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125391

REPORT BY THE

Comptroller General

OF THE UNITED STATES

HHS' Implementation of Superfund Health-Related Responsibilities

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980--referred to as Superfund--requires by Presidential delegation the Environmental Protection Agency (EPA) to clean up toxic waste sites and the Department of Health and Human Services (HHS) to carry out various health-related activities. In August 1981, the President designated EPA as the lead agency for implementing the law and as trustee of the Superfund appropriations.

The Superfund legislation gave HHS considerable latitude concerning how it could implement its health-related responsibilities. HHS' progress in implementing its planned Superfund activities has been adversely affected by funding delays and staffing limitations. Furthermore, the legislation and its history do not clearly define congressional expectations in two key areas--the development and maintenance of registries and the provision of medical care for persons exposed to toxic substances.

The Congress may wish to consider HHS' progress concerning Superfund health-related activities and determine whether changes are needed in how these activities are funded and staffed and whether legislative expectations regarding registries and health care should be clarified.

125391

UNITED STATES GENERAL ACCOUNTING OFFICE

GAO/HRD-84-62
SEPTEMBER 28, 1984

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

B-207182

The Honorable James J. Florio
Chairman, Subcommittee on Commerce,
Transportation and Tourism
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

This report is in response to your request that we review the Department of Health and Human Services' (HHS') implementation of its health-related responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980--referred to as Superfund.

In addition to discussing the adverse effects that funding and staffing limitations have had on HHS' Superfund plans and activities, the report also provides information on HHS' relationship with the Environmental Protection Agency--the lead agency and trustee of the Superfund program--and HHS' interpretation of its responsibilities to develop national exposure and disease registries of and provide medical care to persons exposed to toxic substances.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time we will send copies to interested parties and make copies available to others on request.

Sincerely yours,

Charles A. Bowsher

Comptroller General
of the United States

REPORT BY THE
COMPTROLLER GENERAL
OF THE UNITED STATES

HHS' IMPLEMENTATION OF
SUPERFUND HEALTH-RELATED
RESPONSIBILITIES

D I G E S T

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980--commonly referred to as Superfund--requires the Environmental Protection Agency (EPA) to clean up toxic waste sites and addresses other related issues. The act provides for EPA to accumulate a trust fund--estimated to total $1.6 billion--between fiscal years 1981 and 1985 to accomplish the act's purposes. Money comes from taxes collected from chemical and petroleum companies and appropriations. While EPA has primary responsibility for managing Superfund, several other federal agencies are delegated responsibilities in the act.

The act requires the Department of Health and Human Services (HHS) to carry out various activities, such as developing comprehensive information about the health effects of chemical wastes, providing medical care and testing for persons exposed to toxic substances, and developing safeguards for workers who clean up toxic wastes.

The Chairman, Subcommittee on Commerce, Transportation and Tourism, House Committee on Energy and Commerce, requested GAO to determine to what extent HHS has been carrying out its delegated responsibilities under this legislation and whether HHS' actions have been sufficient to deal with the health issues addressed in the legislation. However, because of the medical and scientific uncertainties concerning the relationship between exposure to toxic substances and adverse health effects and the absence of clear legislative expectations and time frames concerning HHS' health-related responsibilities, GAO restricted its review and this report to identifying HHS' actions since program inception. This report presents matters for the Congress to consider based on HHS' progress to date.

GAO/HRD-84-62
SEPTEMBER 28, 1984

Tear Sheet

PROCESS FOR FUNDING AND STAFFING SUPERFUND HEALTH-RELATED ACTIVITIES

Each fiscal year HHS submits a budget request to EPA describing its planned Superfund activities and estimating the resources needed to accomplish the plans. EPA reviews the budget request, decides how much to approve, and includes it as part of an annual Superfund budget request, which it forwards to the Office of Management and Budget (OMB). OMB subsequently decides on the amount of funding to request. It also recommends how many staff years HHS should devote to its Superfund activities.

Each year EPA receives a no-year appropriation for all Superfund activities. That is, funds not spent in the fiscal year appropriated remain available. Staff positions for HHS Superfund health-related activities are not authorized through this appropriation. Rather, HHS must use existing staff positions and remain within the annual staff ceilings established by OMB for all of HHS. Each year a formal interagency agreement is signed before EPA transfers appropriated funds to HHS. (See pp. 8 and 9.)

STATUS OF HHS' SUPERFUND EFFORTS

Following is a synopsis of HHS' efforts to carry out its health-related responsibilities under the act.

--HHS is to establish and maintain a national registry of persons exposed to toxic substances and a national registry of serious diseases and illnesses. In November 1983, HHS developed guidelines for collecting data for registries. In May 1984, HHS adopted criteria to set priorities for establishing registries at Superfund sites. According to HHS, a central listing of exposed persons has been established at one Superfund site, but no registries are planned until long-term funding and administrative issues are resolved. As of March 31, 1984, HHS was developing plans to establish three disease registries. (See p. 6.)

--HHS is to establish and maintain an inventory of literature, research, and studies on

health effects of toxic substances. HHS planned to add 650 substances to the National Library of Medicine's existing toxicological data base by September 30, 1983. By that date, 324 were added. As of March 31, 1984, another 422 substances had been added to the data base. In addition, HHS planned to install computer software systems in 12 states and 6 urban areas to improve the transfer and understanding of toxicological and other technical information relating to Superfund sites by September 30, 1983. None of these systems was installed as of March 31, 1984, because of funding decreases. (See p. 7.)

--HHS is to establish and maintain a complete listing of areas closed to the public or otherwise restricted in use because of toxic substance contamination. This listing is to include scientific and health data relating to each site. As of March 31, 1984, HHS had developed a list of 255 hazardous waste sites, but the total number of such sites is unknown and HHS did not have health data, such as the nature of contamination problems, at each site. As of August 1984, HHS had contracted for the development of a complete list of these areas, which it expects may be completed by November 1984. (See p. 7.)

--HHS is to provide medical care and testing for persons exposed to toxic substances in cases of public emergencies. Although HHS assists, consults, and coordinates with public and private health care providers, it has decided to provide no direct medical care to exposed individuals. HHS had conducted biological testing at 10 public health emergency sites, as of March 31, 1984. In addition, as part of three special studies, HHS performed biological testing at three other emergency sites. (See p. 7.)

--HHS either independently or as part of other health status survey and screening programs, is to conduct health studies, laboratory projects, and chemical testing to determine relationships between exposure to toxic substances and illness. Except for one health study at Love Canal begun before the Superfund Act was passed, no health studies

or laboratory projects had been completed as of March 31, 1984. Four health studies and six laboratory projects were underway, however, and 10 other health studies were in the planning stage. By September 30, 1983, HHS planned to complete testing of about 70 chemicals or chemical combinations. As of March 31, 1984, tests of 15 chemicals had been started and 1 had been completed. (See pp. 7 and 8.)

--HHS, in cooperation with EPA and the Occupational Safety and Health Administration, is to develop a program to protect the health and safety of workers involved in responding to and cleaning up hazardous waste releases. Using Superfund resources, a worker bulletin entitled Hazardous Waste Sites and Hazardous Substance Emergencies was completed in December 1982. As of September 1984, efforts were underway to complete the Comprehensive Guidance Manual dealing with worker safety and health. As of that date completion of the manual was 12 months behind HHS' estimated completion date of September 30, 1983. HHS had also initiated pilot testing of a training program for persons at the federal, state, and local levels involved in responding to hazardous substance releases. In early 1984 HHS started testing respirators and providing technical support for analyzing hazardous waste sites. (See p. 8.)

WHY HHS HAS MADE LIMITED PROGRESS IN IMPLEMENTING SUPERFUND ACTIVITIES

HHS agencies have made less progress in implementing its Superfund programs than originally planned or possible because of funding delays and reductions by EPA and staffing limitations within HHS.

Through the end of fiscal year 1983 the Congress appropriated $17 million to EPA for HHS' activities, which was $10.5 million more than EPA had recommended and OMB had approved in the annual budgets. However, because EPA did not begin transferring funds to HHS until 5 months after fiscal year 1982

started (which was the second fiscal year of the program) and HHS did not allocate sufficient staff to undertake all planned activities, only $5.1 million had been spent through fiscal year 1983. In fiscal year 1984, an additional $5 million was appropriated for HHS. During the first 6 months of fiscal year 1984, about $3.5 million was spent.

