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BIOMONITORING

EPA Could Make Better Use of Biomonitoring Data

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Natural Resources and Environment



GAO-10-419T

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Highlights

Highlights of GAO-10-419T, a testimony before the Subcommittee on Superfund, Toxics, and Environmental Health, Committee on Environment and Public Works, U.S. Senate

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. One 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

This testimony, based on GAO's prior work, reviews 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.

View GAO-10-419T or key components. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

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 212 chemicals. 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 authorities to require chemical companies to develop such data is limited. However, in September 2009, the EPA Administrator set forth goals for updated legislation to give EPA additional authorities to obtain data on chemicals.

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. While EPA agreed with GAO's recommendation that EPA develop a comprehensive research strategy, the agency has not yet done so.

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 section that authorizes EPA to require companies to develop data focuses on health and environmental effects of chemicals. However, biomonitoring data indicate only the presence of a chemical in the body, not its impact on health. It may be easier for EPA to obtain biomonitoring data under other TSCA sections, 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 a chemical is known to have serious toxic effects and biomonitoring data 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. GAO's 2009 report recommended that EPA clarify this authority, but it has not yet done so. The agency did not disagree, but commented that a case-by-case explanation of its authority might be more useful than a global assessment.

Mr. Chairman, Ranking Member, and Members of the Subcommittee:

I am pleased to appear here today to discuss EPA's use of biomonitoring data. 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 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 regulatory 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, such as the air, soil, water, dust, or food combined." The CDC conducts the most comprehensive biomonitoring program in the country, and in December 2009 it published the fourth in a series of reports on the concentrations of certain chemicals or their by-products in a representative sample of the U.S. population. For example, the CDC reported that 90 percent of the people tested had detectable levels of Bisphenol A (BPA). BPA is an industrial chemical that has been present in many hard plastic bottles and metal-based food and beverage cans since the 1960s. On the basis of results from recent studies using novel approaches to test for subtle effects, the Food and Drug Administration announced in January of this year that it and the National Toxicology Program at the National Institutes of Health (NIH) have some concern

about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.

My testimony today is based on our prior work on federal biomonitoring efforts and discusses EPA's use of current biomonitoring studies, EPA's biomonitoring research strategy, and EPA's authorities under TSCA to obtain biomonitoring data.[1] Specifically, my statement addresses (1) the 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) the extent to which EPA has the authority under TSCA to require chemical companies to develop and submit biomonitoring data to EPA. Our prior work was conducted 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.

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. While, biomonitoring has been used to monitor chemical exposures for 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.

CDC conducts the most comprehensive biomonitoring program in the country under its National Biomonitoring Program and published the first, second, third and fourth National Report on Human Exposure to Environmental Chemicals—in 2001, 2003, 2005, and 2009, 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 each of these reports, the CDC has increased the number

[1]GAO, *Biomonitoring: EPA Needs to Coordinate Its Research Strategy and Clarify Its Authority toObtain Biomonitoring Data*, GAO-09-353, (Washington, D.C.: Apr. 30, 2009).

of chemicals studied—from 27 in the first report, to 116 in the second, to 148 in the third, and to 212 in the fourth. Each report is cumulative (containing all the results from previous reports). These reports provide the most comprehensive assessment to date of the exposure of the U.S. population to chemicals in our environment including such chemicals as acrylamide, arsenic, BPA, triclosan, and perchlorate. These 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.

For decades, government regulators have used 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. 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.

EPA Has Made Limited Use of Biomonitoring Data in Assessing Risks Posed by Chemicals

EPA has made limited use of biomonitoring data in its assessments of risks posed by chemicals. As we previously reported,[2] 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 212 chemicals, whereas EPA is currently focusing its chemical assessment and management efforts on the more than 6,000 chemicals that companies produce in quantities of more than 25,000 pounds per year at one site.[3] Current biomonitoring efforts also provide little information on children. Large-scale biomonitoring studies generally omit children because it is difficult to collect biomonitoring data

[2]GAO-09-353.

[3]Companies must report on most chemicals covered by TSCA that they produce above this 25,000-pound threshold during every fifth year. EPA's estimate of more than 6,000 is based on data chemical companies submitted during the 2005 calendar year.

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. Thus, when samples are available from children, they may not be large enough to analyze.

A second reason we reported 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. In this regard, biomonitoring provides information only on the level of a chemical in a person's body but not the health impact. The detectable presence of a chemical in a person's blood or urine does not necessarily mean that the chemical causes harm. 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. 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. 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, EPA would need additional data on the following to incorporate biomonitoring into risk assessment: health effects; the sources, routes, and timing of exposure; and the fate of a chemical in the human body. However, as we have discussed in 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. In January 2009, we added transforming EPA's process for assessing and controlling toxic chemicals to our list of high-risk areas warranting attention by Congress and the executive branch.[4] Subsequently, the EPA Administrator set forth goals for updated legislation that would give EPA the mechanisms and authorities to promptly assess and regulate chemicals.

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 was able to use biomonitoring data on methylmercury—a neurotoxin that

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

accumulates in fish—because studies have drawn a link between the level of this toxin in human blood and adverse neurological effects in children. EPA also 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.

