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Comptroller General  
of the United States

United States Government Accountability Office  
Washington, DC 20548

**PRESS RELEASE**

**GAO ADDS THREE ISSUES, DROPS ONE OTHER,  
ON 2009 “HIGH-RISK” LIST**

***Financial Institution Regulation System, FDA Oversight of Medical Products,  
And EPA Assessments of Toxic Chemicals Are New Additions***

WASHINGTON, DC (January 22, 2009) – The U.S. Government Accountability Office (GAO) today released the biennial update to its list of federal programs, policies, and operations that are at “high risk” for waste, fraud, abuse, and mismanagement or in need of broad-based transformation.

Gene L. Dodaro, Acting Comptroller General of the U.S. and head of the GAO, announced that the regulatory system governing U.S. financial institutions and markets, the Food and Drug Administration’s (FDA) oversight of medical products, and the Environmental Protection Agency’s (EPA) assessment and control of toxic chemicals have all been added to the High-Risk List. At the same time Dodaro announced enough progress had been made to remove one item from the list: the Federal Aviation Administration’s (FAA) air traffic control modernization. These changes result in 30 programs and operations on GAO’s 2009 High-Risk List.

“The three areas added to this year’s High-Risk List are all vital to the public’s well being. It’s clear that basic changes are needed to how the federal government regulates the financial system, oversees medical products, and assesses and controls toxic chemicals. I am hopeful that the inclusion of these issues will lead to greater scrutiny and spur needed reforms,” Dodaro said.

The Acting Comptroller General released the 2009 list ([GAO-09-271](#)) at a bipartisan briefing on Capitol Hill with leaders of the Senate Homeland Security and Governmental Affairs Committee and the House Oversight and Government Reform Committee. Dodaro also noted that progress had been made, though not yet enough to remove the high-risk designation, in many of the areas remaining on the High-Risk List. “We at GAO look forward to continuing to work with Congress and the new administration to help hasten progress,” Dodaro said.

The list is updated every two years and released at the start of each new Congress to help in setting oversight agendas. Recent Congresses and administrations have been particularly alert to GAO’s High-Risk List and have used its findings to help tailor agency-specific solutions as well as broader initiatives across government.

(more)

“The Department of Defense continues to dominate the High-Risk List. The military’s lack of progress is of growing concern to GAO. DOD owns eight areas on the High-Risk List outright, and it shares government wide responsibility for an additional seven areas,” Dodaro said.

Here is additional information on the 2009 additions:

- **THE OUTDATED U.S. FINANCIAL REGULATORY SYSTEM.** The worst financial crisis since the Great Depression has revealed major weaknesses in the U.S. financial regulatory system, which failed to keep pace with recent market trends, such as the emergence of large, interconnected financial conglomerates, and the development of new, often complex, investment products. In the near term, strong oversight is needed to ensure that the huge sums being deployed by the Treasury Department and other government entities are achieving their goals and are being used efficiently. Long term, GAO believes that modernizing the U.S. financial regulatory system and aligning it to current conditions is an essential step to reducing the likelihood that our nation will experience another financial crisis similar to the current one.
- **FDA OVERSIGHT OF MEDICAL PRODUCTS.** New laws, the complexity of items submitted to FDA for approval, and the globalization of the medical products industry are challenging FDA’s ability to guarantee the safety and effectiveness of drugs, biologics, and medical devices. As a result, the American consumer may not be adequately protected from unsafe and ineffective medical products. FDA needs to improve the data it uses to manage the foreign drug inspection program, do more inspections of foreign establishments that manufacture drugs or medical devices, more systemically review the claims made in drug advertising and promotional material, and ensure that drug sponsors accurately report clinical trial results.
- **EPA’S PROCESSES FOR ASSESSING AND CONTROLLING TOXIC CHEMICALS.** EPA’s ability to protect public health and the environment depends on credible and timely assessments of the risks posed by toxic chemicals. Its Integrated Risk Information System, which contains assessments of more than 500 toxic chemicals, is at serious risk of becoming obsolete because EPA has been unable to keep its existing assessments current or to complete assessments of important chemicals of concern. Overall, EPA has finished only nine assessments in the past three years; at the end of 2007, most of the 70 ongoing assessments had been underway for more than five years. EPA urgently needs to streamline and increase the transparency of this assessment process. The agency also requires additional authority than currently provided in the Toxics Substance Control Act to obtain health and safety information from the chemical industry and to shift more of the burden to chemical companies to demonstrate the safety of their products.

Here is additional information on the 2009 removal:

(more)

- **FAA AIR TRAFFIC CONTROL MODERNIZATION PROGRAM.** Faced with growing air traffic and aging equipment, FAA launched an ambitious effort in 1981 to modernize its air traffic control system. Key projects, however, were plagued by cost overruns, schedule delays, and performance shortfalls. Because of the program's expense-estimated at \$36 billion-and its critical importance to safe and efficient air travel, GAO added FAA air traffic control modernization to the High-Risk List in 1995. GAO is removing this program from its 2009 High-Risk List because of FAA's progress in addressing most of the root causes of its past problems and the agency's commitment to sustaining progress. FAA's efforts have yielded results, including deploying new systems across the country and incurring fewer cost overruns. GAO will continue to monitor the modernization as well as the transition to the planned satellite-based Next Generation Air Transportation System.

There were 14 areas on the High-Risk List when the program was started in 1990. Since then, there have been 37 additions, 19 removals (eight of which were among the original 14), and 2 areas that were consolidated. The full list is attached.

The 2009 High-Risk List is available on-line at: <http://www.gao.gov/docsearch/featured/highrisk.html>. For more information, contact Susan Becker at GAO's Office of Public Affairs: (202) 512-4800.

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# GAO's 2009 High-Risk Series

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## High-Risk List

### Addressing Challenges in Broad-Based Transformations

- Modernizing the Outdated U.S. Financial Regulatory System **(New)**
- Protecting Public Health through Enhanced Oversight of Medical Products **(New)**
- Transforming EPA's Processes for Assessing and Controlling Toxic Chemicals **(New)**
- 2010 Census **(New in March 2008)**
- Strategic Human Capital Management
- Managing Federal Real Property
- Protecting the Federal Government's Information Systems and the Nation's Critical Infrastructures
- Implementing and Transforming the Department of Homeland Security
- Establishing Effective Mechanisms for Sharing Terrorism-Related Information to Protect the Homeland
- DOD Approach to Business Transformation
  - Business Systems Modernization
  - Personnel Security Clearance Program
  - Support Infrastructure Management
  - Financial Management
  - Supply Chain Management
  - Weapon Systems Acquisition
- Funding the Nation's Surface Transportation System
- Ensuring the Effective Protection of Technologies Critical to U.S. National Security Interests
- Revamping Federal Oversight of Food Safety

### Managing Federal Contracting More Effectively

- DOD Contract Management
- DOE's Contract Management for the National Nuclear Security Administration and Office of Environmental Management
- NASA Acquisition Management
- Management of Interagency Contracting

### Assessing the Efficiency and Effectiveness of Tax Law Administration

- Enforcement of Tax Laws
- IRS Business Systems Modernization

### Modernizing and Safeguarding Insurance and Benefit Programs

- Improving and Modernizing Federal Disability Programs
- Pension Benefit Guaranty Corporation Insurance Programs
- Medicare Program
- Medicaid Program
- National Flood Insurance Program

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Source: GAO.