The funding delays and reductions occurred because EPA maintained that HHS had not satisfactorily documented budget requests (see pp. 9 and 10) and interagency agreements between HHS and EPA were not signed until late in some fiscal years (see pp. 10 to 12). Furthermore, EPA and HHS officials told GAO that at first EPA preferred not to involve HHS in Superfund activities (see pp. 12 and 13) though the agencies' relationship has improved since the replacement in 1983 of key EPA personnel (see p. 20).

In fiscal years 1983-84, when funds were made available in a timely manner, HHS provided less staff than needed by its agencies because of Department-wide staff limitations. Although HHS used more staff-years in fiscal years 1983-84 than in fiscal year 1982, according to HHS officials, these were still insufficient to undertake all planned activities.

Staff-Years Proposed by HHS, Recommended by OMB, and Used by HHS for Superfund Activities Fiscal Years 1982-84

Fiscal year	Originally proposed by HHS	Recommended by OMB	Used by HHS
1982	65	47	17
1983	66	39	39
1984	53	21[a]	[b]

[a]In December 1983 HHS decided to exceed OMB's recommendation and use 47 staff-years.

[b]Staff-year data are not compiled until after the end of the fiscal year.

According to HHS, the low level of staffing used in fiscal year 1982 occurred because funds were not made available until late in the year. Also, a proposed reorganization of the HHS agency responsible for coordinating Superfund health-related activities led to considerable debate concerning the agency's mission, structure, and priorities. As a result of the funding and staffing situations, a number of Superfund activities were delayed or postponed. (See pp. 11, 14 to 16, and 18 to 20.)

HHS EFFORTS TO DEVELOP REGISTRIES OF AND PROVIDE MEDICAL CARE TO PERSONS EXPOSED TO TOXIC WASTES

The act does not specify the types of information or sites to be included in national registries, explain to what extent medical care is to be provided, or define the terms "public health emergencies" and "exposed individuals." The specific interpretations of these sections directly affect the implementation of the law and related costs.

HHS has decided to establish exposure registries at a limited number of those hazardous waste sites where there is a strong indication of substantial human exposure and a sound scientific basis for investigating the possible correlation between exposures and health effects among persons living near the sites.

HHS officials stated that they are reluctant to initiate Superfund registries on a broader scale because (1) undertaking any type of registry is costly and (2) they have been offered no assurances of receiving long-term funding (at least 20 years) necessary to maintain the Superfund registries. (See pp. 23 to 26.)

In addition, HHS has decided to not provide direct medical care to persons exposed to toxic waste sites. Instead HHS has decided to assist, consult, and coordinate with private or public health providers in emergencies or other instances where persons may have been exposed to toxic substances. In this regard,

the agency has decided not to obtain comprehensive medical histories, conduct continuing annual physical examinations, provide for periodic laboratory testing, or make available other clinical services to detect early signs of illness due to exposure to toxic substances. (See pp. 26 and 27.)

CONCLUSIONS

The Superfund legislation gave HHS considerable latitude concerning how it could implement its health-related responsibilities. HHS' progress in implementing its planned Superfund activities has been adversely affected by funding delays and staffing limitations. Furthermore, the legislation and its history do not clearly define congressional expectations in two key areas--the development and maintenance of registries and the provision of medical care.

MATTERS FOR CONSIDERATION BY THE CONGRESS

As the Congress deliberates the future of Superfund, particularly HHS' health-related responsibilities, GAO suggests that it consider EPA's responsibility of controlling the funds needed by HHS to carry out its tasks and whether additional staff positions should be authorized for HHS' activities to avert past situations where HHS had inadequate funds or staffing to carry out its plans. (See p. 21.)

Furthermore, if the Congress considers HHS' interpretations of its role under these sections of the act to be inconsistent with congressional intent, it may wish to

--clarify the purpose and intent of national exposure and disease registries and the types of information to be included,

--clarify the extent to which medical care is to be provided, and

--define such terms as "exposed individuals" and "public health emergencies." (See p. 28.)

AGENCY COMMENTS

Both EPA and HHS stated that the report was an essentially accurate description of what has occurred. HHS agreed that the Congress may wish to clarify and define certain authorities and terms contained in the law, but suggested that such clarification be based on technical information obtained from and consultation with HHS and EPA scientists and officials. (See pp. 21, 22, and 28.)

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ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control
EPA	Environmental Protection Agency
FTEE	full-time equivalent employee
GAO	General Accounting Office
HHS	Department of Health and Human Services
OMB	Office of Management and Budget

CHAPTER 1

INTRODUCTION

Congressman James J. Florio, Chairman, Subcommittee on Commerce, Transportation and Tourism, House Committee on Energy and Commerce, requested that we determine to what extent the Department of Health and Human Services (HHS) has been carrying out its Superfund responsibilities and whether HHS' actions have been sufficient to deal with the health issues addressed in the Superfund legislation. On August 10, 1983, we issued Interim Report on the Establishment of the Agency for Toxic Substances and Disease Registry and Adequacy of Superfund Staff Resources (GAO/HRD-83-81). This second report focuses on HHS' implementation of Superfund activities and the chronology of events and management decisions that have affected these activities and discusses HHS' interpretation of its role under the legislation.

BACKGROUND

The Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Public Law 96-510), commonly referred to as Superfund, requires by Presidential delegation the Environmental Protection Agency (EPA) to clean up toxic waste sites and addresses some related issues. Executive Order 12316[1] and the National Oil and Hazardous Substances Contingency Plan,[2] also called the National Contingency Plan, establish EPA's lead role in implementing the Superfund program. While EPA has primary responsibility for Superfund, the executive order also delegates responsibilities to several other federal agencies and departments, including HHS. The act provides for a trust fund to be accumulated between fiscal years 1981 and 1985. At the time the act was passed, $220 million (14 percent) was to come from general revenue appropriations, and an estimated $1.38 billion (86 percent) was to come from taxes collected from the chemical and petroleum industries.

The act requires HHS to establish within the Public Health Service a new agency to carry out the act's health-related activities, which include:

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[1]Executive Order 12316, signed August 14, 1981, delineates in general the responsibilities of the various federal agencies involved in Superfund activities.

[2]The National Contingency Plan specifies the responsibilities and powers of the various federal agencies involved in the Superfund program.

--Establishing and maintaining a national registry of persons exposed to toxic substances and a national registry of persons with diseases and illnesses.[3]

--Establishing and maintaining an inventory of literature, research, and studies on the health effects of toxic substances.

--Establishing and maintaining a complete listing of areas closed to the public or otherwise restricted in use because of toxic substance contamination.

--Providing medical care and testing for persons exposed to toxic substances.

--Conducting health studies, laboratory projects, and chemical testing to determine relationships between exposure to toxic substances and illness.

In addition, HHS' National Institute for Occupational Safety and Health is to coordinate efforts with EPA and the Occupational Safety and Health Administration to develop programs to protect the health and safety of employees assigned to clean up toxic wastes.

From the enactment of the Superfund legislation in December 1980, HHS contended that creating a separate agency to implement its Superfund responsibilities was not necessary. Instead, HHS designated the Centers for Disease Control (CDC) as the lead agency for Superfund activities in July 1981. CDC established the Superfund Implementation Group within the Center for Environmental Health in August 1981 to coordinate HHS' Superfund activities and provide scientific, program, and emergency response support to other HHS agencies, EPA, and state and local organizations.

As of March 31, 1983, the Superfund Implementation Group consisted of 15 full-time staff. Eight of these staff members were stationed in EPA regional offices to provide assistance concerning health aspects of the Superfund program. In addition, the National Institute for Occupational Safety and Health

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[3]An exposure registry is a permanent record of information on persons with particular exposure histories who are followed over time in hopes of defining specific health outcomes. A disease registry is a permanent record of information of persons with diseases or other adverse health outcomes--for example, birth defects--which might be associated with environmental conditions.

and the National Library of Medicine were assigned responsibilities to implement specific Superfund health activities that were consistent with their other responsibilities.

