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June 2010

BIOSURVEILLANCE

Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader

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June 2010

BIOSURVEILLANCE

Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-10-645, a report to Congressional Committees

Why GAO Did This Study

The U.S. government has a history of employing health surveillance to help limit malady, loss of life, and economic impact of diseases. Recent legislation and presidential directives have called for a robust and integrated biosurveillance capability; that is, the ability to provide early detection and situational awareness of potentially catastrophic biological events. The Implementing Recommendations of the 9/11 Commission Act directed GAO to report on the state of biosurveillance and resource use in federal, state, local, and tribal governments. This report is one in a series responding to that mandate. This report addresses (1) federal efforts that support a national biosurveillance capability and (2) the extent to which mechanisms are in place to guide the development of a national biosurveillance capability. To conduct this work, GAO reviewed federal biosurveillance programs, plans, and strategies and interviewed agency officials from components of 12 federal departments with biosurveillance responsibilities.

What GAO Recommends

GAO recommends that the Homeland Security Council direct the National Security Staff to identify, in consultation with relevant federal agencies, a focal point to lead the development of a national biosurveillance strategy to guide the capability's development.

GAO provided a copy of this draft to the 12 federal departments and the National Security Staff.

View GAO-10-645 or key components.
For more information, contact William O. Jenkins, (202)-512-8777.

What GAO Found

Federal agencies with biosurveillance responsibilities—including the Departments of Health and Human Services, Homeland Security, and Agriculture—have taken or plan to take actions to develop the skilled personnel, training, equipment, and systems that could support a national biosurveillance capability. GAO previously reported that as the threats to national security have evolved over the past decades, so have the skills needed to prepare for and respond to those threats. Centers for Disease Control and Prevention (CDC) officials stated that skilled personnel shortages threaten the capacity to detect potentially catastrophic biological events as they emerge in humans, animals, or plants. To address this issue, some federal agencies are planning or have taken actions to attract and maintain expertise using fellowships, incentives, and cooperative agreements. Moreover, CDC has called for the development of a national training and education framework to articulate professional roles and competencies necessary for biosurveillance. The Department of Agriculture has also developed training programs to help ensure that diseases and pests that could harm plants or animals can be identified. In addition, federal agencies have taken various actions designed to promote timely detection and situational awareness by developing (1) information sharing and analysis mechanisms, (2) laboratory networks to enhance diagnostic capacity, and (3) equipment and technologies to enhance early detection and situational awareness.

While national biodefense strategies have been developed to address biological threats such as pandemic influenza, there is neither a comprehensive national strategy nor a focal point with the authority and resources to guide the effort to develop a national biosurveillance capability. For example, the National Security Council issued the National Strategy for Countering Biological Threats in November 2009. While this strategy calls for the development of a national strategy for situational awareness, it does not meet the need for a biosurveillance strategy. In addition, this strategy includes objectives that would be supported by a robust and integrated biosurveillance capability, such as obtaining timely and accurate insight on current and emerging risks, but it does not provide a framework to help identify and prioritize investments in a national biosurveillance capability. GAO previously reported that complex interagency efforts, such as developing a robust, integrated, national biosurveillance capability, could benefit from an effective national strategy and a focal point with sufficient time, responsibility, authority, and resources to lead the effort. Efforts to develop a national biosurveillance capability could benefit from a national biosurveillance strategy that guides federal agencies and other stakeholders to systematically identify risks, resources needed to address those risks, and investment priorities. Further, because the mission responsibilities and resources needed to develop a biosurveillance capability are dispersed across a number of federal agencies, efforts to develop a biosurveillance system could benefit from a focal point that provides leadership for the interagency community.

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Chairman
The Honorable Susan M. Collins
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Bennie Thompson
Chairman
The Honorable Peter King
Ranking Member
Committee on Homeland Security
House of Representatives

A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic, could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security. In January 2010, the bipartisan Commission for the Prevention of Weapons of Mass Destruction Proliferation and Terrorism, which was established by the Implementing Recommendations of the 9/11 Commission Act to address the threat that the proliferation of weapons of mass destruction poses to the United States, gave the nation a failing grade in its efforts to enhance capabilities for rapid response to prevent biological attacks from inflicting mass casualties.[1] The commission reported that unless the world community acts, it is more likely than not that a weapon of mass destruction will be used in a terrorist attack somewhere in the world by the end of 2013. Further, the report stated that such a weapon is more likely to be biological than nuclear.[2]

The U.S. government has a long history of employing disease surveillance activities to help limit malady, loss of life, and economic impact. Traditional disease surveillance activities involve trained professionals

[1]Pub. L. No. 110-53, §§ 1851-59, 121 Stat. 266, 501-04 (2007).

[2]Bob Graham and Jim Talent, Commission on the Prevention of Weapons of Mass Destruction Prolferation and Terrorism, *Prevention of WMD Proliferation and Terrorism Report Card* (Washington, D.C.: Jan. 26, 2010).

engaged in monitoring, investigation, confirmation, and reporting in an effort to further various missions including, but not limited to, detecting signs of pathogens in humans, animals, plants, food, and the environment. However, in recent years experts and practitioners, reacting to an increasing awareness of the speed and intensity with which a biological weapon of mass destruction or highly pathogenic strain of emerging infectious disease could affect the nation, have sought to augment the traditional surveillance activities with biosurveillance programs and systems. The dual purposes of biosurveillance are (1) to detect as early as possible a potentially catastrophic biological event and (2) to enhance situational awareness—including awareness, comprehension of meaning, and projection into the near future about events—by improving the quality of information available to support response and policy actions in the face of such an event.

Since at least the 1990s, there has been an ongoing and evolving effort by the federal government in conjunction with its partners to address the need for a strategic approach to improving disease surveillance and response. Recognizing the potentially devastating consequences that could flow from biological events—both natural and intentional—responsible federal officials and other experts have, in various formats, called for better integration of multiple disparate surveillance and related mission activities to help support a strong national biosurveillance capability. For example, among the federal government's initiatives to confront the threat of biological events was a presidential directive that called for the development of a national, robust, and integrated biosurveillance capability that provides timely warning and ongoing characterization of catastrophic biological events, drawing on the systems, resources, and information from existing human, animal, plant, food, and environmental surveillance activities.[3] Ensuring the development of such a national biosurveillance capability involves attention to the resources—personnel, training, equipment, and systems—that underpin various surveillance efforts across the federal government, as well as mechanisms to help direct effective and efficient use of those resources to support the capability.

Many federal departments and agencies pursue missions and manage programs that might contribute to a national biosurveillance capability.

[3]Homeland Security Presidential Directive 21: *Public Health and Medical Preparedness* (Washington, D.C.: Oct. 18, 2007).

The Department of Health and Human Services (HHS) is the federal agency with primary responsibility for disease surveillance—including food-borne illnesses—in humans. The Department of Agriculture (USDA) is the primary federal agency with responsibility for pest and disease surveillance in animals and plants as well as food-borne illnesses within the agricultural industries. As the agency with lead responsibility for protecting against and responding to threats and hazards to the nation, the Department of Homeland Security (DHS) is concerned with the prevention of bioterrorist attacks as well as preparing the nation to respond to biological events in order to minimize human and economic losses. In addition, the Homeland Security Council was established by executive order in 2001 to serve as a mechanism for ensuring coordination of homeland security-related activities of executive departments and agencies and effective development and implementation of homeland security policies.[4] The establishment of the Homeland Security Council was subsequently codified in statute with the enactment of the Homeland Security Act of 2002.[5]

Around the same time that the President issued a directive calling for a national biosurveillance capability, Congress articulated a similar goal with respect to a biosurveillance capability in the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act)—to enhance the capability of the federal government to rapidly identify, characterize, localize, and track biological events of national concern by integrating and analyzing data relating to human, animal, plant, food, and environmental surveillance.[6] The 9/11 Commission Act also directed us to examine the state of federal, state, local, and tribal government biosurveillance efforts and the federal government's use of resources to implement and execute biosurveillance systems.[7] This report responds in part to that mandate by examining the extent to which a national, robust, integrated biosurveillance capability has been established. Specifically, the report examines the following: (1) federal

[4] See Exec. Order 13,228 66 Fed. Reg. 51,812(Oct. 8, 2001).

[5]Pub. L. No. 107-296 § 901, 116 Stat. 2135, 2258 (Nov. 25, 2002). On May 26, 2009, the President announced the full integration of White House staff supporting national security and homeland security. The Homeland Security Council will be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland.

[6]Pub. L. No. 110-53 § 1101, 121 Stat. 266, 375-79 (2007) (codified at 6 U.S.C. § 195b).

[7]§ 1102, 121 Stat. at 379.

agency efforts to provide resources—personnel, training, equipment, and systems—that support a national biosurveillance capability; and (2) the extent to which mechanisms are in place to guide the development of a national biosurveillance capability.

In December 2009, in response to the same mandate, we issued work addressing the efforts of DHS's National Biosurveillance Integration Center (NBIC), which was established in the 9/11 Commission Act to enhance federal biosurveillance capabilities.[8] We also have ongoing work on state, local, tribal, and territorial biosurveillance activities, from which we expect to issue a report in winter 2011.

