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Report to Congressional Requesters

April 2009

BIOMONITORING

EPA Needs to Coordinate Its Research Strategy and Clarify Its Authority to Obtain Biomonitoring Data

GAO-09-353

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Highlights

Highlights of GAO-09-353, a report to congressional requesters

Why GAO Did This Study

Biomonitoring, which measures chemicals in people's tissues or body fluids, has shown that the U.S. population is widely exposed to chemicals used in everyday products. Some of these have the potential to cause cancer or birth defects. Moreover, children may be more vulnerable to harm from these chemicals than adults. The Environmental Protection Agency (EPA) is authorized under the Toxic Substances Control Act (TSCA) to control chemicals that pose unreasonable health risks.

GAO was asked to review the (1) extent to which EPA incorporates information from biomonitoring studies into its assessments of chemicals, (2) steps that EPA has taken to improve the usefulness of biomonitoring data, and (3) extent to which EPA has the authority under TSCA to require chemical companies to develop and submit biomonitoring data to EPA.

What GAO Recommends

GAO recommends that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments; establish an interagency task force to coordinate federal biomonitoring research; and determine the extent of its legal authority to obtain biomonitoring data under TSCA, asking Congress for more authority if necessary. EPA agreed with the first two recommendations and did not disagree with the third, but provided substantive comments on its implementation.

View GAO-09-353 or key components.
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What GAO Found

EPA has made limited use of biomonitoring data in its assessments of risks posed by commercial chemicals. One reason is that biomonitoring data relevant to the entire U.S. population exist for only 148 of the over 6,000 chemicals EPA considers the most likely sources of human or environmental exposure. In addition, biomonitoring data alone indicate only that a person was somehow exposed to a chemical, not the source of the exposure or its effect on the person's health. For most of the chemicals studied under current biomonitoring programs, more data on chemical effects are needed to understand if the levels measured in people pose a health concern, but EPA's ability to require chemical companies to develop such data is limited. Thus, the agency has made few changes to its chemical risk assessments or safeguards in response to the recent increase in available biomonitoring data.

While EPA has initiated several research programs to make biomonitoring more useful to its risk assessment process, it has not developed a comprehensive strategy for this research that takes into account its own research efforts and those of the multiple federal agencies and other organizations involved in biomonitoring research. EPA does have several important biomonitoring research efforts, including research into the relationships between exposure to harmful chemicals, the resulting concentration of those chemicals in human tissue, and the corresponding health effects. However, without a plan to coordinate its research efforts, EPA has no means to track progress or assess the resources needed specifically for biomonitoring research. Furthermore, according to the National Academy of Sciences, the lack of a coordinated national research strategy has allowed widespread chemical exposures to go undetected, such as exposures to flame retardants. The development of such a strategy could enhance biomonitoring research and link data needs with collection efforts.

EPA has not determined the extent of its authority to obtain biomonitoring data under TSCA, and this authority is untested and may be limited. The TSCA provision that authorizes EPA to require companies to develop data focuses on the health and environmental effects of chemicals. Since biomonitoring data alone may not demonstrate the effects of a chemical, EPA may face difficulty in using this authority to obtain biomonitoring data. It may be easier for EPA to obtain biomonitoring data under other TSCA provisions, which allow EPA to collect existing information on chemicals. For example, TSCA obligates chemical companies to report information that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment. EPA asserts that biomonitoring data are reportable if the chemical in question is known to have serious toxic effects and biomonitoring information indicates a level of exposure previously unknown to EPA. EPA took action against a chemical company under this authority in 2004. However, the action was settled without an admission of liability by the company, so EPA's authority to obtain biomonitoring data remains untested.

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Abbreviations

CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
HPV	high production volume
IUR	Inventory Update Reporting
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NOAEL	no observable adverse effect level
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
PFOA	perfluorooctanoic acid
PFOS	perfluorooctanesulfonic acid
TSCA	Toxic Substances Control Act
VCCEP	Voluntary Children's Chemical Evaluation Program

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United States Government Accountability Office
Washington, DC 20548

April 30, 2009

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable Frank R. Lautenberg
Chairman
Subcommittee on Superfund, Toxics
and Environmental Health
Committee on Environment and Public Works
United States Senate

Biomonitoring, which measures chemicals or their by-products in living tissue or body fluids, has shown that the U.S. population is widely exposed to commercial chemicals, such as phthalates in plastic and brominated flame retardants in furniture. While chemicals are important in the manufacture of a wide variety of products, some chemicals have the potential to cause serious health problems, such as cancer or birth defects. In addition, children may be more vulnerable to certain chemicals than adults because their biological functions are still developing and their size and behavior may expose them to proportionately higher doses.

The mission of the Environmental Protection Agency (EPA) is to protect human health and the environment. To help EPA achieve this objective, the Toxic Substances Control Act (TSCA) authorizes it to regulate the manufacture, processing, and distribution of chemicals. A crucial tool in this process is chemical risk assessment, which involves determining the extent to which populations will be exposed to a chemical and assessing how this exposure affects human health. EPA uses such risk assessments to determine if it needs to take any risk management actions, such as prohibiting or restricting the manufacture, processing, or distribution of a chemical.

A recent proliferation of biomonitoring data has provided new insights into the general population's exposure to chemicals. Biomonitoring studies for certain chemicals, such as lead, have been ongoing for decades, but recent advances in analytic methods have allowed scientists to measure more chemicals in smaller concentrations. This is a promising development. According to the Centers for Disease Control and

Prevention (CDC), "biomonitoring measurements are the most health-relevant assessments of exposure because they measure the amount of the chemical that actually gets into people from all environmental sources (e.g., air, soil, water, dust, or food) combined." The CDC conducts the most comprehensive biomonitoring program in the country and has recently published the first, second, and third *National Report on Human Exposure to Environmental Chemicals* in 2001, 2003, and 2005, respectively, which reported the concentrations of certain chemicals or their by-products in the blood or urine of a representative sample of the U.S. population. For example, the CDC reported in 2005 that 93 percent of the people tested had detectable levels of Bisphenol A, a chemical used to make plastics, in their urine. For each of these reports, the CDC has increased the number of chemicals studied—from 27 in the first report, to 116 in the second, to 148 in the third. The CDC expects to report the concentrations of about 250 chemicals in a fourth report, to be released sometime in 2009.

In this context, in response to your request, we reviewed the (1) extent to which EPA incorporates information from human biomonitoring studies into its assessments of risks of commercial chemicals, (2) steps that EPA has taken to improve the usefulness of biomonitoring data for risk assessment, and (3) extent to which EPA has the authority under TSCA to require chemical companies to develop and submit biomonitoring data to EPA. We focused on whether TSCA impacts EPA's ability to collect chemical data because our prior reports have noted challenges the agency faces in using TSCA to collect chemical information. Specifically, TSCA places most of the burden of obtaining chemical data on EPA, rather than on the chemical industry.

To determine the extent to which EPA incorporates data from human biomonitoring studies into its assessments of risks from chemicals, we reviewed relevant laws, agency policies, and guidance; prior GAO reports; and academic publications. We also interviewed EPA officials and subject matter experts on the current state of biomonitoring research. To determine the steps that EPA has taken to improve the usefulness of biomonitoring data for risk assessment and management activities, we reviewed and analyzed documentation on EPA's biomonitoring-related research efforts and interviewed relevant stakeholders, including special interest groups and members of EPA's Children's Health Protection Advisory Committee. To determine the extent to which EPA has the authority to obtain biomonitoring data from the chemical industry, we interviewed EPA officials and reviewed TSCA and its implementing

regulations, EPA's *Human Health Research Strategy*, and other relevant documents.