HHS established the Agency for Toxic Substances and Disease Registry (ATSDR) in April 1983. Superfund program operations under ATSDR, however, are essentially the same as before it was established. CDC provides administrative support to ATSDR and has detailed 6 of the 15 staff members who had comprised the Superfund Implementation Group to accomplish essentially the same tasks. The Public Health Service agencies previously delegated Superfund activities under the Implementation Group continue to carry out the same tasks under ATSDR.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of our review was to determine to what extent HHS has been carrying out its delegated Superfund health-related activities. The Chairman had also asked that we determine whether HHS' actions have been sufficient to deal with the health issues addressed in the legislation. However, because of the medical and scientific uncertainties concerning the relationship between exposure to toxic substances and adverse health effects, controversy over the efforts needed to adequately address the goals of the legislation, and the absence of statutory target dates and legislative guidance concerning HHS' health-related responsibilities, we did not have sound bases to assess the sufficiency of HHS' actions. As a result, we reviewed HHS' progress in carrying out its planned Superfund activities.

We conducted our review principally at CDC headquarters in Atlanta. In addition, we interviewed six ATSDR staff members at EPA regional offices in Atlanta, Chicago, New York, Boston, Philadelphia, and San Francisco and officials at the Office of Management and Budget (OMB), EPA headquarters, the National Institute of Environmental Health Sciences and the National Library of Medicine in the National Institutes of Health, and the National Institute for Occupational Safety and Health. We also interviewed representatives of the Environmental Defense Fund, a nonprofit organization concerned with environmental issues, and the Chemical Manufacturers' Association, an organization concerned with chemical research and studies, to obtain their perspectives on the Superfund health-related provisions and HHS' actions in carrying out its responsibilities.

Our review was performed in accordance with generally accepted government auditing standards. We reviewed Superfund's fiscal years 1981-85 budget and financial records, such as HHS' funding and staffing requests, EPA and OMB adjustments to HHS' requests, interagency agreements, and HHS' quarterly progress

reports to EPA. We reviewed ATSDR's program plans and reports, particularly for health studies, related resource requirements, associated time charges, and environmental site information requirements. We examined information included in other CDC and National Institute for Occupational Safety and Health registries. We developed estimates of registry costs based on cost data of existing registries. We obtained estimates of staff requirements and costs for medical care and health studies or laboratory projects from HHS records and program officials. We reviewed health-related data developed by HHS on various Superfund sites, including data in HHS' management information system.

We were not able to determine the number of staff-years needed to perform HHS' Superfund activities, but we obtained staffing estimates from the HHS agencies responsible for carrying out these activities, and these data are discussed in this report. We did not attempt to develop information on possible links between chemicals present at sites and the incidence of disease of persons living nearby.

We did not review EPA's Superfund operations; however, we discussed with EPA's Director, Office of Emergency and Remedial Response, and Comptroller, and other key EPA staff members EPA's relationship with HHS.

Our draft report was sent to HHS and EPA for review and comment. We considered their comments and incorporated them into this report as appropriate.

CHAPTER 2

HHS' PROGRESS IN IMPLEMENTING SUPERFUND HEALTH-RELATED ACTIVITIES

During the 45 months since the Superfund legislation was enacted, HHS has experienced various delays and problems that have impeded its implementation of Superfund health-related activities. EPA and OMB contributed to the delays by significantly decreasing HHS' initial funding and staffing requests. Also, EPA did not provide HHS essential hazardous waste site information on a timely basis. The Director of EPA's Office of Emergency and Remedial Response confirmed that EPA's Administrator and its Assistant Administrator for Solid Waste and Emergency Response preferred not to involve HHS in Superfund health-related activities when the act was enacted.

As shown in the table below, HHS spent about $5.1 million of the $17 million appropriated for Superfund health-related activities, as of September 30, 1983. The Congress appropriated $13 million for HHS' ongoing activities and authorized EPA to provide an additional $4 million to HHS for site-specific activities as needed. In fiscal year 1984, an additional $5 million was appropriated for these purposes; during the first 6 months of the fiscal year, HHS spent $3.5 million.

Funding For HHS' Superfund Health-Related Activities, Fiscal Years 1981-84

Fiscal year	HHS budget request	EPA recommendation	Approved by OMB	Appropriated to EPA for HHS	Expenditures	Cumulative appropriations available at end of fiscal year
	(millions)					
1981	$ 1.6	$ 0	$ 0	$ 0	$ 0	$ 0
1982	10.0	3.3	3.3	7.0	1.1	5.9
1983	21.0	3.2	3.2	10.0	4.0	11.9
1984	6.4	4.2	1.9	5.0	3.5[a]	13.4[b]

[a]Estimated expenditures during first 6 months of fiscal year 1984 (Oct. 1, 1983 - Mar. 31, 1984).

[b]As of Mar. 31, 1984.

In addition, as shown in the table below, HHS did not provide the staff levels that its agencies requested and that it originally proposed in its budget submissions to carry out Superfund responsibilities.

Full-time Equivalent Employees Proposed by HHS, Recommended by OMB, and Used by HHS for Superfund Activities, Fiscal Years 1982-84

Fiscal year	Originally proposed by HHS	Recommended by OMB	Used by HHS
1982	65	47	17
1983	66	39	39
1984	53	21[a]	b

[a]In December 1983 HHS decided to exceed OMB's recommendation and use 47 staff-years.

[b]Staff-year data are not compiled until after the end of the fiscal year.

This chapter discusses the status of HHS' efforts to carry out its specific responsibilities and presents a chronology of significant events and decisions that have affected HHS' Superfund activities since the act was passed.

STATUS OF HHS' SUPERFUND EFFORTS

As discussed in chapter 1, HHS has been delegated various health-related responsibilities under Superfund. Following is a synopsis of HHS' efforts to carry out its responsibilities under the act.

--Section 104(i)(1) requires HHS to establish and maintain a national registry of diseases and illnesses and a national registry of persons exposed to toxic substances. According to HHS a central listing of exposed persons has been established at one Superfund site. Questions of long-term funding necessary to assure adequate follow-up on the persons included in such listings and other issues related to the administrative and scientific management of these lists need to be resolved before HHS will consider these to be exposure registries. In November 1983, HHS developed guidelines for collecting data for registries. As of March 31, 1984, HHS was developing plans to establish three disease registries. In May 1984, HHS adopted criteria to set priorities for initiating exposure and disease registries at Superfund sites.

--Section 104(i)(2) requires HHS to establish and maintain an inventory of literature, research, and studies on the health effects of toxic substances. HHS planned to add 650 chemicals to the National Library of Medicine's toxicological data base by September 30, 1983. By that date, 324 were added. As of March 31, 1984, another 422 substances had been added. In addition, HHS planned to install computer software systems in 12 states and 6 urban areas to improve the transfer and understanding of toxicological and other technical information relating to Superfund sites by September 30, 1983. None of these systems were installed as of March 31, 1984. In its comments on our draft report, HHS stated that the scope of this computer-based concept has now been reduced and implementation will be delayed because of the funding decreases.

--Section 104(i)(3) requires HHS to establish and maintain a complete listing of areas closed to the public or otherwise restricted because of toxic substance contamination. This listing is to include scientific and health data relating to each site. As of March 31, 1984, HHS had developed a list of 255 hazardous waste sites. The total number of such sites in unknown. The information on the list was incomplete in that (1) additional sites had been closed, but HHS had not added them to the list and (2) the documentation on the 255 sites did not always include health data, such as the nature of possible contamination problems at each site. As of August 1984 HHS had contracted for the development of a complete list of these areas. HHS told us that the complete list may be developed by November 1984.

--Section 104(i)(4) requires HHS to provide medical care and testing to exposed individuals in public health emergencies. Although HHS assists, consults, and coordinates with public and private health care providers, it has decided to provide no direct medical care to exposed individuals. HHS had conducted biological testing at 10 public health emergency sites as of March 31, 1984. In addition, as part of three special studies, HHS performed biological testing at three other emergency sites.

--Section 104(i)(5) requires HHS, either independently or as part of other health status survey and screening programs, to determine relationships between exposure to toxic substances and illness. This includes conducting health studies, laboratory projects, and chemical testing to determine these relationships. Except for one health study at Love Canal begun before the Superfund Act was

passed, no health studies or laboratory projects had been completed as of March 31, 1984. HHS had received EPA approval in 1983 for three health studies, and these were underway as of March 31, 1984. HHS also had started fieldwork on another health study in early 1984. Using Superfund resources, 10 other health studies were in the planning stage. In addition, six laboratory projects had been started. By September 30, 1983, HHS planned to complete testing about 70 chemicals or chemical combinations. As of March 31, 1984, tests of 15 chemicals had been started and 1 had been completed.

