M5: Overview of Urban Water Risk Assessment

Shirley Clark
Penn State - Harrisburg

Risk Assessment Introduction

- Environmental regulations and the resultant activities are designed to address environmental threats to human (public) and ecological health.
- Question:
  - How did we decide that particular activities and/or pollutant loads cause an environmental health problem that requires addressing?
- Much of this discussion is based on the following sources:
  - Guidelines for Ecological Risk Assessment (Published on May 14, 1998, Federal Register 63(93):26846-26924)
  - Introduction to Chemical Exposure and Risk Assessment

Risk Assessment Overview

- Based on two elements: characterization of effects and characterization of exposure.
- These focus the three phases of risk assessment:
  - problem formulation,
  - analysis, and
  - risk characterization.
Risk Assessment Overview

- **Problem formulation:**
  - Identify purpose, define problem, develop plan for analyzing and characterizing risk.
  - Two products: assessment endpoints and conceptual models.

- **Analysis:**
  - Guided by the products of problem formulation.
  - Evaluate data to determine how, and if, exposure to stressors is likely to occur (characterization of exposure) and, given this exposure, the potential and type of effects that can be expected (characterization of effects).
  - Two profiles as products: one for exposure and one for stressor response.

Questions Addressed by Risk Managers and Risk Assessors

- **Questions principally for risk managers to answer:**
  - What is the nature of the problem and the best scale for the assessment?
  - What are the management goals and decisions needed, and how will risk assessment help?
  - What are the ecological values (e.g., entities and ecosystem characteristics of concern)?
  - What are the policy considerations (law, corporate stewardship, societal concerns, environmental justice, intergenerational equity)?
  - What precedents are set by similar risk assessments and previous decisions?
  - What is the context of the assessment (e.g., industrial site, national park)?
  - What resources (e.g., personnel, time, money) are available?
  - What level of uncertainty is acceptable?
Questions Addressed by Risk Managers and Risk Assessors

- **Questions principally for risk assessors to answer:**
  - What is the scale of the risk assessment?
  - What are the critical ecological endpoints and ecosystem and receptor characteristics?
  - How likely is recovery, and how long will it take?
  - What is the nature of the problem: past, present, future?
  - What is the state of knowledge of the problem?
  - What data and data analyses are available and appropriate?
  - What are the potential constraints (e.g., limits on expertise, time, availability of methods and data)?

Problem Formulation

- **Problem formulation:** process of generating and evaluating preliminary hypotheses about why effects have occurred, or may occur, from human activities.
  - Early in problem formulation, the objectives are refined.
  - Then the nature of the problem is evaluated and a plan for analyzing data and characterizing risk is developed.
  - Three products: (1) assessment endpoints that adequately reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor and assessment endpoint or between several stressors and assessment endpoints, and (3) an analysis plan.
What’s Different When Stressors, Effects, or Values Drive the Process?

- When concerned about stressors, information about stressor and source focuses assessment.
  - Objectives based on determining how the stressor may contact and affect possible receptors.
  - This leads to developing conceptual models and selecting assessment endpoints.
- When responding to observed effect, endpoints are normally established first.
  - Frequently, affected ecological entities (humans, fish, and/or benthos) and their response define assessment endpoints.
  - Protection-based goals are then established, which support development of conceptual models to identify likely stressor(s).
- For value-initiated risk assessments, goals are ecological values of concern (species, communities, ecosystems, or places).
  - Assessment endpoints are measurable interpretations of the goals. They support identifying stressors that may be influencing the assessment endpoints and describing the diversity of potential effects. This information is then captured in the conceptual model(s).

Back to the scenario...

- Values-initiated assessment.
  - The value is stream health and desire to ensure that it currently maintains, and will continue to maintain, the designated use (drinking water source, fishable/swimmable, or agricultural/industrial).
  - Assume that the stream is designated as fishable/swimmable. In the United States, the US EPA has set the water quality criteria for aquatic life. This document can be referenced at the following URL: http://www.epa.gov/waterscience/criteria/nwwq-2006.pdf
  - Assume four pollutants were two nutrients (phosphate and nitrate) and two heavy metals (lead and zinc) and the water type was freshwater. Aquatic life criteria (*25th percentile data for region):

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Criteria Maximum Concentration [CMC] (µg/L)</th>
<th>Criterion Continuous Concentration [CCC] (µg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>65</td>
<td>2.5</td>
</tr>
<tr>
<td>Nitrate</td>
<td>58*</td>
<td>58*</td>
</tr>
<tr>
<td>Phosphate</td>
<td>214*</td>
<td>7*</td>
</tr>
<tr>
<td>Zinc</td>
<td>120</td>
<td>120</td>
</tr>
</tbody>
</table>

Problem Formulation: Integration of Available Information

- Information (actual, inferred, or estimated) initially integrated as a preliminary problem scope.
  - Foundation for problem formulation.
  - Knowledge gained during scoping used to identify missing information and potential assessment endpoints
  - Knowledge provides the basis for early conceptualization.
- Predicting risks from multiple chemical, physical, and biological stressors requires understanding their interactions as best as is possible given current information and models.
- Risk assessments for a region or watershed, where multiple stressors are the rule, require consideration of ecological processes operating at larger spatial scales.

Questions to Ask Concerning Source, Stressor and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

- **Source and Stressor Characteristics**
  - What is the source? Is it anthropogenic, natural, point source, or diffuse nonpoint?
  - What type of stressor is it: chemical, physical, or biological?
  - Intensity of the stress (e.g., the dose/concentration of a chemical, the magnitude or extent of physical disruption, the density or population size of a biological stressor)?
  - What is the mode of action? How does the stressor act on organisms or ecosystem functions?
Questions to Ask Concerning Source, Stressor and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

- **Exposure Characteristics**
  - How often does a stressor event occur (e.g., is it isolated, episodic, or continuous; is it subject to natural daily, seasonal, or annual periodicity)?
  - How long does the event last? How long does the stressor persist in the environment (e.g., for chemical, what is its half-life, does it bioaccumulate; for physical, is habitat alteration sufficient to prevent recovery; for biological, will it reproduce or proliferate)?
  - Timing of exposure? When does it occur in relation to critical organism life cycles or ecosystem events (e.g., reproduction, lake overturn)?
  - Spatial scale of exposure/influence (local, regional, global, habitat-specific, or ecosystem-wide)?
  - Distribution? How does the stressor move through the environment (e.g., for chemical, fate and transport, for physical movement of physical structures, for biological, life-history dispersal characteristics)?