To address our objectives, we reviewed key legislation and presidential directives related to biosurveillance, including the Homeland Security Act of 2002,[9] the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,[10] the Pandemic and All Hazards Preparedness Act of 2006,[11] and Homeland Security Presidential Directives (HSPD) 9, 10, and 21.[12] This report focuses on surveillance efforts for one or more of the following biosurveillance domains: human health, animal health, plant health, food, and the environment (specifically, air and water). It focuses primarily on seven federal departments that have key roles and responsibilities—based on agency missions, statutory responsibilities, presidential directives, or programmatic objectives—for biosurveillance and related mission activities, including protecting public health, agriculture, and national security. These departments are the Departments

[8]See GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

[9]Pub. L. No. 107-296, 116 Stat. 2135 (2002).

[10]Pub. L. No. 107-188, 116 Stat. 594 (2002).

[11]Pub. L. No. 109-417, 120 Stat. 2831 (2006).

[12]HSPD-9, *Defense of United States Agriculture and Food*, was issued in January 2004 to establish a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. HSPD-10, *Biodefense for the 21st Century*, issued in April 2004, discusses the threat of bioterrorism; establishes the four pillars of biodefense—(1) threat awareness, (2) prevention and protection, (3) surveillance and detection, and (4) response and recovery—and describes actions underway or to be taken to strengthen each pillar. HSPD-21, *Public Health and Medical Preparedness*, was issued in October 2007 to establish a National Strategy for Public Health and Medical Preparedness, which builds upon principles set forth in HSPD-10 with the goal of transforming the national approach to protecting the health of the American people against all disasters.

of Agriculture, Defense (DOD), Homeland Security, Health and Human Services, Interior (DOI), as well as the Environmental Protection Agency (EPA) and the United States Postal Service (USPS). To understand how federal agencies have planned or coordinated their biosurveillance efforts, we reviewed key agency and interagency documents, including concepts of operation, surveillance and implementation plans, and biodefense strategies. For example, we reviewed NBIC's Concept of Operations for the National Biosurveillance Integration System, agency strategies and plans for conducting surveillance, and the National Security Council's National Strategy for Countering Biological Threats. We conducted interviews with officials and observed operations at federal agencies—particularly DHS, HHS, and USDA, which have the larger and more direct mission responsibilities for biosurveillance and related mission activities—to understand their roles and responsibilities and how their activities support the national biosurveillance capability. We also collected and analyzed information on the resources, systems, and equipment they use; the other governmental and nongovernmental entities with whom they partner; and the limitations they have encountered in conducting their biosurveillance missions. We also reviewed reports published by nongovernmental entities—for example, the National Academy of Sciences's Institute of Medicine and the Center for Biosecurity—related to public health, disease detection, bioterrorism, biodefense, and emergency management. We also reviewed our prior work on federal surveillance activities, food safety, intergovernmental and interagency collaboration, and national security issues. We compared information we collected from agency documents and officials to our previous work related to national strategies and focal points for leadership to identify mechanisms that could help support crosscutting efforts to build and sustain a national biosurveillance capability.[13] More detailed information about our scope and methods appears in appendix I.

We conducted this work from December 2008 through May 2010 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

[13]See GAO, *Combating Terrorism: Selected Challenges and Related Recommendations*, GAO-01-822 (Sept. 20, 2001) and *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, GAO-04-408T (Washington, D.C.: Feb. 3, 2004) and *Interagency Collaboration: Key Issues for Congressional Oversight of National Security Strategies, Organizations, Workforce, and Information Sharing*, GAO-09-904SP (Washington, D.C.: Sept. 25, 2009).

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

As shown in figure 1, biosurveillance is a concept that emerged in response to increased concern about biological threats from emerging infectious diseases and bioterrorism. Biosurveillance is carried out by and depends on a wide range of dispersed entities. Federal biosurveillance responsibilities, likewise, are spread across an array of agencies and provided for in multiple laws and presidential directives.

Figure 1: Biosurveillance in Brief

What is it?

In the biological context, surveillance is the ongoing collection, analysis, and interpretation of data to help monitor for pathogens in plants, animals, and humans; food; and the environment. The general aim of surveillance is to help develop policy, guide mission priorities, and provide assurance of the prevention and control of disease. In recent years, as concerns about consequences of a catastrophic biological attack or emerging infectious diseases grew, the term biosurveillance became more common in relation to an array of threats to our national security. Biosurveillance is concerned with two things: (1) reducing, as much as possible, the time it takes to recognize and characterize biological events with potentially catastrophic consequences and (2) providing situational awareness—that is, information that signals an event might be occurring, information about what those signals mean, and information about how events will likely unfold in the near future.

Why is it important?

Although catastrophic events are rare, there are a number of threats of biological origin with the potential to cause catastrophic consequences. Since the 1970s, newly emerging diseases have been identified at the unprecedented rate of one or more per year. Moreover, terrorism experts have warned that both terrorists and nations have sought to obtain biological weapons. Finally, the nation's food and agriculture systems face threats from natural and intentional origin that could have devastating consequences in terms of both health and economic loss.

How is it done?

Biosurveillance requires effective organizational systems, people, and technologies to ensure the nation's ability to detect a biological event with potential for catastrophic consequences and to provide situational awareness for response that gives decision makers and the public accurate information about how to prevent, manage, or mitigate catastrophic consequences. The backbone of biosurveillance is traditional disease surveillance systems, which help professionals to recognize unusual disease signals and analyze their meaning, but generally have inherent limitations that affect the speed with which their results can be determined, communicated, and acted upon. Numerous federal, state, local, and private sector entities with responsibility for monitoring plant, animal, and human health, food, and the environment have roles to play both in supporting traditional surveillance activities and in designing systems to focus specifically on enhancing detection and situational awareness. Because of the vast array of activities and entities associated with effective biosurveillance, ongoing interagency and intergovernmental collaboration is crucial.

Source: GAO analysis of agency data; Art Explosion.

Social and Economic Conditions Contribute to the Threat of a Catastrophic Biological Event

Epidemiology

Epidemiology is the study of diseases in populations of humans or other animals, specifically how, when, and where they occur.

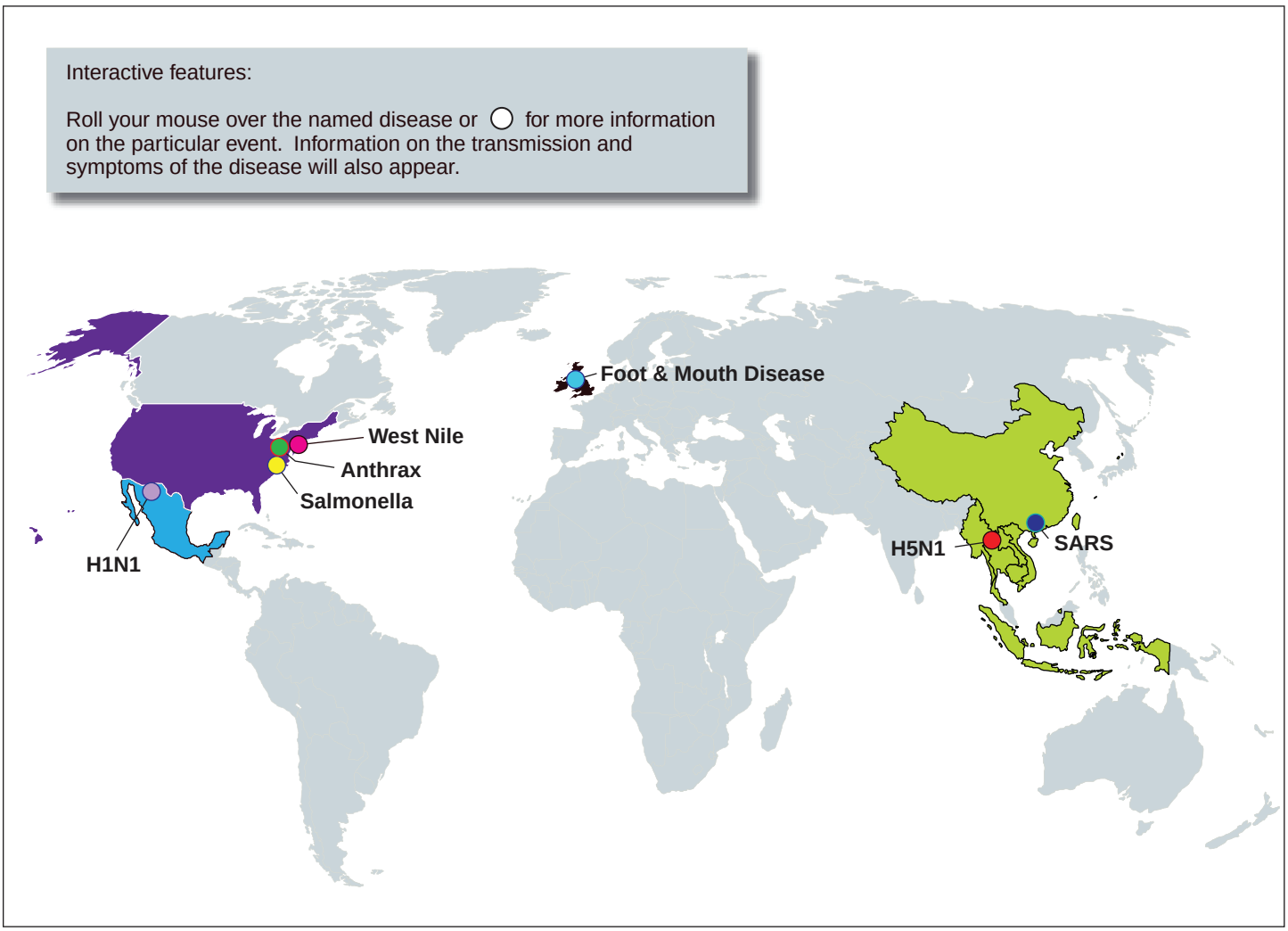
Epidemiologists have an important responsibility in public health matters. It is their goal to determine what factors are associated with diseases (risk factors), and what factors may protect people or animals against disease (protective factors). The science of epidemiology was first developed to discover and understand possible causes of contagious diseases like smallpox, typhoid, and polio among humans. It has expanded to include the study of factors associated with non-transmissible diseases like cancer and of poisonings caused by environmental agents.