--Sections 111(c)(6) and 301(f) require HHS, in cooperation with EPA and the Occupational Safety and Health Administration, to develop a program to protect the health and safety of workers involved in responding to and cleaning up hazardous substance releases. Using Superfund resources, a worker bulletin entitled Hazardous Waste Sites and Hazardous Substance Emergencies was completed in December 1982, and as of September 1984 efforts were underway to complete the Comprehensive Guidance Manual. HHS had also initiated pilot testing a training program for persons at the federal, state, and local levels involved in responding to hazardous substance releases. In early 1984 HHS started testing respirators and providing technical support for analyzing hazardous waste sites.

The following sections of this chapter discuss factors that have impeded HHS' efforts, the chronology of events affecting its progress in implementing Superfund, and its rationale for establishing and conducting health-related activities.

PROCESS FOR FUNDING AND STAFFING SUPERFUND HEALTH-RELATED ACTIVITIES

Each year EPA receives a no-year appropriation to fund all Superfund staff, projects, and activities. That is, funds not spent in the fiscal year in which they are appropriated remain available in later fiscal years. Staff positions for HHS Superfund health-related activities are not authorized through this appropriation. Rather, HHS is to use existing staff positions to accomplish these activities, but remain within the annual staff ceilings established by OMB for all of HHS.

EPA is the trustee for the Superfund program, and EPA's Comptroller is responsible for budgeting and accounting activities involving all federal agencies in the program. Each fiscal year HHS submits its budget justifications to EPA, describing the Superfund health-related activities it plans to undertake

and estimating the resources needed to accomplish the plans. EPA reviews HHS' budget request and decides how much funding HHS is to receive. The HHS request is included in EPA's annual Superfund budget justification and forwarded to OMB for approval. OMB reviews the EPA budget submission and participates in the final executive branch decision on the funds to be requested for Superfund activities, including those to be carried out by HHS. Each year a formal interagency agreement is signed before EPA transfers appropriated funds to HHS. The Congress, as part of the appropriation process, may provide direction to the executive branch concerning how Superfund resources are to be used and designate that funds be earmarked exclusively for use by specific federal agencies.

HHS' annual Superfund budget proposal estimates the staff-years needed to accomplish the proposed health-related activities. After OMB completes its budget review of the funding for Superfund health-related activities, it recommends the number of staff-years to be used to accomplish the activities funded. HHS, however, has the option to use more staff-years for Superfund activities, provided adequate funds are available and it does not exceed OMB's annual staff ceilings for the entire Department. HHS' annual staff ceilings have not been increased to take into account its Superfund responsibilities.

EPA PROVIDED NO FUNDS FOR SUPERFUND HEALTH-RELATED ACTIVITIES IN FISCAL YEAR 1981

The Superfund legislation was enacted on December 11, 1980. Few Superfund activities were undertaken by federal agencies in fiscal year 1981 because EPA did not receive its first Superfund appropriation until July 1981. Also, Executive Order 12316, which specifies the responsibilities of EPA and the other federal agencies under the Superfund legislation, did not become effective until August 20, 1981. This executive order formally established EPA's lead role in carrying out Superfund responsibilities, designated EPA as trust fund manager, and directed EPA to prepare a consolidated Superfund budget for all federal agencies. Under this arrangement all federal agencies and departments involved in Superfund activities are to propose Superfund budgets and obtain funding through EPA. HHS established the Superfund Implementation Group (see p. 2) in August 1981 to coordinate the Department's Superfund activities.

EPA directed HHS to submit its first Superfund budget for health-related activities in fiscal year 1981. HHS submitted a $1.6 million fiscal year 1981 budget in July 1981. Although considerable dialogue took place between EPA and HHS, no fiscal year 1981 funds were provided for HHS Superfund activities.

According to officials in EPA's Office of the Comptroller, HHS had not satisfactorily documented and justified its budget request. As a result, HHS was unable to carry out any of its health-related responsibilities in fiscal year 1981. Furthermore, because its budget proposal was denied by EPA, HHS decided to not assign staff for Superfund activities until funds were provided. According to ATSDR and National Institute for Occupational Safety and Health officials, this delay in beginning health-related activities affected HHS' Superfund efforts in later years.

HHS EXPERIENCED FUNDING REDUCTIONS AND DELAYS IN FISCAL YEAR 1982

In early November 1981, EPA issued its Superfund budget call letter to the other federal agencies involved in the program. That same month, HHS submitted a $10 million budget request to EPA and indicated it planned to use 65 full-time equivalent employees (FTEEs) to carry out its Superfund activities. After considerable dialogue, the EPA Administrator and the OMB Director approved $3.3 million for HHS' Superfund health-related activities, and OMB recommended that HHS use 47 FTEEs.

The fiscal year 1982 interagency agreement to transfer funds to HHS for Superfund activities was not signed until March 4, 1982, 5 months after the fiscal year began. Until then HHS was able to accomplish little under Superfund except to organize its coordinating group, because no staff or funds were available for the health-related activities specified in the approved budget. According to ATSDR officials, because of uncertainty about the level of funding EPA would approve, HHS was unable to scope the size of its Superfund program.

In addition, because of the decreases to its fiscal year 1982 budget request, several projects and activities that HHS proposed to begin had to be delayed or postponed. For example, section 104(i)(2) of the law requires HHS to develop an inventory of literature, research, and studies on the health effects of toxic substances. In addition, under section 104(i)(5) of the law, HHS developed plans to conduct short-term toxicological tests on certain chemicals for which no health data existed. In fiscal year 1982, HHS requested $2,243,000 to develop the inventory and conduct toxicological tests. EPA provided only $232,000--$132,000 for testing and $100,000 for developing the inventory. Because of the limited funding and inadequate environmental data, HHS decided to use the entire amount on the inventory.

HHS originally anticipated that about 300 new chemical records could be added to the existing inventory in fiscal year 1982, but because of the reduced funding level, only 94 such records were added. In addition, as a result of the fiscal year 1982 budget reduction and the delayed signing of the fiscal year 1983 interagency agreement, toxicological testing did not start until April 1983.

EPA's budget reductions and delayed signing of the interagency agreement also affected HHS' efforts to carry out its worker safety responsibilities under Superfund. HHS developed a hazardous waste program proposal recommending that at least $7 million be provided over the 5-year duration of Superfund. HHS requested $2,105,000 for fiscal year 1982 to begin work on proposed program areas. EPA, however, approved only $349,000, which did not become available until March 1982. As a result of this late start, only $94,222 was used for two hazardous waste worker safety projects involving education and training. The following table shows some of the more important program areas in which National Institute for Occupational Safety and Health officials told us they could not begin work in fiscal year 1982 due to the reduction in funds.

National Institute for Occupational Safety and Health Superfund Program Areas in Which Work Was Postponed due to Insufficient Funds in Fiscal Year 1982

Program areas	Estimated first-year costs	Estimated FTEEs
Industrial hygiene monitoring and instrumentation	$102,000	1.5
Personnel protective equipment	76,000	1.0
Special hazardous waste reviews	231,000	2.5
Medical screening surveillance/ acute toxicity studies	51,000	1.5
Emergency response team	105,000	1.0

The Congress passed a supplemental appropriation for HHS health-related activities in fiscal year 1982

In July 1982, the Congress, as part of the Urgent Supplemental Appropriations Act of 1982, directed EPA to make available to HHS, in addition to its original $3.3 million budget allowance, $1.7 million for ongoing activities. Another $2 million was to be made available, as needed by HHS, for performing site-specific activities at locations with hazardous wastes--for example, conducting epidemiologic studies, developing and maintaining a registry of persons exposed to hazardous wastes, and

providing diagnostic services. The supplemental appropriation did not include a provision for staff. Although these funds were earmarked exclusively for HHS' use, HHS did not request additional funds from EPA. Consequently, the funds remained available for HHS projects and activities in later fiscal years.

Despite the availability of funds, HHS spent only about $1.1 million and used only about 17 FTEEs in fiscal year 1982. ATSDR attributed its slow start to (1) a proposed reorganization of the Center for Environmental Health, which led to considerable debate concerning the Center's mission, structure, and priorities; (2) uncertainty about how much funding would be provided for Superfund at the beginning of the fiscal year; and (3) the fact that no funds were made available until almost half the fiscal year had passed. As of September 30, 1982, about $5.9 million remained unexpended for HHS' Superfund health-related activities.

