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Congressional Requesters

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TOXIC CHEMICALS

Long-Term Coordinated Strategy Needed to Measure Exposures in Humans

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Contents

Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control and Prevention
DP-HANES	Defined Population Health and Nutrition Examination Survey
EPA	Environmental Protection Agency
HHS	Department of Health and Human Services
MTBE	methyl t-butyl ether
NCEH	National Center for Environmental Health
NCHS	National Center for Health Statistics
NHANES	National Health and Nutrition Examination Survey
NHATS	National Human Adipose Tissue Survey
NHEXAS	National Human Exposure Assessment Survey
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NRC	National Research Council
NTP	National Toxicology Program
PBT	persistent, bioaccumulative, and toxic
PCB	polychlorinated biphenyls

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Congressional Requesters

State and local officials report continuing public concern over the health risks posed by exposures to toxic chemicals, ranging from heavy metals such as arsenic found at national hazardous waste sites to common pesticides used in and around the home. For example, increasing rates of cancer in various communities have prompted questions about the potential link to residues from pesticides, indoor air pollutants, and other toxic chemicals. Historically, estimates of human exposure to toxic chemicals have been based on the concentration of these chemicals in environmental media—such as air, water, and food—along with assumptions about how people are exposed. Federal monitoring efforts have primarily focused on this type of measurement. However, according to public health experts, measurements of internal doses of exposure—actual levels of chemicals or their metabolites[1] in human tissues such as blood or urine—can be a more useful measure of exposure for some purposes.

Over the past decade, advances in laboratory technology have provided new tools for measuring a broad range of chemicals in human tissues—tools that can help researchers and health officials assess how much of a chemical has been absorbed in the body and provide more accurate measurements of exposure to relate to potential health risks. When gathered for the U.S. population, such data can help identify new or previously unrecognized hazards related to chemical substances found in the environment, monitor changes in exposures over time, and establish the distribution of exposure levels among the general population. These data can also help identify subpopulations—such as children, low-income groups, or ethnic minorities—that might be at increased risk because they face particularly high levels of exposure. State and local health officials can use information on typical exposures in the general population to help assess environmental health risks for specific sites or populations within their borders and to keep local residents informed. For example, local officials in one community collected exposure measurements before,

[1]Metabolites result from the interaction of the chemicals with enzymes or other chemicals inside the body.

during, and after the burning of arsenic-contaminated soil and found that no excess exposure—as compared to typical levels found in the population—had occurred.

In light of the potential benefits offered by these new technologies, you asked us to review efforts to collect and use such information at both the state and federal levels. Specifically, you asked us to (1) determine the extent to which state and federal agencies—in particular, the Department of Health and Human Services (HHS) and the Environmental Protection Agency (EPA)—collect human exposure data[2] on potentially harmful chemicals, including data to identify at-risk populations, and (2) identify the main barriers hindering further progress in such efforts.

We compiled a list of more than 1,400 naturally occurring and manmade chemicals considered by HHS, EPA, and other entities to pose a potential threat to human health. These included chemicals prioritized for safety testing (based on EPA's findings that the chemicals may present unreasonable health risks), chemicals linked to cancer, toxic chemicals frequently found at Superfund sites, and certain pesticides monitored in foods or thought to be potentially harmful to humans. For these chemicals, we assessed the extent to which major HHS and EPA survey efforts—specifically HHS' National Health and Nutrition Examination Survey (NHANES) and EPA's National Human Exposure Assessment Survey (NHEXAS) phase I (pilot surveys)—were collecting human exposure data. We also surveyed 93 environmental health officials in 50 states and the District of Columbia, receiving responses from 81 officials in 48 states for a response rate of 87 percent. At the federal level, we focused on survey data collected for the general (non-occupationally-exposed) population. We excluded federally sponsored academic and private sector research. Appendix I explains our scope and methodology in more detail. We conducted our work from March 1999 through March 2000 in accordance with generally accepted government auditing standards.

[2]The scientific community uses varying terminology when referring to human exposures. Often, external contacts with chemicals are defined as "exposures," and internal measurements of exposure are referred to as "doses." Doses are also considered a measure of exposure. Our review focused primarily on efforts to gather internal exposure measurements through human tissue in the non-occupationally-exposed population. To simplify reporting, we are referring to such internal exposure measurements as "human exposure" data.

Results in Brief

Federal and state efforts to collect human exposure data are limited, despite some recent expansions. HHS and EPA have been able to take advantage of improved technology to measure exposures for more people and for a broader range of chemicals. Still, with existing resources, HHS and EPA surveys together measure in the general population only about 6 percent of the more than 1,400 toxic chemicals in our review. For those toxic chemicals that we reviewed, the portion measured ranged from 2 percent of chemicals prioritized for safety testing to about 23 percent of those chemicals most often found at Superfund sites and considered to pose a significant threat to human health. Even for those chemicals that are measured, information is often insufficient to identify smaller population groups at high risk, such as children in inner cities and people living in polluted locations who may have particularly high exposures. At the state level, efforts are similarly limited. Almost all state officials who we surveyed said they highly valued human exposure data for populations within their borders, and many provided specific examples of how such data have provided useful information for interpreting citizens' health risks and guiding public health actions. For example, state officials in nine states used human samples not only to identify who was exposed to a toxic pesticide illegally sprayed in citizens' homes, but to identify houses most in need of clean-up. Despite this perceived value, most officials reported that they were unable to collect or use human exposure data in most of the cases where they thought it was important to do so.

Three main barriers limit federal and state agencies' abilities to make more progress. First, federal and state laboratories often lack the capacity to conduct measurements needed to collect human exposure data; additionally, for most of the chemicals on our list, no laboratory method has been developed for measuring the chemical levels in human tissues. The second barrier, particularly voiced by state officials, relates to the lack of information to help set test results in context. Public health officials said they need more information on typical exposures in the general population so that they can compare this information with people's levels at specific sites or with specific populations in their states. They also said they needed more research to relate exposure levels to health effects for the chemicals of concern in their states. The third barrier, of particular concern at the federal level, is that coordinated, long-term planning among federal agencies has been lacking, partly because of sporadic agency commitments to human exposure measurement and monitoring. HHS and EPA officials indicated that they have been discussing the merits of establishing a coordinated interagency human exposure program, but they have not yet

formalized or agreed upon a long-term strategy. A long-term coordinated strategy should also ensure adequate linkages between collection efforts and agency goals, provide a framework for coordinating data collection efforts that considers individual agencies' needs and expertise, provide a framework for identifying at-risk populations, and consider states' needs for information. To address these needs, we are recommending that the Secretary of HHS and the Administrator of EPA develop a coordinated federal strategy for the short- and long-term monitoring and reporting of human exposures to potentially toxic chemicals.

Background

EPA projects a continuing upward trend in environmental compliance costs for pollution control measures, amounting to an estimated $148 billion this year. Hundreds of millions of dollars are spent monitoring levels of toxic chemicals in the environment—for example, approximately $139 million of federal funding supported national air-quality monitoring networks in the United States in fiscal year 1999.[3] Despite these expenditures, what often is not known is the extent to which people are exposed to potentially harmful chemicals in their daily lives, the chemicals to which they are most often exposed, the levels of such exposure, how exposures change over time in relation to regulatory policies, and the sources of exposure. Policymakers, regulators, researchers, and public health officials must often rely on estimates of human exposure levels for the general population or for smaller groups thought to be at risk. Such estimates are often derived from data showing the extent the chemicals are found in the air, water, food, or other environmental media and assumptions about how and at what rate the body absorbs the chemicals it contacts. A variety of methods for measuring exposures are considered to be more direct than those that measure chemicals in the ambient environment. These methods measure exposures in people's more immediate environments and include tools such as personal air monitors, which measure chemicals that may be inhaled. For several chemicals and purposes, measuring internal exposure levels in human tissues is considered the most useful and accurate measure and an important piece of the information needed to link contaminants in the environment with adverse health effects.

[3] *The Role of Monitoring Networks in the Management of the Nation's Air Quality,* National Science and Technology Council, Committee on Environment and Natural Resources, Air Quality Research Subcommittee (Mar. 1999).

While officials may be able to collect internal exposure levels at a local level, the results are difficult to interpret without information such as comparative data to show what exposure levels might be considered high or research findings linking exposure levels to specific health effects. Because of the need for improved data on actual human exposures found in the general population, the National Research Council (NRC), an arm of the National Academy of Sciences, recommended in 1991 that the nation adopt a new program to monitor chemical residues in human tissues, such as blood. NRC noted that determining the concentrations of specific chemicals in human tissues could serve to integrate many kinds of human exposures across media such as air, water, or food and over time. As one component of an effort to manage environmental quality and protect public health, NRC reported that a well-designed national program for monitoring toxic chemicals in human tissues was needed.[4] NRC pointed out that human exposure data could be used to help monitor changes in the population's exposure to chemicals and identify population groups—by factors such as age or geographic location—that might be at increased risk because they face higher levels of exposure.

Direct biological monitoring of human exposure to chemicals has been made increasingly possible by recent advancements in analytical chemistry and molecular biology. Methods have been developed to measure smaller levels of toxicants in body tissues and to do so with smaller sample amounts.[5] For example, a few years ago a laboratory would need 100 milliliters of blood to detect dioxins in the part-per-billion range. New test methods use less than 10 milliliters and are capable of detecting concentrations in the parts-per-trillion range. Single samples can also now be used to detect low concentrations of multiple chemicals. Since 1995, for example, laboratory methods have been developed to detect polycyclic aromatic hydrocarbons, a group of more than 100 chemicals formed during

[4]According to NRC, human monitoring data alone can signal the need to conduct studies on specific environmental chemicals, but these data are best viewed as one component of a comprehensive environmental monitoring program. Human measurements are best supplemented with knowledge of contaminant sources, environmental pathways, environmental concentrations, time patterns and locations of exposure, routes of entry into the body, material toxicity, and latency. See NRC, Commission on Life Sciences, *Monitoring Human Tissues for Toxic Substances* (Washington, D.C.: National Academy Press, 1991).

[5]Other human biological tissues that might be used for measurements of chemical concentrations include fat tissue, breast milk, semen, urine, liver specimens, hair, fingernails, or saliva. Human breath has also been used to measure exposure to certain chemicals.

the incomplete burning of coal, oil, gas, garbage, tobacco, and other substances.

Lead is an example of a chemical that has been monitored extensively by measuring absorption into human tissues—specifically, lead levels in the blood. Elevated levels of lead in the blood can cause learning problems and, at extreme levels, result in serious brain or kidney damage. Data on blood lead levels have been collected for the national population since 1976. Public health officials, researchers, and others have used lead exposure data from large- and small-scale studies in many ways to identify at-risk populations, evaluate regulatory actions, improve the models used to estimate exposure, and identify significant sources of preventable exposure, as shown in the following examples.

- Identifying at-risk populations: National blood lead data revealed that low-income children living in houses built before 1946 had a prevalence of elevated blood lead levels of 16.4 percent as compared to 4.4 percent for all children ages 1 through 5; non-Hispanic black children in similar housing had a prevalence of 21.9 percent—the highest risk of elevated blood lead levels of any demographic group. Using this information, state and local health officials can more effectively target screening and treatment efforts.
- Establishing and evaluating public health-related policies: In the 1980s, EPA was considering whether or not to make permanent a temporary ban on lead in gasoline. National data on lead exposure showed a decline in average blood lead levels that corresponded to the declining amounts of lead in gasoline. Based on this and other information, EPA strengthened its restrictions on lead in gasoline and required a more rapid removal of lead from gasoline.
- Improving models used to estimate exposure: Experts indicate that an increasingly important use of human exposure data has been as a "reality check" on other indexes of exposure, such as questionnaires about activities or work histories, to ascertain whether exposures may have occurred. For example, prior to the decision to phase out lead in gasoline, exposure models suggested that eliminating lead in gasoline would have only a slight effect on blood lead levels, while actual testing showed a more dramatic effect.
- Identifying key sources of exposure: When combined with other exposure data, exposure measurements can help reveal the source of the exposure—an essential step in developing and monitoring intervention strategies designed to reduce or eliminate harmful exposures. For example, when no evidence of lead paint—the most

common source of lead contamination—was found in the home of a child whose blood showed abnormal levels of lead, public health officials were baffled. Observational data on how and where the child spent time and environmental data from the surfaces most often encountered revealed that lead-contaminated stuffing in a toy the child chewed likely accounted for the high exposure. The child's blood lead level declined when the contaminated toy was removed.

While lead is unique among chemicals in that it has been extensively studied—decades of research has shown its harmful effects at increasingly lower levels—such research has been possible in part because of laboratory advances in measurement technology. Over the years, as technology improved the ability to measure smaller and smaller amounts of lead in the bloodstream, researchers have been able to identify increasingly subtle adverse effects by linking blood lead levels and changes in neurobehavioral functioning.

Current Measurement Efforts Cover Few Chemicals and Situations

Although HHS and EPA each are expanding their survey efforts to use new technologies and measure a broader range of exposures in the national population, their measurement efforts cover a limited portion of the more than 1,400 potentially harmful chemicals we reviewed. These surveys also remain of limited value for identifying at-risk populations, because in the case of their survey efforts, sample sizes to date have been insufficient—and, for most chemicals, not representative of the general population. In addition, federal efforts to help assess potential disproportionate exposures by collecting data on communities living near Superfund sites have been limited to few locations. State agencies reported that their efforts are also limited, despite the importance they place on using such data in their studies of population- or site-specific situations within their borders. According to state environmental health officials, they are often unable to collect these data.

Federal Efforts Are Expanding

In our examination of the HHS and EPA surveys, we found that the types of chemicals measured have recently increased. For the past 40 years, HHS' Centers for Disease Control and Prevention (CDC) has collected through a survey nationally representative data on the health and nutrition of the U.S. population. Exposure measurements are one component of this survey. In the mid-1990s, EPA's Office of Research and Development initiated a human exposure survey, which is currently in its pilot phase in three locations across the country. A third more recent effort to monitor human

exposures to select chemicals was initiated in 1996 by HHS' National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). For each of these federal efforts, laboratory measurements are largely conducted by the laboratory at CDC's National Center for Environmental Health, which also developed many of the methods for performing these measurements.

CDC's National Health and Nutrition Examination Survey

CDC collects human exposure data as part of NHANES, which has been conducted periodically since 1960 and, beginning in 1999, has been conducted annually. NHANES monitors trends in health status by conducting interviews and physical assessments on a nationally representative sample of about 5,000 people per year. NHANES collects blood and urine samples for many purposes, such as assessing cholesterol levels and the prevalence of diabetes. Since 1976, these samples have also been used to measure exposure to selected chemicals, and excess samples are banked for future research. In the past, CDC's human exposure monitoring efforts have focused largely on lead, cadmium, and a few pesticides and volatile organic compounds—chemical compounds which include a number of animal and known or suspected human carcinogens found in tobacco smoke, building supplies, and consumer products.[6] Starting with the 1999 NHANES, CDC proposed to measure up to 210 chemicals in human tissues as staff and other resources permitted. These chemicals include metals such as mercury, which at high levels may damage the brain, kidneys, and developing fetus; polyaromatic hydrocarbons (a group of compounds found in sources such as foods that have been grilled); and volatile organic compounds, such as benzene. At the time of our review, a CDC official indicated that resources allowed them to include about 74 chemicals for 1999 and 2000. The estimated marginal costs for the environmental exposure-related components of the NHANES 1999 survey were about $5 million.

