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ENVIRONMENTAL PROTECTION

EPA's Problems with Collection and Management of Scientific Data and Its Efforts To Address Them

Statement for the Record by
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Dear Mr. Chairman and Members of the Subcommittee:

I am pleased to offer the Subcommittee GAO's observations on key issues concerning the Environmental Protection Agency's (EPA) collection and management of scientific information and actions the agency has taken to address shortcomings in its peer review process. The federal government's efforts to protect human health and the environment in an affordable manner depend largely on understanding the risks posed by various pollutants, the manner in which they affect people and the environment, and the costs and benefits of alternative strategies to prevent pollution or mitigate its effects. Sound scientific information is essential to achieving an adequate understanding of these issues.

My observations will focus on GAO's completed work dealing with

-- EPA's problems in gathering and managing sufficient quality environmental data needed to perform risk assessments, develop defensible pollutant limitations, and develop other regulations and

-- the status of EPA's efforts to respond to our recommendations and those of other organizations concerning the agency's scientific peer review process, an important component of regulatory decision-making.

Mr. Chairman, in previous reports we have identified numerous long-standing problems with EPA's efforts to collect and manage the scientific data that form the basis of regulatory decisions. We have also pointed out numerous problems in the way the agency implements scientific peer review. In summary, we have reported the following:

-- Many of EPA's scientific data sets are either incomplete, obsolete, or missing altogether, a problem that extends across all media areas. These problems have made it difficult for the agency to conduct scientifically based risk assessments and to measure the results of environmental programs. The agency's problems in obtaining quality data are exacerbated by difficulties in managing the data that are available. In particular, EPA's data management systems have been designed to track or manage information about environmental conditions and results for each environmental medium, thus making scientific assessments of risk across media areas cumbersome and costly.

-- Until recently, EPA has not had adequate peer review procedures needed to ensure the scientific quality of the agency's technical and scientific products, which are used by program offices to support regulations. Nor has the agency had the internal controls needed to ensure that unreviewed documents are not released and perceived as agency policy before they are peer reviewed. EPA is currently taking steps to address problems in its peer review process, such as issuing guidance to all program offices and regions for conducting peer reviews of the agency's technical and scientific products. However,

agency officials also acknowledge that much remains to be done before an adequate and effective peer review process is in place.

BACKGROUND

EPA collects and analyzes vast amounts of data to support the agency's environmental enforcement and protection mission and to evaluate whether its programs are accomplishing the goals of protecting human health and the environment. Federal environmental statutes, for the most part, focus on one medium or set of pollutants (e.g., air, land, water, and emissions of hazardous pollutants into the environment) and thus direct EPA to collect data to address pollution risks for the individual media and pollutants involved. As a result, the agency has not addressed environmental risks in an integrated manner. However, EPA recognizes that an integrated, multi-media approach to assessing environmental risks is critical for the agency to make cost-effective regulatory decisions. In the past, the agency has requested reprogramming authority to support its multimedia research and development efforts.

The Congress is currently considering legislative changes to require more stringent analysis of the costs and benefits of regulating risks. In order to assess risks and determine those that are most likely to cause the greatest harm, EPA needs to have adequate scientific data to conduct risk assessments, set standards, and develop regulations. Such data are also needed by state and local governments to help them meet their environmental responsibilities in a cost-effective manner. The agency has acknowledged problems with its scientific data and processes in its fiscal year 1994 Federal Managers' Financial Integrity Act (FIA) report. In this report, EPA identified several significant material weaknesses related to the agency's research and development capabilities, including weaknesses in facilities, equipment, and data management. For example, one material weakness addresses EPA's lack of top management commitment to and sufficient resources for Information Resources Management activities.

To ensure that scientific assessments are credible, the results of EPA's scientific and technical activities, as well as the data and methods upon which decisions rest, must be independently peer reviewed. Peer review is the critical evaluation of scientific and technical products by independent experts--an important element of EPA's quality assurance process. In the past, the agency has been criticized by outside academicians, such as those on the agency's Expert Panel on the Role of Science at EPA,[1] for the uneven quality of the agency's science and deficiencies in the peer review process. To ensure adequate peer review of scientific information and products, the EPA Administrator recently issued a comprehensive peer review policy intended to ensure that major scientific and technical work products receive appropriate peer

[1]The panel is an independent advisory committee created under the Federal Advisory Committee Act to evaluate how EPA can best meet the goal of using sound science as the foundation of agency decision-making.

review. The Administrator also directed the Assistant Administrator for Research and Development to ensure that better quality assurance systems are in place to support environmental decision-making.

