Presentation to the OSH Standards Board on January 18, 2018 in Oakland, CA
Permissible Exposure Limit (PEL) Updates to Title 8, Section 5155, Airborne Contaminants
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- Division has reviewed and updated PELs since 1970s.
- Advisory process always used to develop new/revised PELs. HEAC/FAC process formalized in 2006.
- Need to update PELs based on new health effects information; consider usage as a factor in review.

Quick History

1977-2005 Airborne Contaminant Advisory Committee

- Division selected members from profession and academia based on expertise
- Members added/replaced as needed; public meetings open to stakeholders
- Members informally summarized OELs, science and made recommendations
- Average of 10-20 substances reviewed every year and recommendations summarized in meeting minutes. Rulemaking updates done every 3-5 years.

2006-2012 Health Experts Advisory Committee /Feasibility Advisory Committee

- Policy and Procedures created three-committee structure (HEAC/FAC/SS)
- Expertise: industrial hygiene, toxicology, epidemiology, medical;
- Members prepared summary document of OEL, studies and recommendation
- Highlights: Priority List developed; 16 recommended new/revised PELS

2016 - Health Effects Advisory Committee

- FAC dissolved and feasibility considered during HEAC process.
- Staff prepares summary document of OEL, studies and recommendation

Chemical Substance Review Process

1. Prioritize: Annually prepare Priority 1 List of Substances from existing ranking (400+). Ranking factors:

- A substantial change in the value of a PEL that could contribute to increased protection of workers

- Evidence of a serious potential hazard not adequately addressed by existing regulations

- Whether a substance is in widespread use in California or there is pervasive worker exposure

- The serious nature of the health hazard presented by the substance

- Substance has no PEL

Chemical Substance Review Process (cont)

2. Review of Scientific/Regulatory data: review published literature since last major review

- review of published literature on PubMed, other - conducted by HESIS
- review of other health effects determinations – ACGIH, NIOSH, USEPA, CalEPA, ATSDR, IARC, others

3. Summarize data and recommendation for discussion with HEAC, stakeholders, and the public at 2 or more HEAC meetings

- Identify key study or studies
- Identify mode of action – portal of entry (ex: irritation) vs systemic (ex: neurologic)
- Present risk-based assessments – evaluate uncertainty factors, dose adjustments, modeling
- Consider need for STEL and other notations

4. Finalize PEL based on comments from HEAC and others with feasibility and economic assessments

- Seek consensus on key study/endpoint to serve as basis for PEL

How is science determined?

From HEAC Policies and Procedures, 2009:

"In evaluating the scientific literature, HEAC will use a "weight-of-evidence" approach rather than attempt to evaluate all existing scientific evidence relevant to a particular substance. "

- Review current scientific literature and secondary sources that include NIOSH, OEHHA, U.S. Environmental Protection Agency (USEPA), the National Toxicology Program (NTP) and other sources, such as ACGIH.

- Recommendations and studies of private industry, the military, and international organizations also used as reference sources. HEAC will discuss with Division staff on an ongoing basis the most efficient and productive approaches to generating these documents.

- Preference will be given to peer-reviewed articles published in recognized scientific journals. Other studies, such as industry-sponsored studies or other unpublished reports, will be considered if they are relevant, sufficiently well documented, and submitted in a timely fashion

How is industry use (epidemiological studies, experience, operations) considered ?

- Review of published industry-sponsored studies subject to peer-review

- Review of historical industry studies frequently cited in support of OELs, especially STELs (IRIS, ACGIH).

- Review of epidemiological studies evaluated on a basis of well-defined chemical concentrations and exposures.

- Review of information/data submitted by stakeholders during the advisory meeting process.

OSHA's hazard banding process

- Once federal OSHA adopts a regulation on hazard banding, the Board has six months to adopt a regulation that is at least as effective.

- Division is aware of the hazard banding recommendations of NIOSH and other organizations.

HEAC selection/vetting

- Division will seek experts from academic institutions, professional associations, experienced health and safety professionals, other state agencies and other interested groups
- Members to disclose fully any organization they represent or affiliations they have which might be a conflict of interest
- HEAC includes at least 8 experts in the following 4 disciplines:

Toxicology (Ph.D. level preferred)	2
Epidemiology (Ph.D. level preferred)	2
Occupational medicine (M.D. level required)	3
Industrial hygiene (M.S. or M.P.H. level and CIH preferred)	4

HEAC selection/vetting (cont.)

The Division identifies candidates through the following types of sources:

- Recommendations of past committee members.
- Recommendations of experts who are unable to participate themselves.
- Recommendations from relevant professional associations.
- Applications and recommendations from interested parties and the public.

PEL Website

http://www.dir.ca.gov/dosh/DoshReg/5155Meetings.html

- Current HEAC Agenda and draft PEL summaries
- Roster of members indicating their affiliations and expertise
- Past HEAC proceedings – minutes and PEL summaries
- Priority List of Substances indicating current PEL, OELs, & notes
- Special presentation to HEAC – sensitization, risk-based methodology

Feasibility

The California OSH Act of 1973 and the federal OSH Act of 1970 are similar regarding establishing regulations to protect employees from toxic materials and harmful physical agents.

