STRATEGIC GOAL 2:

Enhance the Ability of the Nation's Health Care System to Effectively Respond to Bioterrorism and Other Public Health Challenges

HHS has a number of initiatives and programs directed at protecting Americans from bioterrorist attacks and other public health challenges. The events of Hurricane Katrina, September 11, 2001 and subsequent anthrax attacks have reinforced the HHS role in protecting Americans from attacks on our health and food supply by enhancing preparedness and response capabilities.

This report highlights three programs that contribute to achieving this strategic goal including the Food and Drug Administration's (FDA) Field Foods Program, Health Resources and Services Administration's (HRSA) Hospital Preparedness Program, and CDC's Terrorism Preparedness and Emergency Response Program.

FDA works to supply responsive regulatory review of new biodefense medical countermeasures and plays a major role by inspecting high risk domestic food manufacturers and enhancing food import inspections to protect our Nation's food supply and prevent food borne illness. HRSA assists hospitals and other medical facilities to prepare for health consequences of bioterrorism and other mass casualty events. CDC has an integral role in strengthening State and local public health infrastructure to effectively respond to emergencies.

The Office of Public Health Emergency Preparedness (OPHEP) was established to direct the Department's efforts in preparing for, protecting against, responding to, and recovering from all acts of bioterrorism and other public health emergencies that could affect the civilian population. OPHEP serves as the focal point within HHS for these activities, directing and coordinating the development and implementation of a comprehensive HHS strategy.

The goals described in this section represent HHS' progress towards building the necessary infrastructure to respond to bioterrorist and other public health challenges.

Highlighted Programs

- 2a: FDA Field Foods Program
- 2b: HRSA Bioterrorism Hospital Preparedness program
- 2c: CDC Terrorism Preparedness and Emergency Response program

2a Field Foods Program
Food and Drug Administration

Significance
FDA's Prior Notice Center was established in response to regulations promulgated in conjunction with the Public Health Security and Bioterrorism Preparedness Act of 2002. This Act requires notification to the FDA [specifically the Prior Notice Center] that an article of food, including animal feed or pet food, is being imported or offered for import into the United States in advance of the arrival of the article of food at the U.S. border. The Prior Notice Center's mission is to identify imported food products that may be intentionally contaminated with biological, chemical, or radiological agents, or which may pose significant health risks to the American public, and to prevent them from entering into the United States. The Prior Notice Center targets food and animal feed commodities that have been identified as high-risk based on either threat assessments that have been conducted or the receipt of specific intelligence indicating the items may cause death or serious injury due to terrorism or other food related emergencies.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or present the potential of a significant health risk.	45,000	89,034	Met
Data Source: Field Data Systems			

Result Analysis
In FY 2006, FDA achieved this goal by collaborating with the Department of Homeland Security's Customs and Border Protection to direct field personnel to conduct 89,034 intensive security reviews of Prior Notice Submissions in order to identify products that may be contaminated before they enter the food supply. This exceeded the FY 2006 target by 44,034.

It should be noted that the number of import security reviews performed by the Prior Notice Center is contingent on the total number of Prior Notice Submissions that match targeted criteria based on intelligence, known risk factors, and other information regarding individuals and companies of interest involved in the shipping process. FDA is not able to know in advance how many of the prior notices submitted will need to have security reviews since the candidates are selected on the basis of risk factors and not in relation to the volume of submissions.

Trends	Fiscal Year Actual				
Performance Measure	2002	2003	2004	2005	2006
Perform prior notice import security reviews on food and animal feed line entries considered to be at risk for bioterrorism and/or present the potential of a significant health risk.	N/A	N/A	33,111	86,187	89,034

Data Collection
All prior notice data regarding incoming shipments is submitted electronically via the Automated Broker Interface of Department of Homeland Security's Customs and Border Protection's Automated Commercial System and/or FDA's web-based Prior Notice System Interface. It is not until the prior notice contains the minimal data element requirements and has passed the internal validation edits that a prior notice confirmation number is issued electronically to the submitter. The data then is screened against the risk-based criteria and flagged for intensive manual review.

The manually reviewed prior notice data is scrutinized for accuracy and verified in historic and contemporary shipping and law enforcement databases to uncover derogatory information and potential discrepancies. The prior notice data and any additional shipment data obtained from the databases are sorted through an automated targeting system that assimilates the data and further associates it with sensitive information contained in law enforcement databases maintained by Department of Homeland Security's Customs and Border Protection's and other agencies.

Based on the comprehensive outcome of this research, a decision is made whether to allow the shipment to proceed to FDA general admissibility status, to refuse the shipment until all data is submitted correctly and adequately, or to classify the shipment as a potential bioterrorism or significant public health threat following consultation with CBP and direct FDA field investigators and/or the 9,500 CBP field agents available to examine the shipment prior to entering the country.

Completeness
The completeness of the prior notice security review can be assessed at each level of the review process described in the Data Collection section. The first step helps ensure that the prior notice minimally contains data for all the required fields. This step is entirely electronic, and is ascertained for effectiveness routinely by the contractors.

Reliability
Once the completeness of the data has been verified, the next step of the process subjects the data to a series of validation edits. This step is also entirely electronic, and the contractors routinely determine its effectiveness. Throughout the process the data is vetted in conjunction with CBP using internal, external and classified sources. Reviewers also manually complete a research sheet for each shipment that they review.

Adjustments to the editing and rejection process can be tested on the reporting data for effectiveness prior to implementation. Likewise, the separation of high-risk products from the entire pool of prior notice submissions involves establishing electronic criteria that target and mark elements of the prior notice data that coincide with intelligence and prevailing risk assessments.