Appendix I contains a detailed description of our scope and methodology. We conducted this performance audit from October 2007 to April 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

EPA has made limited use of biomonitoring data in its assessments of risks posed by chemicals. One major reason for the agency's limited use of such data is that, to date, there are no biomonitoring data for most commercial chemicals. The most comprehensive biomonitoring effort providing data relevant to the entire U.S. population includes only 148 chemicals, whereas EPA is currently focusing its chemical assessment and management efforts on the more than 6,000 chemicals that it considers the most likely sources of human or environmental exposure. A second reason for the agency's limited use of biomonitoring data is that EPA often lacks the additional information needed to make biomonitoring studies useful in its risk assessment process. This process requires information on how people are exposed—whether through air, water, food, or some other medium—and on the potential health effects of that exposure. Biomonitoring data, on the other hand, indicate only that a person was somehow exposed to a chemical and how much remains in the person's body, but not how the person was exposed or what may be the effect of the chemical. For most of the chemicals studied under current biomonitoring programs, more data on chemical effects are needed to understand whether the levels measured in people pose a health concern, but EPA's ability to require chemical companies to develop such data is limited. Therefore, the agency has made few changes to its chemical risk assessments or safeguards in response to the recent proliferation of biomonitoring data. However, in a few cases, there is enough existing research for EPA to incorporate biomonitoring information into risk assessment. For example, EPA was able to use biomonitoring data on methylmercury—a neurotoxin that accumulates in fish—because studies have drawn a link between the level of this toxin in human blood and adverse neurological effects in children.

While EPA has taken a number of promising steps to better understand and use biomonitoring data, it does not yet have a coordinated strategy for biomonitoring research or for integrating biomonitoring data into its chemical risk assessment process. EPA does have several research efforts with a biomonitoring focus, including research into the relationships between exposure to harmful chemicals, the resulting concentration of those chemicals in human tissue, and the corresponding health effects. For example, EPA is funding a program that collects biomonitoring data in an attempt to understand the environmental causes of autism. Nonetheless, without a coordinated strategy that takes into account EPA's various research efforts, and also those of the CDC and other federal agencies and stakeholders with substantial biomonitoring research efforts, it is unclear how EPA is prioritizing its biomonitoring research, what resources it needs to identify and address the data gaps that prevent it from making better use of biomonitoring data, and what opportunities exist to coordinate federal efforts. In addition, according to the National Academy of Sciences, the lack of a coordinated national research strategy has allowed widespread chemical exposures to go undetected, such as exposures to flame retardants. The development of a coordinated strategy could enhance research efforts and link data needs with collection efforts.

EPA has not determined the extent of its authority to obtain biomonitoring data under TSCA, and this authority is generally untested and may be limited. Several provisions of TSCA are potentially relevant. The provision that authorizes EPA to require data development focuses on data that demonstrate the health and environmental effects of a chemical. While EPA points out that under this provision it may also collect information on chemical characteristics that may affect health, EPA may only do so after meeting certain threshold risk requirements. Therefore, EPA may face difficulty in using this provision to obtain biomonitoring data, since biomonitoring data alone only indicate the presence of a chemical in the body, which by itself may not demonstrate the effects of the chemical. Other TSCA provisions allow EPA to collect existing information on chemicals. While these provisions are limited to information the company already has, knows about, or could easily ascertain, EPA's authority to obtain such information is clearer. For example, TSCA obligates chemical companies to report to EPA any information that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment. EPA asserts in informal guidance that biomonitoring data are reportable if the chemical in question is known to have serious toxic effects, and if the biomonitoring information indicates a level of exposure previously unknown to EPA. The agency took action against a chemical company under this authority in 2004 for failing to report two

sets of biomonitoring data, among other claims. However, this action was settled without an admission of liability by the company, so EPA's authority to obtain biomonitoring data remains untested.

We are recommending that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments, establish an interagency task force to coordinate federal biomonitoring research, and determine the extent of its legal authority to obtain biomonitoring data under TSCA. In addition, EPA should request legal authority specific to biomonitoring from the Congress if the agency determines that doing so is necessary.

In commenting on a draft of this report, EPA generally agreed with the first two recommendations and did not disagree with the third, but provided substantive comments on its implementation. EPA's comments are reprinted in appendix III. See the Agency Comments and Our Evaluation section of this report for our responses to these comments. EPA also provided technical comments, which we incorporated into the report as appropriate.

Background

Biomonitoring—one technique for assessing people's exposure to chemicals—involves measuring the concentration of chemicals or their by-products in human specimens, such as blood or urine. Biomonitoring has been used to monitor certain workers' lead exposure for many decades. More recently, advances in analytic methods have allowed scientists to measure more chemicals, in smaller concentrations, using smaller samples of blood or urine. As a result, biomonitoring has become more widely used for a variety of applications, including public health research and measuring the impact of certain environmental regulations, such as the decline in blood lead levels following declining levels of gasoline lead.

The CDC began collecting health statistics on the U.S. population through its National Health and Nutrition Examination Survey (NHANES) in 1971. This effort evolved over time to include the CDC collecting biomonitoring data in 1976, but only for a handful of chemicals, such as lead and certain pesticides. In 1999, the CDC substantially increased the number of chemicals in the biomonitoring component of the program to 116 and began analyzing and reporting these biomonitoring data in its versions of the *National Report on Human Exposure to Environmental Chemicals*. These three reports have provided a window into the U.S. population's exposure to chemicals, and the CDC continues to develop new methods for collecting data on additional chemical exposures with each report. The

NHANES design does not select or exclude participants on the basis of their potential for low or high exposure to a chemical. The current design of the biomonitoring program does not permit examination of exposure levels by locality, state, or region; seasons of the year; proximity to sources of exposure; or use of particular products. For example, it is not possible to extract a subset of the data and examine levels of blood lead that represent levels in a particular state's population. Some specific uses of data from the CDC's biomonitoring program are to

- determine which chemicals are present in individuals in the U.S. population, and at what concentrations;
- determine, for chemicals with a known toxicity level, the prevalence of people with levels above those toxicity levels;
- establish reference ranges that can be used by physicians and scientists to determine whether a person or group has an unusually high exposure;
- assess the effectiveness of public health efforts to reduce exposure of individuals to specific chemicals;
- determine whether exposure levels are higher among minorities, children, women of childbearing age, or other potentially vulnerable groups;
- track, over time, trends in levels of exposure of the population; and
- set priorities for research on human health effects.

Some states have enacted local biomonitoring programs to identify and address health concerns. For example, Alaska is collecting women's hair samples to test them for mercury and is supplementing those data with information on the women's fish consumption and data on local fish mercury levels collected by the U.S. Fish and Wildlife Service. As another example, California is planning how to implement a statewide biomonitoring program and is currently selecting which chemicals to include in the program. As more data have become available regarding the general population's exposure to a variety of commercial chemicals, public concerns have been aroused over the health risks posed by exposures to chemicals, such as flame retardants used in furniture or common pesticides used in and around the home. However, the utility and interpretation of biomonitoring data remain controversial, and the challenge for environment and health officials is to understand the health implications and to craft the appropriate policy responses.