HHS maintained that EPA attempted to limit HHS' Superfund responsibilities

ATSDR officials said that EPA impeded HHS' implementation of the law by attempting to limit the Department's designated Superfund responsibilities. The EPA Director, Office of Emergency and Remedial Response, confirmed that at first EPA preferred not to involve HHS in Superfund health-related activities. For example, in the November 1981 draft of the National Contingency Plan, the Administrator, EPA, deleted virtually all references to HHS and its responsibilities. An ATSDR official said that EPA deleted the references to HHS to downplay Superfund health activities. HHS appealed this action to OMB and EPA, stating the draft plan was unacceptable to HHS if it was to fulfill its responsibilities under the law. HHS' role was reinstated in the final version of the plan in July 1982.

In commenting on our draft report, EPA stated that the EPA Administrator did not delete references to HHS and its responsibilities to limit HHS' involvement in the Superfund program. Rather, the Administrator believed that a brief reference to HHS in the National Contingency Plan was sufficient because detailed descriptions of HHS' role could be included in subsequent guidance or in an interagency memorandum of understanding. EPA stated that substantive guidance on HHS' responsibilities was being developed in June 1984.

ATSDR and EPA officials indicated that from the start EPA's Administrator and Assistant Administrator for Solid Waste and Emergency Response had little interest in cooperating with HHS to implement Superfund activities. Little interagency planning

occurred, according to the Director, Center for Environmental Health, primarily because of the uncooperative attitude of EPA's key officials at that time. For example, HHS requested preliminary information concerning the hazardous waste sites being considered as Superfund priority sites to ensure HHS involvement and enhance planning. EPA, however, refused to provide any information. EPA claimed there was not enough time to allow HHS to preview the list and that political pressures might occur if the list was released before final designations of priority hazardous waste sites had been made. As a result, the first 115 priority hazardous waste sites were unknown to HHS until EPA made the list public in October 1981. Officials from ATSDR and EPA's Office of Emergency and Remedial Response said that the agencies had a good working relationship at the staff level, but when HHS' proposals and projects were forwarded for approval of EPA top managers, they were usually rejected or ignored.

In another example of EPA attempting to minimize HHS' Superfund role, EPA hired a toxicologist to render health and medical determinations regarding Superfund sites, even though health activities had been delegated to HHS. ATSDR officials expressed concern that with EPA relying on its own medical consultant, HHS' Superfund role and health advice were ignored. For example, at Ft. Smith, Arkansas, HHS, EPA regional office, and Arkansas state health officials agreed that toxic substances posed an immediate public health threat. The EPA toxicologist advised that an immediate public health threat did not exist; therefore, EPA did not believe it was necessary to quickly initiate cleanup activities. Rather than waiting for EPA to act, the state cleaned up the site on its own.

LIMITED STAFFING WAS MAIN IMPEDIMENT TO HHS' IMPLEMENTATION OF HEALTH-RELATED ACTIVITIES IN FISCAL YEAR 1983

For fiscal year 1983, HHS submitted to EPA a Superfund budget proposal of $21 million for health-related activities and indicated that it planned to use 66 FTEEs on these projects. EPA and OMB approved $3.2 million, and OMB recommended that HHS use 39 FTEEs for Superfund activities. In EPA's fiscal year 1983 appropriation act, enacted September 30, 1982, the Congress directed that $10 million be made available specifically to HHS for Superfund--$8 million for ongoing health-related activities and up to $2 million for specific activities at certain hazardous waste sites as needed. This congressional directive made no provision for staffing. The earmarked funds remained available for HHS projects and activities in later fiscal years.

After the fiscal year 1983 budget was approved, EPA and HHS signed an interagency agreement concerning the Superfund projects to be carried out by HHS and the funds to be provided to them. The fiscal year 1983 interagency agreement took effect on April 1, 1983. Until this action, the March 1982 agreement was extended several times so that HHS could continue its Superfund activities. Unlike fiscal years 1981-82, however, when no funding or untimely funding were the primary factors that kept HHS' agencies from carrying out Superfund health-related activities, limited staffing was the main impediment in fiscal year 1983. This is noteworthy because HHS had $5.9 million of unexpended funds available from the previous fiscal year before its fiscal year 1983 funding allocation was approved.

Some projects could not be initiated due to limited staffing

Limited staffing prevented ATSDR from undertaking proposed projects and activities. For example, the Center for Environmental Health proposed initiating 25 health studies and laboratory projects in fiscal year 1983. According to an ATSDR official, these activities were essential to link the effects of toxic substance exposure to disease. Primarily because of staff constraints, only eight studies were approved. The following table includes examples of some important proposed projects that, according to ATSDR officials, could not be approved in fiscal year 1983.

Superfund Projects Not Approved in Fiscal Year 1983 Primarily Because of Insufficient Staff

Studies/projects	Estimated first-year cost	Estimated FTEEs
Health studies[a]		
Review of cancer mortality data around Superfund sites	b	2.5
Developing methods to monitor early fetal death around toxic dumps	$3,938,000[c]	18[c]
Detailed health studies at individual Superfund sites		
(Memphis, Tenn.,	662,104	4
New Bedford, Mass.)	971,118	3
Case-control study of end-stage renal disease around Superfund sites	b	6
Laboratory projects		
Implementation of priority pollutant technology to assess health risk from toxic exposure	120,000	3
Two-dimensional electrophoretic protein mapping for the assessment of health effects from exposure to toxic wastes	155,000	2
Development and evaluation of immunoassays for PCBs, dioxins, and furans	150,000	2
Trace element determinations in biological fluids	120,000	1
Analysis of specific congeners of PCBs	50,000	1
Lipid metabolic profiling for environmental health effects assessment	50,000	1

[a]These estimates of resources needed to conduct the studies do not include related laboratory resource requirements.

[b]Cost estimate not provided by HHS.

[c]Total cost and staff needed over 5 years.

In fiscal year 1983, HHS assigned 11 FTEEs to conduct health studies and laboratory projects. Primarily as a result of this staffing level and the late start in the fiscal year, HHS obligated only $324,612 for the approved studies and projects.

Staff resources at lower-than-requested levels by HHS' agencies impeded worker safety and health activities. For example, in fiscal year 1983, OMB allowed $326,000 and four FTEEs for these activities. The supplemental fiscal year 1982 appropriation and the fiscal year 1983 appropriation together made available nearly $1.9 million for these activities, yet no increase in FTEEs occurred. As a result, the Comprehensive Guidance Manual, dealing with worker safety and health, was still in draft form in September 1984, putting it 12 months behind HHS' estimated completion date, and other planned projects were not initiated.

Some projects were delayed due to limited staffing

Officials in several HHS agencies stated that lack of staff, in addition to preventing some projects from being initiated, delayed approved projects. For example, three health studies approved to start at the beginning of fiscal year 1983 were not started until April 1983, primarily because of lack of staff. Another approved health study, designed to assess the potential health risks of PCBs, required 10 staff members to fully pursue. However, HHS assigned only one staff member to the study. As a result, as of March 31, 1984, after about 14 months, HHS had completed only 14 of 175 planned site evaluations required to identify priority locations for future pilot studies of PCBs. Also, in fiscal year 1983, HHS planned to investigate two counties with Superfund priority sites for evidence of associated birth defects that might have been caused by chemicals deposited at the disposal sites. Preliminary data reviews identified several areas of concern, but lack of staff prevented HHS from beginning the detailed field investigations as of March 31, 1984.

During fiscal year 1983, HHS spent about $4 million on Superfund activities. About half of this amount was spent during the last 3 months of the fiscal year. When the total expenditures were deducted from the amounts available in fiscal years 1982-83, as of September 30, 1983, $11.9 million remained unexpended.

EPA did not develop adequate scientific data for HHS

In addition to the lack of staff, ATSDR officials told us that in fiscal year 1983, some activities were delayed because EPA was slow to develop adequate scientific information at hazardous waste sites. HHS depends on EPA to identify chemicals and compounds at the sites and to share this information with the Department so that it can initiate studies to determine the

potential dangers of these substances. HHS' health-related activities have been adversely affected because, as discussed below, HHS cannot plan and set priorities for its health study activities until EPA provides complete scientific data.

