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SUPERFUND

**Risk Assessment Assumptions
and Issues**

Statement for the record by
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Mr. Chairman and Members of the Subcommittee:

As the Subcommittee considers reauthorizing the Superfund program, we are pleased to provide this statement on the Environmental Protection Agency's (EPA) assessments of the health risks posed by Superfund hazardous waste sites. These risk assessments, which can determine the cost of site cleanups, have been a source of great controversy because they are often based on limited data and therefore frequently rely on assumptions about the health effects of waste sites.

As the Committee requested, our statement (1) presents an overview of EPA's risk assessment process that highlights where risk assumptions are made; and (2) summarizes comments from our own and other reports¹ on some of the more controversial aspects of this process.

In summary:

- EPA's Superfund risk assessment process includes estimating what quantity of contaminants from a site are reaching or could reach human populations and determining how toxic these contaminants are to humans. Using this information, EPA estimates what harm the site could cause if it were left untreated. EPA makes assumptions both about the quantity of contaminants that will reach people and the toxicity of these contaminants, because data on the actual level of these factors is often incomplete. Because EPA assumes more exposure and greater toxicity in some cases than critics think is realistic, these assumptions have been controversial. However, EPA believes that its exposure and toxicity assumptions must be conservative to protect communities around Superfund sites.
- GAO, the EPA Science Advisory Board (SAB), and the National Academy of Public Administration (NAPA) have recently reviewed aspects of EPA's risk assessment process. GAO reported that EPA risk assessors had generally followed the Agency's policies but appeared to make inconsistent assumptions about future land use, an important determinant of risk, and had not fully disclosed the basis for their conclusions about

¹Superfund: Improved Reviews and Guidance Could Reduce Inconsistencies in Risk Assessments (GAO/RCED-94-220, Aug. 10, 1994); Setting Priorities, Getting Results: A New Direction for EPA, National Academy of Public Administration, Apr. 1995; Science Advisory Board: Superfund Site Health Risk Assessment Guidelines, EPA-SAB-EHC-93-007, Feb. 1993.

risks, as required by EPA policy. NAPA endorsed the principles of the Superfund risk assessment process but said that assumptions about risk should be made more explicit when presenting conclusions about site hazards to the public or to decisionmakers. SAB recommended that more data be collected on the actual exposure patterns of populations.

BACKGROUND

With the enactment of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), the Congress created the Superfund program, authorizing EPA to require responsible parties to clean up hazardous waste sites or to recover its cleanup costs from the parties. Since 1980, EPA has included over 1,300 sites on the National Priorities List, its list of the nation's most contaminated sites. EPA begins work at each listed site by conducting a remedial investigation to determine the nature and extent of contamination. Part of this investigation is the risk assessment which calculates the risks that sites would pose to human health if left untreated. The assessment also helps determine how far the level of contamination reaching people needs to be reduced to avoid adverse health effects.

EPA'S RISK ASSESSMENT PROCESS

Our statement focuses on the following two steps in the Superfund risk assessment process: (1) the exposure assessment, which estimates the quantity of contaminants likely to reach people at or near sites and (2) the toxicity assessment, which estimates the contaminant intake level that could harm human health. EPA combines information from both of these assessments to estimate the likelihood that individuals at or near the site could develop cancer or other health problems. A coalition of trade associations interested in Superfund risk assessments has charged that assumptions EPA makes about exposure and toxicity are unduly conservative--that is, they exaggerate site risks--and contribute to unnecessarily costly cleanups.²

Exposure Assessments

The goal of EPA's exposure assessment is to determine whether people in the community may come into contact with contaminants through a number of possible exposure "pathways."

²Exaggerating Risk: How EPA's Risk Assessments Distort the Facts at Superfund Sites Throughout the United States (Hazardous Waste Cleanup Project, June 1993).

For example, people could become exposed through ingesting contaminated groundwater or soil or absorbing contaminants through direct contact with the skin. 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 be developed for homes or a school. In addition to gathering data on actual site use, the exposure assessment makes assumptions about people's rate of contact with contaminated media (such as how much water they drink daily) and how the site will be used in the future.

