Risk Assessment in Regulatory Decision-Making



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Risk Assessment: Regulatory Driver

- Emergence in the 1970s, with framework for regulatory risk assessment established in early 1980s
  - 1983 “Risk Assessment in the Federal Government: Managing the Process” (the “Red Book”), National Academy of Science (NAS)/National Research Council (NRC)
- Red Book clearly distinguishes between:
  - Risk Assessment (i.e., understanding risk); and
  - Risk Management (i.e., deciding what to do about risk)
- Now incorporated into regulatory programs in the U.S. and many other countries across the world

Human Health Risk Assessment: Chemical Exposures

- Hazard Identification: What health effects can be caused by exposure to the chemical?
- Dose Response Assessment: What are the relationships between dose of the chemical and the likelihood and severity of the health effects?
- Exposure Assessment: What is the estimated or measured magnitude, frequency and duration of exposure to the chemical, under the conditions being evaluated?
- Risk Characterization: What is the risk that the exposure may cause an adverse health effect?

Risk Assessment (Still) at a Crossroads

- Central to many regulatory programs
- Increasingly applied to broader issues (e.g., life cycle analysis)

But …

- Credibility being challenged
- Increasingly complex
- Uncertainties can lead to multiple interpretations and "decision-making gridlock" (NAS, 2009)

Risk Assessment Uncertainty

- Uncertainty exists in virtually every risk assessment
- When conducting a risk assessment, must always ask, "Is the level of uncertainty too great to allow for informed decision-making?"

Decision-making gridlock: significant disconnects between the information demands of risk managers and the scientific data available to risk assessors

Opportunity for the EHS Community: Addressing Decision-Making Gridlock

- Improving risk assessment as a decision-making tool
- Improving science used in risk assessment process
- Improving understanding of risk assessment by decision-makers

What Direction OSHA?

- Focus on employer risk assessment/risk reduction plans
  - Hazard characterization and abatement
  - Similarities with European Union approach
- Greater reliance on general duty clause
  - Hazard must be recognized
  - Substantial probability serious harm could result
  - Hazard must be correctable

What Direction OSHA?

- Agencies to take the science lead; Office of Management and Budget (OMB) will weigh in when reviewing regulations
- Increased interaction with EPA on risk assessment issues, e.g.,
  - Requiring manufacturers to provide more complete chemical hazard, exposure, and use data
  - Refining the traditional risk assessment/risk management paradigm

Enhancing Risk Assessment Utility

- Recommended modification to the Red Book risk assessment framework:[1]
  - Traditional process
    1. Risk Assessment (i.e., understand risk)
    2. Risk Management (i.e., decide what to do about risk)
  - Recommended process
    1. Upfront identification of Risk Management options
    2. Risk Assessment to discriminate amongst options
    3. Risk Management to choose option after evaluating Risk Assessment

[1] NAS/NRC Committee on Improving Risk Analysis Approaches Used by the USEPA (2009), "Science and Decisions: Advancing Risk Assessment"

What Direction OSHA?

- My 2009 CHIC presentation…..
  - Update certain PELs for which review is currently underway (e.g., beryllium, silica)
  - OSHA stated that the beryllium PEL “may not be adequate to prevent the occurrence of chronic beryllium disease," in 1999
  - OSHA reportedly will initiate peer review of health effects and risk assessment for beryllium in December 2009
  - Possibly adopt recommendations of other organizations (e.g., ACGIH TLVs)
  - Otherwise, direct resources away from chemical-specific standard setting

Beryllium Indoor Air Criteria (ug/m^3)

	2009	2014
• OSHA PEL	2.0	2.0
• CAL/OSHA PEL	0.2	0.2
• ACGIH TLV (TWA)	0.05	0.05
• EPA Region 9 RSL[1]	0.005	0.005

[1]EPA Region 9 Regional Screening Level (RSL) for industrial air

What Direction OSHA?