HHS has developed a four-step, systematic approach for evaluating the health risks posed by hazardous substances. However, HHS cannot take action at specific hazardous waste sites until EPA scientific information is provided. The first step in the HHS approach is to evaluate in detail the site information EPA collects and maintains. These data include, but are not limited to, EPA's environmental sampling results and any previous health effects data and information from state and local agencies. Second, if a potential health threat exists, based on HHS' review of the site data, the Department conducts a pilot study. The pilot study is a more specific investigation of health effects, but is limited to persons with the greatest likelihood of exposure. Third, if the pilot study discloses a high level of toxic chemicals in these individuals, HHS undertakes a broader investigation of the community to assess the health status of the population. The fourth step is the development of registries and long-term follow-up health studies.

EPA is required by the National Contingency Plan (see p. 1) to identify a national priority list of hazardous waste sites--those warranting the highest priority for Superfund action. In October 1981, EPA released the first list, which contained 115 priority sites. In December 1982, the list was expanded to 418 sites, and in August 1983, 133 additional sites were proposed for inclusion on the list. As of September 30, 1983, however, EPA had collected data to enable HHS to fully assess the health hazards of only 20 Superfund priority sites, largely because EPA's investigations (1) take considerable time and/or (2) had not progressed to the stage during which sufficient data are collected for HHS' purposes.

LIMITED STAFFING IS STILL A PROBLEM IN FISCAL YEAR 1984, BUT HHS' RELATIONSHIP WITH EPA HAS IMPROVED

The ratio of available funds to staffing provided in fiscal year 1984 is comparable to that of fiscal year 1983, and HHS Superfund activities will continue to be restricted primarily because of available staff.

For fiscal year 1984, HHS requested $6.4 million and planned to use 53 FTEEs for its Superfund activities. OMB decided that HHS should receive $1.9 million and recommended 21 FTEEs for Superfund activities. The Congress in EPA's fiscal year 1984 appropriation act directed that $5 million be appropriated to EPA for HHS' Superfund activities and projects.

When the $5 million approved by the Congress was added to the $11.9 million unexpended in previous fiscal years, about $16.9 million was available for Superfund health-related activities. The EPA/HHS interagency agreement for fiscal year 1984 took effect on October 5, 1983. During the first 6 months of the fiscal year, HHS spent about $3.5 million on Superfund health-related activities.

Unlike fiscal year 1983, HHS did not follow OMB's staffing recommendation in fiscal year 1984. Rather, HHS allocated 39 FTEEs for its agencies' Superfund activities at the beginning of the fiscal year as opposed to the 21 FTEEs recommended by OMB. This level, however, still was low considering the funding available. Because of the large amount of funds available, ATSDR appealed its staff allocation to HHS and requested 76 FTEEs to meet basic program needs in fiscal year 1984. In response to this appeal, HHS in December 1983 increased the staff level to 47 FTEEs. In April 1984, ATSDR again appealed to HHS to increase its staff level to 76 FTEEs. In its comments on our draft report, HHS stated that it was considering increasing the fiscal year 1984 staffing to 62 FTEEs.

According to ATSDR officials, because of staffing limitations some of its health-related activities have been adversely affected. For example, the following table shows some of the major Superfund health studies and projects that have been delayed or postponed, according to ATSDR officials, primarily because of insufficient staff in fiscal year 1984.

Superfund Projects Delayed Primarily Because of Staff Restrictions in Fiscal Year 1984

Study/project description	Estimated first-year cost	Estimated FTEEs
Health studies[a]		
Memphis, Tennessee - North Hollywood dump	$ 662,104	4
New Bedford, Massachusetts - PCB exposure	971,118	3
Tacoma, Washington - Arsenic exposure	1,078,908	3
Missouri - Additional dioxin efforts	392,863	4
Tennessee - Low birth weight	200,000	4
National Institute for Occupational Safety and Health studies relating to dioxin exposure among workers (mortality study	681,060	5
and morbidity/birth defects study)	1,775,000[b]	6
Laboratory projects		
Expansion of capabilities for routine clinical laboratory testing for renal function, liver dysfunction, and other requested tests	550,000	8
Assessment of immunocompetence of individuals exposed to environmental toxicants	450,000	5
Expansion of capabilities in inorganic toxicology	500,000	5
Immunoassays to screen for environmental toxicants	300,000	5
Metabolic profiling of nonprotein components of urine specimens from individuals potentially exposed to environmental toxicants	325,000	4
Effects of toxicant exposure on biochemical markers for peripheral lymphocytes; evaluation of enzyme systems, surface antigens, viability, and other characteristics	300,000	2
Automation of extraction techniques for organic toxicants in biological matrices	75,000	2

[a]These cost estimates do not include associated laboratory resource requirements.

[b]Total cost for studies over 2 years.

According to ATSDR, limited staffing also kept it from generating new ideas for additional work. For example, ATSDR officials advised us that if they could acquire more staff with specialized knowledge, such as in immunology or neurologic disabilities, the agency could broaden its research to link the effects of toxic substance exposure to long-term health problems.

Interagency cooperation has improved

Officials in ATSDR and EPA's Office of Emergency and Remedial Response advised us that the relationship between the agencies has improved since the replacement of key EPA personnel in 1983. For example, EPA and HHS implemented the fiscal year 1984 interagency agreement essentially without delay on October 5, 1983. In addition, the previous EPA management reduced HHS' fiscal year 1984 budget request by 35 percent in October 1982, and the prior 2 fiscal years' budgets by even larger percentages. Under the new EPA management, however, HHS' fiscal year 1985 budget request was reduced only 11 percent.

Interagency planning and coordination also improved in 1983 and 1984. For example:

--An HHS scientist spent 4 weeks at EPA headquarters, meeting with Superfund officials and scientists.

--An interagency task force has been formed to develop guidelines to ensure the quality of EPA's site information.

--EPA's Superfund strategy emphasized the necessity for interagency coordination at the Missouri-dioxin sites and confirmed HHS' responsibility to provide health assessments.

--EPA headquarters directed its regional staff to obtain an HHS assessment of the public health threat as a prerequisite to cleanup approval for each asbestos site.

--EPA revised its process of identifying and prioritizing Superfund sites to formally include health data and suggestions from HHS' regional staff.

Despite these planning and coordination improvements, it is too early to identify any measurable results.

CONCLUSIONS AND MATTER FOR CONSIDERATION BY THE CONGRESS

The Superfund legislation gave HHS considerable latitude concerning how it could implement its health-related responsibilities and did not establish specific criteria or time frames for measuring HHS' performance. HHS' progress in implementing its planned Superfund activities has been adversely affected by funding delays and staffing limitations. In considering HHS' accomplishments to date, however, one must keep in mind that establishing links between exposure to toxic chemicals and specific adverse health consequences involves rapidly changing technical and medical issues on which little scientific data have been developed. Also, as HHS pointed out in its comments on our draft report, (1) some of its Superfund tasks are not achievable overnight and require considerable study and deliberation, and (2) time is needed to organize such activities, especially given the unique funding and staffing process envisioned by the statute.

Consequently, as the Congress deliberates the future of Superfund, particularly HHS' health-related responsibilities, we suggest that it consider the workability of the existing arrangement whereby EPA controls HHS funding levels and whether additional staff positions should be authorized for HHS' activities to avert past situations where HHS had inadequate funds or staff to carry out its plans.

AGENCY COMMENTS AND OUR EVALUATION

HHS stated that our report was essentially an accurate description of the progress it had made in implementing its Superfund health-related activities. HHS emphasized that before the Superfund legislation was enacted, (1) little public discussion of the scientific and medical feasibility of the law's provisions was possible and (2) minimal consideration of the resources and time required to implement the health-related responsibilities took place. HHS agreed with our observation that certain events and circumstances had prevented it from attaining the program's goals and objectives.

HHS commented, however, that in addition to the limiting factors our report discusses, time has inhibited the Department's progress toward achieving its Superfund responsibilities. HHS added that the tasks in the law can only be carried out over time by technical staff with the skill and experience necessary to cope with the situations involving communities with possible exposure to hazardous substances. HHS also stated that while Superfund offers a mechanism to address these situations, the development and training of a skilled staff large enough to meet the need requires not only adequate funds, but also <u>time</u>.