The Council of State and Territorial Epidemiologists—an organization of member states and territories representing public health epidemiologists—provides technical advice and assistance to partner organizations and to federal public health agencies such as CDC. The Council supports the use of effective public health surveillance and good epidemiologic practice through training, capacity building, developing standards for practice, and advocating for resources and scientifically based policy.

Source: GAO.

In an era of rapid transit and global trade, the public health and agricultural industries, as well as natural ecosystems including native plants and wildlife, face increased threats of naturally occurring outbreaks of infectious disease and accidental exposure to biological threats. According to the World Health Organization (WHO), infectious diseases are not only spreading faster, they appear to be emerging more quickly than ever before. Since the 1970s, newly emerging diseases have been identified at the unprecedented rate of one or more per year. There are now nearly 40 diseases that were unknown a generation ago. In addition, during the last 5 years, WHO has verified more than 1100 epidemic events worldwide. Figure 2 shows select disease occurrences worldwide in recent decades. Additional information about the occurrences is available electronically in pop-up boxes on the map or in print in appendix II. Examples of emerging infectious disease include Severe Acute Respiratory Syndrome (SARS), H5N1 influenza (avian flu), and the H1N1 influenza that resulted in a global pandemic in 2009. The potential impact of these events is not limited to public health. For example, the avian influenza outbreaks in Asia and Eastern Europe were reminders that the public health sector is intrinsically linked to the agriculture, trade, tourism, economic, and political sectors.

Figure 2: Select Worldwide Disease Occurrences in Recent Decades



Sources: GAO analysis; Map Resources (map).

Due to the rapid and constant movement of people and commodities—such as animals, plants, and food—biological agents can be carried by passengers or containers on airplanes and boats and slip across national borders unnoticed as infectious diseases are transferred from person to person through close contact with one another. Ecological changes, such as changes in land use, and the globalization of the food supply are also associated with the emergence and spread of infectious disease. Animals also face the threat of infectious disease, and in some cases diseases—

known as zoonotic diseases—can be transferred between animals and people. Zoonotic diseases represent at least 65 percent of newly emerging and reemerging infectious diseases in recent decades. Many important factors contribute to the proliferation of zoonotic diseases, including the growth of human and domestic animal populations and the increasingly close physical proximity within which humans and their domestic animals live with wild animals.

Some disease agents can also be weaponized and used as weapons of mass destruction to disrupt economies and endanger human, animal, and plant health. Since the attacks of September 11, 2001, there has been concern that another terrorist attack on U.S. soil could involve biological or other weapons of mass destruction. Groups like the Center for Counterproliferation Research at the National Defense University and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (established by the 9/11 Commission Act) have warned that the biological weapons threat is real, with evidence that terror groups like Al Qaeda have had active biological weapons programs in the past and approximately 12 countries are suspected of seeking biological weapons.

Emerging disease and bioterrorism concerns also surround the nation's agriculture and food supply, as well. Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.

In addition, the United States faces growing food safety challenges from fresh and processed foods that become contaminated well before they reach the consumer, leading to outbreaks linked to foods that have not previously been associated with foodborne illnesses. For example, according to USDA, leafy greens are the category of produce most likely to be associated with an outbreak. Recent outbreaks of foodborne illness have also focused public attention on the increasing potential for widespread dissemination of contaminated products. For example, beginning in September 2006, the United States experienced an outbreak of E. coli 0157:H7 associated with the consumption of tainted spinach grown in California; this outbreak resulted in 205 victims in 26 states suffering severe disease. Three people died. Widespread outbreaks of

other foodborne illnesses, such as Salmonella, have also occurred from contaminated peanut butter and tomatoes.[14]

We reported in March 2005 that although the United States has never experienced a terrorist attack against agriculture, it is vulnerable for a variety of reasons, including the relative ease with which causative agents of diseases that could affect livestock and crops could be obtained and disseminated.[15] Many of these diseases are endemic in other parts of the world and can be extracted from common materials, such as soil. Farms in general are easily accessible because they are located in rural areas and have minimal security, especially crop farms. Moreover, the highly concentrated breeding and rearing practices of our livestock industry may make it a vulnerable target for terrorists because diseases could spread rapidly and be difficult to contain. For example, between 80 and 90 percent of grain-fed beef cattle production is concentrated in less than 5 percent of the nation's feedlots. Therefore, the deliberate introduction of a highly contagious animal disease in a single feedlot could have serious economic consequences.[16] In addition, a number of disease causing agents can infect and be spread by wildlife. According to officials at DOI, it may be difficult to control a novel pathogen if it is introduced into native wildlife. These officials noted that the gregarious habits of many wildlife species can enhance their susceptibility to catastrophic losses from select diseases, and because of their mobility, there is potential for infectious disease to spread quickly to new locations and populations.

Finally, pathogens can be carried through or introduced into the environment, causing damage to health and economies. Drinking water utilities across the country have long been recognized as potentially vulnerable to terrorist attacks of various types, including physical disruption, bioterrorism, chemical contamination, and cyber attack.[17] Damage or destruction by terrorists could disrupt not only the availability

[14]See GAO, *Food Safety: Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness*, GAO-08-794 (Washington, D.C.: June 10, 2008).

[15]See GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, GAO-05-214 (Washington, D.C.: Mar. 8, 2005).

[16]GAO-05-214.

[17]See GAO, *Drinking Water: Experts' Views on How Future Funding Can Best Be Spent To Improve Security*, GAO-04-29 (Washington D.C.: Oct. 31, 2003).

of safe drinking water, but also the delivery of vital services that depend on these water supplies, such as fire suppression. People and animals also face the threat of becoming ill from inhaling certain biological agents, some of which occur naturally in our environment and some that can be weaponized and intentionally released to cause catastrophic disruption. Concerns about weaponized airborne pathogens were amplified by the anthrax attacks conducted through the mail a month after the September 11, 2001, attacks on the World Trade Center and the Pentagon.

Laws and Presidential Directives Direct Agencies to Strengthen Biosurveillance and HSPD-21 Calls for an Integrated National Biosurveillance Capability

As figure 3 shows, federal laws and directives call for HHS, USDA, DHS, and other federal agencies to take action to strengthen biosurveillance. The most recent of these—Homeland Security Presidential Directive-21—synthesizes and reiterates actions in other laws and directives, explicitly calling for a national biosurveillance capability. In calling for this national capability, HSPD-21 discusses certain aspects related to the personnel, training, equipment, and systems needed. For example, among the elements it describes as necessary for a robust and integrated national capability are enhanced clinician awareness, stronger laboratory diagnostic capabilities, integrated biosurveillance data, and an epidemiologic surveillance system with sufficient flexibility to tailor analyses to new syndromes and emerging diseases.

Figure 3: Time Line of Laws and Presidential Directives Related to Biosurveillance

Date		
July 2002	Public Health Security and Bioterrorism Preparedness and Response Act of 2002[a]	• Requires HHS to establish an integrated system of public health alert communications and surveillance networks between and among federal, state, and local public health officials, and public and private health-related laboratories, hospitals, and other health care facilities.
January 2004	HSPD-9: Defense of United States Agriculture and Food	• Directs DOI, USDA, HHS, and EPA to develop—for animals, plants, wildlife, food, human health, and water—robust, comprehensive, and fully coordinated surveillance and monitoring systems, including new tracking systems and integrated laboratory networks that use standardized protocols and procedures. • Directs DHS to create a biological threat awareness capacity to enhance detection and characterization of biological attacks that integrates and analyzes data on human, animal, and plant health; food; and water quality.
April 2004	HSPD-10: Biodefense for the 21st Century	• States that the federal government is working to develop an integrated and comprehensive system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment to permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption.
December 2006	Pandemic and All-Hazards Preparedness Act of 2006[b]	• Requires HHS to establish a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information to enhance early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and other public health emergencies.
August 2007	Implementing Recommendations of the 9/11 Commission Act of 2007[c]	• Requires DHS to establish a center to enhance the ability of the nation to rapidly identify, characterize, localize, and track a biological event of national concern by integrating and analyzing data relating to human health, animal, plant, food, and environmental monitoring systems.
October 2007	HSPD-21: Public Health and Medical Preparedness	• States that the United States must develop a nationwide, robust, and integrated biosurveillance capability, with connections to international disease surveillance systems, in order to provide timely warning and situational awareness.

