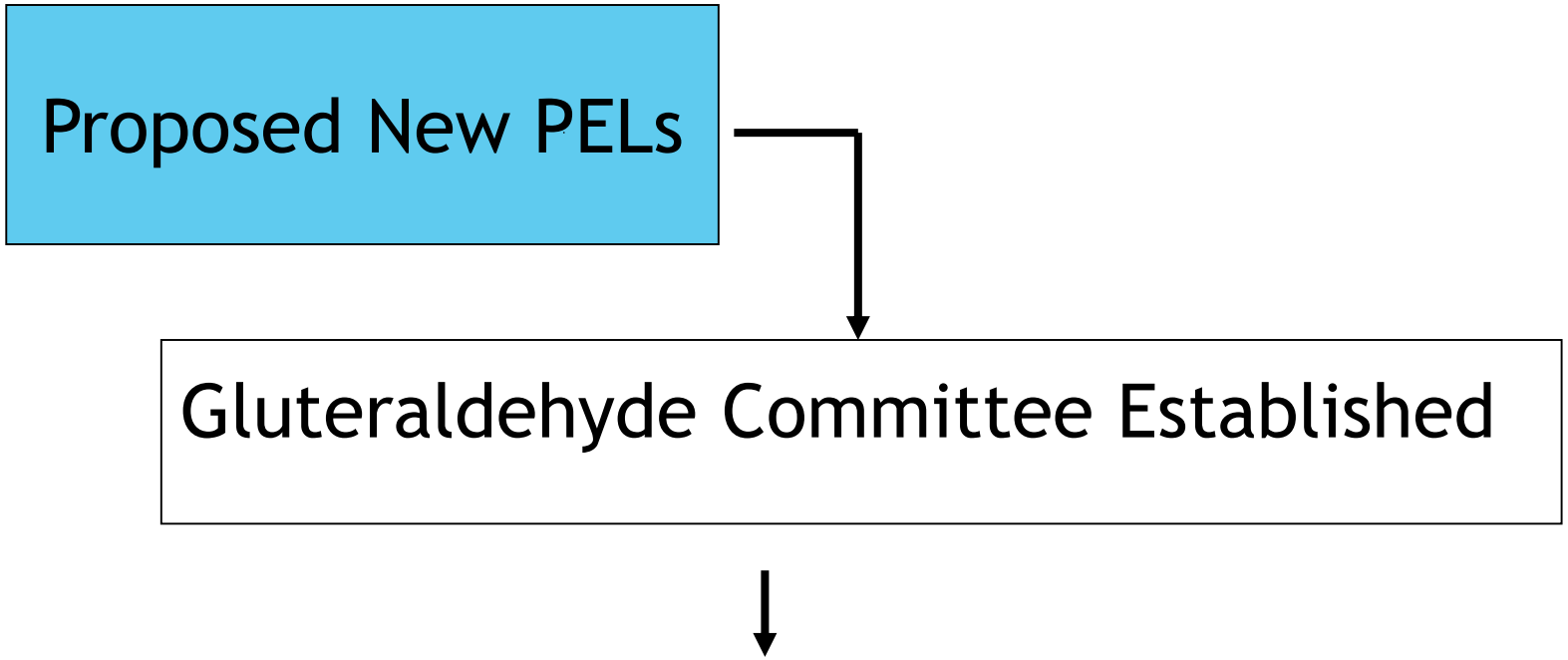
2007 California Process



- Public process; attempt at consensus
- 12 members; 2y term
- Develop "health-based" standards
- Review literature
  peer + human = priority
- Establish guidelines of approach
- Solicit written industry data
- "Agree" on a PEL recommendation
- Write standard format data sheet showing rationale

- Poor baseline data exist
- No economists
- Some appear to be holding objections until this cmtee

Single Substance Committee



Results

- Process is much slower than pre 2004 committees
- PEL proposals that have “passed “ the HEAC and FAC are still awaiting CAL OSHA to present to the Standards Board

Chemical	From	Proposed	PEL lowered by factor of
ethylbenzene	100 ppm	0.5-7 ppm	200
n-methyl-2-pyrrolidone	New	1-10 ppm (AIHA WEEL = 10ppm)	---
hydrogen chloride	5 ppm	0.3 ppm	16
naphthalene	10 ppm	0.03 – 0.75 ppm	333
wood dust (western red cedar)	25 mg/m^3	0.5 mg/m^3	50
trichloroethylene	25 ppm	0.4 ppm	62