For decades, government regulators have used a process called "risk assessment" to understand the health implications of commercial chemicals. Researchers use this process to estimate how much harm, if any, can be expected from exposure to a given contaminant or mixture of contaminants, and to help regulators determine whether the risk is significant enough to require banning or regulating the chemical or other corrective action. The National Academy of Sciences—a private, nonprofit institution that provides science, technology, and health policy advice under a congressional charter—described the four stages of health risk assessment in 1983.[1] The first stage is hazard identification, the determination of whether a particular chemical is or is not causally linked to particular health effects. The second stage is dose-response assessment, which involves determining the relationship between the magnitude of exposure to a contaminant and the probability and severity of adverse effects. These two stages generally involve studies that expose animals to high doses of a chemical and observe the adverse effects. The third stage is exposure assessment—that is, identifying the extent to which exposure is likely to occur. For this stage, risk assessors generally use data on chemical concentrations in the air, water, food, or other environmental media, combined with assumptions about how and at what rate the body is exposed to or absorbs the chemicals. Risk assessors also use assumptions about human behavior based on observational studies—such as the time spent outdoors or, for children, the amount of time spent on the floor—to better estimate an individual's true exposure. The fourth stage of the health risk assessment process is risk characterization—that is, combining the information from the first three stages into a conclusion about the nature and magnitude of the risk, including attendant uncertainty. These assessments typically result in the creation of chemical-specific "reference values" that are based on an intake level or a concentration in an environmental medium. An example of such a reference value is a "reference dose," which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. A reference dose can be derived from a no observable adverse effect level (NOAEL), lowest observed adverse effect level, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Uncertainty factors are used to account for interspecies extrapolation, and intraspecies

[1]National Academy of Sciences, *Risk Assessment in the Federal Government: Managing the Process* (Washington, D.C.: 1983).

variation, and, in some cases, to account for the duration of the study or a lack of a NOAEL. In addition, some legislation is based on the default assumption that children may be more sensitive to chemicals than adults. For example, the Food Quality Protection Act requires a 10-fold safety factor to protect children.

Biomonitoring research is difficult to integrate into this risk assessment process, since estimates of human exposure to chemicals have historically been based on the concentration of these chemicals in environmental media and on information about how people are exposed. Biomonitoring data, however, provide a measure of internal dose that is the result of exposure to all environmental media and depend on how the human body processes and excretes the chemical. To integrate biomonitoring into traditional risk assessment, researchers must determine how to correlate this internal exposure with their prior understanding of how external exposure affects human health.

Although the CDC has been the primary agency collecting biomonitoring data, EPA has specific authority to assess and manage chemical risks, often in coordination with other federal agencies. Several EPA offices are involved in collecting chemical data and assessing chemical risks. The Office of Pollution Prevention and Toxics (OPPT) manages programs under TSCA. The act provides EPA with the authority to collect information about chemical substances or, upon making certain determinations, to require companies to develop information and take action to control unreasonable risks by either preventing or limiting the introduction of dangerous chemicals into commerce or by placing restrictions on those already in the marketplace. TSCA also creates an Interagency Testing Committee to recommend chemicals for priority consideration for further testing to EPA. Furthermore, the EPA Administrator is specifically directed to coordinate with the Department of Health and Human Services and other federal agencies to conduct research, development, and monitoring as necessary to carry out the purposes of TSCA, and to establish and coordinate a system for exchange among federal, state, and local authorities of research and development results respecting toxic chemicals. The Office of Pesticide Programs (OPP) manages programs under the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, which require that EPA review pesticide risks to the environment before allowing a pesticide to be sold or distributed in the United States, and to set maximum pesticide residue levels allowed in or on food.

Risk assessment activities at EPA are carried out by the agency's Office of Research and Development (ORD)—its principal scientific and research arm—and its program and regional offices, including the Office of Air and Radiation, OPP, OPPT, and the Office of Water. ORD's role is to provide program and regional office scientific advice and information for use in developing and implementing environmental policies, regulations, and practices. In fulfilling this role, ORD issues guidance documents for risk assessors, such as its *Exposure Factors Handbook*, and conducts and funds research aimed at addressing data gaps and reducing scientific uncertainty. This research is divided into two categories: core research and problem-driven research. Core research seeks to produce a fundamental understanding of the key biological, chemical, and physical processes that underlie environmental systems, thus forging basic scientific capabilities that can be applied to a wide range of environmental problems. Core research addresses questions common to many EPA programs and provides the methods and models needed to confront unforeseen environmental problems. Problem-driven research, however, focuses on regulatory, program office, or regional needs and may focus on specific pollutants or the development of models or methods to address specific questions.

EPA Has Made Limited Use of Biomonitoring Data to Assess Risks Posed by Chemicals

EPA makes limited use of current biomonitoring studies because such studies cover relatively few chemicals, and EPA rarely knows whether the measured amounts in people indicate a risk to human health. Nonetheless, EPA has taken action in a few cases, when biomonitoring studies showed that people were widely exposed to a chemical that appeared to pose health risks.

The CDC's biomonitoring program provides the most comprehensive biomonitoring data relevant to the U.S. population. The results of the program are summarized in three versions of the *National Report on Human Exposure to Environmental Chemicals*. The latest report, issued in 2005, covered 148 chemicals, and the forthcoming version in 2009 will provide data on about 250 chemicals. However, there are over 83,000 chemicals on the TSCA Chemical Substance Inventory. Of those chemicals, EPA focuses on screening and prioritizing the more than 6,200 chemicals that companies produce in quantities of more than 25,000

pounds per year at one site.[2] About 3,000 of these 6,200 chemicals are produced at more than 1 million pounds per year in total.

Current biomonitoring efforts also provide little information on children. Large-scale biomonitoring studies generally omit children because it is difficult to collect biomonitoring data from them. For example, some parents are concerned about the invasiveness of taking blood samples from their children, and certain other fluids, such as umbilical cord blood or breast milk, are available only in small quantities and only at certain times. When samples are available from children, they may not be large enough to analyze because the test requires more fluids than is available because of the reasons we have previously mentioned. In other cases, the sampling effort uses the sample for other purposes. For example, the CDC collects samples through its health and nutrition survey, but uses these samples to study biological indicators related to nutrition, such as the amount of water soluble or fat soluble vitamins, iron, or trace elements. Thus, the only biomonitoring analysis that the CDC has performed on samples from children under 6 are for cadmium, lead, mercury, cotinine—a by-product of tobacco smoke—and certain perfluorinated chemicals.

Even if biomonitoring information is available for a chemical, it is often of limited use. EPA indicated that it often lacks the additional information needed to make biomonitoring results useful for risk assessment. Biomonitoring provides information only on the level of a chemical in a person's body. The detectable presence of a chemical in a person's blood or urine may not mean that the chemical causes disease. While exposure to larger amounts of a chemical may cause an adverse health impact, a smaller amount may be of no health consequence. In addition, biomonitoring data alone do not indicate the source, route, or timing of the exposure, making it difficult to identify the appropriate risk management strategies. As a result, EPA has made few changes to its chemical risk assessments or safeguards in response to the recent proliferation of biomonitoring data. For most chemicals, additional data on health effects; on the sources, routes, and timing of exposure; and on the fate of a chemical in the human body would be needed to incorporate biomonitoring into risk assessment. However, as we have discussed in

[2]Companies must report on most chemicals covered by TSCA that they produce above this 25,000-pound threshold during every 5th year. EPA chose this as a reporting threshold to approximate the premanufacture low volume exemption threshold described in section 5 of TSCA. This reporting threshold captures information on chemicals accounting for most of the total U.S. production volume that is covered by TSCA.

prior reports, EPA will face difficulty in using its authorities under TSCA to require chemical companies to develop health and safety information on the chemicals they produce. We have designated the assessment and control of toxic chemicals as a "high-risk" area of government that requires broad-based transformation.[3]

EPA has used some biomonitoring data in chemical risk assessment and management, but only when additional studies have provided insight on the health implications of the biomonitoring data. For example, EPA used both biomonitoring and traditional risk assessment information to take action on certain perfluorinated chemicals. These chemicals are used in the manufacture of consumer and industrial products, including nonstick cookware coatings; waterproof clothing; and oil-, stain-, and grease-resistant surface treatments. In 1999, EPA began an investigation after receiving biomonitoring data from a chemical company indicating that perfluorooctanesulfonic acid (PFOS) was found in the general population. Further testing showed that PFOS also was persistent in the environment, was unexpectedly toxic, tended to accumulate in the human body, and was present in low concentrations in the blood of the general population and wildlife worldwide. The principal PFOS manufacturer voluntarily phased out its production in 2002, and EPA then required manufacturers and importers to notify EPA 90 days before manufacturing or importing PFOS and PFOS-related chemicals for certain new uses.[4]

In addition, in September 2002, EPA initiated a review of perfluorooctanoic acid (PFOA)—another perfluorinated chemical. The agency cited biomonitoring data indicating widespread human exposure in the United States, and animal toxicity studies that linked PFOA exposure to developmental effects on the liver and the immune system. EPA has sought to work with multiple parties to produce missing information on PFOA through the negotiation of enforceable consent agreements, memorandums of understanding, and voluntary commitments. In 2006, EPA also launched the a 2010/15 PFOA Stewardship Program, in which eight companies voluntarily committed to reduce facility emissions and product content of PFOA and related chemicals by 95 percent no later

[3]GAO, *High-Risk Series: An Update*, GAO-09-271 (Washington, D.C.: January 2009).

