United States General Accounting Office

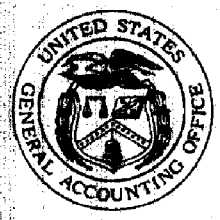
GAO

Report to Congressional Requesters

August 1994

SUPERFUND

Improved Reviews and Guidance Could Reduce Inconsistencies in Risk Assessments



GAO/RCED-94-220

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-257513

August 10, 1994

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
House of Representatives

The Honorable Al Swift
Chairman, Subcommittee on Transportation
and Hazardous Materials
Committee on Energy and Commerce
House of Representatives

EPA's regulations implementing the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) require an assessment of the risks to human health posed by each of the Superfund program's hundreds of hazardous waste sites. Because these risk assessments are a tool, among several, that the Environmental Protection Agency (EPA) uses to determine whether and how sites should be cleaned up, they have been a source of considerable scrutiny and controversy. For example, both industry and environmental groups have criticized risk assessments for inconsistently estimating the amount of contamination to which those living near Superfund sites may be exposed.[1] Partly because of these concerns, the administration's proposal for reauthorizing Superfund calls for writing a new risk assessment regulation that will establish more specifically how risk assessments are to be conducted.

In response to your questions about the way EPA assesses the health risks posed by Superfund sites, we reviewed 20 (2 from each of EPA's 10 regions) of the approximately 70 risk assessments conducted in 1992. In this report, we provide information on (1) whether the risk assessments adhered to EPA's guidance, (2) whether they varied among regions and sites, and (3) how EPA monitors the quality and consistency of risk assessments. As you requested, we focused particularly on how risk assessments measured human exposure to hazardous contaminants and calculated the resulting risk. You also asked for data on the sources of contamination described in these risk assessments and the risks associated with these sources. This information appears in appendixes II through VI.

[1]We discussed some of these issues in Superfund: Risk Assessment Process and Issues (GAO/T-RCED-93-74, Sept. 30, 1993).

Results in Brief

In general, the 20 risk assessments we reviewed adhered to EPA's guidance and were prepared consistently across EPA's 10 regions. Most of the assessments followed the guidance in how they identified which contaminants were present and used similar assumptions in measuring human exposure to hazardous material in the environment. However, some of the assessments we reviewed did not follow EPA's guidance for (1) estimating the level of contamination, (2) adequately describing the assumptions and uncertainty inherent in the assessments, and (3) calculating the total risk from all means of exposure. As a result, risks were estimated to be either higher or lower than they would have been if the risk assessment team had followed the guidance.

Although the risk assessments we reviewed generally followed consistent approaches, they sometimes used different assumptions in estimating exposure, specifically, in (1) judging how sites might be used in the future and how much contamination would remain there and (2) determining how people absorb contaminants through their skin. When such inconsistencies occurred, risks were estimated differently even though the sites had similar characteristics.

To monitor the quality and consistency of risk assessments, EPA has conducted annual quality assurance reviews—collecting extensive data for about half of the assessments conducted each year. But these reviews produce only summary descriptive information on how risk assessments were done and do not analyze for inconsistencies among risk assessments. EPA staff agreed that the reviews could be improved by analyzing for consistency and noted that this would not require significantly more resources because the reviews already gather most of the necessary information.

Background

With the enactment of CERCLA in 1980, the Congress created the Superfund program, authorizing a trust fund to clean up the nation's most severely contaminated hazardous waste sites. The program was extended in 1986 and in 1990 and is now being considered for reauthorization. Under CERCLA, EPA reviews contaminated areas and then places the nation's most highly contaminated sites on a priority list for investigation and cleanup. Since 1980, EPA has included over 1,200 sites on the list.

EPA begins work at each listed site by conducting a "remedial investigation" to determine whether the nature and extent of contamination warrant cleanup. One element of this investigation is the

baseline risk assessment—a scientific evaluation of any current and potential threats to human health the site would pose if no cleanup occurred. The risk assessment looks at the critical components of risk: the toxicity of the contaminants present and the likely exposure to these contaminants. Along with other information, the assessment may be used to determine whether cleanup is warranted and to describe the potential risks for those who must decide how to clean up the site and for the local community.

The risk assessment has four steps: (1) collecting and analyzing data from site samples to determine the types and levels of chemicals present; (2) estimating the extent to which populations living at or near the site might be exposed to these chemicals through various "pathways"—for example, by drinking contaminated water or touching contaminated soil; (3) assessing the toxicity of the chemicals; and (4) calculating the risks from exposure to this contamination. (Figs. I.1 and I.2, in app. I, illustrate the steps of a risk assessment and the ways people can be exposed to hazardous waste.) A team of EPA regional staff that generally includes the site's project manager, a toxicologist, and other technical staff perform these risk assessment steps.

The risk of developing cancer from the chemicals is expressed as a probability, such as 1 in 10,000. The risk of developing other health problems is determined by calculating a numerical "hazard index" that evaluates whether health problems could occur from exposure to the hazardous chemicals. A value greater than 1 means that a risk of health effects exists.

EPA's policy states that risks greater than 1 in 10,000 for carcinogens and greater than 1 for noncarcinogens are considered serious enough to require cleanup action. However, other factors in addition to the risk assessment also influence whether and how a Superfund site is cleaned up. CERCLA states that cleanups must meet "legally applicable" or "relevant and appropriate" requirements (ARARs), including applicable or relevant federal and state environmental regulations. ARARs in some instances require cleanup when the risk assessment's results would not. For example, CERCLA requires that surface water, like ponds or rivers, near hazardous waste sites meet the legally applicable federal Clean Water Act's standards, independently of risk assessment results. EPA must also consider factors such as the cost, feasibility, and ecological risk in deciding how to clean up Superfund sites.[2]

[2]We are currently evaluating the role of risk assessments and other factors in site cleanup decisions.

To improve the quality of risk assessments and promote consistency, EPA issued Risk Assessment Guidance for Superfund in 1989. This document lays out guidelines for each step of evaluating the health risks at Superfund sites, identifies sources of data, and provides values that can be used in calculating exposure and the resulting risk. Because of scientific uncertainty in the data used in calculating risk, as well as the variable conditions at each site, the guidance grants leeway for professional judgment. Nevertheless, the guidance recommends that estimates of risks be conservative—that the estimates include a "margin of safety." In calculating human exposure to site contaminants, EPA recommends using a "reasonable maximum," or higher than average but still realistic number. For example, to measure how long someone might live in a home near a waste site, EPA looked at statistics on how long Americans live in their homes and then selected a value (30 years) that represents the experience of the upper 10 percent of the population. EPA developed this conservative approach in order to ensure that site cleanups done under CERCLA protect human health.

Both the uncertainty and the assumptions about exposure to contamination that are involved in Superfund risk assessments have drawn considerable criticism. Private parties responsible for cleaning up sites have argued that risk assessments use excessively conservative assumptions and that EPA does not use consistent assumptions from site to site. Both industry and environmental advocacy groups have criticized risk assessments for not adequately accounting for scientific uncertainty and variability.