2013 Review Results

Chemical	ACGIH TLV or OSHA PEL?	Proposal
lithium hydroxide	No	1 mg/m^3
2,3,4,5-tetrachloropyridine	No	5 mg/m^3
diisobutylene	No	75 mg/m^3
2,2,2 trifluoroethanol	No	0.3 ppm
triethoxysilane	No	0.05 ppm
1-decene	No	100 ppm
diethylene glycol monoethyl ether	No	5 ppm

Highlighting Differences Between Federal PELs and CA OSHA PELs

	Fed PEL (ppm)	CA PEL (ppm)	CAS	ACGIH TLV (ppm)
p-dichlorobenzene	75	10	106-46-7	10
dichloromonofluoromethane	1000	10	75-43-4	10
1,1 dimethylhydrazine	0.5	0.01	57-14-7	0.01
dioxane (diethylenedioxide)	100	0.28	123-91-1	20

Highlighting Differences Between Federal PELs and CA OSHA PELs

	Fed PEL (ppm)	CA PEL (ppm)	CAS	ACGIH TLV (ppm)
2-ethoxyethanol (cellosolve)	200	5	110-80-5	5
ethylbenzene	100	5	100-41-4	20
Total dust – particulates not otherwise regulated	15 mg/m3	10 mg/m3	None	10 mg/m3 inhalable
triethylamine	25	1 ceiling	121-44-8	0.5 ppm; 1ppm STEL
trichloroethylene	100	25	79-01-6	10

Overview of OELs

- Occupational exposure limits (OELs) exist for a small portion of chemicals in commerce in the US
- Some OELs have regulatory authority; Fed OSHA PELs, CA PELs, Oregon PELs
- Some OELs are advisory in nature; ACGIH TLVs, NIOSH RELs, AIHA WEELs, company derived OELs
- Some lists of OELs are stagnant; Fed OSHA PELs, Oregon PELs
- Some OELs are periodically updated; ACGIH TLVs, NIOSH RELs, CA PELs

Annotated Federal PELs

- In 2016, three federal OSHA Annotated tables were published on the OSHA website
  - Z1 – Limits for Air Contaminants
  - Z2 – Toxic and Hazardous Substances
  - Z3 – Mineral Dusts

CA OSHA v Federal OSHA PELs	Approximately
Number of California PELs; based on unique CAS numbers	775
Number of California PELs lower than Federal PELs (includes CA PELs which have no federal counterpart)	200 (26%)
Oregon State PELs that are lower than Federal PELs or no Federal counterpart	146

OEL toolbox for Industrial Hygienists

1. Federal OSHA PELs – annotated since 2016 with CA OSHA, ACGIH, and NIOSH RELs
2. Cal OSHA PELs (current version Table AC-1)
3. Prop 65 Chemicals known to the state to cause cancer
4. OEHHA – No significant risk levels and maximum allowable dose levels
5. Oregon Air Contaminants (current version Table 1-2)
6. NIOSH RELs
7. ACGIH TLVs (2018 version)
8. OARS/TERA; WEELs and beyond
9. EU indicative occupational exposure limits
10. NIOSH occupational exposure banding process (2017)
11. Company derived OELs

Positives of the CA process

- Public process – with all that this implies
- Standard format for reporting committee analysis & recommendations has been developed; similar to AIHA WEEL and ACGIH TLV documentation
- State agencies are interested
- Industries, trade, and labor groups participate
- Recognition that California is in front of the nation in terms of revising the 30 year old Fed OSHA PELs…no other State has a process to systematically update PELs

Issues

- Resource allocation effecting the length of time it takes for Cal OSHA to devote to PEL development and prepare PEL summaries to the Board
- Struggle on cancer prevention at 1/1000 risk level
- Presumption of HESIS, OEHHA approach as used in Prop 65 NSRLs
- Lack of agreement on uncertainty factor (UF), start by having to argue away from OEHHA risk assessment UF
- Choice of endpoint for PEL basis
- Lack of statistical power in studies
- Definition of the workers we are protecting & level of worker protection including ethnic, gender, age
- PELs lower than Fed, ACGIH levels

Other Issues

- NIOSH, the Division, and CDPH met in Berkeley in 2011 to discuss lead PBPK modeling and research which pointed to reducing the airborne PEL for lead
- A committee was formed and recommendations were made, the effort started in 2011 and concluded in 2015
- Since 2015, the Division's task was to prepare the recommendations for submission to the Standards Board… the economic analysis was completed in in August 2018
- 8 years later this is not done…

Meanwhile, in 2018, Michigan took the step to lower BBL criteria for lead

BLL for employee	Federal	Michigan
Removed from work	50ug/dL (60ug/dL const.)	30ug/dL
Return to work	<40ug/dL	<15ug/dL

On the books but no one does…

- Directors list of hazardous chemicals is supposed to be updated every 2 years
- MSDS are required to be sent to Cal OSHA
- Occupational carcinogens control act – employer required to notify the Division when they use or change process to use a carcinogen

What Industry, Trade Groups, Worker Safety Groups can do…

- Review the list of priority chemicals
- Do you have OELs or recommendations for PELs based on your use of chemicals? P1 and P2 specifically
  - Will you share the rationale with the State?
  - Do you have dose / response data that can be shared?
- Are there practical limits on monitoring and analysis of target chemicals?
- Can you volunteer an MD, epidemiologist, or toxicologist to participate on the committee?