Source: GAO Analysis of Laws and Presidential Directives.

[a]Pub. L. No. 107-188, § 103, 116 Stat. 594, 604 (2002) (codified at 42 U.S.C. § 247d-4(b)).

[b]Pub. L. No. 109-417, § 202(2), 120 Stat. 2831, 2845 (2006) (codified at 42 U.S.C. § 247d-4).

[c]Pub. L. No. 110-53, § 1101, 121 Stat. 266, 375 (2007) (codified at 6 U.S.C. § 195b).

In the case of biological threats, timely detection of biological agents is a precursor to effective response; therefore, a national biosurveillance capability like the one described in HSPD-21 is an essential tool in the nation's preparedness to confront catastrophic threats. Capabilities to carry out any broad emergency management mission—like biosurveillance—are made up of (1) planning, (2) organization and

leadership, (3) personnel, (4) equipment and systems, (5) training, and (6) measurement/monitoring.

A national biosurveillance capability like the one described in HSPD-21 would largely rely on an interagency effort because the mission activities and accompanying resources that support the capability—personnel, training, equipment, and systems—are dispersed across a number of federal agencies. For example, HHS's Centers for Disease Control and Prevention (CDC) has primary responsibility for human health and USDA for plant and animal health. Responsibility for various food sources is split between USDA and HHS's Food and Drug Administration (FDA). DHS, as the agency with primary responsibility for securing the homeland, is responsible for coordinating efforts to prevent, protect against, respond to, and recover from biological attacks. The resources—personnel, training, equipment, and systems–that support a national biosurveillance capability reside within the separate agencies that acquire and maintain them in pursuit of their missions, which overlap with but are not wholly focused on biosurveillance.

A national biosurveillance capability also depends upon participation from state, local, and tribal governments. Few of the resources required to support the capability are wholly owned by the federal government. The responsibility and capacity for collecting most information related to plant, animal and human health, food, and environmental monitoring resides within state, local, and tribal governments, or private sector entities—such as hospital and other private health care providers. In the United States, state and local public health agencies have the authority and responsibility for carrying out most public health actions, and the federal government generally cannot compel state, local and tribal governments, or private sector entities to provide information or resources to support federal biosurveillance efforts. Instead, individual federal agencies, in pursuit of their missions, attempt to build relationships and offer incentives—like grants—to encourage voluntary cooperation with specific federal efforts.

In addition, although traditional disease surveillance systems designed to collect information on the health of humans, animals, and plants are the backbone of biosurveillance—because they, among other things, provide mechanisms for ongoing monitoring and specific information about outbreaks to inform response—they also rely on time-intensive testing and confirmation practices. The inherent time lag, combined with limitations arising from reliance on data not owned by the federal government, presents challenges that limit the promise of traditional disease

Situational Awareness

The term situational awareness is frequently used in the context of emergency response, and has a number of definitions. Officials at CDC with key biosurveillance responsibilities subscribe to a definition that includes three components: (1) awareness that a situation has occurred (e.g., detection of a biological condition that differs from the norm), (2) comprehension of its meaning (e.g., characterization of the nature and scope of a biological event), and (3) projection of its likely course in the near future (e.g., how its nature and scope will evolve and the decision implications of that evolution, particularly whether it may have catastrophic consequences). The projection aspect of situational awareness, sometimes overlooked in other definitions, is crucial in the biological context, because of the high degree of uncertainty and instability as the event unfolds over a period of time, which is not necessarily encountered in more discrete disaster events.

Source: GAO.

Timeliness of Surveillance

According to CDC experts, the timeliness of surveillance is measured by the time between when individuals are first exposed to a disease agent and the time that public action is taken to address the outbreak. Given the nature of disease incubation and other factors, indicators of outbreaks in humans may require days or weeks to become apparent within the traditional public health infrastructure. For many diseases, there is no quantifiable benchmark for timely detection. However, experts agree that recognizing more quickly that a catastrophic biological event may be imminent can improve the effectiveness of mitigation measures by orders of magnitude.

Source: GAO.

surveillance alone to provide the timely detection and situational awareness that is the goal of a national biosurveillance capability. For additional information on the contributions and associated challenges of traditional federal surveillance activities to monitor for pathogens in plants, animals, humans, and food see appendix III. For more information on specific federal programs that can be used to support biosurveillance see appendix IV.

Federal Agencies Have Taken Actions That Support a National Biosurveillance Capability

Federal agencies have taken or are planning some actions to improve the personnel, training, and systems and equipment that support a national biosurveillance capability, including, but not limited to, planning to assess workforce needs, sponsoring recruitment and training efforts, seeking to facilitate information sharing, and applying technologies to enhance surveillance.

Federal Agencies Have Taken Actions to Help Ensure Availability of Personnel to Monitor Human, Animal, and Plant Health Domains for Biosurveillance Purposes

Some of the professions that underpin the surveillance mechanism for a national biosurveillance capability currently face and are expected to continue to confront workforce challenges—particularly workforce shortages; however, some federal agencies with key biosurveillance responsibilities have efforts underway to help confront those challenges. We reported in September 2009 that as the threats to national security—which include the threat of bioterrorism and pandemic outbreak—have evolved over the past decades, so have the skills needed to prepare for and respond to those threats.[18] We also found that like other federal efforts to address modern national security challenges that require collaboration among multiple agencies, an effective biosurveillance capability relies on qualified, well-trained professionals with the right mix of skills and experience. Figure 4 provides examples of the workforce involved with detection and situational awareness activities that support biosurveillance.

[18] GAO-09-904SP.

Figure 4: Examples of Workforce Involved with Biosurveillance Activities

Public health	Animal health	Plant/forest health
 • Hospitals • Physicians • Clinicians • State or local public health officials • Pharmacists • Laboratories • Epidemiologists	 • Veterinarians • Wildlife officials • Zoo officials • Producers • Laboratories • Epidemiologists	 • Agriculture extension agents • Customs and Border Protection and USDA inspection officials • Growers • Foresters • Taxonomists • Laboratories

Source: GAO; Art Explosion.

The Institute of Medicine

The Institute of Medicine is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.

Established in 1970, the Institute of Medicine is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863. Nearly 150 years later, the National Academy of Sciences has expanded into what is collectively known as the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the Institute of Medicine.

Source: GAO.

The public health and health care workforce is expected to continue to confront shortfalls in the coming years, which could threaten the federal government's ability to develop a national biosurveillance capability. According to CDC officials, serious public health and health care workforce shortages currently exist due to factors such as the exodus of retiring workers, an insufficient supply of trained workers, inadequate funding, and uncompetitive salaries and benefits. In discussing concerns about looming workforce shortages, CDC officials pointed to a December 2008 Association of Schools of Public Health estimate that by 2020 the nation will face a shortfall of over 250,000 public health workers.[19] CDC officials said that states and communities nationwide report needing more public health nurses, informaticians, epidemiologists, laboratory workers, statisticians, and environmental health experts. Moreover, the Institute of Medicine stated in 2009 that the unevenness of organizational and technical capacity at state and local levels across the public health system weakens the nation's preparedness to detect and, especially, to respond to and manage the consequences of a major health emergency.[20]

[19]See Association of Schools of Public Health, *ASPH Policy Brief: Confronting the Public Health Workforce Crisis* (Washington, D.C.: December 2008). This projection is based on a ratio of 220 public health workers for every 100,000 U.S. residents, which was the public health force ratio in 1980.

[20]See Institute of Medicine and National Research Council of the National Academies, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version: Summary* (Washington, D.C.: 2009).

We also reported in February 2009 that the animal health field faces workforce shortages that could affect the ability of professionals to be prepared and enabled to detect and warn of biological events.[21] For example, USDA officials have expressed concern about the future size and skills of the veterinarian workforce, particularly veterinary pathologists who are integral to the work conducted in USDA's diagnostic laboratories, including work on diseases that threaten animal and human health. Further, USDA officials have also expressed concern about the availability of taxonomists, whose expertise is critical to characterizing threats and providing warning of a potentially catastrophic biological event involving plants.