[4]EPA excluded certain low volume, controlled exposure uses of PFOS and PFOS-related chemicals—including certain aspects of semiconductor manufacture, aviation hydraulics, photography, and fume/mist suppressant in metal finishing and plating baths—from the definition of a significant new use.

than 2010, and to work toward eliminating emissions and product content by 2015.

EPA also used biomonitoring data in a few other cases. In the 1980s, EPA was considering whether 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. On the basis of these data and other information, EPA strengthened its restrictions on lead. In the 1990s, EPA used biomonitoring studies to develop a reference dose for methylmercury, a neurotoxin. Mercury occurs naturally and in industrial pollution. In water, it can turn into methylmercury and then accumulate in fish. These studies showed that elevated levels of mercury in women's hair and their infants' umbilical cord blood correlated with adverse neurological effects when the children reached aged 6 or 7 years. In its fiscal year 2008 *Performance and Accountability Report*, EPA used results from biomonitoring studies to track its performance in reducing blood levels of lead, mercury, certain pesticides, and polychlorinated biphenyls. Furthermore, EPA used biomonitoring data in evaluating the safety of two pesticides: triclosan in 2008 and chlorpyrifos in 2006. Finally, EPA officials told us that the agency may adopt the use of biomonitoring data as a tool to evaluate the long-term outcomes of risk mitigation efforts.

EPA Lacks a Comprehensive Research Strategy and Has Taken Limited Steps to Improve the Usefulness of Biomonitoring Data

EPA has several biomonitoring research projects under way, but the agency has no system in place to track progress or assess the resources needed specifically for biomonitoring research. EPA also does not separately track spending or staff time devoted to biomonitoring research. Instead, it places individual biomonitoring research projects within its larger *Human Health Research Strategy*. While this strategy includes some goals relevant to biomonitoring, EPA has not systematically identified and prioritized the data gaps that prevent it from using biomonitoring data. Nor has it systematically identified the resources needed to reach biomonitoring research goals or identified which chemicals most need additional biomonitoring-related research. EPA intends to revise its *Human Health Research Strategy* for 2009, and it said that it may include a greater focus on how the agency can interpret biomonitoring data and use them in risk assessments.

Also, EPA lacks a coordinated national strategy for the many agencies and other groups involved in biomonitoring research, which could impair its ability to address the significant data gaps in this field of research. In addition to the CDC and EPA, several other federal agencies have been

involved in biomonitoring research, including the Agency for Toxic Substances and Disease Registry, the Occupational Safety and Health Administration, and entities within the National Institutes of Health (NIH). Several states have also initiated biomonitoring programs to examine state and local health concerns, such as arsenic in local water supplies or populations with high fish consumption that may increase mercury exposure. Furthermore, some chemical companies have for decades monitored their workforce for chemical exposure, and chemical industry associations have funded biomonitoring research. Finally, some environmental organizations have conducted biomonitoring studies of small groups of adults and children, including one study on infants.

A national biomonitoring research plan could help better coordinate research and link data needs with collection efforts. EPA has suggested chemicals for future inclusion in the CDC's National Biomonitoring Program, but has not gone any further toward formulating an overall strategy to address data gaps and ensure the progress of biomonitoring research. We have previously noted that to begin addressing the need for biomonitoring research, federal agencies will need to strategically coordinate their efforts and leverage their limited resources.[5] Similarly, the National Academy of Sciences found that the lack of a coordinated research strategy allowed widespread exposures to go undetected, including exposures to PFOA and flame retardants known as polybrominated diphenyl ethers. The academy noted that a coordinated research strategy would require input from various agencies involved in biomonitoring and supporting disciplines. In addition to EPA, these agencies include the CDC, NIH, the Food and Drug Administration, and the U.S. Department of Agriculture. Such coordination could strengthen efforts to identify and possibly regulate the sources of the exposure detected by biomonitoring, since the most common sources—that is, food, environmental contamination, and consumer products—are under the jurisdiction of different agencies.

EPA has taken some promising steps to address data gaps relevant to biomonitoring, which we discuss in the remaining paragraphs of this section. For example, EPA has funded research to address certain links between chemical exposure, biomonitoring measurements, and health effects. The agency worked with NIH to establish and fund several Centers

[5]GAO, *Toxic Chemicals: Long-Term Coordinated Strategy Needed to Measure Exposures in Humans*, GAO/HEHS-00-80 (Washington, D.C.: May 2, 2000).

for Children's Environmental Health and Disease Prevention Research (Children's Centers). One of these centers is conducting a large-scale study exploring the environmental and genetic causes of autism, and plans to use various types of biomonitoring data collected from parents and children to quantify chemical exposures and examine whether samples from children with autism contained different biomarkers than samples from children without autism. EPA's Children's Health Protection Advisory Committee stated that EPA's Children's Centers program represents an excellent investment that provides both short- and long-term benefits to children's health.

In addition, EPA also awards grants that are intended to advance the knowledge of children's exposures to pesticides through the use of biomarkers, and of the potential adverse effects of these exposures. The grants issued went to projects that, among other things, investigated the development of less invasive biomarkers for common pesticides, related biomarkers to indices of early neurological development, and analyzed the association between pesticide levels in environmental samples and pesticide body burdens. According to EPA, this research has helped the agency to better assess children's exposure to chemicals and assess the risk of certain pesticides.

Furthermore, EPA pursues internal research to develop and analyze biomonitoring data. For example, EPA has studied the presence of the herbicide 2, 4-D in 135 homes with preschool-age children by analyzing soil, outdoor air, indoor air, carpet dust, food, urine, and samples taken from subjects' hands. The study shed important light on how best to collect urine samples that reflect an external dose of the herbicide. It is also helping EPA researchers develop models that simulate how the body processes specific chemicals, which will help them understand the links between biomonitoring data and initial sources and routes of chemical exposure. In another area of research, EPA has partially implemented a National Academy of Sciences recommendation by collecting biomonitoring data during some animal toxicology studies. Collecting this information allows EPA to relate animal biomonitoring data to animal health effects, which is likely to be useful in interpreting human biomonitoring data. However, EPA does not routinely collect this information.

Finally, EPA has collaborated with other agencies and industry on projects that may improve the agency's ability to interpret and use biomonitoring data. For example, EPA collaborated with other federal agencies in the development of the National Children's Study, a long-term study of

environmental and genetic effects on children's health, which is slated to begin collecting data later in 2009. The agency proposes to examine the effects of environmental influences on the health and development of approximately 100,000 children across the country, following them from before birth until age 21. Several researchers have noted that since the study is slated to collect biomonitoring samples and data on environmental exposures in the home while tracking children's health status, the study would provide a unique opportunity to address data gaps and begin linking external exposure sources, biomonitoring measurements, and health outcomes. However, the study depends upon a sustained funding commitment, which it has not yet received, and the National Academy of Sciences has noted concerns regarding funding uncertainty. In a separate effort, EPA cosponsored a private consultant's pilot project to create "biomonitoring equivalents" for four chemicals. These are biomonitoring measurements intended to have a well-understood relationship to existing measures of exposure, such as oral reference doses. This relatively new concept could help better interpret the biomonitoring results for these and other chemicals and could highlight when additional research and analysis are needed.

