Human and Ecological Risk Office (HERO) – Roles and Responsibilities
Site Mitigation and Restoration Program
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Contents

Introduction

The Human and Ecological Risk Office (HERO) supports many programs in DTSC in several areas, including, but not limited to:

- Technical review of human health and ecological risk assessments and of documents that provide the basis for the risk assessments for the Site Mitigation and Restoration Program
- Technical review of human health and ecological risk assessments and of documents that provide the basis for the risk assessments for the Hazardous Waste Management Program,
- Technical review and scientific support for the cases under development by the Enforcement Branch, and
- Toxicological and exposure assessment expertise in development of Chemical/Product Profiles and Alternatives Assessment for the Safer Consumer Products Program.

HERO's Role

HERO's role, within the Site Mitigation and Restoration Program, is to inform the Project Managers on the potential risks and hazards associated with exposure to contaminants at sites under DTSC's oversight. To offer the full range of technical support HERO should be contacted for consultation on:

- The scoping of the project;
- The review and evaluation the site characterization workplans to inform the Project Manager if the sampling planned is likely to be adequate for risk assessment purposes;

- Review and evaluate the site characterization and inform the Project Manager whether it is sufficient for risk assessment purposes (including use of suitable analytical methods and detection/reporting limits);
- Review and evaluate adequacy of the conceptual site model for risk assessment purposes;
- Evaluate if the appropriate exposure parameters are used and inform the Project Manager;
- Verify that the correct toxicity criteria are used in the risk assessment;
- Confirm that the risk/hazard calculations are appropriate and accurate;
- Confirm that any statistical analyses and exposure modeling associated with the risk assessment(s) are performed correctly using appropriate methodologies and assumptions;
- Verify that the conclusions drawn in the risk characterization are adequately supported;
- Review and evaluate remedial investigations and the associated workplan to inform the Project Manager whether the remedy of choice is likely to be protective (i.e., meet one of the two threshold criteria);
- Review and evaluate institutional and engineering controls to inform the Project Manager whether they will be protective;
- Review and evaluate post-remedial risk assessments to inform the Project Manager on whether the remedy of choice is meeting the threshold criteria of protectiveness; and,
- Participate in the 5-year review process.

These roles and responsibilities of the HERO Toxicologists are generally to evaluate and inform the DTSC Project Manager, through the life cycle of the Project, starting from scoping, through site characterization, continuing development of the Conceptual Site Model (CSM), establishment of remedial action objectives, development/screening of alternatives (Feasibility Study), evaluation of the protectiveness of selected remedy, and evaluation of the protectiveness of institutional or/and engineering controls, and evaluation of protectiveness over time (5-year reviews). The HERO project Toxicologist is responsible for determining whether:

I. The Human Health Risk Assessment (HHRA) and/or the Ecological Risk Assessment (ERA) process is properly formulated, supported by adequate empirical and scientific evidence, performed correctly, and the textual summary of the risk and/or hazard accurately reflects the risk assessment calculations; and,

II. The certainty/uncertainty of any portion of the HHRA and/or ERA (HHRA/ERA) which may have significant influence on, the risk management decisions is accurately conveyed to the DTSC Risk Manager.

I. HERO Core Review Comments – Recommendations on Human Health Risk Assessment Calculations and Presentation

A Human Health Risk Assessment (HHRA) is "the process 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" (https://www.epa.gov/risk/human-health-risk-assessment). The HHRA falls under the evaluation step of the voluntary agreement process, and involves using environmental data and scientific knowledge to estimate the nature, magnitude and probability of adverse health effects to people who may be exposed to the contaminated environmental media, now and in the future. Voluntary agreement projects utilize the HHRA as a tool to make decisions about the use or reuse of the property, and to facilitate an effective assessment and cleanup strategy to ensure safe end-use. DTSC's Human and Ecological Risk Office should be involved in the scoping meeting for new voluntary agreements as well as other Cleanup projects (e.g., orphan sites) to provide feedback and guidance on the HHRA process.

After the site is adequately characterized in terms of the chemicals released, there are four steps to the HHRA process:

Hazard Identification: Data collected at the site are used to determine what chemicals are present at the site, and whether they can cause harmful effects (cancer and non-cancer) to people who may come in contact with the contaminated media.

