United States General Accounting Office

150015

GAO

Testimony

Before the Subcommittee on Superfund, Recycling, and Solid Waste Management,
Committee on Environment and Public Works,
U.S. Senate

For Release
on Delivery
Expected at
10:00 a.m. EDT
Thursday
September 30, 1993

SUPERFUND

Risk Assessment Process and Issues

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GAO/T-RCED-93-74

Mr. Chairman and Members of the Subcommittee:

As the Subcommittee considers Superfund reauthorization issues, we are pleased to provide this statement for the record on the Environmental Protection Agency's (EPA) process for assessing risk at Superfund hazardous waste sites. Risk assessments provide key information that affects EPA's management of current and future site risks, including decisions on whether and how to clean up sites. These considerations are particularly important because of the choices EPA must make about cleanup priorities in view of the high cost of hazardous waste cleanups. At your request, our statement focuses on EPA's process for assessing the risks to human health posed by Superfund sites and questions that have been raised concerning some of the assumptions and calculations used in these risk assessments.

In summary, the Superfund risk assessment process has three key steps: (1) the exposure assessment, which evaluates whether people at or near sites may be at risk from the contaminants present; (2) the toxicity assessment, which determines whether these contaminants could have harmful effects on human health at the levels present at the site; and (3) the risk characterization, which uses information from the exposure and toxicity assessments to estimate the likelihood that individuals at or near the site could develop cancer or other health problems. Our work to date has shown that for all three steps in the process, scientific uncertainties and data gaps persist in spite of the enormous quantity of data that EPA gathers about each site.

First, the major exposure uncertainty that EPA must deal with is to gauge how the site's land will possibly be used in the future. That is, if people reside on a site, they will be much more exposed than if they merely work on it. Because EPA cannot with certainty know or control the land's future usage, it has made a policy decision to project a future residential use, unless there is substantial evidence to the contrary. This decision to err on the side of conservatism has been strenuously questioned, especially by the responsible parties who must pay for the cleanups.

Second, EPA's toxicity assessments must rely in large part on available data from animal experiments because experiments on human beings are rarely ethically permissible. Use of the animal data involves extrapolation from animals to human beings and from the high experimental doses given to animals to the low doses present at sites. Data extrapolation is a scientifically uncertain process and therefore controversial. Additionally, some critics have questioned EPA's policies for extrapolating data on carcinogens and noncarcinogens. These policies are designed to provide for an extra margin of safety in the face of scientific uncertainties.

Third, EPA's process for characterizing site risk involves combining the potential exposure to contaminants with data on their toxicity. Criticisms of EPA's risk characterization have focused on (1) how risk assessments should account for uncertainty and variability in site data and (2) whether Superfund's resultant risk formula overstates risk by combining conservative estimates.

Before we begin a more detailed discussion of EPA's risk assessment process, let us provide you with some background information on where risk assessment fits in the overall Superfund cleanup process.

BACKGROUND

Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, or Superfund), EPA evaluates hazardous waste sites and places those having the highest potential human health or environmental risk on the National Priorities List (NPL). Superfund also established a cleanup process for NPL sites, which includes studying and analyzing them to determine if they warrant cleanup, developing an array of potential cleanup remedies, selecting specific remedies, and designing and constructing the cleanup remedies. The law established a fund for cleaning up these priority sites and gave EPA the authority to compel parties responsible for these sites to help conduct or pay for cleanup. In 1986, the Superfund Amendments and Reauthorization Act (SARA) set new requirements for selecting cleanup remedies. In 1990, the Congress reauthorized CERCLA through 1994, bringing its total authorizations to $15.2 billion, without making any substantive changes to the program.

To determine whether contaminated sites threaten human health and/or the environment, EPA evaluates potential risk at several points in the Superfund cleanup process. EPA conducts preliminary assessments and site investigations of sites to identify those that may be serious enough to list on the NPL and to screen out those that are less serious. EPA uses a Hazard Ranking System to assess the hazard associated with a site and places those sites with relatively high scores on the NPL. Once a site has been placed on the NPL, a number of steps take place before actual cleanup activities begin. These steps include a comprehensive site study to analyze site contamination and develop potential cleanup remedies, a formal site cleanup plan, an engineering design for the selected remedies, and construction of the cleanup remedies. EPA can also perform an emergency removal action at any time to respond to situations that immediately threaten human health or the environment, without following all of these steps.

The formal baseline risk assessment, the focus of today's testimony, is part of the comprehensive site study in which the site is analyzed and the potential cleanup remedies are developed. The purpose of the assessment is to estimate the likelihood that

human health and/or the environment will be harmed as a result of exposure to contaminants at the site if no cleanup takes place. EPA will generally take cleanup action if the estimated risk of developing cancer from exposure to the site's contaminants is greater than one in 10,000 or, for noncarcinogenic contaminants, if an individual could be exposed to a potentially harmful dose.

