Wood Dust: Prop 65 and CA OSHA Update

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Prop 65 - Overview

- What is it?
- When was this announced?
- How many chemicals are on the list?
- What do you have to do?
- What happens if you don't?

Prop 65 – What is it?

- Safe Drinking Water and Toxic Enforcement Act of 1986
  - Approximately 800 chemicals, both natural and synthetic, are on the list
  - Requires clear and reasonable warning for dose contributing to “significant risk”
  - Warning can be as labels, placards, notices in the newspaper

Prop 65 – Wood Dust

- On December 18, 2009, California listed wood dust on its list of chemicals known to the state of California to cause cancer
- Trigger was that wood dust met the labor code citation requirements by IARC/NTP finding that wood dust is a carcinogen
- 1995, IARC determined there was sufficient evidence that wood dust causes cancer in humans
- 2002, NTP concluded that wood dust is a human carcinogen
- 12/18/2010, Prop 65 requires wood dust labeling

Evidence that Wood Dust Causes Cancer

- Animals
  - No cancer bioassay has been conducted on “wood dust”
- Humans
  - Studies have shown associations with several endpoints (nasopharynx, oropharynx, hypopharynx, larynx, lung, non-Hodgkins’ lymphoma, Hodgkin’s disease, multiple myeloma, leukemia, digestive tract, etc.)
    - Adenocarcinoma of the nasal cavity and paranasal sinuses yields the most compelling site
    - For other sites there is only limited positive data; data are inconsistent
    - NPC listed by IARC for the first time

Sinonasal

- High relative risks in the UK, France, Italy, the Netherlands, and elsewhere in the EU for nasal adenocarcinoma among workers exposed to hard wood dusts
  - 10 to 20 fold excesses of nasal cancer
  - 100 to 500-fold excess of nasal adenocarcinoma
- In the U.S. and Canada cohort studies show no excess of nasal cancer
  - Case control studies are inconsistent but usually show no increased risk
- North America has not experienced the marked excess of nasal cancer observed in the EU
- Differences between the EU and NA are striking…why?
  - Simply dose? Practices? Species?

Nasopharynx

- IARC 10/2009
- Four new studies were found compelling in listing NPC
  - Two studies were from Asia where strong potential confounding existed but was not controlled
  - Two studies had positive OR but were not statistically significant

Dose Response Modeling

- No Significant Risk Level – Created by agency
  - Not available for wood dust
- “Safe Harbor”
  - Establish data that is lower than 1 in a 100,000 excess risk of cancer
  - No rodent model to establish potency
  - Epidemiology has poor information on workplace exposure
    - No dose response data available
- Meaning?
  - Any generation of airborne dust would constitute a need for labeling?
- What can we use concerning the huge difference between EU and NA study results?

Prop 65 – Intent
Discussion with agency

- Examples to help explain California's thinking
  - Logging Company – "clear need" for warning because workers may be exposed through cutting trees (Differs from OSHA policy)
  - Piece of wood encapsulated in metal/plastic that would not create dust, no need for warning
  - 2x4 sold at big box or mom & pop – would need to provide warning

Prop 65 – How to comply

- Labeling – This product contains a chemical known by the state of California to cause cancer
- Labeling options
  - Placarding at point of sale
    - Watchdog?
    - Retailer placement?
    - Contract placement and verification?
  - On product
    - Feasibility – cut product, printing options
  - Newspaper Notices – how many, how often
  - Others?

Compliance Deadline

- December 18, 2010
- California Attorney General office enforces Prop 65
- Maximum penalty of $2500/violation/day
- Bounty Hunter provision

Cal OSHA Health Expert Advisory Committee

- “Because of the history of lung disease findings at higher wood dust exposure levels, with recent lower wood dust dose studies showing no or little adverse effect, and because of the clear carcinogenicity of wood dust vis a vis sino-nasal cancer, and our workforce’s growing risk factors as described above, HEAC support of ACGIH’s position of lowering the PEL to 1 mg/m^3 seems reasonable and feasible.”