LONG-STANDING DATA QUALITY AND DATA MANAGEMENT PROBLEMS

Cost-effective environmental regulations must be founded on accurate scientific data dealing with key issues such as the different pathways by which pollutants come into contact with people and the environment, the concentrations at which they cause damage, and the effectiveness of alternative strategies to prevent their effects. However, quality scientific data on these and other issues have been in short supply--a problem experienced in the agency's water, pesticides, and other media programs. Data management problems, particularly the agency's reliance on numerous separate and distinct information systems, have exacerbated these difficulties.

Data Quality and Completeness Problems

EPA's water quality program illustrates the kind of data quality problems that have complicated the agency's and the states' efforts to set defensible limitations on facilities' discharges into the environment. The Clean Water Act requires EPA to develop water quality criteria that states use as guidance in setting water quality standards.[2] However, as noted in our June 1994 report, Water Pollution: EPA Needs to Set Priorities for Water Quality Criteria Issues (GAO/RCED-94-117), the agency has long relied on outdated scientific information to support ambient water quality criteria for pollutants designated as priority under the Clean Water Act. Most of the existing criteria are supported by scientific studies and other technical documents that are more than 14 years old, and no new criteria for pollutants have been established over the last 5 years.

This problem can result in underregulation of environmental hazards in some cases, and in overregulation in others. For example, state officials, environmental groups, and others have pointed out that additional ambient water quality criteria are needed for pesticides and marine waters. EPA has acknowledged that many unregulated chemicals may warrant criteria. On the other hand, representatives of the regulated community and states agree that EPA needs to reevaluate and revise existing criteria, noting that some criteria (e.g., metals criteria) are overly stringent and based on outdated science.

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[2]Water quality criteria consist of technical information such as the effects of various concentrations of pollutants on human health or aquatic life. This information is then used by regulators to develop water quality standards, which place limitations on the amount of pollutants that should be allowed in a body of water. Water quality standards, in turn, are used by state permit writers to set individual dischargers' permit limits in such a way that the standards will be achieved.

EPA's pesticides program illustrates similar data quality problems. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the agency regulates the registration (licensing) of pesticides before they are sold, held for sale, or distributed in commerce. Before registering a pesticide, EPA must determine that it will not cause an unreasonable risk to public health or the environment. In our prior work on pesticides, we have reported, among other things, problems with key data the agency has on the benefits and risks of pesticides.

Because benefit and risk assessments of pesticides are an important part of regulatory analysis, we have evaluated EPA's methods of conducting these assessments and the extent to which they are based on adequate data. Specifically, we examined the role of benefit assessments in EPA's special reviews--in-depth analyses of the benefits and risks of already registered pesticides that new evidence suggests may pose an unacceptable risk. In our report Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessments (GAO/RCED-92-32), we found that quantitative estimates of pesticides' benefits are generally imprecise because some of the data on which they are based are frequently of poor quality or missing altogether. We found few sources of reliable data on the quantity of pesticides used on food crops and on the effect that various pesticide alternatives would have on crop yields. In the absence of reliable survey data on usage and quantified field testing, which would demonstrate the effect of pesticides on crop yields, the agency obtains whatever information it can on a case-by-case basis. EPA must also collect and piece together information for benefit assessments from many sources, including commercially available data bases of pesticides' usage, as well as scientific literature and experts. This process has often resulted in data of inconsistent quality and quantity.