Questions to Ask Concerning Source, Stressor and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

- **Ecosystems Potentially at Risk**
  - Geographic boundaries? How do they relate to functional characteristics of the ecosystem?
  - Key abiotic factors affecting/influencing the ecosystem (e.g., climatic factors, geology, hydrology, soil type, water quality)?
  - What drives the ecosystem (e.g., energy source/processing, nutrient cycling)?
  - Structural characteristics of the ecosystem (e.g., species number/abundance, trophic relationships)?
  - What habitat types are present?
  - How do these characteristics influence the susceptibility (sensitivity and likelihood of exposure) of the ecosystem to the stressor(s)?
  - Are there unique features that are particularly valued (e.g., the last representative of an ecosystem type)?
  - What is the landscape context within which the ecosystem occurs?

Questions to Ask Concerning Source, Stressor and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

- **Ecological Effects**
  - What information is available about the ecological effects (e.g., field surveys, laboratory tests, or structure-activity relationships)?
  - Given the nature of the stressor (if known), which effects are expected to be elicited by the stressor?
  - Under what circumstances will effects occur?

Questions to Ask Concerning Source, Stressor and Exposure Characteristics, Ecosystem Characteristics, and Effects (derived in part from Barnthouse and Brown, 1994)

- **Risk Assessment Overview**
  - Question raised during a recent research project: ‘what aspect of urban runoff is causing the biological degradation of urban streams?’
  - A literature review was performed and the results were summarized (Clark et al., 2006). The table includes a column is included on data gaps since part of the project requirements was to summarize the literature and identify the data gaps. As can be seen from the table, the studies do not narrow down the potential causes of degradation. Therefore, any follow-up risk assessments will need to include physical, biological and chemical stressors in the preliminary lists of degradation causes.
Urban Runoff Studies – Water Quality and Habitat

<table>
<thead>
<tr>
<th>Study Area</th>
<th>Study Goals</th>
<th>Results</th>
<th>Data Gap</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provo River, UT</td>
<td>Determine changes in water quality due to urban runoff during summer thunderstorms</td>
<td>Changes proportional to increase in discharge. Returned to previous levels within 12 hr. No significant effects on macroinvertebrates.</td>
<td>Only one summer tested.</td>
<td>Gray, 2004</td>
</tr>
<tr>
<td>Shabakunk Creek, Trenton, NJ</td>
<td>Assessed impact of urban stormwater runoff on stream biota.</td>
<td>Water quality within limits during low flows. Water quality measurements did not indicate any serious problems limiting macroinvertebrates.</td>
<td>Storm flow events not conclusive. Lack of data on flow variety anticipated in yearly urban runoff.</td>
<td>Garie and McIntosh, 1986</td>
</tr>
</tbody>
</table>

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Garie and McIntosh, 1986

Stressors to Consider when Evaluating Different Receiving Water Uses

<table>
<thead>
<tr>
<th></th>
<th>Drainage</th>
<th>Biological life and integrity</th>
<th>Non-contact recreation</th>
<th>Swimming and other contact recreation</th>
<th>Water supply</th>
<th>Shellfish harvesting and other consumptive fishing uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Debris and obstructions (channel conveyance capacity)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Habitat destruction (channel stability, sediment scour and deposition)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Problem Formulation: Selecting Assessment Endpoints

- Express explicitly the actual value that is to be protected – an ecological entity (organism, population, community, ecosystem) and its attributes.
  - Relevance determined by how well it/they target/identify the affected organisms/ecosystems of interest.
  - Usefulness in risk assessment requires that it be measurable (at least be able to be ranked, if it cannot be assigned a numerical value).

- Criteria for Selection
  - Three principal criteria: (1) ecological relevance, (2) susceptibility to known or potential stressors, and (3) relevance to management goals.

  - Ecological Relevance
    - Ecologically relevant endpoints: reflect/identify important characteristics of the system, are functionally related to other endpoints, and may be found at any level (e.g., individual, population, community, ecosystem, landscape).
    - May help sustain the natural structure, function and biodiversity of an ecosystem or its components.
    - Changes quantified (e.g., alteration of community structure from the loss of a keystone species) or inferred (e.g., survival of individuals is needed to maintain populations).
      - Cascading effects where the stressing of one organism affects the survivability or health of another should be considered, especially if changes affect one or more of the keystone species.
    - Aspects to consider:
      - Nature and intensity of potential effects,
      - Spatial and temporal scales where effects may occur, and
      - Potential for recovery.
Problem Formulation: Selecting Assessment Endpoints

- **Susceptibility to Known or Potential Stressors**
  - "Susceptible": when an organism is sensitive to a stressor to which they are, or may be, exposed.
  - Sensitivity refers to how readily an organism/population is affected by a particular stressor and is directly related to the stressor's mode of action (e.g., chemical sensitivity is influenced by individual physiology and metabolic pathways).
  - Influenced by individual and community life-history characteristics.
  - Sensitivity measures: mortality or adverse reproductive effects from toxicant exposure; behavioral abnormalities; avoidance of significant food sources and nesting sites; loss of offspring to predation because of the proximity of stressors such as noise, habitat alteration, or loss; community structural changes; or other factors.
  - Exposure: co-occurrence, contact, or the absence of contact, depending on the stressor and assessment endpoint.
    - Amount and conditions of exposure directly influence how an organism/population will respond to a stressor.
    - Must consider stressor proximity, exposure timing (both in terms of frequency and duration), and exposure intensity during sensitive periods. Don't forget: Delayed effects and multiple-stressor exposures.
  - See toxicology notes!

- **Defining Assessment Endpoints**
  - Once potential assessment endpoints selected, define them operationally.
  - First, a valued ecological entity must be identified (species [e.g., eelgrass, piping plover], a functional group of species [e.g., piscivores], a community [e.g., benthic invertebrates], an ecosystem [e.g., lake], a specific valued habitat [e.g., wet meadows], a unique place, or other entity of concern).
  - Second, the characteristic that is important to protect and potentially at risk must be identified.
  - What distinguishes assessment endpoints from management goals is their neutrality and specificity. Assessment endpoints do not represent a desired achievement (i.e., goal).
  - Assessment endpoints may be the same as measures, depending on the assessment endpoints selected and the type of measures. Note: Surrogate endpoints can be effective.
  - Suggestion: Select an endpoint that is sensitive to many of the identified stressors, yet responds in different ways to different stressors. Suggest selecting so that all the effects can be expressed in the same units.