Although the workforce shortages threaten to diminish capacity to detect signals of potentially catastrophic biological events as they emerge, some federal agencies are planning or have taken actions to help mitigate them. In particular, in its National Biosurveillance Strategy for Human Health, CDC named the biosurveillance workforce as one of its priority areas.[22] To enhance workforce capability, CDC's strategy calls for assessing the current biosurveillance workforce capability, identifying and addressing gaps, ensuring the workforce is competent, developing recruitment and retention strategies for professionals across diverse fields, and establishing a national-level governance body for the biosurveillance workforce across agency boundaries and disciplines. CDC has also taken actions to help increase the number of public health workers, including extending service and learning fellowships in epidemiology, informatics, laboratory, and management.[23]

[21]We previously reported on the need to maintain a veterinarian workforce with sufficient expertise to help protect public and animal health. See GAO, *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, GAO-09-178 (Washington, D.C.: Feb. 4, 2009). In 2005, we also reported that USDA faced a challenge helping states to prepare for animal and plant emergencies because of an insufficient number of Area and Regional Emergency Coordinators. See GAO-05-214.

[22]In response to HSPD-21's charge for HHS to enhance biosurveillance for human health, CDC has created the National Biosurveillance Strategy for Human Health with input from federal and other partners. The strategy identifies six focus areas for enhancing biosurveillance. The six are: (1) electronic health information exchange, (2) electronic laboratory information exchange, (3) unstructured data, (4) integrated biosurveillance information, (5) global disease detection and collaboration, and (6) biosurveillance workforce of the future. More information on the National Biosurveillance Strategy for Human Health appears later in this report.

[23]Informatics is the study and application of information science. It involves collection, classification, storage, retrieval, and dissemination of recorded knowledge.

Moreover, with respect to animal and plant workforce, the federal government is implementing measures to help ensure an adequate workforce. For example, we reported in February 2009 that USDA has set a goal of recruiting at all veterinary colleges and universities. In addition, USDA is using incentives, such as bonuses, to attract and maintain its veterinarian workforce. [24] In addition, USDA has identified tactics to build the capacity and retain the experience of taxonomists. USDA is also using cooperative agreements and funding to enlist taxonomic services from nonfederal institutions to identify and confirm identifications of exotic plant pests. According to USDA officials, they have increased the number and variety of these agreements in recent years, increased availability of professionals who can help identify threats to plants by nearly 50 percent in the past 20 years, and created a career ladder to retain experienced and talented workers. Further, in response to recommendations we made in February 2009 to address veterinarian shortages, in November 2009, the Office of Personnel Management established the governmentwide Veterinary Medical Officer Talent Management Advisory Council. [25] The purpose of the council is to lead the design and implementation of a governmentwide workforce strategy for federal veterinary medical workers. The council held its first meeting in March 2010 and is in the process of gathering workforce data from all federal agencies with veterinarian medical officers.

Federal Agencies Have Supported or Implemented Training and Accreditation Programs

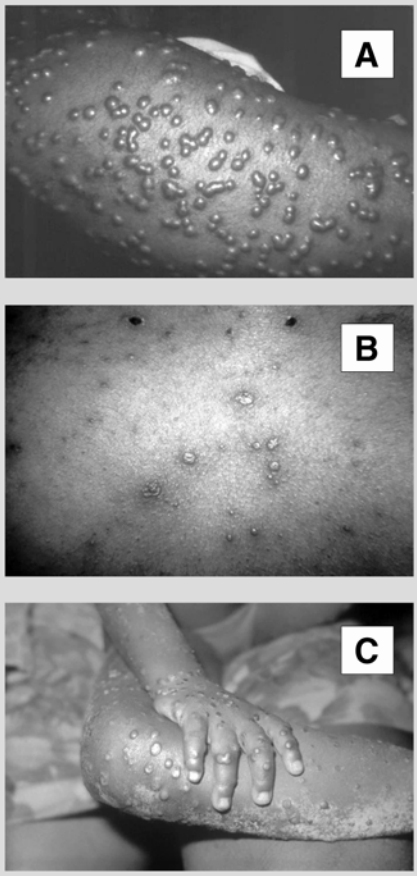
Federal agencies have supported programs to help with workforce development at the state and local levels that respond partially to the ongoing challenge of maintaining a trained cadre of professionals who operate in fields where professional issues, systems, and technologies continue to evolve over time. Training and accreditation programs are essential to developing a knowledgeable workforce with the skills needed to identify potential threats to human, animal, and plant health. An effective medical response to a biological event would depend in part on the ability of individual clinicians and other professionals to identify, accurately diagnose, and effectively treat diseases, including many that

[24] GAO-09-178.

[25] GAO-09-178.

Can you Detect Bioterrorism?

Imagine you are a busy emergency department doctor. Could you identify and correctly diagnose a case of smallpox – now believed to be eradicated as a naturally occurring disease but recognized as a bioterrorism threat agent?



Source: CDC.

A. Smallpox
B. Chickenpox
C. Monkeypox

may be uncommon.[26] The opportunity to evaluate signs and symptoms of diseases of concern relies on trained professionals possessing the knowledge needed to identify and order the right lab test to confirm a diagnosis. In addition, detection and warning of a disease threat also relies on these professionals knowing who to call to report the finding.

One challenge federal officials relayed to us is that because the concept of biosurveillance is relatively new and has been evolving over the last decade, there are few if any specialties or concentrations in biosurveillance within epidemiology or other programs. They further noted that while some university programs are beginning to address the issues in their curricula, the general lack of biosurveillance or cross-domain specialties, curricula, and classes in these programs limits the feedback loop between academics and practitioners that helps support innovative solutions.

Another training challenge is keeping up with changes in issues, technologies, and systems. CDC officials told us that public health workers are always challenged with keeping abreast of developments. For example, when a new laboratory tool or method is developed, public health workers must be trained to use them. Epidemiologists also must be trained and educated about new or emerging health issues, infections, software, information technology systems, and tools. Clinicians require continuing education to remain astute. These CDC officials noted that maintaining expertise in a rapidly changing field is difficult, yet having professionals with the right expertise is critical in protecting the public's health, as well as for emergency preparedness and response. For USDA, the increased risks to animal and public health from animal diseases have presented challenges because the expertise needed to identify and respond to the risks of zoonotic diseases has not been defined.

Further, a DOI official expressed concern about maintaining skills and expertise of wildlife health professionals. According to this official, identifying, characterizing, and mitigating threats involving free ranging fish and wildlife populations call for specific training and expertise in wildlife epidemiology and wildlife disease ecology. These officials

[26]See Institute of Medicine and National Research Council of the National Academies, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version: Summary* (Washington, D.C.: 2009).

expressed concern about whether federal inspectors receive sufficient training or have sufficient resources to address disease in free-ranging wildlife populations.

Federal agencies have taken actions to help respond to the challenges arising from evolving fields of study and increased risks of outbreaks impacting more than one domain. For example, in the National Biosurveillance Strategy for Human Health, CDC has called for the development of a national training and education framework to articulate professional roles and competencies necessary for biosurveillance. The strategy also noted that in addition to the traditional public health professions trained in surveillance, there is a need to recruit professionals from other diverse fields including informatics and computational sciences to enhance data sharing, as well as the plant and veterinary sciences to help understand how diseases flow among humans, animals, and plants. Along these lines, CDC has developed a public health informatics fellowship program, which is designed to help address the need for practitioners with a mastery of sophisticated electronic systems to facilitate communication and data exchange among public health personnel at the local, state, and federal levels. Officials at HHS also noted that the National Institute of Health's National Library of Medicine has funded 18 University-Based Biomedical Informatics Research Training programs, of which 10 have special Public Health Informatics tracks.

USDA has also developed training programs to ensure their first detectors are knowledgeable on diseases and pests of significance. For example, USDA has an accreditation program for veterinarians and views the cadre of veterinarians it has accredited as the front line of surveillance for diseases of significance that are not specifically monitored through a program. These accredited state and federal veterinary officials—as we reported in 2005, approximately 80 percent of the veterinary workforce—are dispersed throughout the country and are trained to observe signs and symptoms of diseases and unusual occurrences of illness or death in

animal populations.[27] According to USDA, the United States depends extensively on accredited veterinarians for official functions, such as inspecting, testing, and certifying animal health. For plant surveillance, USDA's National Plant Diagnostic Network began the National First Detector Training Program in 2003. The program offers training to aid USDA's surveillance of plants for pests and diseases. First detectors are individuals who in the course of their activities are in a position to notice an unusual plant pest outbreak, a pest of concern, or symptoms of a pest of concern. The individuals may include growers, nursery producers, crop consultants, pesticide applicators, and master gardeners, among others. According to USDA officials, the training equips participants with the knowledge to detect and report unusual exotic pest or disease activity, which is key to initiating response and mitigation activities.

