http://www.epa.gov/region4/waste/sf/programs/riskassess/healtbul.html
Last updated on Friday, September 16, 2011

Region 4: Superfund

Human Health Risk Assessment Bulletins-- Supplement to RAGS

INTERIM

Human Health Risk Assessment Bulletins

Suggested citation:
USEPA. 2000. Supplemental Guidance to RAGS: Region 4 Bulletins, Human Health Risk Assessment Bulletins. EPA Region 4, originally published November 1995, Website version last updated May 2000 (currently under revision).

Updates:

September 2008: Update: EPA released a Regional Screening Table back in May of 2008. The Regional Screening Table (RSL) has replaced the Region 3 RBC table, the Region 6 Screening Level table, and the Region 9 PRG table. The RSL was updated and the website location has been changed. Region 4 recommends the use of the Regional Screening Level table for all risk assessment screening on Superfund projects.

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1. HUMAN HEALTH INTRODUCTION

This guidance has been developed by Region 4 risk assessment staff as a supplement to the basic agency-wide guidance, Risk Assessment Guidance for Superfund, Volumes I and II, (RAGS). There are numerous guidance documents issued by EPA program offices and the Office of Research and Development on the topic of quantitative risk assessment. This guidance, Supplemental Guidance to RAGS: Region 4 Bulletins, is issued for exclusive and limited application to risk assessments at hazardous waste sites in EPA's Region 4. These Bulletins supercede all previous risk assessment guidance issued from the Waste Management Division.

The purpose of these bulletins is to clarify and extend RAGS as interpreted and applied by Region 4. In rare cases, as noted in individual Bulletins, this regional guidance will be at odds with RAGS. It should be noted that EPA headquarters has and may again issue agency-wide supplements to the RAGS guidance. These agency-wide supplements to RAGS will be considered as components of the basic risk assessment guidance. RAGS and RAGS supplements issued by EPA headquarters are available from the Superfund Document Center, Washington D.C. 202/260-9760 or the National Technical Information Service, Springfield, VA 703/487-4650 or 1-800-553-6847. Region 4 bulletins are available on request from the Office of Technical Services (OTS) 404/347-1586.

Region 4 bulletins are intended as guidance to all risk assessors preparing human health assessments (and ecological assessments in a separate issuance) for CERCLA NPL sites and federal sites in this region. RAGs and these bulletins may also serve as guidance for risk assessments conducted for RCRA facilities, certain CERCLA removal actions and non-NPL remedial actions. However, such applications are not specifically required in any formal program guidance or regulation.

This guidance does not constitute rulemaking by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. Region 4 reserves the right to take action that is at

variance with this guidance. The intent of this guidance is to aid in the development of high-quality, single draft risk assessments consistent with the criteria of the OTS in its oversight role.

1. Assessment Guidance for Superfund: Volume I-Human Health Evaluation Manual (Part A), Interim Final, Dec. 1989, EPA/540/1-89/002.
2. RAGS/HHEM (Part B), Development of Risk-based Preliminary Remediation Goals, Interim, Dec. 1991. EPA/540/R-92/003.
3. RAGS/HHEM (Part C), Risk Evaluation of Remedial Alternatives, Interim, Dec. 1991. EPA/540/R-92/004.
4. RAGS: Volume II-Environmental Evaluation Manual, Interim Final, March 1989. EPA/540/1-89/001.

2. DATA COLLECTION AND EVALUATION

An objective of the data collection and evaluation effort is to produce data that can be used to assess risks to human health. Each site is unique; data collection strategies for one site may not be appropriate for another site. Carefully designed sampling and analysis plans minimize the subsequent need to caveat the environmental data during the data evaluation phase.

This bulletin includes a bibliography with acronyms for each entry. The acronyms are used in the bulletin along with page numbers for reference purposes.

Data Collection

To ensure that Baseline Risk Assessment (BRA) data needs are met those needs must be evaluated early in the site planning stage. The data necessary for conducting a defensible BRA, in many cases, is a subset of the data required for adequate characterization of a hazardous waste site. RAGS (Chapters 4 & 5), Region 4 HHRA 3 - Exposure Assessment, and EPA's Guidance for Data Useability in Risk Assessment are useful tools for development of the sampling and analysis plan. A site is neither equal to nor confined by the boundaries of any specific property that may give the site its name. The site may not occupy the full extent of the property (e.g., areas that are uncontaminated), but it may also extend beyond the property boundaries. Therefore, the sampling and analysis plan must consider that a hazardous waste site consists of all contaminated portions within the property or use boundaries and any other locations to which contamination may have migrated.

In development of the sampling strategies the current and potential future receptors and their assumed exposure units should be considered. Various combinations of biased, random or systematic sampling designs may be used for the establishment of sample locations (DU p. 65, RAGS p. 5-18). Background samples should be collected for each medium in which on-site samples are collected. The Region 4 Office of Technical Services (OTS) may be contacted regarding approval of specific sampling strategies.

Detection Limits

Detection limits should be reviewed before the sampling and analysis plan is completed to ensure that they do not exceed levels of concern to human health (i.e., preliminary remediation goals) and the environment. See Region 4 HHRA 5 for more information on levels of concern.

Turbidity in Ground Water

Ground water sampling procedures have historically created problems due to high levels of turbidity. For example, direct push technologies are not appropriate for obtaining ground water samples for analysis of some chemicals, especially inorganics. Additionally, high turbidity in samples collected from traditional monitoring wells often results when a bailer is used to collect the sample; low-flow pump sampling protocols, developed by EPA, are effective in reducing this problem.

