Human Health Risk Assessment

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Missouri Department of Health and Senior Services (MDHSS)

MDHSS has primary responsibility for safeguarding the health of the people of Missouri.

Bureau of Environmental Epidemiology (BEE)

BEE has responsibility for the investigation and prevention of illnesses and medical conditions related to the environment.

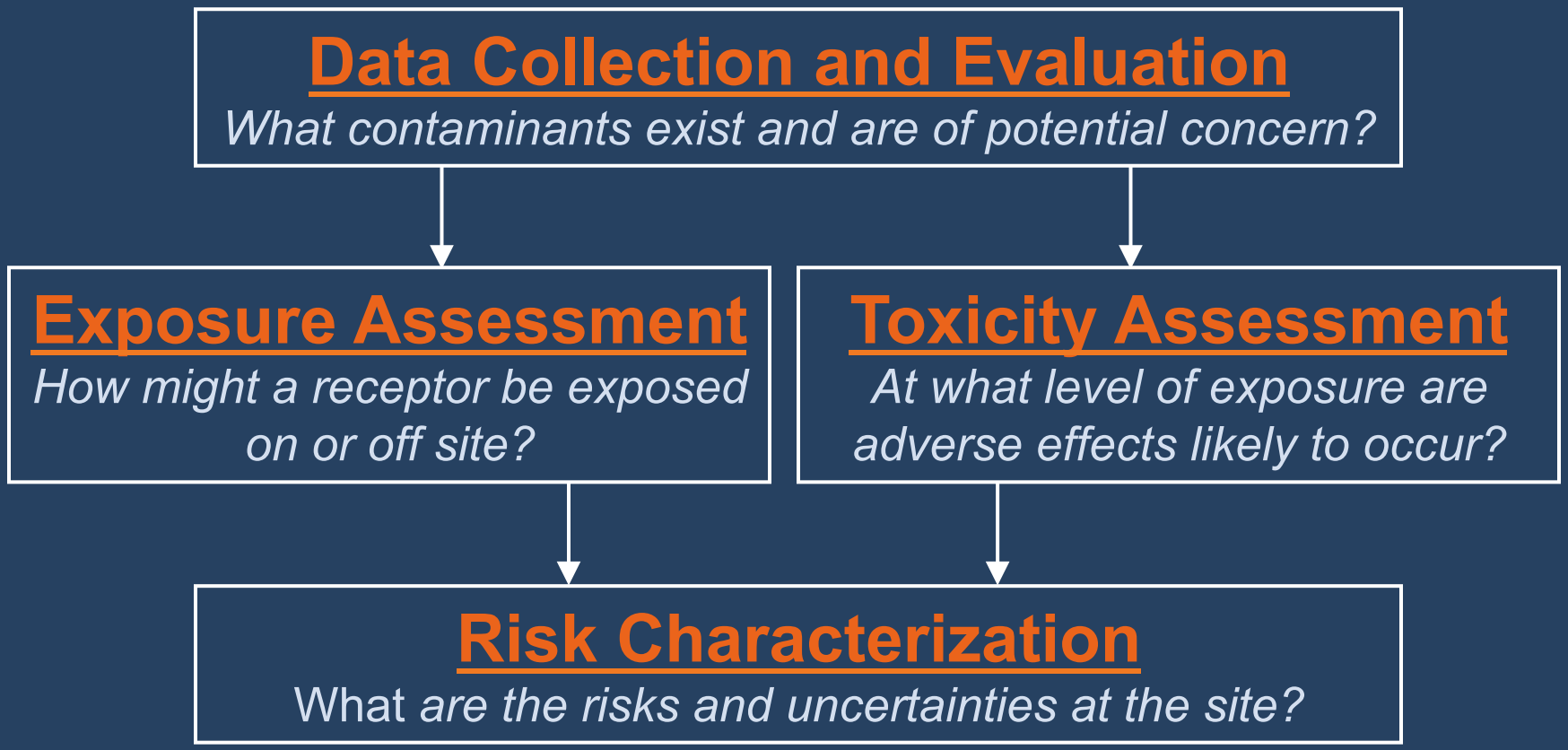
Health and Risk Assessment Program (HRAP)

HRAP is responsible for evaluating human exposure to hazardous substances in the environment and for making health-protective recommendations regarding actions needed.