We have also reported on the lengthy delays associated with reregistering pesticides and removing problem pesticides from the market. Such delays stem, in part, from the inadequate support provided by EPA's information systems for reregistering pesticides.[3] The agency's data base on the health and environmental effects of existing pesticides remains incomplete, and only a few pesticide products have been reregistered after decades of review by EPA. Through fiscal year 1992, the agency had reregistered 31 pesticide products and completed the reassessment of active ingredients--the components that destroy or control the pest--affecting about 2,370 more products. However, about 20,000 pesticide products, containing 642 active ingredients, needed to be reregistered. Meanwhile, most of these products may continue to be sold and distributed even though knowledge of their health and environmental effects is incomplete.[4]

Finally, in our work on the Toxic Substances Control Act (TSCA), we have observed that EPA has made little progress in reviewing the risks of existing chemicals, in part because the

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[3]See Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration (GAO/T-IMTEC-92-3, Oct. 30, 1991) and Pesticides: EPA Lacks Assurance That All Adverse Effects Data Have Been Reviewed (GAO/T-RCED-92-16, Oct. 30, 1991).

[4]Pesticides: Pesticide Reregistration May Not Be Completed Until 2006 (GAO/RCED-93-94, May 21, 1993).

agency's information on chemical effects and exposures is often scarce, incomplete, or outdated.[5] We also noted that EPA's authority to gather data under TSCA is difficult to use and not very effective in supporting the agency's toxic chemical review process. As a result, EPA has reviewed the risks of about 2 percent of the 62,000 chemicals that were already in commerce when the agency began to review new chemicals in 1979. Moreover, as of 1994, EPA had issued regulations to control only nine chemicals in almost 18 years. Agency officials have acknowledged that sufficient data on exposures rarely exist to permit full analysis of a chemical and that the agency has little assurance that its exposure assessments are accurate and complete.

Data Management Problems

Even when quality data do exist, data management problems often make it difficult to access and use these data. Our prior reports have cited EPA's long-standing problems in managing its scientific data, particularly the large data systems the agency uses to assess health and environmental risks.[6] Of particular note, the existence of hundreds of separate and distinct information systems, each with their own structure and purpose, makes it difficult for the agency to assess health and environmental risks comprehensively (i.e., across media), identify and target the most important enforcement priorities, and track the agency's progress.

In 1992, for example, we reported that after having invested $14 million over 3 years in data systems development, EPA could not easily assemble accurate, reliable, and complete information on chemicals in the reregistration process.[7] These information management problems were traceable to inadequate systems planning and poor data management. In addition, we also reported that the Office of Pesticides Programs employed nine separate data base management systems to track or manage information about chemicals pending reregistration.[8] Each of these data systems was designed and developed separately without taking into account ways of using them jointly. EPA staff entered information about pesticide studies numerous times into different

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[5]Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (GAO/RCED-94-103, Sept. 26, 1994).

[6]See Environmental Protection: EPA's Plans to Improve Long-standing Information Resources Management Problems (GAO/AIMD-93-8, Sept. 16, 1993), Environmental Protection: EPA Faces Formidable Challenges Managing Water Quality Data (GAO/T-AIMD-93-2, Aug. 5, 1993), Toxic Substances: EPA Needs More Reliable Source Reduction Data and Progress Measures (GAO/RCED-94-93, Sep. 23, 1994), and Waste Minimization: Major Problems of Data Reliability and Validity Identified (GAO/PEMD-92-16, Mar. 23, 1992).

[7]Pesticides: Information Systems Improvements Essential for EPA's Reregistration Efforts (GAO/IMTEC-93-5, Nov. 23, 1992).

[8]Pesticides: EPA's Information Systems Provide Inadequate Support for Reregistration (GAO/T-IMTEC-92-3, Oct. 30, 1991).

systems. As a result, compiling information about pesticides undergoing reregistration was labor-intensive and time-consuming. The implications of these data problems for public health are illustrated by EPA's response to a spill of the herbicide metam sodium into the Sacramento River in the summer of 1991. At the time, EPA was unaware of information in its files indicating that metam sodium can cause birth defects. As a result, the agency could not provide timely warnings to pregnant women and workers in the area of the spill of the pesticide's hazards.

We observed similar data management problems in the Office of Pollution Prevention and Toxics (OPPT), the office responsible for controlling toxic substances.[9] OPPT has over 200 stand-alone data systems that lack standard definitions and formats. As a result, EPA scientists are forced to work inefficiently, essentially plowing through many separate data systems to assess each chemical. For external users of EPA's data, the cumbersome and scattered nature of the data make it difficult to conduct timely assessments to respond to chemical spills or to take action to protect workers' health and safety. Similar problems have been observed in the water quality and hazardous waste management programs.