EPA's National Human Exposure Assessment Survey

To expand upon and replace its National Human Adipose Tissue Survey (NHATS)—a tissue monitoring program, which ended in 1992—EPA

[6]Special reference studies supported by the Agency for Toxic Substances and Disease Registry were also conducted on nonrepresentative samples of a portion of the people participating in the most recently completed segment of NHANES (conducted from 1991 through 1994). These special studies assessed exposure to 45 pesticides and volatile organic compounds.

initiated in 1993 pilot surveys for NHEXAS in three regions of the country.[7] A goal of the NHEXAS pilots is to obtain knowledge on the population's distribution of total exposure to several classes of chemicals and to test the feasibility of collecting representative survey data on people's total exposures. NHATS focused on monitoring human fat tissues for persistent organochlorine pesticides and polychlorinated biphenyls (PCB); NHEXAS has broadened this focus in two ways. First, in addition to measuring chemical levels in samples such as blood or urine, the NHEXAS pilot surveys included measurements of chemicals in air, foods and beverages, water, and dust in individuals' personal external and internal environments. To conduct these measurements, the pilot surveys used tools such as questionnaires, activity diaries, air-monitoring badges worn by the individual or other air-monitoring devices, and tap and drinking water and food samples. Such data are important for purposes such as identifying the most important sources or routes of exposure and for taking actions to reduce or prevent exposures. Second, the NHEXAS pilot surveys included more types of chemicals than pesticides, such as lead and other heavy metals. The NHEXAS pilots, however, included fewer chemicals than its predecessor—which measured about 130 pesticides and PCBs in human fat tissue—in part because monitoring levels of any given chemical in personal environments and in human tissues requires significantly more laboratory measurements for the same chemical. EPA's NHEXAS pilot surveys, which have tested biological samples from about 460 participants, have collectively measured up to 46 chemicals, including pesticides, heavy metals, and volatile organic compounds in blood, urine, or hair. Once data from these pilot surveys have been further analyzed, EPA intends to assess the feasibility and cost of conducting a national effort to collect total exposure data. To date, EPA has invested about $20 million to support the pilot surveys. Very preliminary estimates by EPA for a national survey range from $20 million to $30 million per year over 10 years or more.

National Institute of Environmental Health Sciences' Human Exposure Initiative

In 1996, NIEHS began an initiative to collect human exposure data. This initiative was started as a collaboration between NIEHS and CDC to improve understanding of human exposures to hormonally active agents—also called "environmental endocrine disrupters"—for the national

[7]Specifically, pilot surveys were conducted in Arizona, Maryland, and EPA's region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin).

population.[8] The effort was intended to build upon the chemical monitoring in NHANES by supporting the development of laboratory methods and measurement of previously unmeasured chemicals in human tissues collected from NHANES and other studies. NIEHS and CDC signed an interagency agreement, under which CDC will develop methods for measuring and will measure in blood, urine, or both up to 80 chemicals thought to be hormonally active agents. For this effort, CDC obtained samples of about 200 people—most of whom are from the ongoing sampling of the general population under NHANES.

In 1999, officials of NIEHS and the National Toxicology Program (NTP)—an interagency effort to coordinate toxicological research and testing activities of HHS, which is administratively housed at NIEHS—proposed to expand upon the initial collaboration and formalized the undertaking as the Human Exposure Initiative. Specifically, they proposed a broader interagency effort to quantify human internal exposures to chemicals released into the environment and workplace. One significant purpose of this effort was to help prioritize those chemicals and chemical mixtures to be studied by NTP, recognizing the limited resources available for toxicological testing and the need for better information to prioritize which chemicals should be tested. According to NTP officials, although NTP is the nation's largest federal toxicology testing program, it can initiate only 10 long-term cancer studies and 10 reproductive studies per year.[9] NIEHS provided a list of 131 chemicals it hoped would be measured through this expanded effort. At the time of our review, however, program officials told us that NIEHS had not published data from the chemicals CDC had measured under this agreement, and CDC was developing the laboratory methods needed to measure many of the chemicals identified by NIEHS as

[8]The concern about endocrine disrupters originated from the finding that some synthetic chemicals in the environment are associated with adverse reproductive and developmental effects in wildlife and mimic the actions of female hormones. According to NRC, although it is clear that exposures to hormonally active agents at high concentrations can affect wildlife and human health, the extent of harm caused by exposure to these compounds in concentrations that are common in the environment is debated. See NRC, Commission on Life Sciences, *Hormonally Active Agents in the Environment* (Washington, D.C.: National Academy Press, July 1999).

[9]According to NTP officials, chemicals are tested for cancer and noncancer endpoints—including effects on reproduction, development, nervous system, and immune systems—using traditional bioassays as well as newly validated tests. Validation of new tests is achieved through an NTP interagency center involving 15 federal agencies or institutes.

needed.[10] (For more information on NHANES, NHATS, NHEXAS, and NIEHS' Human Exposure Initiative, see app. II.)

Despite Expansion, Chemicals Covered in Exposure Measurements Remains Limited

Despite these expanded efforts, NHANES and the NHEXAS pilot surveys cover only about 6 percent (or 81) of the 1,456 potentially harmful chemicals in our review. We compared the chemicals measured by these surveys to eight selected lists of chemicals of concern.[11] Our selection was based, in part, on our assessment and input from experts that these lists contained chemicals of higher concern to human health.[12] However, the listed chemicals represent a small portion of those that are regulated or are of potential public health importance. For example, there are over 7,000 lists of chemical substances and classes that are regulated under the Toxic Substances Control Act and the Emergency Planning and Community Right-to-Know Act.

For those individual lists that we reviewed, the portion of toxic chemicals measured ranged from 2 percent of chemicals prioritized for safety testing (based on EPA's findings that the chemicals may present unreasonable risks) to about 23 percent of chemicals most often found at the nation's Superfund sites and identified as posing the most significant threat to human health. See table 1 for each of the lists reviewed and the extent to which NHANES or the NHEXAS pilots are measuring these chemicals, and appendix I for a discussion of each list included in our review.

[10]CDC officials indicated that, by the end of 1999, it had developed laboratory methods to measure more than half of the chemicals under the agreement with NIEHS.

[11]We excluded NHATS and Human Exposure Initiative chemical lists from our analysis. NRC's 1991 review of the NHATS program raised questions about the representativeness of the results and the methods used to handle the tissue specimens, among other questions. The Human Exposure Initiative measurements were not available at the time of our review and, thus, which chemicals had been or are currently being measured was not known.

[12]We selected these lists based on input from program officials and experts at EPA, HHS, the Association of Public Health Laboratories, and the Pew Commission on Environmental Health and our assessment that the criteria for listing a chemical demonstrated that exposure could potentially be harmful to humans. There are many toxic chemical lists maintained by different programs and agencies for different purposes that we did not include in our review and, as such, the ones we reviewed do not necessarily individually or collectively represent the chemicals of highest concern to human health.

Table 1: Extent to Which Human Exposure Data Are Collected for Potentially Harmful Chemicals Through NHANES or the NHEXAS Pilot Surveys

Priority chemicals		Chemicals measured or being measured	
Description of list	Number in list	Number	Percent
Chemicals found most often at the national Superfund sites and of most potential threat to human health	275	62	23%
EPA's list of toxics of concern in air	168	27	16
Chemicals harmful because of their persistence in the environment, tendency to bioaccumulate in plant or animal tissues, and toxicity	368	52	14
Pesticides of potential concern as listed by EPA's Office of Pesticide Programs and the U.S. Department of Agriculture's Pesticide Data Program	243	32	13
Chemicals that are reported in the Toxic Release Inventory; are considered toxic; and are used, manufactured, treated, transported, or released into the environment	579	50	9
Chemicals that are known or probable carcinogens as listed in HHS' Report on Carcinogens[a]	234	17	7
Chemicals most in need of testing under the Toxic Substances Control Act (Master Testing list)	476	10	2

Note: Our analysis was based on human exposure data collected through NHANES or the NHEXAS pilot surveys through 2000.

[a]The Report on Carcinogens list may also include pharmaceutical agents, substances of primarily occupational concern, and banned substances. According to NIEHS officials, this may account for their lower inclusion in NHANES or the NHEXAS pilots. NIEHS and NTP officials indicated that, in addition to these chemicals, NTP reports results of its chronic bioassays for cancer in its technical report series. There are now approximately 500 reports, which collectively include nearly 250 chemicals found to cause cancer in rodents. Officials indicated that another useful evaluation would assess the proportion of rodent carcinogens for which human exposure data are collected and that NTP is planning to conduct such an evaluation.

While many potentially harmful chemicals in these lists are not measured in the population, NHANES or the NHEXAS pilot surveys contain a greater portion of chemicals considered of higher priority. Two toxic chemical lists we reviewed—one ranking chemicals frequently found at Superfund sites and one ranking selected chemicals compiled by EPA—prioritized chemicals based on their potential to harm human health. We examined the highest-ranked chemicals on these lists and found that higher proportions of these chemicals were or will be measured compared to the overall list. A CDC laboratory official also indicated CDC was in the process of

developing methods to measure a number of the chemicals on these lists and planned to measure other chemicals in future efforts if they have adequate resources to do so.

- Ranking of chemicals frequently found at Superfund sites: Developed by EPA and HHS' Agency for Toxic Substances and Disease Registry (ATSDR), which conducts public health assessments or other health investigations for populations living around national Superfund sites, this list ranks substances that are most commonly found at Superfund sites and pose the most significant potential threat to human health due to their known or suspected toxicity and potential for human exposure. Of the top 40 chemicals on this list, CDC indicated that 9 were currently being measured in NHANES. CDC hopes to include an additional 30 of the top 40 in future efforts; 11 of these 30 chemicals, however, were included in the NHEXAS pilot surveys.
- Ranking of selected toxic chemicals compiled by EPA: These rankings are based on a chemical's persistence, tendency to accumulate in plants and animals, and toxicity. CDC indicated 4 of the top 22 chemicals on this list based on their health hazard[13] were currently being measured in NHANES. CDC hopes to include the remaining 18 in future efforts; 6 of the 18 chemicals were included in the NHEXAS pilot surveys.

Federal Efforts Are Limited for Identifying At-Risk Subpopulations

In recent years, federal agencies have been charged with identifying whether certain populations—including minorities, people with low incomes, and children—disproportionately face greater health risks because they have greater exposure to environmental hazards.[14] Researchers increasingly recognize that the scarcity of adequate and appropriate data, especially for exposures and related health effects,

[13]EPA's prioritized chemical list ranks chemicals based on the length of time to break down, the degree to which they accumulate in plants and animals, and their toxicity. Both ecological and health risk scores are calculated. We used only the health risk scores in our analysis.

[14]Executive Order 12898 requires that each agency identify and address as appropriate disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions. Executive Order 13045 established similar requirements with respect to children.

hinders efforts to more systematically identify groups that may be at risk.[15] Lacking such data, past efforts to identify the exposures of certain demographic groups have often relied on measures of chemical levels in the surrounding environment. For example, some studies around hazardous waste sites and industrial plants have shown that minorities and low-income subpopulations are disproportionately represented within the geographic area around the sites. Such studies are limited in identifying the actual health risk because they must make assumptions about how these substitute measures, such as how close one lives to a hazardous waste site, relate to actual exposures experienced by people.

To identify groups whose exposure is disproportionately greater than that experienced by the remainder of the population—and thereby provide more definitive assessments of whether certain groups potentially face greater health risks—health officials and researchers might measure exposure levels for (1) a representative sample and analyze the characteristics of subpopulations with the highest exposures or (2) a population thought to be at high risk and compare it to measurements from a reference population.[16] We examined the extent to which federal survey data on human exposures collected to date could be used to assess characteristics of those groups most exposed. We also examined the extent to which human exposure data was collected on a population considered to be at higher risk—specifically, those living around national priority hazardous waste sites. In each effort, the information collected has been limited, as discussed below.

Sampling Not Sufficient to Identify Many Highly Exposed Groups

Representative sampling is required to identify at-risk subpopulations in a non-biased way—that is, without presupposing that a certain group is at higher risk. The sample must also be large enough to ensure highly exposed

[15]S. Perlin, K. Sexton, and D. Wong, "An Examination of Race and Poverty for Populations Living Near Industrial Sources of Air Pollution," *Journal of Exposure Analysis and Environmental Epidemiology*, Vol. 9, No. 1 (1999), pp. 29-48.

[16]D. Wagener, D. Williams, and P. Wilson, "Equity in Environmental Health: Data Collection and Interpretation Issues," *Toxicology and Industrial Health*, Vol. 9, No. 5 (1993), pp. 775-95.

subpopulations can be objectively identified.[17] For nearly all chemicals except lead, however, past federal collection of human exposure data in NHANES and the NHEXAS pilot surveys has been insufficient to identify whether disproportionate exposures are occurring in many demographic groups. In the case of NHANES, the sample is generally drawn to reflect the national population as a whole.[18] Consequently, the sample of the group of interest may be too small to draw meaningful conclusions about characteristics, such as exposures, of the group. In the past, most NHANES exposure measurements were conducted among non-randomly-selected samples and from only a portion of the surveyed participants, thus limiting the ability to identify highly exposed groups. Lead was an exception. Data for blood lead levels in children have been the most comprehensively collected, and certain characteristics have been clearly associated with a higher prevalence of blood lead levels. EPA has concluded that the evidence is unambiguous: children of color have a higher prevalence of elevated blood lead levels than white children do, and children in lower-income families have a higher prevalence than children in higher income families. See table 2 for the most recent NHANES analysis.

[17]The feasibility of using a representative survey to identify at-risk subpopulations based on individual characteristics (such as age, race, or income level) or location (such as a city, county, or state) depends on sample design and size—that is, on how the participants are selected and how many participants are included. Generally, the lower the percentage of the population in question in the sample, the less the data can be used to develop precise estimates of exposure or to distinguish exposure levels between subgroups.

[18]Certain groups may be included at a higher rate or oversampled to ensure a greater level of accuracy. For example, between 1988 and 1994, children ages 2 months through 5 years surveyed in NHANES were oversampled.

Table 2: Prevalence of Elevated Blood Lead Levels in Children Ages 1 Through 5, by Selected Demographic Characteristics (NHANES, 1991 Through 1994)

Characteristic of children in sample	Percentage with elevated blood lead levels
Race/ethnicity	
Black, non-Hispanic	11.2%
Mexican-American	4.0
White, non-Hispanic	2.3
Income level	
Low	8.0
Middle	1.9
High	1.0
Age group	
1 through 2	5.9
3 through 5	3.5
Total ages 1 through 5	4.4%

Source: CDC, "Update: Blood Lead Levels—United States, 1991-1994," *Morbidity and Mortality Weekly Report*, Vol. 46, No. 7 (1997), pp. 141-5.

CDC officials told us that representative data, such as that collected for lead, would be collected for a larger number of chemicals starting in 1999. However, CDC plans indicated that for most chemicals monitored, only a portion of NHANES survey participants—generally one-third or fewer, depending on the type of chemical—would be tested. For some chemicals, only certain groups thought to be at higher risk may be tested. For example, NHANES will include measurement of certain persistent pesticides known as organochlorines in one-third of the survey participants ages 12 through 19. Children under 12 will not be assessed.[19] CDC officials indicated that people over 19 may be assessed if adequate resources are available to do so. Although most organochlorines are banned in the United States, some are still used in home and garden products, such as products for treating lice and controlling agricultural and structural pests and flame

[19]According to CDC officials, children under 12 will not be assessed because the volume of tissue samples needed to perform the measurement will not be available. Other measurements—such as those for lead, mercury, and cotinine (a metabolite of nicotine illustrating exposure to cigarette smoke)—will be performed for many in this age group.

retardants used in synthetic fabrics.[20] NHANES data from a one-third subsample will be useful for establishing reference ranges within the population and illuminating exposure levels nationally; they will also be useful for identifying exposures of broad demographic groups, such as males and females. But these data are not enough to enable researchers to assess exposure levels of or characterize many potentially at-risk groups, such as the exposures of inner-city children in low-income families.[21] According to a CDC laboratory official, targeted studies should be considered for groups that represent a small portion of the population.

Similarly, the NHEXAS pilot surveys included representative samples of participants in the three geographic locations covered. However, because of the smaller sample sizes, the work to date has also been too limited for

[20]According to CDC laboratory officials, other NHANES exposure measurements planned for 1999 and 2000 for a subsample of participants includes volatile organic compounds, mercury, nonpersistent pesticides, phthalates, and trace metals. Air toxic exposures to selected volatile organic compounds will be measured in personal measurements—such as chemical levels in the air, measured through badges, and chemicals in water samples—and in blood samples from a subsample of people ages 20 through 59. Mercury will be measured in the hair and blood of participants ages 1 through 5 and women ages 16 through 49. Nonpersistent pesticides or their metabolites are planned for measurement in one-half of participants ages 6 through 11 and one-third of participants ages 12 and over. Surveys and focused research indicate that household use of certain pesticides may be extensive, but little information is available concerning residential or household exposures among the general population. Phthalates are planned for measurement in one-third of the participant ages 6 and older. Seventeen trace metals will be measured in one-third of participants ages 6 and older. Trace metals such as barium and beryllium have been associated with adverse health effects in occupational or laboratory studies but have not been monitored in the general population.

