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Region VIII

REGION 8 SUPERFUND TECHNICAL GUIDANCE

No. **RA-03**: **Contaminants of Concern** September 1994
Risk Assessment (Short Title / Key Words)

TITLE: ***Evaluating and Identifying Contaminants of Concern for Human Health***

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SUMMARY

This regional guidance is intended to clarify the evaluation process for selecting contaminants of concern (COCs) for the human health risk baseline risk assessment process, as generally described in EPA's Risk Assessment Guidance for Superfund (RAGS). This guidance sets forth objective criteria (e.g., comparison to background levels, frequency of detections, essentiality, etc.) and provides explicit recommendations on measuring attainment for each of these criteria in order to evaluate whether or not a site-related contaminant should be retained as a COC.

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EVALUATING AND IDENTIFYING CONTAMINANTS OF CONCERN FOR HUMAN HEALTH

OBJECTIVE

The objective of this Regional Guidance is to outline and describe a selection process whereby preliminary lists of potentially site-related contaminants can be evaluated for elimination or retention as contaminants of concern (COCs) for the human health baseline risk assessment.

BACKGROUND

For certain sites, the list of potentially site-related contaminants and exposure pathways may be lengthy. Carrying a large number of contaminants through a quantitative risk assessment may be complex, and may consume significant amounts of time and resources. In these cases, a selection process should be used to further reduce the number of contaminants of potential concern for each medium to a reasonable and relevant amount. EPA's Risk Assessment Guidance for Superfund (RAGS): Part A (EPA, 1989a) describes general qualitative criteria which should be considered when evaluating contaminants for either elimination or retention as contaminants of concern (COCs) for the baseline risk assessment. The purpose of this Regional Guidance is to present those criteria in a selection process which can be applied on a generic basis to USEPA Superfund sites in Region 8. This Regional Guidance will also present detailed examples of how several criteria presented in the upcoming flow chart can be quantitatively evaluated.

DISCUSSION

EPA's RAGS: Part A (EPA 1989a) recommends that the following criteria be evaluated when determining which chemicals on the initial list of all potentially site-related contaminants should be retained or eliminated as COCs for the Baseline Risk Assessment:

1. Essential Nutrients
2. Exceedance of background concentrations
3. Detection frequency
4. Mobility, persistence, and bioaccumulation

5. Exceedance of ARARs
6. Historical Evidence
7. Concentration and Toxicity

Figure 1 presents a selection process which addresses each of the criteria present in RAGS: Part A (EPA 1989a) and can be used to arrive at a final list of COCs for the risk assessment evaluation. This selection process is explained below:

1. **Is the contaminant an essential nutrient?**

If the contaminant identified is an essential nutrient and is present at low concentrations (i.e., only slightly elevated above naturally occurring levels or below established EPA toxicity values or FDA recommended nutritive levels), it does not need to be considered further in the risk assessment. Examples of EPA toxicity values which can be used are the slope factors or Reference Doses listed on EPA's Integrated Risk Information System (IRIS) Database or Health Effects Assessment Summary Tables (HEAST). The FDA's Recommended Daily Allowance (RDA) of essential dietary minerals and safe supplemental levels of dietary minerals can be used as nutritive indexes. Table I shows the essential elements/nutrients which can be considered in the COC selection process and their corresponding toxicity value or safe nutritive level.

TABLE I

Element/nutrient	Dose (mg/kg/day)
Calcium	14*
Phosphorous	14*
Magnesium	5.7*
Iron	.26*
Zinc	.3 i
Iodine	.0021*
Copper	.037 h
Manganese	.005 i
Fluoride	.06 i
Sodium	No data
Chromium III	1 i
Potassium	.57*
Chloride	.51*
Selenium	.005 i
Molybdenum	.005 i
Cobalt	.06 e

*US RDA (recommended daily allowance) of essential minerals or FDA supplemental dietary mineral levels, for a 70kg adult.

i = IRIS
h = HEAST
e = EPA provisional toxicity value

2. **Does the contaminant exceed background concentrations?**

For the purpose of comparing site-related contamination to background levels of chemicals, EPA's RAGS: Part A (EPA, 1989a) divides background types into naturally occurring chemicals and anthropogenic chemicals. Examples of anthropogenic chemicals include pesticides from agriculture, lead from auto emissions, and PAHs from fossils fuel combustion. This COC selection process will automatically include comparisons of site-related contaminants to naturally occurring chemicals. Inclusion of site comparisons to background anthropogenic chemicals (whether localized or ubiquitous) will be considered on a site-specific basis.

