

**COMMENTS ON CARB'S PROPOSED ATCM
STANDARD FOR FORMALDEHYDE IN
COMPOSITE WOOD PRODUCTS**

**CARB WORKSHOP
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Who Am I

Formal training

- BS: biology,
- MS: physiology, nutrition
- PhD: toxicology, nutrition

Career

- Professor: 14 years; research, teaching, public service; research/teaching emphasis – comparative toxicology, environmental toxicology
- Consulting: 18 years; human health risk assessment, toxicology, risk communication, expert witness, teaching



Focus of My Comments

Premise:

UF-bonded manufactured Composite Wood Products (CWPs) used in California are not sources of formaldehyde that pose an unacceptable public health risk to California citizens

Two areas:

- Comment on CARB's risk characterization
- State scientific reasons why I believe this underlying premise



Comments on CARB's Risk Characterization (CARB, 2006)

Exposure assessment:

– Objective: estimate a representative HCHO indoor air concentration from CPW sources in CA homes

– Approach:

- Used 1995 CPA/USEPA Pilot Home Study – two loading configurations (medium, high), four HCHO sources (PBU, HPWP, doors, cabinets), 1326 ft² new structure
- Extrapolated to 2000 ft² home, used “high” loading configurations
- Generated a “worst case” total emissions (µg/hr) from these data, calculated a maximum concentration (122 µg/m³)
- In range of reported concentrations in homes in CA, AZ (<9 to 285 µg/m³)
- Selected value from literature as exposure point concentration (EPC) for homes (17.2 µg/m³), assumed indoor air HCHO concentration for schools, vehicles, other indoors; calculated TWA daily EPC from all sources of 16.9 µg/m³



Comments on CARB's Risk Characterization (CARB, 2006)

Risk characterization calculation:

- $URF = 6 \times 10^{-6}/\mu\text{g}/\text{m}^3$
- $EPC = 16.9 \mu\text{g}/\text{m}^3$
- Theoretical upper-bound cancer risk:

$$URF \times EPC = 1 \times 10^{-4}$$

- CARB's stated purpose of the proposed ATCM is to reduce this cancer risk

Important question:

- Is this risk characterization reliable for good risk management decision making?



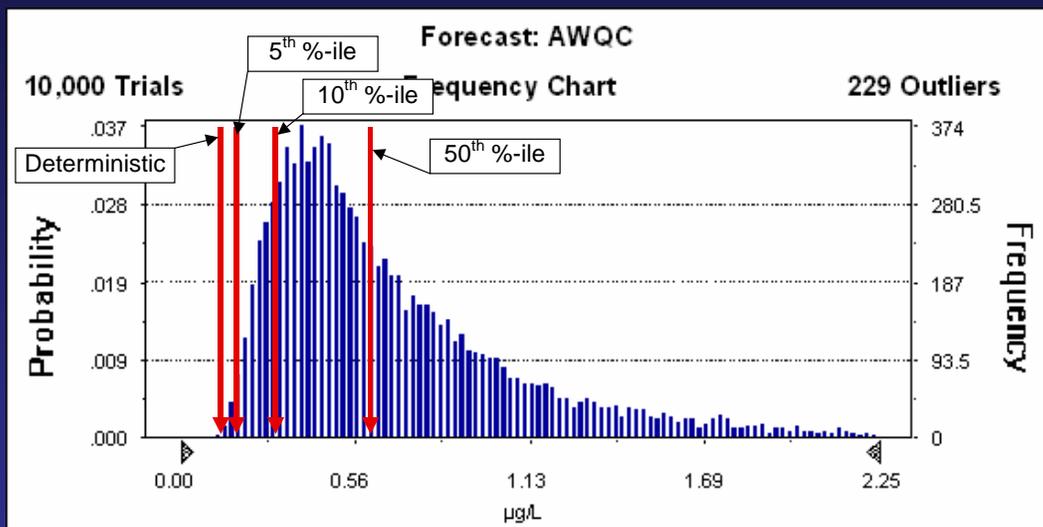
Is this risk characterization reliable for good risk management decision making?

