

HUMAN HEALTH RISK ASSESSMENT (HHRA) NOTE NUMBER 4



**CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC),
HUMAN AND ECOLOGICAL RISK OFFICE (HERO)**

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ISSUE: Guidance for Screening Level Human Health Risk Assessments.

SUMMARY

In a memorandum dated October 28, 1994, HERO recommended guidelines for use of the U.S. EPA Region 9 Preliminary Remediation Goals (PRGs) at military sites (DTSC 1994). In 2008, the U.S. EPA released Regional Screening Levels (RSLs) to replace the PRGs formerly available from several U.S. EPA Regional offices (U.S. EPA 2015). HERO subsequently developed HHRA Note 3 to provide the recommended methodology for use of U.S. EPA RSLs in the HHRA process at DTSC hazardous waste sites and permitted facilities. The latest iteration of HHRA Note 3 was released in April of 2019 (DTSC 2019b). In February 2019, HERO released HHRA Note 10 which addresses the application of *the Toxicity Criteria for Human Health Risk Assessments, Screening Levels, and Remediation Goals* rule (hereafter “Toxicity Criteria Rule”)¹. This updated HHRA Note 4 outlines the current recommended methodology for conducting screening level human health risk assessments, and is an update which replaces our 1994 memorandum and the earlier versions of Note 4.

Historically, U.S. EPA PRGs and RSLs have been used mostly at military facilities. However, the recommendations included in this Note are intended for use at any DTSC site where DTSC has approved the use of U.S. EPA RSLs in a screening risk assessment. Please contact the HERO Section Chiefs² regarding human health risk assessment at properties and facilities other than military facilities (e.g., civilian facilities, schools).

¹ <https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/02/HHRA-Note-10-2019-02-25.pdf>

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WHAT'S NEW

This HHRA Note supersedes HERO's October 26, 2016 version of HHRA Note 4. This revision incorporates HERO recommendations based on the adoption of the Toxicity Criteria Rule and recommendations for sites with vapor intrusion into indoor air.

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I. BACKGROUND

Beginning in the early 1990s, California developed a process for conducting screening level human health risk assessments (HHRAs) at Federal Facilities (open and closed military facilities). Since baseline risk assessments require a more intensive use of resources, time and cost, screening level risk assessments can facilitate the determination of “no further action” (i.e., unrestricted land use) or further evaluation. If the cumulative risk and hazard index estimates are acceptable under the most conservative screening assumptions, then site-specific conditions can be expected to result in acceptable risk and hazard index levels. Consequently, the results of a screening risk assessment indicate whether or not a quantitative baseline risk assessment or further site investigation is warranted.

In a memorandum dated October 28, 1994, HERO recommended guidelines for use of the U.S. Environmental Protection Agency (U.S. EPA) Region 9 Preliminary Remediation Goals (PRGs) at military sites (DTSC 1994). The screening level HHRA process at Federal Facility sites in California historically used the U.S. EPA Region 9 PRGs (U.S. EPA 2004) supplemented with Cal-modified PRGs that were based on California-derived toxicity criteria from Office of Environmental Health Hazard Assessment (OEHHA). In 2008, the U.S. EPA released Regional Screening Levels (RSLs) to replace the PRGs that were formerly available from several U.S. EPA Regional offices (U.S. EPA 2015). This, as well as other updates in the area of risk assessment methodology, necessitated an update to our 1994 recommendations. Subsequently, HHRA Note 4 was developed as a replacement to our 1994 memo. This document is an update to our HHRA Note 4 dated October 26, 2016.

HHRA Note 4 is intended to be used in conjunction with HERO’s HHRA Note 3 (DTSC 2019b). HHRA Note 3 addresses DTSC’s recommended methodology for use of the soil, tap water, and ambient air U.S. EPA RSLs and DTSC-modified screening levels in the risk assessment process and should be used in conjunction with Note 4. The present revision of HHRA Note 3 incorporates HERO’s recommendations based on review of the November 2018 release of the U.S. EPA RSL tables for soil, tap water, and ambient air and is compliant with the DTSC Toxicity Criteria Rule sections (§) 69021(a), (b), and (c). Both HHRA Note 3 and Note 4 will be updated periodically and the DTSC website should be checked to ensure use of the most recent versions.

As discussed in HHRA Note 3, for many of the approximately 800 constituents with U.S. EPA RSLs, HERO recommends use of the soil, tap water, and ambient air values listed in the November 2018 U.S. EPA RSL tables. However, many values listed in the U.S. EPA RSL tables differ from values calculated using the required Cal/EPA toxicity criteria and risk assessment procedures. In HHRA Note 3, HERO has prepared reference tables for soil, tap water, and ambient air which indicate contaminants for which the DTSC-modified screening level (DTSC-SL) should be used. In addition, specific recommendations and discussion are provided for several contaminants. Alternatively and in consultation with HERO, the U.S. EPA RSL On-line Screening Calculator can be used to calculate site-specific values using the toxicity criteria listed in HHRA Note 10 and applying assumptions consistent with HERO’s exposure parameters and other

recommendations (e.g., route-to-route extrapolation between oral and inhalation exposure where no inhalation toxicity value is available but an oral toxicity value is available).

