

Environmental Health Resources Self Learning Module

Risk Assessment



**Agency for Toxic Substances
and Disease Registry**
Division of Community
Health Investigations



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- Arrow keys or
- Page Up and Page Down keys.

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Overview and Objectives

This module has been created to provide local health agencies a quick overview of risk assessment as well as optional, more detailed resources. While geared to local health departments (LHDs), the materials may be useful for other environmental health professionals.

Objectives:

- Gain familiarity with risk assessment **terminology**
- **Raise or enhance understanding of risk assessment process** and the role of local health agencies in risk assessment
- Use the modules to **prepare for community engagement, community requests, or public meetings**



Module Organization

This Risk Assessment resource is organized by:

1. A [printable summary](#) of risk assessment basics.
2. A [self-study module](#) that contains more detailed training and resources about risk assessment.

Risk Assessment

Part One: Summary Overview





Risk Assessment Definition

Risk is defined as **the possibility that something will cause harm.**

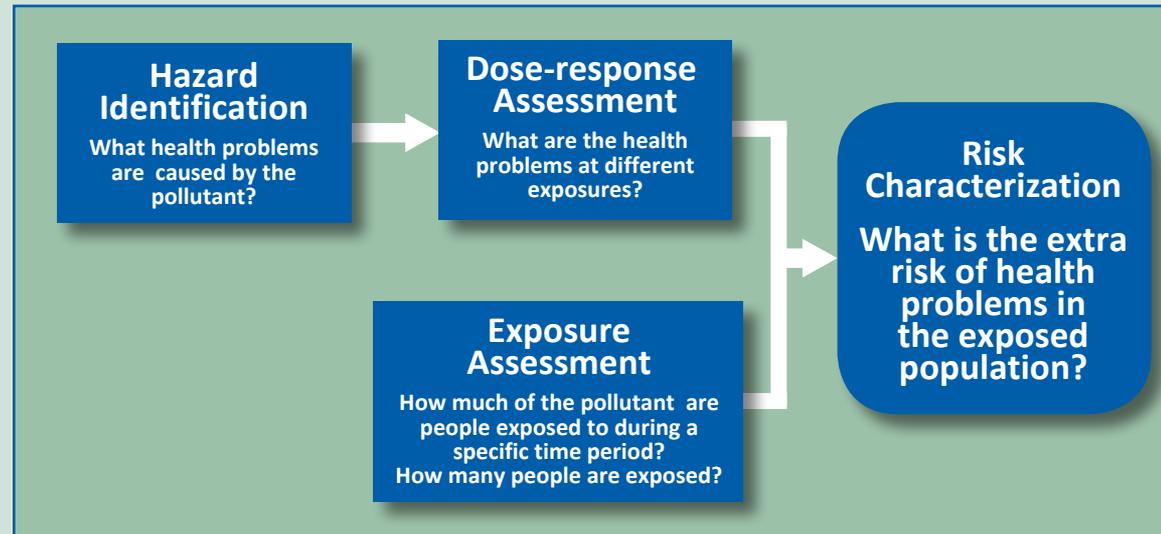
Risk assessment (baseline) is an **analysis of the potential adverse health effects** (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action).



Elements of Risk Assessment

4 Step Risk Assessment Process

Source: <http://www2.epa.gov/risk/conducting-human-health-risk-assessment#tab-2>



The basic elements of risk assessment are:

- Hazard Identification
- Dose-Response Assessment
- Exposure Assessment
- Risk Characterization

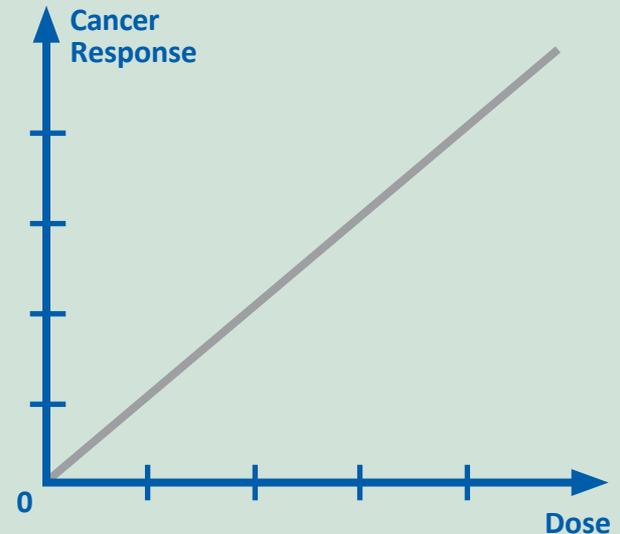


Risk Characterization

Risk Characterization involves reviewing outputs from toxicity and exposure assessments and quantifying the overall risks from individual and multiple chemicals.