Concerns with Draft

- Quality of data in the evaluation
  - Draft correctly notes that there are “limited studies with good exposure data and there are numerous other criticisms of the studies , including small numbers, single industrial focus, exposure data obtained by old methods, etc.”
- 1 mg/m^3 seems “reasonable and feasible”
  - No discussion concerning “inhalable” versus “total”
- Introduction of “metabolic syndrome”
- What is a “safe” level

Quality of Data – Lung Function

- Cross Sectional versus Longitudinal Studies
  - Majority of the literature on lung function reports on cross sectional design
  - These data are conflicting and, when positive, seldom show dose response
  - Controls in different regions or occupations make comparisons difficult
  - American College of Occupational and Environmental Medicine recommends longitudinal lung function evaluation
    - Internal comparison of lung function over time

Studies Showing Virtually No Meaningful Effect on Lung Function

- Andersen et al., 1977
  - No differences, exposed vs. “theoretical values”
  - No differences, high vs. low exposures
- Halpin et al., 1994
  - No difference, exposed vs. controls
  - No difference, high vs. low exposures
- Rastogi et al., 1989
  - Restriction in exposed, vs. controls
  - Highest prevalence in those with shortest exposures

Exposed vs. Control Differences Found, But No Dose-Response Effects

- Al Zuhair et al., 1980
  - Acute changes > than controls
  - No correlation with dust levels
- Chan-Yeung et al, 1980
  - FEV_1 and FVC lower than in controls
  - No correlation with exposure duration
- Dahlqvist et al., 1992
  - FEV_1 lower than in controls
    - Attributed to microorganisms
  - No analysis of relationship to measured wood dust levels

Positive Studies with Important Internal Contradictions

- Whitehead et al., 1981
  - Odds of low FEV_1/FVC in higher cumulative exposure categories
  - “no clear trend” of FVC and FEV_1 with exposure
- Dahlqvist et al., 1994
  - FEV1 workweek declines correlated with longitudinal declines over 27 months, but not over 8 years
  - Dust levels were not measured
- Shamssain, 1992
  - FVC inversely related to exposure duration
  - Odds of low FEV_1/FVC with > 10 years exposure

A Study that Clearly Shows a Dose-Response Relationship, But with Complications

- Holness et al., 1985
  - Inverse relationship of FEV_1 and cumulative exposure
  - Cabinet makers had higher mean FEV_1 than did nonexposed controls (hospital housekeeping and maintenance workers)
  - Larger across-shift declines were found in those with lower current wood dust exposures

Tulane

- This inconsistent response in the literature led to the need for a comprehensive study
- 5-year longitudinal exposure-response study of 1,164 workers in 10 wood processing plants
  - Softwood and hardwood
  - Greenwood and dry wood
  - No sensitizing woods
  - Minimal confounding exposures
  - Minimal use of PPE
  - 1 saw/planer/plywood mill, 1 plywood mill, 1 secondary millworks, 3 cabinet plants, 4 furniture plants

Tulane Findings

- No statistically significant respiratory effects of any wood solid size fraction
  - Includes cellulose, hemicellulose, lignin, tannins, inorganic ash
- No statistically significant respiratory effects on non-respirable residual particulate matter
  - Soils, engine exhaust, glues & binders, wood semi-volatiles, adsorbed water, ETS, microbials

Tulane Study Findings

- Statistically significant effects for respirable residual particulate matter in 2 facilities only
  - 1. Milling facility
    - Effect consistent with obstruction typically seen in cigarette smokers
    - Likely a under reported smoking effect
  - 2. Sawmill-Planer-Plywood Facility
    - Effect consistent with restriction
    - History of pneumonia statistically more prevalent
    - Airborne fungi or bacteria are potential causative agents

WOOD PROCESSING DUST IS HETEROGENEOUS

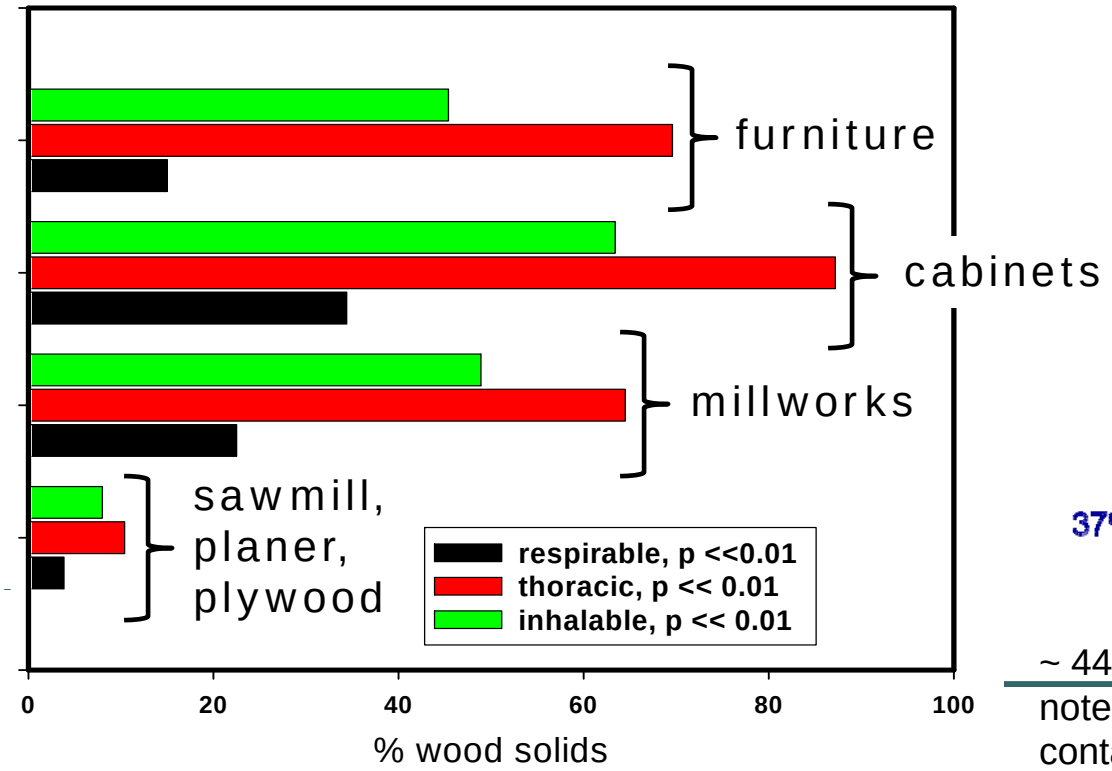
(wood, non-wood)

