4 Using Soil Background in Risk Assessment

This section describes how default and site-specific background for natural or anthropogenic ambient soil background may be used in human health and ecological risk assessment. Most regulatory agencies allow default and site-specific soil background to be used in human health risk assessment to identify whether chemical concentrations posing excess risk at a site may be attributable to site activities or to soil background conditions.

Different regulatory frameworks use different human health risk assessment procedures. For human health, risk assessments can be conducted by comparing site concentrations to a human health risk-based soil value or by using site concentrations to calculate cancer and noncancer health risk estimates (excess lifetime cancer risks and hazard quotients). Similarly, ecological risk assessments can be conducted by comparing site concentrations to an ecological risk-based soil value or by using site concentrations in food chain models to calculate risk estimates (hazard quotients).

State or federal regulatory frameworks recommend the use of either or both of these risk assessment methods, along with the evaluation soil background. When calculating risk estimates, some agencies may require that the portions of the risks attributable to the site and background be presented separately.

Regardless of the receptor considered (human or ecological), many regulatory agencies allow for an initial screening, which typically involves comparison of a site concentration to a risk-based screening value. When the site concentration is greater than a risk-based screening level, it is not unusual to compare the site concentrations to default soil background values, when available and applicable. Chemicals that are present at concentrations greater than the corresponding human health or ecological risk-based screening values and the default background values are typically carried forward in the risk assessment.

For the purposes of this document, a screening risk assessment is defined as the comparison of site concentrations to human health and ecological risk-based screening values and soil background values. When dealing with a single chemical, a conclusion that concentrations are less than those values indicates that there is no need for further evaluation. When dealing with multiple chemicals at a site, different agencies may use different strategies for retaining or excluding chemicals as COPC. In addition, for the purposes of this document, site-specific risk assessments may proceed into more complex methods to estimate human health and ecological risk with chemical toxicity, site-specific exposures, and in the case of ecological assessments, ecological species comparisons between a reference site and the site being evaluated, and may include site-specific background evaluations.

Therefore, the general applications of soil background in the human health and ecological risk assessment process are as follows:

- Screening risk assessment: To potentially eliminate chemicals that are present in soil at concentrations greater than risk-based screening values but less than default soil background from further evaluation.
- Site-specific risk assessment: For human health, risk characterization is used as well as site-specific soil background information to determine whether site concentrations are representative of background and in some cases differentiate risks associated with site activities from those associated with background conditions.

In addition, a site-specific ecological risk assessment may also characterize site risks by comparing receptors and site conditions with conditions at a soil background reference area.

Moreover, soil background is often used to:

- refine the conceptual site model that is the basis for the human health and ecological risk assessments by using site-specific background information to determine whether the presence of a chemical is due to a release and should be carried forward in the risk assessment or if it is consistent with background conditions and the chemical should not be included among the COPC
- establish remedial goals that are consistent with soil background

These applications described above are intended to show a basic overview of how soil background can be used in the risk assessment process. They are not intended to cover any specific steps included in any one regulatory process.

Comparison of site concentrations to background can be completed using one or more of the following approaches:

- Compare site concentrations to a default background threshold value (BTV) during screening
- Compare site concentrations to a site-specific BTV during a site-specific risk assessment
- Statistically compare (using a two-sample hypothesis test) site and site-specific background concentration datasets during a site-specific risk assessment
- Compare ecological receptors and conditions present at a soil background reference area to ecological receptors

and conditions present at the site being evaluated
- Incorporate geochemical evaluations to provide an additional line of evidence whether an inorganic chemical at a site does or does not reflect background concentrations (Sections 5 and Section 6)
- Incorporate environmental forensics to provide an additional line of evidence whether an organic chemical at a site does or does not reflect background concentrations (Section 7)

In some cases (for example, no appropriate default background to use, a highly complex site is being evaluated), a site-specific BTV (or background dataset) might be used during screening. If site-specific background is used in the screening process, it is necessary to ensure that the same criteria outlined in this guidance for site-specific background are followed, including data quality requirements. This type of information is often not readily available during the screening step.

This section describes statistical and non-statistical approaches that can be used to compare a representative site concentration to a default or site-specific BTV, statistically compare a site concentration dataset to a site-specific soil background dataset, calculate potential risks from background concentrations, compare ecological receptors and conditions from a soil background reference area to a site being evaluated, and determine how soil background can be used to establish remedial goals. Please reference Framework 3, which depicts the process for using soil background in risk assessment.

4.1 Representative Site Concentration to Compare to a BTV

When using a default or site-specific BTV in human health or ecological risk assessments, a decision regarding the appropriate site concentration to compare to the BTV must be made. When comparing a site concentration to a risk-based soil value derived based on exposure, toxicity values, and chemical-specific parameters, it is generally accepted to use the 95% upper confidence limit (95 UCL) of the mean concentration (an upper limit of the average site concentrations). This is not the case when comparing site concentrations to soil background to determine whether an area is contaminated since the soil BTV is established using an upper limit value. An upper limit site concentration should be compared to a BTV.

To ensure the chosen site concentration is appropriate, the following items should be considered:

- Type of statistic used to establish the BTV ((USEPA 2015) and Section 11)
    - As discussed in Section 11, each type of statistical value (upper percentile, upper prediction limit, upper tolerance limit, upper simultaneous limit) has its advantages and disadvantages in different situations.
- How the BTV will be used
    - If it is a default soil BTV, it will be used to compare to a large number of sites.
    - If it is a site-specific BTV, it will be used to compare to one site or a small number of similar sites.
- Policies of the regulatory agency
    - Many regulatory agencies have guidance on the representative site concentration they will allow to be compared to a default or site-specific BTV.