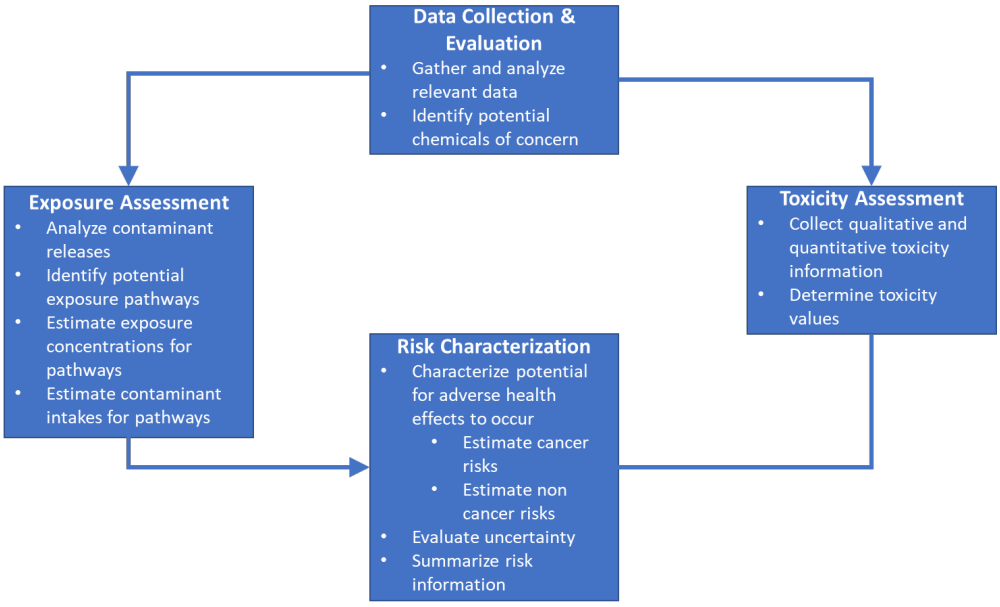
Exposure Assessment: This step is used to identify the current and potential future populations who may come in contact with the contaminants, the various media (for example, soils, soil gas, groundwater, surface water) that may have been affected by the contamination (evaluate fate and transport pathways), pathways of exposures for potentially exposed populations (ingestion, dermal, inhalation), and estimated contaminant concentrations that may be taken up via the various pathways of exposure (intake rates).

Toxicity Assessment: This step is used to incorporate the toxicity information about the chemicals. This information is typically available via USEPA and/or California EPA websites, including in Human Health Risk Assessment Note 3 on DTSC's Human Health Risk Assessment (HHRA) Page. On rare occasions, HERO may have to develop toxicity values for chemicals where such information is unavailable through the USEPA, CalEPA or other authoritative bodies.

Risk Characterization: This step combines information from the previous steps, to evaluate cumulative cancer risks and non-cancer hazards to potentially exposed human populations. This information is used to determine whether the site is safe for the intended use or whether contaminants are present at levels that may pose unacceptable risks/hazards to people and/or the environment, and therefore, may require some form of risk management. Therefore, risk management decisions are

developed based on the results of cumulative cancer risk and non-cancer hazard estimates for a site. An Uncertainty Analysis is included as part of the risk assessment process to discuss the sources and degrees of uncertainty associated with the data collected at the site, exposure assumption and toxicity information that are used to estimate cancer risks and non-cancer hazards to populations at the site, as well as assumptions and input variables associated with models that were employed in the assessments. This information should also be used by the risk managers and incorporated into the risk management decisions for the site, such as the need for remediation and/or operation and maintenance (O&M).

A generalized diagrammatic presentation of these HHRA components as presented in US EPA HHRA guidance (Source: Risk Assessment Guidance for Superfund (RAGS) Part A):



The Human Health Risk Assessment Page on DTSC's HERO website provides documents specific to the details on HERO review including documents outlining site characterization, HHRA guidance and recommendation documents, including:

1. DTSC's Preliminary Endangerment Assessment Guidance Manual for Human Health Screening Evaluation, as well as DTSC's perspective on data collection, analysis and reporting.
2. DTSC HHRA Note 1: Recommended DTSC Default Exposure Factors for Use in Risk Assessment at California Hazardous Waste Sites and Permitted Facilities.
3. DTSC HHRA Note 2: Soil Remedial Goals for Dioxins and Dioxin-like Compounds for Consideration at California Hazardous Waste Sites.

4. DTSC HHRA Note 3: DTSC-modified Screening Levels (DTSC-SLs).
5. DTSC HHRA Note 4: Screening Level Human Health Risk Assessments.
6. DTSC HHRA Note 5: Health-based Indoor Air Screening Criteria for Trichloroethylene (TCE).
7. DTSC HHRA Note 6: Recommended Methodology for Evaluating Site-Specific Arsenic Bioavailability in California Soils.
8. DTSC HHRA Note 8: Recommendations for Evaluating Polychlorinated Biphenyls (PCBs) at Contaminated Sites in California and DTSC's Polychlorinated Biphenyl (PCB) Evaluation Quick Reference Guide.
9. DTSC HHRA Note 10: California Toxicity Criteria Regulation specified toxicity criteria hierarchy for toxicity values required or recommended for human health risk assessments, risk-based screening values and remediation goals.