In several sections of the report, we discuss that time was a factor for HHS, EPA, and the Congress concerning their decisions and activities regarding Superfund. We recognize that a comprehensive program with Superfund's scientific and social complexities cannot be initiated immediately. Furthermore, we appreciate that establishing a well-qualified staff of toxicologists and other scientists and medical doctors to deal with the health-related responsibilities of Superfund takes time. Nevertheless, the thrust of our report remains the same--considering that the enabling legislation was enacted 45 months ago, HHS' achievements and progress under Superfund have been limited. HHS' general comments on our draft report are included in appendix I.

EPA generally concurred with the findings reported, particularly in regard to the funding difficulties experienced by HHS in fiscal years 1981-82, the problems in later years given the limited staffing provided by HHS for Superfund activities, and the improved relations between EPA and HHS since 1983. EPA's general comments on our draft are included in appendix II.

CHAPTER 3

HHS EFFORTS TO DEVELOP REGISTRY OF AND PROVIDE MEDICAL CARE TO PERSONS EXPOSED TO TOXIC WASTES

Following the November 1980 presidential election, a compromise bill for Superfund was introduced. This bill substantially differed from prior bills passed by the House and Senate in that for the first time it contained the authorization for programs to protect public health and activities designed to measure the human health impact from exposure to hazardous or toxic substances, as specified in section 104(i). Little public discussion occurred regarding this part of the bill, and similarly, detailed cost estimates or other analyses of the health-related issues were not obtained.

Section 104(i)(1) of the act requires, in part, that HHS establish and maintain a national registry of persons exposed to toxic substances, but does not specify the type of information or sites to be included. Section 104(i)(4) requires, in part, that HHS provide medical care to exposed individuals in cases of public health emergencies, but does not explain the extent to which medical care is to be provided.

These sections can be interpreted in widely different ways. And specific interpretations could result in significantly different approaches to the implementation of the act. The manner in which HHS has decided to implement these provisions of the law is discussed below.

DEVELOPMENT OF NATIONAL REGISTRY OF PERSONS EXPOSED TO TOXIC WASTES

Section 104(i)(1) requires, in part, that HHS establish and maintain, in cooperation with the states, a national registry of persons exposed to toxic substances. Selected terms in this section, such as "exposed persons" and "national registry," could be interpreted in different ways. For example, the registry of exposed persons could be a compilation of health information for most people who reside near all Superfund hazardous waste sites. On the other hand, HHS has decided to narrow its function and establish registries at a limited number of those hazardous waste sites where there is a strong indication of substantial human exposure and a sound scientific basis for investigating the possible correlation between exposures and health effects among persons living near the sites.

When scientifically appropriate for long-term studies, ATSDR establishes and maintains separate exposure registries. The agency expects to establish registries at a limited number of Superfund sites. It believes that exposure registries are of little scientific value in establishing links between exposure and illness when the latent period between exposure and illness is extended, follow-up is arduous, or individual exposure is difficult to measure, as at most Superfund sites. As of March 31, 1984, the ATSDR was developing methods to be used in establishing and maintaining registries. At that date, it had started to establish one central listing of persons exposed to dioxin at one Superfund site.

ATSDR's approach to establishing a registry is generally the same as the one the Center for Environmental Health used to establish the three exposure registries it developed before Superfund. For example, after a 1973 shipping accident in Michigan, the Center developed a registry of individuals exposed to polybrominated biphenyls. In late 1974, a limited field study, including interviews and blood tests, was conducted for about 200 individuals. When this identified potential widespread exposure, the Michigan Department of Public Health entered into an agreement with CDC to register and study about 4,000 exposed individuals who resided throughout western and central Michigan. According to a CDC official, this type of registry enables the agency to use limited resources more efficiently to draw conclusions about registered individuals and to add to the existing scientific data base.

Registries could also be established for other purposes. ATSDR could establish a national compilation of health information on individuals living near hazardous waste sites for future reference. Under this approach, it could keep potentially exposed persons advised of new scientific and medical developments, new medical tests, and related information. Therefore, if scientists linked a specific chemical exposure to a certain disease, ATSDR could alert exposed individuals. A record of exposed individuals could also provide important medical information if future health studies are necessary. According to ATSDR officials, such a list may also prove useful as documentation for lawsuits involving compensation of persons exposed to toxic wastes.

Collecting and maintaining information for any type of registry is expensive. According to HHS documents, the estimated one-time cost of establishing the Center for Environmental Health or the National Institute for Occupational Safety and Health registries ranged from $8 to $87 a person, depending primarily on the extent of data or tissue collection, the geographic dispersion of exposed individuals, and the recency of

exposure. The cost for the Center for Environmental Health to collect data on the 1979 Three Mile Island nuclear accident was $8 per person and did not include any state support or CDC staff expenses. This registry of a recently exposed population living within 5 miles of the plant was obtained using a simple questionnaire. No tissue data were collected. Similarly, as of March 31, 1984, the cost of establishing the only Superfund central listing at a Missouri-dioxin site was about $31 for each person, not including any CDC support costs. The cost for the Center for Environmental Health to establish the Michigan polybrominated biphenyl registry was $87 a person.

The estimated costs of establishing and maintaining basic registries of persons exposed to toxic substances at identified Superfund sites have not been developed because at each site the affected population varies, the affected geographic area varies, and a unique registry may be developed. To illustrate the potential costs involved to establish registries, we developed a hypothetical scenario. Using CDC's $31 a person experience in establishing the Missouri-dioxin Superfund central listing and assuming that 1,500 persons would be involved in a registry, we estimated it would cost $46,500 to establish a basic exposure registry at one Superfund site.

This cost, of course, would vary depending on the number of persons included and the extent of interviewing and testing called for. If this estimate were projected to the 546 identified Superfund sites and if HHS had the resources, it would cost at least $25 million to establish these registries. The Chief of the Superfund Implementation Group commented that our estimate was reasonable.

ATSDR officials expressed concern about the availability of long-term funding for maintaining registries. The Agency estimated it would need additional funds for at least 20 years for this purpose. In its comments on our draft report, HHS agreed that to be most useful, such registries must be updated and the participants' health status evaluated periodically for many years and pointed out that such activity is labor-intensive and expensive and would be expected by the participants as a condition of being included in a registry. HHS added that long-term commitments of funding for federally supported programs are exceedingly difficult for federal officials to make. In the case of Superfund registries, the Department said the commitment is particularly difficult to make because authorization for the program expires in 1985, and at present there is no guarantee that funds will be provided for costly registries in the future.

The Department also commented that to help clarify the HHS position on exposure and disease registries, a detailed criteria

document was prepared in May 1984. The Department stated that the delay between the enactment of Superfund and release of this criteria document is symptomatic of the difficulties inherent in implementing a law that was enacted to provide for the resolution of extraordinarily complex scientific and social issues without (1) determining the scientific and medical feasibility or benefits of the law's provisions and (2) fully considering the resources--including time--needed to implement the law.

PROVISION OF MEDICAL CARE TO PERSONS EXPOSED TO TOXIC WASTES

Section 104(i)(4) requires, in part, that HHS provide medical care to exposed individuals in cases of public health emergencies related to exposure to toxic substances. The terms "medical care," "public health emergencies," and "exposed individuals" could be interpreted in different ways. For example, HHS could provide a range of direct health care services, such as physical examinations or laboratory services, for an extended period to every person living around hazardous waste sites, which would be costly. HHS, however, has decided to not provide direct medical care to exposed persons. Instead, HHS has decided to assist, consult, and coordinate with private or public health care providers, in emergencies or other instances where persons may have been exposed to toxic substances. HHS has also decided to not obtain comprehensive medical histories, conduct continuing annual physical examinations, provide for periodic laboratory testing, or make available other clinical services to detect early signs of illness due to exposure to toxic substances. According to an ATSDR official, the term "public health emergencies" could be interpreted to include unexpected events, such as explosions or train derailments, but not cover Superfund sites which were designated as priorities.

According to CDC officials, to identify long-term consequences of exposure to hazardous wastes, health services must be provided. In May 1980, HHS' Committee to Coordinate Environmental and Related Programs reported on the potential health effects of toxic chemical dumps. This report concluded that medical care for exposed individuals should be arranged locally and exposed populations should be monitored to ensure that all such persons have access to appropriate medical care.

