

Introduction to Risk Assessment

LTC Stephen Lewandowski, PhD, CPH

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Course Description

Risk assessment involves many disciplines and tools that are used to evaluate and quantify/qualify risks. Environmental risk assessments typically fall into one of two areas: (1) Human Health; and (2) Ecological.

Focusing on human health, we will cover the fundamentals of environmental health risk assessment in-depth. This course provides the tools for understanding the science and art of the risk assessment process to effectively manage and communicate risk.

Course Lesson Objectives

1. Identify and apply fundamental risk assessment concepts and principles.
2. Describe the basic steps in the risk assessment process.
3. Perform fundamental cancer and noncancer calculations used in human health risk assessments.
4. Understand and determine sources of uncertainty and variability in risk assessments.
5. Understand ethical dilemmas inherent to human health risk assessment.
6. Analyze regulatory applications of risk assessment and decision making.

Course Schedule

Readings

Risk Assessment in the Federal Government: Managing the Process (1983) <https://www.nap.edu/read/366/>

Science and Judgement in Risk Assessment (1994) <https://www.nap.edu/read/2125/>

Date	Room	Lesson	Topic	Reading (Primary)	Reading (Simon)	Assignment Posted	Assignment Due
10-Nov	G250	1	Introduction to Risk Assessment	S&D: Introduction	Preface (xxi-xxiii), Chap 1 (1-20)	Presentation Sign-up	
17-Nov	Zoom	2	Hazard Identification & Risk Perception	Red Book: Chap 1	Chap 2 (63-100)	Homework 1	Presentation Sign-up
24-Nov			No Class - Thanksgiving				
1-Dec	G256	3	Dose-Response	S&D: Chap 5 (127-151)	Chap 5 (191-250)		
8-Dec	Lecture Hall A1	4	Exposure Assessment	EPA Guidelines for HEA: Chap 2; RAGS: Chap 6	Chap 4 (129-172)		Homework 1
15-Dec	G256	5	Student Presentations				Presentations
22-Dec			No Class - Winter Recess				
29-Dec			No Class - Winter Recess				
5-Jan	G255	6	Risk Characterization	S&J: Chap 5	Chap 6 (275-354)	Homework 2	
12-Jan	G255	7	Probabilistic Risk Assessment	Maertens et al, 2022	Chap 3 (113-124)		
19-Jan	G255	8	Risk Management	Sunstein, 2003; S&D: Chap 8	Chap 1 (20-48); Sakai suppl.		Homework 2
26-Jan	G255	9	Risk Communication	Risk Communication handout	Chap 8 (431-460)		
2-Feb	G255	10	Review / Case Studies			Final Assessment	
9-Feb	G255	11	Final Assessment				Final Assessment

Science and Decisions - Advancing Risk Assessment (2009) <https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment>

Exposure Science in the 21st Century: A Vision and a Strategy (2012) <http://nap.nationalacademies.org/13507>

Risk Assessment Guidance for Superfund Volume I, Human Health Evaluation Manual (Part A) https://www.epa.gov/sites/default/files/2015-09/documents/rags_a.pdf

EPA Exposure Factors Handbook: 2011 Edition <https://www.epa.gov/expobox/about-exposure-factors-handbook>

EPA Guidelines for Human Exposure Assessment <https://www.epa.gov/risk/guidelines-human-exposure-assessment>

Supplementary Textbook

Environmental Risk Assessment: A Toxicological Approach, 2nd Edition by Ted Simon, CRC Press, 2020, ISBN 9780367250973

Available online through the USU James A. Zimble Learning Resource Center (LRC) at: https://usuhs.primo.exlibrisgroup.com/permalink/01USUHS_INST/38vr5c/alma991000620119206626



Lesson Objectives

1. Define basic risk assessment terms and definitions.
2. Understand how risk assessment is used in different contexts.
3. Understand the regulatory basis for human health risk assessments.

Risk Assessment

Risk assessment is a **scientific process**.

Factors:

- *How much of a stressor is present in an environmental medium (e.g., soil, water, air) over what geographic area?*
- *How much contact (exposure) a person or ecological receptor has with the contaminated environmental medium?*
- *How does a hazard affect the health of humans (e.g., toxicity) or ecological receptors (e.g., fish killed by lack of oxygen)?*