For comparisons with BTV, estimates used to represent site concentrations should be consistent with the statistic used to establish the BTV. Possible site concentrations that are appropriate to use to compare to a default or site-specific BTV are maximum and 95th percentile concentrations, which are discussed in Section 4.1.1.1 and Section 4.1.1.2.

4.1.1.1 Maximum

The maximum site concentration is generally used for an initial comparison to a BTV, regardless of which type of statistic is used to establish the BTV (for example, 95-95 UTL, 95-95 UPL). The maximum detected site concentration of a chemical in soil represents a conservative, high-end (or upper limit) concentration. Using a maximum to compare to a BTV provides a high degree of certainty that the site concentration is attributable to background if the maximum concentration of the site is below the BTV. Alternatively, in some cases, using the maximum value could result in characterizing site concentrations as not likely to be representative of background when they are actually background. Other important factors for determining the use of the maximum site concentration should be considered, including the sample size and its relationship with the 95th percentile. For some regulatory programs, the maximum may be appropriate when there is large variability of the site data or there is an inadequate sample size.

An additional line of evidence can be gained by comparing each individual site concentration to the BTV by performing a point-by-point comparison. This allows presentation of how many of the individual site concentrations exceed the BTV. For example, results showing that one out of 20 site concentrations exceed a BTV by less than an order of magnitude or results showing that 10 out of 20 site concentrations exceed a BTV by two orders of magnitude may lead to two very different decisions by a regulatory agency as to whether site concentrations represent background. Completing a point-by-point comparison provides additional information that can be used by risk assessors and risk managers to make more informed decisions.

If the BTV is calculated based on the USL, the maximum concentration should be used. As discussed in Section 11.7.5 and Section 11.8, the USL represents a limit that no background concentration should exceed and addresses the false positive error. Therefore, if site concentrations and background are similar, then it should be assumed that the maximum site concentration should similarly not exceed the USL BTV.

4.1.1.2 95th percentile

A 95th percentile is an upper limit of the dataset that represents the value below which 95% of the individual data points will fall. In other words, only 5% of the time will a value from that dataset be above the 95th percentile. Section 11.7.1 notes that upper percentiles are reliable for a dataset that is large and representative of a single population; the confidence in this estimate is sample size–dependent. This statistic may be appropriate to use in some cases rather than the maximum but only when the BTV is calculated based on similar statistics, such as a 95th percentile or 95-95 UTL. It is not recommended to be used with a USL for reasons described in Section 4.1.1.1

4.2 Using Default Background

For state programs that use default BTVs, most human health and ecological risk assessments will incorporate them during screening. Due to the short- and long-term cost and potential complexity associated with developing a site-specific BTV and a site-specific background dataset, decisions to collect site-specific background data and/or perform geochemical or environmental forensic evaluations are often not made until it has been determined that a site concentration exceeds a default BTV and/or is associated with risks above regulatory limits.

While default BTVs are used in many states and under many circumstances, there are some states that developed different ways to address the issue of soil background in site cleanup. These approaches do not necessarily fall under either default or site-specific background evaluation. For example, Pennsylvania has a background cleanup standard that, although not part of the risk assessment, addresses soil background through the analysis of soil samples of regulated substances present, but not related to, a release at the site (25 Pa. Code § 250.202(b)). Alabama considered soil background during site characterization but uses a process different from those included in this guidance (ADEM 2017). In addition, some sites are rather complex and may require site-specific background in screening. A thorough understanding of the conceptual site model (Section 8.1) may facilitate identification of the need for site-specific background early in the site investigation process. In extreme cases, because of the complexity of the geology, there could be the need for more than one BTV for a single site.

4.2.1 Comparing a representative site concentration to a default BTV

The first step in comparing a representative site concentration to a BTV is choosing the most appropriate site concentration to use for that purpose (Section 4.1), which includes the maximum and point-by-point concentration comparisons, and upper percentiles. The choice will depend on the statistic that was used to establish the BTV, CSM, DQOs, and the regulatory agency program providing oversight (Section 8 and Section 11.1). Comparing a representative site concentration to a default BTV shows whether the maximum site concentration or an upper bound estimate (upper percentile) is within the range of soil background concentrations and can help identify localized contamination (for example, upper percentile or maximum; see Section 4.1.1.1 and Section 4.1.1.2).

4.2.2 Test for proportions

When the representative site concentration exceeds the default BTV and the regulatory agency requires further assessment, a next step could be comparing the entire site dataset (each individual site concentration not identified as an outlier) to the BTV using the test for proportions available in USEPA's ProUCL software (USEPA 2015) or in other appropriate software packages. The test for proportions evaluates whether the rate of exceedances above the default BTV is significantly different from zero (not attributed to chance). Some regulatory agencies recommend making such comparison before establishing site-specific background since it is easy to do and does not require obtaining any additional data.

As mentioned above, when performing the test for proportions, it is important to eliminate outliers from the site dataset. The decision to eliminate an outlier should not be made based on the outlier test alone. If results from a statistical test show a potential outlier, an investigation should be performed to determine whether it is a true outlier or simply a characteristic of the heterogeneity of soil. Some examples described in Section 11.5 include an error in recording the numerical value or an error by the sampling crew or laboratory in following appropriate quality assurance/quality control procedures.