EPA has other programs that it uses to gather additional chemical test data or to gather production and use information from companies, but these programs are not designed to interpret biomonitoring data. We discuss some of these programs in more detail in appendix II.

EPA's Authority to Obtain Biomonitoring Data under TSCA Is Untested and May Be Limited

EPA's authorities under TSCA to obtain biomonitoring data are generally untested. While our analysis of the relevant TSCA provisions and of recent administrative action suggests that EPA may be able to craft a strategy for obtaining biomonitoring data under some provisions of TSCA, EPA has not determined the full extent of its authority or the full extent of chemical companies' responsibilities with respect to biomonitoring.

Several provisions of TSCA address data development and reporting. These relevant provisions are shown in table 1 and detailed in the text that follows.

Table 1: Selected TSCA Provisions That Address Data Development and Reporting

TSCA provision	Scope of data that can be required	EPA's position on whether scope includes biomonitoring data
Section 4	Development of data on health and environmental effects and chemical characteristics	No formal position, but EPA stated that biomonitoring data can theoretically be obtained under this section.
Sections 5(a) and 5(b)	Test data developed per a section 4 test rule	No formal position, but EPA stated that its authority to obtain biomonitoring data under this section would be the same as under section 4.
Sections 5(a) and 5(d)	Test data that company has or description of data company knows of or should know of regarding health and environmental effects	No formal position, but EPA stated that it has very strong authority to require submission of existing biomonitoring data under these sections.
Section 5(e)	EPA can restrict manufacture of a chemical, which may result in an agreement to develop additional data	No formal position, but EPA stated that it has broad authority to create orders under this section, which might theoretically include generation of biomonitoring data as a support for lifting an order.
Section 8(a)	A variety of chemical data, including data on health and environmental effects	No formal position, but EPA stated that it has strong authority to require the reporting of biomonitoring data under this section.
Section 8(d)	Health and safety studies	No formal position, but EPA stated that biomonitoring data can be obtained under this section given TSCA's broad definition of a health and safety study.
Section 8(e)	Information that reasonably supports the conclusion that the chemical presents a substantial risk of injury to health or the environment	EPA has stated in a court filing and in nonbinding guidance that biomonitoring data can be obtained under this section.

Source: GAO analysis of the Toxic Substances Control Act.

Under section 4 of TSCA, EPA can require chemical companies to test chemicals for their effects on health or the environment, but this process is difficult, expensive, and time-consuming.[6] To require testing, EPA must determine that there are insufficient data to reasonably determine or predict the effects of the chemical on health or the environment, and that testing is necessary to develop such data. The agency must also make one of two additional findings. The first is that a chemical may present an unreasonable risk of injury to human health or the environment. The second is that a chemical is or will be produced in substantial quantities, and that either (1) there is or may be significant or substantial human exposure to the chemical or (2) the chemical enters or may reasonably be anticipated to enter the environment in substantial quantities.

[6]GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005).

EPA has said that it could theoretically require the development of biomonitoring data under section 4 of TSCA, but the agency's authority to do so has not yet been tested. Generally, section 4 allows EPA, if it makes the necessary findings, to promulgate a "test rule" requiring a company to "develop data with respect to the health and environmental effects for which there is an insufficiency of data." Biomonitoring data indicate only the presence of a chemical in a person's body, and not its impact on the person's health. However, EPA told us that biomonitoring data may in some cases demonstrate chemical characteristics—such as persistence, uptake, or fate—that could be relevant to the health and environmental effects of the chemical. Section 4 lists several chemical characteristics as items for which EPA can prescribe standards for development under a test rule, explicitly including persistence but also including any other characteristic that may present an unreasonable risk. Although biomonitoring may not be the only way to demonstrate persistence, uptake, or fate, section 4 also authorizes EPA to prescribe certain methodologies for conducting tests under a test rule, including but not limited to epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole-animal tests. Biomonitoring is not a listed methodology, but EPA stated it could publish a standard test guideline for using biomonitoring as a methodology for obtaining data on health effects and chemical characteristics, or it could include biomonitoring in a section 4 test rule where warranted.

Sections 5(a) and 5(b) of TSCA may be of limited use to EPA in obtaining biomonitoring data from chemical companies. Specifically, section 5(a) requires chemical companies to notify EPA at least 90 days before beginning to manufacture a new chemical or before manufacturing or processing a chemical for a use that EPA has determined by rule is a significant new use. The notice provided by the company must include "any test data in the possession or control of the person giving such notice which are related to the effect of any [manufacture, etc.] on health or the environment," as well as "a description of any other data concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable." As we have previously described, EPA told us that data concerning "environmental and health effects" could include biomonitoring data. While a notice under section 5 may include test data required to be developed under a section 4 test rule, section 5(b) does not provide independent authority for EPA to require the development of any new data. Thus, section 5(b) can only be used by EPA to obtain data that the chemical companies have on hand. EPA has noted that companies are particularly unlikely to have biomonitoring data for new chemicals on

hand because there is little opportunity for exposure to the chemical prior to full-scale manufacture.

Under certain circumstances, EPA may be able to indirectly require the development of new test data using the leverage that it has under section 5(e) to limit the manufacture of chemicals, although the agency has never attempted to do so. Under section 5(e), when a company proposes to begin manufacturing a new chemical or to introduce an existing chemical for a significant new use, EPA may determine (1) that the available information is not sufficient to permit a reasoned evaluation of the health and environmental effects of that chemical and (2) that in the absence of such information, the manufacture of the chemical may meet certain risk or exposure thresholds. If the agency does so, the Administrator can issue a proposed order limiting or prohibiting the manufacture of the chemical. If a chemical company objects to such an order, the matter becomes one for the courts. If a court agrees with the Administrator, it will issue an injunction to the chemical company to limit or prohibit manufacture of the chemical. If and when the chemical company submits data to EPA sufficient for the Administrator to make a reasoned determination about the chemical's health and environmental effects, which may include test data, the injunction can be dissolved. Thus, an injunction would provide an incentive for the chemical company to develop testing data. Also under this section, EPA sometimes issues a consent order that does not prohibit the manufacture of the chemical, but subjects it to certain conditions, including additional testing. EPA typically uses such consent orders to require testing of toxic effects and a chemical's fate in the environment. While EPA may not be explicitly authorized to require the development of such test data under this section, chemical companies have an incentive to provide the requested test data to avoid a more sweeping ban on a chemical's manufacture. EPA has not indicated whether it will use section 5(e) consent orders to require companies to submit biomonitoring data.

EPA's authority to obtain biomonitoring data under sections 8(a) and 8(d) is also untested, but EPA told us that it has broad authority to collect biomonitoring data under these sections. Under section 8(a), EPA can require chemical companies to maintain records and submit reports on a variety of data, including "all existing data concerning the environmental and health effects of the chemical." EPA believes that "data concerning environmental and health effects" could include biomonitoring data; however, only existing data would be obtainable under section 8(a). Under section 8(d), EPA can require chemical companies to submit lists or copies of any existing health or safety studies known or reasonably ascertainable by them. TSCA defines "health and safety study" very broadly as

". . . any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical, substance or mixture, and any test performed pursuant to this chapter."

While the agency has no formal position on whether biomonitoring data can be obtained under section 8(d), an EPA official stated that this provision authorizes the agency to promulgate a rule requiring a company to submit existing biomonitoring data. EPA explained that the presence of a chemical in blood or tissues of workers could indicate occupational exposure to the chemical, qualifying such information as reportable under this section.

