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U.S. EPA Region 5

Waste, Pesticides and Toxics Division

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FACT SHEET: ECOLOGICAL RISK ASSESSMENT IN THE RCRA PROGRAM

Background

Ecological risk assessment activities are performed to meet the requirements of various RCRA regulatory programs including corrective action, permitting, and enforcement. In 1976, Congress passed the Resource Conservation and Recovery Act (RCRA) to promote the protection of health and the environment by encouraging the conservation of material and energy resources and by ensuring the safe disposal of solid and hazardous wastes. RCRA created a framework for the proper management of hazardous and solid wastes, and established a system for controlling hazardous wastes from generation until ultimate disposal, i.e. from cradle to grave .

Congress later amended RCRA through the Hazardous and Solid Waste Amendments (HSWA) of 1984. HSWA expanded the scope and requirements of RCRA to require hazardous waste treatment, storage or disposal facilities (TSD facilities) to clean up contamination resulting from any past, current or potential future releases of hazardous constituents at their sites. According to the law, these cleanup efforts or corrective action activities must be protective of both human health and the environment. Therefore, U.S. EPA recommended that risk assessments be conducted to assist in the decision making process for necessary corrective measures. Risk assessments examine the sources of hazardous constituents, the environmental transport of the contaminants, potential receptors exposed to the contaminants, and the degree of associated toxicity. An analysis of ecological impacts is often required for corrective action sites, facilities subject to permitting, or facilities under an enforcement proceeding.

Ecological Risk Assessment Policy

In the late 1980s and early 1990s, U.S. EPA began to place more emphasis on ecological protection and restoration. Ecosystem protection was declared a high priority and a goal was set to improve the overall ecological health of the environment by protecting the physical, chemical, and biological components and processes of ecosystems. U.S. EPA would strive to restore representative samples of ecosystems, habitat types, and habitat connections across landscapes and biological communities.

Region 5 has a longstanding policy on requiring ecological risk assessments at RCRA facilities. A memorandum issued by Region 5's Waste Management Division Director in April 1991, stated that ecological risk concerns and the preservation of ecological habitats must be considered at all RCRA facilities. This action required, at a minimum, a screening ecological risk assessment (SERA) be performed as part of corrective action activities for all sites.

Ecological risk assessment was more clearly incorporated as part of the overall corrective action process through revisions to the national RCRA Corrective Action Plan in 1994 (OSWER Directive

9902.3-2A) and the Region 5 Quality Assurance Project Plan Policy of April 1998. According to the OSWER Directive, The implementing agency may require the Permittee/Respondent to prepare an analysis of risk at the facility. This analysis may include ecological as well as human health risk. Generally a baseline risk assessment would be conducted during the RFI stage with further analysis occurring during the CMS stage.

A memo from the U.S. EPA Headquarters Superfund program dated August 12, 1994, and titled Role of the Ecological Risk Assessment in the Baseline Risk Assessment further emphasized the need for ecological assessments at hazardous waste sites. As stated in the memo, human health cannot be divorced from the health of the environment. Therefore, the condition of the ecosystem can either enhance or degrade the well-being of humans occupying the ecosystem. By integrating ecosystem protection into current programs (including those that are directed to protect human health), the entire ecosystem will benefit, including the human component.

What is ecological risk assessment?

Ecological risk assessment is a methodology used to evaluate the effects that contaminated media such as air, soil, sediment and/or water have on the plants and animals that make up ecosystems. An ecological risk assessment estimates the likelihood that adverse ecological effects (e.g. mortality, reproductive failure) will occur as a result of releases of hazardous wastes at a site. The risk assessment process provides a way to develop and analyze scientific information, assumptions and uncertainties so that they are relevant to environmental decisions.

When conducted at an industrial facility, the ecological risk assessment process can be used to identify and characterize the environmental stressors (e.g. chemicals of concern, physical or biological impacts), prioritize data collection activities, identify vulnerable and valued ecological resources, evaluate the ecological impacts of alternative remediation strategies, and establish clean-up levels protective of the natural resources at risk.