Now, the current California PEL process

“New” Cal OSHA PEL Process

- After ~five years of inactivity, the Cal OSHA Advisory Committee for the development of airborne PELs was resurfaced in 2016
- CA OSHA assembled 12 members, 7 recycled from the last HEAC, two new MDs, one epidemiologist, one out-of-state participant
- First Meeting 12/6, 2016 (9th meeting held last week)
- Pace for PEL recommendations to the Division remains slow
- Notable Changes

  New Staff Epidemiologist Dr. Garrett Keating acts as chairman

  Feasibility Assessment eliminated and melded into the Health Effects Advisory Committee or done by the Division

  Role of OSHA said to be larger, time will tell

  Encouraging Discussion on evaluating chemical use in the State

Current HEAC Members

***Recycled* Members are in bold**

- Michael Bates, PhD– Epidemiology Professor, UC Berkeley
- Eric Brown, DrPH – Tri Alpha Energy
- **Mike Cooper MPH, CIH – consultant**
- **Will Forest, MPH – Santa Cruz County DPH**
- Robert Harrison, MD – Occupational Medicine UCSF
- Sarah Janssen, MD – Kaiser
- **Linda Moore, MD – Kaiser - resigned**
- **Patrick Owen, MSPH, CIH – Shell Martinez**
- Kent Pinkerton, PhD – Professor, UC Davis Veterinary Medicine, inhalation toxicology
- **Howard Spielman, CIH, CSP – consultant**
- **Mark Stelljes, PhD – SLR International**
- **James Unmack, MSEE, PE, CIH – consultant**

Actions to Date

- **Reviewed** residual HEAC recommendations from 2011-2012
- Note TMA NIOSH limit of detection is 0.002 mg/m3

Chemical / CAS	CA OSHA HEAC Recommendation	Existing CA OSHA PEL	Federal PEL	ACGIH TLV
cyclohexane (110-82-7)	50 ppm	300 ppm	300 ppm	100 ppm
N-propanol (71-23-8)	100 ppm	200 ppm	200 ppm	100 ppm
trimellitic anhydride (552-30-7)	0.0005 mg/m3 (0.5ug/m3)	0.04 mg/m3 ceiling	None	0.0005 mg/m3 TLV (2008) 0.002mg/m3 STEL

Actions to Date - Priorities List Discussion

- Priority for HEAC review should be based ***roughly*** on
  1. **Whether a CA PEL currently exists**
  2. **Substantial change in other Occupational Exposure Limits, NIOSH, TERA/OARS, ACGIH**
  3. **Chemical use (exposure potential) in CA**
  4. **Health effects / toxicity for CA workers**

- Example of polyvinyl chloride dust – why spend State and Committee resources on this?
- The HEAC recently revised the chemical priority list, this becomes the road map for chemicals under consideration by the committee – electronic handout from Cal OSHA

Prioritization flowchart, visual for discussion purposes

Cooper DRAFT, 12/17

Is the chemical used by employees in CA? (TRI, CERS, SDS providers, CDR review

No → **Priority 3:** Re-evaluate as appropriate

Yes ↓

Does a PEL exist for the chemical ?

No → Has a clear clinical endpoint (respiratory/ocular) been reported?

No → **Priority 3:** Re-evaluate as appropriate

Yes ↓

Is there an established analytical method?

No → **Priority 2**

Yes ↓

Priority 1

Yes ↓

Has there been a substantial change (10x or more reduction by a OEL body – ACGIH, OARS/TERA, AEGL, NIOSH) or significant new hazard?