Surface Soil Sampling

OTS defines surface soil available for direct human contact as the top 12 inches. Surface soil samples should be collected from the most contaminated portion of the surface soil. For example, semi-volatiles are usually found in the top few inches whereas volatile organics may be found in the 9-12 inch depth.

Data Evaluation

Chapter 5 of RAGS includes a discussion on the data evaluation process and should be consulted during the development of the sampling and analysis plan as well as the BRA.

RAGS presents the option to reduce the number of chemicals addressed in the BRA (RAGS, p. 5-20). The concentration-toxicity screening recommended in RAGS should not be used (RAGS, p. 5-23). At sites with high risk levels the concentration- toxicity screen often eliminates chemicals which would contribute significantly to an unacceptable risk.

Chemicals of Potential Concern (COPCs) are chemicals that are carried through the risk assessment process. OTS has designed a screening process to identify COPCs which are most likely to contribute to an unacceptable risk.

The process of selecting COPCs includes a toxicity screen that utilizes risk-based concentrations. OTS recommends using Region 3's Risk-Based Concentration (RBC) table. The RBC table is updated periodically and the most recent version should be used. The RBC table provides screening values for environmental media at carcinogenic risk levels of 1x10-6 and non-carcinogenic hazard quotients (HQ) of 1. The Region 3 RBC screening values for non-carcinogenic chemicals need to be adjusted to a level equivalent to a HQ of 0.1 before being used to select COPCs. In the RBC table the non-carcinogenic screening values are denoted in the table by the letter "N" whereas the carcinogenic screening values are identified with the letter "C".

Some chemical values in the RBC table are based on carcinogenic end points that would be more conservatively screened as non-carcinogens based on a HQ of 0.1. If one of the following chemicals is detected, the non-carcinogenic RBC should be calculated using the methodology presented in the text accompanying the RBC table with a target hazard quotient of 0.1.

Captafol Epichlorohydrin Hexachloroethane Hexachlorobutadiene 2,4,6-Trinitrotoluene

COPC Selection Process

1. The data for each chemical should be sorted by medium. For this purpose surface soil and subsurface soil should be considered as separate media. As previously indicated, surface soil is considered the top 12 inches. Identify the background data for each medium.
2. For any data which have qualifiers, decide if the qualified data should be retained. Do not eliminate data based on "J" qualifiers (RAGS, p. 5-11).
3. Present a table with all detected chemicals in the format of the attached sample table. The table should be placed in the BRA in lieu of RAGS Exhibit 5-6 (RAGS, p. 5-25). For each chemical detected in each medium, provide the following parameters in a table format.

Frequency of detection

Range of detection limits

Arithmetic average background concentration

Arithmetic average of detected concentrations

Range of detected concentrations

Risk-based screening value

Basis for elimination or selection as a COPC

- Eliminate chemicals as COPCs based on comparison to blanks (RAGS, p. 5-16).
- Compare maximum detected concentrations in surface soils to the residential screening values for soil ingestion determined at a risk level of 1x10-6 or hazard quotient level of 0.1. Eliminate the chemical as a COPC for human exposures if the concentration is less than the screening level. Industrial screening

Trichloroethylene	5/6	1-5	5-300	160	NA	XX	yes/A
Semi-Volatile Organic Compounds (SVOCs) (ug/l): Pyrene	3/6	5	30 - 95	63	NA	XX	yes/D
Pesticides/PCBs (ug/l): DDT	1/6	0.1	0.12	0.12	NA	XX	no/B
Inorganics (Metals) (mg/l): Arsenic	2/6	5	15 - 50	35	12	XX	yes/A
Chromium	3/6	5	40 - 96	55	12	XX	yes/A

Footnotes:
OPC = Chemical of Potential Concern (yes/no)

- A = Risk-Based Concentration (i.e., 1x10-6 for carcinogens and HQ=0.1 for non-carcinogens)
- B = Risk-Based Concentration (i.e., 1x10-6 for carcinogens and HQ=0.1 for non-carcinogens)
- C = The maximum detected concentration did not exceed twice the average background concentration.
- D = The chemical is a member of a chemical class which contains other COPCs
- E = The chemical is an essential nutrient and professional judgement was used before the chemical was eliminated as a COPC.
- F = No RBC available to quantify risk; other data indicate chemical may be of concern

VOC = Volatile Organic Compounds
SVOC = Semi-Volatile Organic Compounds
ug/l = micrograms/liter
The purpose of this table is to serve as a formatting example.

3. TOXICITY ASSESSMENT

The toxicity assessment presents and discusses chemical-specific quantitative dose-response data for the Chemicals of Potential Concern (COPCs). EPA's National Center for Environmental Assessment (NCEA, formerly OHEA/ECAO) is charged with developing chronic toxicity values in cooperation with other Agency programs for hazardous chemicals in which the Agency has regulatory interest. For many of the hazardous chemicals that occur as waste at Superfund sites, EPA has performed a toxicity assessment and has made the information available.

Sources of Toxicity Data

The Integrated Risk Information System (IRIS) is the primary source of toxicity data. If a toxicity value is available in IRIS, it should be used. Information in IRIS supersedes all other sources (RAGS, Vol. I, Part A, p. 7-13).