The USEPA has issued guidance for ground water detection monitoring programs being conducted under the Resource Conservation and Recovery Act (RCRA). This guidance, entitled "Statistical Analysis of Ground-Water Monitoring Data at RCRA Facilities" (EPA, 1989b) provides a conceptual framework for determining and applying an appropriate statistical method for comparison of background and contaminated groundwater data. This statistical guidance could also be applied to soil background comparisons.

The RCRA guidance details two types of statistical comparisons that can be made between samples collected from background and contaminated sites. These two type of statistical comparisons are (1) distributional tests, and (2) extreme value tests. Distributional tests are statistical tests used to determine whether the central tendencies of two groups of data are similar. Extreme values tests are statistical tests used to compare individual results (i.e., results from an affected site) to results from a distribution (e.g., the distribution of the background data). **The objective of the statistical analysis for the risk assessment is to determine if site concentrations differ significantly from background concentrations, <u>on the average</u>.** Therefore, distributional tests, and generally not extreme value tests, should be chosen for risk analysis.

Figure 2 is an **example** of a flow chart (based on the RCRA guidance) for comparing background and site concentrations using distributional tests, which depend on the percent of detected values for each parameter and distribution of background and site concentrations.

The data analysis process was divided in this way because each statistical method can handle a certain number of detected values before the method becomes ineffective in determining a significant difference. The risk assessor is not limited, however, to those statistical tests shown in Figure 2. The choice of appropriate test should be based on the distribution of the data, the percent of non-detects in background and/or site data, the presence of multiple detection limits, etc.

Caution: Statistical comparisons of data sets may be inappropriate and the interpretation of those tests meaningless when the number of non-detects are high (e.g., > 50%) and the sample sizes are small (e.g., N < 20). It is recommended that a statistician be consulted on the appropriateness of the statistical test(s) especially for unstable data sets.

At some sites, a concern may exist for "hot spots" or situations where a small proportion of the site is contaminated above background, yet application of distributional tests show no difference between site and background levels of randomly sampled data. For example, there may have been too few samples collected at the site, so that perhaps only one or two measurements are elevated above background. One method for dealing with this situation is to compare each site measurement to a "hot measurement" concentration value (Gilbert and Simpson, 1992). This "hot measurement" value can be a risk based number, a standard, or some function of the background data (e.g., upper tolerance limit). Generally the hot measurement value should be selected to identify small areas that may individually present excessive health risk beyond that of average site-wide exposures. If one or more site measurements equal or exceed the hot measurement value, the contaminant can be retained as a COC, and proceed to the Toxicity Concentration Screen. Continue with the screening process below for those potential COCs that exceed background concentrations.

3. **Detection Frequency**

A contaminant with a detection frequency of $5% proceeds into the toxicity concentration screen. A chemical with < 5% detection frequency is *further evaluated with up to **three** additional criteria listed below*.

NOTE: The following three criteria are recommended in EPA's RAGS,

Part A (EPA 1989a) for the further selection of COCs for the baseline risk assessment. However, the practicable utility of these criteria for this purpose is limited, and Region VIII does not recommend their routine in-depth use.

4. Persistence, Mobility, and Bioaccumulation

A chemical is retained as a COC if it is either highly persistent or highly mobile. Several physico-chemical parameters describe these processes, including environmental half-life, water solubility, log K_{ow} and K_{oc}. The log octanol/water partition coefficient (log K_{ow}) is the ratio of the chemical concentration in octanol to the concentration in water. A high log K_{ow}, typically greater than 3, indicates higher concentrations in the octanol rather than in the water. K_{oc} is an equilibrium constant that measures the partitioning between organic carbon and water. K_{oc} is useful for describing mobility potential because it correlates better with adsorption to soil and sediment. A chemical's mobility is generally proportional to its water solubility and inversely proportional to K_{ow} and K_{oc}. Chemicals with log $K_{ow} < 2.7$ and $K_{oc} < 50$ are considered to be highly mobile, while chemicals with log $K_{ow} > 3$ and $K_{oc} > 500$ generally have low mobility potential.