EPA's regions are responsible either for making baseline risk assessments or for overseeing those performed by potentially responsible parties. Science direction comes from EPA's Office of Research and Development (ORD), while policy direction comes from the Office of Solid Waste and Emergency Response. ORD provides general risk assessment guidance for all of EPA's programs and also maintains a data base on the toxicity of environmental contaminants.

EPA distinguishes between risk assessment--in which risk is estimated--and risk management--in which the agency decides whether and how to conduct a site cleanup. The regulations implementing CERCLA require that EPA, in selecting a cleanup remedy, also consider such factors as whether the remedy (1) is cost-effective; (2) reduces the contaminants' toxicity, mobility, or volume; (3) is effective in the short term; and (4) is satisfactory to the state and the community.

With this perspective, we would now like to discuss the three steps in the risk assessment process and some of the most pressing scientific and policy issues.

ASSESSING THE EXTENT OF EXPOSURE TO CONTAMINANTS

The goal of the exposure assessment is to determine whether people in the community may come into contact with contaminants through a number of possible exposure "pathways."[1] To identify and evaluate these pathways, risk assessors gather information about how people currently use the site and nearby areas. For example, if an open field is contaminated, EPA may ask local officials whether children play there. EPA also considers activities that may occur in the future, for example, whether the site may later be developed for homes or a school.

EPA Policies on Land Use

The assumption about how the site and surrounding land will be used in the future is probably the most important decision in the

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[1]Potential pathways include ingesting contaminated groundwater, surface water, or soil; eating fish from contaminated water or home-grown produce from contaminated soil; absorbing contaminants through direct contact with the skin; and breathing contaminated air.

exposure assessment. EPA generally assumes that residential use of land is possible in the future, unless there is substantial evidence to the contrary. Although the current use of most Superfund sites can be readily classified as residential, industrial, or recreational, those involved in the Superfund process disagree about how sites may be used in the future. Future land use affects assumptions about how frequently and in what manner people may potentially be exposed to site contaminants. For example, under a residential-use scenario, EPA might assume that children and adults breathe contaminated air 24 hours per day year-round, while an industrial-use scenario might assume that adult workers are exposed for 8 hours per day for 250 days per year. The differences in these exposure assumptions could affect the risk calculation significantly enough to change the risk manager's choice of a remedy.

Some responsible parties and representatives of industry groups whom we interviewed contend that some EPA risk assessments that assume future residential use of currently industrial sites exaggerate the risks at these sites. EPA officials offered several reasons for making such an assumption. First, EPA officials believe that SARA requires a conservative approach to protecting human health and the environment because of the law's preference for permanence and for treatment to the maximum extent practicable. Second, because EPA cannot directly control land use once a Superfund site has been cleaned up, it believes the residential-use scenario is most protective.

State and local governments often seek to influence EPA's land-use decisions. To avoid having to pay for long-term operations and maintenance, states often push EPA to adopt a residential-use scenario with its more stringent cleanup standards, according to EPA regional staff. Communities sometimes advocate more or less stringent cleanups because they may perceive the selected remedy as not providing a sufficient level of permanence or as having dangerous side effects.

To illustrate the effect that land-use assumptions can have on risk characterization, we reviewed a metal-treating site in Michigan. Metals and organic contaminants leaked into a shallow groundwater aquifer from the adjacent facility. The surrounding land use is currently mixed, and the contaminated aquifer is too shallow to be used for drinking water. Responding to state concerns, EPA assumed a future residential-use scenario, under which it determined that the site posed a future risk driven mainly by drinking the groundwater. However, EPA also considered an alternative, industrial-use scenario, under which it concluded that no significant risks existed at the site. EPA has recently decided to use the future industrial-use scenario and concluded that no cleanup actions, beyond groundwater monitoring and deed restrictions, are necessary. The state opposes EPA's decision. We

have not reviewed this site sufficiently to determine the appropriateness of EPA's decision.

EPA's Use of Site-Specific Data and Standardized Assumptions

In addition to future land use projections, the other key question involves the extent to which exposure estimates are based on site-specific observations versus standardized assumptions. EPA encourages the collection of site-specific data and believes these data can improve the assessment of current risks. For example, at a landfill located in a state park in Illinois, the responsible party collected site-specific data that considerably changed the exposure assumptions that would have been used in the risk assessment. A survey of park employees and visitors showed that, contrary to the original assumptions, a portion of the population regularly caught and ate fish from a pond on-site. The survey also showed that parts of the park assumed to be in frequent use were, in fact, seldom used.