Risk Assessments Adhered to Most Guidance, Except for Three Areas

For the most part, the 20 risk assessments we reviewed adhered to EPA's guidance. Specifically, the assessments used the prescribed equations in calculating people's daily intake of contaminants; justified excluding detected contaminants from further evaluation; combined risks from separate carcinogenic and noncarcinogenic contaminants; used the specified values for the toxicity of contaminants given people's length of exposure; and adequately justified excluding specific types of exposure. However, of the risk assessments we reviewed,

- 3 did not follow EPA's guidance for estimating the level of contamination, thereby overstating the level of contamination;
- 19 did not adequately explain the uncertainty and variability in the data used and the assumptions made; and

- 7 did not include proper calculations of the total risk to people who could come into contact with several sources of contamination, thereby understating risk.

EPA officials said these deviations from the guidance occurred primarily either because the risk assessment team followed different guidance developed in one of EPA's regions or because the team found it difficult to obtain information needed to follow the general guidance EPA provided.

EPA Overstated the Level of Contamination in Three Cases

EPA's guidance recommends that the risk assessment team use data from site samples to calculate the level of contamination that people might actually encounter at the site. In particular, the guidance states that the measure of contamination (such as the milligrams of a contaminant per kilogram of soil) should be an estimate of the average of the site samples.[3] This estimate is important because it helps determine how much contamination people could come in contact with each day.

Three of the 20 risk assessments we reviewed did not follow EPA's guidance on this matter. Instead, they used a higher estimate, resulting in an overstatement of how much contamination people could encounter at the site. Two used the highest level of contamination found, while the other used an estimate much higher than the average but not the highest level found at the site. For example, the risk assessment team for the PSC Resources site, a solvent-recycling facility in Massachusetts, used the sample with the highest amount of contamination to determine how much someone could come in contact with each day.[4] Using the highest contamination level implies that exposed people would spend all their time at the most contaminated part of the site, which is likely to overestimate exposure.

The risk assessment for PSC Resources followed guidance by EPA Region I (Boston) that conflicted with EPA's national guidance. Specifically, guidance by Region I recommended that its risk assessment staff use the highest level of contamination found, rather than the average level. EPA regional and headquarters staff explained that this conflict between headquarters and Region I stemmed from a disagreement they had over

[3]The risk assessment team is supposed to use a standard statistical procedure, with the result that in only 5 out of 100 instances will the actual average be greater than the value EPA uses to describe the level of contamination.

[4]EPA's guidance states that when an adequate number of samples is not available (generally 20 to 30 samples are sufficient), the highest level of contamination found at the site may be used.

the best way to measure the level of contamination. Region I officials said they are now changing the region's policy to make it conform to the national guidance.

Most Risk Assessments Did Not Adequately Discuss Uncertainty and Variability

Precisely estimating risk is difficult because the data used to derive the estimates often are uncertain and variable. Such uncertainty occurs when EPA cannot determine an exact value to use in estimating risk. For example, the risk assessment team would have no way of knowing the exact number of days each year that people living at a given site would be exposed to waste. Data also may vary considerably. For example, because the level of contamination is different at various locations at a site, the potential for exposure—and therefore the risk—will vary from spot to spot. In cases in which precise data are not available, EPA often uses assumptions to help approximate values. Given such uncertainty and variability, it is important to disclose and attempt to measure how the assumptions used in the risk assessment affect its outcome. In so doing, risk assessment teams are supposed to demonstrate that a range of potential risk exists at the site, which is more realistic than a single estimate of risk. Identifying the sources of uncertainty and variability also allows the risk assessment team to decide where better information might improve the risk estimate.

EPA's guidance recommends that a risk assessment communicate the precision of its estimates by explaining the limitations of the data in all of its steps. Such disclosures 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 impact 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, (2) explain how a given assumption (for example, 250 days per year) was selected, and (3) evaluate whether that value would tend to overstate or understate the risk.

Nineteen of the 20 risk assessments we reviewed did not follow EPA's guidance established to encourage 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).

When risk assessments did communicate information about uncertainty and variability, it was easier to understand how the data and assumptions they used affected the risk estimates. For example, the risk assessment for the Revere Textile Prints site in Connecticut included the range of possible values for determining human exposure, such as how many days during the year workers, residents, and trespassers could come in contact with contaminated areas, and how much contaminated material, such as soil or groundwater, they could take in each day. These values often varied by several orders of magnitude. The risk assessment included a table explaining how the risk assessment team selected values from the ranges. (For example, for trespassers, who could be on the site from 1 to 365 days per year, the assessment assumed 52 days on the basis of one or two visits a week during spring, summer, and fall and none in winter.) It also explained that in many cases the assumed values overstated the typical exposure and could result in a high estimate of risk.

EPA officials said that obtaining the information necessary to discuss uncertainty and variability in data is difficult. In particular, the agency only has limited data on the ranges of exposure to contaminants. The officials also told us that their staff had varying levels of training and experience in the statistical analysis tools needed to describe limitations in data and the resultant effect on risk estimates. They noted, however, that staff in Region III (Philadelphia) have become leaders in this area by developing guidance on how to include this uncertainty and variability in the overall assessment of risk.

EPA officials acknowledged that the agency could improve its handling of uncertainty and variability. They noted that although the agency's guidance states that risk assessments should fully disclose such limitations, the guidance is silent on how to statistically measure these limitations and their impact on the overall estimate of risk, as well as how to use the information when selecting a remedy. They added that Region

III's experience could provide a basis for more specific guidance on the issue. However, they cautioned that progress will be slow until further research provides better data on how people are exposed to hazardous waste sites.

A Third of the Assessments Understated Risk by Not Considering Multiple Sources of Contamination

As part of estimating the human health risk at a Superfund site, EPA's guidance directs risk assessment staff to calculate the total risk faced by people who could be exposed to more than one source of contamination while living or working at the site. According to the guidance, risk from different contaminants and sources can be added together—people could drink contaminated water and come in contact with contaminated soil, for example, over the same time period. At 18 of the 20 sites in our review there was the potential for people to be exposed to more than one source of contamination, but in 7 instances the risk assessment did not calculate the total risk from being exposed to contamination from more than one source.

People living at the Revere Textile Prints site in Connecticut, for example, could be exposed to contaminants in both the groundwater and soil. However, the risk assessment calculated the risks from the groundwater and soil separately without combining them to show the total risk to someone living at the site. The assessment estimated that the individual risks of contracting cancer from drinking groundwater and from coming into contact with the soil were 5 in 10,000 and 4 in 10,000, respectively. But the risk assessment for Revere Textile did not include a calculation of total risk even though people exposed to both risks would face, under EPA's guidance, a total risk of 9 in 10,000, or about twice as high as the risks from groundwater or soil considered separately.

