UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

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OSWER Directive 9285.7-28 P

MEMORANDUM

SUBJECT: Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites

FROM: Stephen D. Luftig, Director
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TO: Superfund National Policy Managers
Regions 1 - 10

I. PURPOSE

This guidance is intended to help Superfund risk managers make ecological risk management decisions that are based on sound science, consistent across Regions, and present a characterization of site risks that is transparent to the public. It provides risk managers with six principles to consider when making ecological risk management decisions. The ability to make sound ecological risk management decisions is dependent upon the quality and extent of information provided in the ecological risk assessment (ERA). All ERAs should generally be performed at every site according to the eight-step process described in: *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments* (ERAGS, EPA 540-R-97-006, OSWER Directive # 9285.7-25, June 1997). The principles provided in this guidance supplement the ERAGS guidance and will aid remedial project managers (RPMs) and on-scene coordinators (OSCs) in planning ERAs of appropriate scope and complexity and in identifying response alternatives in the feasibility study or engineering evaluation/cost analysis that are protective of the environment. (See Text Box 1.) By incorporating these principles into their decision-making, risk managers will be able to present a clear rationale for their ecological risk management actions which they can communicate to the public in the proposed plan and the Record of Decision, or the Action Memo. Implementation of this guidance should not restrict the ability of natural resource trustees to investigate injuries to natural resources, assess damages, and/or restore habitats.

II. BACKGROUND

As the Superfund program has matured, it has given more and more consideration to the potential effects of hazardous substances releases on ecological receptors. This increased focus on ecological risks has highlighted the need for more guidance on ecological risk management.

Text Box 1. Risk Management vs. Risk Assessment

This document deals with the application of principles that help to accomplish the management of ecological risk in a consistent and appropriate manner. This includes decisions about whether to respond and how to select a response alternative that is protective. The 1997 ERA guidance provides a standardized approach to identify adverse effects and the severity of those effects. That guidance does not suggest that all ecological risk assessments must be identical, nor does it suggest that all ecological risk assessments will require the same level of effort to allow appropriate risk management decisions.

The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) states that: "Alternatives shall be assessed to determine whether they can adequately protect human health and the environment, in both the short- and long-term, from unacceptable risks posed by hazardous substances, pollutants, or contaminants present at the site by eliminating, reducing, or controlling exposures to levels established during development of remediation goals consistent with § 300.430(e)(2)(I)." (40CRF 300.430(e)(9)(iii)(A)). The NCP establishes a protective risk range for human health, but provides little guidance regarding developing remediation goals considered to be adequate for protecting ecological receptors. The NCP also states that applicable or relevant and appropriate requirements (ARARs) shall be considered in determining remediation goals. Thus, ARARs that are set based on risks to ecological receptors, such as water quality criteria/state standards established under sections 303 and 304 of the Clean Water Act, must be considered in determining remediation goals that are protective, but other factors also influence this determination. Although some states may also have promulgated standards for soil or sediment, there generally are no current federal ARARs for sediment or soil.

Establishing remediation goals for ecological receptors is considerably more difficult than establishing such goals for the protection of human health due to the paucity of broadly applicable and quantifiable toxicological data. Further, owing to the large variation in the kinds and numbers of receptor species present at sites, to their differences in their susceptibility to contaminants, to their recuperative potential following exposure, and to the tremendous variation in environmental bioavailability of many contaminants in different media, protective exposure levels are best established on a site-specific basis.

III. ECOLOGICAL RISK ASSESSMENT/ MANAGEMENT PRINCIPLES

A goal of the Superfund program is to select remedies that are protective of human health and the environment, both in the short-term and long-term. Since ecological receptors at sites exist within a larger ecosystem context, remedies selected for protection of these receptors should also assure protection of the ecosystem components upon which they depend or which they support. Except at a few very large sites, Superfund ERAs typically do not address effects on entire ecosystems, but rather normally gather effects data on individuals in order to predict or postulate potential effects on local wildlife, fish, invertebrate, and plant populations and communities that occur or that could occur in specific habitats at sites (e.g., wetland, floodplain, stream, estuary, grassland, etc.). Ecological risk assessments incorporate a wide range of tests and studies to either directly estimate community effects (e.g., benthic species diversity) or indirectly predict local population-level effects (e.g., toxicity tests on individual species), both of which can contribute to estimating ecological risk. Superfund remedial actions generally should not be designed to protect organisms on an individual basis (the exception being designated protected status resources, such as listed or candidate threatened and endangered species or treaty-protected species that could be exposed to site releases), but to protect local populations and communities of biota. Levels that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of-evidence approach. The performance of multi-year field studies at Superfund sites to try to quantify or predict long-term changes in local populations is not necessary for appropriate risk management decisions to be made. Data from discrete field and laboratory studies, if properly planned and appropriately interpreted, can be used to estimate local population or community-level effects.