In general, chemicals with Log $K_{ow} > 3$ begin to have a high bioaccumulation potential. It is immediately obvious that these criteria would only exclude chemicals with K_{ow}'s of 2.8 and 2.9. For this reason, it is recommended that the parameters of bioaccumulation or mobility **not** be used to exclude contaminants.

Persistence is measured by the number of days required to reduce a chemical's concentration by one-half through biotic and abiotic degradation processes. Chemicals are considered highly persistent if their half-lives in water are > 90 days, and not persistent in water with half-lives < 30 days.

PARAMETER POTENTIAL FOR ACTION:

$K_{ow} > 3$: Bioaccumulation

OR

$K_{ow} < 2.7$: Mobility
$K_{oc} < 50$: "

Do not use criteria for eliminating contaminants. Proceed to Toxicity Concentration Screen.

$t_{1/2} > 90$: Persistence

Proceed to Toxicity Concentration Screen.

5. **Do concentrations exceed Health- and Technology-based Numerical criteria (ARAR's)?**

Numerical criteria are federal and duly-promulgated state environmental and public health laws, requirements, or regulations for the protection of human health from exposure to chemical contaminants. If the maximum contaminant concentration or the 95th percent upper confidence limit of the mean for chemical concentrations exceeds health- and technology-based criteria, proceed to the Toxicity Concentration Screen.

6. **Is there Historical Evidence of the Compound at the Site?**

Chemicals reliably associated with site activities based on historical information generally should not be eliminated from the quantitative risk assessment. If remaining potential COCs have historical use and release, proceed to the Toxicity Concentration Screen.

7. **TOXICITY/CONCENTRATION SCREEN**

{ all retained potential COCs are to be processed through this final screening step to obtain the final list of COCs }

EPA's RAGS: Part A (EPA 1989a) suggests consideration of a toxicity concentration screen based on calculating individual risk factors and eliminating chemicals which do not contribute, for example, more than 1% of the total risk. If one or more chemicals are present at very high concentrations, this method may lead to the elimination of chemicals which do not contribute much to the overall risk, but exceed health-based levels, none the less. For this reason, it is recommended that the toxicity concentration screen be based on generic Preliminary Remediation Goals (PRGs) as calculated by RAGS: Part B (EPA 1991). Region III's Risk-Based Concentration Tables spreadsheet is one such example of screening levels based on the RAGS: Part B PRG equations. EPA's Soil Screening Levels (SSLs) are another example, albeit more conservative. Either the maximum contaminant value or the 95 percent upper confidence limit of the arithmetic mean can be compared to the PRG for exposure to that media. Use of the latter value is recommended as the more scientifically rigorous value for use in

these comparisons. If the contaminant concentration is less than the PRG/10 for non-carcinogens, or less than the PRG calculated at a 10^{-6} risk for carcinogens, the contaminant may be excluded as a COC. For non-carcinogens, the comparison value of 0.1 PRG ensures that any additive adverse effects will still result in a hazard index of less than one.

RECOMMENDATION

For sites where the preliminary list of potentially site-related contaminants is quite lengthy, it is recommended that the selection process outlined and described above be used to evaluate the contaminants and derive the final list of COC's which will be carried through the baseline risk assessment. Use of this selection process, however, may not be appropriate for all sites. It takes a fair amount of time and resources to evaluate each preliminary contaminant in this selection process. Therefore, sites with smaller lists of preliminary contaminants may find it easier to just to carry all of the identified contaminants through the quantitative risk assessment evaluation.

REFERENCES

1. Gilbert, R.O. and Simpson, J.S. (1992). Statistical Methods for Evaluating the Attainment of Cleanup Standards, Volume 3: Reference-Based Standards for Soils and Solid Media, PNL-7409 V3, Rev.1, Pacific Northwest Laboratory, Richland, WA.