EPA headquarters officials acknowledged that the agency's guidance calls for each risk assessment to include a calculation of total risk when appropriate but said that they believed that individually calculating a risk for each medium (groundwater, soil, etc.) was often sufficient to determine whether the site required cleaning up. However, the officials agreed that in order to compare the risks at various Superfund sites, it was necessary to calculate the combined risk posed by all sources of contamination at each site. They said that calculating the total risk posed little technical difficulty and added that the administration's proposed reauthorization bill would require EPA to develop comprehensive risk assessment regulations that would include rules on combining risks from different sources.

Risk Assessments Used Generally Consistent Approaches, but Some Steps Varied

The 20 risk assessments in our review were generally consistent for most aspects of the risk assessment process. For example, the risk assessments generally used consistent assumptions about (1) the quantities of groundwater and soil people consume or ingest each day, (2) the number of days per year people live or work at the sites, (3) the nature of the population exposed to the contamination (i.e., adults, children, or sensitive populations), and (4) the characteristics of exposed populations (i.e., people's weight and number of years of exposure). (See apps. II and III for more information on these values.)

However, in two areas, many of the 20 risk assessments used inconsistent assumptions even when sites had similar contamination. This variation occurred in assumptions about

- how the site would be used in the future, what the routes of exposure would be, and how much contamination would remain at the site and
- how much contamination people absorb through their skin.

These inconsistencies occurred because EPA left to the risk assessment team many of the decisions about how to measure exposure. As a result, different estimates of risk were developed for sites even with similar characteristics. To the extent that these risk assessments are used to make cleanup decisions, this could mean that one site might be cleaned up and another similar site might be left alone only because of arbitrary differences in assumptions. EPA officials said that risk assessment staff were granted such latitude because the assessments must take into account the unique conditions at each site and because scientific uncertainty abounds in certain aspects of the process. However, the inconsistencies we found were not related to differences in sites' conditions. The EPA officials also noted that in several instances, the agency is working on needed clarification to its guidance.

Risk Assessments Made Inconsistent Judgments About Future Land Use and Levels of Contamination

EPA's guidance calls for the risk assessment team to determine (1) how a Superfund site will be used in the future, (2) how people will be exposed to the sources of contamination, and (3) what level of exposure this will generate. The guidance then directs the assessment team to factor these judgments into an evaluation of future exposure to site contamination.

How Land Will Be Used in the Future

Judgments about how land will be used are crucial to determining the potential for human exposure to hazardous waste. In fact, EPA officials noted that assumptions about the future use of land were a major determinant of many cleanup decisions. For example, if the land is used for homes, people are exposed over longer periods than if the land is used for business, and a more stringent cleanup could be required. The 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 assessment team. In addition, EPA encourages the risk assessment team to take a relatively conservative approach in deciding the future use of the land. Reasoning that EPA cannot control local zoning or other land use restrictions, the guidance suggests that the risk assessment assume that in the future, the land will be residential even if no one lives there now.

Consequently, most risk assessments in our review assumed that the land at hazardous waste sites would be used differently in the future than it is now. The risk assessments assumed that residential development would eventually occur on hazardous waste sites, even though few sites had residences directly on them now. We found that under similar circumstances, risk assessments forecast different land uses for their sites. Specifically, 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. (See app. IV for more information on risk assessments' assumptions about the uses of land and app. V for the risk associated with these uses.)

Three landfill sites we reviewed demonstrate the variation in risk assessment teams' 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.[5]

We also found that risk assessments were inconsistent in their evaluation of how the use of adjacent land affected the future use of the site. Ten of the sites in our review had nearby homes: In eight of these cases, the risk assessment used this fact to decide that the site itself could be developed for residences in the future; two other assessments concluded, however, that the sites would not be developed for residential use.

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 is developing 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 the decision. This would offer a more predictable and systematic approach than assuming that residential use would prevail in almost all cases. However, the officials cautioned that some seemingly inconsistent decisions would still occur because it is difficult to craft specific guidance that covers every potential situation concerning land use.

What Future Exposure Routes Will Be

Exposure to contaminants also depends on any restrictions that may be placed on how a site will be used in the future. Such restrictions would include the local government's requiring residents to use water from an uncontaminated source, such as the municipal water supply, rather than private wells—effectively preventing exposure to any contaminated groundwater.

The risk assessments we reviewed were not consistent in selecting future exposure routes, especially when actions to reduce exposure were already in place. For nine of the sites in our review, local governments provided residents with water from an uncontaminated source, rather than a private well. For two of these sites—Idaho Pole Company in Montana[6] and Commencement Bay/Nearshore Tideflats in Washington—the risk

[5]Even though the risk for the Strasburg Landfill was below the level at which action is required, EPA is replacing the site's eroded cap because contamination was expected to increase as the cap continued to erode. In addition, EPA will continue to treat the contaminated water for several nearby residences, according to the site's manager.

[6]For the Idaho Pole Company site, exposure to groundwater from a well at currently unoccupied residences off the plant property was evaluated, although groundwater that could supply future residences on the plant property was not. The site's manager said that the Safe Drinking Water Act's standards would require cleaning up the groundwater even though the risk assessment did not specifically evaluate future on-site residents' exposure to groundwater.

assessment did not include future exposure to contaminated groundwater for on-site residents. For the other seven sites, including Atlantic Wood Industries in Virginia, Hercules 009 Landfill in Georgia, and Farmers' Mutual Cooperative in Iowa, the risk assessment did include exposure to groundwater. When exposure to groundwater was evaluated, it often resulted in estimates of substantial risk—residential exposure to contaminated groundwater was the most common source of risk in the risk assessments we reviewed. (See app. VI.)

EPA headquarters officials explained that when in doubt, risk assessments should include exposure to contaminated groundwater, disregarding the alternate water supply. While this is a conservative approach, EPA officials explained that it is consistent with the agency's policy that assessments measure risk before any actions are taken to reduce exposure. The officials said that as part of their revision to the guidance on assessing future land use, they would clarify how to treat actions already taken to control exposure to waste.

How Much Contamination Will Remain

Hand in hand with determining how land will be used, risk assessments also must estimate how much contamination will remain on that land in the future. EPA's guidance acknowledges that many models exist for predicting future levels of contamination and therefore leaves the decision of how to calculate this contamination up to the risk assessment team. As a result, the risk assessments we reviewed calculated the level of future exposure differently even for sites with similar types of contamination.

Although most of the risk assessments in our review took the conservative approach of assuming that people who lived or worked on the site in the future would encounter the same levels of contamination as today, two assumed that the level of contamination would decrease over time. For example, the risk assessment for the Idaho Pole Company site in Montana, a wood treating facility, assumed that contaminants in soil and water would degrade over time to between 13 percent and 50 percent of their current concentration. The site's project manager told us that he consulted with several experts in the agency about the model used to determine how much the chemicals would degrade. In contrast, the risk assessment for the Atlantic Wood Industries site in Virginia, another wood treating facility with many of the same contaminants, assumed that contamination would remain at its current level.