The test for proportions determines whether an allowable proportion (for example, 1%, 5%, 10%) of the site dataset would likely exceed the BTV (Table 11-3). USEPA's ProUCL User Guide (USEPA 2015) and Technical Guide (USEPA 2015) include details regarding how to perform the test and other items to consider, as well as the potential for errors.

4.3 Using Site-Specific Background

When conducting a site-specific human health or ecological risk assessment, a site-specific background dataset can be obtained and used to:

- establish a site-specific BTV as discussed in Section 3.7 for comparison to a representative site concentration (Section 4.3.1)
- compare the site-specific background concentration dataset to the site concentration dataset

In some cases (for example, no appropriate default background to use, or a highly complex site is being evaluated), a site-specific BTV (or background dataset) might be used during screening. Site-specific BTVs provide a more accurate representation of background concentrations in the vicinity of the site than default background concentrations. Thus, when such a value is available (or can feasibly be derived) and it is acceptable within the site's regulatory context, it should be preferred over a default BTV.

When using site-specific background datasets, it is common to:

- establish a site-specific BTV to compare to a representative site concentration to understand if the site concentrations are within the distribution of soil background and to identify localized contamination (for example, a BTV is often compared to the site maximum as part of a screening-level step)
- compare the central tendencies of the site and background datasets using two-sample hypothesis statistical tests (for example, a *t*-test). By comparing their central tendencies and variances, it is possible to identify if there may be slight but pervasive contamination.

The two procedures are therefore complementary, as they test for the presence of different types of contamination, and they can be performed together. If a given chemical in a site dataset fails either test, it may be examined further using geochemical evaluation (for inorganics) or environmental forensics (for organics) to confirm or rule out the actual presence of site-related contamination, if necessary.

4.3.1 Comparing a representative site concentration to a site-specific BTV

A site-specific BTV can be established and used to take a more site-specific look at whether site concentrations are reflective of background conditions. Site-specific BTVs are established using a dataset collected at a background area that has been determined to reasonably match the characteristics of the site being evaluated. Default BTVs are generally applicable to a larger number of sites over a larger area and include the site being evaluated plus many others. Comparing site concentrations to a site-specific BTV determines whether the site concentrations are within the range of soil background concentrations and can help identify localized contamination. The appropriate measures of a site concentration for comparison to a BTV include the maximum and upper percentiles. The choice will depend on the statistic that was used to establish the BTV and the CSM, DQOs, and the regulatory program requirements (Section 8 and Section 11.1). Professional judgment informed by site history can also be used to support decision-making at this point.

If the site concentration is above the site-specific soil BTV, the site dataset may be compared to the BTV using a hypothesis test (for example, test for proportions). The test for proportions is available in USEPA's ProUCL software ((USEPA 2015)) discussed in Section 4.2.2. Other software (for example, R) can also be used to conduct the proportions test or other relevant tests to compare site data to background data (as discussed in Section 4.3.2).

4.3.2 Comparison of site concentration dataset to site-specific background concentration dataset

A statistical comparison of a site dataset's and site-specific background datasets' central tendencies can be conducted using the two-sample hypothesis tests listed in Table 11-5, which also describes the advantages and disadvantages of using each test. These tests can be used to determine whether site concentrations are generally higher than background; in this way, slight but pervasive contamination at the site can be detected statistically. Results from a statistical test alone do not necessarily indicate whether site concentrations are within background. Multiple lines of evidence (for example, Q-Q plots, box plots, geochemical evaluation, environmental forensics) and professional judgment (based on knowledge of site history) should be used to determine whether site concentrations represent background (Section 11.1.5 and Section 11.4). Section

14.6 provides an example of using forensic methods combined with site history and spatial tools to identify site concentrations that are inconsistent with background concentrations and chemical fingerprints and that were potentially influenced by known or suspected sources.

Statistical test results are only as good as the quality of the data used and the validity of the underlying assumptions. Statistical methods are very useful to test the hypothesis that two groups of samples belong to the same population; however, other lines of evidence can be used to support the conclusions drawn from test results. Weight of evidence approaches are useful to reduce uncertainty in risk assessment and decision-making.

4.3.3 Community composition comparison

While this guidance is focused on the chemical aspect of background conditions, ecological risk assessments also often consider one or more biological or ecological background conditions (or "reference conditions"). Ecological risk assessors often use a weight of evidence approach to characterize risk, including various chemical, biological, and toxicological lines of evidence (for example, bioaccumulation modeling or soil toxicity tests). Together these lines of evidence will either point together toward an impact or they will point in different directions, indicating uncertainty. The biological communities at one or more suitable background sites can provide a reference against which to judge the condition of the biological community at the site. Concepts, methods, and limitations of biological surveys and the use of related data in risk assessments are outside the scope of this guidance; relevant guidance should be sought elsewhere. The use of biological background or a "reference condition" is only one of several lines of evidence that can be considered in addition to chemical background (described herein).

4.3.4 Geochemical evaluations and environmental forensics

Geochemical evaluation for inorganics and environmental forensics evaluation for organics are additional tools that can help determine whether site concentrations are from background only or whether there is contamination. In some situations, it may make sense to perform these evaluations early on, in the initial screening step or at the start of the site-specific step, especially for highly complex sites, but in many cases they are not accomplished until the end of the site-specific risk assessment (Section 5, Section 6, and Section 7).