2b National Bioterrorism Hospital Preparedness Program
Health Resources and Services Administration (HRSA)

Significance
The goal of the Bioterrorism Hospital Preparedness program, which is part of the President's Homeland Security Initiative, is to ready hospitals and supporting health care entities to deliver coordinated and effective care to victims of terrorism and other public health emergencies. The program requires that States in cooperation with hospitals and other health care entities develop plans to address surge capacity in response to potential terrorist and other threats. Surge capacity is the hospital and supporting health care entity's ability to evaluate and care for a markedly increased volume of patients—one that exceeds normal operating capacity. This requirement is based on the concept that improved outcomes can be achieved when critical components of preparedness are formalized in a plan and organized into a system of care. While a plan alone is insufficient to being prepared, the plan is foundational. Without a plan a State's hospitals and health care system will not be prepared. The performance measure indicates the extent to which program awardees have met the requirement to develop plans to address surge capacity.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
Percent of awardees that have developed plans to address surge capacity	100%	100%	Met
Data Source: Grantees' progress reports			

Result Analysis
The number of awardees that have developed plans for a potential incident involving at least 500 casualties per million in each jurisdiction contributes to an adequate level of preparedness to respond to a mass casualty event. By FY 2005, 100 percent of awardees had developed such plans, and, as awardees were the same, 100 percent had surge capacity plans in FY 2006, meeting the target. Plans for surge capacity address the following issues: (1) hospital bed capacity for adults and children, (2) the capability for isolation and decontamination, (3) appropriate staffing, (4) appropriate medical prophylaxis and treatment for hospital staff and their family members, (5) personal protective equipment, (6) capacity for trauma and burn care, (7) capacity for mental health care, (8) communications and information technology, and (9) hospital laboratory connectivity and capacity. Plans focus on *capacity* of the delivery system. Now that all awardees have plans in place, the program is focusing on *capability*, i.e., the ability to operate based on the plan as indicated by training, exercises, evaluation, and corrective actions.

Trends	Fiscal Year Actual				
Performance Measure	2002	2003	2004	2005	2006
Percent of awardees that have developed plans to address surge capacity	N/A	59%	89%	100%	100%

Data Collection
Information for this measure was obtained through review of awardees' FY 2004 end-of-the-year progress reports, and awardees' FY 2005 mid-year progress reports.

Completeness
All data submitted by awardees are self-reported. The completeness of this data is checked through progress report reviews and site visits conducted by project officers.

Reliability
All data submitted by awardees are self-reported. The reliability of this data is checked through progress report reviews and site visits conducted by project officers.

2c Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention (CDC)

Significance
It is important to exercise preparedness plans to identify gaps, prepare and implement corrective action plans, and evaluate activities. The Division of State and Local Readiness (DSLR) provides funding and written guidance via the Public Health Emergency Preparedness Cooperative Agreement to 62 States, territories, and local public health departments.

The public health system's ability to respond may be validated by either mock events or actual events. Mock events may include one or more activities (e.g., case studies, scenarios, tabletop/desktop exercises, partial-system/whole-system exercises, small-/large-scale multi-jurisdictional exercises, etc.). Mock events allow CDC to quickly identify and address gaps (e.g., preparedness plans, staffing, equipment, training) that prevent timely, efficient and effective responses.

Performance Measure	Fiscal Year 2006		
	Target	Actual	Result
100 percent of state public health agencies improve their capacity to respond to exposure to chemicals or category A agents by annually exercising scalable plans and implementing corrective action plans to minimize any gaps identified.	100%	12/2006	Deferred
Data Source: Grantee Progress Reports			

Result Analysis

The FY 2005 target of 25 percent was met for this measure. FY 2006 data are expected by December 2006. Grantees submit semi-annual progress reports on May 1 and November 30 of each year. The May reports are included with grantee applications, budgets and work plans; the November reports are included with Financial Status Reports and cover activities for the fiscal year. All reports are submitted via the Division of State and Local Readiness' (DSLR) electronic management information system, DSLR MIS. Following the analysis of the November reports, the FY 2006 result will be updated. Because the performance measure was established during DSLR's FY 2005 PART review, FY 2005 was the first required reporting year.

Trends	Fiscal Year Actual				
Performance Measure	2002	2003	2004	2005	2006
100 percent of State public health agencies improve their capacity to respond to exposure to chemicals or category A agents by annually exercising scalable plans and implementing corrective action plans to minimize any gaps identified.	N/A	N/A	N/A	94% of state public health agencies have developed plans for at least one priority agent	12/2006

Data Collection
Via DSLR MIS, each grantee submits an annual application, work plan and two semi-annual grantee progress reports. The Public Health Emergency Preparedness Cooperative Agreement provides the format for applications. The DSLR MIS simultaneously notifies the CDC Project Officer when the application is ready for review and prevents further changes by the grantee until the Project Officer provides recommended changes. A detailed technical review is conducted by CDC Project Officers and Subject Matter Experts. DSLR's Outcome, Monitoring, and Evaluation Branch monitor MIS, review data entered by grantees, and collaborate with Project Officers to address identified issues. The Director also meets weekly with Division Directors for briefings on status, priority issues and action plans.

Completeness
DSLR MIS provides a standard format for data reporting among grantees. Semi-annual progress reports are self-reports by grantees, which may affect the quality of data reported. Through the above monitoring process, and ongoing communication with grantees, DSLR's Outcome, Monitoring, and Evaluation Branch (or more appropriate subject) helps ensure the highest possible level of accuracy of information at the time of release.

Reliability
DSLR's Outcome, Monitoring, and Evaluation Branch continually works to validate received data and strengthen the link between technical assistance, training, tools and written guidance provided by CDC and the enhancement and maintenance of state and local public health capacity. The review and monitoring processes facilitate reliability by emphasizing consistent standards, multi-level reviews, ongoing communication and information-sharing.