Federal Agencies Have Efforts Underway to Develop Equipment and Systems to Support Their Biosurveillance Missions

Our analysis of relevant presidential directives and our discussion with federal officials with central responsibilities for monitoring disease and protecting national security indicate that a national biosurveillance capability depends upon systems and equipment that enable rapid detection and communication of signals that might indicate a potentially catastrophic biological event, quick and effective analysis of those signals, and timely dissemination of high-quality and actionable information to

[27]We reported in March 2005 that this USDA accreditation process does not require veterinarians to demonstrate their ability to recognize or diagnose basic clinical signs of foreign animal diseases. Furthermore, once granted, accreditation is valid for life and no continuing education is required. USDA recognized the need to modernize its accreditation process. See GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, GAO-05-214 (Washington, D.C.: Mar. 8, 2005). In 2009, USDA issued a final rule in the *Federal Register* amending the regulations regarding the National Veterinary Accreditation Program with the intent of increasing the level of training and skill of accredited veterinarians in the areas of disease prevention and preparedness. Pursuant to the rule, the accreditation process includes completing an orientation program for foreign animal disease. The rule also requires that veterinarians renew their accreditation every 3 years by completing supplemental training. 74 Fed. Reg. 64, 998 (Dec. 9, 2009).

decision makers.[28] In this vein, federal agencies have taken various actions designed to promote timely detection and situational awareness by developing (1) information sharing and analysis mechanisms, (2) laboratory networks to enhance diagnostic capacity, and (3) equipment and technologies to enhance early detection and situational awareness.

Information Sharing and Analysis Mechanisms

Because the data needed to detect an emerging infectious disease or bioterrorism may come from a variety of sources, the ability to share and analyze data from multiple sources may help officials better collaborate to analyze data and quickly recognize the nature of a disease event and its scope.[29] As illustrated in figure 5, observing related symptoms in human and animal populations, or cross-domain surveillance, may bring concerns into focus more quickly than monitoring human symptoms alone. This may be particularly important as many disease agents have the potential to be weaponized and many of the recent emerging infectious diseases are zoonotic.[30]

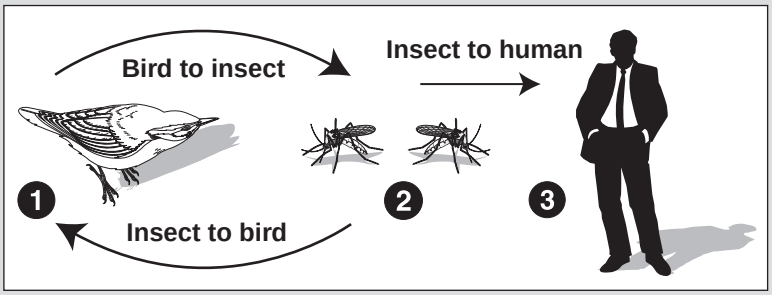
[28]The biodefense HSPDs, as well as the Pandemic and All-Hazards Preparedness Act, address systems as an element to help support the timely detection and situational awareness goals of biosurveillance. HSPD-9 calls for the Secretaries of the Interior, Agriculture, Health and Human Services, the Administrator of the Environmental Protection Agency, and the heads of other appropriate federal departments to build upon and expand current monitoring and surveillance programs to develop robust, comprehensive, and fully coordinated surveillance and monitoring systems. HSPD-10 notes that early warning, detection, or recognition of biological weapons attacks to permit a timely response to mitigate their consequences is an essential component of biodefense, and that development of an integrated and comprehensive attack warning system to rapidly recognize and characterize the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment will permit the recognition of a biological attack at the earliest possible moment and permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption. HSPD-21 calls for the robust and integrated biosurveillance capability previously discussed. The Pandemic and All-Hazards Preparedness Act calls for an interoperable network of systems to support a nationwide situational awareness capability. Pub. L. No. 109-417, § 202(2), 120 Stat. 2831, 2845 (2006).

[29]HSPD-21 and the 9/11 Commission Act each specifically point to the need to integrate data from across various domains, such as human health, animal health, agricultural, meteorological, environmental, and intelligence data. Pub. L. No. 110-53, § 1101, 121 Stat. 266, 375-79 (2007).

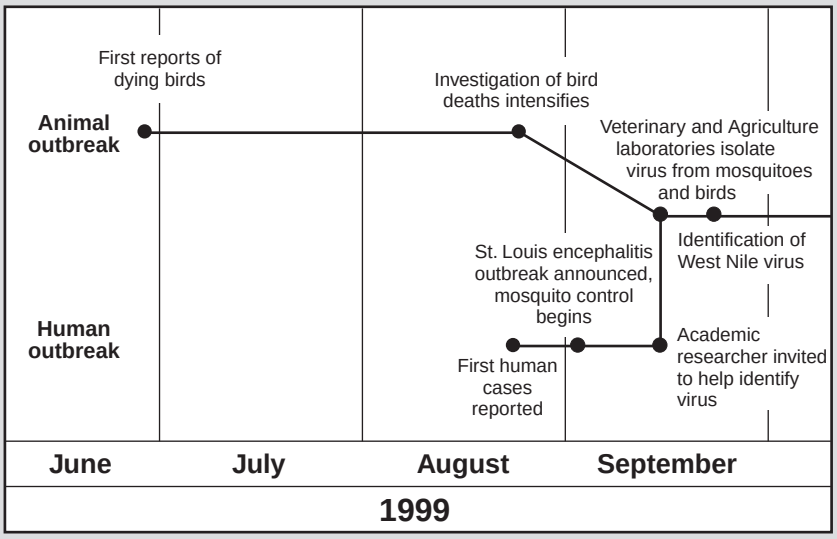
[30]Emerging zoonotic disease outbreaks have brought increased attention to the need for disease surveillance that links and provides information across human and animal health sectors for early detection and response. See G. T. Keusch, M. Pappaioanou, M. C. Gonzalez, K. A. Scott, and P. Tsai, Editors, National Research Council of the National Academies, Committee on Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin, *Sustaining Global Surveillance and Response to Emerging Zoonotic Diseases* (Washington, D.C.: 2009).

Figure 5: West Nile Virus: A Case Study in the Value of Cross-Domain Surveillance

West Nile Virus—a virus with a 3-15 percent fatality rate that passes from mosquitoes to birds and humans—first appeared in the Western hemisphere in 1999.



In reviewing the federal response, we reported that the analysis of the outbreak continued for weeks as separate investigations of sick people and of dying birds.[a] Only after the investigations converged, and after several parties had independently explored other possible causes, was the link made and the virus correctly identified.



We concluded that the time it took to connect the bird and human outbreaks signaled a need for better coordination among public and animal health agencies.

Source: GAO; Art Explosion.

[a]West Nile Virus Outbreak: Lessons for Public Health Preparedness, GAO/HEHS-00-180 (Washington D.C.: Sept. 11, 2000).

One example of a federal initiative designed to improve sharing of biosurveillance information is DHS's National Biosurveillance Integration Center's (NBIC) Biological Common Operating Picture (BCOP), a manually updated Google Maps application of current worldwide biological events being tracked.[31] Officials can view the BCOP on the Homeland Security Information Network.[32] The BCOP provides a situational awareness tool for the National Biosurveillance Integration System (NBIS)—the community of federal and other stakeholders that have information that can be used to enhance the safety and security of the United States against potential biological events of national significance. NBIC supports the BCOP through a system—the Biosurveillance Common Operating Network (BCON)—that monitors, tracks, and disseminates available NBIS-partner information, but relies largely on information from publicly available sources, such as news articles. One of the primary data sources for BCON is an international information gathering service called Global Argus, a federally funded program in partnership with Georgetown University. The service searches and filters over 13,000 overseas media sources, in more than 34 languages.

A similar type of initiative underway at some federal agencies involves developing and maintaining communication tools for information sharing within specialized disciplines. These communication tools may include functions that allow users to send and receive information or view the status of ongoing events. One such tool is a Web-based forum that provides a secure environment for the exchange of information on case reports and allows users to request information or expertise from other users. For example, one such communication tool developed by CDC, known as Epi-X, provides a secure Web-based forum for public health officials to post case reports of conditions and ask other health officials whether they have also seen cases of the condition. The officials can also discuss similarities in the cases that may indicate how the disease is spreading and suggest mitigation measures—for example, product recalls—that could be implemented. In this way, health officials can leverage both information and analytical capacity across agencies, levels

[31]We previously reported on NBIC and the challenges it has faced in obtaining data and resources from its NBIS partners. See GAO-10-171.

[32]The Homeland Security Information Network is a comprehensive, nationally secure and trusted Web-based platform able to facilitate Sensitive but Unclassified information sharing and collaboration among federal, state, local, tribal, private sector, and international partners.

of government, and different regions of the country to help support the early detection and situational awareness goals of biosurveillance. For example, the forum may help them to more quickly and comprehensively determine whether diseases seem to be widespread and what caused them and to discuss treatment options in a secure environment. For more information on specific communication tools, see appendix IV.