Toxicological information developed and submitted after inclusion of a toxicity value for a given chemical in IRIS will be considered as a basis for an alternate toxicity value. However, departing from the IRIS value is not appropriate in cases where the information submitted consists of data previously evaluated in the development of that toxicity value.[1]

If a value is not available in IRIS, the next source to be consulted should be the most recent update of the Health Effects Assessment Summary Tables (HEAST). HEAST is available from the National Technical Information Service (NTIS), Springfield, VA at (703)487-4650 or 1-800-553-6847.

If values for a chemical are in neither IRIS nor HEAST, the Office of Technical Services (OTS) should be consulted to determine if other sources are appropriate.

Therefore, the hierarchy for toxicity values is:

1. IRIS
2. HEAST
3. Other sources as approved by OTS

These other sources may include provisional values developed by NCEA, Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles, World Health Organization (WHO) documents or publications in the primary toxicological literature.

Toxicity values for particular chemicals may once have been included in IRIS or HEAST but were later removed. In general, it is appropriate to use these toxicity values in the risk assessment if no replacement value exists in approved sources. However, if such a chemical becomes a risk driver at a particular site, the risk assessor should consult Region 4 OTS personnel.

Chemicals without Toxicity Values

Quantitative risk assessment cannot be performed for chemicals without chronic toxicity values. Nonetheless, they should not be excluded as COPCs on this basis, and their potential health effects should be considered in the risk assessment.

When a chemical has no chronic toxicity values, the value of a chemical that is related both chemically and toxicologically, i.e structure-activity relationship, is used. For example, the RfD for naphthalene should be used for 2-methylnaphthalene.[2] If a risk assessor is unsure about the use of a surrogate, an inquiry should be made to the OTS.

There are chemicals for which chronic toxicity values or surrogate values are not available. Such a chemical may come to be considered a potential risk driver at a site based on its relatively high acute toxicity. In this case, best professional judgement should be applied in determining the overall site risk and the appropriate remedial response.

The implications of the presence of chemicals without toxicity values and their absence from the quantitative risk assessment should be discussed in the Uncertainty Section (RAGS, Vol. I, Part A, p. 7-19).

Presentation of Toxicity Values

Toxicity values used in the risk assessment are best presented in a table. A sample table is shown on the page following this guidance. Note that Reference Doses (RfDs) and Cancer Slope Factors (CSFs) are presented together. For systemic toxicants (non-carcinogens), the table should present the critical effect upon which the RfD is based, the Uncertainty Factors (UF), Modifying Factors (MF), the confidence level and the source (e.g. IRIS, HEAST) of the toxicity value. For carcinogens, the table should present the type of cancer observed in the toxicological study, the animal species used in the study and the weight-of-evidence classification. Inhalation and oral toxicity values should be presented where appropriate, generally in the same table (see sample at the end of the section). Dermal toxicity values should also be presented, and it is often more convenient to present dermal values in a separate table. Because the number of significant figures reflects some of the uncertainty associated with the toxicity data, values should be presented with the same number of significant figures as in their sources.

A short description of all known toxic effects of each COPC in non-technical language should be included in the toxicity assessment. For non-carcinogens, this description should identify the critical effect andthe concentration below which adverse effects in humans are not expected. For carcinogens, the description should discuss the range of tumor types observed and whether the toxicity value was derived from human or animal data (RAGS, Vol. I, Part A, p. 7-20). The description can be brief for those chemicals that occur in the IRIS database or ones that have a Toxicological Profile document prepared by ATSDR. Appropriate references should be included.

Inhalation Toxicity Values

Inhalation toxicity values should be used for fugitive dust emissions and chemicals volatilized from soil. Region 4 OTS also recommends the use of the inhalation toxicity values for estimates of volatile organic chemical (VOC) exposure from showering.[3]

Inhalation toxicity values are given as reference concentrations for systemic toxicants or air unit risks for carcinogens. The conversion to an inhalation reference dose or inhalation slope factor is accomplished as follows: For non-carcinogens: For carcinogens:

Dermal Toxicity Values

Most RfDs and slope factors are expressed as the administered dose. Exposure estimates for the dermal pathway are expressed as absorbed dose. Hence, for the dermal pathway, it is usually necessary to adjust oral toxicity values from administered to absorbed doses.

RAGS provides a method for adjusting RfDs and Cancer Slope Factors for dermal absorption (RAGS, Vol. I, Part A, pp. A-2 to A-3).

When appropriate published data are available on oral absorption of a specific chemical, they should be used to make the administered/absorbed dose adjustment. Aside from the primary toxicological literature, a good source of absorption efficiencies is the ATSDR Toxicological Profile of the chemical in question.

Appendix A of RAGS states that in the absence of chemical-specific data, an absorption efficiency of 5% should be used as a protective assumption (RAGS, Vol I, Part A, p. A-3). The Region 4 OTS believes that the default assumption of 5% absorption efficiency is too conservative and leads to an exaggerated importance of the dermal route for most chemical exposures. In the absence of chemical-specific data, the Region 4 OTS has adopted the following oral absorption efficiencies as interim default values:

80% for volatile organic chemicals (VOCs)

50% for semi-volatile organic chemicals (SVOCs)

20% for inorganic chemicals Although it is most preferable to use chemical-specific absorption efficiencies, the default values above are considered reasonable assumptions based on the limited scientific literature. Until the science is more complete or an EPA-wide policy is developed, these values should be considered as Region 4 guidance.