[21]The current design of NHANES samples allows several years of data to be combined. If exposure for chemicals is measured consistently over several years, then assessing risk factors may be increasingly possible over time. CDC officials indicated that for any annual NHANES full sample, a limited number of estimates for broad population subgroups can be developed. More detailed measures for smaller subgroups (for example, analyses by age, gender, and race and ethnicity) will require more years of data, generally 3 through 6 years—and even longer if a subsample is used—of data collected for all participants. Based on an annual sample of one-third of the participants, CDC indicated that estimates may be possible for very broad subgroups, such as males or females; participants ages 6 through 19 or over 20; or a few major race and ethnicity groups, depending on the prevalence of the condition examined.

much analysis of at-risk populations.[22] The pilot surveys included biological measurements for about 200 people in six Midwestern states, about 180 people in Arizona,[23] and about 80 people in Baltimore.

Federal Efforts to Identify Communities of Concern Valuable, but Human Exposure Data Are Limited

A second method to identify a subpopulation disproportionately at risk of adverse health effects is to compare exposure levels for a group thought to be at high risk with baseline measurements from a reference population.[24] This method can be used to determine, for example, the extent to which people in a neighborhood, community, or geographic location are exposed relative to others. In cases where exposure levels have been identified as high compared to reference populations but potential health effects associated with those levels have not been researched, public health actions can help prevent further or increasing exposures, and these groups can be assessed for any subsequent health outcomes.

[22]One assessment of the data from Midwestern states provided some indication of potential differences in personal exposures between age groups, races, income segments, and house construction dates. Researchers cautioned that the data for some categories examined were small. This assessment did not report on exposure measurements from biological sampling in this survey. (See E. D. Pellizzari, R. L. Perritt, and C. A. Clayton, "National Human Exposure Assessment Survey: Exploratory Survey of Exposure Among Population Subgroups in EPA Region V," *Journal of Exposure Analysis and Environmental Epidemiology*, Vol. 9 (1999), pp. 49-55.

[23]These participants provided biological samples, such as blood and urine. Larger participant groups in the study areas provided environmental and food monitoring samples and responded to questionnaires. This excludes a related but separate study done in Minnesota reviewing pesticide exposures that was not one of the three formal pilot surveys.

[24]Determining the distribution of chemical exposure among a non-occupationally-exposed population establishes a "reference range" that shows what can be considered background exposure and what can be considered high. With reference range information, officials concerned about exposures of groups can compare the groups' exposures to those of the general population and determine whether public health action is warranted to prevent or reduce high levels of exposure.

One federal effort, conducted by ATSDR, analyzes risks faced by communities near hazardous waste sites. ATSDR estimates that 12.5 million people live within 1 mile of the nation's 1,300 Superfund sites. The agency can collect biological samples through exposure investigations as part of the public health assessment process or in response to requests from the public.[25] ATSDR officials said that human exposure data collected at Superfund sites have been useful in deciding on actions such as stopping or reducing exposures, relocating residents, referring residents for medical follow-up, reducing community anxiety, influencing priorities on site-specific clean-up, making referrals to researchers for assessing health links, and educating community and other health providers. As evidence, they pointed to the conclusions of an expert review panel, which stated in March 1997 that human exposure data were as important to exposure investigations and public health assessments as environmental monitoring results at the sites of concern.[26] However, the number of investigations that included human exposure data has been limited. Between 1995 and July 1999, ATSDR had gathered biological samples at only about 47 of the more than 1,300 Superfund sites. At least 34 of these investigations detected contaminants in people and 16 found elevated levels.

Other federally conducted efforts designed to monitor or collect data on the exposures of populations within selected communities or geographic regions have also been infrequent.[27] One such regional-scale effort under way is collecting data on exposures within selected communities along the border between Texas and Mexico. Officials from Mexico and federal and state agencies in the United States are comparing exposures of people in

[25]ATSDR conducts exposure investigations when (1) people have likely been exposed to a contaminant, (2) more information is needed on the exposure, (3) an exposure investigation will provide that information, and (4) that investigation will affect public health decisions.

[26]In its report, panel members suggested many improvements to ATSDR's exposure investigations, including creating a technical planning group to review emerging and innovative technologies and establishing a national clearinghouse of collected data. ATSDR officials indicated that they had not been able to act on some of the panel's suggestions because of limited staff and resources and other barriers to collecting data, such as the lack of laboratory methods for testing chemicals of interest. ATSDR has nine staff to conduct exposure assessments for sites across the nation and can only respond to requests from communities or state or local officials for assistance rather than conducting such assessments as part of every new investigation.

[27]Federal agencies also might fund academic research that is designed to identify communities of concern. Assessing the extent that federally supported academic research included or focused on human exposure data to identify at-risk population was beyond the scope of our review.

the border area with those in areas away from the border. Another study examined the exposures of people along the Arizona border compared to the exposures of people elsewhere in the state. This study collected environmental samples for pesticides, metals, and volatile organic chemicals. Blood and urine samples were also tested to relate the environmental measurements to the measurements in human tissues for these chemicals.

State Officials Value Human Exposure Data for Studies and Investigations but Do Not Often Include Them

Most state officials who we surveyed highly valued human exposure data. However, most could not include it in their exposure-related health studies, investigations of concerns such as disease clusters, or surveillance efforts. Almost half of the officials responding to our survey estimated that they had participated in 10 or more exposure-related studies or investigations since 1996, with about 16 percent estimating they participated in 50 or more. However, about half of officials indicated they could seldom if ever collect exposure data through human samples in their efforts. When data were developed, officials listed five main uses: (1) environmental health epidemiologic studies, (2) surveillance of diseases or conditions with suspected environmental causes, (3) investigations of citizen concerns, (4) planned or accidental chemical releases, and (5) disease clusters (see table 3).[28] State officials we spoke with noted that human exposure data are often the most valid and persuasive evidence available to demonstrate whether, and to what extent, exposure has occurred or changed over time. In highly charged situations, where community trust has eroded, such data may be the only evidence acceptable to area residents.

[28]Since most states conduct surveillance for lead exposure, we asked officials to not include these efforts in their responses. See app. III for a copy of our survey.

Table 3: Examples of How State Officials Use Human Exposure Data

Purpose	Example
Environmental health epidemiologic studies	Using blood and urine samples from people who ate sport fish and were concerned about undue exposure to dioxins, pesticides, and other chemicals, health officials determined these people had exposure to some chemicals from 2 to 10 times higher than levels in a reference population. Based on these results, officials will focus a larger health effects study on exposure to those chemicals.
Surveillance of diseases or conditions with suspected environmental causes	Virtually all states collect information on blood lead levels in children to monitor and prevent lead poisoning. Some also monitor exposure to pesticides and other chemicals such as mercury and arsenic.
Investigation of citizen concerns	Health officials used human tissue measurements and citizens' reports of illnesses to demonstrate that the combined effect of chemicals released into the environment posed a health hazard severe enough to warrant evacuating nearby residents. State and federal officials subsequently closed a manufacturing plant because of the harmful health effects of its chemical releases.
Investigation of planned or accidental chemical releases	Officials in nine states asked CDC to test tissue samples from almost 17,000 individuals thought to have been exposed to methyl parathion, a deadly pesticide. CDC's ability to measure the pesticide in human tissue and compare exposures across states was critical to identifying individuals with high exposures and houses most in need of clean-up. Because relocating residents and removing the pesticide from homes cost up to $250,000 per household, the exposure data helped officials avoid spending limited funds on houses that did not pose a health risk to the people living in them. One state official said the exposure results reduced the number of houses needing pesticide removal from hundreds to fewer than 10.
Investigation of disease clusters	State health officials reviewed data on individual cases of cancer in one community and for the entire state. When available data on known risk factors did not account for the increased incidence of breast cancer, officials began a more detailed study that included human tissue analysis. Blood samples were obtained from women before and after treatment began and from women in a control group. Results will be compared to reference range data developed by CDC. One goal of such studies is to help identify environmental factors that contribute to breast cancer risk.

While mercury, arsenic, and pesticides were most often reported as being studied in human samples, some state officials reported using human exposure data for chemicals that CDC has since 1991 developed methods to measure. For example, about 15 percent of officials conducted studies of human exposure to volatile organic compounds, and almost 30 percent reported studies of exposure to PCBs using data from tissue analysis.

Regardless of whether state officials had collected or used human exposure data in the past 4 years, about 90 percent of those officials responding to our survey said human exposure data from tissue samples was extremely or very important for addressing environmental health concerns. Despite the perceived value of such data, almost two-thirds of officials said they could include human exposure data in fewer than half of the exposure-related studies, investigations, and surveillance efforts where

they considered it important. More than one-third said they seldom could include such data.

Several state health and laboratory officials whom we interviewed expressed frustration at the missed opportunities for collecting biological samples as part of their studies and investigations for reasons such as limited laboratory capacity. For example, health officials in one state could not examine the role played by methyl t-butyl ether (MTBE)—an additive designed to promote more efficient burning of gasoline—in a major respiratory disease outbreak because state staff lacked the expertise and CDC staff lacked the time to conduct the needed tests. In 1995, after MTBE was added to gasoline and thousands of citizens reported becoming ill, state officials wanted to measure MTBE or its by-products in blood from samples of individuals with and without symptoms to determine whether MTBE exposure might be the cause or a contributing factor. Objective measures of individual exposure might have allowed public health officials to conclusively demonstrate or rule out a link between the outbreak and exposure, something that was not possible with environmental data and epidemiologic surveys. The chemicals officials most often cited as wanting to study using human exposure data but could not were pesticides and volatile organic compounds.

Significant Information and Infrastructure Gaps Point to Need for Strategic Planning and Coordination

As part of our survey and interviews, we asked public health experts and state and federal officials to identify barriers they considered significant to their efforts to collect and use human exposure data. Officials cited two primary barriers: the lack of laboratory capacity or methods to analyze tissue samples and the lack of information to help set exposure test results in context. Addressing these barriers takes time and resources. In that regard, we identified a third barrier to more effective use of existing resources: HHS and EPA lack a long-term strategic plan to address infrastructure and science barriers, coordinate efforts to meet federal and state needs, and address the many questions about how to set priorities given their limited resources.

Laboratory Capacity and Methods to Measure More Chemicals Needed

State officials frequently said insufficient laboratory capacity in their states and at the federal level hindered their ability to obtain human exposure data in cases where they thought such data were important. Over half of the officials said their states lacked sufficient numbers of trained laboratory staff, sufficient laboratory capacity to analyze samples, or sufficient laboratory equipment. Many officials attribute such capacity limitations to funding constraints because tissue analyses can be time-consuming and expensive to perform. For example, according to a CDC official, each test to measure dioxins in a sample requires (1) a laboratory free from chemicals that could compromise test results, (2) specialized equipment that costs about $500,000, and (3) highly trained and experienced staff to complete. Officials of a professional organization representing public health laboratories told us that, although many state laboratories perceive they have a role in conducting tests to detect toxic substances in humans, very few currently have such capacity.[29]

State and federal officials we interviewed told us that because few state laboratories have the necessary equipment and expertise, they often rely on CDC's environmental health laboratory staff to analyze tissue samples. Given the specialized laboratory requirements, CDC's environmental health laboratory is generally considered the best-suited to analyze tissue samples for a range of chemicals and has, in fact, developed many of the methods to do so, according to federal and state officials. CDC's laboratory performs measurements for most federal and many state efforts to gather human exposure data. Many officials said CDC's laboratory capacity is essential to their efforts and needs to expand to meet growing needs. A few state officials said CDC's laboratory consistently returned test results when people's lives were at risk but was less able to help states assess health risks more generally. An official in one state said that, while CDC's assistance is invaluable, the state's laboratory capacity allowed public health officials to obtain human exposure data and investigate citizen's concerns more frequently than they could if they had to rely soley on CDC's laboratory capacity.

[29]This organization actively supports expanding state and local laboratory capacity to participate in a human biomonitoring program to provide human exposure data that would enhance the effectiveness of environmental policy and regulatory decisions. In addition, this group helped states apply for the four grants CDC offered to increase state and local laboratory capacity to detect in human fluids and tissues chemicals that could be used in a terrorist attack. Illustrating their interest in developing such laboratory capacity, 31 state and 2 local health departments applied for the four grants.

Another significant issue is the lack of analytical laboratory methods to measure chemicals of concern. Despite advances over the past 2 decades in analytic chemistry and molecular biology, laboratory methods have not been developed to measure about 88 percent of the 1,456 chemicals in our review, according to information provided by CDC and EPA officials. Although laboratory staff at CDC have quickly applied scientific and technological advances to develop new and more efficient laboratory methods, they are concerned about the lack of methods to test a single human sample for several related toxics. For example, a method exists to measure arsenic in blood but not to measure arsenic and other heavy metals at the same time. Such methods make more efficient use of the samples that are gathered and greatly reduce the time and money needed to test large numbers of samples. While CDC's laboratory continuously develops new chemical testing methods, current resources limit the number to about 10 annually.

Even when analytical methods exist, efforts to gather human exposure data are sometimes limited by problems with the methods used to gather the samples. This is especially true for young children, a group thought to be particularly susceptible to harmful effects from exposure. In some cases, existing laboratory methods require sample volumes that can only be obtained through invasive techniques. That is, blood samples must be obtained by puncturing a vein rather than by pricking a finger. Many people will not allow their children to participate in studies that require such techniques. Similarly, urine samples can be difficult to obtain from children who wear diapers. For example, substances in the diapers can compromise test results.

Information Needed to Interpret Human Exposure Measurements

To help interpret the results of laboratory analysis and determine what actions, if any, are needed to protect the public's health, state and federal officials cited the need for two types of context-setting data: comparative (or reference range) information that shows exposure levels among the general population and research that links exposure to adverse health effects. At the state level, where many of the specific actions regarding at-risk situations are taken, almost three-fourths of responding officials cited the lack of such information as a problem.

State officials said that reference range data, when available, allowed them to determine whether exposures are sufficiently high to merit action to reduce or prevent further exposure. For example, in one state, public health officials, with help from CDC, responded to citizens' reports of foul

odors from leaking tanks at a waste cleanup site by gathering and analyzing blood samples from those living nearby. CDC's analysis of the blood samples showed that residents near the site had exposure levels at the high end of a CDC-developed reference range. State and federal officials ordered the contractor to move the cleanup operations to another location. Over 60 percent of state officials responding to our survey said the lack of reference range data prevented them from using human exposure data in their work. State officials said the problem for research about adverse health effects was similar. Much of the data linking exposure to health effects concerns high-level occupational exposures or higher doses administered to laboratory animals. Consequently, translating the results of such research to lower-level exposures of people and determining how best to advise people about potential effects is problematic.

Federal health officials and researchers also cited a need for both types of information in their investigations, particularly for federally supported work in specific geographic areas. ATSDR officials said the lack of reference ranges was a particular reason they could not generate human exposure data more often in public health assessments and exposure investigations. When data allow officials to put exposure into context, concerns can be investigated and addressed. For example, in one community, where citizens were concerned about exposure to dioxins from nearby chemical manufacturing plants, ATSDR officials had CDC's laboratory analyze blood samples and found that some residents had levels of several dioxins above the highest levels in a CDC-ATSDR-developed reference range. In response, ATSDR helped residents obtain assistance from medical professionals expert in dioxins and, working with state and federal environmental agencies, began environmental testing to locate the exposure source.

Stronger Interagency Efforts Needed for Strategic Planning and Coordination

The barriers outlined above present daunting challenges to state and federal agencies. The number of chemicals that remain to be investigated and the kinds of information needed are substantial, the research is often expensive, and progress is often slow. At the same time, the level of resources available for dealing with the issue is limited, and responsibilities are fragmented among many state and federal agencies. Many studies have pointed to the need for better coordination. While HHS and EPA efforts have been coordinated through, for example, participation on advisory committees and the use of CDC's laboratory for performing the actual measurements, such coordination falls short of what is needed for long-term planning. This need is illustrated by the growing convergence of

interest in the planned expansions of NHANES and NHEXAS. To ensure as much progress as possible with available resources, HHS and EPA need a strategic planning effort that reflects a clear set of priorities, a framework for coordinating data collection and reporting efforts, and a tie to performance goals.