Prior to implementing the use of U.S. EPA RSLs in screening level risk assessments, the U.S. EPA RSL User's Guide and Frequently Asked Questions should be consulted to ensure familiarity with how the numbers were derived and the limitations on their use (U.S. EPA November 2018). This HHRA Note reiterates many of the points discussed in the U.S. EPA RSL User's Guide.

Limitations associated with the use of U.S. EPA RSLs and DTSC-SLs for screening level HHRAs must be carefully noted and understood prior to making risk management decisions. As discussed in more detail below, it is critical that a site-specific conceptual site model (CSM) or site exposure model be developed prior to conducting a screening level risk assessment. This will ensure that the assumptions used to derive the U.S. EPA RSLs and DTSC-SLs are applicable and inclusive of all potentially complete exposure pathways and receptors at a site. For example, the derivation of the U.S. EPA RSLs and DTSC-SLs for soil and tap water do not include an evaluation of the intrusion of vapors from the subsurface to indoor air. Vapor intrusion to indoor air from volatile chemicals in soil or groundwater has become recognized as a potentially major exposure pathway.

Finally, this HHRA Note addresses HERO's recommendation that screening level risk evaluations for hazardous waste sites and permitted facilities include the calculation of both the site-related risk and hazard index, and the total risk and hazard index on a site-specific basis. The latter presents the risk and hazard associated with exposure to all detected chemicals prior to elimination of inorganic chemicals that are determined to be consistent with site-specific background or ambient concentrations. This information may be helpful for making risk management decisions about appropriate land uses and for public transparency.

II. SCREENING LEVEL HUMAN HEALTH RISK ASSESSMENTS

A. LAND USE AND HUMAN RECEPTORS

A screening level human health risk assessment provides a general indication of whether there is potential risk to human health and helps identify areas of concern at a site where a release of hazardous chemicals has occurred. It normally uses established risk-based screening levels such as U.S. EPA RSLs and DTSC-SLs to estimate the cancer risks and noncancer hazards, and is intended to be a health-protective preliminary evaluation of potential risk and hazard (DTSC 2015). If a site fails the screening level risk assessment, e.g., cancer risks are greater than 1×10^{-6} and/or noncancer hazards are greater than 1, then further investigation and/or a more site-specific baseline risk assessment may be necessary to evaluate the potential risk to all receptors.

In general, HERO recommends that a residential scenario be assumed for site screening at all facilities, both active and closing/closed. HERO assumes that reuse of hazardous waste sites could result in a change of ownership and land use, including potential residential reuse of the property. For active facilities, HERO considers the residential scenario evaluation a health-conservative approach. However, the residential scenario would not necessarily be protective of unrestricted land use for those chemicals that bioaccumulate in food products (e.g., dioxins which are addressed in HHRA Note 2 [DTSC 2017]) or for those chemicals exceeding risk-based concentrations left in place at depths greater than 10 feet bgs. Please speak with the DTSC Project Manager and HERO toxicologist if the later situation occurs at your site.

If a residential scenario is not implemented in the screening evaluation, documentation should be provided that unrestricted land use will not occur in the future and DTSC approval should be obtained prior to conducting the risk assessment. For open Military Facilities, the Base Master Plan should indicate that unrestricted land use evaluation is required if future land use changes. For closed Bases or civilian facilities other than Department of Defense (DoD) facilities, a land use control (LUC) may be needed to restrict future residential use of the property if a risk assessment has not been conducted for a residential scenario.

Screening-level human health risk assessments may also include an evaluation of the industrial scenario using industrial U.S. EPA RSLs and DTSC-SLs. Evaluation of the industrial scenario provides additional information that may be used to evaluate receptors under current industrial use scenarios and to support risk management decisions. Although sites with acceptable risk under the residential land use scenario will likely have acceptable risk under other scenarios such as industrial land use, the inverse is not necessarily true. Sites with acceptable risk under the industrial land use could pose unacceptable risk under the residential land use scenario.

Construction scenarios cannot be evaluated in the screening level process because of the lack of applicable screening levels. Historically, it has been generally assumed that an evaluation of the residential land use scenario should be protective of construction worker receptors unless specific exposure pathways unique to construction workers exist (e.g., dermal contact with and inhalation of vapors from water in a trench). If such pathways are anticipated at a site, it would be necessary to proceed with a baseline site-specific human health risk evaluation to address potential risk to construction workers. In such cases, HERO recommends upfront discussion and agreement between DTSC and the responsible party regarding which of the following risk assessment approaches will be used: 1) screening level risk assessment for residential and industrial receptors, and a baseline risk assessment for construction workers; or, 2) a baseline risk assessment for all receptors. Please note that because of greater soil exposure to construction workers, an industrial use scenario is not necessarily protective of construction workers. Similarly, screening levels for trespasser and recreational use are also not available. Site specific variability in these exposure

scenarios makes development of screening levels impractical. A baseline risk assessment should be performed for these scenarios if they are relevant for the site.

B. ECOLOGICAL RISK ASSESSMENT

This HHRA Note does not address ecological risk assessment. It is important to understand that ecological receptors were not considered in the calculation of the screening levels. That is, the U.S. EPA RSLs and DTSC-SLs apply to human receptors only and are not necessarily protective of ecological receptors. A separate ecological risk evaluation must be conducted if significant ecological habitat is present onsite or there is potential transport of contaminants to offsite habitat. A screening risk assessment for human receptors is never adequate to address the need for ecological risk assessment. Responsible parties should refer to DTSC's Ecological Guidance and EcoNOTEs for more information on appropriate procedures (Section 2.6 of DTSC 2015, DTSC 1996, and DTSC EcoNOTEs³). Prior to conducting an ecological risk assessment, the HERO toxicologist should be contacted.