- **Common Problems in Selecting Assessment Endpoints**
  - Endpoint is a goal (e.g., maintain and restore endemic populations)
  - Endpoint is vague (e.g., estuarine integrity instead of eelgrass abundance and distribution)
  - Ecological entity is better as a measure (e.g., emergence of midges can be used to evaluate an assessment endpoint for fish feeding behavior)
  - Ecological entity may not be as sensitive to the stressor (e.g., catfish versus salmon for sedimentation)
  - Ecological entity is not exposed to the stressor (e.g., using insectivorous birds for avian risk of pesticide application to seeds)
  - Ecological entities are irrelevant to the assessment (e.g., lake fish in salmon stream)
  - Importance of a species or attributes of an ecosystem are not fully considered.
  - Attribute is not sufficiently sensitive for detecting important effects (e.g., survival compared with recruitment for endangered species)

- **Conceptual Models**
  - Conceptual Models: written description and/or visual representation of predicted relationships between ecological entities and the stressors to which they may be exposed.
    - May include ecosystem processes that influence receptor responses or exposure scenarios that qualitatively link land-use activities to stressors.
    - May describe primary, secondary, and tertiary exposure pathways or co-occurrence among exposure pathways, ecological effects, and ecological receptors.
  - Developed from information about stressors, potential exposure, and predicted effects on an ecological entity (the assessment endpoint).
  - Conceptual models consist of two components:
    - A set of hypotheses that describe predicted relationships among stressor, exposure, and assessment endpoint response, along with the rationale for their selection
    - A diagram that illustrates the relationships presented in the risk hypotheses.
Problem Formulation: Conceptual Models

- **Risk Hypotheses**: proposed answers (assumptions) to the questions of how exposure will occur and what responses the endpoints will show when they are exposed to stressors.
- Clarify relationships that are proposed in the conceptual model and from other sources.
  - Not equivalent to statistical testing of null and alternative hypotheses.
  - However, predictions generated from risk hypotheses can be tested in a variety of ways, including standard statistical approaches.
- **Conceptual Model Diagrams**: visual representation of risk hypotheses.
- **Design factors**: the number of relationships depicted, the comprehensiveness of the information, the certainty surrounding a linkage, and the potential for measurement.

**Examples of Risk Hypotheses**

- **Stressor-initiated**: Chemicals with a high Kow tend to bioaccumulate. Chemical A has a Kow of 5.5 and molecular structure similar to known chemical stressor B.
- **Hypotheses**: Based on the Kow of chemical A, the mode of action of chemical B, and the food web of the target ecosystem, when chemical A is released at a specified rate, it will bioaccumulate sufficiently in 5 years to cause developmental problems in wildlife and fish.
- **Effects-initiated**: Bird kills were repeatedly observed on golf courses following the application of the pesticide carbofuran, which is highly toxic.
  - **Hypotheses**: Birds die when they consume recently applied granulated carbofuran; as the level of application increases, the number of dead birds increases. Cascading exposure and effects occur when dead and dying birds are consumed by other animals. Birds of prey and scavenger species will die from eating contaminated birds.
- **Ecological value-initiated**: Waquoit Bay, Massachusetts, supports recreational boating and commercial and recreational shellfishing and is a significant nursery for finfish. Large mats of macroalgae clog the estuary, most of the eelgrass has died, and the scallops are gone.
  - **Hypotheses**: Nutrient loading from septic systems, air pollution, urban runoff and lawn fertilizers causes eelgrass loss by shading from algal growth and direct toxicity from nitrogen compounds. Fish and shellfish populations are decreasing because of loss of eelgrass habitat and periodic hypoxia from excess algal growth and low dissolved oxygen.

**Uncertainty in Conceptual Models**

- **One of the most important sources of uncertainty**.
  - **Why?** Uncertainty arises from lack of knowledge about how the ecosystem functions, failure to identify and interrelate temporal and spatial parameters, omission of stressors, and/or overlooking secondary effects.
- Uncertainty explored by considering alternative relationships.
- To address uncertainty, the risk assessor should do the following when developing the conceptual model:
  - Be explicit in defining assessment endpoints; include both an entity and its measurable attributes.
  - Reduce or define variability by carefully defining boundaries for the assessment.
  - Be open and explicit about the strengths and limitations of pathways and relationships depicted in the conceptual model.
  - Identify and describe rationale for key assumptions made because of lack of knowledge, model simplification, approximation, or extrapolation.
  - Describe data limitations.

**Back to the scenario…**

- The draft conceptual model could look something like this.
  - Zinc, phosphate, lead and nitrate are known stressors to organisms in freshwater streams in this area. The sources of these pollutants are unknown; therefore, that will need to be determined. The fish in the community are exposed to these pollutants in two ways – one, through ingestion of contaminated food and water; and two, through skin adsorption or “inhalation” of these pollutants as part of “breathing.”
  - Phosphate and nitrate also will affect the algal composition of the stream, potentially encouraging the excessive growth of specific algae (eutrophication) that deplete the oxygen supply. The change in the algal community structure also may change the microbial community structure, encouraging the growth of specific microorganisms that have a toxic effect on the fish.
  - In addition, zinc and lead will sorb to the stream sediments where they may have an effect on the benthos, which is needed for the organisms that support the food web in that stream.
  - Therefore, the final assessment will need to look at the effects of the pollutants themselves on the fish through the various routes of exposure, but also will need to look at the effects on dissolved oxygen and on the benthos.
Problem Formulation: Analysis Plan

- Final stage of problem formulation.
- Risk hypotheses are evaluated to determine how they will be assessed.
- Includes the assessment design, data needs, measures, and methods for conducting the analysis phase of the risk assessment.
- Includes pathways and relationships identified during problem formulation that will be pursued during the analysis phase.
  - Rationale incorporated.
  - Data gaps acknowledged.
  - Uncertainties acknowledged.

Selecting Measures

- Selection of appropriate measures complicated when a cascade of ecological effects is likely to occur from a stressor.

Three categories of measures:
- Measures of effect: measurable changes in an attribute of an assessment endpoint or its surrogate in response to a stressor to which it is exposed.
- Measures of exposure: measures of stressor existence and movement in the environment and their contact or co-occurrence with the assessment endpoint.
- Measures of ecosystem and receptor characteristics: measures of ecosystem characteristics that influence the behavior and location of entities selected as the assessment endpoint, the distribution of a stressor, and life-history characteristics of the assessment endpoint or its surrogate that may affect exposure or response to the stressor.

- When direct measurement of assessment endpoint responses is not possible, the selection of surrogate measures is necessary.

Examples of a Management Goal, Assessment Endpoint, and Measures

**Goal:** Viable, self-sustaining cold water trout fishery in a natural stream below an urban stormwater discharge outlet draining a primarily industrial area.

**Assessment Endpoint:** Trout breeding success, fry survival, and adult population sustainability.

**Measures of Effects**
- Egg and fry response to low dissolved oxygen
- Adult behavior (reproductive and genetic) in response to discharged toxins
- Egg survival with changes in sedimentation

**Measures of Ecosystem and Receptor Characteristics**
- Water temperature, water velocity, and physical obstructions
- Abundance and distribution of suitable breeding substrate
- Abundance and distribution of suitable food sources for fry
- Feeding, resting, and breeding behavior
- Natural reproduction, growth, and mortality rates

**Measures of Exposure**
- Toxic chemical concentrations in water, sediment, and fish tissue.
- Nutrient and dissolved oxygen levels in ambient waters
- Riparian cover, sediment loading, and water temperature

Problem Formulation: Analysis Plan

- Back to our scenario...