In addition, we reported in May 2003 that electronic reporting of data can facilitate data exchange among different databases and allow more rapid and accurate analysis of information from multiple sources.[33] CDC officials noted that laboratory reports could be received by CDC in 72 hours if exchanged through an electronic system, as opposed to the up to 2 weeks it can take for laboratory report hard copies to be sent through the mail. Further, because it facilitates data exchange, standardization can help support the vision of integrated surveillance systems articulated in HSPD-9 and 21. According to CDC officials, the potential benefits of electronic reporting of data in a standardized format are striking and can eliminate the need for analysts to dedicate valuable time to processing and translating data provided in different formats expressed using various terminologies. For example, during the 2001 anthrax event, the results of laboratory tests for anthrax were reported in different formats (e.g., emailed text, mailed hard copy, as attachments in different software programs), and using different terminology, such as "*Bacillus anthracis*," "*B. anthracis*," and "*Anthrax*."[34] These variations in report format and language required analysts at CDC to spend time translating and compiling the data into information that could inform decision making during the event.

To support effective and efficient information sharing, some agencies have efforts underway to promote electronic reporting of information in a standardized format. For example, CDC's Public Health Information Network (PHIN) initiative aims to advance the development of interoperable surveillance and other public health systems at federal, state, and local levels. The initiative defines data and messaging standards

[33]GAO, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Abilities to Respond to Public Health Emergencies*, GAO-03-139 (Washington, D.C.: May 30, 2003).

[34]In 2001, letters laced with anthrax were sent through the mail to two U.S. senators and members of the media. The letters led to the first cases of anthrax disease related to bioterrorism in the United States.

and provides guidance for public health entities to follow in building systems that meet compatibility and interoperability standards for enhanced electronic information sharing. Additionally, HHS, through initiatives to support nationwide health information exchange, has defined specific standards that promote the exchange of biosurveillance information among health care providers and public health authorities.

Within CDC, several surveillance systems have been developed and implemented in accordance with PHIN standards to promote electronic information sharing. One of these is the National Electronic Disease Surveillance System (NEDSS). A primary goal of NEDSS is the ongoing, automatic capture and analysis of data that are already available electronically to minimize the problems of fragmented, disease-specific surveillance systems. The initiative is intended to promote efficient and effective data management and information sharing by eventually consolidating the data collection of CDC's various programmatic disease surveillance activities in one place. For more information on programs that support standardization and electronic data exchange, see appendix IV.

To further enhance and support biosurveillance activities, CDC, DHS and other federal agencies have developed or taken action to gather electronic data from syndromic surveillance systems. Syndromic surveillance uses health-related data collected before diagnosis to look for signals or clusters of similar illnesses that might indicate an outbreak. Examples of syndromic surveillance data are prediagnostic health-related information like patients' chief complaints recorded by a health care worker at the admissions desk of a hospital emergency room and information collected on over-the-counter sales of antidiarrheal medicines that could indicate gastrointestinal disease outbreaks. We reported in 2004 that because these syndromic systems monitor symptoms and other signs of disease outbreaks instead of waiting for clinically confirmed reports or diagnoses of a disease, some experts believe they can increase the speed with which outbreaks are identified. However, we also reported in September 2004 and November 2008 that the ability of syndromic surveillance to more rapidly detect emerging diseases or bioterror events has not yet been

demonstrated, and questions about its cost-effectiveness arise.[35] An example of a syndromic surveillance system is CDC's BioSense—another CDC system that was developed and implemented in accordance with data and message standards defined by the PHIN initiative. BioSense collects electronic data that are voluntarily shared by participating state, local, and other federal public health entities, including data related to infections, injuries, and chronic diseases. Currently the system collects chief complaint data from 570 hospitals and 1,100 federal clinics, and sales data from over 10,000 pharmacies. Because the data and messages are sent and received in standardized formats, the data are integrated into the BioSense system, reducing the need for analysts to manually interpret or manipulate data and are analyzed by the system to enhance the nationwide situational awareness capabilities of public health analysts at CDC.

Even as standardization and data and information-sharing tools improve, other challenges will likely impede information sharing for biosurveillance purposes across federal, state, and local levels of government. We and others have noted that numerous challenges have impeded efforts to coordinate and collaborate across organizational boundaries to integrate biosurveillance and other national security activities.[36] Some such challenges are inherently intergovernmental issues and arise because most of the information needed for biosurveillance is generated and owned outside of the federal government. Therefore, there is limited assurance that state and local governments can or will fully participate in federal information sharing and standardization initiatives like PHIN. CDC officials expressed concern about the differing levels of capacity and

[35]See GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: September 30, 2004) and GAO, *Health Information Technology: More Detailed Plans Needed For the Centers for Disease Control and Prevention's Redesigned BioSense Program*, GAO-09-100 (Washington, D.C.: November 20, 2008).

[36]See, for example, GAO-10-171 and GAO-09-904SP and *National Security: Key Challenges and Solutions to Strengthen Interagency Collaboration*, GAO-10-822T (Washington, D.C.: June 9, 2010).and G.T. Keusch, M. Pappaioanou, M.C. Gonzalez, K.A. Scott, and P. Tsai, Editors, National Research Council of the National Academies, Committee on Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin, *Sustaining Global Surveillance and Response to Emerging Zoonotic Diseases* (Washington, D.C.: 2009) and *Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats*: First Report to the National Biosurveillance Advisory Subcommittee. Health and Human Services, Centers for Disease Control and Prevention, (Washington, D.C.: April 30, 2009). Health and Human Services, Centers for Disease Control and Prevention, (Washington, D.C.: Apr. 30, 2009).

willingness among states to participate in data standardization and electronic information-sharing initiatives.

Moreover, information-sharing challenges also occur among the federal agencies. As we reported in December 2009, NBIC has faced collaboration challenges and has been largely unsuccessful in obtaining from federal partners key resources needed to support data integration and shared analytical capacity.[37] Federal officials from agencies participating in the National Biosurveillance Integration System—such as CDC, USDA, and FDA—described challenges to sharing such information, including concerns about trust and control over sensitive information before it is vetted and verified. In addition, NBIC officials told us and we previously reported that much of the information available to help achieve biosurveillance goals is unstructured and not readily processed by a computer system; while, data that are more easily computer processed often lack the context needed to make appropriate conclusions about whether anomalies actually signal a potential problem.[38]

Laboratory Networks to Enhance Laboratory Diagnostic Capacity

Over the past decade, the federal government has leveraged and enhanced its laboratory capabilities, capacity, resources, and expertise for detecting and warning about biological threat agents by developing and implementing laboratory networks at the federal, state, and local level.[39] In

[37]See GAO-10-171. We recommended that the Director of NBIC work with its interagency partners to finalize a collaboration strategy that clearly defines NBIC's mission and purpose, along with the value of participating for each agency partner; addresses challenges to sharing data and personnel, including clearly and properly defining roles and responsibilities in accordance with the unique skills and assets of each agency; and develops joint strategies, procedures, and policies for working across agency boundaries. DHS concurred with our recommendations. DHS's Chief Medical Officer, who is the head of the organizational unit that houses NBIC, testified in March 2010 that NBIC was working to implement the recommendations and that he recently convened interagency partners to begin discussing the challenges we outlined.

[38]GAO-10-171.

[39]HSPD-9 calls for nationwide laboratory networks for food, veterinary, plant health, and water quality that integrate existing federal and state laboratory resources, that are interconnected, and use standardized diagnostic protocols and procedures. HSPD-21 also calls for strengthening laboratory diagnostic capabilities and capacity in order to recognize threats as early as possible. GAO has previously reported concerns with specific laboratory network procedures and integration efforts. See GAO-05-214 and *Agriculture Production: USDA Needs to Build on 2005 Experience to Minimize the Effects of Asian Soybean Rust in the Future*, GAO-06-337 (Washington, D.C.: Feb. 24, 2006). However, it was beyond the scope of this report to evaluate the individual laboratory networks' capabilities. The ICLN is included here as an illustrative example of efforts agencies are taking to enhance detection and situational awareness.

addition, the federal government led an effort to establish a consortium of laboratory networks that further integrates a number of these networks. In June 2005, 10 federal agencies signed a Memorandum of Agreement establishing the Integrated Consortium of Laboratory Networks (ICLN).[40] The purpose of this consortium is to establish a coordinated and operational system of laboratory networks that provide timely, high-quality, and interpretable results for early detection of acts of terrorism and other events that require integrated laboratory response capabilities. ICLN's individual laboratory networks focus on detecting biological threat agents that affect humans, animals, or plants that contaminate the air, water, or food supply. These laboratory networks which comprise the ICLN are shown in table 1.

Table 1: Laboratory Networks That Comprise the ICLN.