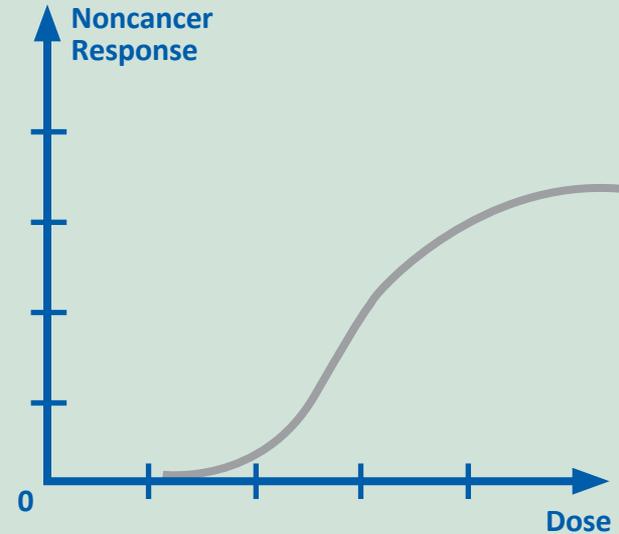
The health risks associated with cancer causing chemicals are evaluated differently than the health risks of non-cancer causing chemicals.

For **cancer causing chemicals**, the EPA assumes there is no dose of exposure that is considered safe, or without risk. Even a very low exposure to the chemical can increase the risk of cancer. The straight dose-response line assumes that for each unit increase in exposure (dose), there is an increase in cancer risk.





For **non-cancer causing chemicals**, or the non-cancer effects of chemicals, there is a “no observable adverse effect level” (NOAEL) at which a person can be exposed to the chemical and experience no effects. At very low doses, the body can repair damage caused by the chemical. However, the dose at which there is an effect varies depending on the chemical, the individual, and the type of health effect.





Terms to Know for Risk Assessment

Reference Dose (RfD) is an estimate (with some degree of uncertainty), of a daily exposure level for the human population, including sensitive subgroups, that is likely to be without “appreciable risk” for negative health effects.



Exposure in both cancer and non-cancer risk calculation is calculated similarly. Further information on the complete risk assessment process can be found in the [EPA Exposure Assessment](#) overview. Exposure terms are provided below:

- **Intake (I) (dose)** is a measure of milligrams of the chemical entering the body per kilogram body weight per day (mg/kg-d)
- **Concentration (C)** is a measure of the chemical per unit it is in. For example milligrams chemical per kilogram food (mg/kg) or milligrams chemical per cubic meter air (mg/m³)
- **Ingestion or Inhalation Rate (IR)** is the rate at which a chemical is ingested (eaten) or inhaled per day (mg/day) or (m³/day)
- **Event Frequency (EV)** is the frequency of exposure and can be measured as events per hour or day (event/day)
- **Exposure Frequency (EF)** is a measure of exposure days per year (days/year)
- **Exposure Duration (ED)** is the amount of time a person is exposed, for example hours, days, or years
- **Averaging Time (AT)** is the period over which the exposure is averaged, measured in days
- **Body Weight (BW)** is measured in Kilograms



Daily Exposure Dose

$$\text{Dose} = \frac{C \times IR \times EF \times ED \times CF}{BW \times AT} = \text{mg/kg-day}$$

C = concentration (mg/kg- soil; mg/L- water; ug/m³- air)

IR = intake rate (mg soil/day; L water/day; m³/day)

EF = exposure frequency (days/yr)

ED = exposure duration (yrs)

CF = soil conversion factor (10⁻⁶ kg/mg)

BW = body weight (kg)

AT = averaging time (days)

Default Values for Dose Calculation

ATSDR-Recommended Body Weights in Health Evaluations (Kilograms, Kg)