C. EXPOSURE PATHWAYS CONSIDERED IN THE CALCULATION OF THE RESIDENTIAL AND INDUSTRIAL SOIL, TAP WATER AND AMBIENT AIR SCREENING LEVELS

Before conducting a screening level human health risk assessment, a site-specific CSM is required to ensure all appropriate receptors and exposure pathways are addressed by the U.S. EPA RSLs and DTSC-SLs.

The residential and industrial soil screening levels consider several exposure routes: ingestion, inhalation of particles and volatile chemicals in ambient air, and dermal absorption.

The tap water screening levels are based on assumed residential exposure to water via ingestion from drinking, inhalation of volatile chemicals released during household use (e.g., showering, dish washing), and dermal exposure to tap water during showering/bathing.

The air screening levels address ambient air exposure scenarios and are based on assumed indoor air exposure of a 24-hour time period for a resident and an 8-hour time period for an industrial worker.

Although the soil, tap water, and ambient air screening levels account for many typical exposure pathways they do not account for the following additional potential exposure pathways (discussed with respect to PRGs/RSLs in U.S. EPA 2018, as applicable):

³ <https://dtsc.ca.gov/ecological-risk-assessment-hero/>

- i. The residential and industrial soil U.S. EPA RSLs do not account for exposure to indoor air vapors from intrusion of soil gas; ingestion of plants (home-grown fruits and vegetables), meat, or dairy products; or inhalation of particles (fugitive dust) generated by activities which elevate particulate emissions such as truck traffic and use of heavy equipment.
- ii. Pathways in the calculation of the tap water U.S. EPA RSLs or DTSC-SLs do not include subsurface vapor intrusion to indoor air from volatile organic compounds (VOCs) present in groundwater, ingestion of water during swimming, and transfer of contaminants in the water column to aquatic organisms or terrestrial plants with subsequent ingestion by humans. The U.S. EPA RSL On-line Calculator and User's Guide do however include equations which can be used to calculate screening level fish concentrations assuming human consumption of fish. These equations do not address impacts to fish; but rather, human consumption of fish which may be contaminated. The U.S. EPA RSL On-line Calculator and User's Guide also includes equations which can be used to calculate soil and surface water screening levels for recreational receptors.
- iii. The residential and industrial ambient air U.S. EPA RSLs or DTSC SLs cannot be used directly as screening levels for soil gas. The air screening levels may be used for screening VOCs in soil gas data when used in concert with an appropriate attenuation factor as described in DTSC's 2011 Guidance for the Evaluation and Mitigation of Subsurface Vapor Intrusion to Indoor Air (VIG) (DTSC 2011a). DTSC recommended default attenuation factors for preliminary screening evaluations can be found in Table 2 of DTSC's 2011 VIG. DTSC also recommends that screening assessments evaluate the default attenuation factor of 0.03 for sub-slab soil gas and "near-source" exterior soil gas, released in 2015 by U.S. EPA. For detailed recommendations on the vapor intrusion to indoor air pathway and evaluation of soil gas and indoor air data, please consult DTSC's 2011 VIG, or contact the DTSC site toxicologist to ensure appropriate use of air screening levels on a site-specific basis.
- iv. At this time, HERO does not recommend the use of the Johnson and Ettinger (J&E) soil gas and groundwater models for risk assessment of vapor intrusion into indoor air.

If pathways not considered in the derivation of the soil, tap water, and ambient air screening levels are anticipated at the site, a screening level risk evaluation may underestimate risk. In addition, if there are exposure scenarios other than residential and industrial land uses, a screening level risk evaluation using U.S. EPA RSLs and DTSC-SLs may not be appropriate (e.g., sites in which trench workers may be exposed to shallow groundwater). In such cases, the evaluation of risk to human receptors at the site should proceed with the baseline human health risk assessment process, at least for those receptors for which a screening level risk assessment is not appropriate. For reference, HERO has compiled a summary of recommended exposure factors which may be used as default values in baseline human health risk assessments at California hazardous waste sites and permitted facilities (DTSC 2019a). In other instances, the

screening risk assessment may overestimate risk. In these cases, preparation of a baseline human health risk assessment is an option.

Additional Considerations Regarding the Use of Industrial Screening Levels

The tap water screening levels are calculated using residential land use assumptions. As such, these screening levels are not reflective of industrial exposures and may overestimate exposures from water exposure pathways.

Screening level evaluations using the industrial soil screening levels do not account for the following pathways: all uses of groundwater; exposure via vapor intrusion to indoor air; exposure to contaminated surface and groundwater, and inhalation of particulates released from wind, truck traffic and use of heavy equipment. If these exposure pathways are significant at a site, screening risk assessment using U.S. EPA RSLs and DTSC-SLs is not appropriate.

D. EVALUATION OF THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

As noted above, the U.S. EPA RSLs and DTSC-SLs do not account for risk and hazard from the vapor intrusion to indoor air pathway. When significant concentrations of VOCs are present, the vapor intrusion pathway often generates the highest cancer risk and hazard index. Therefore, when vapor intrusion is a potentially complete exposure pathway, it is essential that it be included in the screening risk assessment.