Agreement About Need for Better Planning and Coordination of Efforts Is Widespread

In 1991, NRC reported that "although a successful monitoring program must be highly relevant to regulatory needs, it could and should serve a wide range of client programs and must not be dominated by any one of them." NRC reported that the approaches of EPA, CDC, and ATSDR are each important in the identification and control of environmental hazards to human health and that coordination among the programs would enhance federal monitoring efforts and benefit researchers, health professionals, and the public.[30]

Officials and experts agree that interagency interaction is needed to take advantage of all approaches and information available to develop the most cost-effective, least burdensome approach for collecting needed exposure data. Towards this end, HHS agencies and EPA have at various times attempted to collaborate in their respective exposure monitoring efforts. For example, EPA solicited broad interagency input into the design of NHEXAS and established interagency agreements with CDC and others to assist in performing laboratory measurements, quality control, and other support functions. Also through interagency agreements, CDC has broadened the exposure monitoring component of NHANES to incorporate the needs of EPA researchers.

[30]While NRC found EPA in the best position to house a human exposure monitoring program, it also found that the ambivalence within EPA about the National Human Monitoring program's future indicated that the match of program goals, potential benefits, and EPA mandates was not perfect.

Outside reviews and involved researchers and officials indicate that even with recent efforts, coordination has fallen short in ensuring adequate interaction and linkages between agencies. For example, EPA's scientific advisers reviewed the NHEXAS pilot surveys and concluded that, while NHEXAS was an excellent project and highly relevant for providing needed information, a strategic plan was needed for follow-up studies. They also urged that EPA link NHEXAS exposure data with biological data from NHANES, where possible, and develop a more collaborative process for gathering input for chemical selection. Attendees at a September 1999 NIEHS conference on the Role of Human Exposure Assessment in the Prevention of Environmental Disease also called for a coordinated interagency effort in assessing human exposure.[31] One theme and recommendation from the discussions was the need to bridge scientific disciplines and agency missions to address knowledge gaps in assessing human exposure.

State officials and others have also indicated that better linkages and partnering are needed between federal, state, and local agencies. For example, an official of the Association of Public Health Laboratories told us that one way to improve states' involvement in a national exposure monitoring program would be to further their capability to assess levels of toxic chemicals in their own populations relative to national levels. This would require, in this official's view, the transfer of new monitoring technology to state public health laboratories, along with the resources necessary to support that technology. Improved capacity at the state level would allow federal laboratories to concentrate on developing more and faster analytical methods for measuring chemicals in tissues and on responding to crisis situations. Other experts have also called for better linkages between federal efforts and communities and community concerns. For example, the NHEXAS reviewers recommended that EPA improve communication between NHEXAS investigators and state and local health officials. Another theme of the conference on human exposure assessment was that efforts to assess human exposure be in line with public health goals and community concerns.

[31]The NIEHS-supported conference addressed many opportunities and challenges in exposure assessment research, including exposure-analysis methodology, exposure-disease relationships, regulatory and legislative issues, gene-environment interactions, disease prevention and intervention, and some current federal initiatives related to exposure assessment. One area of discussion was the need for and limitations of biological measures of exposure.

Individual Priorities Contribute to Difficulties in Coordinating Efforts

The challenges federal and state agencies face in setting priorities for which chemicals to assess in their individual programs likely contribute to the difficulties they have in collaborating with one another. The expense of conducting exposure measurements in ongoing surveys—especially for the number of samples required to establish national or regional trends and levels—necessitates that priorities be set. However, agreeing on priorities—or even agreeing on the process for setting priorities—is challenging and resource-intensive. For example, to identify chemicals to measure in NHEXAS, EPA undertook an extensive selection process, soliciting input from regional and program offices.[32] EPA's scientific advisers, while supportive of the program, cited the criteria for selecting target chemicals as a weakness. NHANES is even less formal in this regard, with no documented priority-setting process for chemicals to be measured. Chemicals measured are largely determined by CDC's laboratory scientists based on such factors as the availability of analytical methods for measuring the chemical and the laboratory's capacity to perform the measurements.[33] According to a CDC official, CDC's limited staff and laboratory resources cannot develop the administrative infrastructure to establish a scientific review process for selecting priority chemicals.

Another challenge in setting priorities, according to some officials, is the appropriate balance between gathering exposure information on chemicals about which little is known and gathering information on those already considered to be toxic. NHANES and NHEXAS, for example, focus largely on chemicals that are considered to be toxic at some level. By contrast, the National Toxicology Program's Human Exposure Initiative is intended to help set priorities for chemical toxicological testing and might gather baseline information on chemicals and chemical mixtures occurring in the population that are not necessarily already known as harmful.

[32]Because of its emphasis on evaluating total human exposure, NHEXAS emphasized those chemicals that can be measured in multiple environmental media (for example in air, water, and food) as well as human tissues.

[33]CDC's laboratory officials indicated that their choice of chemicals is determined by the availability of high-quality analytical methods with adequate throughput, whether the chemical is a known or suspected cause of health problems, whether the chemical is on EPA and ATSDR priority lists, the number of persons likely exposed, and the availability of funding from collaborators.

Officials we interviewed raised many other concerns that would need to be addressed when trying to coordinate efforts among multiple federal and state agencies and programs:

- For what specific purpose(s) will these data be collected?
- What chemicals should be measured, in what order, how frequently, and in what specific tissues?[34]
- What chemicals should be measured concurrently with or only through personal environmental measurements?
- What is the best way to identify populations that might be at higher risk of exposure?
- What chemicals should be monitored in humans nationally, versus regionally or locally?[35]
- How can exposure data be coupled with our increasing knowledge about the effect genetic factors have on risk from exposure to improve the understanding about an individual's risk from chemical contaminants?
- What role should state agencies have in conducting human exposure measurements and in planning federal efforts?

The fragmentation of responsibilities and efforts for assessing human exposure reflect larger issues in the fragmentation of responsibility for environmental health. For over a decade, a number of studies have pointed

[34]Several officials pointed to the importance of developing a breast milk monitoring program. Many environmental agents are fat soluble and are released into breast milk at significant concentrations. Examples include dioxins and PCBs. According to NIEHS researchers, 6 months of nursing could result in dioxin or PCB concentrations in infants which are 10 times higher than in the mother. Breast milk monitoring programs operate in several European countries including Sweden, Germany, and the Netherlands.

[35]EPA's scientific advisers' review of the NHEXAS pilot surveys illustrates some of the trade-offs in determining the appropriate balance between large population surveys and more targeted follow-up surveys. The advisers reported that population studies are the only means for collecting baseline information for such uses as trend analysis. NHANES is an example of such a probability study. On the other hand, more targeted special studies tend to assess high-end exposure groups more precisely. Additionally, the review illustrated how total exposure data may be unnecessary to collect for chemicals at a national level, depending on the chemical. The advisers pointed out that targeted special studies can be used to identify sources and factors associated with high-end exposures. While identification of major sources, media, and pathways for populations experiencing high exposures are essential to reduce unacceptably high risks, if the majority of the national population is exposed to pollutants at levels under health-related benchmarks, source identification for such exposures is not a priority from a health standpoint.

to the need for improved coordination between regulatory and health agencies (see table 4).

Table 4: Examples of Reports Calling for Coordination in Environmental Health

Report	Description
Environmental Health Data Needs: An Action Plan for Federal Public Health Agencies (Public Health Foundation, 1997)	Called for the federal government to facilitate stronger ties between environmental protection and public health agencies, perhaps by strengthening organizational links and coordinating funding for federal (EPA and HHS) programs. Also indicated that priority environmental health information needs included more complete exposure data, including laboratory data such as biological measurements.
Burke, Shalauta, and Tran, The Environmental Web: Impact of Federal Statutes on State Environmental Health and Protection (Public Health Service, Jan. 1995)	Found that progress in understanding the relationship between human health and the environment will require, among other actions, improved cooperation between the many health and environmental agencies at the federal, state, and local levels.
Researching Health Risks (Office of Technology Assessment, 1993)	Reported that although agencies are expanding their research efforts, few incentives exist for them to collaborate, and the lack of collaboration can only hinder progress in applying newly developed techniques and knowledge to understanding the potential links between exposure and adverse health effects.
The Potential for Linking Environmental and Health Data (National Governors' Association, 1990)	Reported that linkage of environmental and health data to investigate possible connections between exposure and adverse health effects cannot occur without interagency communication and cooperation, which rarely evolves naturally.
The Future of Public Health (Institute of Medicine, 1988)	Found that separating environmental health from public health programs impeded desirable coordination and could limit the depth of analyses given to the health implications of environmental hazards.

Potential for Convergence of Effort Is Increasing

The importance of planning and coordination is magnified by the possible overlap in current plans to expand human exposure monitoring efforts. This potential can be seen in HHS' and EPA's plans for NHANES and proposed expansions of the NHEXAS pilots. Although nearly two-thirds of the chemicals measured in the NHEXAS pilot surveys are currently measured or planned for NHANES, the two efforts have taken differing approaches in the past to monitoring the population's exposure to these chemicals.[36] The NHEXAS pilots have focused on "total" exposure, which entailed measurements in human tissues, water, air, food, dust, and other potential sources in participants' living environments, and data-gathering has focused on three selected regions of the country. Total exposure

[36]The follow-up to the NHEXAS pilots has not been planned, so the identity of the chemicals to be measured is not known.

measurements can help identify those sources that most contribute to exposure—a critical part of determining how to take action to reduce or prevent exposures. However, measuring total exposure requires several types of laboratory measurements and is thus more expensive. By contrast, NHANES has focused its exposure monitoring on human biological measurements and on a sample that is generally representative of the nation as a whole. Biological monitoring data demonstrate exposure from all sources, but determining exposure sources usually requires additional environmental measurements. Other than the few chemicals it covered, NHANES has historically been considered an awkward vehicle for including exposure monitoring—in large part because of its wide range of competing goals and lack of a primary commitment to monitoring tissues for exposures.

Changes to the 1999 NHANES, such as the following, show a greater emphasis in environmental health. These changes along with EPA's plans to expand NHEXAS suggest a convergence of the two approaches and a growing and overlapping interest among agencies in exposure measurement and monitoring.

- NHANES now has a goal of monitoring exposures. Starting with NHANES 1999, CDC formalized its commitment to monitoring trends in the nation's environmental exposures by establishing this as a stated goal of NHANES.[37] In line with this goal, CDC's laboratory plans to issue

[37]At this writing, NHANES' goals are to (1) estimate the number and percentage of persons in the United States and designated subgroups with selected diseases and risk factors; (2) monitor trends in the prevalence, awareness, treatment, and control of selected diseases; (3) monitor trends in risk behaviors and environmental exposures; (4) analyze risk factors for selected diseases; (5) study the relationship between diet, nutrition, and health; (6) explore emerging public health issues and new technologies; and (7) establish a national probability sample of genetic material for future genetic research. CDC officials told us that the emerging focus in NHANES on environmental health issues reflects advances in technology as well as the public's increasing priority for understanding the impacts of environment on health. Part of CDC's responsibility is to report on environmental hazards and determinants of health. Section 306 of the Public Health Service Act (42 U.S. C. 242k) directs the National Center for Health Statistics, the CDC agency that conducts NHANES, to collect statistics on subjects such as the extent and nature of illness and disability of the population; environmental, social, and other health hazards; determinants of health; health resources; and utilization of health care.

this year a "National Exposure Report Card" using NHANES samples.[38] This goal is similar to EPA's goal as proposed for NHEXAS' follow-up survey—to document the status and trends of the national distributions of human exposure to potentially high-risk chemicals.

- NHANES will include selected environmental measurements. Starting with NHANES 1999, environmental measurements, such as contaminant levels in water and house dust, and levels measured through personal air monitors worn by participants will be included in the survey to help identify potential sources of exposure.[39]
- NHANES will be conducted continuously rather than periodically, allowing for more flexibility in the measurements it includes. According to CDC officials, the new annual sampling design will enable them to include emerging and changing priorities in the data collected through the survey and thus allow for a broader collection of data than in previous surveys, including exposure and measurements in people's personal environments.

Other planned changes to NHANES and NHEXAS also indicate a growing overlap in approaches and interests. For example, pending analysis and evaluation of its pilot surveys, EPA is proposing to expand NHEXAS beyond the regional focus of its pilot to include a nationally representative sample similar to the framework of NHANES. Also, both CDC and EPA would like to eventually include a component in NHANES and NHEXAS to monitor special populations. EPA's proposed expansion of NHEXAS would eventually include "special studies" to examine high-end exposures in more detail and with greater precision. Small populations for further study would be identified through the national survey. CDC also plans to add a component to NHANES that will gather selected NHANES health and nutrition data, possibly including exposure measurements, on specific subpopulations in geographic areas of interest or among specific racial or ethnic minority populations. This effort to add a subpopulation component

[38]According to CDC laboratory officials, the first report card will provide data on exposure levels of the population to 25 chemicals that have not yet been determined. These might include selected heavy metals, indoor air pollutants, nonpersistant pesticides, and phthalates.

[39]Because of the wide range of other health and nutrition questions addressed in NHANES, environmental measurements currently included are less extensive than those included in NHEXAS because, for example, food and beverage samples are not conducted.

to NHANES was initiated in response to the needs of state health officials and others for local level data.

Funding Is Sporadic, and Funding Priorities Change

Part of the difficulty in collaborating and in planning human exposure monitoring efforts to meet longer-term needs may also arise from issues of sporadic funding and resources to support these efforts. As compared to the hundreds of millions spent on monitoring contaminants in environmental media, we estimate that less than $7 million was spent collectively by CDC (including ATSDR) and EPA on their respective human exposure efforts in 1999.[40]

Neither CDC nor EPA has provided a dedicated funding stream for their exposure measurement efforts. Funding for efforts has, to a large extent, depended on priorities established year to year. For example, funding for the exposure and other environmental components of NHANES depends to some extent on the interests of other federal agencies and their willingness to pay for related data gathering and analysis.[41] CDC estimated it would spend about $4.7 million for laboratory measurements and laboratory staff costs in 1999 for NHANES-related exposure measurements such as lead, mercury, cotinine, heavy metals, pesticides, volatile organic compounds, and other chemical classes. Interagency agreements document the receipt of about $1.2 million from collaborators for some of those laboratory measurements. If other agencies do not pay CDC to conduct laboratory tests—with the exception of some "core" measurements, such as lead—CDC performs tests as time and laboratory resources allow. For example,

[40]NIEHS-CDC interagency agreements document that NIEHS had provided about $3.3 million to CDC between fiscal years 1996 and 2000 for performing environmental exposure measurements for its Human Exposure Initiative. No funding was provided in fiscal year 1999.

[41]NHANES 1999, for example, received $15.9 million in appropriated funding and, according to CDC officials, an additional $6.8 million from collaborating institutions. Interagency agreements related to environmental measurements performed in conjunction with NHANES document the receipt of about $1.4 million from collaborators at EPA and other agencies for environmental exposure measurements. In addition to EPA's support for measurement of certain chemicals in human tissues, an estimated $125,000 was received from the Department of Housing and Urban Development for performing dust sampling and an estimated $30,000 from the Mickey Leland National Urban Air Toxics for personal measurements of volatile organic compounds. CDC laboratory officials indicated that the increase to their fiscal year 2000 funding for the environmental health laboratory has improved their ability to support needed laboratory measurements for NHANES and other efforts. This funding increased by about $5 million between fiscal years 1999 and 2000.

although CDC initially proposed for the survey starting in 1999 to measure up to 210 chemicals in tissues of a subset of NHANES survey participants, CDC officials indicated that those chemicals could be measured only as resources allowed.[42] At the time of our review, a CDC laboratory official indicated that resources might allow them to include about 74 chemicals in 1999 and 2000.

EPA's commitment to funding NHEXAS also remains uncertain. EPA officials estimated that approximately $20 million was spent on NHEXAS from 1993 through 1999—with a decreasing amount designated to the project in 1999 and 2000. While EPA's independent scientific advisers commended the design for NHEXAS and said it could be the basis for an effective national program, they expressed concerns about the limited resources allocated to analyze the data gathered in the pilot projects.[43] At a national level, EPA has dedicated approximately three full-time positions to evaluate the data from the NHEXAS pilots and design future expansions.