Age Group (year(s), yr)	Mean (Kg)
Birth to < 1yr	7.8
1 to <2 yr	11.4
2 to < 6 yr	17.4
6 to <11 yr	31.8
11 to <16 yr	56.8
16 to <21 yr	71.6
Adult (>21 yr)	80
Pregnant Woman	73

ATSDR Default Exposure Factors

Exposure Factor	Receptor	Value (days/year, d/yr)	CTE/RME (Central Tendency/ Reasonable Maximum Estimate)
Exposure Frequency	Residential	Daily for 365 d/yr	Both
	Occupational	5 d/7d, 350 d/yr	Both
Exposure Duration	Residential	33 yr	RME
		12 yr	CT
	Occupational	25 yr	RME
		6.6 yr	CT
Inhalation Exposure	Residential	24 hr/24 hr	Both
	Occupational	8 hr/24 hr	Both

Source: Exposure Dose Guidance for Body Weight, ATSDR, November 2014.



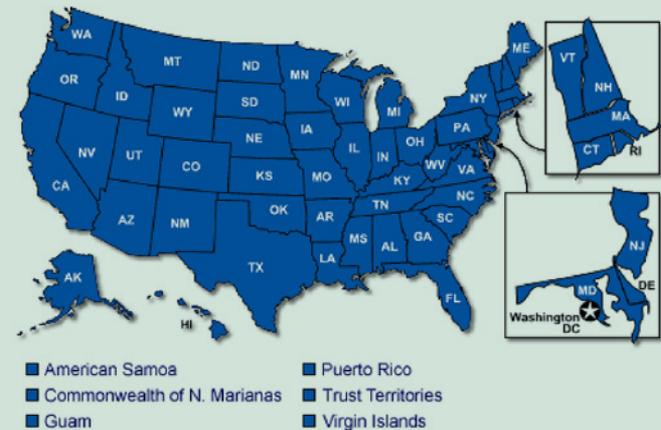
ATSDR Public Health Assessment (PHA) and Health Consultation (HC)

ATSDR incorporates elements of risk assessment into its PHA process.

Since 1986, ATSDR has been required by law to conduct a PHA at each of the sites on the [EPA National Priorities List](#). The aim of these evaluations is to find out if people are being exposed to hazardous substances and, if so, whether that exposure is harmful and should be stopped or reduced.

Please view this link to learn more about the PHA, HC, and other ATSDR health protection processes: <http://www.atsdr.cdc.gov/hac/products/pha.html>

Residents, agencies, and others can petition ATSDR for a Public Health Assessment or Health Consultation: <http://www.atsdr.cdc.gov/hac/pha/index.asp>





Click here to view the ATSDR Overview and Health Assessment Process video: http://www.atsdr.cdc.gov/videos/health_assessment_process.htm



Risk Assessment Example: Sandies Dry Cleaner and Laundry Site

Sandies Dry Cleaner and Laundry, located in Little Chute, Wisconsin, was open from 1957 to 2003. The most recent owner used tetrachloroethylene (also known as PCE or PERC), a manufactured chemical solvent commonly used in dry cleaners and for metal degreasing. PCE is a volatile organic compound and of concern because of its acute and long term health effects.

For Sandies Dry Cleaner, we can follow the 4 steps of Risk Assessment:



1. Hazard Identification

- Collection of data from various sources and from toxicological and epidemiologic studies
- Identify physical and chemical properties of substance
 - » PERC is a colorless liquid with an ethereal odor. It is an excellent solvent of greases, oils, fats, and waxes
- Identify route, duration, and frequency of exposure
 - » PERC can enter the soil and travel through groundwater where vapors can enter neighboring sites and be **inhaled** (route) by residents. Contaminated soil and air were found in the properties adjacent to Sandies. **Duration** and **frequency** of exposure depended on the amount of time spent on contaminated sites.