Please consult DTSC's vapor intrusion to indoor air guidance for a more detailed discussion of this topic (DTSC 2011a). DTSC guidance recommends that multiple lines of evidence, such as soil gas, indoor air, and groundwater data be used for preliminary screening evaluations of vapor intrusion. Soil gas data provide a direct measurement of the VOCs that may migrate to indoor air. If soil gas data are not available for a given site, a soil gas investigation should be conducted. For sites where groundwater is contaminated with VOCs, DTSC recommends that vapor intrusion to indoor air be evaluated using both soil gas and groundwater data. This recommendation is particularly applicable for sites where groundwater is shallow and there is a large capillary fringe. Technical difficulties in sample collection and preservation of VOCs in soil matrix, as well as uncertainties associated with the use of partitioning equations make soil matrix data less than ideal for estimating vapor intrusion. However, in some cases, there may be no alternative and this should be discussed with the project team prior to conducting the vapor intrusion evaluation. Additionally, please consult your site toxicologist regarding any questions about the use of groundwater data for modeling potential vapor intrusion to indoor air. As discussed above, HERO no longer recommends using the DTSC-Modified soil gas and groundwater J&E models to predict theoretical indoor air concentrations from soil gas and groundwater data and the models have been removed from HERO's website. The J&E models have not been updated and are not based on the most current J&E model spreadsheet tool from U.S. EPA.

Another option for evaluation of this pathway is indoor air monitoring, subslab or crawl space sampling. HERO should be contacted before undertaking any form of vapor intrusion sampling.

Risk and hazard from this exposure pathway must be summed with risk and hazard from other pathways to estimate the total site risk and hazard index (See Section III-D entitled “Additivity of Risk and Hazard”).

E. EVALUATION OF IMPACTS TO SURFACE WATER AND GROUNDWATER

The derivation of residential and industrial soil screening levels does not consider the potential for contaminants to migrate to groundwater or surface water. The U.S. EPA RSL Tables do however list risk-based and maximum contaminant level (MCL)-based screening levels for soil (SSLs), which identify chemical concentrations in soil that may impact the groundwater. The DTSC geologist, Project Manager and the California Regional Water Quality Control Board (RWQCB) should be contacted regarding the protection of groundwater and surface water.

If it is determined that groundwater has been impacted, exposure to groundwater must be quantitatively evaluated in the screening level risk evaluation unless no VOCs are present in the groundwater and a written statement is available from the RWQCB indicating that groundwater from the site has no beneficial uses. If VOCs are present in groundwater, vapor intrusion to indoor air must be evaluated, regardless of beneficial use designations.

Contaminated surface water must also be evaluated in screening risk assessments. If tap water screening levels are used to screen surface water, limitations and uncertainties associated with the derivation of tap water screening levels relative to anticipated surface water exposure scenarios such as ingestion of water during swimming must be addressed. Alternatively, the U.S. EPA RSL On-line Calculator and User’s Guide includes equations which can be used (in conjunction with the required and recommended California exposure and toxicity factors) to calculate surface water screening levels for recreational receptors.

In most cases, HERO recommends that unfiltered water be used in the risk evaluation given that unfiltered water may be of potable quality at some sites (U.S. EPA 1989). If only grab sample groundwater data are available at a site, they can be used for assessing risk. However, because grab groundwater samples may be associated with high levels of particulate matter, the risk assessment should discuss the potential for additional uncertainty in the risk estimates due to the use of grab sample groundwater data.

Finally, as discussed previously in Section II-B entitled “Ecological Risk Assessment”, the tap water screening levels only address human health. It cannot be assumed that these screening levels are protective of aquatic organisms and wildlife.

F. AIR MODELS USED IN THE CALCULATION OF THE SOIL SCREENING LEVELS

The following points related to the air modeling used in the calculation of the screening levels must be considered during the screening level risk evaluation at sites:

The soil screening levels do not consider the potential for enhanced volatilization of compounds which can occur in the presence of landfill gases such as methane. In addition, the soil screening levels consider exposure to VOCs in outdoor (ambient) air, but not the subsurface vapor intrusion to indoor air pathway. Volatilization from shallow groundwater may be an additional source to ambient air.

Various assumptions were utilized in the air modeling. For example, 0.5 acres was used as the default source area. HERO recommends an evaluation of whether the default assumptions are reasonable for a specific site. If the default assumptions are significantly less health-protective or not representative of the actual conditions at the site, use of the screening levels is not appropriate and a site-specific evaluation is needed.

Some soil screening values (annotated with an “s” in the U.S. EPA RSL tables) and DTSC-SLs (bold values in Note 3’s Table 1) are marked to indicate that the screening level exceeds the soil saturation concentration (C_{sat}) for that chemical. The U.S. EPA RSL User’s Guide defines C_{sat} as the contaminant concentration in soil at which the absorptive limits of the soil particles, the solubility limits of the soil pore water, and saturation of soil pore air have been reached. At levels exceeding the C_{sat} concentration, the soil contaminant may be present in free phase (i.e., nonaqueous phase liquids [NAPLs] for contaminants that are liquid at ambient soil temperatures and pure solid phases for compounds that are solid at ambient soil temperatures). This is important because the volatilization model used to calculate the screening levels is not applicable when free-phase contaminants are present. Cases in which the C_{sat} is exceeded need to be addressed in the risk assessment. These should be discussed with the DTSC toxicologist prior to performing a risk assessment.