Human Health Risk Assessment (HHRA)

- **Seeks to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future - Important to note that results of a risk assessment are estimates of the potential for adverse effects, not certainties;**
- **A tool used in cleanup decision-making; and**
- **An iterative process that provides a scientific & defensible rationale.**

Basic 4-Step HHRA Process



HHRA Purpose

The HHRA process provides a consistent framework for evaluating and documenting potential public health threats from a site for the purpose of guiding decision-making on appropriate response actions. Baseline risks are evaluated to document potential health effects from exposure in the absence of any actions to control or mitigate the site (i.e., under an assumption of no action).

Specifically, results of an HHRA are used to:

- provide an analysis of baseline risks to help determine whether response action is necessary at the site;
- provide a basis for determining levels of chemicals that can remain onsite and still be adequately protective of public health; and
- provide a basis for comparing potential health impacts of various response actions.

Risk Assessment vs. Risk Management

RISK ASSESSMENT (DHSS Role)

- Unbiased scientific approach to assessing potential health risks.

RISK MANAGEMENT (Regulator's Role)

- The process of weighing policy alternatives and selecting the most appropriate regulatory action by integrating the results of risk assessment with other considerations, such as feasibility, cost, etc.

DHSS Role in Risk Management

Although risk assessment and risk management are distinctly different processes, they go hand-in-hand.

DHSS Role

- DHSS serving as the lead risk assessment agency for Resource Conservation and Recovery Act (RCRA) sites
- Provide risk assessment technical support to risk management agencies (DNR/EPA):
  - Participate in planning phases of the Corrective Action Process
  - Review work plans and sampling/quality assurance plans from the regulated community to ensure data collected is of sufficient quality and quantity for risk-assessment purposes
  - Review HHRA from the regulated community to ensure appropriate application of risk assessment methodology and to ensure site risks are adequately characterized
  - Review site cleanup objectives, goals, and options to ensure response actions will be adequately protective of human health

RCRA LEAN

The RCRA Corrective Action Lean process is intended to eliminate redundancies and expedite the review and approval of supporting documentation for the environmental investigation.

RECOMMENDATIONS INCLUDE:

Involving key stakeholders and shifting work to the front of the process in an effort to:

- Exchange information and standard objectives
- Exchange and address concerns
- Discuss criteria and expectations
- Hold open, candid discussions
- Debate variations in viewpoints
- *Build trust*
- *Reach agreement*

RCRA LEAN and HHRA

To support the Lean process, the following items should be provided upfront to risk assessors to expedite the process and bring DHSS staff up to speed on sites:

- A site summary which summarizes historical and current operations, current and expected future land use, past investigations/actions, and sources and extent of known contamination.
- A detailed map showing the site location and showing the site relative to surrounding properties/land uses.
- A preliminary conceptual site model that defines contaminant sources, release mechanisms, contaminant transport, and exposure routes and receptors – this should be provided during planning and should be refined throughout the project based on additional site data and information.
- A clear definition of whether the focus is a site-wide investigation and old Areas of Concern/Solid Waste Management Units (AOCs/SWMUs) will be revisited along with other potential source areas or whether the focus is only on specific defined areas.

DHSS Sampling Recommendations

- Site data collection activities should be planned to not only define nature and extent of contamination, but should satisfy requirements for completion of the human health risk assessment
  - Data usability considerations include:
    - Analytical methods and detection limits must be able to meet risk-based levels of concern
    - Data should be of sufficient quality for risk assessment-purposes (representativeness, precision, accuracy, comparability, completeness)
    - Data should be of sufficient quantity to accurately quantify potential risk (a sufficient number of samples should be collected for valid statistical analysis)

DHSS HHRA Recommendations

- HHRA should follow EPA Risk Assessment Guidance for Superfund (RAGS) methodology and EPA Screening Levels should be used for HHRA chemicals of potential concern (COPC) screening, not Missouri Risk-Based Corrective Action (MRBCA)!
- RAGS Part D tables may be used, but not necessary.
- Future land use determinations – if future residential is not assumed, a justification providing the basis for the land use assumptions must be provided.
- Both Onsite and Offsite risks should be appropriately evaluated in the HHRA.
- Baseline risks (assuming no actions/controls) using Reasonable Maximum Exposure (RME) scenarios should be evaluated in the HHRA.
- Future groundwater use must be evaluated in the HHRA if groundwater is of sufficient quality and quantity to support drinking water use.