4.3.4.1 Geochemical evaluations

Geochemical evaluations can be used to provide an additional line of evidence to support whether or not site inorganic concentrations represent background during human health and ecological risk assessments. Geochemical evaluations are based in part on selected elemental ratios, and they are used to identify the processes controlling element concentrations in soil and to confirm or rule out the presence of contamination in individual samples (Section 5). Accordingly, geochemical evaluations can be used during background studies, such as to verify whether statistical outliers should be retained in a candidate background dataset, and they can be used during comparisons of site versus background datasets. This topic is covered in Section 5 and Section 6. Although these methods may be used at any step in the risk assessment process, in some cases they are not accomplished early in the process due to their complexity, which requires an expert as well as additional resources and funding.

4.3.4.2 Environmental forensics

Environmental forensics evaluations can be used to provide an additional line of evidence to support whether or not site organic concentrations represent background during human health and ecological risk assessments. Certain classes of organic chemicals such as polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs), and dioxins are complex mixtures of structurally related compounds that, depending on source, occur in unique relative amounts forming distinctive compositional patterns (Section 7). Environmental forensics can be used to determine whether such organic chemicals in candidate background samples share characteristic compositional features consistent with background conditions, and the techniques can also be used to compare site and background datasets. This topic is covered in Section 7. Although these methods may be used at any step in the risk assessment process, in some cases they are not accomplished early in the process due to their complexity, which requires an expert as well as additional resources and funding.

4.3.5 Characterizing risks from background

The primary goal of many environmental regulatory agencies, and of the statutes under which such agencies work, is to protect public health and the environment from current and potential threats posed by uncontrolled or illegal releases of hazardous substances, pollutants, and contaminants. Some of these chemicals may be present in the site soil not only because of releases but also from other natural or anthropogenic ambient sources that are not attributable to site activities, or to other anthropogenic point sources (for example, a release from an adjacent facility). When the total cancer risks and noncancer hazards assessed for a specific receptor at the site exceed either risk-based values (for example, risk-based screening values, ARARs) or their regulatory target risk level (incremental excess lifetime cancer risk (ECR) or hazard quotient (HQ)), it might be useful to evaluate what portion of the risk is associated with exposure to background concentrations and what portion is associated with exposure to site concentrations. The USEPA OSWER 9285.6-07P states that “COPC that have both release-related and background-related sources should be included in the risk assessment.” USEPA further states that “if data are available, the contribution of background to site concentrations should be distinguished.” It also states “when concentrations of naturally occurring elements at a site exceed risk-based screening values, that information should be discussed qualitatively in the risk characterization” (USEPA 2002). This can also be accomplished quantitatively, which is the topic of this section. Understanding the potential risk associated with exposure to naturally occurring and anthropogenic ambient background concentrations may provide risk assessors and managers with an additional line of evidence to facilitate informed decisions.

Under CERCLA, USEPA assesses and uses total risk at Superfund sites, including risks from all CERCLA hazardous substances present on site, to establish the baseline risk levels, determine a basis of action, and select an appropriate remedy. The Hazard Ranking System Final Rule defines the site as any “[a]rea(s) where a hazardous substance has been deposited, stored, disposed, or placed, or has otherwise come to be located” (40 CFR 300). Hazardous substances present on the site from non-CERCLA sources are commingled with a CERCLA release, contribute to the total risk at the site, and therefore are included in the total risk for the site. Reporting total site risk levels by subtracting background risk levels from the site risk levels is inconsistent with the CERCLA definition of site risks and the basis for action and would generally not be appropriate for use at a Superfund site. Distinguishing risks contributed by background from risks contributed by a site, however, is consistent with CERCLA guidance ((USEPA 2002), (USEPA 2018)). As noted in USEPA guidance “[if] background risk might be a concern, it should be calculated separately from site-related risk” ((USEPA 1989), (USEPA 2018)). Background levels are relevant to the CERCLA risk assessment and risk management where the risk-based cleanup levels are lower than the background concentrations. In such situations, USEPA generally selects background as the cleanup level. Other federal cleanup programs, such as the Resource Conservation and Recovery Act (RCRA) Corrective Action Program, use this same approach to background. In addition, quantitative risk assessment of background concentrations may provide useful information for communicating site risks to community members and other stakeholders. State and local regulatory agencies may follow different approaches in using background in risk assessment and risk management that permit the approaches discussed below. Also, USEPA regions may vary regarding how they handle calculating risks from soil background. It is best to discuss the approach to background with the lead regulatory agency early in the risk assessment process.

4.3.5.1 Incremental risk analysis of soil background

Risk characterization used in human health risk assessment summarizes and integrates the outputs of toxicity and exposure assessments to characterize baseline risk, using both quantitative expressions and qualitative statements (USEPA, 1989). Quantitative estimates for carcinogenic COPC are presented as the ECR, which is an increase in probability of developing cancer over a lifetime exposure to COPC. For noncarcinogenic COPC, quantitative estimates are presented as an HQ, which is an estimate of the potential for an individual to develop adverse health effects. Cumulative ECRs are calculated by summing individual ECRs for all COPC. Hazard indexes (HI) are calculated by summing all HQs for all the COPC that act on the same target organ, or by the same mechanism, considering all potentially complete exposure pathways and media for each receptor considered in the CSM.

When COPC that are related to site-specific background condition are included in the risk characterization, the calculated site ECRs and HIs may overestimate risks resulting solely from site-related releases or operations. Incremental risk analysis provides insight on the magnitude of the relative contribution that exposure to background COPC has on the calculated total cancer risks and noncancer hazards.