An analogous section of the HERO website on the Ecological Risk Assessment (ERA) page provides ERA guidance and recommendation documents, including:

1. Part A: Overview: Guidance for Ecological Risk Assessments at Hazardous Waste Sites and Permitted Facilities, Part A: Overview, dated July 4, 1996. This document contains the description of the DTSC-recommended phased method for conducting an ecological risk assessment.
2. Part B: Scoping Assessment: Guidance for Ecological Risk Assessments at Hazardous Waste Sites and Permitted Facilities, Part B: Scoping Assessment, dated July 4, 1996. This document contains the more detailed description of the contents of the initial Scoping Assessment with example tables, exposure route diagrams and conceptual site model diagrams.
3. EcoNOTE1: Depth of burrows for burrowing mammals. Default exposure depths for burrowing mammals in ERAs differ from the HERD default exposure depth for HHRA of 10 feet.
4. EcoNOTE2: Calculation of intake for vertebrate receptors in a Phase I Predictive Assessment.
5. EcoNOTE3: Calculation of an action level/preliminary cleanup goal for dibutyltin (DBT) in surface, ground, and sediment interstitial water for protection of saltwater aquatic life.
6. EcoNOTE4: Use of Navy/Biological Technical Assistance Group (BTAG) Toxicity Reference Values (TRVs) in ecological risk assessment.
7. EcoNOTE5: Revised U.S. Environmental Protection Agency (USEPA) Region 9 BTAG Mammalian TRV for Lead: Justification and Rationale.
8. EcoNOTE6 - Cadmium: A revision to the cadmium TRV for birds used by regulatory agencies and resource trustees in California for predictive ecological risk assessments.
9. Currently Recommended U.S. Environmental Protection Agency Region 9 Biological Technical Assistance Group (BTAG) Mammalian and Avian Toxicity Reference Values (TRVs), 2/24/09.
10. Individual Body Weight Files: Individual Body Weight Files are currently available for avian receptors for use in Phase 1 Predictive Assessments.

11. USFWS Clutch Size: The rationale for considering reduction in clutch size as a significant measurement endpoint for ecological risk assessments.
12. ECO Checklist: List of critical components of a site-related ecological evaluation.

II. HERO Potential Review Comments - Areas of Uncertainty Affecting HHRA Characterization

The development of the HHRA requires general evaluation of the sufficiency of site characterization data and selection of site-specific components which are critical to application of the HHRA and/or ERA estimations of risk and/or hazard to remedial decisions for site.

HERO comments on the relative certainty/uncertainty of the risk assessment should normally focus on issues such as:

1. Site characterization issues related to how well characterized the concentration of the media sampled appears to be. For example, does it appear that the site/facility 95% Upper Confidence Limit on the mean might be not be a reasonable upper bound site concentration based on whether:
    a. The analytical methods are appropriate and reporting limits satisfactory to perform a HHRA/ERA;
    b. The area of the site-characterization sampling is large and not representative of the future land use (e.g., the 95% UCL over a 40-acre site does not accurately represent a reasonable EPC for a future residential exposure scenario);
    c. The statistical variance of the sampling results is too large to draw meaningful conclusions;
    d. Elevated sample contaminant concentrations are part of a small data set;
    e. Results of formal Quality Assurance/Quality Control (QA/QC) assessment are satisfactory;
    f. Potential 'outliers' (e.g., samples with unreasonably elevated concentrations) are eliminated from the dataset without full presentation of the process and rationale;
    g. The concentrations of the media sampled appear to include a 'hot spot' or 'hot spots' of multiple samples with unreasonably elevated concentrations;
    h. Uneven spatial distribution of contaminants (not necessarily "hot spots");
    i. Exposure unit inconsistent with Conceptual Site Model;
    j. The concentration of the media sampled appears to increase approaching the site boundary or appears to increase dramatically with depth in the lowest depths sampled;
    k. Detected elements and/or organic compounds appear to reflect the stated past history of activities on the site;

   l. The upper threshold values (UTVs) or Background Threshold Values (BTVs) are adequately developed and justified, especially if they will be used as a part of COPC/COPEC selection process. COPC/COPECs are accurately identified and listed in the text, with clear description and rationale of any COPC/COPEC selection process.