- Since the health of the stream and of the fish is the concern, we will likely want to sample some representative fish [fish tissue and fish gut content] (especially if we are concerned that these pollutants will accumulate [bioaccumulate in an organism or biomagnify in the food web] in the fish or in the prey of these fish.

- Obviously we are concerned about the water concentration.

- The sediment concentration also would be a concern since the benthos will feed on the sediment and possibly accumulate these pollutants in their system.

- An additional measure might be biochemical oxygen demand, since we have expressed a concern about dissolved oxygen changes at night if the area undergoes eutrophication.

- The chemical measures (water and sediment column) likely will be repeated as potential sources are identified.
How Do Water Quality Criteria Relate to Assessment Endpoints?

• Regulatory Goal
  - Clean Water Act, §101: Protect the chemical, physical, and biological integrity of the Nation’s waters

• Program Management Decisions
  - Protect 99% of individuals in 95% of the species in aquatic communities from acute and chronic effects resulting from exposure to a chemical stressor

• Assessment Endpoints
  - Survival of fish, aquatic invertebrate, and algal species under acute exposure
  - Survival, growth, and reproduction of fish, aquatic invertebrate, and algal species under chronic exposure

• Measures of Effect
  - Laboratory LC50s for at least eight species meeting certain requirements
  - Chronic no-observed-adverse-effect levels (NOAELs) for at least three species meeting certain requirements

• Measures of Ecosystem and Receptor Characteristics
  - Water hardness (for some metals)
  - pH

The water quality criterion is a benchmark level derived from single-species toxicity data. It is assumed that the species tested adequately represent the composition and sensitivities of species in a natural community.

Analysis Phase

• “Analysis” examines the two primary components of risk—exposure and effects—and their relationships between each other and ecosystem characteristics.

• Products: summary profiles that describe exposure and the relationship between the stressor(s) and response.

• During the analysis phase, the risk assessor:
  - Selects the data that will be used on the basis of their utility for evaluating the risk hypotheses
  - Analyzes exposure by examining the sources of stressors, the distribution of stressors in the environment, and the extent of co-occurrence or contact
  - Analyzes effects by examining stressor-response relationships, the evidence for causality, and the relationship between measures of effect and assessment endpoints
  - Summarizes the conclusions about exposure and effects.

Analysis Phase: Evaluating Data and Models for Analysis

• Strengths and Limitations of Different Types of Data
  - Many types of data can be used for risk assessment.
    - Laboratory studies
    - Field studies
    - Process model results
  - Ecologists and epidemiologists observe patterns and processes in the field and often use statistical techniques (e.g., correlation, clustering, factor analysis) to describe an association between a disturbance and an ecological effect.
  - Much of the data on human exposure comes either from extrapolation of laboratory data or from epidemiologic data on human populations (often as a result of occupational exposure).
  - See epidemiology notes!
Analysis Phase: Evaluating Data and Models for Analysis

- May be single variable data or index values (e.g., RBP results, IBI data).
- Index data advantages:
  - Overall indication of biological condition by incorporating many attributes from individual to ecosystem levels.
  - Evaluate responses from a broad range of anthropogenic stressors.
  - Minimize the limitations of individual metrics for detecting specific types of responses.
- Process models can be used to predict effects:
  - Particularly useful when measurements cannot be taken.
  - Provide estimates for times or locations that are impractical to measure.
  - Provide basis for extrapolating beyond the range of observation.

Evaluating Measurement or Modeling Studies

- Study should include a description of the purpose, methods used to collect data, and results of the work.
- Compare study objectives with those of the risk assessment for consistency (see questions in text box below).
- Evaluate whether the intended objectives were met and whether the data are of sufficient quality.

Analysis Phase: Evaluating Uncertainty

- Objective: describe and quantify what is known and not known about exposure and effects in the system of interest.
  - Uncertainty analyses increase the credibility of assessments by explicitly describing the magnitude and direction of uncertainties, and they provide the basis for efficient data collection or application of refined methods.
  - Uncertainties characterized during the analysis phase are used during risk characterization, when risks are estimated and the confidence in different lines of evidence is described.
- This section discusses sources of uncertainty relevant to the analysis of ecological exposure and effects. Readers are also referred to the discussion of uncertainties in the exposure assessment guidelines (U.S. EPA, 1992b).

Questions for Evaluating a Study’s Utility for Risk Assessment

- Are the study objectives relevant to the risk assessment?
- Are the variables and conditions the study represents comparable with those important to the risk assessment?
- Is the study design adequate to meet its objectives?
- Was the study conducted properly?
- How are variability and uncertainty treated and reported?
Analysis Phase: Sources of Uncertainty

- Variability/heterogeneity.
- Uncertainty about a quantity’s true value.
- Data gaps.

Addressing sources of uncertainty:
- Variability – present a distribution or specific percentiles from it (e.g., mean and 95th percentile).
- Uncertainty (about its magnitude, location, or time of occurrence) – take additional measurements. Described by sampling error (or variance in experiments) or measurement error. Know study’s significance and power.
- Data gaps – usually bridged with a combination of scientific analyses, scientific judgment, and perhaps policy decisions. Data gaps must be noted.

- Results can be presented as a series of point estimates with different aspects of uncertainty reflected in each. Classical statistical methods (e.g., confidence limits, percentiles) can readily describe parameter uncertainty.

Back to the scenario...

Now to go in search of historical data that could be incorporated into the risk assessment. First, we want to search for information on zinc toxicity to the specific fish of interest. For example, a search on zinc provides information on the toxicity of a form of zinc, zinc phosphide. A search on Google found EXTOXNET (Extension Toxicity Network), which provides information on pesticides. Zinc phosphide (which may or may not be the form of zinc in the stream) is a pesticide with a list of known toxicities. Here is an excerpt from that website:

EXTOXNET Results for Zinc Phosphide

**Toxicological Effects:**
- **Acute toxicity:** Zinc phosphide ingested orally reacts with water and acid in the stomach and produces phosphine gas. Symptoms of acute zinc phosphide poisoning by ingestion include nausea, abdominal pain, tightness in chest, excitement, agitation, and chills. Other symptoms include vomiting, diarrhea, cyanosis, rapid pulse, fever, and shock. In rats, the LD50 for the technical product (80 to 90% pure) is 40 mg/kg, while the LD50 values for lower concentration formulations are slightly higher, indicating lower acute toxicity. In sheep the LD50 ranges from 60 to 70 mg/kg. The compound is non irritating to the skin and eyes.
- **Chronic toxicity:** Rats fed zinc phosphide over a wide range of doses experienced toxic effects. Increased liver, brain, and kidney weights, and lesions on these organs, were noted in rats exposed to around 14 mg/kg/day. Body hair loss, reduction in body weight, and reduction of food intake were all noted at 3.5 mg/kg/day. There have been no observed symptoms of chronic poisoning due to zinc phosphide exposure in humans.
- **Reproductive effects:** No data are currently available.
- **Teratogenic effects:** No data are currently available.
- **Mutagenic effects:** No data are currently available regarding the mutagenicity of zinc phosphide. However, its metabolite, phosphine, has shown a concentration-dependent increase in chromosomal aberrations in studies using human lymphocyte cultures. Thus, its mutagenicity is unclear.