Better Linkages to Program Goals and Performance Monitoring Needed

The Government Performance and Results Act of 1993 (Results Act) provides federal agencies a structured framework to coordinate efforts in crosscutting programs when agency missions overlap. The Results Act requires federal agencies, as part of their mandated responsibilities, to prepare annual performance plans that discuss agency goals and performance measures. Past reviews have shown that EPA, HHS, and other federal agencies have not fully used the Results Act planning process to explain how each would coordinate crosscutting efforts with other agencies. Few agency plans attempt the challenging task of discussing planned strategies for coordination and establishing complementary performance goals and common or complementary performance measures.

A major weakness of EPA's fiscal year 2000 Annual Performance Plan was the lack of sufficient detail describing crosscutting goals and activities or how EPA planned to coordinate with other federal agencies on related

[42]According to CDC officials, uncertain funding may limit their ability to perform NHANES measurements for dioxins, furans, coplanercoplanar PCBs, phytoestrogens, certain heavy metals, phthalates, and polyaromatic hydrocarbons.

[43]EPA officials indicated that at the individual study level, approximately $250,000 was allocated for analyses of the NHEXAS pilot data in fiscal year 1999; EPA plans to spend approximately $170,000 in fiscal year 2000.

strategic or performance goals.[44] For example, under its plan's "safe food" objective, EPA discusses coordinating with HHS and other agencies to reduce health risks from pesticides. However, it did not outline specific projects and strategies, responsibilities, and products that must be coordinated for EPA to accomplish its goals. Similarly, HHS' performance plan lacked details regarding how crosscutting activities and goals would be coordinated with other agencies.

In their fiscal year 2001 performance plans, EPA and CDC make limited use of human exposure data to measure or validate performance, and neither agency describes how data collection efforts relate to complementary goals of other federal agencies. For example, EPA and CDC have the common goal of reducing childhood lead poisoning, but only CDC uses data on blood lead levels to validate progress toward this goal. Although EPA has goals that are clearly related to reducing human exposure to other toxic chemicals, the human exposure data collected by EPA and CDC have largely not been linked with or used to measure progress. Such data show potential for helping elucidate federal progress in environmental efforts, but EPA has not yet acted to fully realize such potential. For example, NHEXAS data are used to help assess children's exposure to pesticides. However, a related goal to reduce public exposure to pesticides does not use human exposure data; instead, it relies on the number of activities to educate agricultural workers and the public. The effectiveness of these efforts could be assessed, in part, through measured reductions in actual human exposure to specific pesticides. During 1999, CDC maintained a goal to develop methods to measure toxic substances in humans and added a goal to measure and report on human exposure to toxic substances. However, neither goal discusses how CDC will coordinate with EPA and other federal programs in meeting these goals and ensuring that newly developed methods and measured substances meet priority data needs.

Successful Models for Planning and Coordination Point to the Need for High-Level Mandate, Process for Inclusion, and Mechanism for Reporting

Program officials at HHS and EPA told us in early 2000 that they were discussing the merits of establishing a new interagency program in human

[44]See *Observations on the Environmental Protection Agency's Fiscal Year 2000 Performance Plan* (GAO/RCED-99-237R) July 20, 1999.

exposure monitoring.[45] At the time of our review, the proposal was in early stages of discussion and officials had not clarified how a new program would consider states' information needs, differ from or relate to NHANES and the NHEXAS pilot surveys, or resolve past issues about differing agency goals and priorities.

Several experts and agency officials have pointed to successful models of interagency collaboration in environmental health issues that could help shape an HHS-EPA interagency effort. One such model is the collaboration on children's environmental health issues. In this case, Executive Order 13045, signed by the President on April 21, 1997, established a Task Force on Environmental Health Risks and Safety Risks to Children to develop and recommend federal strategies for children's environmental health and safety. Among the elements that have been cited as contributing to success were a clear mandate to collaborate and a process to respond to the input and data needs of different stakeholders. According to involved officials, a high-level interagency work group has worked closely to address its charges. These charges include developing general policy and annual priorities; a coordinated federal research agenda; recommendations for partnerships among federal, state, local, and tribal governments and the private, academic, and nonprofit sectors; and identifying high-priority initiatives to advance protection of children's environmental health.[46]

A second model with a top-down mandate and a process to respond to stakeholders is NTP, established in 1978 as an HHS-wide effort to provide regulatory and research agencies needed information about potentially toxic and hazardous chemicals nationwide and to strengthen the science base in toxicology. According to officials, part of NTP's success in fostering collaboration are an inclusive executive committee and an established process for decisionmaking. The NTP Executive Committee, which provides policy oversight of NTP, includes agencies outside of HHS, such as EPA and the Consumer Product Safety Commission. The NTP Executive Committee also serves as a decisionmaking body, in that members cast votes on key issues, such as prioritization of chemicals for study and for

[45]This effort was coordinated through the White House Office of Science and Technology Policy.

[46]Executive Order 13045 also indicates such strategies are to include proposals to enhance public outreach and communication and a statement regarding the desirability of new legislation to fulfill or promote the purposes of the order.

listing in NTP's Report on Carcinogens.[47] Involved officials believe the voting requirement helps move key issues forward and provides an effective means of resolving disagreements. NTP also has an inclusive process for identifying chemicals to be considered by the Executive

Committee. NTP's chemical testing nominations are solicited from sources in academia, federal and state regulatory and health agencies, industry, and unions, as well as environmental groups and the general public.

Several officials indicated that reports on exposures in the national population to toxic chemicals are needed to help inform policymakers, researchers, and the public. Specifically, such reports can help identify serious human health risks, help officials link exposures to sources, determine appropriate interventions to help reduce these risks, and document the effectiveness of interventions in reducing exposures. Moreover, agencies could use such reports to validate or measure progress in meeting goals established under the Results Act. A key element of NTP is its biennial reports. As informational scientific and public health documents, these reports are not only used by federal and state agencies but are considered an important medium for informing the public and policymakers on the status of substances considered likely to be carcinogenic for humans.

Conclusions

The nation has a long way to go in measuring human exposures to potentially harmful chemicals. While federal efforts are increasingly covering chemicals of potential concern, there are substantial gaps in current information on exposure levels, the health risks that result, and those who may be most at risk. Recent advances in laboratory technology show promise for improving the collection and analysis of some of the information needed to understand and measure human exposures. However, a more long-term and concerted effort to address infrastructure and scientific limitations in measuring exposure will be required if substantive progress is to be made. Applying and continually improving

[47]The Director of NTP issues the Report on Carcinogens pursuant to a 1978 amendment, section 301(B)(4) of the Public Health Services Act, which requires the Secretary of HHS to publish a list of all substances that are either known to be human carcinogens or may reasonably be anticipated to be human carcinogens and to which a significant number of persons residing in the United States are exposed. NTP issues a revised Report on Carcinogens every 2 years.

upon these advances to cover an increasing number of chemicals and issues will require both time and resources. CDC's laboratory to date has been able to meet many demands for human exposure data for federal and state measurement and monitoring efforts. However, its capacity, given current resources, will continue to limit progress to develop new methods and include more people and chemicals in federal and state efforts.

Federal agencies are currently planning whether and how they can expand existing programs to meet the significant needs for human exposure data. Collaboration in such planning is essential, because agencies have different capacities and skills, and separate attempts have fallen short of supporting the large efforts that are needed. So far, no clear strategy has emerged for how to carry out this major task, particularly given the growing and overlapping interests among many agencies for understanding and measuring human exposures to potentially harmful chemicals. In our view, developing such a strategy is a challenging but necessary first step.

In the meantime, state and local health officials must try to understand and communicate the risks from environmental contaminants to concerned citizens—a difficult, if not impossible, task when information is unavailable to help them interpret the risks from the exposures citizens face in their daily environments. State officials indicate they need more of the information that is collected through federal efforts to help interpret those levels faced by citizens in their states. And to collect measurements for their studies and investigations, state officials are faced with finding laboratories that have the equipment and capacity to perform the complex measurements. Federal capacity, largely centered at CDC, cannot meet states' needs in many situations, and laboratory capacity is lacking in most states.

To help meet the gaps in environmental exposure data at all levels of government, EPA and the various HHS agencies with environmental health responsibilities need to work closely together to forge a strategic plan laying out the necessary next steps for addressing human exposure information and concerns. In addition to considering states' needs and capacities for collecting human exposure data, such a plan could

- provide long-term structure to human exposure monitoring as an interagency effort,
- establish a mechanism for setting program priorities in line with agency goals and performance measures,
- clarify agency roles and minimize duplication, and

- help agencies share expertise.

Policymakers, agencies, and the public seek many types of information on exposure trends and levels in the national population as well as for groups considered potentially at risk of disproportionate exposures. Resolution is also needed on what information should be reported on national trends and levels of exposure. A strategic plan could help agencies resolve the many different informational needs to determine what exposure information should be reported and how agencies can work together to report such information.

Recommendations to the Secretary of HHS and the Administrator of EPA

We recommend that the Secretary of HHS and the Administrator of EPA develop a coordinated federal strategy for the short- and long-term monitoring of human exposures to potentially toxic chemicals. In developing such a strategy, the Secretary and the Administrator should assess the need for an interagency program to collect and report data on human exposures, the extent current surveys and agency efforts can be used as part of such an effort, and the funding needs and sources to sustain a viable program for monitoring human exposures to toxic substances. Such a strategy should

- address individual agency needs and expertise,
- provide a framework for coordinating efforts to gather data needed to improve understanding of human exposures,
- assess needed federal and state laboratory capacity,
- establish research priorities for laboratory methods development and a mechanism or process for setting chemical monitoring priorities,
- develop a framework for identifying at-risk populations, and
- consider states' informational needs.

We further recommend that the agencies identify common or complementary performance goals or measures to reduce, monitor, or develop methods for measuring human exposures to toxic chemicals. Such goals or measures can be a basis for structuring and supporting interagency collaborations to collect and use human exposure data.

As part of this coordinated strategy, we recommend that the Secretary of HHS and Administrator of EPA periodically publish a report on levels and trends in the national population of exposures to selected toxic substances.

Agency Comments

We provided HHS and EPA an opportunity to comment on a draft of this report. Both agencies generally concurred with our conclusions and recommendations—that a long-term coordinated federal strategy was needed for monitoring human exposures to potentially toxic chemicals and that such efforts could be linked through common or complementary performance goals—and indicated that they would work together to implement our recommendations. (See apps. IV and V, respectively.) HHS and EPA also both stressed the importance, as discussed in our report, of expanding the scope of their efforts to monitor and measure human exposures to toxic chemicals beyond the limited number of chemicals covered today. To support such expansions, HHS noted the importance of additional resources for improving laboratory capacity and methods.

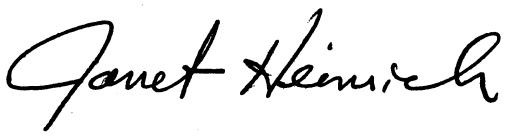
HHS and EPA provided several other comments raising points that one or both agencies consider important to monitoring human exposures to toxic chemicals. These included the need to (1) coordinate any exposure monitoring in the general population with monitoring of occupational exposures; (2) consider adding the monitoring of breast milk in a national program; (3) depending on the chemical and the purpose for the data collection, consider measures of human exposure other than the concentration in human tissues for collection; and (4) consider the option of expanding the scope of NHANES as a means of improving data needed to identify potentially at-risk subgroups. We agree that the points raised in these comments are important and that they should be considered during development of any coordinated federal strategy.

EPA also said that additional federal partners, including the Departments of Defense, Transportation, and Energy should participate in developing and supporting a coordinated federal strategy. We agree that it would be appropriate to obtain input from all involved and interested agencies. HHS and EPA also provided a number of clarifying and technical comments, which we incorporated where appropriate.

We are sending copies of this report to the Honorable Donna E. Shalala, Secretary of HHS, and the Honorable Carol M. Browner, Administrator, EPA. We are also sending copies to Jeffrey P. Koplan, Director, CDC, and Administrator, ATSDR; Ruth Kirschstein, Acting Director, NIH; Kenneth Olden, Director, NIEHS; Richard J. Jackson, Director, National Center for Environmental Health; Edward J. Sondik, National Center for Health Statistics; Norine Noonan, Assistant Administrator for Research and

Development, EPA; and other interested parties. We will make copies available to others upon request.

If you or your staff have any questions, please contact me at (202) 512-7119. Other major contributors are included in appendix VI.



Janet Heinrich
Associate Director, Health Financing
and Public Health Issues

List of Requesters

The Honorable Nancy Pelosi
House of Representatives

The Honorable Maxine Waters
House of Representatives

The Honorable Eleanor Holmes Norton
House of Representatives

The Honorable Patsy Mink
House of Representatives

The Honorable Anne G. Eshoo
House of Representatives

The Honorable Nydia Velazquez
House of Representatives

The Honorable John Conyers
House of Representatives

The Honorable Louise Slaughter
House of Representatives

The Honorable Henry A. Waxman
House of Representatives

Objectives, Scope, and Methodology

Nine members of the Congress asked us to study the nation's data collected to assess human exposure to potentially toxic chemicals in the environment. As agreed with our requesters, we focused our work primarily on efforts to measure chemical exposures in human tissue samples, such as blood, hair, and urine. This report discusses (1) the extent to which state and federal agencies—specifically, HHS and EPA—collect human exposure data on potentially harmful chemicals, including data to identify at-risk populations, and (2) the main barriers hindering further progress in such efforts.

Scope of Our Review

Although laboratory measurements of chemical exposure are only one part of the data collected to address environmental health concerns, they merit attention because new technology makes it increasingly easy to measure the degree to which a chemical has been absorbed into human tissues. Such measurements are often a more accurate and useful approach to assessing exposure than environmental measurements, according to public health experts.

Because federal agencies that collect human exposure data collect these data for different purposes, we were not able to assess the overall adequacy of the nation's efforts to address environmental health concerns. Therefore, we focused our work at the federal level on the efforts of two agencies—HHS and EPA—and the subcomponents of these agencies involved in exposure measurement and monitoring in the U.S. population:

- EPA's Office of Research and Development,
- HHS' National Center for Environmental Health (NCEH),
- HHS' National Center for Health Statistics (NCHS),
- HHS' Agency for Toxic Substances and Disease Registry (ATSDR), and
- HHS' National Institute of Environmental Health Sciences (NIEHS).

We focused our work mainly on nonoccupational environmental exposure to chemical agents known or thought to pose a health hazard by one or more of these agencies.

To gather information about activities of state officials, we surveyed environmental health officials in state public health agencies and conducted site visits to six states.

Methodology of Our Review

To assess the extent to which the federal agencies we reviewed have collected human exposure data, we met with key officials responsible for efforts intended to collect human exposure data at each agency. We focused on what we identified as being the most significant federal efforts in human exposure assessment at EPA and HHS related to nonoccupational human exposure to environmental contaminants. We reviewed four major activities: EPA's National Human Exposure Assessment Survey (NHEXAS), CDC's National Health and Nutrition Examination Survey (NHANES), NIEHS' Human Exposure Initiative, and ATSDR's exposure investigation activities around hazardous waste and other sites. We also obtained information on EPA's National Human Adipose Tissue Survey (NHATS), which ended in 1992.

We also interviewed officials and obtained documentation on how these various programs were planned and organized and to assess the extent data were collected in a manner that allows the identification of at-risk subpopulations by such factors as income, race and ethnicity, age, and geographic location. We obtained relevant budget information for 1999 and reviewed related agency performance plans.

To assess barriers to progress in collecting or using human exposure data, we interviewed federal officials involved in such efforts about past and current views on such barriers. In addition, we reviewed the general literature on human exposure to environmental chemicals and interviewed officials from organizations representing state epidemiologists, state public health laboratory directors, local public health officials, the chemical industry, environmental advocates, and public health experts.

To gather nationwide data on the views of state public health officials, we surveyed officials with environmental health responsibilities related to chemical exposure in state public health agencies. We identified 93 officials in each of the 50 states and the District of Columbia—referred to collectively as states—with assistance from the Council of State and Territorial Epidemiologists and officials in each of the 51 states.

We also conducted on-site work at EPA, CDC agencies, and NIEHS and in six states—California, Louisiana, Massachusetts, North Carolina, Oregon, and Washington. These six states were selected to represent diverse geographic areas and environmental health programs. In the six states, we interviewed state public health officials. We also interviewed officials in state environmental protection and agriculture agencies, academic and

independent researchers, and representatives of community advocacy organizations.

We excluded efforts to collect human exposure data within occupational settings from the scope of our review. Similarly, we excluded federally supported academic and private sector research efforts.

Our work was conducted from March 1999 through March 2000 in accordance with generally accepted government auditing standards.