2. Hazard Evaluation or Dose Response Assessment

- Calculate the dose-effect or RfD. When calculating, include a safety or uncertainty factor to account for susceptible or vulnerable individuals that they will not experience adverse effects.
 - » Uncertainty factors are often valued at 10 to account for differences in individuals or extrapolation from animals to humans
- **E.g. $RfD = NOAEL / UF_s$**



3. Exposure Assessment

- Identify affected population
 - » Businesses and residences adjacent to Sandies
- Calculate the amount, frequency, length of time and route of exposure
 - » Interview business owners and residents to determine exposure parameters, such as exposure frequency and duration
- Identify sources of contaminant
 - » Historic dumping of PERC which moved through the soil and into groundwater from which it evaporates
- Identify exposure pathways and environmental fate
 - » PERC evaporates quickly from water in the air. It breaks down very slowly in the air and can travel long distances
- Measure or estimate intake (dose) based on the calculations:

$$\text{Dose} = \frac{C \times IR \times EF \times ED \times CF}{BW \times AT} = \text{mg/kg-day}$$



4. Risk Characterization

- Characterize the nature and extent of exposures
 - » Exposure was caused by contaminated soil. 116 tons of PERC contaminated soils and one drum containing solvents contaminated with PERC were removed from the site.
- Identify susceptible populations
 - » Susceptible populations included the businesses and residences in the contaminated areas



End of summary overview.

For a hard copy of the Risk Assessment **summary overview, print pages 5–20.**

Proceed to the [self-study module](#) on Risk Assessment.

Risk Assessment Part Two: **Self-study Materials**





This self-study resource may help you identify and discuss the **four steps of risk assessment**.



Risk Assessment Resources

EPA's Risk Assessment Website

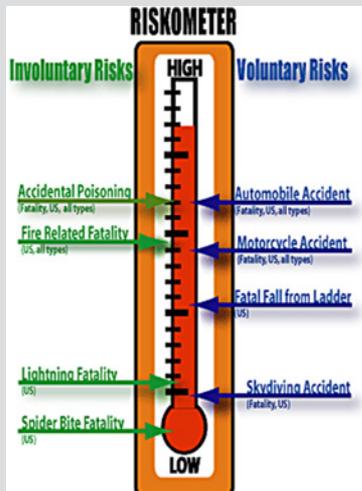
On EPA's [risk assessment website](#) you can learn the basics about environmental risk assessments for the public. Additionally, this website also provides links to current EPA tools, as well as EPA guidance and guidelines.

Integrated Risk Information System (IRIS)

EPA's [IRIS](#) is a human health assessment program which explores the potential health effects of exposures to environmental contaminants, to support regulatory activities. Currently, the IRIS database contains information on over 550 chemicals.

Risk Assessment Information System (RAIS)

The RAIS is a website that provides risk tools and information to conduct human health and ecological risk assessments. Included on this website are also several trainings including [What is Risk Assessment?](#), and the [RAIS Main Tutorial](#). Additionally, there is a [Powerpoint presentation](#) available under "Training Coursework Powerpoint Presentation" which details how the RAIS website can be used effectively to conduct a risk assessment.





ATSDR Health Assessment Resources

The Public Health Assessment Process and the Community



The [Health Assessors Training](#) is divided into three modules:

1. Mission and Community
2. Exposure Pathways and Toxicologic Evaluation
3. Evaluating Health Effects Data and Determining Conclusions and Recommendations

Each section provides detailed step by step guidance through the topic area.



Public Health Assessments & Health Consultations



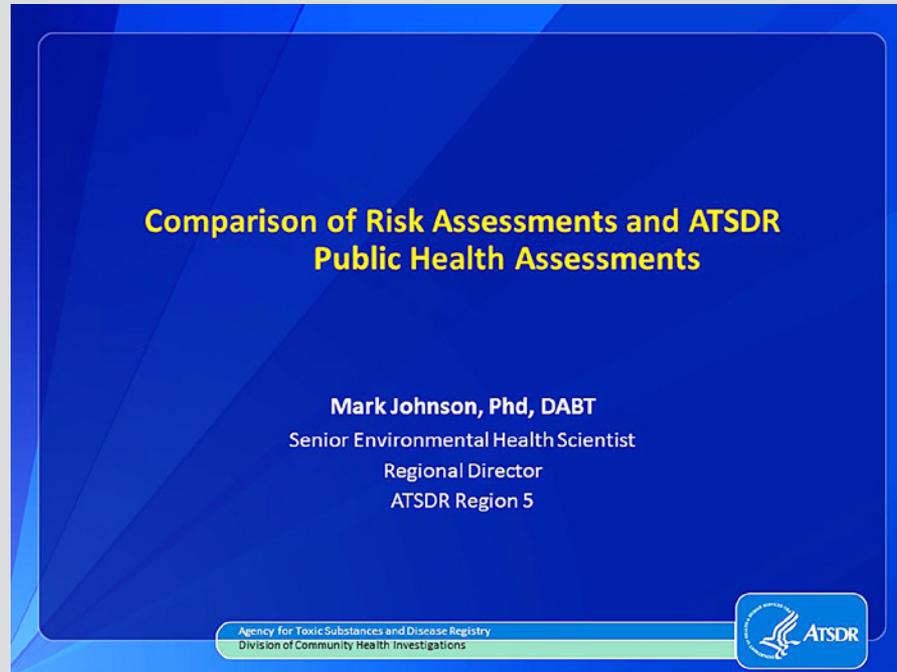
- American Samoa
- Commonwealth of N. Marianas
- Guam
- Puerto Rico
- Trust Territories
- Virgin Islands