EPA headquarters officials said that risk assessment teams are uncertain about how to calculate future levels of contaminants because they

increase or degrade into another hazardous chemical. Given this uncertainty, EPA said that many risk assessment teams make the assumption that the contamination level will not change rather than take on the complex task of estimating degradation, especially if the degradation will not have a significant impact on the selected cleanup. The officials said that because EPA currently lacks the resources to model the degradation of a range of contaminants under various conditions, the agency is unlikely to provide specific guidance in this matter in the foreseeable future. As a result, some risk assessments are likely to develop different estimates of future risk under similar conditions.

Risk Assessments Inconsistently Determined How People Absorb Contaminants Through Their Skin

EPA's guidance tells risk assessment teams to determine ways that people are likely to be exposed to contamination through their activities at a site. Such exposure routes include dermal (skin) contact, ingestion (swallowing), or inhalation (breathing). Many of the risk assessments we reviewed assumed that dermal exposure to chemicals in soil occurred differently. Specifically, we found inconsistencies in

- whether risk assessments evaluated dermal absorption of chemicals in soil and
- how the assessments estimated the level of contamination people absorb through their skin.

EPA officials explained that such differences arose because good information for how people absorb contaminants from soil was unavailable. Consequently, some risk assessments did not include this type of exposure, and some used inconsistent approaches to measuring exposure from touching contaminated soil.

Some Risk Assessments Did Not Evaluate Dermal Exposure to Soil

Because data on absorption rates (the percentage of a contaminant that is absorbed into the bloodstream) often are lacking for many chemicals found in soil that may be absorbed through the skin, EPA has left to the risk assessment team the decision of whether to include this route of exposure. As a result, of the 13 risk assessments in our review that addressed contaminated soil, 3 excluded dermal contact with the soil as a means of exposure—even when other types of exposure to contaminated soil were included. EPA staff told us they often were uncomfortable evaluating dermal contact with soil because known absorption rates for chemicals in soil exist for only three of the hundreds of contaminants that can be found at hazardous waste sites. For example, risk assessment staff in Region II

(New York) believed that inadequate absorption data made the calculations too uncertain. Therefore, they adopted a policy of never calculating dermal exposure for contaminants without absorption factors. In contrast, risk assessment staff in other regions calculated dermal exposure at their sites by substituting the known absorption rates for similar contaminants.

In those cases in which dermal contact with soil was included, it resulted in calculations of substantial risk. For six of the risk assessments we reviewed, the dermal exposure route alone resulted in a cancer risk in excess of 1 in 10,000, EPA's threshold for requiring cleanup action.

Risk Assessments Used Different Dermal Absorption Rates

When risk assessment teams decided to evaluate dermal contact with soil, they used different approaches to estimating the amount of exposure. The risk assessment team must determine whether people exposed to the chemicals in soil will actually absorb them into their bodies. However, EPA's guidance is largely silent on how to estimate absorption rates and suggests that risk assessment staff consult scientific literature on the topic. Consequently, we found that risk assessments frequently used a default absorption rate of 100 percent, and those that assumed lower absorption often used different rates for the same chemicals. This problem was most prevalent in risk assessments that considered the risk of dermal exposure to cancer-causing contaminants known as volatile organic compounds (VOC) in soil.

Nine of the risk assessments we reviewed evaluated dermal exposure to VOCs. Two of the assessments assumed that the absorption rate for these chemicals was 10 percent; two assumed it was 25 percent; three assumed it was 50 percent; and two assumed it was 100 percent. In these cases, the ten-fold difference in absorption rates between the lowest and the highest would be enough to change the estimated chance of contracting cancer in a lifetime from 1 in 100,000 to 1 in 10,000.

EPA headquarters and regional officials acknowledged that considering dermal contact is important to measuring exposure to contaminated soil. The officials also acknowledged that risk assessments should not come to different conclusions about the level of exposure and risk when people are exposed to similar contamination. Superfund officials said they recently asked EPA's Office of Research and Development to review its policy on dermal contact with soil. Specifically, the review will focus on whether it is appropriate to calculate risk without the proper absorption factors for

specific site contaminants. Accordingly, EPA expects to establish a more consistent policy this year on the basis of this review.

Headquarters' Reviews Do Not Identify Inconsistencies in Risk Assessments

EPA regions are responsible for conducting risk assessments in accordance with national guidance. Since 1990, the Office of Solid Waste and Emergency Response (OSWER) in EPA headquarters has conducted annual quality assurance reviews intended to monitor whether regions were following EPA's guidance for risk assessments. This effort has included (1) extracting from site documents information about how the assessment was conducted, (2) compiling and analyzing the information, and (3) reporting the results (based on about half the risk assessments completed each year) to regional staff. We reviewed both the worksheets OSWER staff used to record the results of their risk assessment reviews and the summary reports based on these reviews.

We found that OSWER had collected extensive, generally accurate data during its quality assurance reviews. We also found that OSWER's reviews checked for compliance with important risk assessment guidance and revealed some problems. For example, the reviews showed that some risk assessments were not calculating the level of site contamination as recommended. OSWER officials used this information to identify which areas of guidance risk assessments generally were not following.

OSWER gathered information on all four steps of the risk assessment process: collecting and analyzing data, estimating the extent of exposure, assessing the toxicity of contaminants, and calculating the resultant risk. For each risk assessment reviewed, extensive data on how the above steps were conducted were entered into a worksheet. OSWER staff then rolled up the data from each worksheet into a package of summary information describing the characteristics of each region's risk assessments for the year. For example, the packages included tables identifying which sources of contamination and land uses were evaluated in the past year's risk assessments.

However, our review of the summary reports and our discussions with regional officials indicated that OSWER neither analyzed the information nor communicated the results in ways that help risk assessment teams improve the consistency of their work. For example, OSWER did not seek to determine whether different absorption rates were used for the same contaminants even though its quality assurance review worksheets contained information on the absorption rates used in risk assessments.

Instead, most of the data generated were simply frequencies, expressing, for instance, how often risk assessments evaluated contaminants absorbed through the skin or selected residential as the land use for the future.

EPA regional officials told us that while the descriptive information in the quality assurance reports was interesting, they would find it more useful to receive critical feedback on individual risk assessments—specifically, whether their individual risk assessments were consistent with other risk assessments. OSWER officials told us that the quality assurance reviews were originally designed to describe the results of the regions' risk assessments and to help the regions to follow the agency's guidance more closely. However, they noted that since most of the data needed to analyze risk assessments for consistency is already gathered annually, it would not be difficult to add this type of analysis as part of the quality assurance reviews. OSWER officials acknowledged that if they had analyzed the assessments in this way, their quality assurance reviews could have uncovered the kind of inconsistent approaches to risk assessments we identified in our review. In addition, OSWER officials told us that by including measures of consistency in headquarters' reports to the regions, they could have emphasized the need for such consistency and pointed out specific places where it was lacking.