Methodology for Chemical List Analyses

To assess the extent to which human exposure data are available for chemicals of high concern to human health, we analyzed a number of chemical lists maintained by HHS and EPA agencies. We also identified chemicals measured through HHS and EPA representative surveys.

Chemical data were gathered from various sources, including EPA's Offices of Pesticide Programs, Air and Radiation, Pollution Prevention and Toxics, and Research and Development; the National Toxicology Program (NTP) headquartered at NIEHS; CDC's ATSDR; and NCEH and NCHS within ATSDR. Several toxic chemical lists were identified through a review of related reports and literature on environmental exposure issues. To narrow the scope, we also contacted staff in relevant offices within these agencies and asked them to identify key lists of chemicals of concern. We consulted experts and public health laboratory officials at the Pew Commission for Environmental Health and the Association for Public Health Laboratories.

From the many available chemical lists, we judgmentally selected eight based on our assessment that each list contained chemicals thought to have a high potential for causing harm to human health and input and recommendations from experts. These eight lists, which contained more than 1,400 unique chemicals, provide a conservative number of the chemicals agency officials consider a concern for human health. To ensure that chemicals with more than one name were not included more than once, we used Chemical Abstract Service numbers, a unique identifier. These lists, whether singly or combined, do not necessarily reflect the highest priorities of the federal government or the agencies or programs we contacted. The lists we reviewed are described below.

- Chemicals found most often at the nation's Superfund sites: HHS' ATSDR, which conducts public health assessments or other health investigations for populations living around national priority hazardous

waste sites, and EPA prepare a list, in order of priority, of hazardous substances. This list contains substances that are most commonly found at facilities on the National Priorities List (Superfund) and pose the most significant potential threat to human health due to their known or suspected toxicity and potential for human exposure.

- EPA's list of toxics of concern in air: The Congress established the original list of 188 hazardous air pollutants that EPA would regulate through the Clean Air Act. EPA periodically must revise the list to add or, when warranted, remove substances. EPA adds substances that it determines to be air pollutants that are known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects.
- Chemicals harmful because of their persistence in the environment, tendency to bioaccumulate in plant or animal tissues, and toxicity: EPA's Office of Solid Waste and Office of Pollution Prevention and Toxics created this list of persistent, bioaccumulative, and toxic (PBT) chemicals. PBT chemicals do not readily break down or decrease in potency after they are released into the environment, even if released in quantities that are very small and legally permitted. Over time, these chemicals are likely to accumulate in soils or other environmental media, be absorbed or ingested by animals and plants, accumulate in animal and plant tissue, pass through the food chain, and potentially cause long-term human health or ecological problems.
- Priority pesticides of potential concern: We combined two lists of potentially harmful chemicals to develop this list. EPA's Office of Pesticides Programs provided a list of pesticides of concern that were classified as organophosphates; carbamates; or group B1, B2, or C carcinogens. According to a program official, these classes of pesticides are generally considered among the most potentially harmful to human health. We combined this list with the U.S. Department of Agriculture's Pesticide Data Program list of pesticides that are measured in selected commodities or foods. Pesticides monitored by the program in 1997 included insecticides, herbicides, fungicides, and growth regulators in fresh and processed fruit and vegetables, whole milk, and grains.
- Chemicals that are known or probable carcinogens: HHS' Report on Carcinogens includes substances known or reasonably thought to be cancer-causing based on evaluations of substances performed by scientists from NTP, other federal health research and regulatory agencies, and nongovernment institutions. The list of substances in the report represents an initial step in hazard identification. Substances listed as "known to be human carcinogens" are those for which there is sufficient evidence of carcinogenicity (cancer-causing potential) in

humans to indicate a causal relationship between exposure to the agent, substance, or mixture and human cancer. Substances listed as "reasonably anticipated to be human carcinogens'' are those for which there is limited evidence of carcinogenicity in humans, insufficient evidence of carcinogenicity in experimental animals, or both.

- Chemicals that are considered toxic and used, manufactured, treated, transported, or released into the environment: EPA publishes the Toxics Release Inventory containing information on the release and other waste management activities of toxic chemicals by facilities that manufacture, process, or otherwise use them. This database is made available to the public and is considered useful to citizens, businesses, and governments for purposes of working together to protect the quality of their land, air, and water and for evaluating the probability that chemical releases could impact human health in communities.
- Chemicals most in need of testing required by the Toxic Substances Control Act: The Master Testing list contains those chemicals that are prioritized for safety testing based on EPA's finding that (1) a chemical may present an unreasonable risk of injury to human health or the environment and/or the chemical is produced in substantial quantities that could result in significant or substantial human or environmental exposure, (2) the available data to evaluate the chemical are inadequate, and (3) testing is needed to develop the required data.

We compared the combined list of these chemicals, totaling 1,456, and each individual list with those chemicals identified by EPA and CDC officials as measured in the NHEXAS and NHANES human exposure efforts through 2000. We excluded NHATS' and the Human Exposure Initiative's chemical lists from our analysis. NRC's 1991 review of the NHATS program raised questions about, for example, the representativeness of the results and the methods used to handle the tissue specimens. NIEHS' Human Exposure Initiative measurements were not complete at the time of our review and thus it was not known which chemicals had been or are currently being measured.

Survey Development and Distribution and Analysis

To develop survey questions, we reviewed documentation on environmental health programs prepared by HHS and EPA agencies, professional organizations representing state epidemiology and public health laboratory officials, and public health experts. We also spoke with officials and representatives from each of these groups.

We pretested our survey in person with state environmental health officials in two states and in teleconferences with officials in two additional states. We asked knowledgeable people in EPA and CDC and in the environmental and public health fields to review the survey instrument. We refined the questionnaire in response to their comments to help ensure that potential respondents could provide the information requested and that our questions were fair, relevant, answerable with readily available information, and relatively free of design flaws that could introduce bias or error into our study results. We mailed questionnaires to the 93 officials in August 1999. We sent at least one follow-up mailing and conducted telephone follow-ups to nonrespondents. We ended data collection in December 1999; had received responses from 81 officials in 48 states for a response rate of 87 percent.

In preparing for our analysis, we reviewed and edited the completed questionnaires and checked the data for consistency. We tested the validity of the respondents' answers and comments by comparing them with data we gathered through interviews with public health experts and other public health officials and with documentation obtained at federal agencies and in case study states.

The survey and survey results are presented in appendix III.

Reported Gaps in Human Exposure Data and History of Federal Efforts

Since the 1980s, reports reviewing environmental health data needs have recommended the broader collection of human data showing actual human exposures to chemical contaminants in the environment. Various federal agencies have collected such human exposure data for a number of purposes; historically, these collection efforts have been limited to selected chemicals, subpopulations, and time periods.

Various Reports Discuss the Gaps in Human Data Showing Measured Exposure to Chemical Contaminants

Data on actual levels of chemicals in humans has been a longstanding gap in the information needed to establish human health risks from exposures to environmental contaminants. While data on the concentration of chemicals in environmental media—such as air, water, and food—have historically been used to estimate human exposure to harmful chemicals, this approach to detect or define human health risks has limitations. According to the NRC, there are too many chemicals, too many sources, and too many routes of exposure to rely solely on environmental monitoring. Measurements of internal doses of exposure—actual levels of chemicals or their metabolites found in human tissues, such as blood or urine—are generally considered an accurate measure of human exposure. Such measurements can reflect exposures from all routes and that may be accumulated over time, modified by individual differences in physiology, and difficult or impossible to assess by environmental measurements (such as hand-to-mouth ingestion in young children). In 1991, NRC reported that a program of human tissue monitoring is critical to the continued improvement of understanding of exposure to toxic chemicals and recommended that such a program be given high priority for funds and other resources.[1]

Several other federal reviews have pointed to information needs in this area. An interagency assessment of federally supported databases conducted in the early 1990s concluded that federal data systems generally lacked data on actual human exposures, including information about contact between the chemical and the human body (personal exposures) and the amount of the chemical absorbed (internal doses). The review also found substantial value in collecting and analyzing these data in a comprehensive and systematic manner and that the costs associated with

[1]NRC, Commission on Life Sciences, *Monitoring Human Tissues for Toxic Substances.*

establishing and maintaining appropriate databases were justified.[2] A discussion of some of these reviews follow.

- HHS, NCHS, *Environmental Health: A Plan for Collecting and Coordinating Statistical and Epidemiologic Data* (Washington, D.C.: Government Printing Office, 1980): This report found that "acceptable ranges of physiologic measurements and normal levels of trace elements must be determined before any attempt can be made to associate health outcomes with environmental exposures. Many of these baseline data do not exist for particular populations of interest or for specific pollutants. In addition, early indicators and symptoms of disease that might be environmentally related are not clearly understood." The report identified a number of research directions to help define the association between health effects and specific environmental exposures, including the establishment of baseline data on physiological measurements of trace elements in tissue and blood for the population.
- HHS, NIEHS, *Issues and Challenges in Environmental Health* (Washington, D.C.: National Institutes of Environmental Sciences, 1987): This report found that due to "gaps in data systems established for monitoring and surveillance of environmental exposure, effort should be made to foster better linkage among existing systems. . . . Existing data systems should be expanded to include biochemical and cellular indicators of early stages of disease. . . . The group found there is a need for more research and more systematic collection of data on the exposure of human populations to harmful substances. Reliable exposure data are necessary for assessing the probability that exposed populations will develop adverse health effects and the likelihood of success in intervening to reduce those risks."
- K. Sexton and others, "Estimating Human Exposures to Environmental Pollutants: Availability and Utility of Existing Databases": This report found that while "the evidence suggests that existing data systems contain a substantial amount of information that is relevant to exposure estimation . . . the quality of the data is inconsistent and difficult to assess and that understanding and accessing the information is often difficult. Furthermore, these systems demonstrate a striking absence of data on actual human exposures, including a lack of information about

[2]See K. Sexton and others, "Estimating Human Exposures to Environmental Pollutants: Availability and Utility of Existing Databases," *Archives of Environmental Health*, Vol. 47, No. 6 (1992), pp. 398-407.

contact between the agent and the human body (exposure) and about the amount of the agent or its metabolites that enters the body (dose)."

- NRC, *Hormonally Active Agents in the Environment*: This report found that "determining the risk of environmental hormonally active agents to humans and wildlife is difficult because exposure to these agents has not been routinely monitored . . . . Background concentrations of hormonally active agents in humans, particularly in adipose (fat) tissue and blood, and other biota need to be established. In particular, routes of exposure and the effects of diet need to be assessed to provide a framework for examining the effects of these compounds in the general population and in highly-exposed subpopulations."

History of Federal Efforts to Collect Human Exposure Data

Since 1967, HHS and EPA have conducted federal surveys to assess the U.S. population's exposures to toxic chemicals from the analysis of human tissue samples. While their efforts measured some of the same exposures and covered some of the same time periods, their goals differed and most did not include a nationally representative sample of citizens. EPA's efforts first monitored exposure to pesticides and, more recently, have attempted to link human exposure data to specific routes of exposure. CDC's periodic surveys are intended to monitor trends in the health and nutrition status of the population but, over time, have included exposures to environmental toxics as one component of the general survey. NIEHS' Human Exposure Initiative, established in the late 1990s, is intended to help the agency prioritize chemicals for further toxicology and carcinogenicity testing. Within these studies, various subgroups have been used to develop human exposure estimates, but in most cases, sampling has not been for all participant groups or random. Consequently, the results cannot be projected to the U.S. population as a whole for most chemicals. See table 5 for the time frames and numbers of chemicals covered for major federal efforts.

Table 5: Number of Chemicals and Time Frames for Select Federal Efforts

Duration	Number of participants providing biological samples	Number of chemicals measured for any participants	Number of chemicals measured for all participants (ages 1 and older)
Second National Health and Nutrition Examination Survey (NHANES II)			
1976-1980	20,000 examined[a]	36	1
Third National Health and Nutrition Examination Survey (NHANES III)			
1988-1994	30,000 examined[a]	47	1
National Health and Nutrition Examination Survey, 1999 (NHANES)			
1999-ongoing	5,000 per year[b]	74[c]	2[d]
National Human Adipose Tissue Survey (NHATS)			
1967-1992	14,000	128	20[e]
National Human Exposure Assessment Survey (NHEXAS) Pilot Study			
1995-1999	460[f]	46[c]	6

[a]The number of participants in NHANES II and NHANES III who received physical examinations is used as a proxy for the number providing biological samples, as the latter number was not readily available.

[b]The number of persons examined in a calendar year is planned to be about 5,000.

[c]For NHANES, the list of potentially toxic chemicals covered was provided by CDC laboratory officials. For NHEXAS, the list of potentially toxic chemicals covered was provided by EPA NHEXAS officials.

[d]According to a CDC laboratory official, lead and cadmium are measured in all participants. Cotinine will also be measured in many participants—specifically, those ages 4 and older.

[e]Chemicals analyzed by NHATS varied over time. NHATS collected data on 20 pesticides between 1970 and 1981. NIEHS chemicals are not included because data were not available at the time of our review.

[f]Excludes a related but separate study done in Minnesota reviewing pesticide exposures that was not one of the three formal pilot surveys.

A description of these federal efforts to collect human exposure data follows.

- *CDC's National Health and Nutrition Examination Surveys*: NHANES, conducted multiple times since 1960 by NCHS, is designed to provide national estimates of the health and nutrition status of the noninstitutionalized civilian population of the United States. Estimates are obtained by examining randomly selected participants in a manner that accurately reflects the demographic characteristics of the U.S. population. Participants are given comprehensive physical examinations (including tissue samples) and are interviewed on issues

such as their nutritional habits, health conditions, and housing characteristics. NHANES data are used for a number of purposes. For example, in addition to monitoring changes in blood lead levels, uses of NHANES include development of national standards for blood pressure and cholesterol levels and for determining infection rates for diseases. CDC's laboratory housed at NCEH performs the measurements of chemicals in human tissues for NHANES.

- *Second National Health and Nutrition Examination Survey*: NHANES II was designed to provide national estimates of the health and nutritional status of the civilian noninstitutionalized population of the United States for persons aged 6 months to 74 years. Children, the elderly and people classified as living at or below the poverty level were oversampled in order to increase the reliability of the estimates for these groups. Measurements of pesticide residues were taken from participants who were between the ages of 12 and 74 years of age.[3] Blood lead measurements were taken from participants in all age groups in the survey.
- *Third National Health and Nutrition Examination Survey*: NHANES III was designed to provide national estimates of health and nutritional status of the civilian noninstitutionalized population of the United States ages 2 months and older. Children ages 2 months through 5 years, blacks, Mexican-Americans, and persons ages 60 or older were oversampled to increase the reliability of the estimates for these groups. Blood lead measurements were taken from all participants ages 1 year or older. Cadmium measurements were taken from all participants ages 6 years or older. In addition, some participants ages 20 through 59 years had measurements taken for volatile organic compounds and pesticides. Participants volunteered for these additional measurements, so the results cannot be projected to the population as a whole. However, the results still serve as the reference ranges for these chemicals.
- *National Health and Nutrition Examination Survey, 1999*: In 1999, NCHS changed the design of NHANES so that it will now be conducted as a continuous survey of about 5,000 participants annually. Like the previous surveys, NHANES will yield nationally representative results for the civilian noninstitutionalized population. The NHANES design will allow for oversampling to vary between years; persons aged 12 to 19, persons aged 60 and over, blacks, and Mexican-Americans are being oversampled. It will be tied to related federal government data

[3]Data were not publicly available, as CDC is resolving some methodological issues associated with data collection.

collections conducted on the general U.S. population, in particular, the National Health Interview Survey.[4] NCHS also plans to release results from the survey every year after the first 3 years of data collection. More than 1 year of data will be required for many estimates, particularly among detailed subgroups of the population. While lead and cadmium will be the only potentially toxic chemicals measured for all participants ages 1 and older (although cotinine, a metabolite which illustrates exposure to environmental tobacco smoke, will be measured for most age groups—those ages 4 and over), NCHS and NCEH plan to get nationally representative data for specific chemicals for persons in specific demographic groups, such as mercury measurements in women ages 16 through 49. NCHS will also measure household lead dust, drinking water contaminants, and exposure to volatile organic compounds for selected participants. In addition to conducting an annual national survey, NCHS is developing a smaller, more targeted health survey—the Defined Population Health and Nutrition Examination Survey (DP-HANES). NCHS recognizes that NHANES cannot collect information that would be directly useful at the local or state level or for small populations. DP-HANES is intended to address this issue through the use of small mobile examination centers that would visit areas of interest and examine 2,000 to 3,000 participants for each special study. DP-HANES participants would not receive the full range of tests given under NHANES; rather, the DP-HANES examination would be tailored to the specific needs of the population under study.