Section 8(e) has in recent years garnered more attention than any other section of TSCA as a potential means of collecting biomonitoring information, but this potential remains unclear. Section 8(e) requires chemical companies, on their own initiative, to report to EPA any information they have obtained that reasonably supports the conclusion that a chemical presents a substantial risk of injury to health or the environment. "Substantial risk" is currently defined by EPA in nonbinding guidance as "a risk of considerable concern because of (a) the seriousness of the effect, and (b) the fact or probability of its occurrence." EPA asserts that biomonitoring data are reportable as demonstrating a substantial risk if the chemical in question is known to have serious toxic effects and the biomonitoring data indicate a level of exposure previously unknown to EPA. However, this is the extent of EPA's current guidance on the subject. Industry has asked for expanded guidance covering specific criteria for when biomonitoring data are reportable, specific guidance on the reportability of occupational biomonitoring results versus biomonitoring results from the general population, and factors that would render biomonitoring data unreportable. EPA has not yet revised its guidance in response to industry request.

This difficulty of enforcement is highlighted by the history leading up to an EPA action against the chemical company E. I. du Pont de Nemours and Company (DuPont). Until 2000, DuPont used the chemical PFOA to make Teflon® at a plant in West Virginia. In 1981, DuPont took blood samples of several female workers and two babies born to those workers. The levels of PFOA in the blood from the babies showed a measurable amount of PFOA crossed the placental barrier. DuPont moved its female employees away from work in areas of the plant where PFOA was used. However, after conducting additional animal testing, DuPont concluded that the

exposure levels associated with workers posed no reproductive risks and moved the women back into these areas. DuPont did not report the human blood sampling results to EPA, even when EPA requested all toxicology data associated with PFOA. DuPont also did not report to EPA the results of blood testing of 12 people living near the plant, 11 of whom had never worked in the plant and had elevated levels of PFOA in their blood. EPA initially received the 1981 blood sampling information from counsel for a class action lawsuit by citizens living near the West Virginia facility. DuPont argued that none of the blood sampling information was reportable under TSCA because the mere presence of PFOA in workers' and community members' blood did not itself support the conclusion that exposure to PFOA posed any health risks.

EPA subsequently filed two actions against DuPont for violating section 8(e) of TSCA by failing to report the biomonitoring data, among other claims. In December 2005, EPA and DuPont settled both of these actions. DuPont did not admit that it should have reported the biomonitoring data, but it agreed to a settlement totaling $16.5 million. Furthermore, EPA used the biomonitoring data it received in a subsequent risk assessment, which was reviewed by the Science Advisory Board, together with other information that was available at that time. Upon review, the board suggested that the PFOA cancer data are consistent with the category of "likely to be carcinogenic to humans" described in EPA Guidelines for Carcinogen Risk Assessment. As a result of this finding and other concerns associated with PFOA and PFOA-related chemicals, DuPont finally agreed to phase out the use of PFOA by 2015, in tandem with seven other companies. Thus, while EPA ultimately succeeded in using TSCA to remove PFOA from the market, it encountered great difficulty in doing so—that is, even when biomonitoring data, coupled with animal toxicity studies, arguably helped point out serious risks to human health associated with PFOA, DuPont's position was that section 8(e) did not require it to submit the biomonitoring data it had collected on PFOA. DuPont did not provide the biomonitoring data on its own initiative, and EPA may never have received these data if they had not been originally provided by a third party. Without the biomonitoring information, EPA may never have completed the risk assessment that led to the phaseout of PFOA.

Conclusions

Biomonitoring provides new insight into the general population's exposure to chemicals. However, scientists have linked biomonitoring data with human health effects for only a handful of chemicals to date. As the volume of biomonitoring data continues to increase, EPA will need to

strategically plan future research that links environmental contamination, biomonitoring measurements of exposure, and adverse health effects. The nation thus far has no long-term strategy to coordinate the biomonitoring research that EPA and other stakeholders perform. Nor does the agency gather reliable information on the amount of resources needed for addressing data gaps and incorporating biomonitoring research results into its chemical risk assessment and management programs. In addition, while federal agencies and other stakeholders could pursue various methods to address biomonitoring data gaps, such as routinely collecting biomonitoring in animal toxicology studies, coordination and agreements among EPA and the various other entities are needed to systematically pursue these options. A national biomonitoring research strategy could enhance the usefulness of biomonitoring data by identifying linkages between data needs and collection efforts and providing a framework for coordinating research efforts and leveraging stakeholder expertise.

One of the first steps in interpreting biomonitoring data is to better understand how chemicals impact human health, including how we might be exposed to them and what levels of exposure pose a risk. However, information is sparse on how people are exposed to commercial chemicals and on the potential health risks for the general population. We have previously noted that EPA faces challenges in using TSCA to obtain the information needed to assess the risks of chemicals. These challenges also affect EPA's ability to require that chemical companies provide biomonitoring data. Such data can provide additional insights on exposure levels and susceptible populations. However, EPA has not determined the extent of its authority to require a company to develop and submit biomonitoring data that may aid EPA in assessing chemicals' risks, and EPA has not developed regulations or formal guidance concerning the conditions under which biomonitoring data might be required. While EPA has attempted to get additional information on chemical risks from voluntary programs, such programs have had mixed results and are unlikely to be a complete substitute for a more robust chemical regulatory program.

Recommendations for Executive Action

To ensure that EPA effectively obtains the information needed to integrate biomonitoring into its chemical risk assessment and management programs, coordinates with other federal agencies, and leverages available resources for the creation and interpretation of biomonitoring research, we recommend that the EPA Administrator take the following two actions:

- Develop a comprehensive biomonitoring research strategy that includes the data EPA needs to incorporate biomonitoring information into chemical risk assessment and management activities, identifies federal partners and efforts that may address these needs, and quantifies the time frames and resources needed to implement the strategy. Such a strategy should
  - identify and prioritize the chemicals for which biomonitoring data or research is needed,
  - categorize existing biomonitoring data,
  - identify limitations in existing data approaches,
  - identify and prioritize data gaps, and
  - estimate the time and resources needed to implement this strategy.
- Assess EPA's authority to establish an interagency task force that would coordinate federal biomonitoring research efforts across agencies and leverage available resources, and establish such a task force if it determines that it has the authority. If EPA determines that further authority is necessary, it should request that the Executive Office of the President establish an interagency task force (or other mechanism as deemed appropriate) to coordinate such efforts.

In addition, to ensure that EPA has sufficient information to assess chemical risks, the EPA Administrator should take the following action:

- Determine the extent of EPA's legal authority to require companies to develop and submit biomonitoring data under TSCA. EPA should request additional authority from the Congress if it determines that such authority is necessary. If EPA determines that no further authority is necessary, it should develop formal written policies explaining the circumstances under which companies are required to submit biomonitoring data.

Agency Comments and Our Evaluation

We provided a draft of this report to the EPA Administrator for review and comment. EPA generally agreed with our first two recommendations, and did not disagree with the third, but it provided substantive comments on its implementation. We present EPA's written comments in appendix III. EPA also provided technical comments, which we incorporated into the report as appropriate. The following paragraphs summarize EPA's comments and our responses.

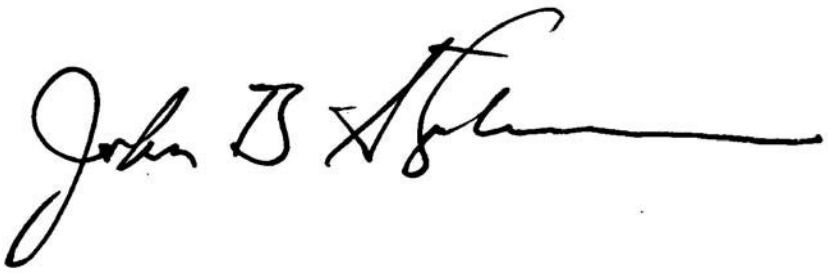
While EPA agreed that it should develop a comprehensive biomonitoring research strategy, the agency noted that its research program is addressing important questions relevant to interpreting biomonitoring data. We agree that EPA is conducting important biomonitoring related research. However, as noted in our report, while EPA has biomonitoring research projects under way, it has no system in place to track overall progress or assess the resources needed specifically for biomonitoring research. EPA also agreed that an interagency task force is needed to coordinate federal biomonitoring research, and says that such a task force should be developed under the auspices of the Office of Science and Technology Policy. We do not disagree with this approach. EPA said that our report underemphasized the importance of considering assumptions about human behavior and the need to collect biomonitoring data for young children. We agree that EPA needs to consider human behavior and other factors that impact human health risk, and we note in the report that EPA uses assumptions about human behavior on the basis of observational studies—such as the time spent outdoors or, for children, the amount of time spent on the floor—to better estimate an individual's true exposure. We also note that current biomonitoring efforts provide little information on children and that children may be more vulnerable to certain chemicals than adults because (1) their biological functions are still developing and (2) their size and behavior may expose them to proportionately higher doses. In our recommendations, we indicate that EPA should prioritize data gaps, and we believe that the lack of data on children should be a priority.