OSWER officials pointed out that in addition to disseminating the descriptive information in the quality assurance reviews, they have developed some ad hoc procedures for sharing information on risk assessments. For example, regions participate in a monthly telephone conference, in which they discuss specific policies on risk assessment and their implementation. EPA also organizes work groups on particular problems with risk assessments, such as the one formed to consider dermal exposure to contaminated soil. OSWER officials acknowledged, however, that they could promote better compliance and consistency by supplementing these discussions with improved information from the annual quality assurance reviews.

Conclusions

On the whole, the 20 risk assessments we reviewed adhered to EPA's guidance and were relatively consistent with one another—both in following the guidance and showing a high degree of consistency in most areas we reviewed. However, our review uncovered several areas in which clearer guidance could improve the consistency of risk assessments. For example, we found that EPA guidance permitted—and risk assessment teams used—different approaches to determine how people could absorb

hazardous contaminants through their skin and describe the level of precision in risk estimates. To the extent that risk assessments are used to make cleanup decisions, this could mean that one site might be cleaned up and another similar site might be left alone only because of differences in how the assessments were done rather than actual differences between the sites.

EPA has acknowledged many of the gaps we found in its guidance and should be commended for its ongoing effort to give more specific direction rather than requiring risk assessment teams to improvise when data are lacking. In particular, EPA's plans to provide better guidance on estimating future land use, dermal exposure to contaminated soil, and the rates at which contaminants are absorbed into the bloodstream will help to produce more consistent risk assessment methods.

Despite these improvements, EPA headquarters staff acknowledged that the agency could make better use of its reviews of how its regions conduct risk assessments. Although EPA has in place an extensive and detailed quality assurance and monitoring system, that system does not analyze risk assessments to determine whether they are consistent with one another. Analyzing for consistency would not require significantly more resources given that the annual reviews already gather most of the necessary data. Furthermore, such analysis would help EPA identify additional areas in which guidance or research is needed to increase the consistency of risk assessments. It would also serve as the basis for feedback to regions that would better meet regional staff's needs.

Recommendation

We recommend that the Administrator of EPA ensure that the agency's quality assurance reviews be used to identify and reduce inconsistencies in risk assessments by

- analyzing individual risk assessments to determine whether they are consistent with national practices and
- providing the results of this analysis to the regions.

Agency Comments

As requested, we did not provide a draft of this report to EPA officials for written comment. However, we met with EPA officials, including the Deputy Director of the Hazardous Site Evaluation Division, representatives from OSWER and the Office of Research and Development, and regional staff and discussed with them the facts in this report. They

agreed with the information provided, and we have incorporated their comments, suggestions, and responses where appropriate throughout the report. We also have noted various improvements the agency plans to make, including providing better guidance on determining land use and evaluating dermal exposure to contaminants, and the agency's acknowledgment that it could use the results of quality assurance reviews to promote greater consistency among risk assessments.

Scope and Methodology

To obtain information on each of the three issues raised in the request, we reviewed 20 risk assessments approved in fiscal year 1992. (See app. VII for a list of the sites.) These selections covered not only each of EPA's 10 regions, but also the major types of Superfund sites (e.g., mining, landfill, and industrial). We also reviewed headquarters' and regions' risk assessment guidance. Our review focused primarily on the way EPA assesses human exposure to contamination, and calculates and characterizes the risks sites pose. In these areas, we identified nine major requirements and evaluated whether risk assessments followed them. We also summarized and compared the information risk assessments used in estimating exposure to hazardous contaminants to determine whether they used similar values and methods. In addition to reviewing risk assessments, we interviewed EPA officials, such as project managers and toxicologists, and private parties responsible for cleaning up the sites we reviewed. We evaluated EPA's quality assurance process by reviewing the available worksheets for our risk assessment case studies and the summary reports and by interviewing the OSWER officials who designed the reviews and the regional staff who use them. We conducted our review from September 1993 to April 1994 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of the report to the Administrator of EPA. We will also make copies available to others on request.

Please contact me on (202) 512-6112 if you or your staff have any questions. Major contributors to this report are listed in appendix VIII.

Peter F. Guerrero
Director, Environmental
Protection Issues

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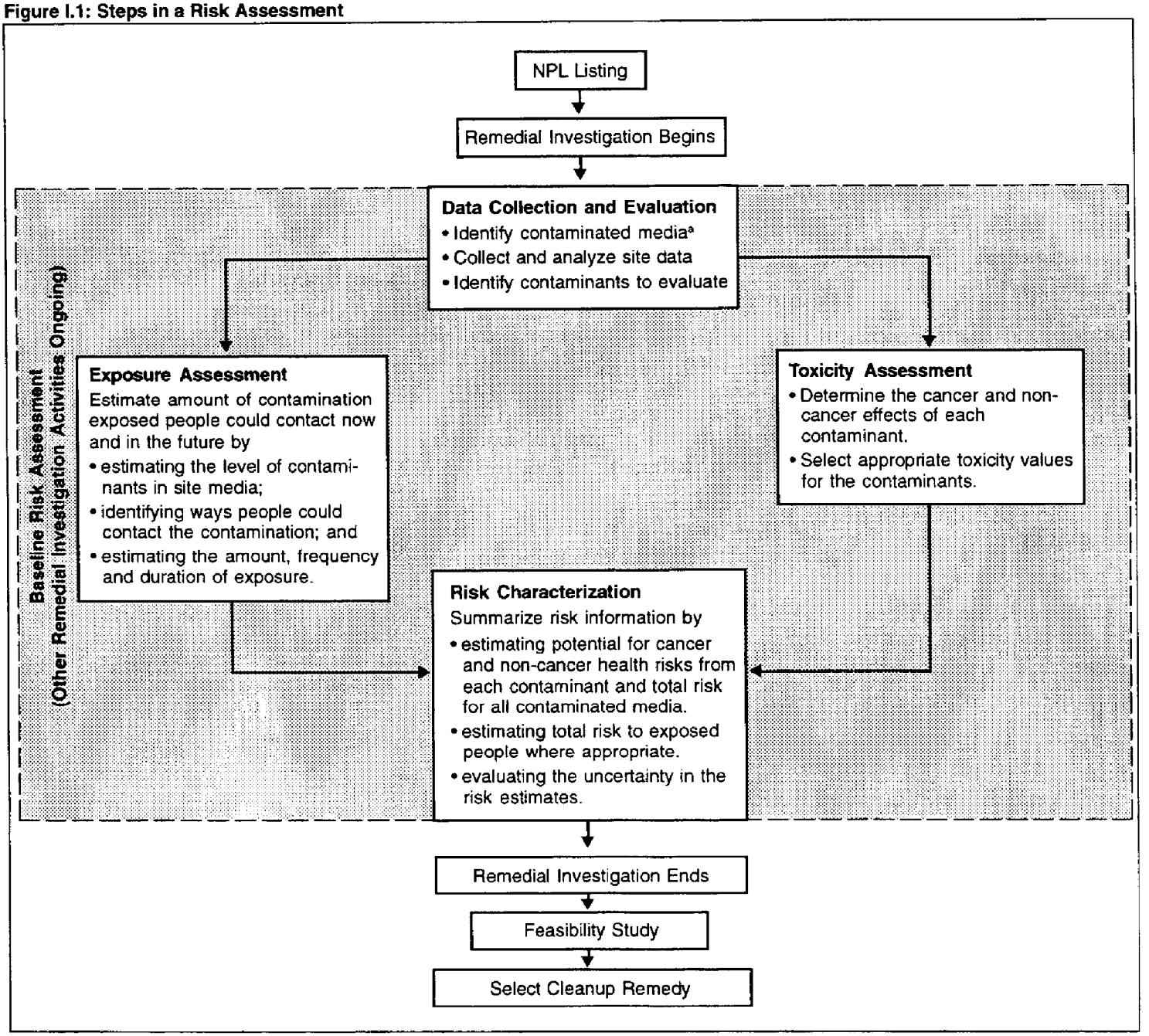
Abbreviations