Toxicity of Dioxin and cPAHs

Chlorinated Dioxins and Furans

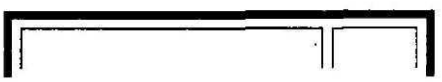
Toxicity assessment for chlorinated dioxin and furan congeners is performed with Toxicity Equivalence Factor (TEF) methodology. The total amount of toxic dioxin and furan congeners present at a site is usually expressed as toxic equivalents (TEQ) of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) present. The following TEFs should be used to convert concentrations of dioxin and furan congeners to TEQ of TCDD.[4]

Current information can be found at the following link: www.who.int/ipcs/assessment/tef_update/en/

Carcinogenic PAHs

As an interim procedure, until more definitive Agency guidance is established, Region 4 has adopted a similar TEF methodology for carcinogenic Polycyclic Aromatic Hydrocarbons (cPAHs) on the Target Compound List. These TEFs are based on the relative potency of each compound relative to that of benzo(a)pyrene (BaP). The following TEFs should be used to convert each cPAH concentration to an equivalent concentration of BaP.[5]

Toxic Equivalence Factors for cPAHs



Compound	TEF
Benzo(a)pyrene	1.0
Benzo(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
Benzo(k)fluoranthene	0.01
Chrysene	0.001
Dibenzo(a,h)anthracene	1.0
Indeno(1,2,3-c,d)pyrene	0.1

Although RAGS, Volume I, Part A recommends that dermal exposure to carcinogenic PAHs not be assessed quantitatively, the Region 4 OTS differs from this viewpoint. Dermal contact with cPAHs should be assessed using the appropriate oral CSFs and their TEFs with a default absorption efficiency of 50% (SVOCs).

As with the ingestion and dermal routes, concentrations of inhaled cPAHs should be assessed as benzo(a) pyrene equivalents. Provisional inhalation toxicity values for the carcinogenic PAHs have been developed by NCEA based on a hamster inhalation study using benzo(a)pyrene. The inhalation slope factor is 3.1 (mg/Kg-day)-1 and the inhalation unit risk is 0.88 (mg/m3)-1.[6]

Total Petroleum Hydrocarbons (TPH) TPH occurs with some frequency at hazardous waste sites, especially at military bases.

TPH generally represents gasoline and diesel fuel. TPH may include benzene or other VOCs. A full scan analysis should be performed for at least 20% of the samples at a hazardous waste site to ensure that all hazardous chemicals have been detected. This full scan will detect some chemicals that comprise TPH.

The numbers in the table above were developed for the state of Massachusetts as provisional toxicity values for classes of chemicals in TPH.[7] These chemicals are not considered carcinogens. Reference doses are taken from surrogate compounds. In the absence of official Agency guidance for TPH toxicity, NCEA believes that this method is appropriate, and it has been adopted by Region 4.[8]

To use the toxicity values given in the table above, a specific analytical procedure must be used. This procedure consists of specific analysis by gas chromatograph and Flame Ionization Detector/Photo Ionization Detector (FID/PID) to determine which chain length fractions are present. Details of these analytical methods and other questions regarding TPH risk assessment should be referred to the Region 4 OTS.

Bioavailability Factors

The actual bioavailability of environmental chemicals is usually not determined in the risk assessment process. Health-based toxicity values are typically developed using intake levels (i.e. administered doses in controlled animal studies). The portion that is actually absorbed by the receptor, therefore bioavailable, is not determined in these studies. Hence, the actual bioavailability is irrelevant as long as risk conclusions are based on comparisons between calculated human intakes and toxicity values developed from administered doses, i.e. equivalent and appropriate dose-response comparisons.

Bioavailability questions arise as to potential differences in uptake levels under study conditions versus environmental exposure conditions, i.e. the matrix effect. Chemical-specific data is rarely sufficient to quantify this difference in bioavailability for all receptors under their varied exposure conditions. Therefore, Region 4 does not accept any adjustment in the 100% bioavailability default assumption in the exposure equation without extensive supporting data. Specific questions on the use of bioavailability factors should be referred to OTS.

Subchronic Toxicity Values

RAGS indicates that a subchronic exposure period can vary from 2 weeks to 7 years (RAGS, Vol. I, Part A, p. 8-11). In some scenarios, adult exposure duration may be relatively short. The most widely used example is the construction worker. Subchronic RfDs (where available) should be used for these relatively short (< 1 year) duration adult exposure scenarios. If a subchronic RfD is not available from EPA, the chronic RfD should be used.

EPA has defined the childhood exposure period from ages 0 to 6 years old. Although the strict definition of a subchronic RfD suggests that subchronic RfDs should be used to derive HQ values for children, the Region 4 OTS does not consider subchronic RfDs sufficiently protective for children. Therefore, subchronic toxicity values are not to be used for childhood exposure.

Assessment of Lead

EPA recommends using the current version of the Integrated Exposure Uptake Biokinetic (IEUBK) model to assess lead exposures to children 7 years of age and less.[9,10,11] A copy of this model and supporting documentation can be ordered from the National Technical Information Service (NTIS) at (703)487-4650 or 1-800-553-6847.

The screening level for lead in soil is 400 mg/kg.[12] and the action level in drinking water is 15 g/ .[13] If either of these levels is exceeded, the model should be used to assess childhood exposure to lead.

If the risk assessor believes that there may be significant adult exposure to lead in a situation where exposure to children is not occurring, the Region 4 OTS should be consulted.