Regarding our recommendation that EPA should determine the extent of its legal authority to obtain biomonitoring data, EPA commented that a case-by-case explanation of its authority might be more useful than a global assessment of that authority. However, we continue to believe that an analysis of EPA's legal authority to obtain biomonitoring data is critical. Fuller consideration of EPA's authority is a necessary precondition of the two other recommendations that we make in this report, with which the agency agreed. That is, EPA would be best equipped to formulate a biomonitoring research strategy and contribute to an interagency task force if it were more fully aware of what data it can obtain. Furthermore, while we understand that EPA can clarify its authority to obtain biomonitoring data in individual regulatory actions, few such opportunities have arisen with regard to biomonitoring so far, and EPA provided no information suggesting it will have more opportunities to consider the issue in the near future. In addition, companies must sometimes submit chemical information independent of an EPA rule requiring submission of the data. For example, under section 8(e),

chemical companies must submit certain adverse health and safety information at their own initiative. Such situations do not provide EPA with an initial opportunity to clarify its authority to obtain biomonitoring data. We continue to believe that formal written guidance would be useful in these circumstances.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to other appropriate congressional committees, the EPA Administrator, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IV.



John B. Stephenson
Director, Natural Resources
and Environment

Appendix I: Objectives, Scope, and Methodology

To determine the extent to which the Environmental Protection Agency (EPA) incorporates data from human biomonitoring studies into its assessments of risks from chemicals, we reviewed relevant laws, agency policies and guidance, and our prior reports relevant to EPA's assessment of chemicals and to EPA's activities related to children's health issues. In addition, we reviewed EPA's prior and planned uses of these data, academic publications, National Academy of Sciences reports, and government and industry-sponsored conference proceedings to gain an understanding of the current state of biomonitoring research. We supplemented this information with that obtained from interviews with EPA officials working on biomonitoring and risk assessment issues in the Office of Research and Development, the Office of Children's Health Protection, the Office of Water, the Office of Air and Radiation, the Office of Pesticide Programs, and the Office of Pollution Prevention and Toxics. To review how EPA addresses challenges that limit the usefulness of biomonitoring data for risk assessment and management activities, we collected documentation on EPA's biomonitoring-related research efforts, including EPA's *Human Health Research Strategy*, and financial and program data for grant programs that have funded biomonitoring research. In addition, we interviewed stakeholders—such as the Centers for Disease Control and Prevention (CDC) and the Children's Health Protection Advisory Committee as well as the American Chemistry Council, the Environmental Defense Fund, and the Environmental Working Group—to gauge EPA's involvement with a variety of stakeholders working to further biomonitoring research. To determine the extent to which EPA has the authority to obtain biomonitoring data from the chemical industry, we reviewed relevant legislation and prior legal actions, and interviewed officials from EPA's Office of General Counsel to understand EPA's authorities for collecting biomonitoring data from companies.

We conducted this performance audit from October 2007 to April 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Information on Selected EPA Programs to Gather Chemical Data

EPA has programs intended to increase its knowledge of the toxic effects and levels of human exposure to certain chemicals, such as the agency's Inventory Update Reporting (IUR) rule and voluntary programs, such as the Voluntary Children's Chemical Evaluation Program (VCCEP) and the High Production Volume Challenge Program (HPV Challenge Program). However, these programs have significant limitations and no clear link to biomonitoring. For example, EPA's IUR rule is intended to gather more information on how existing chemicals are used and how they come into contact with people. However, the agency does not collect biomonitoring data as part of this program. Furthermore, in 2003 and 2005, EPA amended the rule in ways that may reduce the amount of certain information that companies report about chemicals they produce. Although the 2003 amendments added inorganic chemicals to the substances for which companies were required to report and required other potentially useful information, the agency also raised the reporting threshold. This threshold is the level of production above which a company must provide data on a chemical to EPA. The agency increased the threshold from 10,000 pounds at a single site to 25,000 pounds, which may reduce the number of chemicals for which companies provide production data to EPA. In 2005, the agency also reduced the frequency with which chemical companies must report their production volume of chemicals. Before 2005, companies were required to report the production volume every 4 years for a chemical that met the reporting threshold in the 4th year. In 2003, the agency changed the reporting requirement so that companies have to report every 5 years, thus reducing the availability of production volume data. As with the earlier rule, companies are only required to report data for a single year, not for any of the years prior to the reporting year. However, EPA officials are considering ways to collect additional production volume information, such as requiring companies to report production volume for each of the 5 years whenever a company meets the reporting requirement of 25,000 pounds of production for the 5th year.

EPA did require chemical companies to report some new information when it made these changes in 2003. Companies must now supply additional information relating to the manufacture of the reported chemicals, such as the number of workers reasonably likely to be exposed to the chemical, and relating to the physical form and maximum concentration of the chemical. In addition, for those chemicals produced in quantities of 300,000 pounds or more at one site, companies must now report "readily obtainable" information on how the chemicals are processed or used in industrial, commercial, or consumer settings, including whether such chemicals will be found in or on products intended for children. However, the definition of "readily obtainable" excludes

information that requires extensive file searches or surveys of the manufacturers that purchase the chemicals. Furthermore, an industry representative told us that it is often difficult for chemical companies to determine whether a chemical they produce will eventually be used in a product intended for children, since the companies do not directly sell children's products and may not know how manufacturers will use their product. Therefore, it is unclear whether EPA will receive significant information as a result of this new reporting requirement.

EPA has also attempted to collect data on toxicity and human exposure using voluntary programs. For example, in 2000 the agency launched VCCEP to ensure that it had adequate information to assess the potential risks to children posed by certain chemicals. EPA asked companies that produce or import 23 specific chemicals to volunteer to "sponsor" their chemical by making certain data on the chemical's toxicity available to the public. The companies volunteered to sponsor 20 of the 23 chemicals. However, VCCEP has proceeded slowly and has not provided EPA with the data needed to interpret biomonitoring research. Of the 23 VCCEP chemicals, EPA has received what it deems to be sufficient data for only 6 chemicals. In addition, it has asked for additional data that some of the sponsors declined to provide. For example, one sponsor declined to conduct additional reproductive toxicity testing for 2 chemicals, which EPA needed to use biomonitoring data in exposure assessments. Several environmental and children's health groups, including EPA's Children's Health Protection Advisory Committee, have stated that VCCEP has not met its goal of ensuring that there are adequate publicly available data to assess children's health risks from exposure to toxic commercial chemicals. Specifically, the groups have noted the lack of risk-based prioritization for collecting chemical data; the lack of specific guidance and criteria for the sponsor-developed studies and data; inadequate involvement of stakeholders; and problems with accountability, credibility, and data transparency. In 2008, EPA requested public comments on the VCCEP program and held a listening session. Nonetheless, EPA is still considering what further actions to take and has not set a goal for when it will complete its review of the program.