Unfortunately, it is difficult to gather site-specific data on many potential sources of exposure. Measurements of actual human exposure can be difficult, time-consuming, and expensive to collect. Also, the science has not yet advanced enough to (1) detect all contaminants and (2) determine whether those contaminants present in body tissues can be traced back to a specific source. Additionally, surveys of local residents may help describe current site use, but not future use, and not all community members may agree to participate. Furthermore, the Paperwork Reduction Act requires that any federal agency's survey of 10 or more nonfederal persons or entities be reviewed and approved by the Office of Management and Budget, a potentially lengthy process that may delay the risk assessment and site cleanup.

Instead, EPA uses standardized exposure assumptions to describe how people might come into contact with site contaminants. EPA frequently relies on national studies to provide information on factors needed to complete the exposure assessment, such as the volume of water consumed daily and the length of time that people typically live in one residence. However, the resultant standardized exposure values used may over- or understate actual local exposure, thus raising uncertainty about the risk assessment's results.

EPA has been criticized for not adequately modifying such standardized assumptions by taking into account site-specific conditions. Responsible party representatives report that such standardized exposure assumptions overstate site risk. For example, they believe that lowering the number of days that individuals will come into contact with soil in a northern latitude from an assumed 365 days to a number that more appropriately

reflects the local climate and annual snow days, would result in a more accurate exposure assessment. However, replacing the hundreds of exposure assumptions that go into a complex risk assessment has the potential to further delay the Superfund cleanup process. EPA officials said that unless the data significantly differ from the standardized assumptions, the effort may not be worthwhile.

ASSESSING THE HAZARDS OF CONTAMINANTS PRESENT

To determine how and whether hazardous contaminants present may affect the health of people at or near a site, EPA conducts a toxicity assessment. Because data on the actual human health effects of contaminants are often not available, EPA uses available data from animal experiments. To use the animal data, EPA must extrapolate in two different ways--from animals to human beings and from the high experimental doses given to animals to the low doses present at Superfund sites. Data extrapolation is a scientifically uncertain process and therefore controversial. EPA has developed specific policies for extrapolating data on carcinogens and noncarcinogens to provide for an extra margin of safety in the face of scientific uncertainties.

Extrapolation From High Doses Given to Animals to Low Doses for Human Beings

Data on the human health responses to contaminants are scarce; therefore, EPA's toxicity assessment depends upon data extrapolations that have raised several difficult scientific and policy questions. Two major questions concern extrapolations from animals to human beings and from high experimental doses to the low doses found at sites.

First, EPA generally relies on animals for toxicity data, because experiments on human beings are only rarely ethically permissible. Even if the animal experiments are done well, an extrapolation from animals to human beings is needed to understand the experiments' possible relevance to human health. The major concern centers on whether contaminants that have been shown to cause carcinogenic or other adverse health effects in experimental animals also cause comparable effects in human beings.

Second, use of data from animal experiments involves extrapolation from the high doses given to experimental animals to the relatively low doses found at Superfund sites. Uncertainty exists about whether a particular contaminant will have the same adverse effect at low doses, and for many contaminants it is unknown whether a dose threshold exists below which no carcinogenic effects would be expected. Superfund critics contend that although the use of excessively high doses in animal studies leads to cancer in animals, such studies are not relevant to human beings who are likely to be exposed at lower levels.

Compensating for Uncertainty in Data About Carcinogens and Noncarcinogens

To respond to the need to extrapolate from existing toxicity data, EPA has developed specific policies for both carcinogens and noncarcinogens. EPA's policy for all of its programs assumes that any amount of exposure to a carcinogen carries some risk of developing cancer. As a result, some critics have stated that Superfund risk assessments are overstated because they are primarily driven by the relative carcinogenicity of site contaminants. However, others contend that this focus on carcinogens may understate overall risks at some sites because other kinds of adverse health effects, such as breathing problems, skin rashes, and birth defects, may be given insufficient weight.

For noncarcinogens, EPA's policy is to adjust the toxicity values derived from animal studies to provide an extra margin of safety. EPA multiplies the estimated toxicity value by 10 for each uncertain aspect. For example, EPA increases the toxicity of toluene measured in animal studies by 1,000 to adjust for three uncertainties: the differences between rats and humans, the need to generalize long-term effects from short-term study results, and the limited data on toluene's toxicity to reproductive systems and to fetal development. EPA recognizes that the risk may be overstated, partly as a result of this policy, but believes that it is important that the agency not underestimate risk to help ensure that its decisions protect human health.

CHARACTERIZING THE LIKELIHOOD THAT HEALTH PROBLEMS WILL OCCUR

The final step in EPA's risk assessment process entails characterizing the risks of adverse health effects likely to occur now or in the future if no cleanup actions take place. EPA combines individuals' estimated exposure to each contaminant with each contaminant's estimated toxicity, summing the results for those exposed to more than one contaminant or to contaminants from a variety of sources. (For example, an individual near a site might both drink contaminated water and inhale contaminated air.) The end result is an estimate of total site risk that will vary, depending upon the exposure scenarios used.