(Adobe PDF Reader Required)
Sample Table for Presentation of Toxicity Values (PDF, 11K)

References

1. Use of IRIS Values in Superfund Risk Assessment, OSWER Directive 9285.7-16, December 21, 1993, Farland WH, Longest HL.
2. Risk Assessment Issue Paper for: Feasibility of RfD Derivation for 2-Methylnaphthalene, NCEA, July, 1993 and Memorandum, Proposed Provisional RfD for 2-Methylnaphthalene, NCEA, July, 1995
3. Guidance on Estimating Exposure to VOCs During Showering, July 10, 1991, Patton DE.
4. Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs) and 1989 Update, EPA/625/3-89/016, March, 1989.
5. Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons, EPA/600/R93/089, July 1993.
6. Risk Assessment Issue Paper: Status of Inhalation Cancer Unit Risk for Benzo(a)Pyrene, NCEA, December 22, 1994.
7. Interim Final Petroleum Report: Development of Health-Based Alternative to the Total Petroleum Hydrocarbon (TPH) Parameter, August, 1994, Office of Research and Standards, Massachusetts Department of Environmental Protection and ABB Environmental Services.
8. State of Massachusetts Method to Evaluate Petroleum Contaminated Soils, Jan. 20, 1995, Dollarhide JS and Velazquez S.
9. Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), ver. 0.99d, USEPA 9285.7-15-2, PB94-501517.
10. Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children, 1994, EPA/540/R-93/081, PB93-963510.
11. Technical Support Document: Parameters and Equations Used in Integrated Exposure Uptake Biokinetic Model for Lead in Children (v 0.99d), 1994, EPA/540/R-94/040, PB94-963505.
12. Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities, OSWER Directive.#9355.4-12, July 14, 1994, Laws EP.
13. Action Level for Lead in Drinking Wate, OERR, OWPE, June 21, 1990.

1. Human Health Introduction
2. Data collection and Evaluation
3. Toxicity Assessment
4. Exposure Assessment
5. Risk Characterization
6. Development of Risk-Based Remedial Options

4. EXPOSURE ASSESSMENT

The objective of the exposure assessment is to estimate the type and magnitude of exposures to chemicals of potential concern present at or migrating from a site. The exposure assessment should include the following sections.

- Characterization of Exposure Setting
- Identification of Exposure Pathways
- Quantification of Exposure

This bulletin includes a bibliography with acronyms for each entry. The acronyms are used in the bulletin along with page numbers for reference purposes.

Characterization of Exposure Setting

The general physical characteristics of the site and of the populations on and near the site should be presented in this section. Populations should be addressed relative to those characteristics that influence exposure, such as location and activity patterns. In addition, the presence of sensitive subpopulations should be discussed. Current receptors as wells as potential future receptors should be considered.

Identification of Exposure Pathways

This section should identify the pathways by which the previously identified populations may be exposed. A conceptual site model should be developed for each site. The conceptual site model should include known and suspected sources of contamination, types of contaminants and affected media, known and potential routes of migration, and known or potential human and environmental receptors. In addition to the narrative discussion of pathways, a figure following the format of the example presented in the RI/FS guidance should be presented (RI/FS, p. 2-8). Institutional controls (e.g., fences or guards) should not be used as the justification for elimination of a pathway in the baseline risk assessment for current or future scenarios. However, institutional controls may be used in the determination of exposure frequency for current exposure.

Generally, the baseline risk assessment should consider the reasonably anticipated future land use. However, it may be valuable to evaluate risks associated with a variety of future land uses especially where there is some uncertainty regarding the anticipated future land use (LUG, p. 6).

Residential Scenario

A future residential scenario should be included in the baseline risk assessment unless there is a strong reason to do otherwise, e.g., an industrial area expected to remain industrial or a wetland. If the future residential scenario is not included, a justification for not considering the residential scenario should be presented and prior approval from the Remedial Project Manager in consultation with the Office of Health Assessment (OTS) should be obtained.

If the groundwater is considered to be potable, the future consumption of groundwater for residential purposes should be evaluated. Ingestion and inhalation of chemicals volatilized from groundwater should be considered (RAF, p. 1).

Trespasser Scenario

The evaluation of current exposure scenarios at most sites should include the trespasser or visitor scenario. Region 4 considers the typical trespasser to be an adolescent aged 7-16 (10 year exposure duration) with a body weight of 45 kg as representative of this age range. Trespasser exposure frequency should consider site-specific factors such as distance from the site to residences and the attractiveness of the site to the trespasser.

Evaluation of Soil Pathways

The baseline risk assessment should address surface soils as those from land surface to 1 foot below land surface for exposures resulting from direct contact. Contamination in subsurface soils should be evaluated relative to protection of groundwater from soil leaching. Also, if site specific conditions are appropriate, an evaluation of subsurface soils relative to short-term exposures for a construction worker may be evaluated. Additionally, if subsurface soil is likely to be moved to the surface, then the long-term direct exposure to this soil should be evaluated. OTS should be consulted prior to evaluation of subsurface soil exposure pathways.

This consultation should preferably take place during the project scoping phase to ensure adequate data are available for the evaluation.

Quantification of Exposure

Chemical-specific exposure for each exposure pathway identified should be presented in terms of the mass of substance in contact with the body per unit body weight per unit time - most often as mg chemical per kg body weight per day or mg/kg-day. These exposure estimates are termed "intakes." Standard intake equations are presented in Section 6 of RAGS.