Feasibility

California Labor Code

Section 144.6. In promulgating standards dealing with toxic materials or harmful physical agents, the board shall adopt that standard which most adequately assures, **to the extent feasible**, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to a hazard regulated by such standard for the period of his working life…

Feasibility

United States Code, Title 29

Section 655(b)(5). The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, **to the extent feasible**, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life…

Feasibility

The U.S. federal courts have already established what evidence federal OSHA must provide to demonstrate that a regulation[1] is “feasible.”

Since the California and federal laws are similar, the U.S. federal court decisions are also useful for California rulemaking.

1. Specific to regulations for toxic materials and harmful physical agents.

Feasibility

U.S. Court of Appeals D.C. Circuit December 22, 2017 No. 16-1105 (Silica)[2]:

- Two types of feasibility
  - Technological Feasibility:
  - Economic Feasibility:

2. https://www.cadc.uscourts.gov/internet/opinions.nsf/03C747A5AB141C90852581FE0055A642/$file/16-1105-1710179.pdf

Technological Feasibility

D.C. Circuit: "To establish technological feasibility, OSHA, after consulting the 'best **available** evidence,' must prove a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the [standard] in most of its operations."

Technological Feasibility

D.C. Circuit: Various examples of infeasibility for certain firms or certain operations do not undermine:

- OSHA's overall finding of feasibility for the typical firm in most operations
- or the evidence on which OSHA relied.

Technological Feasibility

D.C. Circuit: "Even if sufficient controls do not yet exist, Industry's challenge to OSHA's feasibility finding nonetheless fails. In considering which controls can feasibly be implemented, OSHA "is not bound to the technological status quo." "Because the OSH Act is a 'technology forcing' statute, OSHA can also 'force industry to develop and diffuse new technology'" to meet its standard."

Technological Feasibility

D.C. Circuit: So long as OSHA "gives industry a reasonable time to develop new technology" and "presents substantial evidence that companies acting vigorously and in good faith can develop the technology," it can "require industry to meet PELs never attained anywhere."

Economic Feasibility

D.C. Circuit:

- "A rule is economically feasible in a particular industry so long as it does not threaten massive dislocation to, or imperil the existence of, the industry."
- "[a] standard is not infeasible simply because it is financially burdensome or even because it threatens the survival of some companies within an industry."

Economic Feasibility

D.C. Circuit:

- OSHA must also provide "a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms."
- "Courts, [moreover], 'cannot expect hard and precise estimates of costs.'"

“Burden of Proof”

California Administrative Procedure Act, Government Code sections 11340 et seq.

- The agency proposing a regulation must provide evidence for the need for the regulation and the costs/benefits of the regulation.
- Federal agencies have similar requirements under the U.S. Administrative Procedure Act , Pub.L. 79–404, 60 Stat. 237.

“Burden of Proof”

D.C. Circuit: OSHA must support its finding of technological feasibility with substantial evidence. Substantial evidence does not require absolute certainty… the mere “possibility of drawing two inconsistent conclusions from the evidence does not prevent [the] agency’s finding from being supported by substantial evidence.”

“Burden of Proof”

- **D.C. Circuit:** So long as “OSHA makes reasonable predictions based on ‘credible sources of information’ (e.g., data from existing plants and expert testimony), then the court should defer to OSHA’s feasibility determinations.”

"Burden of Proof"

D.C. Circuit: The substantive issues are governed by the **"substantial evidence"** standard, 29 U.S. Code § 655(f), under which we require OSHA to "identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument."

“Burden of Proof”

OSHA must support its significant risk finding with substantial evidence. Although it must rely on a “body of reputable scientific thought” when assessing risk, OSHA does not have to “calculate the exact probability of harm” or support its finding “with anything approaching scientific certainty,”

Feasibility: Cal/OSHA HEAC meeting

- Research existing industrial hygiene monitoring data in peer reviewed scientific journals
- Research occupational exposure limits in other jurisdictions
- Research existing monitoring data from NIOSH, federal OSHA, and Cal/OSHA.
- Request monitoring, use and cost data from stakeholders

Feasibility: Cal/OSHA HEAC meeting

- Determine if substance is used in California
- Determine whether it is technically possible to measure exposures at the proposed level
  - Validated sampling methods from OSHA, NIOSH
- Determine means and methods to control exposures to the proposed level.
- Determine if a delayed effective date benefits feasibility.

Feasibility: Cal/OSHA HEAC meeting

- Are some or many employers already meeting lower exposure limits being considered?
  - What controls are being used and what is the cost of the controls?
- What must other employers do to meet the lower exposure limits being considered?
  - Gap between existing levels and proposal
  - Cost of engineering and administrative controls
- Will respirators be needed for certain operations to meet the lower exposure limit being considered?

Feasibility: Title 8 PEL Rulemaking

- Estimate costs and benefits using available information from research and stakeholder input.
- Recent federal rulemaking (beryllium, silica) provides estimates on costs of controls
  - May overestimate costs due to inclusion of other component not in a PEL update (written control programs, regulated areas, hygiene practices, housekeeping, medical monitoring, recordkeeping, etc.)