Approach is not consistent with Federal and State of CA risk characterization guidance:

- Is a screening-level risk assessment (examples):
 - Used generic survey data to assess risk, not specifically HCHO from CWP sources
 - Assumed indoor air HCHO concentrations from UF-bonded CWP in schools and other indoor environs
 - By using the URF instead of CPF for HCHO, assumes lifetime exposure – 24/7, 365 days/yr for 70 yrs
- Guidance and other scientific organizations (Ex. NAS) strongly recommend “tiered” approach:
 - Tier 1: Screening
 - Tier 2: Refined deterministic
 - Tier 3: Probabilistic



Probabilistic vs. Deterministic Risk Assessment



50th percentile = 0.58 µg/L
10th percentile = 0.31 µg/L
5th percentile = 0.24 µg/L



Is this risk characterization reliable for good risk management decision making?

Exposure assessment:

- Not representative of current CWP use in CA:
Ex. Declining use of PBU and HPWP
- Very conservative:
Ex. Emissions decay from CWPs ignored
Ex. Assuming 24/7, 365 day/yr, 70 yrs exposure to the same indoor air concentration
- Result: overestimation of lifetime exposure to HCHO from CWPs



Is this risk characterization reliable for good risk management decision making?

Toxicity assessment:

- OEHHA's 1992 CSF/URF based on LMS model and rat inhalation data with no adjustments
- Values are obsolete and should not be relied on as a reason for the proposed ATCM standard

Some reasons why values are obsolete:

- Over 50 epidemiology studies now thoroughly analyzed
 - Inconsistent, no definitive cause-effect relationship of cancer, even in highly exposed populations
- HCHO completely detoxified at <2 ppm in air, by all tissues of the body
- Mode of action now well understood
- Strong evidence for a "threshold" dose-response

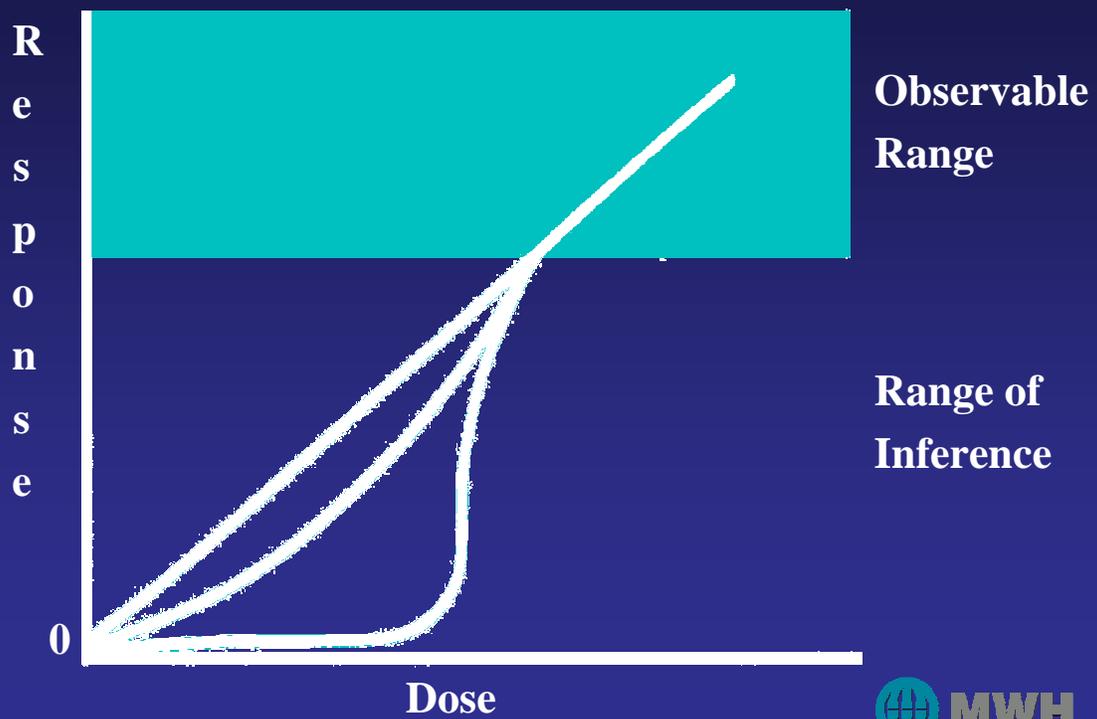
Result:

- Overestimation of theoretical upper-bound cancer risk, possibly several orders of magnitude



Dose-Response Relationship

Threshold or Non-threshold?



