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OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

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MEMORANDUM

SUBJECT: Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions

FROM: Don R. Clay
Assistant Administrator

TO: Directors, Waste Management Division
Regions I, IV, V, VII, VIII
Director, Emergency and Remedial Response Division
Region II
Directors, Hazardous Waste Management Division
Regions III, VI, IX
Director, Hazardous Waste Division,
Region X

Purpose

The purpose of this memorandum is to clarify the role of the baseline risk assessment in developing Superfund remedial alternatives and supporting risk management decisions.

Specifically, the following points are made in the memorandum:

- Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10(-4) and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted.

- Other chemical-specific ARARs may also be used to determine whether a site warrants remediation.

- A risk manager may also decide that a baseline risk level less than 10(-4)is unacceptable due to site specific reasons and that remedial action is warranted.

- Compliance with a chemical-specific ARAR generally will be considered protective even if it is outside the risk range (unless) there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure).

- The upper boundary of the risk range is not a discrete line at 1 X 10(-4), although EPA generally uses 1 x 10(-4) in making risk management decisions. A specific risk estimate around 10(-4) may be considered acceptable if justified based on site-specific conditions.

- The ROD should clearly justify the use of any non-standard exposure factors and the need for remedial action if baseline risks are within the generally acceptable risk range. The ROD should also include a table listing the final remediation goals and the corresponding risk level for each chemical of concern.

Background

The 1990 National Contingency Plan (NCP) (55 Fed. Reg. 8665-8865(Mar. 8, 1990)) calls for a site-specific baseline risk assessment to be conducted, as appropriate, as part of the remedial investigation(Section 300.430(d)(1)). Specifically, the NCP states that the baseline risk assessment should "characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain" (Section 300.430(d)(4)). The primary purpose of the baseline risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health and the environment posed by the site and any uncertainties associated with the assessment. This information may be useful in determining whether a current or potential threat to human health or the environment exists that warrants remedial action.

The "Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual - Part A" (HHEM)(EPA/540/1-89/002) provides guidance on how to conduct the human health portion of the baseline risk assessment. Volume II of the "Risk Assessment Guidance for Superfund" the "Environmental Evaluation Manual" (EPA/540/1-89/001) and the companion manual, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference" (EPA/600/3-89/013) provide guidance on conducting the environmental portion of the baseline risk assessment. Other

pertinent guidance includes the "Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA" (RI/FS guidance, EPA/540/G-89/004), which describes how the baseline risk assessment fits into the overall RI/FS process. "Guidance on Preparing Superfund Decision Documents" (ROD guidance) (EPA/624/1-87/001) provides information on how to document the results of the baseline risk assessment in the ROD.

Objective

The objective of this memorandum is to provide further guidance on how to use the baseline risk assessment to make risk management decisions such as determining whether remedial action under CERCLA Sections 104 or 106 is necessary. This memorandum also clarifies the use of the baseline risk assessment in selecting appropriate remedies under CERCLA Section 121, promotes consistency in preparing site-specific risk assessments, and helps ensure that appropriate documentation from the baseline risk assessment is included in Superfund remedy selection documents.

Implementation

RISKS WARRANTING REMEDIAL ACTION

Whenever there is a release or substantial threat of release of a hazardous substance into the environment (or a release or threat of release into the environment of a pollutant or contaminant "which may present an imminent and substantial danger to public health or welfare"), Section 104(a)(1) of CERCLA provides EPA with the authority to take any response action consistent with the National Contingency Plan it deems necessary to protect public health or welfare or the environment. Section 106 of CERCLA grants EPA the authority to require potentially responsible parties (or others) to perform removal or remedial actions "when the President determines that there may be an imminent and substantial endangerment to the public health or welfare or the environment because of an actual or threatened release of a hazardous substance form a facility."

As a general policy and in order to operate a unified Superfund program, EPA generally uses the results of the baseline risk assessment to establish the basis for taking a remedial action using either Section 104 or 106 authority. EPA may use the results of the baseline risk assessments to determine whether a release or threatened release poses an unacceptable risk to human health or the environment that warrants remedial action and to determine if a site presents an imminent and substantial endangerment. The risk assessment methodology for all sites should be the same regardless of whether the RI/FS or remedial

design and remedial action is performed by EPA or potentially responsible parties.