Although EPA encourages the collection of site-specific exposure data, measurements of actual human exposure can be difficult, time-consuming, and expensive to collect. Also, it is not always possible or practical to (1) detect all contaminants in the body tissues of people potentially affected by a site and (2) determine the source of contaminants that are detected. Additionally, surveys of local residents may help describe current site use, but not future use, and not all community members may agree to participate.

When site-specific exposure data are lacking, EPA often uses standardized exposure assumptions to describe how people might come into contact with site contaminants. Superfund's standard assumptions are based primarily on the Agency's Exposure Factors Handbook, which provides assumed exposure levels that, according to EPA officials, are used by other EPA programs and other federal agencies. The handbook provides information on such factors as the volume of water people consume daily and the length of time that people typically live in one residence.

Some of the handbook's exposure assumptions exceed the actual exposure level of most people. For example, while the handbook assumes that people drink two liters of water per day at home, an analysis produced by the American Industrial Health Council, an industry association, reported that only about 10 percent of people drink more than two liters of water per day at home.³ The Council's analysis also estimated that only about 7 percent of people live at a residence for longer than the 30 years that EPA assumes in its risk assessments.

EPA sets its exposure assumptions above the average level because the agency believes it has a mandate to protect most people (including children and other susceptible persons), not

³Exposure Factors Sourcebook, American Industrial Health Council, 1994.

just the average person. Critics complain that high exposure levels for individual risk factors are unlikely in and of themselves, but, and when combined, describe the risk of only a small proportion of the population--e.g., those who drink an unusually large amount of water and live in their house for a much longer than average period, and exceed other typical behaviors.

In calculating risk, EPA also estimates the future exposure of people living or working on or near the site as well as their current exposure. Estimating future exposure requires an assumption about how the site and surrounding land will be used in the future. It is one of the most important steps in the exposure assessment because assumptions about the future use of land are a major determinant of many cleanup strategies. For example, if the land is used for homes, people are assumed to be exposed over longer periods than if the land is used for business, and a more stringent cleanup could be required. To be conservative, EPA generally assumes that residential use of land is possible in the future, unless there is substantial evidence to the contrary. Critics contend that EPA assumes residential uses for sites that will be used solely for industrial purposes for the foreseeable future.

Toxicity Assessments.

In addition to estimating the volume of contaminants to which people on or near a site are exposed, EPA risk assessments also estimate the toxicity of the contaminants. Because data on the actual human health effects of contaminants are often not available, EPA uses data from animal experiments. To use this data, EPA must extrapolate in two different ways--from animal to human beings and from the high experimental doses given to animals to the low doses commonly originating from Superfund sites.

This extrapolation is a scientifically uncertain process and therefore controversial. First, there are uncertainties about whether contaminants that have been shown to cause adverse health effects in experimental animals would cause comparable effects in human beings. EPA is concerned that people may react more strongly to contaminants than animals. To compensate for this possibility, EPA reduces the contaminant intake level that causes harmful effects in animals when estimating the intake level that will harm humans. This reduction can be as high as a factor of one thousand. This practice of reducing the acceptable intake level is also followed by the Food and Drug Administration. Second, although for many contaminants it is unknown whether an intake threshold exists below which no carcinogenic effects would be expected, EPA assumes that there are adverse effects for all exposure levels. Superfund critics contend that although studies

showing that very high doses of contaminants lead to cancer in animals, such studies are not relevant because human beings are likely to be exposed at much lower levels. The National Research Council, however, recommended that EPA continue to assume adverse effects from lower doses in the absence of other information.⁴