ARAR	applicable or relevant and appropriate requirement
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA	Environmental Protection Agency
NPL	National Priorities List
OSWER	Office of Solid Waste and Emergency Response
VOC	volatile organic compound

Steps in a Risk Assessment and Ways People Can Be Exposed to Hazardous Contaminants

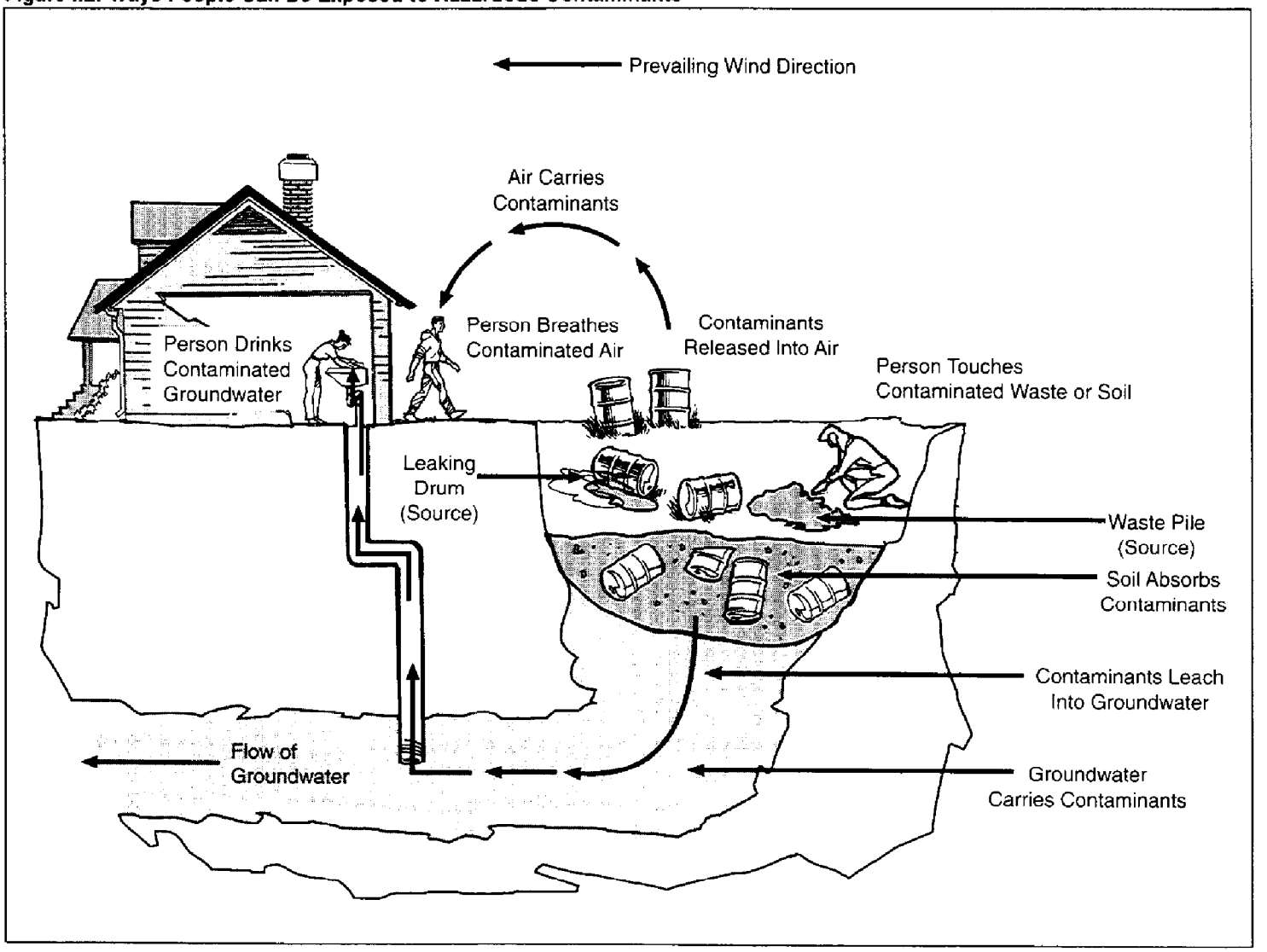
Figure I.1: Steps in a Risk Assessment



[a]"Media" refers to specific parts of the environment, including groundwater, soil, and air.

Source: The Environmental Protection Agency's (EPA) risk assessment guidance.

Figure I.2: Ways People Can Be Exposed to Hazardous Contaminants



Source: EPA's risk assessment guidance.

Intake Rates for Drinking Groundwater and Swallowing Soil

In calculating exposure to hazardous waste, risk assessments estimate the amount of contamination people take in each day (the intake rate). Part of this calculation requires determining how much soil or groundwater or air people consume daily. To analyze the specific data the Environmental Protection Agency (EPA) used to measure exposure to contaminants and resulting risk, we reviewed each exposure pathway in our 20 risk assessment case studies. "Exposure pathway" refers to the specific way someone contacts contaminants. A pathway is defined by

- how the land is used (whether the use is residential, industrial, etc.);
- what the source of the contamination is (groundwater, soil, etc.);
- whether the exposure is now or in the future;
- how old the exposed person is (whether the person is an adult or child); and
- how the contact occurs (touching, swallowing, etc.).

One pathway might be defined by an adult resident of the site drinking groundwater in the future. We identified 357 separate pathways in the 20 risk assessments we reviewed. Risk assessments varied greatly in the number of pathways they evaluated—ranging from 3 to 48 pathways for a single site.

EPA recommends that risk assessment teams assume that residents (both adults and children) on or near a Superfund site consume 2 liters of groundwater per day. EPA's guidance also recognizes that people inadvertently consume a small amount of soil during the course of the day and recommends that the risk assessment teams assume that adults swallow about 100 milligrams (mg) of contaminated soil per day. (The typical aspirin tablet contains 325 mg of aspirin.) Because children's activities bring them into contact with soil more frequently, EPA recommends a higher value of 200 milligrams of soil per day for them. Table II.1 shows that although risk assessment teams may develop their own estimates on the basis of information about the site, most of the risk assessments in our review used the recommendations in EPA's guidance.