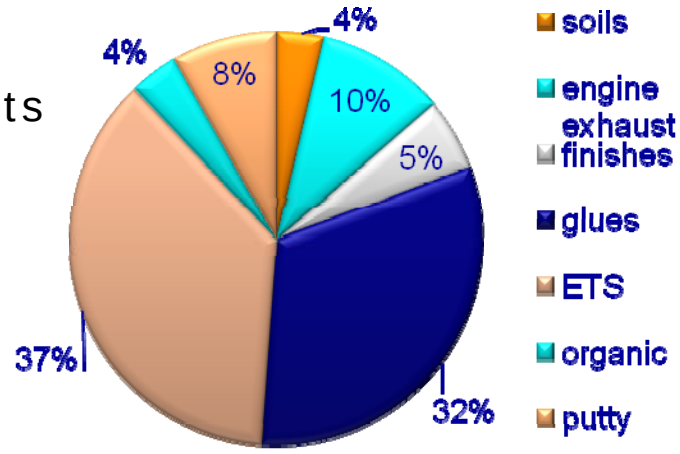
WOOD SOLIDS

- **cellulose**
- **hemicellulose**
- **lignin**
- **tannins**
- **inorganic ash**

RESIDUAL PARTICULATE MATTER

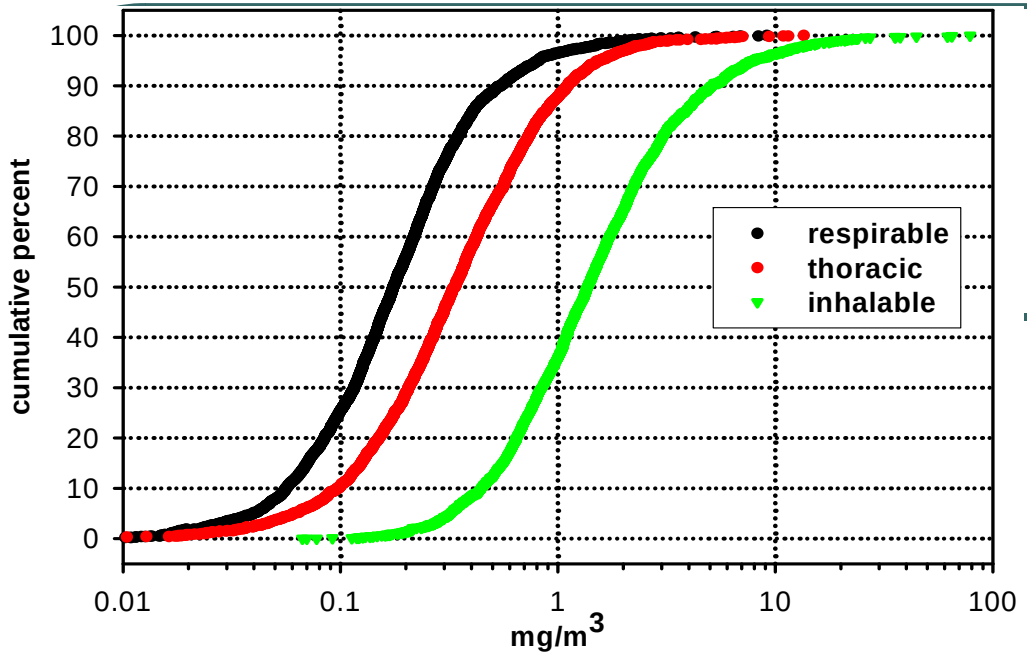
- soils
- engine exhaust
- PSV aerosols
- glues & binders
- wood semi-volatiles
- adsorbed water
- ETS
- microbials