In risk characterization equations, the receptor-specific exposure point concentration (EPC) for a COPC directly affects the ECR or HQ for that receptor. If all other parameters stay the same, a change in the EPC will typically result in a proportional change in the cancer risk and HQs for the COPC.

When comparing the risk associated with exposure to background COPC to that from exposure to COPC present because of site-related activities, the EPCs for both the site-related releases and background should be based on estimates of central tendencies (for example, 95% UCL of the mean).

The incremental risk analysis method is based on a statistical relationship between the risk estimates (ECR and HQ) from exposure to site-related COPCs and exposure to site-specific background COPC. Site-specific EPCs for both the site-related releases and background are used in incremental risk analysis to determine the relative contribution of background to the estimated total site risk. It is important that the EPCs for background used in the incremental risk analysis are based on site-specific background data collected using a similar sampling design as the site data and collected from similar soil material and depth for each complete receptor exposure pathway. In addition, when comparing background risk to site-related risk, the reasonable maximum exposures should be calculated using the same type of EPC. The EPC for background should be developed consistent with the methodology used to calculate the EPCs for the risk characterization using site data (ITRC 2015). Refer to Section 9 for specifics on sampling design.

The following sections discuss specific approaches for using site-specific background in incremental risk analysis.

COPC identification

Incremental risk analysis begins with identification of constituents that are a background condition. Statistical tests discussed in Section 11 and Section 4.3.2 can be used to identify site-related COPC that are consistent with a background condition. In addition, geochemical evaluations and environmental forensics discussed in Section 5, Section 6, and Section 7 may be used to identify COPC to provide a line of evidence on site-specific background condition. The geochemical evaluation determines whether site-related metals data are consistent with site-specific background conditions, and if the metals data needs to be evaluated further in the incremental risk analysis. Geochemical evaluation can assist in distinguishing low-level site-related COPC concentrations from naturally occurring background COPC concentrations, which allows the risk assessor or risk management team to decide whether a COPC should be retained as a COPC for risk characterization. Environmental forensics in the context of this guidance is focused on determining whether the observed chemical concentrations in soils may be representative of natural or anthropogenic ambient soil background.

Based on the outcome of these evaluations, if selected COPC are identified as statistically correlated to the site background condition, then a site-specific background EPC can be calculated for the selected COPC. When assessing the risk, the reasonable maximal exposure should be developed using an exposure point concentration that is an estimate of the central tendency (for example, 95% UCL of the mean) and not an upper bound threshold value (for example, 95-95 UTL, 95th percentile) for both the site-related releases and background, as pointed out in ((ITRC 2015), Section 6.2.5.1).

Cumulative Risk Approaches

The cumulative incremental risk analysis method evaluates the potential contribution of site-specific background to the total site ECRs and HI. Total site risks are calculated using an EPC for the site, and background-related risks are calculated using EPCs for background. The same exposure model, exposure equations and assumptions, and toxicity values are used in calculation of the total site and background ECR and HIs. Refer to specific regulatory agency guidance on inputs to exposure equations and toxicity values.

Once total site risks and background-related risks are calculated, the risks are compared using one of or any combination of the following methods:

- Subtraction method—the total ECR and HI calculated for background are subtracted from the total site ECR and HI to differentiate the portion of the cancer risks and noncancer hazards that are from site-related releases and background ((ITRC 2015), Section 6.2.5.2).
- Percent contribution method—calculates the potential percent contribution of background ECR and HQ to the total site ECR and HQ to differentiate the portion of the cancer risks and noncancer hazards that are from site-related releases and background.
- Comparison method—compares the total site ECR and HI to the ECR and HI calculated for background. In this method, the difference between total site risk and background risk is not quantified.

Note that regulatory agencies typically require reporting of the total site risks, so the emphasis of these methods is on comparison of total site risks and risks related to background condition. The acceptability and specific approach of applying these methods may be USEPA region-, state-, and/or project-specific. It is best to discuss the approach for evaluating distinction of background and site-related risks with the lead regulatory agency. The subtraction method and the percent contribution method would generally be inappropriate for use under CERCLA or RCRA and would not be accepted by USEPA. Information gained from the comparison method may be useful for risk communication, but generally would not be appropriate for CERCLA or RCRA decision-making (USEPA 2018).

Cumulative Risk Example (USEPA generally does not accept this method)

An incremental risk analysis for a site identified that excess cancer risk (ECR) for an industrial worker and hazard index (HI) for a construction worker exceeded the regulatory agency ECR and HI targets of 1×10^{-6} and 1 (target risk levels may vary; please consult the lead regulatory agency regarding the appropriate target risk level to use), respectively. Potentially complete exposure pathways for the industrial worker and construction worker included exposure to COPCs in soil via direct contact (for example, incidental ingestion and dermal contact) and inhalation of volatiles and particulates.

Using the site-specific background exposure point concentration (EPC) developed for the site, the site-specific background cumulative cancer risks for the industrial worker ($ECR_{background}$) and noncancer hazards for the construction worker ($HQ_{background}$) were calculated. The same exposure assumptions, exposure equations, and toxicity values used to calculate total risk were used to develop the background incremental excess lifetime cancer risk ($IELCR_{background}$) and $HI_{background}$ for each receptor. A site-specific background EPC was developed using the same statistical method (95UCL of the mean) as the EPC in the calculation of the site cumulative ECR (ECR_{Site}) and HI (HI_{Site}).