G. LISTING OF STRICTLY RISK-BASED SCREENING LEVELS IN SCREENING-LEVEL TABLES

The soil screening levels are risk-based. They do not consider physical limitations such as soil saturation, and some U.S. EPA RSLs exceed the “ceiling limit” concentration of 1×10^5 mg/kg. Soil U.S. EPA RSLs that exceed C_{sat} are denoted as “s” and DTSC-SLs are in bold text. Soil U.S. EPA RSLs exceeding 1×10^5 mg/kg are denoted as “m” and DTSC-SLs are italicized, meaning that the chemical represents more than 10% by weight of the soil sample. At such concentrations, the assumptions for soil contact used to derive the screening levels may no longer be valid. Cases in which the chemicals are present at concentrations exceeding 1×10^5 mg/kg or C_{sat} need to be identified and

addressed in the risk assessment. These cases should be discussed with the DTSC toxicologist prior to performing a risk assessment.

III. ADDITIONAL CONSIDERATIONS RELATED TO SCREENING LEVEL HUMAN HEALTH RISK ASSESSMENTS

A. SAMPLING AND ANALYSIS PLANS/ RISK ASSESSMENT WORK PLANS

HERO recommends that sampling and analysis work plans and risk assessment work plans be submitted to DTSC for review and approval prior to sampling activities and the preparation of a risk assessment. A consensus with the regulatory agencies prior to field activities will aid in ensuring that the collected data meet the requirements of a risk assessment. The risk assessment work plan provides the opportunity to resolve issues related to risk assessment methodology so that the risk assessment can be performed in a more efficient and timely manner as well as limiting the potential for having to repeat sampling because the initial sampling event did not meet HERO requirements.

i. Detection Limits.

The work plan should address the adequacy of the method detection limits. In general, the method detection limits must be sufficiently low to detect chemicals below the medium-specific and compound-specific screening levels or applicable risk-based screening criteria. If this is not technically feasible, chemicals for which the method detection limits exceed risk-based screening levels should be discussed in the Uncertainty Section of the screening level risk assessment report.

ii. Soil Sampling.

The work plan should address the proposed soil sampling depths and methodology for review by HERO, DTSC site geologist and Project Manager. For risk assessment purposes, HERO currently recommends that discrete (rather than composite) soil samples be collected given that composite samples can mask hot spots of contamination. HERO supports the use of the Incremental Sampling Methodology (ISM) at a site when wide-spread release is in agreement with the Conceptual Site Model, however, prior to implementing ISM at a site the HERO toxicologist should be consulted. The site project team, including the DTSC Project Manager, Geologist, Toxicologist, and Responsible Party should have an understanding of the advantages and limitations of ISM, appropriate size of the decision units, how to implement ISM sampling and how to use and assess the data. Proposed new sampling methodologies might result in HERO altering this recommendation. If the sampling recommendations change, HERO will reflect this in an update to this HHRA Note. Contacting the HERO toxicologist when developing the sampling plan can provide an early indication of any possible changes.

For screening evaluation of current and future residential land use scenarios, soil samples from the 0 to 10 foot (ft) bgs interval should be collected. However, collecting soil samples to 10 ft bgs may not be sufficient, particularly if contamination

has extended past 10 ft bgs and the soil contamination has not been fully delineated. DTSC's Preliminary Endangerment Assessment (PEA) Manual (2015) recommends collecting sufficient subsurface soils samples "to determine whether a release has occurred, to assess the vertical and horizontal extent of contamination, and to determine if there is a potential impact to groundwater." Additionally, U.S. EPA recommends that subsurface samples are collected from the ground surface until no contamination is detected or groundwater is encountered (U.S. EPA 1996). If contamination is suspected at depths greater than 10 ft bgs contact the site toxicologist and the DTSC Project Manager.

While recommended soil sampling depths may vary based on site-specific conditions; in general, discrete soil samples should be collected from both surface (0 to 0.5 ft bgs) and subsurface soil. Collection of surface soil is particularly important for contaminants such as lead which have limited vertical mobility in the soil column. A lack of surface soil data for use in assessing risk could lead to a significant underestimate of risk. Please see Section III-E below for a discussion of exposure point concentrations to be used for screening level risk assessments.

Use of incremental sampling methodology presents particular issues for evaluating such data in risk assessments. Incremental sampling data should not be combined with discrete sampling results in the risk evaluation. If incremental sampling is to be conducted, the HERO toxicologist needs to be involved in the development of the sampling plan.

iii. Key Chemical Groups.

The work plan must address the proposed chemical analyses and analytical methods for the collected samples. Typically, HERO recommends that the following comprehensive suite of analytes be included during site investigations: metals, semivolatile organic compounds (SVOCs), VOCs, pesticides, polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (PAHs). In addition, analyses for additional chemicals (e.g. polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), hexavalent chromium, per- and polyfluoroalkyl substances, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) may be warranted depending on the site history. The screening level risk evaluation should provide a clear and scientifically defensible rationale for selecting the chemical analytes. Unless it can be shown that there is no reason to suspect the presence of a particular chemical group, HERO recommends that the full suite of analyses be conducted.

iv. Total Petroleum Hydrocarbons (TPH).

