Role of Background in the CERCLA Cleanup Program

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Table of Contents

Purpose

This document clarifies the U.S. Environmental Protection Agency (EPA) preferred approach for the consideration of background constituent concentrations of hazardous substances, pollutants, and contaminants in certain steps of the remedy selection process, such as risk assessment and risk management, at Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund") sites. To the extent practicable, this document may also be applicable to sites addressed under removal actions and time-critical actions. In general, the presence of high background concentrations of hazardous substances, pollutants, and contaminants found at a site is a factor that should be considered in risk assessment and risk management.

The primary goal of the CERCLA program is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances, pollutants, and contaminants. Contamination at a CERCLA site may originate from releases attributable to the CERCLA site in question, as well as contamination that originated from other sources, including natural and/or anthropogenic sources not attributable to the specific site releases under investigation (EPA, 1995a). In some cases, the same hazardous substance, pollutant, and contaminant associated with a release is also a background constituent. These constituents should be included in the risk assessment, particularly when their concentrations exceed risk-based concentrations. In cases where background levels are high or present health risks, this information may be important to the public. Background information is important to risk managers because the CERCLA program, generally, does not clean up to concentrations below natural or anthropogenic background levels.

A comprehensive investigation of all background substances found in the environment usually will not be necessary at a CERCLA site. For example, radon background samples normally would not be collected at a chemically contaminated site unless radon, or its precursor (radium, Ra-226) was part of the CERCLA release. Also, EPA normally would not analyze background samples for Ra-226 at a cesium (Cs-137) site, or dioxin at a lead site where dioxin was not the subject of a CERCLA release into the environment.

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

Some of the statutory provisions described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the

circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

History

Background issues are discussed in a number of EPA documents[1]. A need for CERCLA-specific guidance was identified during risk assessment reform discussions with stakeholders in 1997. An issue that is often raised at CERCLA sites is whether a reliable representation of background is established (EPA, 1989). To assist Regions with this issue, EPA developed a peer-reviewed practical guide to sampling and statistical analysis of background concentrations in soil at CERCLA sites (EPA, 2001b).

EPA has developed this policy to respond to questions about the general application of background concentration during the CERCLA remedial investigation process.[2] This policy encourages national consistency and responds to the Agency's goals for risk characterization and communication of risks to the public as expressed in other EPA policy and guidance, including:

- *Policy for Risk Characterization* which provides principles for fully, openly, and clearly characterizing risks (EPA, 1995b); and,

- *Cumulative Risk Assessment Guidance* which encourages programs to better advise citizens about the environmental and public health risks they face (EPA, 1997c).

Definitions of Terms

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[1] *Risk Assessment Guidance for Superfund Volume I, Human Health Evaluation Manual* [RAGS] (EPA, 1989).
Preamble to the National Oil and Hazardous Substances Pollution Contingency Plan (NCP, 1990a).
Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (EPA, 1991).
Determination of Background Concentrations of Inorganics in Soils and Sediments at Hazardous Waste Sites (EPA, 1995a).
Soil Screening Guidance: User's Guide (EPA, 1996).
Ecological Risk Assessment Guidance for Superfund (EPA, 1997a).
Rules of Thumb for Superfund Remedy Selection (EPA, 1997b).
Soil Screening Guidance for Radionuclides: User's Guide (EPA, 2000).
ECO Update. The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments (EPA, 2001a).

[2]The process of determining when risks warrant remedial actions and the degree of cleanup for specific hazardous substances, pollutants, and contaminants involves many factors that are not addressed in this document. Additional guidance is provided in the EPA (1991) *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*.

For the purposes of this policy, the following definitions are used.

Background refers to constituents or locations that are not influenced by the releases from a site, and is usually described as naturally occurring or anthropogenic (EPA, 1989; EPA, 1995a):

> 1) *Anthropogenic* – natural and human-made substances present in the environment as a result of human activities (not specifically related to the CERCLA release in question); and,
>
> 2) *Naturally occurring* – substances present in the environment in forms that have not been influenced by human activity.

Chemicals (or constituents) of concern (COCs) are the hazardous substances, pollutants, and contaminants that, at the end of the risk assessment, are found to be the *risk drivers* or those that may actually pose unacceptable human or ecological risks.[3] The COCs typically drive the need for a remedial action (EPA, 1999a).