The risk assessment process provides an opportunity for stakeholders such as local communities, state and federal government agencies to cooperate and mutually agree upon project objectives or resources to be protected. The risk assessment results can form the basis for comparing different remediation options, and enable decision makers and the public to make better informed decisions about the management of ecological resources.

What are the goals of an ecological risk assessment?

- to determine the likelihood of harmful effects to animals and plants exposed to site-related hazardous chemicals (referred to as a significant risk);
- if there is significant risk, to calculate a protective cleanup level that would reduce the risk to animals and plants;
- to determine the potential impact of clean-up activities on habitats, plants and animals;
- to provide baseline information that can be used for long-term biological monitoring programs

to determine if the clean-up is effective.

When is an ecological risk assessment performed at a RCRA facility?

Ecological risks must be evaluated through a screening ecological risk assessment (SERA) process. A SERA is ideally conducted early in the RCRA facility investigation or permitting schedule. This process begins with the identification of goals, such as the environmental values to be protected, and the ecological endpoints to measure. Endpoints should define both the valued ecological entity (e.g. specific species, resource, habitat type) at the site and a characteristic of the entity to protect (e.g. reproductive success, survival, areal extent). A SERA most often consists of a desktop effort which compares measured concentrations in environmental media against conservative ecological screening values.

If the screening processes identifies potential risks, a more detailed study is conducted. The detailed study would focus only on those specific stressors (e.g. chemicals) identified and species affected in the SERA. In some cases, further analysis of risk is necessary later in the RFI process. Alternatively, a site specific assessment may be included in the Corrective Measures Study or during later stages when final cleanup goals or permit limits are developed.

What steps are followed in an ecological risk assessment?

5. ***Risk management goals for decision making.*** The risk assessor, risk manager (e.g. the project manager), and other interested stakeholders work together to develop theories about possible relationships between undesirable ecological effects and observable stressors. The risk manager's key role is to identify the goals of the risk assessment and ensure that it provides relevant decision making information. The risk manager states why the risk assessment is needed, what decisions it will support, and what information is required. The risk assessor translates the goals identified by the risk manager into ecological values that can be evaluated in the risk assessment process. The risk assessor ensures that science is effectively used to address ecological concerns.
6. ***Problem formulation.*** This process narrows the scope of the assessment to a few species or groups of species that are appropriate for indicating if ecological risks exist. Risk assessors look at which components of an ecosystem should be protected, that is, the species or habitats to be focused on in the ecological risk assessment. Only wild plants and animals are considered, domesticated species are excluded. The problem formulation stage includes the critical steps of identifying hazardous contaminants, describing site characteristics, defining project objectives, and developing the site conceptual model and selecting relevant endpoints as detailed below.
7. ***Develop conceptual model.*** The risk assessor depicts how site contaminants are expected to behave in the environment. This picture includes fate and transport of chemicals through various media (soil, sediment, surface or ground water). Fate describes the break down or persistence of a contaminant in the environment. Transport describes the movement of a contaminant through the environment and into different media. Species of plants and animals

- are referred to as receptors . The chemical contaminants are called stressors . Other types of stressors include physical factors such as temperature or water supply and biological factors such as species competition, predation, or diseases.
8. **Select assessment and measurement endpoints.** The risk assessor, in consultation with the risk manager and other stakeholders, decides what important species or habitat characteristics should be protected and studied at a site. These specific environmental values are called assessment endpoints and focus the risk assessment on particular components of the ecosystem that could be adversely affected by site contaminants. Measurement endpoints are testable hypotheses used to determine whether or not a potential threat to the assessment endpoints (e.g. goals for ecological protection) exists.
 9. **Characterize ecological exposure and effects.** The risk assessor describes the potential adverse ecological effects of the contaminants. This includes an exposure profile, described in terms of intensity, space and time, that identifies contaminant pathways to each ecological receptor (e.g. ingestion through the food chain). Information is gathered from scientific literature and studies to determine contaminant amounts that must be absorbed to cause an adverse effect. Data is summarized about the extent of site contamination, frequency and duration of exposure, and the measured or estimated uptake of the contaminant by the ecological receptors.
 10. **Characterize risk.** The risk assessor estimates the amount of chemical exposure to specific plants and animals (ecological receptors). This estimate is then compared to a reference value (dose) known to cause adverse effects. Several alternate methods (e.g. field observational studies, entire stressor-response relationship, and variability in exposure and/or effects) exist to quantify the ecological risk estimate. The risk assessor interprets and discusses available information about risks to the assessment endpoints in the risk description narrative. This narrative supports the risk estimate by evaluating lines of evidence and interpreting the significance of adverse effects on the endpoints.
 11. **Summarize uncertainties.** The risk assessor describes the uncertainties associated with the assumptions, extrapolations, and limitations of knowledge and their possible effects on the outcome or conclusions of the ecological risk assessment.