AREAS TO IMPROVE EPA'S RISK ASSESSMENT PROCESS

GAO, EPA's Science Advisory Board (SAB), and the National Academy of Public Administration (NAPA) have recently reviewed aspects of EPA's Superfund risk assessment policies. We reported in August 1994 that a sample of assessments produced in each of the 10 EPA regions generally followed agency guidance. However, we found that assessments appeared to make inconsistent assumptions about future land use and that most of the assessments did not adequately discuss uncertainties in the data or assumptions as well as the range of possible risks. Along these same lines, SAB recommended that EPA develop risk assessments that recognized that all members of a community are not at equal risk from a site but that there is a range of risks along which members fall. NAPA also recommended that EPA make better disclosure of the assumptions and uncertainties in its risk assessments. NAPA concluded, however, that while EPA's risk assessment policies need to be refined, they are essentially sound.⁵

Determination of Future Land Use

In our 1994 report, we said that judgments about how land will be used--whether for residential, industrial or other purposes--are crucial to determining the potential for human exposure to hazardous waste. EPA's risk assessment guidance gives general directions on determining how land might be used in the future, such as looking at population trends and zoning plans, but leaves the decision to the risk assessors. In addition, EPA encourages the assessors to take a relatively conservative approach in deciding the future use of land. Because EPA cannot control local zoning or other land use

⁴Science and Judgment in Risk Assessment, National Research Council, 1994.

⁵The National Research Council's 1994 report entitled Science and Judgment in Risk Assessment examined the use of risk assessments in EPA's Clean Air program. The risk assessments used in this program are similar in some ways to those used in the Superfund program. The National Research Council said "Because of limitations on time, resources, scientific knowledge, and available data, EPA should generally retain its conservative, default-based approach to risk assessment..."

restrictions, the guidance suggests that risk assessors assume that in the future, the land will be residential even if no one lives there now.

Consistent with this guidance, most of the risk assessments we evaluated in our 1994 review assumed that residential development would eventually occur on hazardous waste sites, even though few sites then had residences directly on them. However, we found some apparent inconsistencies in assessors' forecasts of future use. Specifically, under similar circumstances, risk assessments forecast different land uses for sites. Of the 17 sites in our review that were either abandoned or used for industrial or recreational purposes, risk assessments assumed that 12 would have homes built on them in the future but that 5 would never be used for residential purposes.

Three landfill sites we reviewed demonstrate the variation in risk assessors' judgments about future land use. All three sites had similar conditions: inadequate coverings over the landfill, nearby residences, and contaminated groundwater affecting the residents' drinking water. Although landfills seem unlikely sites for residential development, at the Hercules 009 Landfill in Georgia and the Woodstock Landfill in Illinois, the risk assessments concluded that people would build homes on them in the future--exposing residents to contaminated soil and water every day. In contrast, at the Strasburg Landfill in Pennsylvania, the risk assessment concluded that the site would not be developed but that occasional trespassers would come in contact with the contamination at the site. The risks measured at the Hercules 009 and Woodstock landfills indicated the need for cleanup, but the risk at the Strasburg site did not exceed the criteria for cleanup.

EPA officials acknowledged that estimating how land might be used is a somewhat subjective and often contentious step in the risk assessment, but, they pointed out, the agency has drafted new guidance on forecasting land use that directs the risk assessment team to consult with the local community on such issues as zoning and the use of adjacent land in making an early determination of future land use. This might offer a more realistic approach than assuming that residential use would prevail in almost all cases.

Better Recognizing the Range of Possible Risks

EPA's exposure assumptions have the effect of standardizing risk factors for people in the vicinity of a site. For example, the risk assessments often assume that persons exposed to site contaminants are all the same weight, live in their houses for the same number of years, and all drink the same quantity of water daily. In reality, people in the population exposed to the

site fall in a range for each of these factors. Critics from both the scientific community and industry contend that risk assessments suffer from false precision because they present a single risk value and ignore the actual variation in risks. In addition, as noted above, industry sources charge that combining the standardized assumptions overstates community exposure.