Chemicals (or constituents) of potential concern (COPCs) generally comprise the hazardous substances, pollutants, and contaminants that are investigated during the baseline risk assessment. The list of COPCs may include all of the constituents whose data are of sufficient quality for use in the quantitative risk assessment, or a subset thereof (EPA, 1989).

Screening is a common approach used by risk assessors to refine the list of COPCs to those hazardous substances, pollutants, and contaminants that may pose substantial risks to health and the environment. Screening involves a comparison of site media concentrations with site-specific risk-based values.[4]

Consideration of Background in Risk Assessment

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[3]Guidance for determining if site risks are unacceptable is discussed in the EPA (1991) *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*. As stated in the EPA (1991) memorandum, "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." The risk used in this decision generally is the "cumulative site risk" to an individual using reasonable maximum exposure (RME) assumptions for either current or future land use and includes all exposure pathways which the same person may consistently face. See also EPA (1989) RAGS, Section 8.3.

[4]Risk-based values or concentrations are generally based on a cancer risk of one-in-a-million ($1x10^{-6}$) or a hazard quotient of 1.0 for noncarcinogens (EPA, 1996) or screening-level ecological risk values (EPA, 1997a; EPA, 2001a). COPCs with concentrations below the screening levels might be excluded from the risk assessment unless there are other pathways or conditions that are not addressed by the screening values (EPA, 1996).

A baseline risk assessment generally is conducted to characterize the current and potential threats to human health and the environment that may be posed by hazardous substances, pollutants, and contaminants at a site. EPA's 1989 *Risk Assessment Guidance for Superfund* (RAGS) provides general guidance for selecting COPCs, and considering background concentrations. In RAGS, EPA cautioned that eliminating COPCs based on background (either because concentrations are below background levels or attributable to background sources) could result in the loss of important risk information for those potentially exposed, even though cleanup may or may not eliminate a source of risks caused by background levels. In light of more recent guidance for risk-based screening (EPA, 1996; EPA, 2000) and risk characterization (EPA, 1995c), this policy recommends a baseline risk assessment approach that retains constituents that exceed risk-based screening concentrations. This approach involves addressing site-specific background issues at the end of the risk assessment, in the risk characterization. Specifically, the COPCs with high background concentrations should be discussed in the risk characterization, and if data are available, the contribution of background to site concentrations should be distinguished.[5] COPCs that have both release-related and background-related sources should be included in the risk assessment. When concentrations of naturally occurring elements at a site exceed risk-based screening levels, that information should be discussed qualitatively in the risk characterization. To summarize:

- The COPCs retained in the quantitative risk assessment should include those hazardous substances, pollutants, and contaminants with concentrations that exceed risk-based screening levels.

- The Risk Characterization should include a discussion of elevated background concentrations of COPCs and their contribution to site risks.

- Naturally occurring elements that are not CERCLA hazardous substances, pollutants, and contaminants, but exceed risk-based screening levels should be discussed in the risk characterization.

This general approach is preferred in order to:

- Encourage national consistency in this area;

- Present a more thorough picture of risks associated with hazardous substances, pollutants, and contaminants at a site; and,

- Prevent the inadvertent omission of potentially release-related hazardous

[5]Technical guidance should be consulted for sampling and analysis of background concentration data (EPA, 2001b).

substances, pollutants, and contaminants from the risk assessment.

This approach is consistent with the *Policy for Risk Characterization* which provides principles for fully, openly, and clearly characterizing risks (EPA, 1995b). Risks identified during the baseline risk assessment should be clearly presented and communicated for risk managers and for the public. Risk characterization is one of many factors in determining appropriate CERCLA risk management actions (EPA, 1991; EPA, 1995b).

Consideration of Background in Risk Management

Where background concentrations are high relative to the concentrations of released hazardous substances, pollutants, and contaminants, a comparison of site and background concentrations may help risk managers make decisions concerning appropriate remedial actions. The contribution of background concentrations to risks associated with CERCLA releases may be important for refining specific cleanup levels for COCs that warrant remedial action[6].