- *EPA's National Human Adipose Tissue Survey*: NHATS was intended to be a continuously operating survey that would collect, store, and analyze samples of autopsy and surgical specimens of human adipose tissue from major metropolitan areas of the country. It was established by HHS in 1967 and was transferred to EPA in 1970. During its existence, NHATS data documented the widespread and significant prevalence of pesticide exposures in the general population. NHATS data also showed that reduced use of polychlorinated biphenyls (PCB) and DDT and dieldrin (common insecticides) resulted in lower tissue concentrations of these compounds. A trend analysis for 1970 through 1981 of NHATS data showed a dramatic decline in PCB concentrations after the regulation of PCBs in 1976. During the 1980s, problems with NHATS' survey design, management, and goals were compounded by insufficient financial support and caused the usefulness and quality of NHATS to

[4]The sampling will be conducted on different people, but some questions asked in each survey will be the same.

deteriorate. In 1991, NRC conducted a study to review and evaluate the effectiveness and potential applications of NHATS.[5] The study concluded that a more comprehensive national program of human tissue monitoring was a critical need for understanding human exposures to environmental toxics. In addition, EPA needed a human tissue monitoring program in order to evaluate the need and effectiveness of EPA's regulatory programs. The study recommended that NHATS be completely redesigned to provide more useful data based on probability samples of the whole U.S. population and that funding be increased to permit the program to fulfill its mission. EPA ended the NHATS in 1992 and replaced it with the NHEXAS pilot surveys.

- *EPA's National Human Exposure Assessment Survey Pilot Surveys:* The NHEXAS pilot surveys were designed to obtain knowledge on the multiple pathways and media population distribution of exposures to several classes of chemicals and to test the feasibility of conducting a national survey to provide estimates on the status of human exposure to potentially high-risk chemicals. NHEXAS was also designed to measure "total exposure"—the levels of chemicals participants take in through the air they breathe; the food, drinking water, and other beverages they consume; and in the soil and dust around their homes. Measurements have also been made of chemicals in biological samples (such as blood and urine) provided by some participants. Participants completed questionnaires to help identify possible sources of exposure to chemicals. As designed, NHEXAS has three phases. Phase I is intended to develop and validate NHEXAS methods, phase II is designed to obtain nationally representative exposure data in a manner similar to that used by NHANES to get health data, and phase III is designed to follow up on information developed from phase II and will study selected subpopulations. EPA conducted NHEXAS phase I (pilot) surveys in Arizona, Maryland, and EPA's region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin). About 460 participants in the pilot surveys provided biological samples; examinations measured a variety of chemicals, such as volatile organic compounds, heavy metals, and pesticides. Human tissue measurements were performed under interagency agreement by CDC's environmental health laboratory. EPA has completed most of the fieldwork for the NHEXAS phase I surveys and is now analyzing the results. Based on these results, EPA will finalize the scope and methods for NHEXAS phases II and III.

[5]NRC, Commission on Life Sciences, *Monitoring Human Tissues for Toxic Substances.*

- *ATSDR's Exposure Investigations*: As part of its health assessment process or in response to requests, ATSDR may conduct limited biological monitoring at hazardous waste sites or other locations through a process called exposure investigations. In response to the recognition that the conclusions drawn from indirect methods of measuring exposures were often not accurate and not reliable for assessing potential health impacts and the need for more direct measures of exposures, ATSDR formally established an exposure investigation unit within its Division of Health Assessments and Consultation. The Exposure Investigation Section was established in 1995 and is comprised of nine staff members who respond to requests to conduct exposure investigations around hazardous waste sites. These investigations involve gathering biological samples, conducting personal monitoring for site-related contaminants and their byproducts, and analyzing environmental data using computational tools.

  In 1996, ATSDR convened an expert review panel to comment on ATSDR's exposure investigation program, including whether ATSDR was on the right track in providing exposure information to improve public health decisionmaking intended to address environmental releases from hazardous waste sites. The panelists endorsed many aspects of ATSDR's investigative process, including the following:

- Conducting exposure investigations prior to preparing public health assessments, which makes agency responsibilities easier because information is provided that enables federal agencies to take action and respond to community concerns in a timely manner.
- Considering exposure determinations to be as important as obtaining environmental monitoring results.
- Emphasizing the human element of exposure investigations, which illustrates that the federal government responds to community concerns.

  The panel also made several suggested improvements to the process, including establishing a national clearinghouse of exposure investigation data and results and developing site criteria and a protocol for identifying who will decide on sites to target for exposure investigation.

  ATSDR's exposure investigations have been valuable but limited in scope. ATSDR used biological monitoring in conducting 47 exposure investigations between 1995 and July 1999. Of these investigations, 17

were done in support of the 460 health assessments done at that time. Unlike NHANES and the NHEXAS pilot surveys, exposure investigations usually have a small number of participants (less than 100) who volunteer to participate in the study. While the exposure investigations are not intended to be used for generalizations about larger populations, the studies have proven very useful in ATSDR's community outreach and intervention activities.

- *NIEHS' Human Exposure Initiative*: In 1996, this initiative, a collaboration between NIEHS and CDC, was started to improve understanding of human exposures to hormonally active agents—also called "environmental endocrine disrupters"—for the national population. CDC's environmental health laboratory under an interagency agreement is developing methods for and measuring up to 80 chemicals thought to be hormonally active agents in blood, urine, or both. Human tissue samples used for these measurements are largely obtained from the ongoing sampling of the general population under NHANES and total about 200 in number.

  In 1999, NIEHS and NTP officials proposed to expand the initial collaboration between NIEHS and CDC by quantifying human internal exposures to selected chemicals that are released into the environment and workplace. NTP officials indicated this information would benefit public health and priority-setting in a number of ways. First, it would strengthen the scientific foundation for risk assessments by allowing (1) the development of more credible relationships between exposure and response in people thereby improving cross-species extrapolation, (2) the development of biologically based dose-response models, and (3) the identification of sensitive subpopulations and for estimates of risk based on "margin of exposure." Second, it would provide the kind of information necessary for deciding which chemicals should be studied with the limited resources available for toxicological testing. For example, there are 85,000 chemicals in commerce today, and NTP can provide toxicological evaluations on 10 to 20 per year. Third, the information could be used to identify and help focus research on those mixtures of chemicals that are actually present in people's bodies. Fourth, the types and amount of chemicals in children and other potentially sensitive subpopulations would be identified. Determinations of whether additional safety factors need to be applied to children must rest in part upon comparative exposure analyses between children and adults. Fifth, this initiative, taken together with the environmental genome initiative, will provide the science base

essential for meaningful studies on gene and environment interactions, particularly for strengthening the evaluation of epidemiology studies. Finally, efficacy of public health policies aimed at reducing human exposure to chemical agents could be evaluated in a more meaningful way if human exposure data were available over time, including remediation around Superfund sites and efforts to achieve environmental equity.

Survey of State Environmental Health Officials and Results

U.S. General Accounting Office
Survey of State Environmental Health Officials and Results

Introduction

At the request of members of Congress, the U.S. General Accounting Office is conducting a study on the use of and need for measurements in human tissue of exposure to chemicals in federal and state environmental health programs. In view of growing concerns about possible health effects from environmental chemicals, human exposure data can be very useful to state and federal officials in their efforts to protect citizens.

As part of our study, we are contacting state environmental health officials in all 50 states plus the District of Columbia. We are seeking information on the extent to which state officials use and need human exposure data and general information on environmental health concerns. The questions below should take about 20 minutes to complete. Most can be answered quickly by checking applicable answers.

Instructions

We realize that human exposure data encompass a range of measures, including chemical concentrations in media such as personal air, household dust and food as well as data from questionnaires. **Our study pertains only to chemical concentrations or other markers of exposure detected in human tissue.** For our study, please use the following guidelines:

- Human exposure data are the direct measurements of chemical concentrations or other markers of exposure found in human biological samples, such as blood, hair, urine, or fat. Health officials can use information derived from the data to assess the exposure of residents near hazardous waste sites or chemical spills and conduct surveillance of conditions such as pesticide exposure. **In this survey, we use the term human exposure data to include both the direct measurements and the information, such as reference ranges of exposure, derived from those measurements.**

- Because each state conducts surveillance for lead exposure using measurements of lead concentration in blood, we want to know about the use of human exposure data for studies, investigations and surveillance of **exposure to substances other than lead**.

Please answer the questions below based on your own experience with the human exposure and health studies you participate in, including serving as an advisor. Copies of the survey may also have been provided to other officials in your state. Please provide your name and title, program, and telephone number so that we may consult with you if necessary.

Name and Title _____
Program and Agency_____
Telephone number (____)_____Email_____

Responses from all the states will be incorporated into our final report and a copy will be sent to you once it is issued. If you have questions about this survey, please contact Cheryl Williams at (503) 235-8451. Please return the completed copy at your earliest convenience, or no later than **<date>,** to

Cheryl Williams
U.S. General Accounting Office
1500 N.E. Irving Street, #414
Portland, Oregon 97232
Fax: 503/235-8492 E-mail: williamsc.sro@gao.gov

Thank you for taking the time to answer these questions.

81 state officials returned the questionnaire; however, some did not answer all the questions. The "N" for each question is the number of officials who answered that question.

Use of Currently Available Human Exposure Data[1] for Substances Other than Lead

1. State officials and others can use human exposure data collected by federal agencies for studies, investigations, surveillance or other health or policy analyses. Federal agencies, including the Centers for Disease Control and Prevention and the Environmental Protection Agency, collect and analyze human biological samples in efforts such as the National Health and Nutrition Examination Surveys (NHANES) and National Human Exposure Assessment Survey (NHEXAS). Since January 1996, have you used human exposure data collected by federal agencies for any study, investigation or surveillance you participated in?

   (N=81) *(check one)*

   48 Yes (specify source _____)
   33 No

2. To address environmental health concerns **other than lead exposure** in your state, how important is the federally compiled human exposure data you have used in studies, investigations, or surveillance you participate in?

   (N=77) *(check one)*

   26 Extremely important
   25 Very important
   15 Somewhat important
   11 Of little or no importance

3. State health officials may also gather human tissue samples, either directly or by request, as part of their studies or investigations. Since January 1996, have you gathered human tissue samples as part of any study, investigation or surveillance you participated in?

   (N= 80) *(check one)*

   54 Yes
   26 No

4. To address environmental health concerns **other than lead exposure** in your state, how important is the human exposure data you have gathered, either directly or by request, for studies, investigations, or surveillance you participate in?

   (N=76) *(check one)*

   33 Extremely important
   29 Very important
   7 Somewhat important
   7 Of little or no importance

[1]In this survey, we use the term human exposure data to include both direct measurements of chemical concentration in human tissue and information derived from those measurements. Exposure information includes such things as reference ranges of exposures in the general population; the distribution of exposures in a particular subpopulation, such as ethnic minorities or children; and the relative contribution to total exposure from various exposure routes, such as inhalation or ingestion.

5. Listed below are purposes for which state health officials may use human exposure data. Indicate below any purposes for which you have found human exposure data important in your work.

(N=77) *(check all that apply)*

- 48 Surveillance of diseases or conditions, other than lead exposure, that may have environmental causes
- 41 Investigation of disease clusters, including those reported by citizens
- 42 Investigation of planned or accidental chemical releases, including those in occupational settings
- 46 Investigation of citizen concerns about other perceived sources of contamination
- 28 Assessment of exposures in the state's general population
- 39 Assessment of exposures of one or more subpopulations that might be more susceptible to exposure for age, economic, or other reasons
- 53 Epidemiological studies of environmental health concerns
- 33 Epidemiological studies of occupational health concerns
- 31 Research on the relationship between human exposure and disease
- 6 Other purposes (please specify _____)

6. Consider all the exposure-related health studies, investigations of concerns such as accidental chemical releases or disease clusters, and surveillance efforts in which you participate, including as an advisor or reviewer. Estimate how many such studies, investigations, and surveillance efforts you have participated in since January 1996.

(N=81) *(check one)*

- 41 Fewer than 10
- 19 10 – 25
- 8 25 – 50
- 6 50 – 100
- 7 more than 100

7. Of the studies, investigations, or surveillance efforts you have participated in since January 1996, how often was human exposure data from tissue samples included?

(N=81) *(check one)*

- 38 Seldom, if ever
- 32 Less than half of the times
- 5 About half of the times
- 0 Over half of the times
- 6 Always or almost always

8. Of the exposure-related work you have participated in since January 1996, list below up to 5 chemicals for which data on concentration levels were obtained from analyzing human tissue samples. Please include chemicals that, in your opinion, might pose a significant health risk to residents or communities in your state.

(N=65) *(list up to 5 chemicals)* _____

Environmental Health Concerns and Human Exposure Data Generally

9. In addition to the health agency, various agencies or academic organizations in each state may study the human health effects of environmental exposures and may use human exposure data in these efforts. They may also collaborate with the state health agency in health-related efforts. Indicate below whether any other agencies or academic organizations in your state might use human exposure data and whether you have collaborated in any of these efforts since January 1996.

Indicate in

Part A: Whether the agency or organization in your state has used human exposure data in health studies, investigation or surveillance.

Part B: If you answered "yes" in Part A, indicate whether your office has collaborated with the agency in any health studies that used human exposure data since January 1996.

		Part A Used human exposure data in health studies *Check one*				**Part B** You collaborated in studies that used human exposure data since January 1996 *Check one*		
		Yes	No	Don't Know		Yes	No	Don't Know
Agency that may be separate from the state health agency								
1. Environmental Quality or Environmental Protection (environmental regulatory oversight)	(N=74)	34	15	25	If yes->	28	5	1
2. Natural Resources	(N=66)	6	26	34	If yes->	6	0	0
3. Health Protection or Sanitation	(N=63)	16	18	29	If yes->	12	4	0
4. Agriculture	(N=70)	20	15	35	If yes->	16	4	0
5. Occupational Health and Safety	(N=68)	26	13	29	If yes->	16	9	1
6. State Grantee–Agency for Toxic Substances and Disease Registry (ATSDR)	(N=64)	40	7	17	If yes->	33	6	1*
7. State Grantee–Environmental Protection Agency (EPA)	(N=62)	24	9	29	If yes->	18	4	2*
Academic organization								
8. State University or Medical School	(N=72)	42	7	23	If yes->	34	6	2*
9. Private University or Medical School	(N=62)	19	8	35	If yes->	11	7	1*
10. Other–please specify _____	(N=19)	4	6	9	If yes->	4	0	0

*These individuals did not answer Part B.

10. Consider all the exposure-related studies, investigations, and surveillance efforts you have conducted since January 1996. In these efforts how often could you include human exposure data from human tissue samples when you thought it was important?

(N=80) *(check one)*

- 13 Always or almost always
- 5 Over half of the times
- 10 About half of the times
- 21 Less than half of the times
- 31 Seldom, if ever

11. For the exposure-related work you have conducted since January 1996, list below up to 5 chemicals for which you could not use human exposure data when you thought it was important. Please include chemicals that, in your opinion, might pose a significant health risk to residents or communities in your state.

(N=42) *(list up to 5 chemicals)* _____

12. Listed below are reasons that might prevent a public health official from using human exposure data in a study, investigation, or surveillance effort. Indicate which, if any, account for why you have not used human exposure data when you thought it was important.

(N=75) *(check all that apply)*

1. 32 Insufficient numbers of epidemiology staff trained to design and implement studies and analyze data
2. 22 Insufficient numbers of state public health laboratory staff trained to analyze samples
3. 20 No equipment in our state public health laboratory needed to analyze samples
4. 22 No laboratory methods (assays) to test human samples for chemicals we want to study
5. 46 Lack of information on the distribution of exposure—reference ranges—among the general population to compare with measurements from our work
6. 45 Lack of research to link chemicals we want to study with specific human health effects
7. 28 Information on concentrations of chemicals in environmental media are not sufficiently detailed
8. 21 Lack of protocols, training, or equipment to collect and store samples
9. 37 Large number of samples needed would be too expensive or overwhelm available laboratory capacity
10. 19 Too difficult to obtain informed consent from potential participants
11. 19 Division of responsibility for health and environmental protection among different state agencies makes such studies difficult to undertake
12. 29 Other—please specify _____

13. Of the reasons you checked in question 12, indicate which items were most important in your decision not to use human exposure data when you thought it was important.