Because many of the exposure and toxicity factors used to characterize risks are inherently uncertain and variable, responsible parties have criticized the accuracy of EPA's risk assessments.[2] In particular, these criticisms have focused on two

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[2]Uncertainty is introduced into risk assessments when a factor--for example, the amount of soil that adults typically ingest each day--cannot be accurately measured. Variability is introduced when a factor--for example, the amount of contamination in the

issues: (1) how EPA should account for uncertainty and variability in its risk assessments and (2) whether EPA's resultant risk formula overstates risk by combining high-end estimates together.

Data Uncertainty and Variability

EPA generally uses single values for exposure and toxicity when calculating risk, despite the uncertainty and variability in these data. While this practice simplifies the process of risk characterization, it has resulted in criticism from both the scientific community and responsible parties that risk assessments suffer from false precision because they present a single risk number based on highly uncertain data.

EPA's Science Advisory Board has advocated using techniques, such as Monte Carlo simulation,[3] that explicitly include uncertainty, and Superfund risk assessment guidance recognizes Monte Carlo simulation as a method for uncertainty analysis. However, such approaches have seldom been used in Superfund risk assessments because, according to EPA officials, (1) the required data ranges, such as the amount of soil that adults typically swallow each day, are often unavailable and (2) most Superfund staff do not have the training to conduct or evaluate Monte Carlo analyses.

In addition to Monte Carlo analysis, risk analysis experts and statisticians whom we interviewed suggested that sensitivity analysis might be another useful tool for describing and attempting to quantify the magnitude and effect of data uncertainty and variability on the risk assessment's results. Sensitivity analysis involves varying important factors of the risk assessment equation one at a time to determine if the variability has a substantial impact on the outcome. For example, if the risk assessor was uncertain about future land uses for a site, several scenarios could be calculated and compared to determine the effects of the land-use decision.

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air--can be measured but tends to change over time. Consequently, factors commonly used in risk assessments, such as the concentration of a contaminant in soil at the site, the number of years people live in one residence, and the amount of soil ingested per day, can all be expressed as a range of values with an average, a high, and a low.

[3]Monte Carlo simulation estimates potential risk by repeatedly selecting random values from data distributions for each of the risk assessment factors in order to come up with a statistical distribution of site risk.

Combining High-End Values

As previously noted, Superfund sites can present the risk assessor with information on many contaminants, possible exposure scenarios, and sources of scientific uncertainty. EPA characterizes risk for each contaminant by combining the exposure estimates, which sometimes have been increased to account for uncertainty. A recent report by an industry group criticized EPA for this practice of characterizing site risks. In its view, combining overestimates of exposure and toxicity "exaggerates" the risk.[4]

Our review showed that Superfund's current guidance on exposure assessments requires using central, or average, values for many factors, with high-end values being used only for the most variable factors. For example, the contaminant concentration and body weight factors used in the standard exposure assessment are average values. However, factors describing human behavior, such as length of residence at the site and the amount of water consumed per day, are high-end values. The use of such an approach would result in a conservative, but not extreme, description of potential exposure; however, we did not evaluate the extent to which EPA adheres to this guidance.

SUMMARY

Risk assessments are integral to EPA's attempts to balance competing Superfund program goals of cleaning up as many hazardous waste sites as possible while trying to ensure effective cleanups. However, as we have noted, characterizing risks at Superfund sites is, perhaps, one of the most difficult tasks that EPA undertakes. EPA must deal with unpredictable patterns of human behavior that affect the way individuals and communities are exposed to hazardous wastes, as well as with the scientific uncertainty about the extent to which contaminants adversely affect human health. In addition, risk assessments require an accurate knowledge of the type of contaminants present at a site and procedures for quantifying how these contaminants might interact under a variety of scenarios.

Although more research and data may yield improvements, it is impossible to remove all imprecision from the risk assessment process. EPA's solution has been to rely on models and assumptions about the way individuals come into contact with and the danger from contaminants. In accordance with its interpretation of the statute, EPA also has made a policy decision to err on the side of caution. It has determined that future as well as current risks

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[4]Exaggerating Risk: How EPA's Risk Assessments Distort the Facts at Superfund Sites Throughout the United States (Hazardous Waste Cleanup Project, June 1993).

should be considered and that, whenever in doubt, its assessments should overestimate rather than underestimate risk.

EPA's policy decision has led to a number of criticisms, especially from those industrial parties responsible for cleanups. Most critics have focused on EPA's procedures for dealing with scientific uncertainty and the assumptions---particularly about future land use--made in the absence of better site-specific data.

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