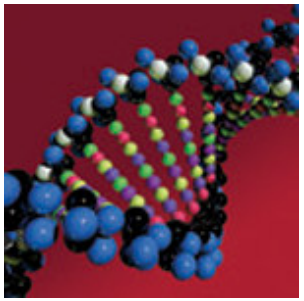
Risk Assessment – Key Regulatory Driver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Risk Assessment: Regulatory Driver

- 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?

Views on Risk Assessment: EPA Administrator

- "It is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace and the environment".
- "It is now time to revise and strengthen EPA's chemicals management and risk assessment programs"

Lisa Jackson, EPA Administrator, January 23, 2009, Opening Memo to EPA Employees

Some Views on Risk Assessment: Nominee to Head OSHA

- "Risk assessment, explicit and implicit, is the motor that drives regulation. It can be a valuable tool for assisting regulatory agencies in selecting priorities and setting standards."
- "It is also a means through which opponents of regulation can manufacture uncertainty and impede implementation of appropriate public health and environmental protection programs."

David Michaels (Nominee, Assistant Secretary of Labor for OSHA). The Pump Handle (on-line post). January 2007.

Risk Assessment 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

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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?

- 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)

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

- [2]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)

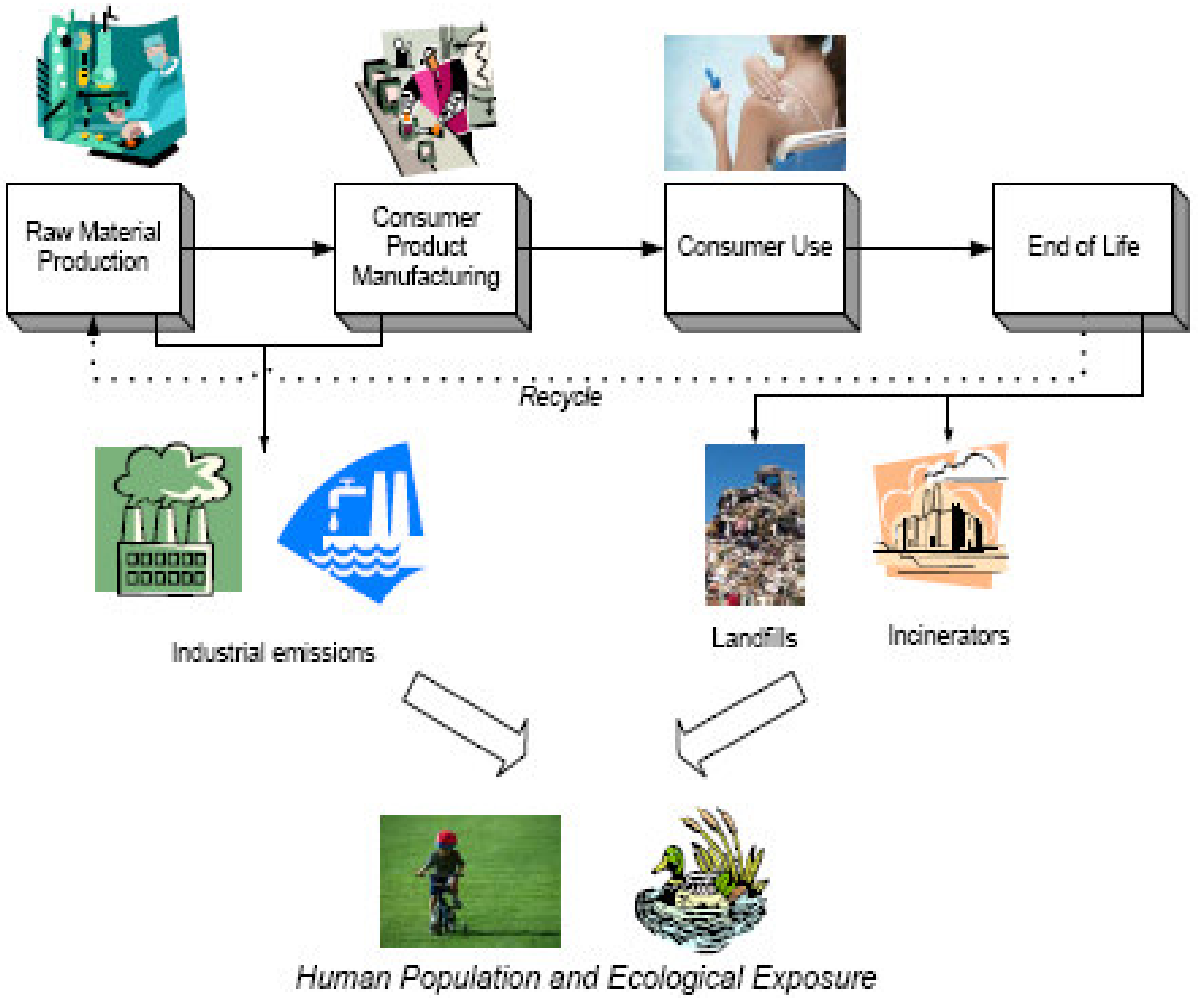
- OSHA PEL 537,000
- CAL/OSHA PEL 135,000
- ACGIH TLV (TWA) 54,000
- Cal OEHHA RSL[1] 600
- EPA Region 9 RSL[2] 6

- [1]Office of Environmental Health Hazard Assessment Reference Exposure Level for air (non-cancer endpoints)
- [2]EPA Regional Screening Level for industrial air (cancer endpoint)

Life Cycle Assessment

- Quantitative support for decision-making under product stewardship and sustainability programs
- In environmental context:
  - Document material and energy flows over product's life (i.e., "cradle to grave")
  - Apply principles of risk assessment to evaluate potential adverse health effects of material and energy flows
- Examples:
  - EPA's Essential Principles for Reform of Chemicals Management Legislation
  - California "Green Chemistry" Initiative

Life Cycle Concept



Source: Tom Theis, Director, Institute for Environmental Science and Policy, University of Illinois at Chicago (derived from US EPA website)

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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