**Ecological Effects:**
- **Effects on birds:** highly toxic to wild birds. The most sensitive birds are geese (LD50 of 7.5 mg/kg for the white-fronted goose), pheasants, mourning doves, quail, mallard ducks, and the horned lark are also very susceptible to this compound. Blackbirds are less sensitive.
- **Effects on aquatic organisms:** highly toxic to freshwater fish. The fish species which have been evaluated include bluegill sunfish (LC50 of 0.8 mg/L) and rainbow trout (LC50 of 0.5 mg/L). Carp were also found to be susceptible to zinc phosphide, especially in weakly acidic water.
- **Effects on other organisms:** toxic to non-target mammals when ingested directly. Some of the toxic effects to predators have been due to the ingestion of zinc phosphide that was in the digestive tract of the target organism. Studies on secondary organisms have focused on coyotes, fox, mink, weasels, and birds of prey.
Analysis Phase: Characterization of Exposure

- Describes potential or actual contact or co-occurrence of stressors with receptors.
- Based on measures of exposure and ecosystem and receptor characteristics that are used to analyze stressor sources, their distribution in the environment, and the extent and pattern of contact or co-occurrence.
- Produce a summary exposure profile that identifies the receptor (i.e., the exposed ecological entity), describes the course a stressor takes from the source to the receptor (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact. Includes variability.
- Combined with an effects profile to estimate risks.

Source(s)
- Definition: the place where the stressor originates or is released (e.g., a smokestack, historically contaminated sediments) or the management practice or action (e.g., dredging) that produces stressors.
- Location of a source and the environmental media that first receive stressors are two attributes that deserve particular attention.

Questions for Source Description
- Where does the stressor originate?
- What environmental media first receive stressors?
- Does the source generate other constituents that will influence a stressor’s eventual distribution in the environment?
- Are there other sources of the same stressor?
- Are there background sources?
- Is the source still active?
- Does the source produce a distinctive signature that can be seen in the environment, organisms, or communities?

Additional questions for introduction of biological stressors:
- Is there an opportunity for repeated introduction or escape into the new environment?
- Will the organism be present on a transportable item?
- Are there mitigation requirements or conditions that would kill or impair the organism before entry, during transport, or at the port of entry?

Analysis Phase: Characterization of Exposure

- Back to the scenario...
- Potential sources of these pollutants must be identified. Supposing that the watershed of interest draining to the stream was shown in the following aerial photograph, several potential sources could be identified. For the zinc and lead, roofing materials would be suspect – particularly in the area where galvanized and painted roofs were used (such as the industrial area). For the nutrients, potential sources would include leaking sewers (septic systems, if applicable) and fertilizer applications. At that point, historical data on these sources would be collected if it exists.
- Focusing on zinc, fortunately, earlier studies have investigated the potential contribution of zinc to stormwater runoff from galvanized roofs, such as the one that tested simulated runoff from 60+-year-old galvanized painted roofing panels. A review of this study showed that the “sprayed” category was a simulated rainfall where the panels were “raimed on” for three days intermittently. This would be useful data, especially if stormwater is a potential source.
- Other sources of data may include runoff data collected in that watershed or in similar watersheds. In the United States, a relatively-new tool called the National Stormwater Quality Database (NSQD) has been developed. This database presents summaries of monitoring data collected by municipalities as part of their requirements for their Phase I NPDES permit. The database can be found at: [http://rpil.eng.ua.edu/Research/ms4/mainms4.shtml](http://rpil.eng.ua.edu/Research/ms4/mainms4.shtml).

Analysis Phase: Characterization of Exposure

- Distribution of the Stressors or Disturbed Environment
- Describe the spatial and temporal distribution of stressors in the environment.
  - For physical stressors that directly alter or eliminate portions of the environment, the assessor describes the temporal and spatial distribution of the disturbed environment.
  - Because exposure occurs when receptors co-occur with or contact stressors, this characterization is a prerequisite for estimating exposure.
  - Stressor distribution in the environment is examined by evaluating pathways from the source as well as the formation and subsequent distribution of secondary stressors.
- Stressors can be transported via many pathways.
Questions to Ask in Evaluating Stressor Distribution

• What are the important transport pathways?
• What characteristics of the stressor influence transport?
• What characteristics of the ecosystem will influence transport?
• What secondary stressors will be formed?
• Where will they be transported?

General Mechanisms of Transport and Dispersal

**Physical, chemical, and biological stressors:**
• By air current
• In surface water (rivers, lakes, streams)
• Over and/or through the soil surface
• Through ground water

**Primarily chemical stressors:**
• Through the food web

**Primarily biological stressors:**
• Splashing or raindrops
• Human activity (boats, campers)
• Passive transmittal by other organisms
• Biological vectors

Analysis Phase: Characterization of Exposure

• For a chemical stressor, the evaluation usually begins by determining into which media it can partition. Key considerations include physicochemical properties such as solubility and vapor pressure. Bioaccumulation and biomagnification also must be considered.
• The attributes of physical stressors also influence where they will go.
• The dispersion of biological stressors can be described in two ways: diffusion and jump-dispersal. Diffusion involves a gradual spread from the establishment site and is primarily a function of reproductive rates and motility. Jump-dispersal involves erratic spreads over periods of time, usually by means of a vector.
• Ecosystem characteristics influence the transport of all types of stressors.