Cancer Risks Estimated by Three Different Models

	OEHHA 1992 URF	Draft USEPA 1991 Unit Risk Factor		CIIT 1999 Clonal Growth Unit Risk Factor	
		Upper- bound	Maximum Likely Estimate	Upper- bound; smokers	Upper- bound; non- smokers
Risk at 1 $\mu\text{g}/\text{m}^3$	6×10^{-6}	2.7×10^{-7}	3.4×10^{-9}	5.4×10^{-9}	2.2×10^{-10}
Cancer Cases Per Million Population (1 $\mu\text{g}/\text{m}^3$)	6	0.27	0.0034	0.0054	0.00022
Risk at CARB's Baseline TWA (16 $\mu\text{g}/\text{m}^3$)	101	4.6	0.057	0.091	0.0037



Premise – True or False?

Premise:

UF-bonded manufactured Composite Wood Products (CWPs) used in California are not a source of formaldehyde that pose an unacceptable public health risk to California citizens

My conclusion:

– True



Recommendations

Exposure assessment:

- Compile better data on current uses of UF-bonded CWP in CA buildings
 - Homes
 - Schools
 - Commercial buildings
- Gain a better understanding of decay factors and how they affect indoor air HCHO concentrations temporally
- Perform a Tier 2 or 3 exposure assessment
 - Develop distributions for individual parameters (probabilistic)
 - Apply more realistic exposure factors (Ex. 30 yrs = 95th percentile period of time a U.S. citizen resides in a single residence)



Recommendations

Toxicity assessment

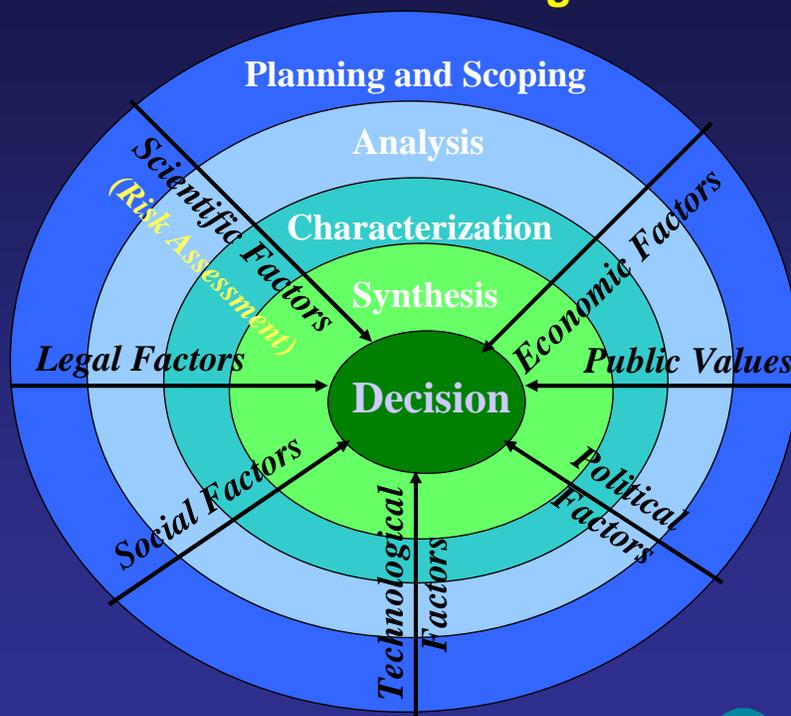
- Reassess HCHO carcinogenicity pursuant to the revised Federal Cancer Assessment Guidelines (2005)
- All scientific indicators point to a much less conservative cancer potency factor for HCHO

Other recommendations

- Work in partnership with the industry
- Develop an ATCM standard that the industry can live with, then confirm that this level does not pose an unacceptable theoretical upper-bound cancer risk using best available science
- Don't do serious damage to a valuable California industry on the unfounded premise that you're reducing cancer risk



Federal Government's Recommendation on How Risk Characterization Should be Applied in Risk-Based Decision Making



From: USEPA, 2000. Risk Characterization Handbook.



Thank You!