The "exposure unit" concept should be considered in the development of the exposure assessment. An exposure unit denotes an areal extent of a receptor's movements during a single day - analogous to the idea of a home range used in an ecological risk assessment. For example, a young child under the age of 6 will probably range over the area of a typical residential lot (less than a acre) where a maintenance worker at a large industrial facility may move about the entire facility. This concept is important in determining which samples should be included in the calculation of the exposure point concentration.

The exposure assessment for a large site with one or more small areas of highly contaminated media should consider a hot-spot analysis. The hot-spot analysis involves the use of the Fraction Ingested (FI) Term applied to the appropriate exposure unit. Contact the Office of Health Assessment for site-specific hot-spot exposure assessment applicability.

EPA has established default assumptions for many parameters in an effort to establish consistency. However, default values are undesirable when the determination of realistic current risks are sought. Data based on observation of receptor populations are most desirable in deriving site specific current exposure assumptions. Future exposure assumptions may be represented by default values that reflect behavior resulting in reasonable maximum exposure (RME) risk estimates. This Bulletin presents intake assumptions which reflect RME scenarios. The accompanying Risk Characterization Bulletin indicates that quantitative risk values should be developed for central tendency exposure (CTE) assumptions. The Agency will be preparing formal guidance on CTE default assumptions.

Concentration Term

The concentration term in the intake equation is an estimate of the arithmetic average concentration for a chemical within an exposure unit. Ideally the exposure point concentration should be the true average concentration within the exposure unit. However, because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used as the concentration term (CCT, p. 1). However, if the calculated UCL exceeds the maximum detected value the maximum detected value should be used as the concentration term (RAGS, p. 6-22). It is generally reasonable to assume that Superfund soil sampling data are lognormally distributed (CCT, p. 4).

Region 4 makes an exception to the use of the UCL as the exposure point concentration for groundwater. Groundwater exposure point concentrations should be the arithmetic average of the wells in the highly concentrated area of the plume (ERGC, p. 3). Also, it is unacceptable to use data from filtered ground water samples in a baseline risk assessment (RAGS, p. 6-27).

Chemical degradation or attenuation should not be considered in the baseline risk assessment unless site-specific chemical-specific data are available and prior approval from the RPM and OTS is obtained.

Air concentration can be represented by modeled values or long-term monitoring. PM10 values should be used for particulates.

Ingestion

Soil ingestion rates should be as follows: Resident Child 200 mg/day; Resident Adult 100 mg/day; Worker 50 - 480 mg/day, depending on type of worker assumed (SDEF, pp. 6, 10). Sediments in an intermittent stream should be considered as surface soil for the portion of the year the stream is without water. In most cases it is unnecessary to evaluate human exposures to sediments covered by surface water.

Potable water ingestion rates should be as follows: Resident Child 1 /day; Resident Adult 2 /day; Worker 1 /day (EFH, p. 2-3).

Ingestion of 50 ml/hour of surface water should be used for exposures to water during swimming (RAGS, p. 6-

36). Intake rates for exposure to surface water during wading should be 50 ml/hour for children 1-6 and 10 ml/hour for adolescents and adults.

Fish ingestion is highly variable and site specific intake assumptions are most desirable since data vary greatly. Default fish ingestion should be considered at 54 g/day (in combination with a exposure frequency of 350 days/year) unless a site specific fish ingestion study has been performed (SDEF, p. 12). If a site specific fish study is used to determine the number of meals of fish consumed during a given time period, Region 4 suggests a default value of 145 grams per meal. If site-specific information indicates the presence of subsistence fisherman, an evaluation of their greater intake should be considered.

Dermal Contact

The areas of the body receiving exposure to the specific media should be considered and summed to obtain the skin surface area. The Exposure Factors Handbook (EFH), Dermal Exposure Assessment: Principles and Applications (DERMAL), or RAGS can be used to determine the surface area of each portion of the body which is exposed.

Where chemical-specific information is not available, dermal absorption factors of 1.0% for organics and 0.1% for inorganics should be used as defaults in determining the uptake associated with dermal exposure to contaminated soils (this includes the soil matrix effect).

The soil to skin adherence factors given in RAGS (1.45 mg/cm2 to 2.77 mg/cm2) are outdated. New data in this area indicates that this range should be changed to 0.2 mg/cm2 to 1.0 mg/cm2 (DERMAL, p. 8-17). The value of 1.0 mg/cm2 is considered appropriate for evaluation of RME intake assumptions.

Dermal-aqueous permeability coefficients should be obtained from tables or calculated from equations presented in EPA's Dermal Guidance. Table 5-3 should be used for inorganics and Table 5-7 should be used for organics (DERMAL, pp. 5-9, 5-39). Additionally, ATSDR Toxicological Profiles are an acceptable alternative source.

Inhalation

The default inhalation rate for adults is 20 m3/day (SDEF, p. 6). Children should be considered at 15 m3/day (EFH, p. 3-41). Site specific inhalation rate should be considered based on the worker activity at the site; 20 m3/work day is an acceptable default (SDEF, p. 10).

Exposure to VOCs During Showering

It should be assumed that showering exposure is equivalent to exposure from ingestion of two liters of contaminated water per day based on the recommendation of The Risk Assessment Forum (RAF, p. 1-2). This method includes exposures via inhalation and dermal routes and is applied to adolescents and adults.