In its February 1993 report, the SAB reviewed EPA's guidance for assessing Superfund human health risks. Among other things, SAB recommended that EPA move toward an assessment approach that recognized that all people in the communities affected by Superfund sites are not at equal risk. To achieve this, SAB suggested that EPA develop data showing how many members of the affected population have certain combinations of risk factors, such as lower body weight with long-term residence near the site and high consumption of water, etc. Development of the frequency of these combinations would disclose what portion of the population would be at high or low risk from the site or at what stage in between.

EPA officials said that they recognize that this method of estimating risk would be a valuable technique when adequate data are available. However, the officials said that current data is not available for routine application of this analysis. EPA Administrator Browner, responding to SAB's recommendations, made this point, stating that "SAB emphasizes methods that, if the pertinent data were available, might do much to reduce uncertainty; whereas, ...all too often, limitations of resources, time, or technology prevent [assessors] from obtaining the data they would most like to have."

Nevertheless, in response to concerns about developing more information on risk ranges, the EPA Administrator issued a memorandum in March 1995 announcing an updated policy on risk characterization. According to EPA, under this new policy, the agency will explore ways to better characterize the likely exposures of populations around contaminated sites and will train staff to use ranges of values for risk factors more often in its assessments. However, the EPA emphasizes that its efforts must strike a balance between the desire for "perfect" data and real constraints of time, money, and a community member's right-to-privacy.

Disclosing Uncertainty in Risk Assessments

Both GAO and NAPA have reported that EPA's Superfund risk assessments need to adequately disclose and discuss their underlying assumptions and limitations. EPA's risk assessment guidance also recommends that an assessment communicate the precision of its estimates by explaining the limitations of the data in all of its steps. Such disclosures, according to the

guidance, should include a description of any uncertainty, variability, or assumptions used in the risk assessment. Specifically, EPA states that the risk assessment should provide the ranges of possible values in the data used throughout the assessment. EPA also directs that the assessment explain both the reasons for the values or assumptions used and their effect on the calculated level of risk. For example, when determining how frequently people are exposed to waste when working at a site, a risk assessment would be expected to (1) provide a realistic range for the number of days people typically spend at work per year, (2) explain how an assumption (for example, 250 days per year) was selected, and (3) evaluate whether that value would tend to overstate or understate the risk.

Our August 1994 report, however, disclosed that 19 of 20 risk assessments we reviewed did not follow, in one or more respects, EPA's guidance requiring full disclosure of the limitations of the data. Specifically,

- 18 did not include any information on the ranges of possible values to measure exposure (for example, the number of days people might typically work at the site);
- 7 did not explain how they arrived at the values or assumptions used in calculating risk (for example, why a risk assessment included an assumption that people would work 250 days per year at the site); and
- 10 did not explain how the values or assumptions affected the risk estimate (for example, whether using 250 working days per year would tend to overstate or understate the risk.)