Here you can easily search and find [Public Health Assessments and Health Consultations](#) by **US State, territory or ATSDR region**.



Comparison of Risk Assessments and ATSDR Public Health Assessments

The following resource (starting on the next page) is a PowerPoint slide presentation that provides information on exposure and health assessment evaluation and limitations.



Comparison of Risk Assessments and ATSDR Public Health Assessments

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RISK ASSESSMENT VS. HEALTH ASSESSMENT

Outline

- **Comparison of Risk Assessment vs. Health Assessment**
- **Details of Health Assessment Process**

Risk Assessment vs. Health Assessment

- **Environmental agencies are charged with:**
 - Protecting human health and the environment
 - Identifying contaminants at hazardous waste sites
 - Characterizing risks of exposures for decision-makers
 - Cleaning up contamination
- **Public health assessment agencies are charged with:**
 - Providing assistance to environmental agencies
 - Developing assessments to identify needed actions
 - Providing public health advice to affected communities
 - Providing framework for public health intervention and research

Comparison of Risk Assessment vs. Health Assessment

- **Risk Assessment** is a predictive estimate of *potential* health impacts
- Health Assessment focuses on the measurement of *actual* health impacts and addressing *perceived* health impacts

Issues	Health Assessments	Risk Assessments
Objectives	Address public health concerns Fill data gaps Define needed public health interventions Support decision-makers	Support objective and consistent regulatory decisions – human health and ecological risk
Timeframe	Past, present, future	Present and future
Legal implications	Low	High
Qualitative/quantitative	More qualitative	More quantitative

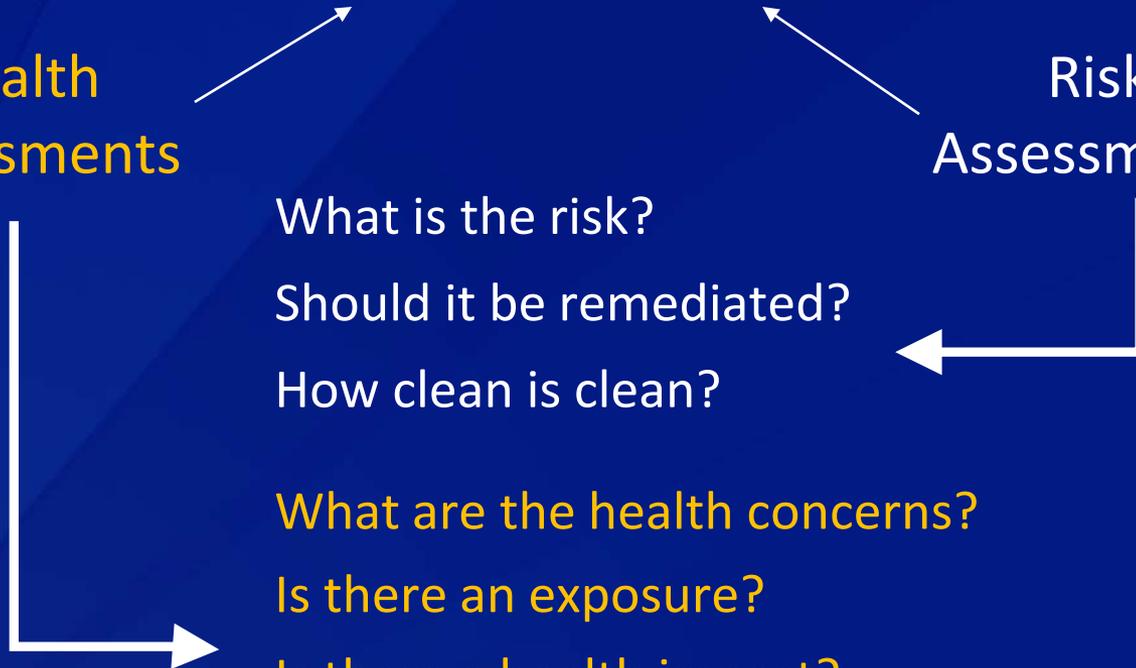
Environmental Hazards

Health Assessments

Risk Assessments

What is the risk?
Should it be remediated?
How clean is clean?