When is a Quality Assurance Project Plan required?

Any data collected in support of an ecological risk assessment must follow appropriate U.S. EPA guidance on quality assurance/quality control procedures. A Quality Assurance Project Plan (QAPP) ensures that data collected will be of sufficient quality and quantity to support a risk assessment. The QAPP describes in detail the goals of an investigation, and defines the project data needs. For example, any project involving an ecological risk assessment must define the ecological target decision levels (e.g. screening levels) to which site data can be compared to determine potential risk. Therefore, reporting and detection limits must be set to yield data with suitable sensitivity for the risk analysis.

Comparison of sampling results with pre-determined screening levels will result in accurate and

protective decisions only if the data is adequately sensitive. Region 5 has generated a set of Ecological Screening Levels (ESLs) to be used during the risk assessment process. Other appropriate or site-specific screening levels must be discussed with the EPA project manager.

What are the objectives of ecological risk management?

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. Ecological risk management seeks to balance the interests of protecting individuals (e.g. threatened or endangered species), communities, populations or ecosystems from adverse ecological effects. The risk assessment results are used in conjunction with other criteria to determine the course of action at a particular site. Frequent coordination among the risk manager, risk assessor, and other stakeholders is critical in selecting remedies that provide acceptable levels of protection for all resources.

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 a 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.

An ecological risk management decision may also consider whether or not the affected area is part of a highly sensitive or ecologically unique environment. For example, Region 5 places a high priority on protecting and restoring the ecological processes of the Midwest which maintain and enhance high quality ecosystems. These ecosystems include: areas of high indigenous biodiversity, ecological self-sustaining ecosystems, and areas containing rare, endangered or threatened species or communities. RCRA corrective action activities should be aware of the larger ecosystem and possible interrelations between cleanup at nearby sites or within similar ecosystems.

Other factors to be considered include the recovery potential of the affected ecological receptors, the magnitude of the expected effects, the expected persistence of the chemicals of concern under present site conditions, and other physical and biological impacts. The reduction and virtual elimination of persistent, bioaccumulative and highly toxic chemicals (PBTs) is a high priority of the Agency. Sites contaminated with PBT compounds will be focused on to achieve active remediation and expedited cleanup actions.

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 protection of the environment. At these sites, a long term monitoring plan may be incorporated into the final cleanup 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.

In ecological risk assessments, high-risk groups or individuals are usually only considered as part of a sensitive life stage evaluation within a population. However, Congress has determined that for endangered species and migratory birds, individuals as well as populations, communities, ecosystems and habitats will be protected.

Regional guidance:

U.S. EPA Region 5. *Ecological Screening Levels for RCRA Appendix IX Hazardous Constituents*, Draft, January 1999.

U.S. EPA Region 5. *Quality Assurance Project Plan Policy*, April 1998.

U.S. EPA Region 5. *Ecological Risk Assessment Guidance for RCRA Corrective Action*, Interim Draft, October 1994.

National guidance:

U.S. EPA. *Ecological Risk Assessment and Risk Management Principles for Superfund Sites*, Final, October 1999. OSWER Directive 9285.7-28 P.

U.S. EPA. *Guidelines for Ecological Risk Assessment*, Final, April 1998, EPA/630/R-95/002F.

U.S. EPA. *Ecological Risk Assessment Guidance for Superfund, Process for Designing and Conducting Ecological Risk Assessments*, Interim Final, June 1997.

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