No → **Priority 3:** Re-evaluate as appropriate

Yes ↓

Priority 1

Chemical Use in CA

- Data Bases

  CERS – mandated California Environmental Reporting System

  facilities report storage/use of hazardous materials

  HMBP – resubmitted every 3y, HMIS verified each year

  55 gallons (liquids), 500 pounds (solids), or 200 cubic feet for a compressed gas

  May present a problem with State EPA resources to mine data

  Solicit Companies that provide SDS services (Eric Brown approach)

  Companies agree to scrub company data, offer this as a service to customers in keeping them up-to-date on PEL activity in the State

  3E

  MSDS Online

  Safetec

Priority 1 List

	TLV/PEL	Year / Source
benzophenone	New	HESIS
SO2	TLV = 5ppm, 0.25ppm STEL	2009
Turpentine, monoterpines	TLV = 100ppm	2003
Di(2-ethyl)-phthalate (DEPH)		
n- butanol	Recommended 20ppm	
MIBK	Recommended 5ppm, STEL 75ppm	
t- butyl alcohol	Recommended 1 ppm (oral)	
manganese	Recommended 0.02 mg/m3 respirable and 0.1mg/m3 total	

Other Discussions of late- arguably for separate committees:

- Wildfire smoke
- PM2.5

Priorities cont.

- 49 chemicals on the Priority 2 list; Cr(VI), methylisopropylketone, calcium silicate, etc.
- 43 chemicals are on the secondary Priority 2 list; methanol, boron trichloride, thiourea, zinc chromate
- Of interest is the growing “Special committee” list – 24 chemicals at last count

  Be, arsine, bisphenol A, diacetyl, formaldehyde, silica, styrene

Data Needed for HEAC Technical Review

Dose / Response !!

What is the most significant endpoint?
Do employees show signs/symptoms of exposure?
Are employees re-assigned due to exposures?
Are medical monitoring data correlated to exposures?
Do the data suggest a NOAEL or LOAEL?
Do dose/response data exist?
Are data for human exposure available?
Have any reviews been published by Industry groups?

PEL Recommendation

- What is the OEL used by industry or industry groups?
- What is the basis for the OEL?

Data Needed for HEAC Technical Review

Quantitation & Monitoring

- What monitoring methods are available?
- Are the methods validated?
- What are the practical detections limits?
- What are the limits of quantitation?
- What are the typical error bars?

Meanwhile, back at AIHA…

Recall the statement that *updating OELs* has been the number 1 public policy issue for AIHA for decades?

WEEL Committee Changes

- In 2011, AIHA had a 35 year tradition of the WEEL committee setting workplace environmental exposure limits (WEELs) for substances without Federal OSHA or the ACGIH TLV OELs.
- WEELs are health-based guide values for chemical stressors; air concentrations intended to protect most workers adverse health effects related to occupational chemical exposures
- Approximately 120 WEELs have been developed and maintained current.
- WEEL/BEIs (biological exposure indices) were published annually by the AIHA and documentation was available for purchase.
- AIHA funded the WEEL committee through their non-profit AIHA Guideline Foundation

Changes in 2011

- ACGIH was sued by concrete industry group and others claiming that the TLV process did not adequately include industry input and that TLVs were being used by regulatory agencies. AIHA supported ACHIH in the lawsuit.
- On September 28, 2011, the AIHA Board of Directors passed the following motion:

  "*AIHA will no longer provide direct or indirect funding to the 501(c)(3) AIHA Guideline Foundation activities related to WEELs and BEELs effective January 1, 2012.*"
- Hence the WEEL committee was defunded. Apparently the committee, in addition to the voluntary technical work, was supposed to also fund-raise.
- In response, an initiative called OARS, managed by Ohio based Toxicology Experts for Risk Assessment (TERA), was formed by the "old" WEEL committee .

What is OARS /TERA?

- TERA Toxicology Assessment for Risk Assessment is a Cincinnati based independent non-profit (501(c)(3)) organization, founded in 1995 by Dr. Michael Dourson, a toxicologist who worked with the EPA for 15 years.
- OARS is the Occupational Alliance for Risk Science.
- OARS is an initiative managed by TERA
- The basic goals of OARS
  - Facilitate sharing of information with workers and occupational health & safety professionals
  - Provide a forum for information exchange about exposure guidance for chemical stressors, methods of improving occupational risk assessments, and training opportunities
  - Establish a scientific forum to develop health-based OELs for high priority chemicals lacking others OELs

Impact of OARS WEELs

- WEEL values and their full documentation will be available at no charge on TERA website and published in a journal to increase access
- There is an option for stakeholders to sponsor a WEEL and provide a data package to facilitate the process. Tax deductible grants for WEEL development can be made; 8-10k per WEEL depending on database size
- The OARS committee provides an independent review for OELs that have been developed to assist stakeholders with a 3rd party independent review
- The high quality science and committee process remain the same
- OARS contact is Dr. Pat McGinnis

Questions?

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See – HEAC, Cal OSHA Advisory Committee – Section 5155 for chemical priority list, agenda, minutes, proposals, etc.