What are the health concerns?
Is there an exposure?
Is there a health impact?
What are the appropriate actions?



Objectives of Public Health Assessments

- **Determine nature and extent of contamination**
- **Identify exposure pathways**
- **Determine size/susceptibility of exposed population**
- **Compare exposure levels to levels known to be associated with health effects**
- **Evaluate Health Outcome Data for the exposed population**
- **Draw conclusions about association of exposures with health effects**

Sources of Information

- **Site visit**
- **Environmental Sampling Data**
- **Health Outcome Data**
- **Exposure Investigation Results**
- **Community knowledge**
- **Health concerns of community**

Health Assessment Process

- Exposure assessment
- Toxicological assessment
- Review of health outcome data
- Conclusions of health hazards
- Recommendations for public health protection

Exposure Assessment-Step 1

- Identification and Evaluation of Exposure Pathways
 - Source, fate and transport
 - Point and route of exposure
 - Exposed population
 - Identification of susceptible individuals
 - Exposure investigations

Exposure Pathways

- Soil - ingestion,dermal,inhalation
- Water - ingestion,dermal,inhalation
- Air - inhalation
- Sediment - dermal
- Fish - ingestion

Exposure Assessment- Step 2

- Compare maximum environmental levels to media-specific comparison values (e.g., soil, air, water)
- If screening levels are exceeded for specific chemicals, evaluate further

Exposure Assessment-Step 3

- Calculate community-specific exposure dose estimates
- An exposure dose is an estimate of the total amount of a chemical that enters a person's body through inhalation, ingestion, or dermal contact
- Expressed as mg/kg/day

Exposure Dose

- Dose is determined by the:
 - chemical concentration
 - exposure activity
 - frequency of exposure
 - duration of exposure
 - body weight

Daily Exposure Dose

$$\text{Dose} = \frac{C \times IR \times EF \times ED \times CF}{BW \times AT} = \text{mg/kg-day}$$

C = concentration (mg/kg-soil; mg/L-water; ug/m³-air)

IR = intake rate (mg soil/day; L water/day; m³/day)

EF = exposure frequency (days/yr)

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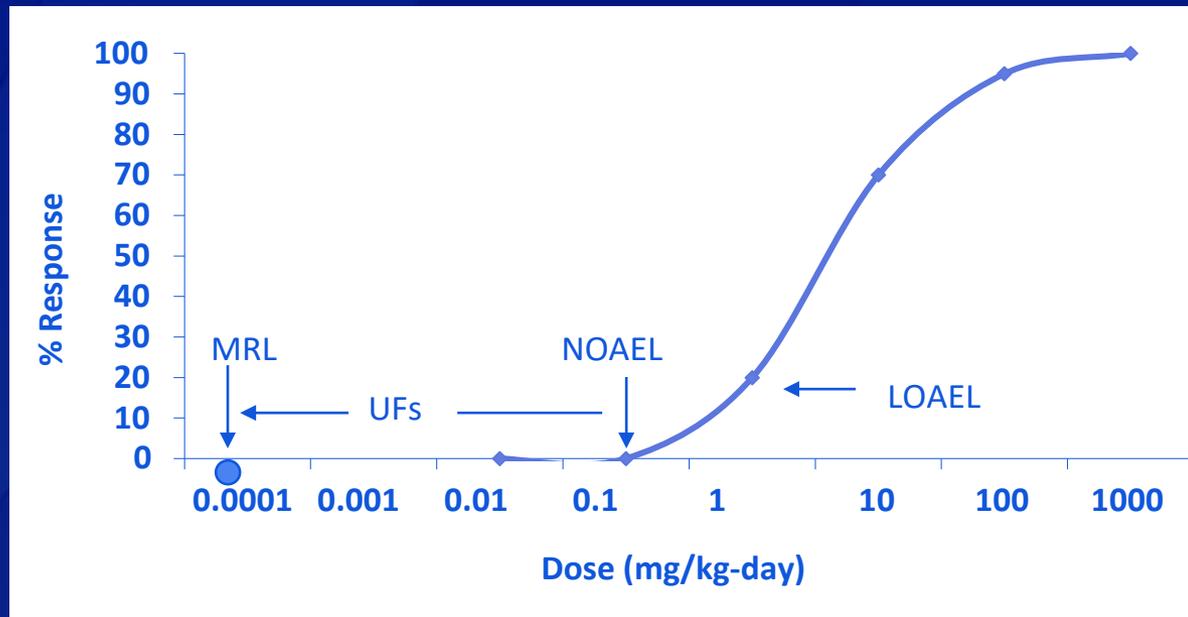
Evaluation of Exposure Doses