Generally, where the baseline risk assessment indicates that a cumulative site risk to an individual using reasonable maximum exposure assumptions for either current or future land use exceeds the 10(-4) lifetime excess cancer risk end of the risk range, action under CERCLA is generally warranted at the site. For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10(-4), action generally is not warranted, but may be warranted if a chemical specific standard that defines acceptable risk is violated or unless there are noncarcinogenic effects or an adverse environmental impact that warrants action. A risk manager may also decide that a lower level of risk to human health is unacceptable and that remedial action is warranted where, for example, there are uncertainties in the risk assessment results. Records of Decision for remedial actions taken at sites posing risks within the 10(-4) to 10(-6) risk range must explain why remedial why remedial action is warranted.

The cumulative site baseline risk should include all media that the reasonable maximum exposure scenario indicates are appropriate to combine and should not assume that institutional controls or fences will account for risk reduction. For noncarcinogenic effects of toxicants, unacceptable risk occurs when exposures exceed levels which represent concentrations to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, as appropriate to address teratogenic and developmental effects.

Chemical specific standards that define acceptable risk levels (e.g., non-zero MCLGs, MCLs) also may be used to determine whether an exposure is associated with an unacceptable risk to human health or the environment and whether remedial action under Section 104 or 106 is warranted. For ground water actions, MCLs and non-zero MCLGs will generally be used to gauge whether remedial action is warranted.

EPA uses the general 10(-4) to 10(-6) risk range as a "target range" within which the Agency strives to manage risks as part of a Superfund cleanup. Once a decision has been made to make an action, the Agency has expressed a reference for cleanups achieving the more protective end of the range (i.e., 10(-6)), although waste management strategies achieving reductions in site risks anywhere within the risk range may be deemed acceptable by the EPA risk manager. Furthermore, the upper boundary of the risk range is not a discrete line at 1 x 10(-4), although EPA generally uses 1 x 10(-4) in making risk management decisions. A

specific risk estimate around 10(-4) may be considered acceptable if justified based on site-specific conditions, including any remaining uncertainties on the nature and extent of contamination and associated risks. Therefore, in certain cases EPA may consider risk estimates slightly greater than 1 x 10(-4) to be protective.

When an ARAR for a specific chemical (or in some cases a group of chemicals) defines an acceptable level of exposure, compliance with the ARAR will generally be considered protective even if it is outside the risk range (unless there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure). Conversely, in certain situations EPA may determine that risks less than 1 x 10(-4) are not sufficiently protective and warrant remedial action.

Where current conditions have not resulted in a release posing risks that warrant action but there is a significant possibility that a release will occur that is likely to result in an unacceptable risk, remedial action may also be taken. The significance of the potential future release may be evaluated in part based on the quantities of material at the site and the environmental setting.

RISKS CONSIDERED IN RISK MANAGEMENT DECISION

As noted above, both current and reasonably likely future risks need to be considered in order to demonstrate that a site does not present an unacceptable risk to human health and the environment. An adequate consideration of future risk may necessitate the assessment of risks assuming a land use different from that which currently exists at the site. The potential land use associated with the highest level of exposure and risk that can reasonably be expected to occur should be addressed in the baseline risk assessment. Further, this land use and these exposure assumptions should be used in developing remediation goals.

The preamble to the NCP states that EPA will consider future land use as residential in many cases. In general, residential areas should be assumed to remain residential; and undeveloped areas can be assumed to be residential in the future unless sites are in areas where residential land use is unreasonable. Often the exposure scenarios based on potential future residential land use provide the greatest risk estimates (e.g., reasonable maximum exposure scenario) and are important considerations in deciding whether to take action (55 Fed. Reg. at 8710).

However, the NCP also states that "the assumption of future residential land use may not be justifiable if the probability

that the site will support residential use in the future is small. "Sites that are surrounded by operating industrial facilities can be assumed to remain as industrial area unless there is an indication that this is not appropriate. Other land uses, such as recreational or agricultural, may be used, if appropriate. When exposures based on reasonable future land use are used to estimate risk, the NCP preamble states that the ROD “should include a qualitative assessment of the likelihood that the assumed future land use will occur" (55 Fed. Reg. at 8710).

Unacceptable environmental risks also may prompt remedial action and may occur where there is no significant risk to human health. Threats or potential threats to sensitive habitats, such as wetlands, and critical habitats of species protected under the Endangered Species Acts are especially important to consider when determining whether to take an action under CERCLA Section 104 or 106. Ambient Water Quality Criteria for aquatic organisms are chemical-specific standards that will generally be considered when determining whether to take an action based on the environmental risk of releases to surface waters.