2. U.S. Environmental Protection Agency (EPA). 1989a. Risk Assessment Guidance for Superfund, Vol.1: Human Health Evaluation Manual. Office of Emergency and Remedial Response. EPA/540/1-89/002.

3. U.S. Environmental Protection Agency (EPA). 1989b. Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities, Interim Final Guidance. Office of Solid Waste, Waste Management Division. EPA/530-SW-89-026, April 1989.

4. U.S. Environmental Protection Agency (EPA). 1991. Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Part B: "Development of Risk-based Preliminary Remediation Goals". Office of Emergency and Remedial Response. OSWER Directive 9285.7-01B.

Figure 1 - Selection Process for COC's

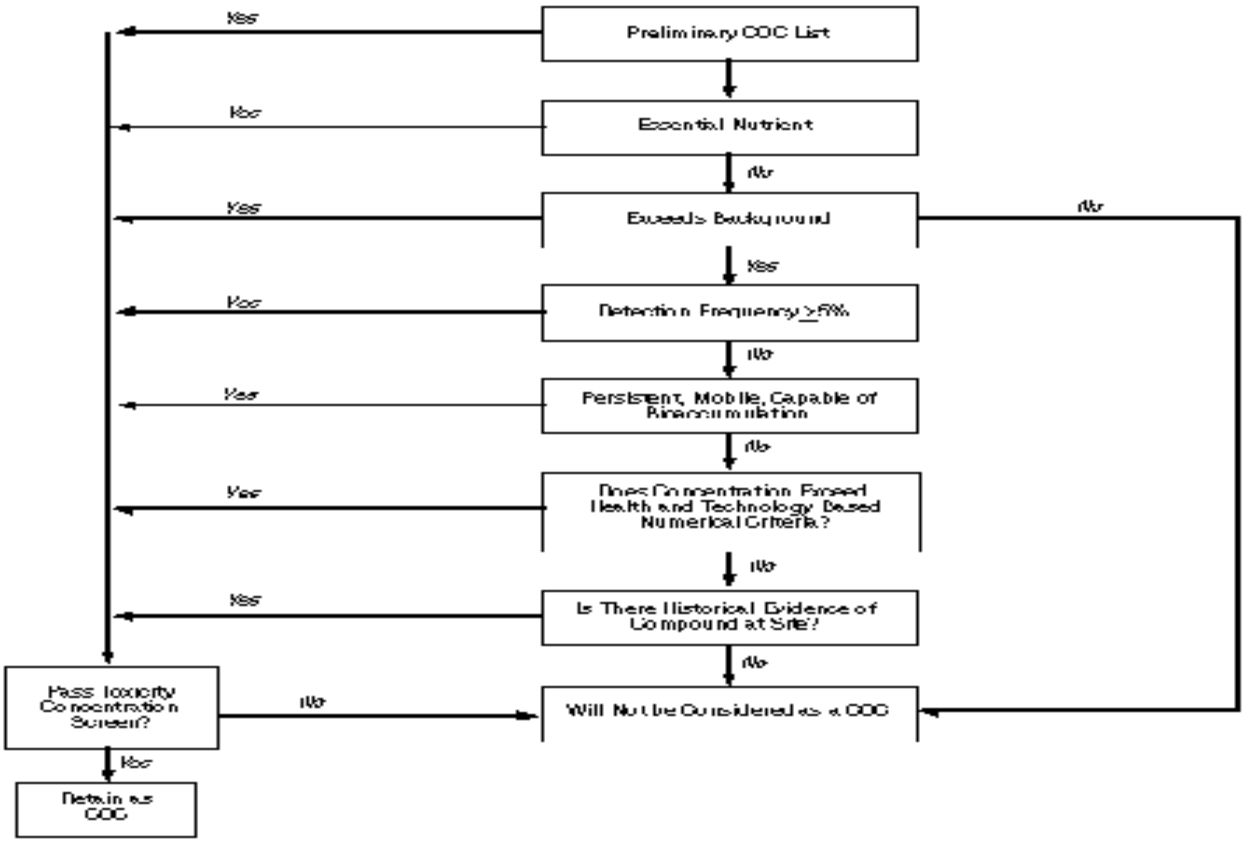
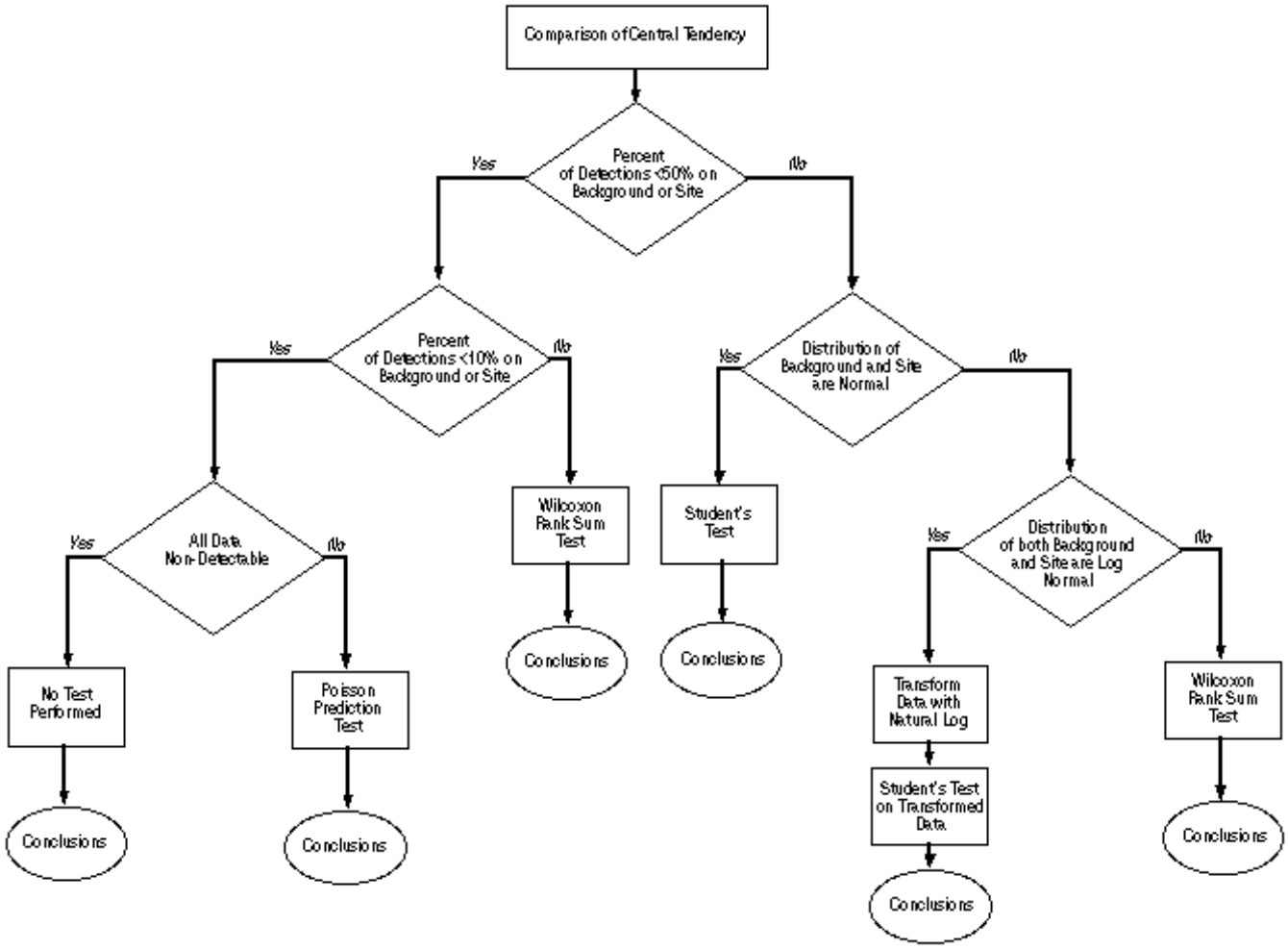
Figure 2 - Decision Tree for Comparisons of Central Tendency