DHSS HHRA Recommendations

Data Collection and Evaluation

- A data quality evaluation should be appropriately presented in the HHRA.
- Generally only current data should be used in the HHRA, although historical data should be discussed qualitatively.

DHSS HHRA Recommendations

Data Collection and Evaluation continued

- Screening Considerations :
  - All receptors and pathways should be adequately accounted for in screening to select COPCs.
  - Be aware that delineation criteria to determine nature and extent and contaminant screening to select COPCs for the HHRA are interrelated, but two separate steps.
    - Delineation Criteria should be selected to support the development and evaluation of proposed response actions (Maximum Contaminant Levels (MCLs), MO water quality standards, risk-based screening levels, leaching to groundwater levels, etc. - generally the most conservative applicable remediation standard should be used as the point of compliance).
    - HHRA COPC Screening – All data is evaluated as part of the HHRA; selection of COPCs to carry forward through the quantitative risk assessment includes:
      - Screening contaminants detected against risk-based screening levels (Target Cancer Risk=1E-6, Target Hazard Index=0.1)
      - Screening detection limits of nondetected contaminants against screening levels
      - Elimination of contaminants may also be conducted based on data quality issues (such as blank contamination), contaminants being essential nutrients, or frequency of detection.
      - Contaminants should not be eliminated based on background. Site-related chemicals must be included in the HHRA and contribution of background should be addressed appropriately as per EPA's background guidance.

DHSS HHRA Recommendations

Exposure Assessment

- Typical receptors include:
  - Residential
  - Commercial/Industrial Workers
  - Construction Workers
- Other receptors should be evaluated depending on site-specific circumstances.
- All applicable exposure routes should be appropriately evaluated.
- Current EPA equations/models and current default exposure values should be used.
- Exposure point concentrations should be 95% Upper Confidence Limits (UCLs).
- Site-specific conditions may warrant deviation with respect to receptors and exposure assumptions; however, deviations should be adequately justified.

DHSS HHRA Recommendations

Toxicity Assessment

- EPA's toxicity value hierarchy should be appropriately used:
  - Tier 1 – EPA Integrated Risk Information System (IRIS)
  - Tier 2 – EPA Provisional Peer-Reviewed Toxicity Values (PPRTV)
  - Tier 3 – Other sources, such as the Agency for Toxic Substances and Disease Registry (ATSDR), California Environmental Protection Agency (CalEPA), Health Effects Assessment Summary Tables (HEAST)
    - In selecting Tier 3 sources, the following criteria should be used: the source provides toxicity information based on similar methods and procedures as those used by EPA, the values are peer-reviewed, are available to the public, and there is transparency about the methodology used to develop the values.

DHSS HHRA Recommendations

Risk Characterization

- Cumulative risks should be accounted for and presentation of results should include:
  - Risk for each chemical
  - Risk for each route of exposure
  - Risk for each medium
  - Total receptor risk
- Segregation of non-cancer hazards by target organ may be conducted when appropriate.
- Risks should be evaluated and presented in relation to EPA's target risk range (Target Cancer Risk Range of 1E-6 to 1E-4, Target Hazard Index of 1)

DHSS HHRA Recommendations

Risk Characterization

- The risk characterization should identify chemicals and pathways that contribute most significantly to risks (risk drivers).
- An unbiased uncertainty evaluation should be presented to provide an understanding of the uncertainties and bias inherent in the evaluation.
- Overall, the risk characterization should clearly communicate key findings, assumptions, strengths, weaknesses, and uncertainties in order to provide a sound scientific basis for selection of risk management options.

QUESTIONS

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