Risk managers should generally adhere to the six principles listed below when scoping ecological risk assessments and when making ecological risk management decisions.

Principle No. 1 -Superfund's goal is to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota. The goal of the Superfund program is to select a response action that will result in the recovery and/or maintenance of healthy local populations/communities of ecological receptors that are or should be present at or near the site. Superfund risk managers and risk assessors should select assessment endpoints and measures (as defined in the 1997 ERAGS) that: 1) are ecologically relevant to the site; i.e., important to sustaining the ecological structure and function of the local populations, communities and habitats present at or near the site, and 2) include species that are exposed to and sensitive to site-related contaminants. In addition, if individual threatened or endangered species or critical habitats for such species are present at a site, the federal Endangered Species Act or a state endangered species act may be an ARAR.

Principle No. 2 - Coordinate with Federal, Tribal, and State Natural Resource Trustees. It is Superfund's goal that our response actions will not only achieve levels that are protective, but will also minimize the residual ecological risks at sites. Due to factors such as technical

implementability and response costs at some sites, however, EPA recognizes that its response action may not lead to complete recovery of the ecosystem and that additional restoration activities by the natural resource trustees may be needed to bring natural resources back to their baseline condition within an acceptable time frame. It is important, however, that EPA and the Trustees coordinate both the EPA investigations of risk and the trustee investigations of resource injuries in order to most efficiently use federal and state monies and to not duplicate efforts.

Principle No. 3 - Use site-specific ecological risk data to support cleanup decisions. Site specific data should be collected and used, wherever practicable, to determine whether or not site releases present unacceptable risks and to develop quantitative cleanup levels that are protective. Site-specific information can include, but is not limited to, plant and animal tissue residue data, toxicity test data, bioavailability factors, and population- or community-level effects studies. Data collection efforts should be coordinated with other efforts to collect data for a human health assessment or for a natural resource injury assessment by trustees. As in all risk assessments, its scope should be tailored to the nature and complexity of the site problems being addressed and the response alternatives being considered, including their costs and implementability.

Principle No. 4 - Characterize site risks. When evaluating ecological risks and the potential for response alternatives to achieve acceptable levels of protection, Superfund risk managers should characterize site risks in terms of: 1) magnitude; i.e., the degree of the observed or predicted responses of receptors to the range of contaminant levels, 2) severity; i.e., how many and to what extent the receptors may be affected), 3) distribution; i.e., areal extent and duration over which the effects may occur, and 4) the potential for recovery of the affected receptors. It is important to recognize, however, that a small area of effect is not necessarily associated with low risk; the ecological function of that area may be more important than its size.

Principle No. 5 - Communicate risks to the public. Superfund risk managers, in collaboration with ecological risk assessors, should clearly communicate to the public the scientific basis and ecological relevance of the assessment endpoints used in site risk assessments and the relationship between the effect or exposure measures used to determine if there are any adverse effects to any of the assessment endpoints. For example, earthworms are not normally perceived by the public as important to ecosystem functioning but are very important in many habitats as they are the main food source for many birds and small mammals and they play a critical role in recycling soil nutrients and in improving the soil quality for other plants and invertebrates.

Principle No. 6 - Remediate unacceptable eco risks. Working within the framework of the NCP, Superfund's goal is to eliminate unacceptable ecological risks due to any release or threatened release. Contaminated media that are expected to constrain the ability of local populations and/or communities of plants and animals to recover and maintain themselves in a healthy state at or near the site (e.g., contamination that significantly reduces diversity, increases mortality, or diminishes reproductive capacity) should be remediated to acceptable levels. (See the following discussion under question #3 for additional guidance).

IV. QUESTIONS RISK MANAGERS AND RISK ASSESSORS SHOULD ADDRESS

Although all site cleanup decisions are ultimately the responsibility of EPA's Regional Administrator or the appropriate designee, no ecological risk management decisions should be made without coordinating with the regional ecological risk assessor, usually the Regional Biological Technical Assistance Group (BTAG) Coordinator, and the representative(s) from the appropriate natural resource trustee agency(s). The BTAG Coordinators are listed at the end of this document. Frequent coordination among the risk manager, risk assessor, and trustees is critical in selecting remedies that provide acceptable levels of protection. The eight-step ERAGS process with its five key risk assessor/risk manager decision points (Scientific/Management Decisions Points) should always be used in conjunction with this guidance. Addressing the following four questions, which highlight fundamental ecological risk assessment and risk management issues, should facilitate reaching sound decisions at these five points in the process.