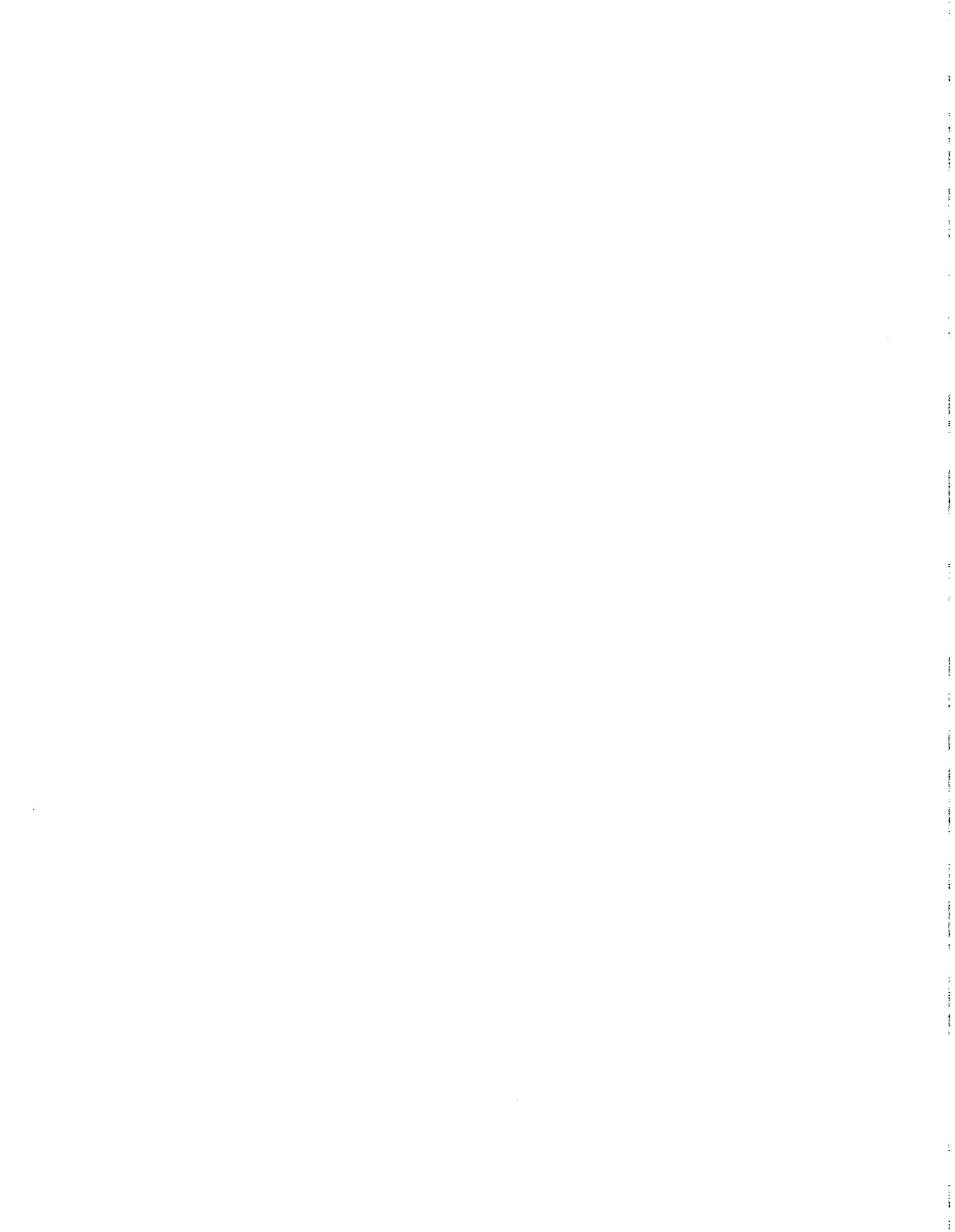
In its April 1995 report, NAPA said that an essential feature of a good risk analysis is a clear discussion of the limits of the analysis, the significance of assumptions, and the consequences of the value-based decisions imbedded in that analysis. Consequently, NAPA recommended that EPA's risk characterizations provide all decisionmakers and the public with clear explanations of the assumptions, biases, and uncertainties inherent in their analyses.

In response, EPA officials acknowledged that the agency could improve its handling of uncertainty and variability in its risk assessments. To help address these concerns, in March 1995 EPA issued guidance to the agency's program and regional offices instructing them that risk assessments should identify all major uncertainties and how the uncertainties can influence the assessment.

SUMMARY

In summary, the principle controversy over EPA Superfund risk assessments has involved the margin of safety these assessments build into their estimates of the dangers from sites. EPA believes that it is required by law to protect the whole community and for this reason must calculate the risks of above average exposure and allow for uncertainties about the toxicity of contaminants. Some industry critics think that the margin of safety is excessive. GAO and other independent reviewers have called for better disclosure of the assumptions underlying risk assessments and the uncertainties in their conclusions and more information on actual exposure. In a recent major policy statement, the EPA Administrator acknowledged a need for this type of information and said the agency will take steps to better characterize the likely exposures of populations around contaminated sites. Better information about actual risks and the assumptions in risk assessments might shed light on the appropriateness of EPA's margin of safety. However, the level of safety that is chosen will remain a matter of policy.

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