In another voluntary program, begun in 1998, EPA attempted to collect certain information on the health and environmental effects of high production volume (HPV) chemicals, which are those manufactured or imported in amounts of at least 1 million pounds per year. Approximately 3,000 chemicals meet this criterion. Before the start of the program, EPA found that data on basic toxicity were available for only 57 percent of these chemicals, and that the full set of six basic chemical safety tests (i.e.,

acute toxicity, chronic toxicity, reproductive toxicity, mutagenicity, ecotoxity, and environmental fate) were available for only 7 percent. This information is necessary for EPA to conduct even a preliminary screening-level assessment of the hazards and risks of these chemicals, and for it to interpret any relevant biomonitoring data. Through the HPV Challenge Program, EPA asked chemical manufacturers and importers to voluntarily sponsor chemicals by submitting information on the chemicals' physical properties, environmental fate, and health and environmental effects. The agency also asked companies to propose a strategy to fill data gaps.

However, the HPV Challenge Program has serious limitations. First, EPA has been slow to evaluate chemical risks. More than a decade after starting the program, the agency has completed "risk-based prioritizations" for only 151 of the more than 3,000 HPV chemicals. Risk-based prioritizations are preliminary evaluations that summarize basic hazard and exposure information known to EPA. The agency intends to use these evaluations to assign priorities for future action on the basis of the risks presented by these chemicals. Second, data on almost 300 HPV chemicals are lacking because they were not sponsored by any chemical company—these unsponsored chemicals are referred to as "orphans." The exact number of HPV orphan chemicals changes over time, with changes in sponsorship and production. EPA can require companies that manufacture or process orphan chemicals to conduct tests, but it has done so for only 16 of these almost 300 chemicals. This is largely because it is difficult to make certain findings regarding hazard or exposure, which section 4 of TSCA requires before EPA may issue a "test rule." However, EPA did issue a second proposed HPV test rule in July 2008 for 19 additional chemicals and anticipates proposing a third test rule in 2009 for approximately 30 chemicals. Third, the HPV Challenge Program does not include inorganic chemicals, or the approximately 500 emerging chemicals that reached the HPV production threshold after 1994. EPA recently introduced a proposal for an inorganic HPV program, but officials did not provide us with a date regarding when they expect to launch this program. Finally, EPA allowed chemical companies to group the chemicals they sponsored into categories and to apply testing data from only a handful of the chemicals to the entire category. Some environmental advocacy organizations have claimed that such categories will not adequately identify the hazards of all the chemicals in the category.

Despite the limitations of the available data on toxicity and exposure, EPA plans by 2012 to conduct a basic screening-level assessment of the potential risks of more than 6,200 chemicals and to prioritize these chemicals for possible future action as the first step in its new Chemical

Assessment and Management Program. EPA intends to apply the information on chemical hazards obtained from the HPV Challenge Program, among other programs, and extend its efforts to cover moderate production volume chemicals—those produced or imported in quantities of more than 25,000 and less than 1 million pounds per year. EPA plans to use any available biomonitoring data to help prioritize the chemicals for further review but does not have a formal plan for doing so. Although EPA has occasionally used biomonitoring in connection with these voluntary programs, it is not attempting to use these programs as a means to make biomonitoring data more useful. To do so, the agency would not only have to collect data more effectively from companies, but also collect the specific kinds of data that would allow it to understand the human health implications of biomonitoring data.

Appendix III: Comments from the Environmental Protection Agency

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

APR 13 2009

John B. Stephenson,
Director
Natural Resources & Environment
United States Government Accountability Office
441 G Street, N.W. Room 2075
Washington D.C. 20548

Dear Mr. Stephenson,

Thank you for the opportunity to review and comment on the draft report of the Government Accountability Office (GAO) entitled *BIOMONITORING – EPA Needs to Coordinate Its Research Strategy and Clarify Its Authority to Obtain Biomonitoring Data.* The draft report recommends that the Environmental Protection Agency (EPA) develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments, establish an interagency task force to coordinate federal biomonitoring research, and determine the extent of its legal authority to obtain biomonitoring data under Toxic Substances Control Act (TSCA).

EPA agrees with the first two GAO recommendations, specifically, that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring data in its risk assessments, and that EPA establish an interagency task force to coordinate federal biomonitoring research. Consistent with our comments on the Statement of Facts, EPA agrees that the GAO report accurately reflects the current problems and challenges inherent in using biomarkers data in risk assessment.

EPA's research program is addressing important research questions relevant to interpreting biomonitoring data. This research is directed at understanding the linkages between biomarker data and health outcomes in the forward direction from source to outcome, and in the reverse direction from outcome to source. Furthermore, EPA has used biomonitoring data in some of its chemical assessments. For example, EPA's National Center for Environmental Assessment in the Office of Research and Development (ORD) used biomonitoring data in the Integrated Science Assessment for lead (Pb) in support of the Pb NAAQS, although this is barely noted in the GAO report. In addition, the Office of Air Quality Planning and Standards (OAQPS) uses biomonitoring data to estimate risk reductions.

EPA agrees that inter-agency partnerships and their coordination are of paramount importance. We agree that a coordinated, cross-agency research strategy should be developed and then implemented. However, we would recommend that such a strategy be developed under the auspices of the Office of Science and Technology Policy (OSTP) / National Science and Technology Council (NSTC) Committee on the Environment and Natural Resources (CENR), and specifically its Toxics and Risk Subcommittee (T&R). This is consistent with the CENR's purpose, which is to advise and assist the NSTC on how to increase the overall effectiveness and productivity of Federal R&D efforts in the area of the environment and natural resources. In that regard, the T&R Subcommittee has successfully established inter-agency workgroups (e.g., Endocrine Disruptors; Pharmaceuticals in the Environment) in a manner that obligates Federal agencies to work together to formulate and implement such national strategies.

With respect to the Draft Report, EPA's comments (enclosed) emphasize several important issues that are insufficiently addressed or under-emphasized including: 1) the importance of considering assumptions about human behavior and other factors that impact health risk; 2) the need to collect biomonitoring data for young children; 3) ongoing biomarker and Children's Health research in EPA under the Human Health and Safe Pesticides/Safe Products Research Programs; and 4) an existing biomonitoring research framework. Specific comments also point out a few inaccuracies in the report.

EPA agrees that any action to require submission of biomonitoring data should be informed by an understanding of the legal authority for such a requirement. However, EPA's assessment of its authority is necessarily context-specific. Whether EPA may require biomonitoring data may depend upon variables such as the nature of the biomonitoring data, the use to which the data will be put, and the state of existing knowledge that might be advanced through submission of such data, just to mention a few. Therefore a global assessment of EPA's legal authority, such as is suggested in the draft report, in advance of a specific data need may be of limited value to the Agency, and might even mislead policymakers if they wrongly believe that a particular authority applies in all circumstances. Rather, as EPA considers the usefulness of biomonitoring data in specific contexts, the Agency can determine the extent of its legal authority. Further, EPA can explain the basis for any data development and/or reporting requirement, consistent with the statutory requirement, in any regulatory action requiring such data. EPA typically assesses questions of legal authority in the context of specific matters and issues, rather than in the abstract.

However, as indicated in the draft Report, EPA has given some consideration to the question of authority for requiring submission of biomonitoring data, and believes that in many cases sufficient authority already exists. In the event that a lack of authority regarding a data need is identified, EPA can then more appropriately address questions regarding additional authority.

Thank you again for the opportunity to comment on this report. If you have any questions relating to our response, please contact EPA's GAO Liaison, Bobbie Trent at 202-566-0983.

Sincerely,

James J. Jones, Acting Assistant Administrator
Office of Prevention, Pesticides and Toxic Substances

Lek Kadeli, Acting Assistant Administrator
Office of Research and Development

Enclosure

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Ed Kratzer, Assistant Director; Elizabeth Beardsley; David Bennett; Antoinette Capaccio; Crystal Huggins; Karen Keegan; Ben Shouse; and Peter Singer also made important contributions to this report.

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