The cumulative ECR_{Site} calculated for the industrial worker was 8 x 10^{-6} and the HI_{Site} was 3 for the construction worker. The $ECR_{background}$ for the industrial worker was calculated to be 1 x 10^{-6} and the $HI_{background}$ for the construction worker was 2.

The following presents an analysis of the incremental risk of site-specific background on the cumulative ECR_{Site} and HI_{Site} for the construction worker.

Industrial Worker

Subtraction Method

$$Incremental\ Risk\ Without\ Background = ECR_{Site} - ECR_{background}$$

$$Incremental\ Risk\ Without\ Background = 8 \times 10^{-6} - 1\ \times 10^{-6} = 7\ \times 10^{-6}$$

Percent Contribution Method

$$\frac{ELR_{background}}{ECR_{Site}} = \frac{1\ \times 10^{-6}}{8 \times 10^{-6}} \times 100 = 0.125\%$$

Comparison Method

$$\frac{Total\ Site\ ECR}{8\ x\ 10^{-6}} \quad \frac{Background\ ECR}{1\ x\ 10^{-6}}$$

Construction Worker

Subtraction Method

$$Incremental\ Risk\ Without\ Background = \ [HI]\ \_Site - \ [HI]\ \_background$$

$$Incremental\ Risk\ Without\ Background = 3 - 2 = 1$$

Percent Contribution Method

$$\frac{HI_{background}}{HI_{Site}} = \frac{2}{3} \times 100 = 66.7\%$$

Comparison Method

$$\frac{Total\ Site\ HI}{3} \quad \frac{Background\ HI}{2}$$

Based on the incremental risk analysis, the site-specific background condition is not significantly contributing to the cumulative ECR for the industrial worker scenario. The contribution of the site-specific background ECR ($ECR_{background}$) to the ECR for the site (ECR_{site}) is 0.125%. When the ECR calculated for the site-specific background condition $ECR_{background}$ is subtracted from the ECR calculated based on the EPC (ECR_{Site}), the ECR still exceeds the regulatory agency target level of 1 x 10^{-6}.

However, for the construction worker, the contribution of the site-specific background HI ($HI_{background}$) is 66.7% and when the $HI_{background}$ is subtracted from the HI calculated based on the EPC (HI_{Site}), the cumulative HI is reduced to 1 and does not exceed the regulatory agency target level of 1.

Therefore, ECR for the industrial worker is site-related and may warrant remedial action. For the construction worker, the majority of the elevated HI is attributable to the site-specific background condition and may not require remedial action

Risk Drivers

Another incremental risk analysis method is focused on potential contribution of site-specific background to the risk drivers identified in the risk characterization step. Risk drivers are defined as those chemicals that pose an unacceptable risk to human or environmental receptors and potentially trigger a need for response action ((USEPA 2001), (USEPA 2001)). The same calculations discussed under Cumulative Risk Approaches are used to compare the ECRs and HQs for the COPC-specific risk drivers using the EPCs for the site and background.

This method is a streamlined approach and is focused solely on risk drivers for potentially complete exposure pathways and does not evaluate the cumulative risk from all site-specific background data. A benefit from using this approach includes decreased level of effort (time and costs) to identify contribution of site-specific background to COPC that may require remediation because of a site-specific risk assessment. Risk managers may then incorporate this information in risk management decisions.

Risk Driver Example (USEPA generally does not accept this method)

From the previous example, arsenic and benzo(a)pyrene in surface soil were identified as risk drivers for the industrial worker exposure scenario. Site-specific background EPCs developed for these COPCs were used to evaluate potential contribution of background conditions to risk drivers using the percent contribution method. Both background and site EPCs were based on the 95% UCL of the mean.

Value	**Arsenic**	**Benzo(a)pyrene**
COPC ECR	1×10^{-6}	4×10^{-6}
Site-related EPC	4.22 mg/kg	10.4 mg/kg
Background EPC	3.55 mg/kg	0.208 mg/kg

The arsenic background EPC is divided by the arsenic total site EPC to determine a potential contribution to the EPC from the site-specific background condition.

$$\frac{Background\ EPC_{arsenic}}{Total\ EPC_{arsenic}} = \frac{3.55\ ^{mg}/_{kg}}{4.22\ ^{mg}/_{kg}} \times 100 = 84\%$$

The site-specific background condition for arsenic may be contributing up to 84 percent of the total EPC for arsenic. To calculate a potential incremental risk from the site-specific background condition, the COPC ECR is multiplied by the percent contribution of risk from background. It should be noted that $Background_{incremental}$ risk is rounded to 1 significant figure ((USEPA 1989)).

$$Background_{incremental\ risk} = COPC\ IELCR \times 84\%$$

$$Backgound_{incremental\ risk} = 1 \times 10^{-6} \times 84\% = 1 \times 10^{-6}$$

Similar to the arsenic evaluation, the potential contribution to the ECR from the site-specific background condition is calculated using the following equations for benzo(a)pryene.

$$\frac{Background_{benzo(a)pryene}}{Site-related\ EPC_{benzo(a)pryene}} = \frac{0.208\ ^{mg}/_{kg}}{10.4\ ^{mg}/_{kg}} \times 100 = 2\%$$

$$Background_{incremental\ risk} = COPC\ IELCR\ \times 2\%$$

$$Background_{incremental\ risk} = 4\ x\ 10^{-6} \times 2\% = 8\ x\ 10^{-8}$$

This evaluation provides support that the majority of the risk associated with arsenic is a background condition and that arsenic is not a site-related COPC. Conversely, this evaluation suggests that the majority of risk associated with benzo(a)pyrene is not a background condition and that benzo(a)pyrene is a site-related COPC rather than attributable to a site-specific background condition. Therefore, this risk driver evaluation helps inform the risk manager of potential response action that may be warranted based on the concentrations of benzo(a)pyrene detected in soils at the site.