DTSC's Interim Guidance for Evaluating Human Health Risks from TPH dated June 16, 2009 is no longer active or available on the internet. HERO is currently working on updating and revising the TPH guidance document. The PEA Manual (DTSC 2015) discusses appropriate approaches for addressing petroleum hydrocarbon contamination and provides toxicity criteria to evaluate aliphatic and aromatic components of TPHs. Additionally, HERO recommends that certain constituents of

petroleum be evaluated in risk assessments including benzene, toluene, ethylbenzene, and xylene (BTEX), methyl tert-butyl ether (MTBE), hexane, other petroleum components, PAHs, and metals as appropriate for the particular petroleum contamination involved. Depending on site-specific conditions and the results of the screening level evaluation, additional evaluation of TPH using the methodology outlined by others such as the Massachusetts Department of Environmental Protection may be recommended until the revised DTSC TPH Guidance becomes available. Released in November 2018, the Interstate Technology Regulatory Council (ITRC) Total Petroleum Hydrocarbons (TPH) Risk Evaluation at Petroleum-Contaminated Sites⁴ guidance document is another source. This guidance is aimed to assist with evaluating risk and establishing cleanup requirements at petroleum release sites and focuses on factors that are unique to TPH releases and builds on previously released and available guidance documents on TPH. The DTSC toxicologist should be contacted for any questions on this issue.

B. SELECTION OF INORGANICS AS COPCs AND CALCULATION OF BACKGROUND RISK AND HAZARD INDEX

Previous HERO guidance (DTSC 1997) provides a recommended methodology for selecting inorganic constituents as chemicals of potential concern (COPCs). Historically, inorganic chemicals eliminated as COPCs were not carried forward into the quantitative risk assessment. More recent U.S. EPA (2002) guidance recommends the inclusion of naturally occurring inorganic chemicals in the risk assessment. Background issues for inorganic chemicals are to be addressed during risk characterization.

HERO recommends the screening level risk assessment include the calculation of both the site-related risk and hazard index, and the total risk and hazard index on a site-specific basis. The latter presents the risk and hazard associated with exposure to all detected chemicals prior to elimination of inorganic chemicals that are determined to be consistent with site-specific background or ambient concentrations. This information is useful for risk management decisions about appropriate land uses and for public transparency. It is critical that different expressions of the risk assessment results (i.e., site-related and total risk) be based on the same statistical basis in order to be comparable.

The HERO toxicologist should be contacted if there are questions in this regard. In particular, at some sites, it may not be necessary to calculate total risk and hazard. In addition, an important distinction between the approach outlined herein and U.S. EPA's 2002 guidance is that HERO does not allow the elimination of compounds as COPCs based on comparison to risk-based screening levels. HERO's reference to the 2002 U.S. EPA guidance does not imply concurrence with the screening-out of individual chemicals as COPCs based on U.S. EPA RSLs, DTSC-SLs or other risk-based criteria.

⁴ <https://tphrisk-1.itrcweb.org/>

C. “SCREENING-OUT” COPCs

In general, HERO recommends that all detected compounds be selected as COPCs and be included in the quantitative risk evaluation. In limited cases, HERO may agree to eliminate specific chemicals from full consideration in the risk assessment; however, such cases must be discussed with and agreed to upfront by the DTSC toxicologist. To facilitate an evaluation regarding whether it is appropriate to exclude a detected chemical from the risk assessment, a rationale should be provided for each chemical proposed for elimination which considers factors such as the frequency of detection, detection limit, chemical toxicity, concentration detected, site history, co-location of high concentrations (i.e., a ‘hot spot’), essential nutrient status, and/or comparison to background for inorganics as discussed in Section III-B above. Potential chemical breakdown products must also be considered, and the rationale should not be based on a “brightline” approach (e.g. preliminary cancer risk $<1 \times 10^{-7}$, preliminary hazard quotient <0.1). As detailed above, inorganics which are determined to be present at concentrations consistent with background will still need to be included in the total risk and hazard evaluation.

D. ADDITIVITY OF RISK AND HAZARDS

For each site-related chemical, the chemical concentrations in each relevant medium should be divided by their corresponding soil, tap water, and air risk-based screening levels. Please see HHRA Note 3 for a listing of chemicals which HERO recommends DTSC-SLs as alternate values other than the U.S. EPA RSLs. For compounds with non-threshold effects (carcinogens), the ratio must be multiplied by 10^{-6} to provide an estimate of risk. Risk must be summed across all carcinogenic chemicals and exposure pathways (including vapor intrusion to indoor air evaluated separately from comparison to screening levels). Similarly, hazard quotients must be summed across all chemicals and exposure pathways (including vapor intrusion to indoor air evaluated separately from comparison to screening levels) for threshold (non-carcinogenic) effects to provide a hazard index. Please note that the soil, tap water, and indoor air “supporting” tables available on the U.S. EPA RSL website provide RSLs based on both cancer (non-threshold) and non-cancer (threshold) effects for most carcinogens. Since May 2013, U.S. EPA has provided new tables with target hazard quotients (THQ) of 1.0 and 0.1. In general, HERO does not recommend using screening levels based on a THQ of 0.1, and screening levels based on a target hazard quotient of 1 should be used. Carcinogens should be evaluated both for carcinogenicity and for threshold toxicity (noncancer hazard). If the summed hazard index for the site is greater than one, then the hazard index may be recalculated for chemicals which have the same toxic manifestation or which affect the same target organ.