Exposure Frequency

Default exposure frequency should be considered at 350 days/year for residents and 250 days/year for workers (SDEF, pp. 5, 9). Current exposure assumptions should represent conservative actual occurrences as accurately as possible. As a default, Region 4 believes swimming frequency in the southeast should be 45 days/year. However, for backyard swimming pools, in the southern portion of the region, a substantial increase in exposure frequency over the 45 days/year should be considered based on site specific information. Region 4 recommends that a backyard swimming pool exposure frequency of 90 days/year should be considered.

Exposure Duration

A 30 year exposure duration (6 years as a child and 24 years as an adult) is the default assumption for residents. Default worker exposure duration should be 25 years (SDEF, pp. 5, 9).

Use of the Fraction Ingested (FI) Term

Office of Technical Services should be consulted regarding the use of the FI term. A FI of 100% is used except in hot spot exposure assessments and in the evaluation of exposures to intermittent streams.

Bibliography

assessments for sites in this region.

One topic mentioned in the risk characterization guidance should now be addressed in Region 4 risk assessments. Quantitative risk values should be developed for "central tendency" exposure assumptions. The central tendency values may be derived as point estimates by use of the standard RAGS exposure equations or through a Monte Carlo type approach with the 50 percentile (and 95 percentile if desired) risk values presented and discussed in an uncertainty sub-section of the risk characterization section. The preamble to the Superfund regulation states that EPA will use reasonable maximum exposure (RME) values and assumptions in its risk assessments and that RME estimates will provide the basis for the development of protective exposure levels for future use.[2]

Therefore, Region 4 considers RME based on point estimates as the high end values on which the remedial decision will be based. The central tendency and high end values derived by Monte Carlo analysis is information to provide perspective for the risk manager and compliance with Agency guidance.

Risk values other than those representing RME and discussion of these values should be placed in the uncertainty sub-section of the risk characterization section. Tables with side-to-side central tendency and RME risk levels in the body of the report tend to confuse the reader as to the risk basis for remedial decisions. In this regard, it should be noted that the Agency is working on, but has not yet derived, formal guidance on central tendency default exposure assumptions or on the use of Monte Carlo in risk assessments.

References

1. EPA Risk Characterization Program: Policy and Guidance for Risk Characterization, Browner, CM, EPA Administrator, March 21, 1995.
2. Federal Register Vol. 55, No. 46, pg. 8712, March 8, 1990. National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule, 40 CFR part 300.

6. DEVELOPMENT OF RISK-BASED REMEDIAL OPTIONS

Throughout the process of remediating a hazardous waste site, a risk manager uses a progression of increasingly site-specific acceptable media levels, so called "cleanup levels," for the consideration of remedial alternatives. Prior to conducting a risk assessment, Preliminary Remediation Goals are established for hazardous substances believed to be on site based on past disposal practices or extant sampling. Region 4 OTS suggests that a range of Remedial Goal Options (RGOs) be presented for the risk manager's use as the last component of the risk assessment. From the RGOs the risk manager chooses Remediation Levels for the Chemicals of Concern, and these numbers, derived from RGOs, are addressed in the Feasibility Study and are included in the Proposed Plan and the Record of Decision.

This bulletin details the development of remedial goal options and discusses the development of acceptable media levels that will ultimately become the RLs for the Chemicals of Concern.

Preliminary Remediation Goals

Preliminary Remediation Goals (PRGs) are either risk-based levels of hazardous chemicals in various environmental media or Applicable or Relevant and Appropriate Requirements (ARARs). PRGs are established early in the Remedial Investigation (RI) process, usually at scoping, and serve as the basis for the RI Sampling and Analysis Plan. PRGs help to ensure that (1) proposed analytical methods will have adequate quantitation limits; (2) the site will be adequately characterized; and (3) the remedial alternatives can achieve the target cleanup levels identified in the FS.

Any PRGs based on ARARs should be clearly identified. Calculation of risk-based PRGs should be performed in accordance with RAGS, Part B.1 Region 3 Risk-Based Concentration Tables were developed utilizing this part of RAGS. PRGs are not intended to be remediation levels.

Chemicals of Concern

Chemicals of Concern (COCs) are the Chemicals of Potential Concern (COPCs) that significantly contribute to a pathway in a use scenario for a receptor (e.g. hypothetical future child resident, current youth trespasser, current adult construction worker, etc.) that either (a) exceeds a 10-4 cumulative site cancer risk; or (b) exceeds a non-carcinogenic hazard index (HI) of 1. Note: generally, a 10-4 cumulative site risk level and an HI of 1 are used as the remediation "trigger." The exact level used as the "trigger" is at the discretion of the risk manager.2 The carcinogen "trigger" represents the summed risks to a receptor considering all pathways, media, and routes per land use scenario. The HI represents the total of the hazard quotients (HQs) of all COPCs in all pathways, media, and routes to which the receptor is exposed. If the HI exceeds 1.0, then more specific HIs should be developed by summing HQs of COPCs with Reference Doses (RfDs) based on toxic effects on the same target organs. This specific target-organ based HI should form the basis of COC selection.

Chemicals are not considered as significant contributors to risk and therefore are not included as COCs if their individual carcinogenic risk contribution is less than 10-6 and their non-carcinogenic HQ is less than 0.1 (See 1 for more on COPCs).

If the level of a chemical in a given medium exceeds a state or federal chemical-specific ARAR, that chemical should also be included as a COC.