4.4 Use of Background for Remedial Goals

Typically, when site conditions are associated with unacceptable risks, the lead regulatory agency requires some form of response action. Some response action may include numeric remedial goals, which are frequently based on site-specific risk-based values. When a risk-based remedial goal is within the range of the soil background concentrations of the same chemical, the soil background concentration may be used as the achievable remedial goal instead of the risk-based concentration.

There are two ways to use soil background to set a remedial goal:

- use a default or site-specific BTV
- compare the soil background dataset to the site dataset to determine which areas may require a response action

Remedial goals can be based on two types of BTVs: those that are based on a central tendency BTV, and those based on an upper limit. The type of BTV to use is a risk management decision, not a risk assessment decision. On one hand, using a central tendency BTV as a remedial goal is a more conservative approach than using an upper limit BTV. On the other hand, a remedial goal based on a central tendency BTV is more likely to give false positive errors (concluding that a soil sample is contaminated when it is well within the bounds of background) than one based on an upper limit BTV. Conversely, using an upper limit BTV may be more susceptible to false negative errors (concluding that a soil sample is not contaminated when it is contaminated).

Regardless of which type of BTV is used, it is important to ensure that both the BTV and the site concentration used to compare to the BTV are of the same type of statistics. For example, if an upper limit BTV is used as the remedial goal, then the site concentration to compare to the upper limit BTV should also be an upper limit. If a central tendency BTV is used as the remedial goal, then the site concentration to compare to the central tendency BTV should also be a central tendency.

One possible approach, often adopted as a first-tier comparison, is comparing site concentrations to a remedial goal set to a BTVs on a point-by-point basis. This can focus remediation planning on those areas where concentrations exceed the BTV (for example, hot spots of contamination). For example, all areas of the site with concentrations exceeding the BTV might be remediated to background levels. There are alternative approaches for comparing site concentration to a BTV, including comparing a representative site concentration to a BTV (Section 4.2.1 and 4.3.1) or a test for proportions (Section 4.2.2).

A site dataset and soil background dataset may also be compared to determine which areas require cleanup using statistics. Hypothesis testing may be used to indicate whether hot spot removal can reduce site concentrations to a level similar to background without remediating all areas of the site. Hypothesis testing may also be used to support the decision to remediate soil across the entire site when low-level, pervasive contamination is present. In cases where low-level, pervasive contamination is present, hot spot removal would not reduce site concentrations to background levels.

Ultimately, the choice of which BTV to use for setting a remedial goal will depend on many different factors, including which regulatory agency is providing oversight, the applicable regulatory framework, and negotiation among stakeholders. The rationale for selecting a specific type of BTV for a given site should be clearly explained and documented to ensure transparency in the decision-making process.

As noted in previous sections, it may be prudent to incorporate geochemical evaluation and/or chemical forensic analyses at this stage or earlier in the risk assessment process to confirm whether site and background datasets are chemically representative of background (not just statistically comparable). When possible, it is recommended that these analytical tools be incorporated earlier in the risk assessment process to ensure that background characterization and risk characterization are well supported.

4.5 Additional Considerations

When considering soil background in risk assessment, additional considerations such as bioavailability of chemicals and uncertainties should be accounted for and addressed, when possible and if necessary.

4.5.1 Bioavailability of chemicals in site and background soil

Bioavailability is important to understand when using soil background because it makes the chemical more (or less) available for uptake. The relative bioavailability of a chemical in the background soil may be different from the relative bioavailability of the same chemical in the exposure area (where there is contamination). How to account for background bioavailability is described in detail in Section 9.2.3 of the ITRC's Bioavailability of Contaminants in Soil Guidance document (ITRC 2017). For human or ecological exposures, contaminants in soil may not be as bioavailable as the forms used in the toxicity tests used to develop risk-based criteria. When calculating the relative bioavailability of a COPC in the background reference area, it is important to make sure that the conditions (for example, sample depth, soil type) are comparable to those on the site. Although bioavailability is better understood for lead, arsenic, and PAHs ((USEPA 2007), (USEPA 2012), (ITRC 2017)), particularly for the incidental ingestion of soil, states such as Hawaii recommend bioavailability testing when site concentrations exceed default BTVs (HI DOH 2011).

If the bioavailability of a chemical was considered or modified in generating a BTV, the conditions of the site must closely match the background study. This is of the utmost importance because bioavailability is greatly influenced by soil characteristics, including mineralogy, grain size, pH, and soil organic matter.

Although it is unlikely that bioavailability of chemicals will be considered in developing a BTV, methods for some chemicals and receptor types have been developed that simultaneously consider background chemical concentrations and bioavailability in site soils. One approach developed for ecological receptors (plants and invertebrates) and metals, for example, is to develop soil cleanup values based on background concentrations and bioavailability modeling of "added metal" (the metal concentration greater than background) (Checkai et al. 2014). An example of a freely available and flexible tool for developing bioavailability-based soil guidelines that incorporates background soil concentrations of metals is available from Arche Consulting (2020).