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

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. For example, EPA awarded grants that are intended to advance the knowledge of children's exposure to pesticides through the use of biomonitoring 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 biomarker than blood samples—such as analyses of saliva or hair samples—to measures of early brain development. Furthermore, EPA has studied the presence of an herbicide in 135 homes with preschool-age children by analyzing soil, air, carpet, dust, food, and urine as well as samples taken from subject's hands. The study shed important light on how best to collect urine samples that reflect external dose of the herbicide and how to develop models that simulate how the body processes specific chemicals. Nonetheless, EPA 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 the chemicals that need the most additional biomonitoring-related research.

Also, EPA has not coordinated its biomonitoring research with that of 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 U.S. Department of Health and Human Service's Agency for Toxic Substances and Disease Registry, entities within the U.S. Department of Health and Human Service's NIH, and the U.S. Department of Labor's Occupational Safety and Health Administration. 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.

As we previously reported, a national biomonitoring research plan could help better coordinate research and link data needs with collection efforts.[5] 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.[6] Similarly, the National Academies of Science found that the lack of a coordinated research strategy allowed widespread exposures to go undetected, including exposure to flame retardants known as polybrominated diphenyl ethers—chemicals which may cause liver damage, among other things, according to some toxicological studies. 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.

We have recommended that EPA develop a comprehensive research strategy to improve its ability to use biomonitoring in its risk assessments.[7] However, though EPA agreed with our recommendation, the agency still lacks such a comprehensive strategy to guide its own research efforts. In addition, we recommended that EPA establish an interagency

[5]GAO-09-353.

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

[7]GAO-09-353.

task force that would coordinate federal biomonitoring research efforts across agencies and leverage available resources. If EPA determines that further authority is necessary, we stated that it should request that the Executive Office of the President establish an interagency task force to coordinate such efforts. Nonetheless, EPA has not established such an interagency task force to coordinate federal biomonitoring research, nor has it informed us that it has requested the Executive Office of the President do so.

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

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. For example, under section 4 of TSCA EPA can require chemical companies to test chemicals for their effects on health or the environment.[8] However, biomonitoring data indicate only the presence of a chemical in a person's body and not its impact on the person's health. EPA told us that biomonitoring data may demonstrate chemical characteristics that would be relevant to a chemical's effects on health or the environment and that the agency could theoretically require that biomonitoring be used as a methodology for developing such data. EPA's specific authority to obtain biomonitoring data in this way is untested, however, and EPA is only generally authorized to require the development of such data after meeting certain threshold risk requirements that are difficult, expensive, and time-consuming.[9] EPA may also be able to indirectly require the development of biomonitoring data using the leverage it has under section 5(e) of TSCA, though it has not yet attempted to do so.[10] Under certain circumstances, EPA can use this section to seek an injunction to limit or prohibit the

[8]15 U.S.C. § 2603(a) (2006).

[9]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.

[10]15 U.S.C. § 2604(e) (2006).

manufacture of a chemical.[11] As an alternative, EPA sometimes issues a consent order that subjects manufacture to certain conditions, including testing, which could include biomonitoring. 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.

Other TSCA provisions allow EPA to collect existing information on chemicals that a company already has, knows about, or could reasonably ascertain.[12] For example, section 8(e) requires chemical companies 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.[13] 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. Industry has asked for more guidance on this point, but EPA has not yet revised its guidance. Confusion over the scope of EPA's authority to collect biomonitoring data under section 8 (e) 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®. In 1981, DuPont took blood from several female workers and two of their babies. The levels of PFOA in the babies' blood showed that PFOA had crossed the placental barrier. DuPont also tested the blood of twelve community members, 11 of whom had elevated levels

[11] 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.

[12] 15 U.S.C. §§ 2604(a), 2604(b), 2607(a), 2607(d), 2607(e) (2006).

[13] 15 U.S.C. § 2607(e) (2006).

of PFOA in their blood. DuPont did not report either set of results to EPA. After EPA received the results from a third party, DuPont argued that the information was not reportable under TSCA because the mere presence of PFOA in 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. DuPont settled the claims but did not admit that it should have reported the data. However, based on the data it had received, EPA conducted a subsequent risk assessment, which contributed to a finding that PFOA was "likely to be carcinogenic to humans." In turn, this finding contributed to an agreement by DuPont and others to phase out the use of PFOA by 2015. However, EPA's authority to obtain biomonitoring data under section 8(e) of TSCA remains untested in court.

Given the uncertainties regarding TSCA authorities, we have recommended that EPA should determine the extent of its legal authority to require companies to develop and submit biomonitoring data under TSCA. We also recommended that EPA request additional authority from Congress if it determines that such authority is necessary. If EPA determines that no further authority is necessary, we recommended that it develop formal written policies explaining the circumstances under which companies are required to submit biomonitoring data. However, EPA has not yet attempted a comprehensive review of its authority to require the companies to develop and submit biomonitoring data. The agency did not disagree with our recommendation, but commented that a case-by-case explanation of its authority might be more useful than a global assessment. However, we continue to believe that an analysis of EPA's legal authority to obtain biomonitoring data is critical.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions that you or other Members of this Subcommittee may have.

GAO Contact and Staff Acknowledgements

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