Remedial Goal Options

The baseline risk assessment should include a section that outlines the remedial goal options (RGOs) for the chemicals and media of concern. This section should include both ARARs and human health-based cleanup goals for all media considered.

The RGO section should contain a table of media-specific cleanup levels for each COC in each land use scenario evaluated in the baseline risk . The table should include cleanup levels for 10-6, 10-5 and 10-4 cancer sk levels for each carcinogenic COC. The table should also include cleanup levels for each non-carcinogenic COC at HQ levels of 0.1, 1 and 3.

Region 4 has adopted the HQ range of 0.1 to 3 to span the uncertainty, perhaps an order of magnitude or greater, inherent in the RfD (RAGS, p. 7-5). The range of cleanup levels is provided to address specific chemicals for which the use of an HQ greater or lesser than 1 may be justified.

These cleanup levels should be presented for each COC in each medium and use scenario. The table should also contain any chemical-specific ARARs (state and federal), appropriate groundwater protection levels, state guidance concentrations and any other cleanup numbers that may pertain.

This table permits the risk manager to view the cleanup goals in a relatively condensed way. The purpose is to provide the risk manager with a range of risk-related media levels as a basis for developing remediation aspects of the Feasibility Study and Proposed Plan or the Corrective Measures Study.

RAGS, Part B is not appropriate for the development of RGOs because it does not consider site specific exposure information. Also, the Region III Risk-Based Concentrations should not be presented as RGOs.

Calculation of RGOs

There are two methods to calculate RGOs. The first method consists of combining the intake levels of each chemical by a receptor from all appropriate routes (i.e. inhalation, ingestion and dermal) for a particular medium within a use scenario and rearranging the site-specific risk equations to solve for the concentration term. Generic equations for soil and groundwater are given in the appendix at the end of this section.

The second method is a simplified method based on site specific exposure data. The ratio between the target risk and the calculated risk due to a specific chemical in a specific medium is used. This ratio provides the multiplier for the Exposure Point Concentration (EPC), and this product is the RGO.

Hence, the proportion is:

EPC[chemical i]/Calculated Risk[chemical i] = RGO[chemical i]/Target Risk

Therefore, RGOs can be calculated for the target risks of 10[-6], 10[-5] and 10[-4] as follows:

RGO[chemical i] = EPC[chemical i] x Target Risk/Calc.Risk[chemical i]

Target HQs of 0.1, 1 and 3 can be substituted for the target risks, the calculated HQs substituted for the calculated risks, and this same equation used to develop RGOs for non-carcinogens.

It is important to include all significant pathways and routes (ingestion, inhalation, dermal contact) in the calculation of RGOs. If all pathways and routes have not been included and summed in the risk assessment, it may not be appropriate to use the second method discussed above. The risk assessor is encouraged to consult with OTS in this regard.

Remediation Levels

Remediation Levels (RLs) are chosen by the risk manager for COCs and are included in the Proposed Plan and the Record of Decision. These values, derived from RGOs, are considered the levels the remedial actions intend to achieve.

ReferencesAppendix

Equations for Calculating RGOs

Below are the equations used to calculate RGOs for soil derived by rearrangement of the standard risk equations.

$$RGO = \frac{TR \times BW \times AT \times 10[6](mg/Kg)}{EF \times ED \times FI \times (A + B + C)}$$

For carcinogens:
A = ingestion pathway = CSF[oral] X IR[oral] B = dermal pathway = CSF[dermal] X SSA X SAF X DA C = inhalation pathway = CSF[inhalation] X IR[inhalation] X (1/VF + 1/PEF)

For non-carcinogens:
A = ingestion pathway = 1/RfD[oral] X IR[oral} B = dermal pathway = 1/RfD[dermal] X SSA X SAF X DA C = inhalation pathway = 1/RfD[inhalation] X IR[inhalation] X (1/VF + 1/PEF)

RfDoral Oral Reference Dose
RfDdermal Dermal Reference Dose
RfDinhalation Inhalation Reference Dose

CSForal Oral Cancer Slope Factor CSFdermal Dermal Cancer Slope Factor CSFinhalation Inhalation Cancer Slope Factor

Below are the equations used to calculate RGOs for groundwater derived by rearrangement of the standard risk equations.

$$RGO = \frac{TR \times BW \times AT}{EF \times ED \times FI \times (A + B + C)}$$

For carcinogens:

A = ingestion pathway = CSF[oral] X IR[oral}
B = dermal pathway = CSF[dermal] X ET X SSA X PC X 10[-3](Li/cm[3])
C = inhalation pathway = CSF[inhalation] X IR[inhalation surrogate]

For non-carcinogens:

A = ingestion pathway = 1/RfD[oral] X IR [ORAL]
B = dermal pathway = 1/RfD[dermal] X ET X SSA X PC X 10[-3](Li/cm[3])

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C = inhalation pathway = 1/RfD[inhalation] X IR[inhalation surrogate]

TR Target Risk/Hazard (unitless)
BW Body Weight (Kg)
AT Averaging Time (days)
EF Exposure Frequency (days/yr)
IRoral Daily Water Ingestion Rate
ED Exposure Duration (yr)
PC Permeability Coefficient (cm/hr)
ET Exposure Time (hr/day)
IR inhalation surrogate
    Daily volume of water contributing
    to showering exposure of surrogate
FI Fraction Ingested (unitless)
SSA Exposed Skin Surface Area (cm2)
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