Generally, under CERCLA, cleanup levels are not set at concentrations below natural background levels. Similarly, for anthropogenic contaminant concentrations, the CERCLA program normally does not set cleanup levels below anthropogenic background concentrations (EPA, 1996; EPA, 1997b; EPA, 2000). The reasons for this approach include cost-effectiveness, technical practicability, and the potential for recontamination of remediated areas by surrounding areas with elevated background concentrations. In cases where area-wide contamination may pose risks, but is beyond the authority provided under CERCLA, EPA may be able to help identify other programs or regulatory authorities that are able to address the sources of area-wide contamination, particularly anthropogenic (EPA, 1996; EPA, 1997b; EPA, 2000). In some cases, as part of a response to address CERCLA releases of hazardous substances, pollutants, and contaminants, EPA may also address some of the background contamination that is present on a site due to area-wide contamination.

The determination of appropriate CERCLA response actions and chemical-specific cleanup levels includes the consideration of nine criteria as provided in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP, 1990b). In cases where applicable or relevant and appropriate requirements (ARARs) regarding cleanup to background levels apply to a CERCLA action, the response action generally should be carried out in the manner prescribed by the ARAR. In the case where a law or regulation is determined to be an ARAR and it requires cleanup to background levels, the ARAR will normally apply and be incorporated into the Record of Decision, unless the ARAR is waived.

Consideration of Background in Risk Communication

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[6]For example, in cases where a risk-based cleanup goal for a COC is below background concentrations, the cleanup level may be established based on background.

EPA strives for transparency in decision-making (EPA, 1995c) and encourages programs to better advise citizens about the environmental and public health risks they face (EPA, 1997c). The presence of high background concentrations of COPCs may pose challenges for risk communication. For example, the discussion of background may raise the expectation that EPA will address those risks under CERCLA. The knowledge that background substances may pose health or environmental risks could compound public concerns in some situations.

On the other hand, knowledge of background risks could help some community members place CERCLA risks in perspective. Also, the information about site and background risks can be helpful for both risk managers who make an appropriate CERCLA decision, and for members of the public who should know about environmental risk factors that come to light during the remedial investigation process.

As a general policy matter, EPA strives for early and frequent outreach to communities in order to share information and encourage involvement (EPA, 2001c). EPA has made a clear commitment to fully, openly, and clearly characterize and communicate risks (EPA, 1995b; EPA, 1995c). There is no one-size-fits-all technique that can help explain risks associated with CERCLA releases or with background levels, or the basis of risk management decisions. Approaches will depend on the site, the issues, and the level of community interest. Early on in the process, Regions should clarify their understanding of stakeholder expectations and clearly explain the relevant constraints and limitations of the CERCLA remedial process (EPA, 1999b; EPA, 2001c).

In some cases where area-wide contamination may pose a risk, but is beyond the authority of the CERCLA program, communication of potential risks to the public may be most effective when coordinated with public health agencies. Examples of situations where Regions might coordinate risk communication with local, state or federal health officials are sites where widespread lead contamination or high levels of naturally occurring radiation have been found, but are not the subject of a CERCLA release into the environment. Public health agency officials may combine education and outreach efforts to inform residents about ways to reduce exposures and risks.

Hypothetical Case Examples

Three general hypothetical case examples are given to show how background may be considered in risk assessment and risk management at CERCLA sites:

Case 1 presents an example of a chemical site with widespread background contamination.

Case 2 presents an example of a radiation site with both natural- and release-related sources.

Case 3 presents an example of a site with hazardous substances, pollutants, and contaminants from both natural- and release-related sources.

In these examples, it is presumed that adequate samples are collected from appropriate background reference locations and evaluated using appropriate statistical methods. It is presumed that background is not used to screen out substances from the risk assessment. For simplicity, only one pathway[7] is used for hypothetical human health risk assessments.[8]

Based on the presumptions above, the basic concepts these examples are designed to highlight are:

- Background issues should be discussed in the risk characterization portion of the baseline risk assessment in order to inform risk management decisions;
- Information about unacceptable risks should be communicated to public; and,
- Other factors, such as the nine criteria provided in the NCP, should be considered by the risk manager in making final decisions.

Hypothetical Case 1

The ABC Industrial Site risk assessment included all COPCs that exceed site-specific risk-based concentrations for soil pathways. The results of the risk assessment identified the following COPCs with risks above or at the high end of the 10^{-4} to 10^{-6} risk range: arsenic, dieldrin, and 4,4-DDT. The hazard quotients were below 1.0.