- Update 2014: Beryllium
  - September 5: OSHA submitted proposed rule for Beryllium exposure to Office of Management and Budget *(OSHA has been working toward rulemaking since 2002)*
  - Rule may include construction workers, in addition to general industrial workers
  - Rule may set a short term standard in addition to the 8-hr standard

Beryllium Indoor Air Criteria (ug/m^3)

	2009	2014	Future
• OSHA PEL	2.0	2.0	0.1 ?
• CAL/OSHA PEL	0.2	0.2	?
• ACGIH TLV (TWA)	0.05	0.05	?
• EPA Region 9 RSL[1]	0.005	0.005	?

[1]EPA Region 9 Regional Screening Level (RSL) for industrial air

Improving Science of Risk Assessment

- Improvements generally slow, incremental
- Some areas of substantial focus:
  - Cumulative risk assessment
  - Harmonizing dose-response assessment
  - Incorporation into life cycle analysis

Cumulative Risk Assessment

- Generally defined as "the combined risks from aggregate exposure to multiple agents or stressors"[1] (including biological, chemical, and physical stressors)
- Still very much in its infancy as a regulatory driver (despite over 20 years of guidance from the agencies!)

[1] USEPA. Framework for Cumulative Risk Assessment. May, 2003.

Cumulative Chemical Risk Assessment

- Groups of chemicals that induce a common toxic effect by a common mechanism of toxicity
- In practice:
  - Usually simplified to common target organs (lack of information on mode of action and pharmacokinetics)
  - Additivity is generally assumed
  - Synergism/antagonism rarely taken into account
- Improvements may be possible through:
  - epidemiologic investigations
  - physiologically based pharmacokinetic modeling

Cumulative Chemical Risk Assessment: Examples

- EPA's IRIS database includes toxicity values for some chemical mixtures (e.g., coke-oven emissions; diesel-engine exhaust)
- Cumulative risk assessments of four groups of pesticides with a common mechanism of toxicity (organophosphates, N-methyl carbamates, triazines and chloroacetanilides)[1]

[1] USEPA. 2002. "Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity"

Harmonizing Dose-Response Assessment

- Historically, dose-response assessments conducted differently for cancer & non-cancer endpoints
  - Cancer: Assumed no dose threshold for effect
  - Non-cancer: Assumed dose threshold for adverse affects
- Regulatory decision-making driven by difference in approach – emphasizing the cancer endpoint
- Recent NAS/NRC proposed "unified approach to dose-response assessment"
  - Incorporate "probability of harm" into non-cancer assessment
  - Improve risk-benefit comparisons and risk management decision-making

Example: Assessing Worker Risks

- OSHA and EPA have agreed that OSHA generally will take the lead role in addressing occupational exposures
- However, EPA may evaluate worker risks under certain circumstances (e.g., subsurface contaminants that may be contributing to the indoor air of workplaces)
- Example: migration of TCE from groundwater into indoor air at an industrial facility
- TCE classified by ACGIH as a suspected human carcinogen

TCE Criteria in Indoor Air (ug/m^3)

	2009	2014
• OSHA PEL	537,000	537,000
• CAL/OSHA PEL	135,000	135,000
• ACGIH TLV (TWA)	54,000	54,000
• Cal OEHHA RSL[1]	600	600
• EPA Region 9 RSL[2]	6	**3**
• **EPA Region 9 RAL[3]**	-	**8-24**

- [1]Office of Environmental Health Hazard Assessment Reference Exposure Level for air (non-cancer endpoints)
- [2]EPA Regional Screening Level (RSL) for industrial air (cancer endpoint)
- [3]EPA Regional Interim Response Action Level (RAL) for commercial/industrial exposure (non-cancer endpoint)

Recent Region 9 TCE Indoor Air Response Action Levels[1] (ug/m^3)

- Accelerated Response Action Level 8
- Urgent Response Action Level 24

- [1]EPA Region 9 Interim TCE Indoor Air Response Action Levels for commercial/industrial exposure scenario (8-hr workday) based on non-cancer endpoint, from *EPA Region 9 Response Action Levels and Recommendations to Address NearTerm Inhalation Exposures to TCE in Air from Subsurface Vapor Intrusion (July 9, 2014)*

Conclusions

- Risk assessment continues to be a key regulatory driver
- Opportunities for the EHS community
  - Improving risk assessment as a decision-making tool
  - Improving science underlying risk assessment process
  - Improving understanding of risk assessment by decision-makers