2. Exposure scenarios accurately reflect the potential future use(s) of the site or facility and potential transport pathways. Potential exposure scenarios serve to protect off-site receptors, who may be down-gradient and potentially exposed to impacted media from the site or facility (e.g., stormwater sediments, groundwater plumes, transported dusts or unbounded soil gas plumes).
3. Exposure parameters are current and accurately incorporated into the calculation of exposure.
4. Fate and Transport calculations, where considered, are appropriate and accurately incorporated into characterization of exposure.
5. Toxicity value uncertainty factor and adverse effects are discussed, where appropriate, with other sources of uncertainty.
6. Estimates of cancer risk and/or non-cancer hazard are accurately calculated and presented in summary tables.
7. Description of site/facility cancer risk and/or non-cancer hazard in the text accurately reflect the actual mathematical calculations.
   a. Mathematical risk assessment calculations are often presented in Appendices. Elevated risk and/or hazard levels in these Appendices must be accurately presented in the text of the HHRA/ERA.
8. COPCs or COPECs which make the greatest contribution to the cancer risk (i.e., 'risk drivers') and non-cancer hazard are correctly identified.
   a. The greatest contributors to the risk and/or hazard frequently are the most significant contaminants for evaluation of remedial alternatives.
9. Uncertainty Section, where presented, accurately reflects the influence of uncertainty on the exposure and cancer risk and/or non-cancer hazard estimates (e.g., overestimate, neutral, underestimate).

Focus of HERO Comments

The general goal of HERO review comments should be to produce a risk assessment which is:

- Protective of Human Health & the Environment;
- Scientifically Accurate; and,
- Legally Defensible

HERO comments to the Project Manager on these issues should be directed at addressing data gaps or shortcomings in the HHRA/ERA with recommendations to:

- Reduce the uncertainty in the HHRA/ERA;

- Make the results of the HHRA/ERA useful in providing more realistic protection of human health and the environmental protection for current receptors and potential future exposures; and,
- Be of greater utility in making risk management decisions for the site/facility being evaluated.

Disagreement Resolution Process

HERO billing of hours to specific EnviroStor requests and non-EnviroStor requests such as SPWP support is managed by direction to HERO Staff, such that:

a) HERO scientific staff will assess the size/complexity of the document to be reviewed or the length of the task associated with each EnviroStor Work Request and reach an agreement with the Project Manager or requestor regarding the number of hours allocated to complete the request at the expected level of quality;
b) HERO scientific staff will strive to work within the agreed-upon time allocated in the EnviroStor work requests;
c) In the event it becomes obvious that the complexity of the assigned review or task is more complex than expected, it is incumbent upon the HERO scientific staff assigned to the Work Request to contact the Project Manager or requestor immediately and discuss the need for additional hours.
    i. An unexpected increase in the level of review effort or an inability of the requestor to increase the hours available for review may require a reduction in the overall level of the review. For example, a critical flaw analysis rather than a complete risk assessment review;
d) The DTSC Project Manager responsible for the project can elevate the discussion of time needed for review by having their Unit Supervisor contact the Senior Toxicologist for the unit of the assigned HERO scientific staff; and,
e) In the event an agreement cannot be reached, or the Unit Supervisors fail to find a solution, the Branch Chief of the requestor's unit should contact the HERO Supervising Toxicologist to discuss the number of allotted hours and the type of support that can be provided within the limits of the allocated hours.

An analogous sequential process should be followed to resolve any disagreement regarding HERO technical comments contained in the review memorandum.

Dispute Resolution – Stepwise Process

HERO employs a stepped Dispute Resolution process with the work requestor:

1. In the event of any disagreement between the Requestor/PM and the toxicologist/risk assessor regarding the toxicologist/risk assessor comments, work products, or tasks included in the draft work product, the Requestor/PM and toxicologist/risk assessor should attempt to resolve the disagreement by themselves.
2. If a resolution cannot be reached between the Requestor/PM and the toxicologist/risk assessor within five workdays, the issue should be referred to their immediate Supervisors for resolution.
3. If the Supervisors cannot resolve the matter within five workdays, they will refer the matter to their respective Branch Chiefs.
4. If the Branch Chiefs cannot resolve the matter within five workdays, they will refer the matter to their respective Division Chiefs.
5. If the Division Chief cannot resolve the matter, the Deputy Director of the Cleanup & Site Mitigation Program will make the final decision.

The Program's decision will be documented in a memorandum or email to the appropriate parties and recorded in the administrative record.