Arsenic is a potential background substance – it is a common naturally occurring element – but is also a hazardous substance that was released at this site. The available site characterization data indicate that soil arsenic concentrations may be naturally occurring or consistent with background concentrations. Dieldrin and DDT are present at high concentrations that contribute to an unacceptable site risk. However, only dieldrin is known to be associated

[7] At most CERCLA sites, risks for the reasonably maximum exposed individual typically are combined across several exposure pathways to estimate the total risks at a CERCLA site. This is done only for the pathways which the same individual would be likely to face consistently (EPA, 1989). Depending on the particular CERCLA site, risks could be calculated for the entire area of the site or for separate units (see Section 4.5 of RAGS (EPA, 1989)). More technical guidance for characterizing background concentrations and comparing data sets is provided in EPA (2001b) and other technical references cited previously in this document.

[8] Guidance on the consideration of background concentrations during screening level ecological risk assessments is provided in EPA (2001a).

with the CERCLA site activities and releases. Since there are no known historical uses of DDT at this CERCLA site, the RPM suspects that the DDT in soil originated from area-wide agricultural pesticide applications in this part of the state. Based on this information, the RPM requests additional sampling of background locations for arsenic and DDT analysis. A statistical comparison of sampling data for arsenic and 4,4-DDT in on-site samples and background samples indicates that site concentrations for DDT are consistent with background concentrations. Local and regional data support the conclusion that DDT is an area-wide contaminant. The additional data indicate that arsenic concentrations on the site are above background concentrations. Therefore, the arsenic risks cannot be attributed solely to background.

In this example, arsenic and dieldrin are the soil COCs for which cleanup goals should be derived. The risk characterization should present information about DDT as an area-wide background contaminant that is unrelated to releases at this site, and the Agency should explain whether or not it will be addressed. The RPM should consider whether other regulatory programs or authorities are able to address the area-wide DDT contamination in a coordinated response effort. If available, the location(s) of additional information on pesticide use in this part of the state should be provided for concerned citizens.

Hypothetical Case 2

At ABC Radium Production Site, site characterization data indicate that radium (Ra-226) and inorganics are present in soil. Arsenic concentrations exceed screening levels but are assumed to be within naturally occurring levels. To confirm this assumption, the RPM evaluates site-specific background samples for comparison to site concentrations. The site-specific background analysis confirms that arsenic concentrations collected on the site are consistent with background concentrations in soils. There are no known regional anthropogenic sources of arsenic (such as smelters or pesticide manufacturers). Arsenic, in this case, is considered to be a naturally occurring substance and is excluded from further consideration in the quantification of site risks. However, the finding of natural background arsenic at concentrations that may pose health risks should be discussed in the text of the risk characterization.

The risk assessment indicates that Ra-226 exceeds the high end of the acceptable risk range of 10^{-4} to 10^{-6}. It is commonly known that Ra-226 occurs naturally in the environment. Samples collected in an appropriate background location near this site indicate that Ra-226 levels from natural sources are lower than the site levels, but are associated with a risk at the upper end of the risk range (10^{-4}).

In this example, only Ra-226 should be a COC for which a cleanup goal should be derived. The risk characterization, however, should include a discussion of natural background levels of both arsenic and Ra-226.

Hypothetical Case 3

XYZ Site contains buried chemical wastes, but some anecdotal accounts indicate that radium may have been used. Preliminary site characterization data show that arsenic, manganese, and Ra-226 concentrations exceed the site-specific, risk-based concentrations. A comparison of arsenic and manganese concentrations in groundwater samples collected from upgradient background locations indicates that only manganese site concentrations are consistent with background levels and considered to be naturally occurring. Naturally occurring manganese is not considered further in the quantification of risks, but is included in a qualitative discussion of risks in the risk characterization.

The RPM decides to analyze for Ra-226 both at the site and in background locations because it is commonly known that Ra-226 occurs naturally in the environment. Samples are collected in an appropriate background location near this site. The samples indicate that Ra-226 levels at this site are not different from naturally occurring levels. Therefore, Ra-226 is not a COPC for further consideration in the quantification of risks. Subsequent site investigation data confirms the use of chemicals, but not radionuclides.

In this example, only arsenic risks are quantified in the risk assessment. The baseline risk for groundwater indicates that arsenic poses an unacceptable risk. The risk characterization should include a discussion of the natural Ra-226 and manganese concentrations because the levels exceeded risk-based concentrations. Site characterization data indicate that site disposal activities caused naturally occurring arsenic in soil to be mobilized and leach to groundwater. Arsenic, therefore, is the subject of a CERCLA release into the environment and a cleanup goal for it should be derived.

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