1. *What ecological receptors should be protected?*

ERAGS provides information on identifying and selecting assessment endpoints for evaluating the ecological risk to biotic receptors at sites. An assessment endpoint is defined as: "an explicit expression of the environmental value that is to be protected." Superfund risk assessments should use site-specific assessment endpoints that address chemical specific potential adverse effects to local populations and communities of plants and animals (e.g., reductions in populations of fish-eating birds, or reductions in survival, reproduction or species diversity of indigenous benthic communities). The number and breadth of the assessment endpoints depends on the number and type of contaminated habitats at the site. Risk assessment measures (i.e., measures of effect, measures of exposure, measures of ecosystem and receptor characteristics) should then be selected based on site-specific conditions and used to infer effects on the local population or community of concern. Examples might include: toxicity test results, tissue concentrations, and physio-chemical measurements related to fate and transport of the contaminants.

2. *Is there an unacceptable ecological risk at the site?*

Unless the ecological impacts are apparent (e.g., no vegetation will grow on the contaminated portion of the site or no benthic organisms exist in the sediment downstream from the release), site specific biological data should be developed in order to determine if there are unacceptable risks. The baseline risk assessment may include site-specific toxicity tests with test organisms that address the assessment endpoints selected for the site. These readily available test organisms are considered surrogates for the actual species exposed. The Regional BTAG coordinator can identify the tests and species most appropriate for the site. Other techniques to estimate the magnitude and severity of risks may include modeling to predict food-chain transfer and secondary toxicity of bioaccumulative chemicals to upper trophic level receptors, the measurement of tissue concentrations, the performance of species diversity studies (e.g., Rapid Bioassessment Protocols), and *in-situ* bioassays (e.g., caged fish/bivalves). Through the use of

field studies and/or toxicity tests, several types of data may be developed to provide supporting information for a lines-of-evidence approach to characterizing site risks. This approach is far superior to using single studies or tests or measurements to determine whether or not the observed or predicted risk is unacceptable.

If studies or tests performed with site soil, sediment, or water demonstrate or predict serious adverse effects (e.g., increased mortality, diminished growth, impaired reproduction, etc.) on the selected assessment endpoints as compared to studies or tests conducted at an appropriate reference site or using reference media, there is usually sufficient evidence to assume that unacceptable adverse effects have occurred or may occur at the site. Indigenous species, however, may be more or less sensitive than test organisms, and although toxicity tests may demonstrate that contaminants are present in amounts potentially toxic to susceptible organisms, the actual risks to site organisms may be of limited severity, very short-lived or reversible. Conversely, the adverse effects may result in the loss of a critical species, which may entirely change the dominant structure and properties of the community.

Sufficient information should be collected in the ecological risk assessment to allow the risk assessor to make a reasoned decision about: (1) causality between levels of contamination and effects, (2) whether the observed or predicted adverse effect on the site's local population or community is of sufficient magnitude, severity, areal extent, and duration that they will not be able to recover and/or maintain themselves in a healthy state, and (3) whether these effects appear to exceed the natural changes in the components typical of similar non-site-impacted habitats (i.e., reference areas). The information gathered in the ecological risk assessment should provide a clear and concise estimate of overall risk to the site under review.

3. *Will the cleanup cause more ecological harm than the current site contamination?*

Whether or not to clean up a site based on ecological risk can be a difficult decision at some sites. When evaluating remedial alternatives, the NCP highlights the importance of considering both the short-term and long-term effects of the various alternatives, including the no action alternative, in determining which ones "adequately protect human health and the environment." Even though an ecological risk assessment may demonstrate that adverse ecological effects have occurred or are expected to occur, it may not be in the best interest of the overall environment to actively remediate the site. At some sites, especially those that have rare or very sensitive habitats, removal or *in-situ* treatment of the contamination may cause more long-term ecological harm (often due to wide spread physical destruction of habitat) than leaving it in place. Conversely, leaving persistent and/or bioaccumulative contaminants in place where they may serve as a continuing source of substantial exposure, may also not be appropriate.