<https://www.epa.gov/risk/about-risk-assessment#whatisrisk>

Risk Assessment Framework

EPA Risk Assessment Framework

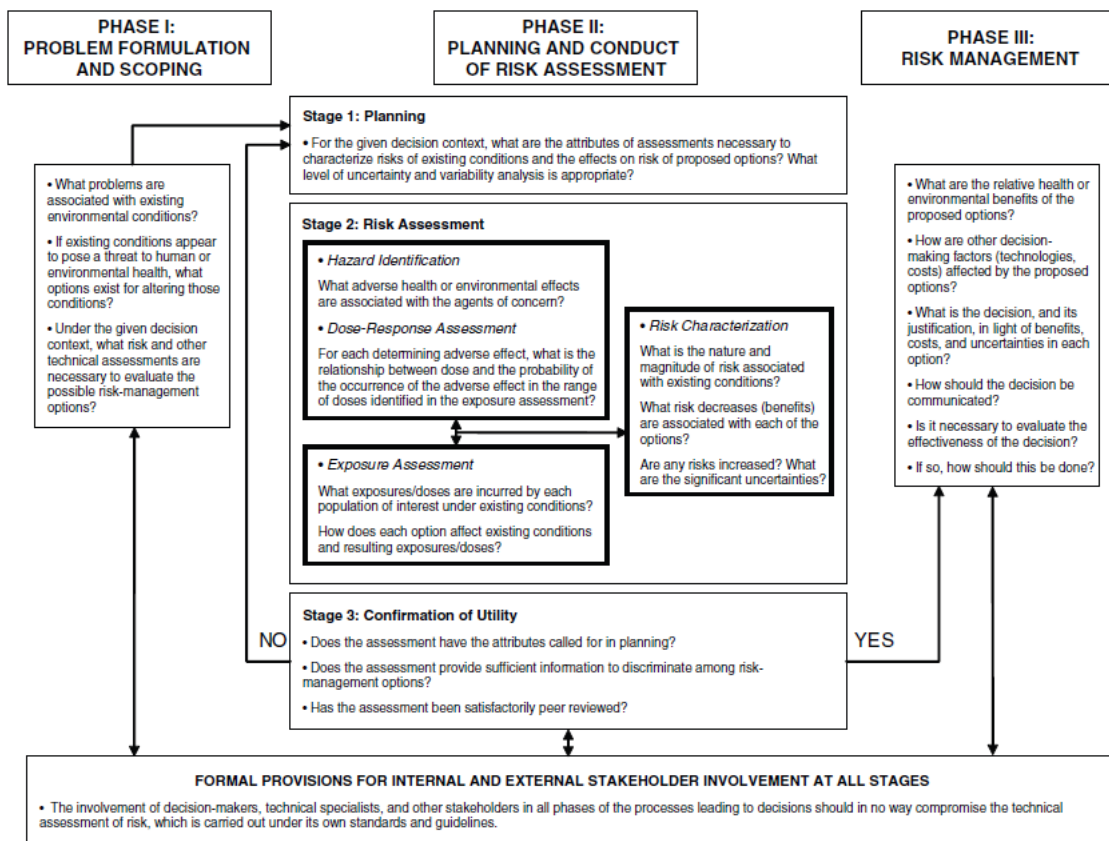
EPA Superfund Risk Assessment Video

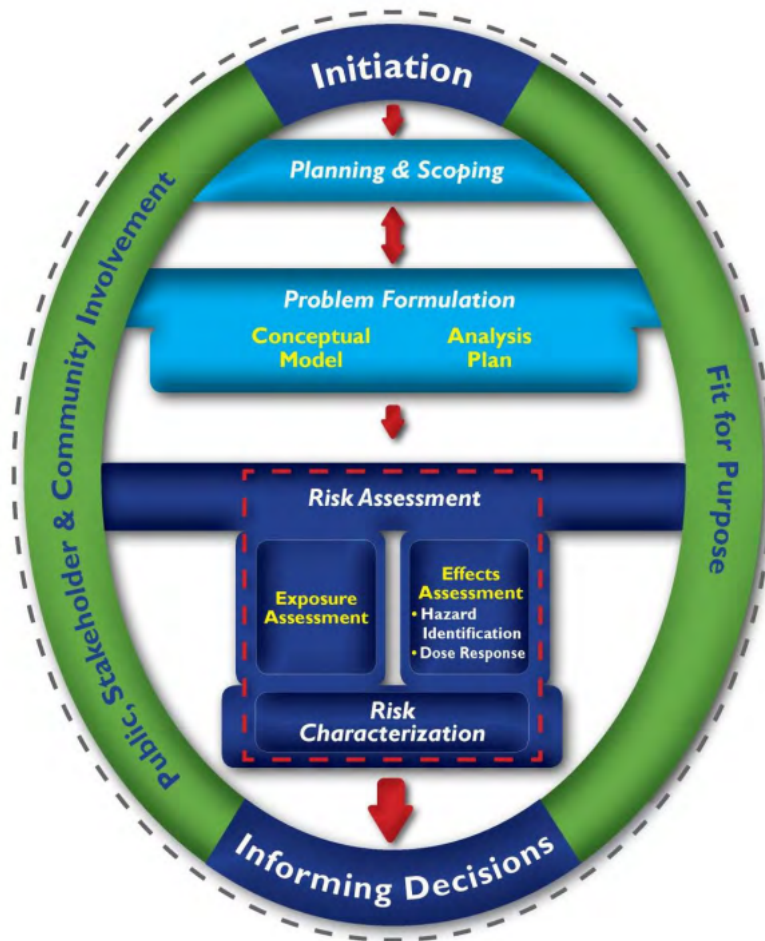
https://clu-in.org/video/sf_risk_assessment_overview.htm