Table II.1: Intake Rates Used in Risk Assessments Compared With EPA's Recommended Rates

Exposure pathway, population, and recommended level	Number of exposure pathways using		
	Recommended level	Higher than recommended level	Lower than recommended level
Drinking groundwater			
Adult (2 liters)	23	0	0
Swallowing soil			
Adult (100 mg)	11	1	1
Child (200 mg)	8	0	4
Total	**42**	**1**	**5**

Exposure Frequency

To help the risk assessment teams measure exposure accurately, EPA provides recommendations on the number of days per year that someone could be exposed to waste. According to EPA, residents should be expected to spend 350 days at home each year, and workers 250 days per year at their jobs. Although risk assessment teams may develop their own estimates on the basis of information about the site, we found that more than half of the assessments used the recommendations in EPA's guidance.

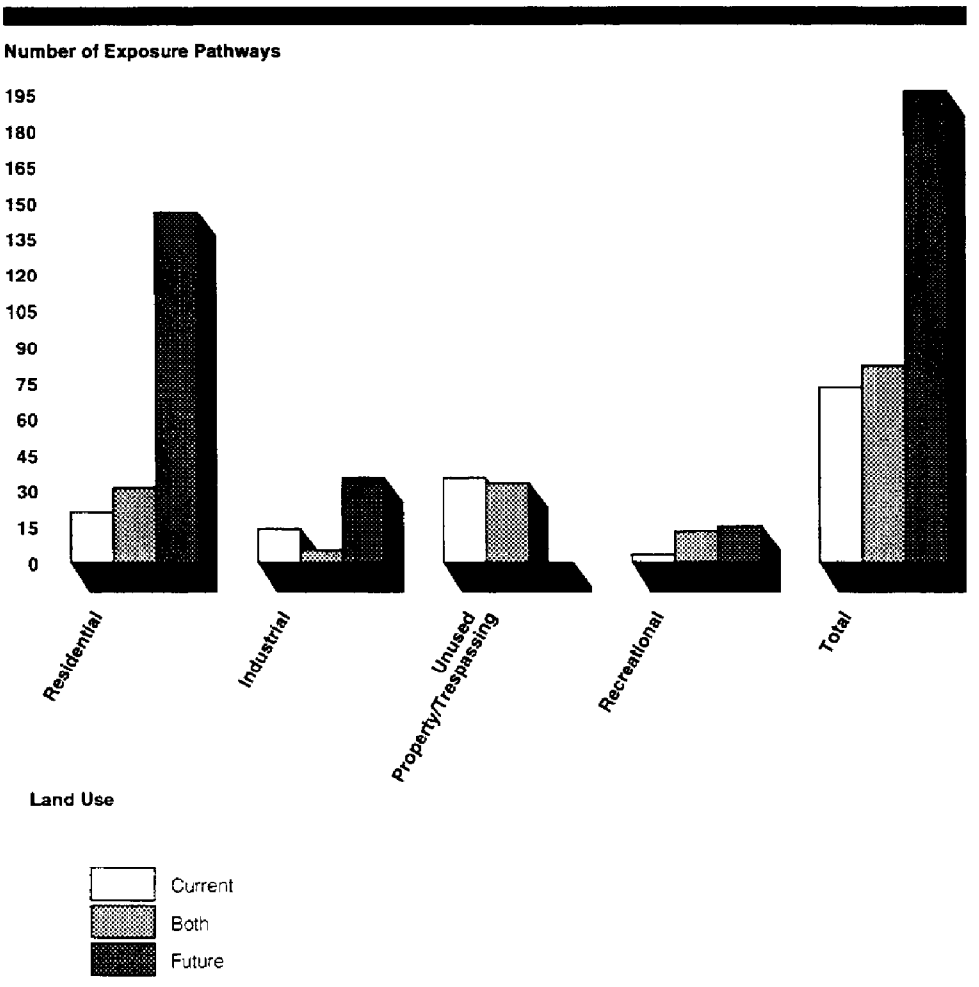
Table III.1: Number of Days Used to Estimate Exposure in Risk Assessments Compared With EPA's Recommended Number

	Number of exposure pathways using		
Land use and recommended number of days	**Recommended number of days**	**More than recommended number of days**	**Fewer than recommended number of days**
Residential (350 days)	113	33	52
Industrial (250 days)	40	0	14
Total	**153**	**33**	**66**

Land Uses

EPA's guidance directs the risk assessment team to determine how land at and near a hazardous waste can be used currently and in the future. Land use largely determines how much people are exposed to waste—residential use of land generally leads to the highest exposure. Figure IV.1 illustrates that future residential use predominated in the exposure pathways. Of all pathways evaluated in the 20 risk assessments we reviewed, 56 percent were for future residential use of the site.

Figure IV.1: Number of Exposure Pathways Evaluated in Risk Assessments, by Current and Future Land Uses

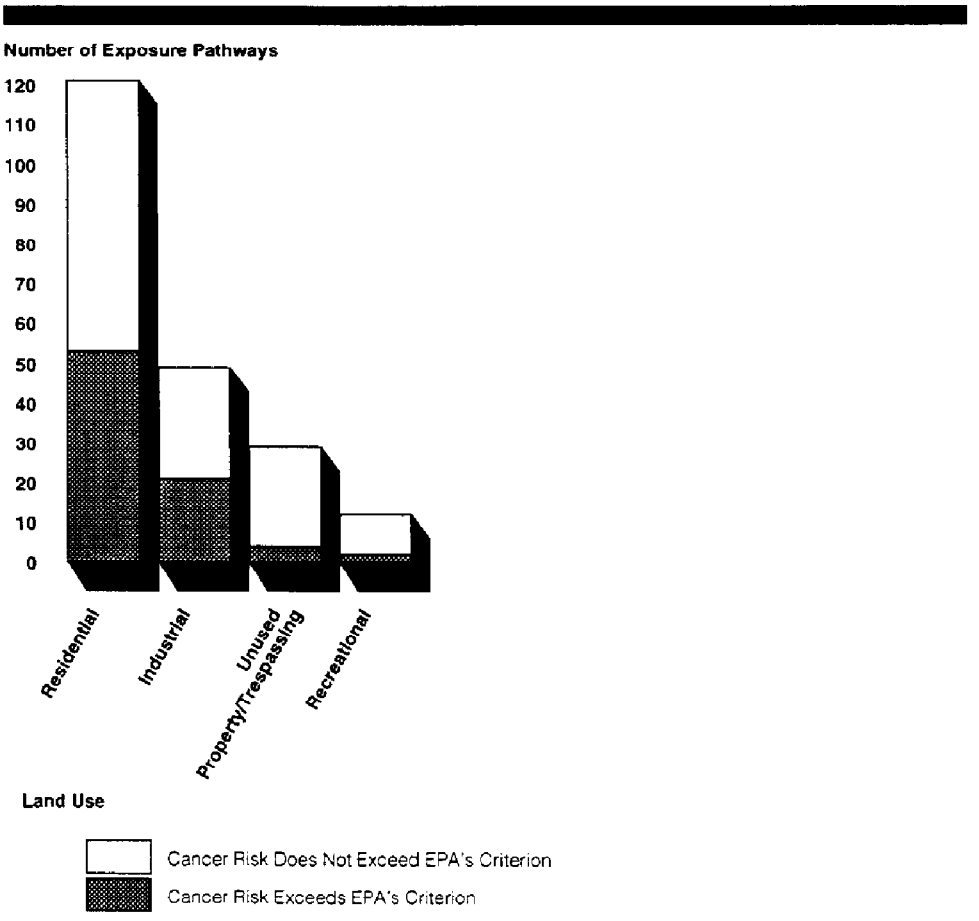


Note: In some cases, risk assessments assumed land would be used in the same way now as in the future. These pathways are categorized as "both" current and future exposures.