When site-specific BTVs are generated, due to site concentrations exceeding a risk-based screening level or default BTVs, an assessment of a contaminant's bioavailability at a site may be considered.

4.5.2 Uncertainty and assumptions

A common thread among all the assumptions in using a default or developing the site-specific soil BTV is to lean toward being acceptably conservative to be protective of the most sensitive receptors. The consideration of soil background in a risk assessment will allow a focus on the risks actually associated with a release or site. Therefore, it is important to clearly identify and explain the assumptions and uncertainties made when establishing default or site-specific BTVs. In contrast with default BTVs, site-specific BTVs are developed for each individual site and are often not readily applicable elsewhere. The use of a BTV, especially a site-specific BTV, should be approved by the proper regulatory agency prior to the completion of the risk assessment.

4.5.2.1 Physical setting

When using soil BTVs for a specific area, there is uncertainty about the physical setting because geochemical and physical processes are important to consider along with geological characteristics.

To use default soil background values, both physical and chemical parameters need to be similar at both the site and the locations used during the background study. Based on the amount of information needed, the level of detail required to characterize a highly variable site does not typically allow the comparison to a default BTV. For sites with highly variable soil properties, equally detailed site-specific BTV are most appropriate for comparison. Background concentrations will be inherently variable depending on spatial distribution of the samples. This variability is rooted largely in the heterogeneous nature of soil. Before using a site-specific BTV in an area of interest that has high natural variability, confirm that the variability pairs well with the data used to generate the site-specific BTV (Section 3.7).

Assuming the geochemical and physical processes that determine background, the chemical concentration for a constituent of interest can guide how the background concentration is determined. An assumption of aerial deposition may lead to the collection of surface soil samples in the study used to develop default BTV. On the other hand, knowing that chemicals such as metals, are naturally occurring, one could assume that metals are widely spread throughout the soil column. In that case, it would, therefore, be appropriate to compare samples from various sample depths to a default BTV (while also considering soil depths that are appropriate to the exposure of the human or ecological receptors being evaluated in the risk assessment). Comparing site data to a BTV should follow the same assumptions and sampling schemes. This may limit the applicability of a default BTV.

It is important to consider if the geology of the location where a default BTV was developed is similar to the location that is being evaluated to ensure that the value was established from an area with similar geological characteristics. In many cases, this will be less of an issue with site-specific soil BTV development due to a more narrowed focus on choosing an area that has similar geology. If the area of interest falls in an area with a high degree of geological variation, the development or use of site-specific BTV may not be approved by the lead oversight agency. The remainder of geological considerations should have previously been addressed during both the sampling (Section 9) and establishment of default soil BTV (Section 3.7).

There is also uncertainty in potentially changing conditions of background reference areas over time due to unexpected events (for example, flooding, wildfires, runoff). Areas prone to natural disasters or in a dynamic environment will experience temporal changes. Data collected at one of these locations may represent only a snapshot in time and the applicability of a BTV may be limited. Additionally, unknown off-site activities that increase or decrease background concentrations may underestimate or overestimate naturally occurring constituents. Site-specific BTV may be needed; however, site-specific values generated from previous studies carry additional uncertainties that increase with the age of the data and whenever different parties conduct the studies. Additional care in the form of geochemical evaluations (Section 5) or environmental forensics (Section 7) may be needed to determine whether the site data are representative of site-specific background.

4.5.2.2 Methods

The statistical methods used will influence the calculated BTV (refer to Section 11). The study's handling of nondetect values (Section 11.3), outliers (Section 11.5), and sample location each carry uncertainty into the risk assessment. Methods and assumptions used in determining a BTV balance between two outcomes: false positive or false negative error rates. Methods to estimate BTV typically attempt to reduce the number of false positives or to reduce the number of false negatives. Understanding how the BTV is established and the assumptions made are essential for their scientifically sound use. It is important to ensure that the analytical chemistry method used to quantitate COPC in a soil sample is sensitive enough to detect reliably amounts of COPC smaller than the correspondent risk-based concentrations (for example, screening levels, remedial goals). Much uncertainty can come from the exclusion of certain chemicals due to missing or unknown risk-based screening values or lack of sampling for those chemicals. If chemicals were previously eliminated due to data limitations, the consequences for excluding those chemicals should be discussed (USEPA 1989).

As technology and laboratories' ability to detect lower concentrations continually improve, previously established default BTV can become out of date. For more information on detection limits and their incorporation in soil background risk assessments, refer to Section 10.

Soil collection method is a consideration that is made early in the DQO process and will impact how site data can be used in the risk assessment. According to ITRC (2020), although discrete and ISM samples could be combined with some caveats, in practice, there are no established methods for combining discrete and ISM data. The underlying theory between the two types of sampling methods is different enough that the results of the average would conceptually not make sense. Section 9.4 lists advantages and disadvantages of different sample types.

4.5.3 Professional judgment

A large part of professional judgment will be addressing the assumptions noted in Section 4.5.2. Professional judgment should be used to make decisions regarding sampling or whether a default background study is appropriate for comparison. If site conditions fail to meet the parameters/assumptions of the default BTV study and are, therefore, unable to be used, developing site-specific values is an option.

Section 4.1 describes options available for comparison of site concentration and a default BTV. The data and considerations used in the development of the default BTV and the site's dataset for a compound will identify some options as inappropriate for use. Professional judgment and communication with the regulatory agency are essential when considering background concentrations of chemicals in a risk assessment.