ATSDR's limited medical care role of assisting, consulting, and coordinating with private or public health care providers in cases of public health emergencies or other instances of probable exposure includes consultations with local health officials, literature searches, and site visits. ATSDR has not defined the terms "medical care," "public health emergencies," and

"exposed individuals" and has not conducted detailed studies to develop precise cost data concerning the provision of medical care.

In its comments on our draft report, the Department acknowledged that it does not provide direct medical care to persons exposed to hazardous substances in public health emergencies, but added that emergency medical care, although authorized by Superfund, is almost always more immediately available at the scene of the emergency event through private physicians, hospitals, and clinics. HHS also commented that its medical and toxicology staffs are available and provide consultation and advice to emergency care providers on appropriate measures to be used in specific exposures to hazardous substances.

The cost of providing direct medical care to persons exposed to toxic wastes could be substantial. In October 1981, HHS conservatively estimated that the fiscal year 1982 cost of such medical care would be $279 million. As of March 31, 1984, the only experience concerning the provision of medical care costs at a Superfund site relates to Triana, Alabama. In 1983, as a result of litigation, a chemical manufacturer agreed to pay $5 million for medical care for about 1,000 local residents. This would basically cover direct health care and monitoring for patients' general health needs. The funds could also provide group medical insurance, health education programs, and the collection of medical data related to health effects of exposure to the chemical manufactured by the company.

SUMMARY

No legislative guidance was provided regarding sections 104(i)(1) and (4) of the act, which were quickly drafted and passed. As a result, parts of these sections may be interpreted in widely different ways. The interpretation of those sections will affect the number of persons provided medical care, the extent of medical care provided, and the cost of developing registries and providing medical care.

The registry approach of ATSDR is consistent with other Center for Environmental Health registries. ATSDR officials advised us that they chose this approach because it allows efficient use of limited resources and provides precise scientific data. However, exposure registries could also be established for other purposes. In any event, information for registries will be expensive to collect and maintain.

Section 104(i)(4) requires HHS to provide medical care to exposed individuals. ATSDR has not provided direct medical care, although the act could be interpreted to mean that some care should be provided. The cost of direct medical care, however, could be substantial.

MATTERS FOR CONSIDERATION BY THE CONGRESS

If the Congress considers HHS' interpretations of its role under these sections of the act to be inconsistent with congressional intent, it may wish to

--clarify the purpose and intent of the national exposure and disease registries and the types of information to be included,

--clarify the extent to which medical care is to be provided, and

--define such terms as "exposed individuals" and "public health emergencies."

AGENCY COMMENTS AND OUR EVALUATION

HHS agreed that the Congress may wish to clarify and define certain authorities and terms contained in the law, but suggested that such clarification be based on technical information obtained from and consultation with HHS and EPA scientists and officials. We agree that the Congress should invite HHS and EPA scientists and officials, as well as other knowledgeable representatives from the public and private sectors, to participate in clarifying and defining these important issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

JUN 26 1984

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report "HHS' Implementation of Superfund Health-Related Responsibilities." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Richard P. Kusserow
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED "HHS' IMPLEMENTATION OF HEALTH-RELATED SUPERFUND ACTIVITIES" DATED MAY 16, 1984

General Comments

This draft report, the product of an intensive 15-month General Accounting Office (GAO) investigation, is an essentially accurate description of the progress of the Department of Health and Human Services (HHS) in implementing the health-related activities of a major new piece of environmental legislation.

As GAO correctly points out on page 33 of the draft report, the Bill which was passed by the Congress and signed into law on December 11, 1980 as P.L. 96-510, "The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund)," was substantially different from earlier bills directed toward the protection of the environment from releases of hazardous substances and from abandoned hazardous waste disposal sites. None of the earlier bills contained the authorization for programs to protect public health and provide for worker safety and health or for activities designed to measure the human health impact from exposure to hazardous or toxic substances. Thus, little public discussion of the scientific and medical feasibility or benefit of the resources and time required to implement these health-related provisions occurred prior to the law's enactment. HHS has a long history of programs of research and public health protection directed to a broad range of environmental conditions including radiation, sanitation, toxic chemicals, injuries, occupational safety and health, and severe climate and geological conditions. Superfund mandated the implementation of a major effort within the Department to address the scientifically complex and politically controversial issues of the health effects from hazardous substance exposures in community settings. The law mandated the creation of a sixth new agency of the Public Health Service; the Agency for Toxic Substances and Disease Registry (ATSDR) for the purpose of effectuating most of the health authorities. Also, as the GAO draft report points out, this legislation, with its significant but unexpected sections related to human health, was passed immediately after a presidential election, a major transition period for the Executive Branch of Government.

These three conditions: (1) the passage of a major new law, (2) the mandate for a new operational component, and (3) with enactment during a transition period in the Federal Government's leadership; could easily have resulted in delays of many more months in the implementation of the public health provisions of the law. In fact, there was immediate action on the part of HHS officials to assume an active role in the earliest Superfund planning meetings at the Council of Environmental Quality and in the drafting of the National Contingency Plan. As a result of this aggressive action, the HHS services and programs available under the Superfund are now widely recognized by the general public, the news media, the Congress, and the scientific community.

The cover summary statement that "HHS has made less progress in implementing its Superfund program than originally planned or possible given the availability of funds" is open to misinterpretation. A more accurate and clearly understandable statement is that "HHS made less progress than originally planned or possible because funding for its Superfund programs was not made available on a timely basis."

As GAO notes in the cover summary, certain events and circumstances conspired to prevent HHS from attaining the ambitious goals and objectives the health program staff set for the Department's Superfund program. The GAO audit trail clearly leads back to a core of public health scientists and managers from several cooperating PHS agencies who established priorities for work to be carried out under Superfund. They developed program and project plans for these priorities, defined the budget and staffing needs for these projects, and implemented those activities which could be carried out with resources made available after decisions were made on the distribution of fiscal and personnel support among competing programs.

The GAO draft report fails to recognize the inevitability of time as a factor which continues to inhibit progress toward the ultimate and complete achievement of the HHS responsibilities defined in Superfund. The tasks and the expectations implicit and explicit in the law can only be carried out over time by technical staff with the skill and experience necessary to cope with the situations involving communities of people with possible exposure to hazardous substances. The people living near these Superfund areas raise questions and experience fears that the sciences of medicine, toxicology, and epidemiology are not yet able to answer or resolve. Superfund offers a mechanism necessary to help address the concerns, but the development and training of a skilled staff large enough to meet the need requires not only dollars and a full-time-equivalent employment (FTEE) ceiling, but also time.

HHS agrees with the suggestion made by GAO that the Congress may wish to consider providing HHS with clarification and definition of certain authorities and terms contained in the law. However, HHS also suggests that such clarification should be based on technical information and consultation from agency scientists, managers, and officials which could be obtained through briefings and legislative hearings.

GAO note: The Department's technical comments have not been included here; however, we considered them in preparing our final report.

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

JUN 28 1984

OFFICE OF
POLICY, PLANNING AND EVALUATION

Mr. J. Dexter Peach
Director
Resources, Community and
Economic Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Peach:

On May 24, 1984, the General Accounting Office (GAO) sent the Environmental Protection Agency (EPA) a draft report for comment. The report is entitled "HHS' Implementation of Superfund Health-Related Responsibilities." As required by Public Law 96-226, EPA has prepared this formal response on the draft report for GAO's use when preparing the final report.

I wish to emphasize that the relationship between EPA and the Department of Health and Human Services (HHS) has improved dramatically over the past year, as pointed out by GAO. This improvement is attributable to the policies of the current Agency management and to a better understanding by the organizations of their roles and responsibilities in implementing the Superfund statute.

The report accurately presents the HHS implementation of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) and the EPA role in funding the HHS activities. We generally concur with the findings of the report concerning EPA, particularly in regard to the funding difficulties experienced by HHS in FY 1981 and 1982; the problems in subsequent years with implementation of the statute given the limited staffing provided by HHS for Superfund activities and the significantly improved relations between EPA and HHS since 1983.

GAO note:	The Agency's technical comments have not been included here; however, we considered them in preparing our final report.

We appreciate the opportunity to comment on the draft report, and hope that GAO will find these comments useful.

Sincerely yours,

Milton Russell

Milton Russell
Assistant Administrator
for Policy, Planning and Evaluation

(102556)

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