View 0:00 - 6:00 minutes

Risk assessment is a dominant public-policy tool

- Informs risk managers and the public about different policy options for protecting public health and the environment
- Instrumental in fulfilling the missions of the U.S. Environmental Protection Agency (EPA) and other federal and state agencies
 - Evaluating public health concerns
 - Informing regulatory and technological decisions





- Setting priorities for research and funding
- Developing approaches for cost-benefit analyses

Science and Decisions

Risk Assessment Challenges

- Subject to considerable scientific, political, and public scrutiny
- The science is increasingly complex
 - Multiple chemical exposures
 - Multiple risks
 - Susceptibility in populations
 - Life-cycle analysis
 - Costs, benefits, and risk trade-offs
- Process is bogged down: major risk assessments for some chemicals take more than 10 years (*e.g., trichloroethylene, formaldehyde, dioxin*)
- Tens of thousands of chemical in commerce

Risk Assessment Development History



“Red Book” (1983)

- Defines risk assessment as: the use of the factual base to define the health effects of exposure of individuals and populations to hazardous materials and situations
- Advocated for the separation of risk assessment from risk management



“Blue Book” (1994)

“Silver Book” (2009)

Statutes and Regulatory Structure

- Statutes provide various standards and procedures related to the scientific analyses used to evaluate the risk potential of pollutants subject to the statutes
- Provide agencies authority to regulate many forms of pollution
- Enabling legislation for major EPA program offices:
 - Air and radiation
 - Water
 - Solid waste
 - Pesticides
 - Toxic substances
- Enacted prior to the emergence of risk analysis as an integrative discipline in the late 1970s and early 1980s

- Addressed issues from Clean Air Act Amendments
- Themes:
 - Default values
 - Validation of data and models
 - Information and data needs
 - Uncertainty
 - Variability
 - Aggregation of Risks



- Recommendations to improve quality of the technical analysis and utility of risk assessments
- Encouraged inclusion of quantitative estimates of uncertainty and variability at all key computational steps



Major U.S. environmental and occupational health laws

Year	Legislation
1963	Clean Air Act (amended in 1965, 1966, 1967, 1969, 1970, 1977, 1990)
1969	National Environmental Policy Act (NEPA)
1970	Williams-Steiger Occupational Safety and Health Act
1972	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (amended by Food Quality Protection Act of 1996)
1974	Safe Drinking Water Act (SDWA)(amended in 1996)
1976	Resource Conservation and Recovery Act (RCRA)
1976	Toxic Substances Control Act (TSCA)
1977	Clean Water Act (CWA)
1980	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)(amended in 1986 –SARA)
2016	The Frank R. Lautenberg Chemical Safety for the 21st Century Act

Statutory Language Examples

Clean Water Act

“adequate to protect public health and the environment from any reasonably anticipated adverse effects” (CWA § 405 (d)(2)(D))

Clean Air Act

Addressing criteria pollutants:

“reflecting the latest scientific knowledge”

“national primary ambient air quality standards to . . . protect public health with an adequate margin of safety” (CAA §§ 108,109)

Toxic Substances Control Act

Primary purpose:

“to assure [that technologic] innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment” (TSCA § 2 (b)(3))

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Criterion for registering a pesticide:

“it will perform its intended function without unreasonable adverse effects on human health and the environment” (FIFRA § 3)

1996 Safe Drinking Water Act Amendments

“The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable – Each population addressed by any estimate of public health effects – The expected risk or central estimate of risk for the specific populations – Each appropriate upper-bound or lower-bound estimate of risk” (SDWA § 300g-1 (b)(3)).

Risk Assessment Vocabulary

- Agent-based risk assessments
- Benchmark Concentration
- Benchmark Concentration Limit
- Benchmark Dose
- Benchmark Dose Limit
- Benchmark response
- Dose-response assessment
- Exposure assessment
- Hazard identification
- Inhalation unit risk
- Lifestage
- Lowest-observed-adverse-effect level
- No-observed-adverse-effect level
- Place-based risk assessments
- Probabilistic modeling
- Reference concentration

- Reference dose
- Risk characterization
- Risk description
- Risk estimation
- Sensitivity
- Slope factor
- Stressor
- Susceptibility
- Uncertainty
- Uncertainty/variability factor
- Variability
- Vulnerability

Risk Assessment in the News

- EPA published the Final Fifth Drinking Water Contaminant Candidate List (CCL 5) <https://www.asdwa.org/2022/11/02/epa-publishes-final-fifth-contaminant-candidate-list-for-potential-drinking-water-regulations/> <https://www.epa.gov/ccl/contaminant-candidate-list-5-ccl-5>
- European exposure science strategy published <https://doi.org/10.1016/j.envint.2022.107555>
- Sharm-El-Sheikh Adaptation Agenda launched <https://unfccc.int/cop27>