NO-ACTION DECISIONS

If the baseline risk assessment and the comparison of exposure concentrations to chemical-specific standards indicates that there is no unacceptable risk to human health or the environment and that no remedial action is warranted, then the CERCLA Section 121 cleanup standards for selection of a Superfund remedy, including the requirement to meet applicable or relevant and appropriate requirements (ARARs), are not triggered. CERCLA section 121 (a) requires only that those remedial actions that are "determined to be necessary ... Under section 104 or ... 106 ... be selected in accordance with section 121." If EPA determines that an action is necessary, the remedial action must attain ARARs, unless a waiver is invoked. Of course, sites that do not warrant action under CERCLA sections 104 or 106 may warrant action under another State or Federal statute, such as RCRA subtitle D requirements for the appropriate closure of a solid waste landfill.

The decision not to take action at an NPL site under section 104 and 106 should also be documented in a ROD. The decision documentation process should include the preparation of a proposed plan for public comment, ROD and eventually a closeout report and Federal Register deletion notice.

POINT OF DEPARTURE WHEN ACTION WARRANTED

Once remedial action has been determined to be warranted,

the results of the baseline risk assessment may be used to modify preliminary remediation goals. These preliminary goals are developed at scoping based on ARARs and the 10(-6) cancer risk point of departure pursuant to NCP section 300.430(e)(2)(I).

USE OF BASELINE RISK ASSESSMENT TO MODIFY PRELIMINARY REMEDIATION GOALS

Remediation goals developed under CERCLA section 121 are generally medium-specific chemical concentrations that will pose no unacceptable threat to human health and the environment. preliminary remediation goals are developed early in the RI/FS process based on ARARs and other readily available information, such as concentrations associated with 10(-6) cancer risk or a hazard quotient equal to one for noncarcinogens calculated from EPA toxicity information. These preliminary goals may be modified based on results of the baseline risk assessment, which clarifies exposure pathways and may identify situations where cumulative risk of multiple contaminants or multiple exposure pathways at the site indicate the need for more or less stringent cleanup levels than those initially developed as preliminary remediation goals. In addition to being modified based on the baseline risk assessment, preliminary remediation goals and the corresponding cleanup levels may also be modified based on the given waste management strategy selected at the time of remedy selection that is based on the balancing of the nine criteria used for remedy selection (55 Fed. Reg. at 8717 and 8718).

EARLY AND INTERIM ACTIONS

Early operable unit actions (e.g., hot spot removal and treatment) and interim actions (e.g., temporary storage or ground water plume containment) may be taken to respond to an immediate site threat or to take advantage of an opportunity to significantly reduce risk quickly (55 Fed. Reg. at 8705). For example, an interim containment action may be particularly useful early in the process for complicated ground water remedial actions, where concentrations greater than MCLS provide a good indication that remediation of a potential drinking water source is necessary; such quick remedial action is important to prevent further spread of the contaminant plume while a final ground water remedy is being developed.

Early and interim action RODs do not require a completed baseline risk assessment, although enough information must be available to demonstrate the potential for risk and the need to take action. Data sufficient to support the interim action decision can be extracted from the ongoing RI/FS for the site and set out in a focused feasibility study or other appropriate document that includes a short analysis of a limited number of

alternatives (55 Fed. Reg. at 8704). These data should include a summary of contaminants of concern, concentrations and relevant exposure information. A discussion should accompany these data explaining the need for immediate remedial action based on the presence of contamination that, if left unaddressed in the short-term, either contributes immediate risk or is likely to contribute to increased site risk or degradation of the environment/ natural resources. The early and interim action RODs should note that some exposure pathways at the site may not be addressed by the action.

An interim action ROD eventually must be followed by a subsequent ROD for that operable unit based on the complete RI/FS, that includes the baseline risk assessment, in order to document long-term protection of human health and the environment at that portion of the site. The interim action ROD, however, should demonstrate qualitatively (and quantitatively if possible) that there is a risk or potential for risk and explain how the temporary measures selected will address a portion of this risk.

DOCUMENTATION OF BASELINE RISK ASSESSMENT RESULTS IN THE ROD

The Summary of Site Risks section of the ROD should include a discussion of the risks associated with current and future land use and a table presenting these risk levels for each exposure medium (e.g., direct contact with soil by potential future residents exposed via incidental soil ingestion and dermal contact). In some situations, risks from exposure via more than one medium (e.g, soil and drinking water) will affect the same potentially exposed individual at the same time. It is appropriate in these situations to combine the risk that an individual may be exposed to from a site.

