



Highlights of [GAO-06-595](#), a report to the Chairman, Committee on Environment and Public Works, U.S. Senate

Why GAO Did This Study

Over 100,000 chemicals, pollutants, and toxic substances are used in the United States and regulated by the Environmental Protection Agency (EPA). EPA uses risk assessment to determine the health risk from exposure to these substances, collectively referred to as contaminants. In the last 12 years, independent reviewers have examined this process and made recommendations for how it could be improved. GAO was asked to (1) identify the significant recommendations that have been made to improve human health risk assessment; (2) describe what EPA has done to modify its human health risk assessment process; (3) determine the effects these past modifications have had on the preparation of risk assessments; and (4) identify any additional actions experts believe EPA could take to improve its process, and the barriers it would face in doing so.

What GAO Recommends

GAO recommends that EPA enhance early planning of each risk assessment, identify and communicate data needs to the public and private research community, and support development and implementation of in-depth training for risk assessors and managers. EPA neither agreed nor disagreed with our findings and recommendations. However, the agency provided specific technical comments, which we incorporated as appropriate.

www.gao.gov/cgi-bin/getrpt?GAO-06-595.

To view the full product, including the scope and methodology, click on the link above. To view the results of GAO's survey of EPA's risk assessors, click www.gao.gov/cgi-bin/getrpt?GAO-06-637SP. For more information, contact John Stephenson at (202) 512-6225 or stephensoj@gao.gov.

HUMAN HEALTH RISK ASSESSMENT

EPA Has Taken Steps to Strengthen Its Process, but Improvements Needed in Planning, Data Development, and Training

What GAO Found

Since 1994, independent reviewers recommended that EPA better plan its risk assessments. In doing so, they said EPA should better utilize scientific data it has and identify other data it needs on the potential adverse effects from exposure to contaminants, and prioritize and support research to meet those needs. Furthermore, reviewers recommended that EPA better evaluate the analytic tools it uses and employ more powerful tools when appropriate. Reviewers also recommended that EPA better analyze and characterize the sources of uncertainty in its risk assessments. Finally, they recommended that EPA enhance its analysis of variability in exposure to contaminants and in susceptibility to harm from exposure, and improve how it considers the effects of exposure to multiple contaminants and through many sources.

EPA has strengthened its risk assessment process since 1994 and improvement efforts are ongoing. For example, EPA has increased planning for assessments and has initiated actions to develop missing or incomplete scientific data. EPA has also begun to embrace new methodologies, such as ones to predict how the body will react to a contaminant. Furthermore, EPA now uses a tiered approach to conducting uncertainty analysis, employing more sophisticated analysis as warranted. Finally, EPA has made progress in characterizing variability due to differences in both exposure and susceptibility of exposed individuals and has begun to take steps to address exposure to multiple contaminants and through multiple sources.

According to EPA's risk assessors, the modifications EPA has made have generally helped improve risk assessments. Many EPA risk assessors believe that agencywide guidance has helped them prepare risk assessments and have resulted in greater consistency across program offices. Furthermore, while most assessors report collaboration with internal and external entities is effective and has improved the quality of risk assessments, some said conflicting priorities and poor communication hindered collaboration among some EPA offices. Finally, while risk assessors said training has helped them gain skills and knowledge, over 70 percent said that more in-depth or relevant training would improve their risk assessment abilities.

Experts identified additional actions EPA could take to further improve its risk assessment process, recognizing that it may face barriers in doing so. Experts said EPA could improve its planning process by better focusing on scientific data needs and involving stakeholders early to obtain their concurrence with EPA's approach. Experts also said EPA could more thoroughly evaluate methods and models, transparently document its analytic choices, and enhance internal review. Finally, experts said EPA could provide additional training for risk assessors, managers, and stakeholders on the risk assessment process. Experts, however, said that the scientific complexity of risk assessment, the difficulty of obtaining and applying data, and a cultural resistance to deviating from established methods could act as obstacles to successfully making such changes.