E. EXPOSURE POINT CONCENTRATIONS

In general, HERO recommends that the maximum detected concentrations of COPCs be used as the exposure point concentrations in screening level risk evaluations. Use of the 95 percent upper confidence limit (95% UCL) on the arithmetic mean concentrations must be approved by the DTSC toxicologist. In most cases, use of the maximum detected concentrations is appropriate because of the screening-level nature of such evaluations and because the screening-level sampling is usually limited.

F. SURROGATE COMPOUNDS

Compounds for which screening levels are not available should be evaluated in the risk assessment through the selection of a surrogate chemical. Surrogates should have similar structure, activity, and mechanisms of toxicity. The HERO toxicologist should be contacted regarding the selection of the most appropriate surrogates.

G. CALCULATION OF TETRACHLORODIBENZO-P-DIOXIN AND BENZO(A)PYRENE EQUIVALENTS

Dioxins and furans are evaluated based on quantitative comparison of the 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)-equivalent concentration with the TCDD U.S. EPA RSL. If congener-specific polychlorinated biphenyl (PCB) data are available, these should also be included in the calculation of TCDD-equivalent concentrations. HERO recommends use of the 2005 World Health Organization (WHO) toxic equivalency factors (TEFs) (Van den Berg, 2006). These values can be found in the U.S. EPA RSL User's Guide and are also summarized in HERO's HHRA Note 2 (DTSC 2017).

In some cases, benzo(a)pyrene (BaP)-equivalent concentrations are calculated and used in screening-level risk evaluations to assess risk from carcinogenic PAHs, if they are not evaluated individually. Please note that naphthalene is not included in the calculation of the BaP-equivalent concentration. Rather, this carcinogen is evaluated separately using the naphthalene soil screening levels. If the BaP-equivalent concentration is calculated, the U.S. EPA-recommended potency equivalency factors (PEFs) should be used (U.S. EPA 2015) and these values are also summarized in the PEA Manual (DTSC 2015). If you have any questions regarding the calculation of BaP-equivalent concentrations, please contact your site toxicologist.

H. EVALUATION OF LEAD

In 2007, Cal/EPA OEHHA developed a new toxicity evaluation of lead replacing the 10 µg/dL threshold blood lead concentration with a source-specific "benchmark change" of 1 µg/dL (OEHHA 2007, 2009). One µg/dL is the estimated incremental increase in children's blood lead that would reduce IQ by up to 1 point. In light of the updated Cal/EPA lead toxicity criterion, as well as the need for revision to ensure that the model is adequately protective of women of child-bearing age, a new version of the DTSC

LEAD RISK ASSESSMENT SPREADSHEET (LeadSpread 8) has been developed (DTSC 2011b⁵).

Worksheets 1 and 2 of the LeadSpread 8 file include PRG90 calculations for soil under residential and industrial land use scenarios (80 mg/kg and 320 mg/kg, respectively). These PRG90s represent concentrations in soil corresponding to a 90th percentile estimate of blood lead in a child or the fetus of a pregnant adult worker equal to 1 µg/dL. While DTSC has historically used the 99th percentile estimate of blood lead, HERO considers the 90th percentile of the distribution appropriate for use in evaluating lead exposures given that the target blood lead level of concern was updated to the more recent health-protective incremental criterion of 1 µg/dL.

Use of PRG90s is a departure from the previously utilized Cal-modified U.S. EPA Region 9 PRGs of 150 mg/kg for residential land use and 800 mg/kg for industrial land use. For the residential evaluations, HERO implements the risk-based concentration as a residential use scenario Exposure Point Concentration (EPC), calculated as the 95 percent upper confidence limit on the arithmetic mean (95% UCL) of 80 mg/kg or less soil lead. For industrial/commercial scenarios, the risk-based concentration is implemented as an EPC, calculated as the 95% UCL of 320 mg/kg or less soil lead.

With regard to assessment of lead risk and evaluating cleanup options, HERO recommends calculating the 95% UCL on the arithmetic mean lead concentration for each exposure area (assuming sufficient data are available for such a calculation). If individual samples exceed the PRG90, it would not mean that the exposure area itself is in exceedance of the PRG90 as long as the 95% UCL itself is below ~80 mg/kg for residential and ~320 mg/kg for industrial/commercial, assuming hot spots are not present. If “hot spots” (i.e., geographically collocated areas of elevated concentration), or “outliers” (i.e., individual samples with elevated concentrations) are present, they must be addressed separately.

For initial site screening where data are insufficient to calculate a 95% UCL, comparison of the maximum detected concentration to the PRG90s would be appropriate. If individual sample results exceed the PRG90s, depending on site-specific conditions and sampling results, additional investigation, evaluation, and potentially remediation may be warranted to address concerns about lead exposure.

It is important to note that background exposures to lead, and media other than soil which may be impacted by lead, are not considered in LeadSpread8. If lead is present at levels above background in media other than soil (e.g., water, air) or if the home grown produce pathway is anticipated at the site, please contact the HERO toxicologist. DTSC’s LeadSpread model is currently undergoing additional revision, and we hope to incorporate additional exposure pathways and environmental media in the near future.

⁵ <https://dtsc.ca.gov/leadsread-8/>

IV. CONCLUSIONS

Screening level risk evaluations are useful for determining whether a finding of “no further action” may be warranted with respect to human health. Such evaluations can also provide preliminary estimates of risk and hazard at a site prior to conducting a baseline risk assessment. There are important limitations which need to be considered when using screening level risk estimates for risk management decisions. Many of the limitations and important aspects of screening level risk evaluations are summarized herein.