In addition to summarizing the baseline risk assessment information, the ROD (except no-action RODs) should include how remedial alternatives will reduce risks by achieving cleanup levels through treatment or by eliminating exposures through engineering controls for each contaminant of concern in each appropriate medium.

The Comparative Analysis should include a discussion of each of the nine criteria; consideration of risk is part of the discussion of several of the criteria. The discussion of overall protection of human health and the environment should include a discussion of how the remedy will eliminate, reduce, or control risks identified in the baseline risk assessment posed through each pathway and whether exposure levels will be reduced to acceptable levels. For example, if direct human contact with contaminated soil is identified as a significant risk at a site, the ROD (except no-action RODs) should indicate how the selected

remedy will eliminate or control exposures to ensure protection of human health. The discussion of long-term effectiveness and permanence should include, where appropriate, an assessment of the residual risk from untreated residual waste remaining at the site. The short-term effectiveness discussion should address risks during remedial action to those on-site and nearby.

Finally, that part of the Decision Summary in the ROD that focuses on the selected remedy should show:

- the chemical-specific remediation level and corresponding chemical-specific risk level(s) to be attained at the conclusion of the response action and the points (or area) of compliance for the media being addressed; and

- The lead agency's basis for the remediation levels (e.g., risk calculation, ARARs).

The attached table, "Remediation levels and Corresponding Risks," provides a direct means of displaying this information for health risks and, where appropriate, environment protection (Table 1). The table should be completed for all media for which the ROD selects final cleanup levels. The table should serve as a summary of text in the selected remedy section of the ROD Decision Summary. For interim action RODs, only qualitative statements may be possible.

Additional guidance on the baseline risk assessment and its role in remedy selection is available from several sources. For guidance on the baseline risk assessment contact:

David Bennett, Chief
Toxics Integration Branch (OS-230)
Hazardous Site Evaluation Division
Office of Emergency and Remedial Response
phone: (FTS) or (202) 475-9486.

For additional guidance on the interaction of the baseline risk assessment and Superfund remedy selection, contact:

David Cooper
Remedial Operations and Guidance Branch (OS-220W)
Hazardous Site Control Division
Office of Emergency and Remedial Response
phone: (FTS) 398-8361
commercial phone: (703) 308-8361.

For guidance on enforcement-lead sites contact:

Stephen Ells
Guidance and Evaluation Branch (OS-510)
CERCLA Enforcement Division
Office of Waste Programs Enforcement
phone: (FTS) or (202) 475-9803.

TABLE 1
Remediation Goals and Corresponding Risks[a]

Final Remediation Levels[b]					Corresponding Risk Levels[c]	
					Chemical-Specific RME Risk[d]	
Medium	Chemical	Remediation Level[e]	Point of Compliance[f]	Basis of Goal	Cancer	Non-Cancer
SOIL	A	2.0 ppm	All facility	HI	N / A	0.5
	B	17.0 ppm	grounds	Risk	1.0×10^{-5}	N / A
	C	5.0 ppm		GW Risk	N / A	N / A
GROUND WATER	B	0.1 ppm	Waste	Risk	1.0×10^{-5}	N / A
	C	4.0 ppm	Management	MCL	1.0×10^{-5}	N / A
	F	7.0 ppm	Unit	MCLG	N / A	0.2
	G	15.0 ppm	Boundary	MCL	6.0×10^{-6}	0.09
SEDIMENT	Q	100.0 ppm	Downstream from point A	Ecological Effects	N / A	N / A

a. Prepare summary sheets for selected remedy.

b. Final Remediation Levels are based on preliminary remediation goals developed in the Feasibility Study (FS) (RI / FS Guidance 4.2.1) as modified through the nine criteria evaluation and engineering design. In the process of achieving remediation levels for each chemical, some chemicals will be reduced to concentrations below their remediation levels.

c. Chemical-specific risks correspond to associated remediation levels. Risks do not consider effects of exposures to other chemicals or media. If appropriate, risks may be summed to calculate media-specific risks. Short-term effectiveness is not considered.

d. Cancer risks are measured as individual incremental lifetime; non-cancer as Hazard Quotients.

e. Bases for values should be explained in the earlier Record Of Decision (ROD) table.

f. Bases for location and method for determining attainment (e.g., maximum value detected over area XYZ) should be explained in the description of the selected remedy.

N / A - Not applicable