Analysis Phase: Characterization of Exposure

**Back to the scenario...**
• For zinc phosphide (from EXTOXNET).... These data may be used to predict fate and transport of zinc phosphide in the environment
  • **Physical Properties:**
  • **Appearance:** Zinc phosphide is an amorphous black-grey powder with a garlic-like odor [1]. It is stable when dry and decomposes in moist air.
  • **Chemical Name:** trizinc diphosphide
  • **CAS Number:** 1314-84-7
  • **Molecular Weight:** 258.09
  • **Water Solubility:** Practically insoluble in water (decomposes slowly)
  • **Solubility in Other Solvents:** Practically insoluble in alcohol; slightly soluble in benzene and carbon disulfide
  • **Melting Point:** >420 C
  • **Vapor Pressure:** Negligible in the dry state (as solid)
  • **Partition Coefficient:** Not Available
  • **Adsorption Coefficient:** Not Available
Analysis Phase: Characterization of Exposure

- **Evaluating Secondary Stressors.**
  - For chemicals, usually focus on metabolites, biodegradation products, or chemicals formed through abiotic processes.
  - Can also be formed through ecosystem processes.
    - Field rates may differ greatly from laboratory rates! Also may not be able to effectively replicate field process in a laboratory!
  - Physical disturbances can also generate secondary stressors. Task is to identify the specific consequences that will affect the assessment endpoint.
    - The removal of riparian vegetation, for example, can generate many secondary stressors, including increased nutrients, stream temperature, sedimentation, and altered stream flow. However, it may be the temperature change that is most responsible for adult salmon mortality in a particular stream.
- Back to the scenario...
  - Here is where we would measure BOD5. The depression of the stream's dissolved oxygen is a secondary stressor on our fish of interest.

Questions To Ask in Describing Contact or Co-Occurrence

- Must the receptor actually contact the stressor for adverse effects to occur?
- Must the stressor be taken up into a receptor for adverse effects to occur?
- What characteristics of the receptors will influence the extent of contact or co-occurrence?
- Will abiotic characteristics of the environment influence the extent of contact or co-occurrence?
- Will ecosystem processes or community-level interactions influence the extent of contact or co-occurrence?

Analysis Phase: Characterization of Exposure

- **Describe Contact or Co-Occurrence**
  - Extent and pattern of co-occurrence or contact between stressors and receptors (i.e., exposure).
  - This is critical—if there is no exposure, there can be no risk.
  - Include situations where exposure may occur in the future, where exposure has occurred in the past but is not currently evident (e.g., in some retrospective assessments), and where ecosystem components important for food or habitat are or may be exposed, resulting in impacts to the valued entity.
  - Exposure can be described in terms of stressor and receptor co-occurrence, actual stressor contact with receptors, or stressor uptake by a receptor.

Analysis Phase: Characterization of Exposure

- Most stressors must contact receptors to cause an effect. Function of amount or extent of stressor in environmental and activity or behavior of the receptors.
  - For biological stressors, contact assumed to occur in areas and during times where the stressor and receptor are both present. Mode of transmission important!
  - For chemicals, contact is quantified as the amount of a chemical ingested, inhaled, or in material applied to the skin (potential dose).
  - For ingested media (food, soil), modeled or measured concentrations combined with assumptions or parameters describing the contact rate (U.S. EPA, 1993b).
  - Some stressors must not only be contacted but also must be internally absorbed. Uptake is usually assessed by modifying an estimate of contact with a factor indicating the proportion of the stressor that is available for uptake (the bioavailable fraction) or actually absorbed.
  - Abiotic attributes may increase or decrease the amount of a stressor contacted by receptors. Biotic interactions can also influence exposure.
  - Three dimensions should be considered when estimating exposure: intensity, time, and space.
    - Intensity may be expressed as the amount of chemical contacted per day or the number of pathogenic organisms per unit area.
    - The temporal dimension of exposure has aspects of duration, frequency, and timing. Duration can be expressed as the time over which exposure occurs, some threshold intensity is exceeded, or intensity is integrated.
    - Spatial extent most commonly expressed in terms of area (e.g., hectares of paved habitat, square meters that exceed a particular chemical threshold).
Analysis Phase: Characterization of Exposure

- Back to the scenario...
- Contact is a critical variable in this risk assessment. Because stormwater runoff is a concern, sampling needs to encompass both dry- and wet-weather flows. In addition, to minimize the cost of management actions, the sources of concern in the watershed need to be identified. For example, for the zinc and lead, the industrial area of the site is of most concern. Sampling for these parameters may be targeted for that location.
- In order to appropriately quantify the contributions from the various sources in the watershed, a statistically-sound sampling plan will need to be developed.

Analysis Phase: Characterization of Exposure

- Exposure Profile
  - Exposure described in terms of intensity, space, and time in units that can be combined with the effects assessment.
  - Summarize paths of stressors from the source to the receptors, completing the exposure pathway.
  - Assessor explains how each of the three general dimensions of exposure (intensity, time, and space) was treated. The profile should also describe how exposure can vary depending on receptor attributes or stressor levels.
  - The exposure profile should summarize important uncertainties (e.g., lack of knowledge). In particular, the assessor should:
    - Identify key assumptions and describe how they were handled
    - Discuss (and quantify, if possible) the magnitude of sampling and/or measurement error
    - Identify the most sensitive variables influencing exposure
    - Identify which uncertainties can be reduced through the collection of more data.

Questions Addressed by the Exposure Profile

- How does exposure occur?
- What is exposed?
- How much exposure occurs? When and where does it occur?
- How does exposure vary?
- How uncertain are the exposure estimates?
- What is the likelihood that exposure will occur?

Analysis Phase: Characterization of Effects

- Link stressor effects to assessment endpoints.
- Evaluate how effects change with varying stressor levels.

Response Analysis

- Examines three primary elements: the relationship between stressor levels and ecological effects, the plausibility that effects may occur or are occurring as a result of exposure to stressors, and linkages between measurable effects and assessment endpoints when the latter cannot be directly measured.

Stressor-Response Analysis

- A.k.a. in human risk assessment, dose-response relationships in human risk assessment
- Depend on the scope and nature of the risk assessment as defined in problem formulation and reflected in the analysis plan.
- Curve shape may be needed to determine the presence or absence of an effects threshold or for evaluating incremental risks.
A simple example of a stressor-response relationship.


Questions for Stressor-Response Analysis

- Does the assessment require point estimates or stressor-response curves?
- Does the assessment require the establishment of a “no-effect” level?
- Would cumulative effects distributions be useful?
- Will analyses be used as input to a process model?

Analysis Phase: Characterization of Effects

- **Median Effect Levels**
  - Median effects are those effects elicited in 50% of the test organisms exposed to a stressor, typically chemical stressors. Median effect concentrations can be expressed in terms of lethality or mortality and are known as LC50 or LD50, depending on whether concentrations (in the diet or in water) or doses (mg/kg) were used. Median effects other than lethality (e.g., effects on growth) are expressed as EC50 or ED50. The median effect level is always associated with a time parameter (e.g., 24 or 48 hours). Because these tests seldom exceed 96 hours, their main value lies in evaluating short-term effects of chemicals. Stephan (1977) discusses several statistical methods to estimate the median effect level.
  - In addition, dose-response relationships can be used to compare responses among organisms to determine which organisms have a greater tolerance for a particular stressor.