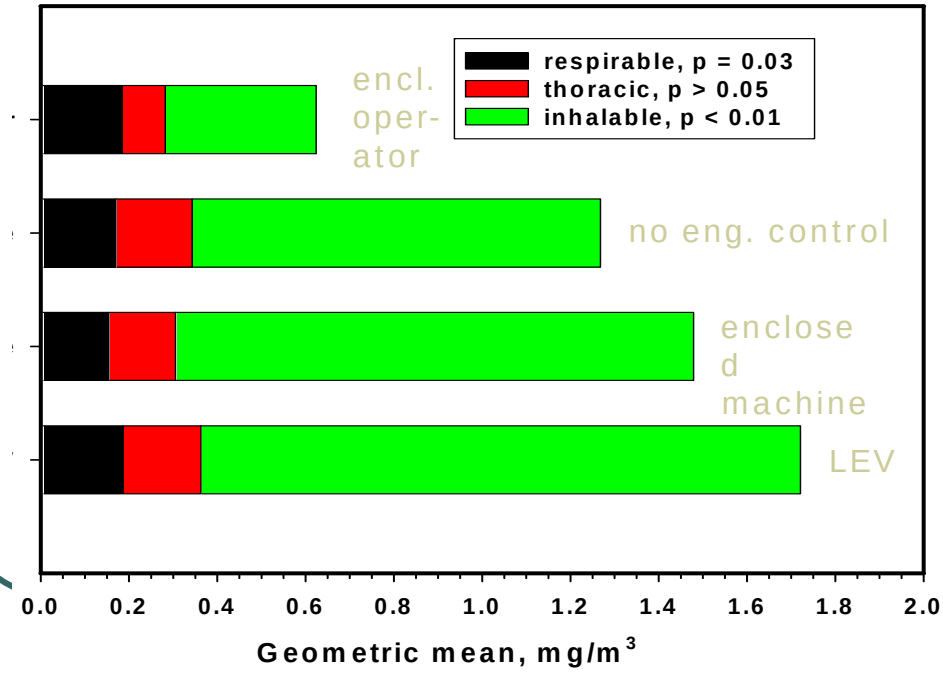




~ 44% of personal dust samples noted to contain potential non-wood contaminants.

Personal Dust Measures in the Tulane Study





Inhalable Dust (mg/m^3)	% greater than
0.5	86
1	65
2	37
3	23
5	10
10	2.4

Is Cal OSHA HEAC Proposal Reasonable?

- Historical health data are generally as total dust
- Current PEL in CA is 5 mg/m^3 total
- No units in draft: inhalable versus total – confusion???
  - Favor ACGIH that is (I)
  - ACGIH has a nominal conversion factor of 2.5
  - 1 mg/m^3 (I) converts to 0.4 mg/m^3 total dust
  - This amounts to a 10 fold reduction in current PEL

Is CA OSHA HEAC Proposal Feasible?

- “Exposure levels are at or near the recommended PEL of 1 mg/m^3”
- Tulane evaluation (n=2363)
  - 65% > 1 mg/m3
  - 37% > 2 mg/m3
  - 23% > 3 mg/m3
  - 10% > 5 mg/m3

Discussion of Metabolic Syndrome

- The draft includes the statement, “the US has 34 MM asthmatics and 16 MM with chronic bronchitis/chronic obstructive pulmonary disease, with estimated 14 MM with COPD undiagnosed. 47 MM US citizens have metabolic syndrome, characterized by obesity, diabetes, abnormal cholesterol and hypertension. 24% of the US workforce has metabolic syndrome. Obesity is now considered an independent risk factor for lung disease. These figures are all expected to rise over the next 20-30 years.”
- How does this statement relate to wood dust?

What is the “Safe” value

- Blott, et al. finds no excesses of sino-nasal cancer in NA populations
  - Suggested that 5 mg/m^3 total dust may be a threshold for this disease
- The Tulane study shows no decline in lung function across wood mill types
- Is current voluntary exposure level of 5 mg/m^3 total dust sufficient?

Summary

- Wood dust is considered a known human carcinogen
- Manufacturers of wood products sold in California will need to provide appropriate warnings by 12/18/2010
- Enforcement can be up to $2500/violation/day

Summary

- Cal OSHA is reviewing the scientific need and feasibility of lowering the wood dust PEL
- Science will be completed first (this year) with feasibility to follow
- California may set a precedent to be followed by other states of federal OSHA