Land Use and Associated Risks

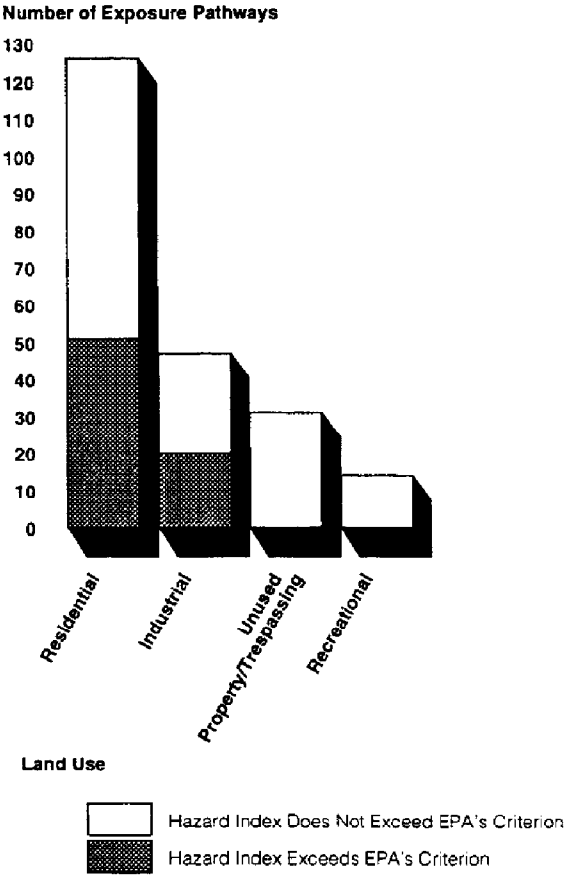
We found that residential and industrial settings produced the highest proportion of exposure pathways with risk estimates exceeding the level at which EPA requires cleanup action. This was true for both cancer and non-cancer risks. Fifty-three of 121 residential exposure pathways had cancer risks in excess of 1 in 10,000, and 51 of 126 pathways had hazard indexes greater than 1. (See figs. V.1 and V.2). Residential and industrial land uses assume more frequent exposure to waste than other kinds of land use.

Figure V.1: Number of Exposure Pathways With Cancer Risks Exceeding EPA's Criterion, by Land Use



Note: This figure includes both current and future land uses.

Figure V.2: Number of Exposure Pathways With Non-Cancer Risks Exceeding EPA's Criterion, by Land Use



Note: This figure includes both current and future land uses.

Risks Associated With Contaminated Media

EPA requires cleanup if the chance of developing cancer exceeds 1 in 10,000 for a pathway or combination of pathways. For non-cancer health problems, EPA requires cleanup if the calculated "hazard index" exceeds a value of 1. In the 20 risk assessments we reviewed, of the exposure pathways that included an estimated risk, 41 percent had cancer risks and 42 percent had non-cancer risks requiring cleanup under EPA's policy. Risks exceeding EPA's criteria most commonly resulted from groundwater and soil ingestion, particularly for future exposures. (See tables VI.1 and VI.2.)

Table VI.1: Cancer Risks Associated With Selected Exposure Pathways

	Cancer risk exceeds 1 in 10,000			
	Current exposures[a]		Future exposures	
Media and exposure route	**Yes**	**No**	**Yes**	**No**
Groundwater				
Ingestion	4	4	18	6
Dermal	2	4	5	6
Inhalation	0	5	3	7
Soil				
Ingestion	4	9	13	10
Dermal	4	17	12	12
Inhalation	0	3	2	5
Air				
Inhalation	9	15	5	9
Total[b]	**23**	**57**	**58**	**55**

Note: Tables VI.1 and VI.2 include some of the same pathways. When site contaminants were thought to cause both cancer and other health problems, exposure pathways included both types of risks.

[a]In some cases, risk assessments assumed that land would be used in the same way in the future as it is now. We included these in the "current" column.

[b]This table does not include all 357 pathways in the risk assessments we reviewed because (1) some pathways did not evaluate cancer risk and (2) we did not include infrequent pathways, such as eating produce grown in contaminated soil.

Table VI.2: Hazard Index Levels Associated With Selected Exposure Pathways

	Hazard index exceeds value of 1			
	Current exposures[a]		Future exposures	
Media and exposure route	**Yes**	**No**	**Yes**	**No**
Groundwater				
Ingestion	6	2	23	2
Dermal	1	5	3	8
Inhalation	1	4	3	4
Soil				
Ingestion	4	9	9	14
Dermal	4	15	4	18
Inhalation	1	2	1	1
Air				
Inhalation	6	12	7	5
Total[b]	**23**	**49**	**50**	**52**

Note: Tables VI.1 and VI.2 include some of the same pathways. When site contaminants were thought to cause both cancer and other health problems, exposure pathways included both types of risks.

[a]In some cases, risk assessments assumed that land would be used in the same way in the future as it is now. We included these in the "current" column.

[b]This table does not include all 357 pathways in the risk assessments we reviewed because (1) some pathways did not evaluate non-cancer health risk and (2) we did not include infrequent pathways, such as eating produce grown in contaminated soil.

List of Case Study Sites

Region I	PSC Resources, Massachusetts Revere Textile Prints, Connecticut
Region II	Endicott Village Wellfield, New York Witco Chemical Corp., New Jersey
Region III	Atlantic Wood Industries, Virginia Strasburg Landfill, Pennsylvania
Region IV	Chem-form Inc., Florida Hercules, Inc. 009 Landfill, Georgia
Region V	Torch Lake, Michigan Woodstock Municipal Landfill, Illinois
Region VI	American Creosote Works, Louisiana Fourth Street Refinery, Oklahoma
Region VII	Farmer's Mutual Cooperative, Iowa Red Oak City Landfill, Iowa
Region VIII	Eagle Mine, Colorado Idaho Pole Company, Montana
Region IX	Pacific Coast Pipeline, California San Gabriel Valley, California
Region X	Commencement Bay/Nearshore Tideflats, Washington Joseph Forest Products, Oregon

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