Example dose-response curves. A: Human response to ethanol as a function of dose; B: percentage of mouse pups with cleft palate as a result of the material dose of 2,3,7,8-TCDD (tetrachloro dibenzo-p-dioxin) – a very toxic dioxin and the contaminant of concern in Agent Orange.
Variations in stressor-response relationships. These curves illustrate a range of responses to pesticide exposure on plant survival, where 2/98R and 10/99S are variants of the same wild oat species. agspsv34.agric.wa.gov.au/.../Hashem_Dhammu.htm

Uptake of mercury and the response for different levels of mercury in the diet.

Analysis Phase: Characterization of Effects

- Data from individual experiments can be used to develop curves and point estimates both with and without associated uncertainty estimates.
- Advantages of curve-fitting approaches: use all available experimental data; ability to interpolate to values other than the data points measured.
- If extrapolation is required, assessors should justify that the observed experimental relationships remain valid. A disadvantage of curve fitting is that the required amount of data to complete an analysis may not always be available.
- Other measures that are derived from these curves include the derivation of no-effect levels.

Analysis Phase: Characterization of Effects

- No-Effect Levels Derived From Statistical Hypothesis Testing
  - Statistical hypothesis tests have typically been used with chronic chemical toxicity tests to evaluate multiple endpoints.
  - For each endpoint, the objective is to determine the highest test level for which effects are not statistically different from the controls (the no-observed-adverse-effect level, NOAEL) and the lowest level at which effects were statistically significant from the control (the lowest-observed-adverse-effect level, LOAEL).
  - Range between the NOAEL and the LOAEL is sometimes called the maximum acceptable toxicant concentration, or MATC. The MATC, which can also be reported as the geometric mean of the NOAEL and the LOAEL (i.e., GMATC), provides a reference with which to compare toxicities of various chemical stressors.
  - Reporting the results of chronic tests in terms of the MATC or GMATC has been widely used within the Agency for evaluating pesticides and industrial chemicals (e.g., Urban and Cook, 1986; Nabholz, 1991).
### Analysis Phase: Characterization of Effects

#### Establishing Cause-and-Effect Relationships (Causality)
- Relationship between cause (one or more stressors) and effect (response to the stressor(s)).

#### General Criteria for Causality (Adapted From Fox, 1991)
- **Criteria strongly affirming causality:**
  - Strength of association
  - Predictive performance
  - Demonstration of a stressor-response relationship
  - Consistency of association
- **Criteria providing a basis for rejecting causality:**
  - Inconsistency in association
  - Temporal incompatibility
  - Factual implausibility
- **Other relevant criteria:**
  - Specificity of association
  - Theoretical and biological plausibility

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### Questions to Consider when Extrapolating From Effects Observed in the Laboratory to Field Effects of Chemicals Exposure Factors

- How will environmental fate and transformation of the chemical affect exposure in the field?
- How comparable are exposure conditions and the timing of exposure?
- How comparable are the routes of exposure?
- How do abiotic factors influence bioavailability and exposure?
- How likely are preference or avoidance behaviors?

#### Effects factors:
- What is known about the biotic and abiotic factors controlling populations of the organisms of concern?
- To what degree are critical life-stage data available?
- How may exposure to the same or other stressors in the field have altered organism sensitivity?

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### Analysis Phase: Characterization of Exposure

- **Stressor-Response Profile**
  - Objective: ensure that the information needed for risk characterization has been collected and evaluated.

#### Questions Addressed by the Stressor-Response Profile
- What ecological entities are affected?
- What is the nature of the effect(s)?
- What is the intensity of the effect(s)?
- Where appropriate, what is the time scale for recovery?
- What causal information links the stressor with any observed effects?
- How do changes in measures of effects relate to changes in assessment endpoints?
- What is the uncertainty associated with the analysis?

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### Analysis Phase: Characterization of Effects

- **Koch’s Postulates** (Pelczar and Reid, 1972)
  - A pathogen must be consistently found in association with a given disease.
  - The pathogen must be isolated from the host and grown in pure culture.
  - When inoculated into test animals, the same disease symptoms must be expressed.
  - The pathogen must again be isolated from the test organism.
  - Often it is necessary to extrapolate/estimate effects in the field from laboratory data. The following text box provides guidance on the questions to consider.
Risk Characterization

- Final phase!
- Assessors can now clarify the relationships between stressors, effects, and ecological entities and to reach conclusions regarding the occurrence of exposure and the adversity of existing or anticipated effects.

Risk Estimation

- Integrate exposure and effects data and evaluates any associated uncertainties.
- Risk estimates can be developed using one or more of the following techniques: (1) field observational studies, (2) categorical rankings, (3) comparisons of single-point exposure and effects estimates, (4) comparisons incorporating the entire stressor-response relationship, (5) incorporation of variability in exposure and/or effects estimates, and (6) process models that rely partially or entirely on theoretical approximations of exposure and effects.

Field Observational Studies

- Field observational studies (surveys) can serve as risk estimation techniques because they provide empirical evidence linking exposure to effects.
- They measure biological changes in natural settings through collection of exposure and effects data for ecological entities identified in problem formulation.
- Advantage of field surveys is that they can be used to evaluate multiple stressors and complex ecosystem relationships that cannot be replicated in the laboratory.
- Disadvantages: (1) a lack of replication, (2) bias in obtaining representative samples, or (3) failure to measure critical components of the system or random variations. Further, a lack of observed effects in a field survey may occur because the measurements lack the sensitivity to detect ecological effects.
- Several assumptions or qualifications need to be clearly articulated when describing the results of field surveys. A primary qualification is whether a causal relationship between stressors and effects is supported.

Categories and Rankings

- This approach is most frequently used when exposure and effects data are limited or are not easily expressed in quantitative terms. Ranking techniques can be used to translate qualitative judgment into a mathematical comparison.