- Compare exposure doses to Health Guidelines levels
 - MRL= minimal risk level (ATSDR)
 - RfD= reference dose (EPA)
 - RfC= reference concentration (EPA)

Minimum Risk Levels (MRL)

- Defined as the dose level that is not associated with an adverse health effect; considered to be a “safe” level of exposure for any individual
- Duration of exposure
 - Acute: up to 14 days
 - Intermediate: 14 days – 1 year
 - Chronic: more than 1 year

Determination of a Safe Level of Exposure-Minimum Risk Level (MRL)



LOAEL- lowest observed adverse effect level

NOAEL- no observed adverse effect level

UFs- uncertainty factors

MRL- no adverse effects for human population

Exposure Investigations

- Environmental
 - Ambient air: hydrogen sulfide
 - Indoor air: TCE, PCE
 - Personal monitors: asbestos
- Biological
 - Blood: dioxins, PCBs, lead, beryllium
 - Urine: mercury, arsenic, pesticides
 - Hair: arsenic
 - Exhaled air: mercury

Evaluation of Health Outcome Data

Health Outcome Data: Data Sources

- Death certificates
- Birth certificates
- Fetal death reports
- Cancer/tumor registries
- Birth defects/congenital malformation registries
- Disease registries

Priority Health Conditions with Possible Environmental Associations

- Birth Defects/ Reproductive disorders
- Cancer- specific tissues
- Immune function disorders
- Kidney dysfunction
- Liver dysfunction
- Lung and respiratory diseases
- Neurological disorders

Health Outcome Data: Evaluation Factors

- Complete exposure pathways
- Extent and duration of exposures should be known
- Plausible association of health outcome with exposure to the contaminant under evaluation
- Health data for the area where exposed population is located should be used
- Evaluation should address community concerns

Health Outcome Data: Limitations

- Evaluations **cannot** establish a cause and effect link
- Available data may represent populations that are larger than the exposed population
- Details about exposures may be lacking

Health Outcome Data: Follow-up

- If an elevated rate of disease is found:
 - Conduct case confirmation study
 - Conduct disease surveillance study to ensure most up-to-date information is available
 - Evaluate geographical pattern of cases to determine if there is a correlation with potential exposures
 - Conduct full-scale health study

Epidemiological Study

- Evaluates the association between estimated or measured exposures and health outcomes in communities
- Attempts to provide more information about possible causes of a disease
- Can provide additional perspective about community exposures and health outcomes

Epidemiology- Limitations

- Exposure variability over time
- Latency periods between exposure and health outcome (e.g., cancer)
- Confounding factors (e.g., smoking, alcohol use, genetic susceptibility)
- Different measurement points for exposure
- Incomplete or inaccurate monitoring systems
- Small study size

Health Hazard Conclusions

- Based on the weight-of-evidence evaluation of the impact of exposures
- Considers health outcome data and community concerns
- Identifies Data Gaps

Conclusions: Public Health Hazard Categories

Urgent Public Health Hazard

Public Health Hazard

Indeterminate Public Health Hazard

No Apparent Public Health Hazard

No Public Health Hazard

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For more information please contact Agency for Toxic Substances and Disease Registry

4770 Buford Hwy, NE Chamblee, GA 30341

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.atsdr.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



If you need assistance in understanding concepts in this resource, please contact your State Health Department, your [ATSDR Regional Office](#), or send an email to atsdr.landreuse@cdc.gov.