Over the years, we have made numerous recommendations to EPA to address its data collection and data management problems. For example, to address problems with the management of pesticide reregistration data, we recommended that EPA strengthen its conformance with federal guidance and generally accepted practices for automated systems development so that the Office of Pesticide Programs' information systems are consistently planned, developed, and enhanced. In response to this recommendation, EPA has integrated its different reregistration support systems into a single chemical review system. Similarly, in order to improve the efficiency and effectiveness of data collection and dissemination under TSCA, we recommended that EPA (1) complete a strategic information resources management plan based on external users' needs as well as an analysis of internal users' functional and information needs and (2) implement an information systems architecture to guide the development and evolution of future systems. The agency has taken steps to address these recommendations and other information resource management deficiencies. However, many data quality and management problems have not been corrected and will continue to require commitment by management and an appropriate allocation of the agency's resources.

EPA HAS IMPLEMENTED NEW PROCEDURES TO ADDRESS SHORTCOMINGS IN ITS PEER REVIEW PROCESS

As noted earlier, EPA's peer review process is instrumental in ensuring that the agency's science is of sufficient quality to support the agency's policies and regulations. In a February 1994 review, we reported that although the EPA Administrator had issued a policy statement on

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[9]EPA Toxic Substances Program: Long-standing Information Planning Problems Must Be Addressed (GAO/AIMD-94-25, Nov. 17, 1993).

peer review, it did not specify the procedures and steps needed to perform peer review.[10] We also found that the agency did not have consistent agencywide controls over the products being sent for external peer review to prevent the premature release of the agency's products and the perception that draft products represented the agency's official policy. In order for EPA's January 1993 peer review policy to be successful, we recommended that EPA (1) set a schedule for developing, completing, and implementing agencywide peer review procedures and (2) develop and implement controls to protect against the premature release of documents by peer reviewers. According to officials from EPA's Office of Research and Development, the agency has taken a number of steps to implement our recommendations.

In a June 7, 1994, memorandum, the EPA Administrator reaffirmed the central role of peer review in the agency's efforts to ensure that the agency's policy decisions rest on sound, credible science and data. The new peer review policy outlines the general principles for peer reviews and requires that EPA program and regional offices implement them. Since October 1994, EPA has had peer review procedures in place for its major scientific and technical work products. Under these procedures, standards and regulations with significant scientific or technical content are externally peer reviewed to ensure that all relevant data have been examined and applied in a sound scientific manner.

Within the framework of the agencywide peer review policy, each of EPA's regions and program offices issued procedures that address its unique needs and has started implementing them to varying degrees. For example, according to EPA officials, the offices that were doing peer reviews are now doing them better and paying more attention to addressing comments by reviewers, and the offices that were not doing peer reviews have started doing them. Moreover, EPA's new policy recognizes that peer reviews take several different forms depending upon the type and complexity of the product. The policy directs EPA's Science Policy Council to work with the various offices on their practices to help ensure as much uniformity as practical. In addition, the Assistant Administrator for Research and Development was recently appointed as EPA's Science and Technical Services Planner, with responsibility for coordinating and integrating science planning and peer review across the agency. Agency officials added that while they have already seen improvements in the agency's peer review process, the relative newness of the procedures (about 7 months) and the resulting few products that have been peer reviewed under them make continued oversight necessary to ensure the policy's success.

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In conclusion, Mr. Chairman, our prior work has shown numerous problems with the quality of EPA's scientific data and the way the agency manages its data systems. These problems cut across the various media and pollutants regulated by EPA and have limited the agency's ability to

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[10]Peer Review: EPA Needs Implementation Procedures and Additional Controls (GAO/RCED-94-89, Feb. 22, 1994).

assess risks and measure environmental results. EPA has acknowledged these problems in its fiscal year 1994 FIA report. To its credit, the agency has taken action to address some problems associated with data management systems and has implemented procedures to improve its peer review process.

Mr. Chairman, as the Congress considers legislation to strengthen requirements for conducting risk and benefit assessments (which provide a critical basis for regulatory decision-making), the need for accurate and complete data will be even more important. We believe that EPA's ability to meet such requirements will depend on its continued emphasis on improving the quality of its data and its data management systems.

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