Risk Characterization: Single-Point Exposure and Effects Comparisons

- Quotient: ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration. Quotients are commonly used for chemical stressors, where reference or benchmark toxicity values are widely available.
- Advantages: simple and quick to use and risk assessors and managers are familiar with it. It is an efficient, inexpensive means of identifying high- or low-risk situations that can direct risk management decisions without the need for further information.
- Limitations: may not help in making a decision requiring an incremental quantification of risks. Other limitations may be caused by deficiencies in the problem formulation and analysis phases.
- Interactions and effects may be critical to characterizing the full extent of impacts from exposure to the stressors (e.g., bioaccumulation, eutrophication, loss of prey species, opportunities for invasive species).
- Finally, in most cases, the quotient method does not explicitly consider uncertainty.
- In human epidemiology, uncertainty is inherently reported in a study’s results. The results of an epidemiologic study are reported as a rate ratio, either a relative risk or an odds ratio.
Risk Characterization

Comparisons Incorporating the Entire Stressor-Response Relationship

- If dose-response curve available, then examine risks associated with varying levels of exposure.
  - Applicable mostly when outcome is not based on exceeding regulatory level/standard.
- Advantages of comparison of dose-response & cum. exposure:
  - Slope of effects shows:
    - Magnitude of change in effects due to incremental changes in exposure
    - Capability to predict changes in magnitude and likelihood of effects for different exposures.
    - Uncertainty shown using error bounds on stressor-response or exposure estimates.
- Limitations:
  - Limitations from the problem formulation and analysis phases may limit usefulness of the results. Examples:
    - Not fully considering secondary effects
    - Assuming exposure pattern behind stressor-response curve is comparable to the environmental exposure pattern
    - Failure to consider uncertainties, such as extrapolations from tested species to the species or community of concern.

Comparisons Incorporating Variability in Exposure and/or Effects

- If exposure or stressor-response curves describe variability in exposure or effects, then many different risk estimates can be calculated.
- Exposure variability in exposure used to estimate risks to moderately or highly exposed organisms.
- Effects variability used to estimate risks to average or sensitive population members:
  - Advantage: ability to predict changes in the magnitude and likelihood of effects for different exposure scenarios comparing different risk management options.
  - Limitations: increased data requirements; implicit assumption that full range of variability in the exposure and effects data is represented.
  - Can be used to rank susceptibility if multiple organisms are being evaluated, or it will allow a relative ranking of the stressors/hazards.

Application of Process Models

- Useful tools also in risk characterization.
- Advantage: Consider "what if" scenarios; forecast beyond limits of observed data.
- Advantage: Process model can also consider secondary effects.
- Advantage: Some process models can forecast the combined effects of multiple stressors.
- Outputs: point estimates, distributions, or correlations.
- Caution: Interpret with care. May imply a higher level of certainty than is appropriate and are all too often viewed without sufficient attention to underlying assumptions.
Risk Characterization

Back to the scenario…

- Two types of process models may be of interest here.
- One type will could predict the fate and transport of these pollutants from source to ultimate “disposal” in the urban stream.
- Models also can be run a second time to determine whether specific management options will be effective.
- The second type of model will use the toxicity and fate-and-transport data to predict whether toxic effects may be seen in the organisms in the stream. Toxicity models will allow for a prediction to be made as to the overall health of the stream both at the current concentrations and after source management has been implemented.

Risk Description

- After generating risk estimate, now interpret the data and discuss it!
- Risk description: evaluation of the lines of evidence supporting or refuting the risk estimate(s) and an interpretation of the significance of the adverse effects on the assessment endpoints.

Lines of Evidence

- Lines of evidence show how conclusions were reached (as well as addressing uncertainty)
- Not the kind of proof demanded by experimentalists, nor is it a rigorous examination of weights of evidence.
- Increased confidence results from multiple lines of evidence.
- Three areas to consider when evaluating lines of evidence: (1) data adequacy and quality, (2) degree and type of uncertainty, and (3) relation of evidence to original questions.
- Data quality directly influences how confident risk assessors can be in the results of a study and conclusions they may draw from it. One major source of uncertainty comes from extrapolations.

Risk Characterization

• Back to the scenario…

- Historical data has shown that the watershed is likely a source of these pollutants.
- The pollutants have been measured in the water and sediment at concentrations of concern based on both historical toxicity data and on the additional tests that were run as part of this risk assessment.
- Therefore, the source data and outfall data, when combined with the toxicity and stream concentration data, has likely shown that one or more of the pollutants identified as possible stressors are actual stressors to the system.
- The management options available to control the stressors is outside of the scope of the risk assessment but it is incorporated into the risk management decision-making framework.

Determining Ecological Adversity

- Next step: interpret whether these changes are considered adverse.
- Adverse ecological effects: undesirable changes because they alter valued structural or functional attributes of the ecological entities.
- Risk assessment evaluates the degree of adversity using following criteria:
  - Nature of effects and intensity of effects
  - Spatial and temporal scale
  - Potential for recovery.
- It is important for risk assessors to consider both the ecological and statistical contexts of an effect when evaluating intensity.
- Recovery can be evaluated in spite of the difficulty in predicting events in ecological systems.
- For example, it is possible to distinguish changes that are usually reversible (e.g., stream recovery from urban discharge), frequently irreversible (e.g., establishment of new energy gradients in a stream due to increased discharge energy post-urbanization), and always irreversible (e.g., extinction).
Risk Characterization

Reporting Risks

- At end, should be able to estimate ecological risks, indicate the overall degree of confidence in the risk estimates, cite lines of evidence supporting the risk estimates, and interpret the adversity of ecological effects.

Possible Risk Assessment Report Elements

- Describe risk assessor/risk manager planning results.
- Review the conceptual model and the assessment endpoints.
- Discuss the major data sources and analytical procedures used.
- Review the stressor-response and exposure profiles.
- Describe risks to endpoints, including risk estimates and adversity evaluations.
- Review uncertainty and approaches used to address them.
  - Discuss scientific consensus (if exists) in key areas of uncertainty.
  - Identify major data gaps and indicate if more data would add significantly to the overall confidence in the assessment results.
  - Discuss science policy judgments/assumptions used to bridge information gaps and the basis for these assumptions.
  - Discuss how quantitative uncertainty analysis are embedded.

Risk Characterization Report

Clear, Transparent, Reasonable, Consistent Risk Characterizations

For clarity:
- Be brief; avoid jargon.
- Make language and organization understandable.
- Fully discuss/explain unusual issues specific to this risk assessment.

For transparency:
- Identify the scientific conclusions separately from policy judgments.
- Clearly articulate major differing viewpoints of scientific judgments.
- Define and explain the risk assessment purpose.
- Fully explain assumptions and biases (scientific and policy).

For reasonableness:
- Integrate all components into an overall conclusion of risk.
- Acknowledge uncertainties and assumptions.
- Describe key data as experimental, state-of-the-art, or generally accepted scientific knowledge.
- Identify reasonable alternatives and conclusions supported by data.
- Define the level of effort (e.g., quick screen, extensive characterization) and reason(s) for selecting level of effort.

For consistency with other risk characterizations:
- Describe how the risks posed by one set of stressors compare with the risks posed by a similar stressor(s) or similar environmental conditions.
- Example ecological risk assessment performed by the US Army Corps of Engineers can be found at: [http://www2.mvr.usace.army.mil/umc-iwwens/documents/env16_summary.pdf](http://www2.mvr.usace.army.mil/umc-iwwens/documents/env16_summary.pdf). This summary links the various pieces into a brief narrative that highlights the pertinent findings of the risk assessment.