The likelihood of the response alternatives to achieve success and the time frame for a biological community to fully recover should be considered in remedy selection. Although most receptors and habitats can recover from physical disturbances, risk managers should carefully weigh both the short- and long-term ecological effects of active remediation alternatives and

passive alternatives when selecting a final response. This does not imply that there is a preference for passive remediation; all reasonable alternatives should be considered. For example, the resilience and high productivity of many aquatic communities allows for aggressive remediation, whereas the removal of bottomland hardwood forest communities in an area in which they cannot be restored due to water management considerations may argue heavily against extensive action in all but the most highly contaminated areas.

The evaluation of ecological effects resulting from implementing various alternatives should be discussed in the Feasibility Study or the Engineering Evaluation/Cost Analysis and should include input from the ecological risk assessor and the federal and/or state trustees responsible for the resources that may be impacted by the response. (See Text Box 2.)

Text Box 2. Deciding Whether to Respond

Before making a response decision, the risk manager, in consultation with an ecological risk assessor, should consider in the context of a nine-criteria evaluation under the NCP at least the following factors:

- the magnitude of the observed or expected effects of site releases and the level of biological organization affected (e.g., individual, local population or community),
- the likelihood that these effects will occur or continue,
- the ecological relationship of the affected area to the surrounding habitat,
- whether or not the affected area is a highly sensitive or ecologically unique environment,
- the recovery potential of the affected ecological receptors and expected persistence of the chemicals of concern under present site conditions, and
- short- and long-term effects of the remedial alternatives on the site habitats and the surrounding ecosystem.

4. *What cleanup levels are protective?*

When a decision is made that a response action should be taken at a site based on unacceptable ecological risk, the risk manager normally then selects chemical-specific cleanup levels that are acceptable; i.e., provides adequate protection of the ecological receptors (as represented by the selected assessment endpoints) at risk. The risk assessor can use the same toxicity tests, population or community-level studies, or bioaccumulation models that were used to determine if there was an unacceptable ecological risk to identify appropriate cleanup levels. Sufficient testing and interpretation should be performed at various site locations to quantify the relationship between chemical concentrations and effects. The data can then be used to establish a concentration and response gradient to define the concentration that represents an acceptable (i.e., protective) level of risk. At some relatively small sites, however, it may be more cost effective to remove, treat, or contain all contamination rather than to generate a concentration and response gradient.

The difficulty is in determining the acceptable level of adverse effects for the receptors to be protected; e.g., what percent reduction in fish survival or in benthic species diversity is no longer protective? There is no "magic" number that can be used; it is dependent on the assessment endpoints selected and the risk assessment measures used including chemical and biological data gathered from the range of contaminated locations and compared to the reference locations. While it may be desirable to identify a standard numerical level of risk reduction that is protective, it is impracticable to do this for each possible species that could be exposed. It is for this reason that surrogate measures or representative species are used to evaluate the ecological risks to the assessment endpoints at the site. The acceptable level of adverse effects should be discussed by the risk assessor and risk manager as early as possible in the risk assessment process and should be coordinated with the trustees. At sites in locations where a large amount of data exists relating abundances or population/community indices with chemical concentrations (e.g., Puget Sound, San Francisco Bay, the states of Ohio and Florida, and some of the Environmental Monitoring and Assessment Program provinces), biotic indices, instead of chemical concentrations, may also be used to select acceptable levels and to delineate the area needing remediation.

V. IMPLEMENTATION

These principles should be followed at all sites with a planned or on going baseline ecological risk assessment. It is the responsibility of the risk manager, in consultation with the risk assessor, to select and document a response and cleanup levels for the site that are protective of human health and the environment and meet or waive ARARs. The final selection of the remedy from among alternatives that satisfy these threshold criteria can be made only after a thorough consideration of the other seven balancing and modifying NCP criteria. The complex nature of ecosystems, the many parameters that can affect bioavailability, and the large number of species potentially affected at a given site may result in a relatively high degree of uncertainty concerning the levels deemed necessary to provide overall protection of the environment. At these sites, the risk manager should incorporate a long-term monitoring plan and a review schedule in the Record of Decision. The data collected should be adequate to determine if recovery is occurring in an acceptable and ecologically relevant time frame or if any additional response action is warranted.

The Superfund program may update this guidance as more scientific information becomes available regarding the nature of adverse effects on ecological resources resulting from hazardous substance releases and the effectiveness of various response alternatives in alleviating those effects. For any additional information or questions about this guidance, please contact Steve Ells (703) 603-8822 or David Charters (732) 906-6825.

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NOTICE: This document provides guidance to EPA staff and is designed to communicate national policy on assessing and managing ecological risks. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it does not impose legally-binding requirements on EPA, states, or the regulated community, and may not apply to a particular situation based upon the circumstances of the site. EPA may change this guidance in the future, as appropriate.

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