

US EPA ARCHIVE DOCUMENT




# Risky Business?

## An Overview of Risk Assessment and RCRA



### What is Risk?



**R**isk is a measure of the likelihood that damages or harm will occur as a result of exposure to a hazard or a physical threat. Whether a risk is significant depends on the context in which the hazard occurs and the potential consequences. Furthermore, the perception of risk might differ from one person to the next depending on the nature of the risk. For example, risks from chemical hazards are often viewed differently than other known or easily recognized risks, such as driving a car or crossing the street. Risk assessment is used by the U.S. Environmental Protection Agency (EPA) to analyze the potential for adverse human health or ecological effects due to the presence of toxic chemicals in the environment. Risks of concern to EPA's hazardous waste program, such as ground water or soil contamination, might be unknown to the individuals or communities affected by them and might not always be readily traced to a particular source or activity. In addition, EPA is concerned about risks that might occur in the future and the need to take actions to prevent environmental contamination or minimize the potential for exposure.



## How are Risks Assessed?

**R**isk assessment draws upon technical and scientific information from a variety of disciplines, including toxicology, epidemiology, and ecology, as well as chemistry, physics, and mathematics. Risk assessment typically involves four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. Hazard identification refers to the scientific data used and the weight of the evidence gathered concerning the negative effects of a chemical agent or environmental stressor. The dose-response assessment (also referred to as stressor-response relationships in the context of ecological assessments) attempts to quantify the relationship between chemical/hazardous exposure or dose and a specific adverse effect in an organism, community, or ecosystem. Exposure assessment deals with the identification of potential exposure pathways and exposed populations, as well as the estimation of the dose received by a particular receptor. Exposures might occur as a result of toxic chemicals being released from landfills, incinerators, storage piles, or other waste management units. Exposure assessment generally

involves the use of fate and transport models<sup>1</sup> to predict the chemical concentrations expected and might include the results of environmental sampling and analysis. All of the information is pulled together in the risk characterization report, where the major findings of the assessment are described, and the strengths, weaknesses, limitations, and uncertainties are discussed.

Both quantitative and qualitative measures are used to describe risk. These risk measures may include both the likelihood of the event and the type and severity of an adverse effect. They may include a wide variety of effects ranging from different kinds of cancers to reproductive, developmental, or other systemic toxic effects. Risks to the general population, to individuals residing in a given locale or belonging to a particular subpopulation (such as risks to children, the elderly, or other susceptible populations), or risks to specific socioeconomic groups are often a concern.



## What is Risk Management?

**T**raditionally, risk assessment is distinguished from risk management in that risk assessment attempts to answer the questions, “Is there a risk from exposure to a chemical substance? What do we know about the risk? Who is most affected by it?” In contrast, risk management addresses questions such as, “Should we be concerned about the risk? If so, what should be done about it? How can we best mitigate the risk?” In practice, risk assessment is used to address questions raised by decision-makers on issues of public concern and, for this reason, risk assessment is generally an iterative process that engages decision-makers and the public at various points along the way. Opportunities for public input include notice and comment on proposed rules or permitting actions, public hearings or forums

<sup>1</sup> Fate and transport models are mathematical models that simulate the behavior of contaminants in various environments to predict contaminant concentration and mobility.



on specific issues or topics, and peer reviews of scientific studies and technical reports.

Risk management is a decision process that considers social, economic, and legal factors. The results of the risk assessment, together with information on alternative waste management approaches, are evaluated in an effort to arrive at an action or response that is appropriate given the nature of the hazard and the magnitude of the risk. Risk management must consider uncertainties that are inherent in the risk assessment process. Outcomes of risk assessment and management may include public education efforts, enforcement and compliance activities, cleanup of contamination, changes in regulations, or new regulatory initiatives.

## Risk Assessment and RCRA

**E**PA's hazardous waste program was established under the Resource Conservation and Recovery Act (RCRA). Risk assessment is used in a variety of ways in the RCRA program. Risk information is an essential factor in determining which industrial wastes are judged to be hazardous wastes and should therefore be managed under the RCRA hazardous waste system. Risk assessment is also used in developing waste management programs for nonhazardous wastes. Risk information is used in targeting waste minimization efforts, issuing operating permits, determining the need for cleanup actions at permitted facilities, and setting cleanup goals. Risk assessment is also used in cost-benefit analysis for major rules and regulations and to chart strategic directions for the RCRA program. The goal of all of these efforts is to avoid or minimize risks from the generation and management of hazardous wastes.





## Key References

*Understanding Risk: Informing Decisions in a Democratic Society*, National Research Council, National Academy Press, Washington, DC, 1996.

*Risk Assessment in the Federal Government: Managing the Process*, National Research Council, National Academy Press, Washington, DC, 1983.



## Other Resources

*RCRA: Reducing Risk from Waste*, U.S. Environmental Protection Agency, Washington, DC, 1997. EPA530-K-97-004

*Guidance for Risk Characterization*, Science Policy Council, U.S. Environmental Protection Agency, Washington, DC, 1995.

## For More Information

### U.S. Environmental Protection Agency

[www.epa.gov/epaoswer/osw/index.htm](http://www.epa.gov/epaoswer/osw/index.htm)

Office of Solid Waste Economics, Methods, and Risk Analysis Division (5307W)  
1200 Pennsylvania Avenue, NW.  
Washington, DC 20460  
Phone: 703 308-8855  
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### EPA's Science Policy Council (SPC)

[www.epa.gov/ORD/spc/index.htm](http://www.epa.gov/ORD/spc/index.htm)

The goal of the SPC is to help guide EPA decision-makers in their use of scientific and technical information. The SPC works to implement and ensure the success of initiatives recommended by external advisory bodies such as the National Research Council and the EPA Science Advisory Board.

### EPA's Risk Assessment Forum (RAF)

[www.epa.gov/ncea/raf/index.html](http://www.epa.gov/ncea/raf/index.html)

The RAF is a standing committee of senior EPA scientists that was established to promote consensus across EPA programs on difficult and controversial risk assessment issues. The RAF assembles risk assessment experts in a formal process to study, discuss, and report on issues from a scientific perspective and to assist in the development of guidance documents for use by EPA program offices.

### EPA's Integrated Risk Information System (IRIS)

[www.epa.gov/ngispgm3/iris/index.html](http://www.epa.gov/ngispgm3/iris/index.html)

IRIS is an electronic database containing information on toxicity benchmarks and human health effects that might result from exposure to chemical substances in the environment. IRIS was initially developed for EPA staff in response to a need for consistent information on chemical substances for use in risk assessments, decision-making, and regulatory activities.

### EPA's Superfund Risk Assessment site

[www.epa.gov/superfund/programs/risk/index.htm](http://www.epa.gov/superfund/programs/risk/index.htm)

EPA's Office of Emergency and Remedial Response (a.k.a., Superfund) offers a variety of tools and information on risk assessment. Although Superfund guidance (e.g., Risk Assessment Guidance for Superfund (RAGS)) is intended for use at hazardous waste sites listed on the National Priorities List (NPL), it is also used as a technical resource by risk assessors in the RCRA program.

### Society for Risk Analysis (SRA)

[www.sra.org/index.htm](http://www.sra.org/index.htm)

SRA is a nongovernmental organization that provides an open forum for persons interested in risk analysis. SRA defines risk analysis broadly to include risk assessment, risk characterization, risk communication, risk management, and policies relating to risk. SRA members are concerned with risks to human health and the environment from physical, chemical, and biological agents and from a wide variety of human activities and natural events.