    (list up to three of the numbered items you checked in question 12)

    74, 64, 54

14. Are there environmental health concerns your state does not address that you think it should?

    (N=73) *(check one)*

    42 Yes → please specify _____

    31 No → go to question 16

15. Describe below why your state is not addressing environmental health concerns you think it should.

    (N=45) _____

16. If you have any additional comments about the role of human exposure data in the study of environmental health concerns or your office's ability to make use of such data, please write them in the space provided below.

    (26 respondents provided comments; 55 respondents did not provide comments)

Thank you for participating in this study.

Comments From the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Washington, D.C. 20201

APR 24 2000

Ms. Janet Heinrich
Associate Director, Health Financing
and Public Health Issues
United States General
Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

Enclosed are the Department's comments on your draft report, "Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided extensive technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Michael Mangano
for June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Comments of the Department of Health and Human Services on the General Accounting Office Draft Report Entitled, "Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans" GAO/HEHS-00-80

General Comments

The Department of Health and Human Services (the Department) thanks the General Accounting Office (GAO)for providing the opportunity to comment on their draft report. In general, the report is an accurate and forward-thinking document. The issues that surround the need for a coordinated strategy to measure exposures in humans are important to real public health concerns, and this report will hopefully energize the evolution of ongoing efforts within the Department and the Environmental Protection Agency (EPA).

The Department agrees that GAO's decision to focus on nonoccupational environmental exposures in the report is appropriate, but it may be worth mentioning that a coordinated Federal effort in human exposure monitoring should be linked if not tied directly to Federal efforts that monitor or evaluate occupational exposures. While there are many good reasons to distinguish the two types of exposures, it is important to realize that public health is best served if Federal efforts that focus on occupational and nonoccupational exposures do not operate in isolation.

The GAO report appropriately focuses on Federal efforts that directly attempt to monitor human exposures on a national scale. As stated in the report, the many basic scientific advances in human exposure research, as well as research establishing linkages between environmental exposures and adverse health effects that are essential for State and Federal agencies to make decisions regarding public health, will come from a coordinated Federal effort in human exposure monitoring. It is also important to realize that such advances have in the past and will continue to result from federally-sponsored and private sector research.

The Department agrees with the emphasis placed on at-risk populations and the recommendations made regarding the opportunities for exposure assessment to provide a better base from which to address at-risk populations. We also believe that the report could emphasize the importance of developing a breast milk monitoring program. Many environmental agents are fat soluble and are released into breast milk at significant concentrations. Examples include dioxins and polychlorinated biphenyls (PCBs) where 6 months of nursing results in dioxin or PCB concentrations in infants which are ten times higher than in the mother. Information on chemicals present in breast milk and trends over time would be valuable information in establishing priorities and strategies for children's health programs (see Hooper and McDonald, Environmental Health Perspectives, 108(5) 387-92, 2000).

The GAO report's comments on the effectiveness of Federal/State interactions on exposure assessment issues are clearly on target. In addition to the points made in the GAO report, we believe that a number of other issues could be emphasized. These include the direct application of exposure information to fill knowledge gaps that create uncertainties in risk assessment. For example, there is increasing use of margin of exposure analysis in risk assessment guidelines for

both State and Federal regulatory agencies. Information on blood and urine levels in generalized or specific populations is essential for rational use of margin of exposure analysis. These kinds of data would also improve the ability of State agencies to monitor the effectiveness of regulations setting acceptable ambient levels at the fencelines of industrial facilities. Improved availability of exposure information would provide more credible ways for States to set fish advisories for agents such as methlymercury. This is important because fish is a good source of dietary protein and consumption of fish should only be discouraged when necessary because of mercury contamination.

The GAO report could better characterize how the Department's Centers for Disease Control and Prevention (CDC) has enabled other agencies to use human tissue measurements through interagency collaborations and agreements. While this is mentioned for the National Institute of Environmental Health Sciences (NIEHS), it is not well described for EPA's National Human Exposure Assessment Survey (NHEXAS) pilots or for the Agency for Toxic Substances and Disease Registry.

We do not believe that the GAO report clearly conveys the broad scope of the National Health and Nutrition Examination Surveys (NHANES). The NHANES has many objectives, only one of which is monitoring environmental exposures. A reader of this report who is not familiar with NHANES would likely come away with the impression that the primary purpose of NHANES is to monitor environmental exposures. This impression comes about particularly because of the tendency in the report to compare NHANES to EPA's NHEXAS, which is devoted solely to exposure monitoring.

To illustrate the breadth of NHANES, the following is a list of diseases, medical conditions, and health indicators that NHANES examines in addition to environmental exposures: anemia, cardiovascular disease, diabetes, equilibrium, HIV seroprevalence, infectious diseases and immunizations, urologic disorders, mental health, nutrition and dietary behaviors, obesity, oral health, osteoporosis, physical fitness, reproductive history, respiratory disease, sexually transmitted diseases, skin diseases, tuberculosis, and vision and hearing problems.

One issue not explicitly discussed in GAO's report but which results in difficulties in using NHANES for monitoring environmental exposures relates to NHANES' relatively small yearly sample size. For example, in any 1 year, even for some exposures for which the entire sample is tested, the sample size will not allow yearly estimates by multiple demographic domains simultaneously. The full range of options should be considered when addressing how to improve the ability of the Federal Government to monitor environmental exposures. One option that should be seriously considered is to take advantage of the substantial investment already made in the NHANES infrastructure and substantially increase the sample size. If accompanied by a substantial investment in laboratory capacity, the increased sample size would greatly increase the ability of NHANES to provide expedient data on exposures for major demographic subgroups.

Exposure data is valuable to the process of identifying people being exposed to hazardous substances in the environment and the needed health follow-up actions to address these

exposures. Therefore, the findings and recommendations of GAO's report should help to ensure that the Department continues to make progress to enhance the collection of, the methodology development for, and the utility of environmental human exposure data. We look forward to working with our partners in the Federal and State governments to address the recommendations set forth in GAO's report.

GAO Recommendation

We recommend that the Secretary of HHS and the Administrator of EPA develop a coordinated federal strategy for the short- and long-term monitoring of human exposures to potentially toxic chemicals.

Department Comment

The Department concurs that there is a need for a viable short- and long-term strategy for monitoring human exposures. While improved coordination may be useful, coordination alone would only be the first step in the process. Improved coordination would likely produce agreement on the need to improve laboratory capacity, to develop methods for monitoring of more chemicals, to undertake monitoring of additional chemicals, and perhaps to increase sample size. As a practical matter, however, these improvements will not occur without addressing the problem of limited resources as mentioned in the report.

Resources needed to enhance coordination should not be taken from existing limited resources in such a manner that might diminish ongoing analyses and programmatic efforts. We believe the report should make a clear statement that human tissue measurements of exposure to contaminants is essential to all agencies, and that future interagency coordination should be based on the value of using human measurements of exposure assessment to achieve agency goals.

Additionally, the Department believes that this recommendation overlooks the enormous amount of work already done toward this end, especially at the CDC. The EPA and NIEHS sit on the advisory board of CDC's National Center for Environmental Health to make sure efforts are coordinated between the organizations. The CDC has performed all the biomonitoring measurements in the NHEXAS study and has had numerous discussions, including ongoing ones, of how CDC measurements could be used in future exposure assessments of the United States population and at-risk populations. This recommendation is partially being met now, but we could always do better at it.

GAO Recommendation

We further recommend that the agencies identify common or complementary performance goals or measures to reduce, monitor, or develop methods for measuring human exposures to toxic chemicals.

Department Comment

The Department concurs that any effort undertaken as a result of the first recommendation should have performance goals.

General Comment on Recommendations

Even if the Department and EPA were to successfully and efficiently implement the preceding recommendations, there would be no guarantee of the collection and use of important human exposure data to prevent disease and death. The GAO identified in its report the large need for "expanded" scientific effort (not just coordinating existing efforts) to address the more than 1400 chemicals identified by agencies as high priority. The Department believes that this expanded scientific effort is crucial if substantive progress is to be made.

Comments From the Environmental Protection Agency

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

APR 20 2000

OFFICE OF
RESEARCH AND DEVELOPMENT

Ms. Janet Heinrich
Associate Director, Health Financing and Public Health Issues
Health Education and Human Services Division
General Accounting Office
441 G Street N.W.
Room 5A36
Washington, DC 20548

Dear Ms. Heinrich:

We appreciate having been given the opportunity to review and comment on the draft April 2000 report entitled, "Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans," and congratulate the GAO on their insightful review. We greatly appreciate the professionalism of the GAO auditors, as well as their efforts to keep us informed and consider our views.

The GAO captured the essence of the issues associated with obtaining human exposure data, with one significant exception, namely an over-emphasis and reliance on the measurement of pollutants in blood/tissue/urine, i.e., biomarkers (see enclosure General Comment 2 for more on this issue).

We strongly support the general conclusion that far more research is needed to understand human exposures to potentially dangerous chemicals and the recommendation that the "Secretary of HHS and the Administrator of EPA be charged with developing a coordinated federal strategy for the short- and long-term monitoring and reporting of human exposures to potentially toxic chemicals." The recommendations include reports on levels and trends of exposure and identifying the need to develop common, complementary performance goals or measures related to collecting and using human exposure data. To be consistent, we would urge that the specific guidance about increasing coordination (page 4) also include the concept presented in the main text that efforts need to be expanded, rather than merely coordinated (e.g., first bullet on page 42).

Now on page 6.

Now on page 41.

As mentioned in your report, HHS and EPA initiated discussions last fall on the need for an integrated, interagency program on human exposure. Under the auspices of the Toxics and Risk Subcommittee of the Committee for the Environmental and Natural Resources, a small working

group has been developing a framework document that will hopefully serve as the basis for expanded discussions across the Federal government and with other key stakeholders (e.g., states). The GAO report reinforces the timeliness and appropriateness of this understanding.

We offer additional general and technical comments for your consideration in the enclosure. Dr. Harold Zenick will continue to serve as the overall lead for my office, while Dr. Judy Graham will serve as the technical lead. Please feel free to contact them at (919) 541-2283 and (919) 541-0349, respectively, if additional clarification of our comments is needed. Again, thank you for considering these comments as you finalize this report.

Sincerely,

Norine E. Noonan

Norine E. Noonan, Ph.D.
Assistant Administrator

Enclosure

Enclosure

EPA Comments on GAO Draft Report
Toxic Chemicals
Long-Term Coordinated Strategy Needed to Measure Exposures in Humans
(GAO/HEHS-00-80)

General Comments

- Need additional federal partners. We request that the GAO consider the benefits of the participation of additional federal entities with interests in improved knowledge of exposure, such as the Department of Defense (e.g., de-contamination of bases and knowledge requirements relative to clean-up), the Department of Transportation (pollution related to where roads and highways may be constructed/expanded including associated commercial/industrial activities that may follow) and the Department of Energy (e.g., radiation exposures). Also, the report emphasizes environmental exposure, without commenting on occupational exposure. Risks result from total exposure to chemicals, making it important to public health to determine whether a person is also exposed occupationally. Scientifically, there is a growing merger of occupational and environmental exposures, as the workplace shifts from a factory to an office building to a residence. When performing a measurement study, all these elements should be considered.

- Limitations of biomarkers. For selected chemicals and applications, biomarkers are very useful and probably the best measure of exposure. However, there are other measures of human exposure that may be better suited, less burdensome, provide more information, or are less costly for many applications. As examples, for exposure to volatile organic compounds, for which inhalation is expected to be the primary route, passive personal air monitors may be the better choice. For pesticides which are rapidly excreted from the body and for which intermittent exposures are expected, passive integrated air or dust samples may provide more useful information. Finally, there are thousands of chemicals having no current biomarkers of exposure. For these chemicals, at least in the short-run (the next 10 years), other measures of exposure must be used. We believe that for each chemical, the study objectives need to be decided, the available methods for measuring exposure evaluated, and the most appropriate method selected. We do not believe that biomarkers should be selected *a priori* as the best method in all cases. In fact, the preferred situation may be to obtain an integrated suite of measures that allow for better understanding and interpretation of exposures related to a particular chemical/class of chemicals.

  Where biomarkers are available, they may be very useful if exposure can be quantified, interpreted, and the sources of personal exposure identified. For example, the mere presence of a chemical in blood does not denote toxicity: certain concentrations (unknown for most biomarkers) indicate a potential for an adverse health outcome. The need to place biomarkers

Now on page 5.

Now on page 7.

Now on page 31.

in a health context is also mentioned by state officials (page 4). Source identification is needed so that the cause of excessive exposure can be identified and prevented. If high levels of biomarkers are observed, it is essential to know whether they resulted from, for example, inhalation exposure from industries in the vicinity or food contamination. Such knowledge is fundamental to cost-effective corrective/preventive action. The need to make biomarkers part of a more comprehensive monitoring program has been identified by the NRC (footnote 4 at bottom of page 5) and EPA's Scientific Advisory Board (footnote at the bottom of page 34).

Biomarkers measure the amount of chemicals remaining in the body at the time of the measurement. Some chemicals, notably lead and dioxin, remain in the body for long periods of time following exposures. These tend to provide an index of "long-term" (i.e., months to years) exposures, and integrate over multiple exposure events. Others, notably "non-persistent" pesticides, are excreted within hours or days after the exposure. For these chemicals, changes over time may be more closely related to the duration of a specific exposure event, rather than to changes in population exposure measurements over time. In such cases, if the sampling time is very different from the exposure event, the exposure may go unrecognized.

See page 26.

- Information Needed to Interpret Human Exposure Measurements (p. 26 ff). This section contains several excellent examples of how knowledge of biomarkers was useful to officials concerned with pollution from point sources. For example, a nearby waste site was suspected to contaminate people living nearby. Blood of residents was examined for those few chemicals at the site of interest. This shows how biomarkers can be used along with additional exposure information to identify potential problems and mitigate exposure and health risks. In this example, information had already been collected on the source of the chemicals, the time frame of exposure, the proximity of the individual to the source, and the potential routes of exposure. To extend this concept to a general population survey, we would also need to collect similar information on potential sources and routes of exposure, along with biomarker levels. Measuring biomarkers alone would not enable officials to take protective action for chemicals having ubiquitous sources or multiple pathways of exposure. For example, pesticide exposure can result from contaminated air, water, soil, and food. Thus, if blood levels of a certain pesticide are very high, was this due to a nearby waste site or a transport through the air or track-in of contaminated soil?

- Future NHEXAS and NHANES. The primary goal of NHANES is to collect information on the health and nutritional status of the U.S. population with the goal of monitoring exposures being secondary. Exposure data can only be collected in NHANES if it imposes a minimum burden on the study participants and does not interfere with the primary data collection goals. This constraint limits the amount of a sample that can be collected for measuring biomarkers which in turn limits the number of biomarkers that can be measured. Because of "participant burden", it also severely limits the number and types of personal exposure monitoring samples that can be collected and the number of survey questions that can be asked about

exposure and potential sources. While the NHANES environmental goal appears to be similar to that of NHEXAS, the NHEXAS approach provides information about both the distributions and the determinants of human exposures (i.e., sources, environmental concentrations, and activities). We are impressed by NHANES increased emphasis on monitoring for chemicals and EPA has provided some financial support for it. However, there are still profound differences in the level of attention that NHANES can pay to environmental exposures and still maintain their other multiple (and worthy) goals.

Major Contributors to This Report

GAO Contact

Katherine Iritani, Evaluator-in-Charge, (206) 287-4820

Staff Acknowledgments

The following individuals made important contributions to this report: Frank Pasquier served as Assistant Director; Cheryl Williams, Senior Evaluator, performed the literature review, assessed barriers, performed state site visits, and—along with Anita Kay, Intern—administered the survey of state environmental health officials; Tim Clouse, Evaluator assessed federal efforts and evaluated information collected for identifying at-risk populations; Sharon Silas, Intern, and Evan Stoll, Technical Analyst, compiled and analyzed the lists of toxic chemicals; Sylvia Shanks served as attorney-adviser, and Stan Stenersen guided the message development and report writing.

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