Of importance is the fact that screening level risk assessments conducted using U.S. EPA Regional Screening Levels and DTSC screening levels do not consider potential harm to ecological receptors (see Section II-B). A separate ecological risk evaluation must be conducted if ecological habitat is present onsite or there is potential for transport of contaminants to offsite habitat.

Vapor intrusion into indoor air is frequently an important exposure pathway. Since the RSLs and DTSC screening levels do not include this pathway, this HHRA Note provides recommendations to address this deficiency (see Section II-D).

If you have any questions on this HHRA Note, please contact Kimberly Gettmann, Ph.D., HERO Staff Toxicologist at (916) 255-6685, Kimberly.Gettmann@dtsc.ca.gov or Michael Wade, Ph.D. HERO Staff Toxicologist, at (916) 255-3608, Michael.Wade@dtsc.ca.gov.

REFERENCES

Department of Toxic Substances Control. Guidance for Ecological Risk Assessments - EcoNOTEs.

(<https://dtsc.ca.gov/ecological-risk-assessment-hero/>)

Department of Toxic Substances Control. 1994. Recommended Outline for Using U.S. Environmental Protection Agency Preliminary Remediation Goals in Screening Risk Assessments at Military Facilities.

(<http://www.dtsc.ca.gov/AssessingRisk/upload/PRG-HERD-Memorandum-OCT-1994.pdf>)

Department of Toxic Substances Control. 1996. Guidance for Ecological Risk Assessments Part A: Overview and Part B: Scoping Assessment.

(<https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/overview.pdf>,
<https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/scope.pdf>)

Department of Toxic Substances Control. 1997. Selecting Inorganics as Chemicals of Potential Concern at Risk Assessments at Hazardous Waste Sites and Permitted Facilities. (<https://dtsc.ca.gov/wp-content/uploads/sites/31/2016/01/backgrnd.pdf>)

Department of Toxic Substances Control. 2011a. Final Guidance for the Evaluation and Mitigation of Subsurface Vapor Intrusion to Indoor Air (Vapor Intrusion Guidance).

(https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/Final_VIG_Oct_2011.pdf)

Department of Toxic Substances Control. 2011b. Lead Risk Assessment Spreadsheet (LeadSpread 8).

(<https://dtsc.ca.gov/leadspread-8/>)

Department of Toxic Substances Control. 2015. Preliminary Endangerment Assessment Guidance Manual. (https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/PEA_Guidance_Manual.pdf)

Department of Toxic Substances Control. 2017. HERO HHRA Note 2: Soil Remedial Goals for Dioxins and Dioxin-like Compounds for Consideration at California Hazardous Waste Sites.

(<https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/01/HHRA-Note-2-dioxin-2017-04-06.pdf>)

Department of Toxic Substances Control. 2019a. HERO HHRA Note 1: Recommended DTSC Default Exposure Parameters for Use in Risk Assessment at California Hazardous Waste Sites and Permitted Facilities. Dated April 9, 2019.

(<https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/04/HHRA-Note-1-April-2019.pdf>)

Department of Toxic Substances Control. 2019b. HERO HHRA Note 3: DTSC-modified Screening Levels (DTSC-SLs). Dated April 2019. (<https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/04/HHRA-Note-3-2019-04.pdf>)

Department of Toxic Substances Control. 2019c. HERO HHRA Note 10: Toxicity Criteria. Dated February 25, 2019. (<https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/02/HHRA-Note-10-2019-02-25.pdf>)

Office of Environmental Health Hazard Assessment. 2007. Development of Health Criteria for Schools Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment. (<https://oehha.ca.gov/risk-assessment/crnrfinal-report-chrc-lead>)

Office of Environmental Health Hazard Assessment. 2009. Revised California Human Health Screening Levels for Lead. (<http://www.oehha.ca.gov/risk/pdf/LeadCHHSL091709.pdf>)

U.S. Environmental Protection Agency. 1989. Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual, Part A, Interim Final. EPA/540/1-89/002. (<http://www.epa.gov/oswer/riskassessment/ragsa/index.htm>)

U.S. Environmental Protection Agency. 1996. Soil Screening Guidance: User's Guide. Second Edition. EPA/540/R-96/018. July. (<https://semspub.epa.gov/work/HQ/175238.pdf>)

U.S. Environmental Protection Agency. 2002. Role of Background in CERCLA Cleanup Program. OSWER 0285.6-07P. (<http://www.epa.gov/oswer/riskassessment/pdf/role.pdf>)

U.S. Environmental Protection Agency. 2015. OSWER Technical Guide for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air. June 2015. OSWER Publication 9200.2-154 (<https://www.epa.gov/sites/production/files/2015-09/documents/oswer-vapor-intrusion-technical-guide-final.pdf>)

U.S. Environmental Protection Agency. 2018. Regional Screening Levels. User's Guide and Frequently Asked Questions. (<https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide>)

Van den Berg et al. 2006. The 2005 World Health Organization Reevaluation of Human and Mammalian Toxic Equivalency Factors (TEFs) for Dioxins and Dioxin Like Compounds. Toxicological Sciences. 93(2), 223-241. (<http://toxsci.oxfordjournals.org/content/93/2/223.full.pdf>)