Laboratory network	Members	Mission and capabilities
HHS/CDC's Laboratory Response Network (LRN)	Over 150 federal, military, state, local, and international laboratories	LRN is charged with maintaining an integrated network of federal, military, state, local, and international laboratories that can respond to bioterrorism, chemical terrorism, and other public health emergencies. The biological component of LRN provides network capacity to test for biological agents in a variety of formats including clinical specimens, and food and environmental samples. The laboratories in this component are classified as either reference, national, or sentinel laboratories, depending on the types of tests that the laboratory can perform and how it handles infectious agents.a
USDA's Animal and Plant Health Inspection Service (APHIS) and the National Institute of Food and Agriculture's (NIFA) b National Animal Health Laboratory Network (NAHLN)	Fifty-eight NAHLN laboratories in over 40 states. Nine of these laboratories are also part of the LRN network.	NAHLN is responsible for a functional national network of existing veterinary diagnosis laboratories to rapidly and accurately detect and report animal diseases of national interest. These laboratories include federal, state, and university laboratories. Federal laboratories include the National Veterinary Services Laboratory, which serves as in international reference laboratory and conducts tests and confirms tests for other laboratories, and the Foreign Animal Disease Diagnostic Laboratory, which tests for highly contagious diseases such as foot-and-mouth disease.
USDA's APHIS and NIFA's National Plant Diagnostic Network (NPDN)	The NPDN consists of network of five regional hub laboratories that coordinate plant diagnostic activities in 50 states and 2 territories.	The NPDN is charged with helping federal, state, local, university, and private laboratories to rapidly detect and identify high-consequence pests and pathogens introduced deliberately or accidentally into commercial and natural ecosystems and report these pests and pathogens to appropriate decision makers and responders.

[40]Signatory federal agencies to this agreement include the Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, State and the Environmental Protection Agency.

Laboratory network	Members	Mission and capabilities
USDA's Food Safety Inspection Service and HHS's FDA's Food Emergency Response Network (FERN)	Over 130 FERN laboratories in 50 states. These laboratories include over 100 microbiological-capable facilities. Membership is limited to laboratories from public institutions performing regulatory and diagnostic analytical work.	FERN integrates the nation's food-testing laboratories at the federal, state, and local levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The network also seeks to strengthen laboratory capacities and capabilities, as well as act as surge capacity.
EPA's Environmental Response Laboratory Network (ERLN)	The ERLN integrates capabilities of existing public sector labs with accredited private sector labs to support, as needed, large-scale environmental responses.	The mission of ERLN is to provide federal, state, and local decision makers with reliable, high-quality analytical data used to identify chemical, biological, and radiological contaminants collected in support of response and clean-up activities. ERLN goals include providing laboratory testing capability and capacity to meet EPA's responsibilities for surveillance, response, decontamination, and recovery from incidents involving release of chemical, biological, or radiological contaminants; facilitating the coordination of labs capable of responding efficiently and effectively to incidents; and establishing relationships and priorities with other federal laboratory networks through the ICLN. The ERLN includes the Water Laboratory Alliance, which was developed in response to HSPD-9's call for nationwide laboratory networks for water quality. Its purpose is to provide the water/wastewater sector with an integrated nationwide network of laboratories with the analytical capability and capacity to support monitoring, surveillance, and remediation in response to intentional and unintentional water contamination events involving chemical, biological, and radiochemical contaminants.

Source: GAO analysis of federal agency data.

[a]Reference laboratories can perform tests to detect and confirm the presence of a threat agent and ensure a timely response. Sentinel laboratories are hospital-based facilities that are in direct contact with the public. If these laboratories detect suspicious specimens, they forward the suspect samples to reference laboratories. National laboratories have unique resources to handle highly infectious diseases and to identify and definitively characterize new strains and novel agents.

[b]NIFA is the former USDA Cooperative State Research, Education, and Extension Service (CSREES).

Equipment and Technologies to Enhance Early Detection and Situational Awareness

The federal government is developing and implementing equipment and technologies that can provide additional information to support early detection and situational awareness. For example, the federal government is applying diagnostic technologies to help detect and monitor biological events. Studying disease agents at the molecular level can provide information for situational awareness. Techniques to determine and attribute the source of biological events can be important for both natural and intentional events. In a natural event—such as a foodborne illness—it can help speed detection, focus the investigation, and characterize the extent and severity of disease. For intentional events, it can provide

critical information to help determine the scope of the attack and contribute to law enforcement investigations.[41] One example of such a system is CDC's PulseNet, a national network of public health laboratories that perform DNA "fingerprinting" as a means to help with early identification of outbreaks of foodborne illness with a common source and enhance situational awareness during an event. The PulseNet program provides a tool for participating laboratories to upload and then compare the genetic "fingerprints" of foodborne pathogens isolated from samples taken from sick individuals. The network can identify and label each fingerprint pattern to permit the rapid comparison of these patterns with others in the PulseNet database. PulseNet officials told us that this process can take roughly 2 weeks after receiving a sample. FDA, USDA, CDC, and state public health officials have access to the PulseNet database. See appendix IV for more information on foodborne disease monitoring systems and diagnostic technologies.

Federal agencies have also developed technologies to detect biological agents in drinking water and air. Drinking water utilities across the country have long been recognized as potentially vulnerable to terrorist attacks of various types, including physical disruption, bioterrorism, chemical contamination, and cyber attack.[42] People also face the threat of becoming ill from inhaling certain biological agents—whether naturally occurring or intentionally weaponized and released to cause disease and disruption. EPA has developed a system to detect contamination of drinking water and USPS, DOD, and DHS have developed sensor technologies to detect aerosolized biological agents in the air. EPA's Water Security Initiative program developed a contamination warning system to allow local water utilities to monitor drinking water for contamination by chemical, biological, and radiological agents. The contamination warning system has been designed to provide timely detection and appropriate response to biological events.

Salmonella Outbreak: Case Study in Food Monitoring

In November 2008, CDC's PulseNet staff noted a multistate outbreak of an unusual strain of salmonella infections which was eventually attributed to a brand of peanut butter and peanut paste from a single production facility. It resulted in over 700 confirmed cases of salmonella infection in 46 states.

On November 10, 2008, CDC PulseNet identified a multistate cluster of Salmonella Typhimurium infections (13 cases reported in 12 states) and began monitoring for additional reports of cases with the same DNA fingerprint. On November 24, 2008, PulseNet identified a second multistate cluster of cases (27 cases reported in 14 states) and continued monitoring to identify additional cases.

Based on preliminary information stemming from CDC and states' epidemiological investigation, and collaborating with USDA and public health officials, FDA began its investigation to identify the source of the contaminated peanut butter by inspecting the facility where the implicated peanut butter was made. Following FDA confirmation that salmonella was found at their Blakely, GA facility, on January 13, 2009, the company recalled affected products.

Salmonella Typhimurium

Source: CDC; GAO analysis.

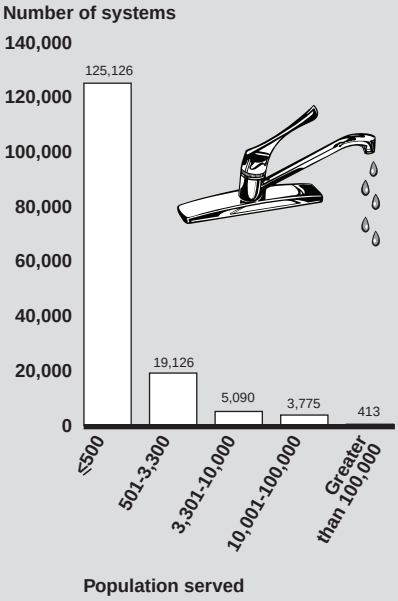
[41]For example, HSPD-10 states the following: Deterrence is the historical cornerstone of defense, and attribution—the identification of the perpetrator as well as method of attack—forms the foundation upon which deterrence rests. Biological weapons, however, lend themselves to covert or clandestine attacks that could permit the perpetrator to remain anonymous. The nation is enhancing deterrence posture by improving attribution capabilities, the ability to perform technical forensic analysis, and the capability to assimilate all-source information to enable attribution assessments.

[42]See GAO, *Drinking Water: Experts' Views on How Future Federal Funding Can Be Best Spent To Improve Security*, GAO-04-29 (Washington D.C.: Oct. 31, 2003).

Monitoring the Nation's Water Supply

According to the EPA, federal oversight of all water utilities, given the size and complexity of the various systems around the country, is not feasible.

EPA reported in 2009 that nationwide, there were more than 150,000 public water systems varied greatly in size. Over 125,000 of these water systems served 500 or fewer people. Only 413 systems served more than 100,000 people each, but these systems, located primarily in urban areas, accounted for nearly half of the total population served.



Source: GAO; Art Explosion.

The system, however, is not widely distributed. Currently, the Greater Cincinnati Water Works in Cincinnati, Ohio is the only locality that has the system fully operating. EPA is assisting local water districts in four other locations—New York City, San Francisco, Dallas, and Philadelphia—with implementation the contamination warning system as part of a five-city pilot project each of which EPA officials stated is to last for four years and be complete in 2012. Local water utilities are to implement this system on a voluntary basis and operate it at their own expense. According to EPA officials, no contamination warning systems has yet been proven to be effective and sustainable for drinking water systems, but the Water Security Initiative is attempting to design, deploy, and test an effective and sustainable system. For more information on the Water Security Initiative, see appendix IV.

USPS, DOD, and DHS have developed and implemented technologies to sample the air and test for specific biological agents.[43] One of these, DHS's Biowatch program, has been implemented in more than 30 metropolitan areas and tests for the presence of multiple biological threat agents.[44] USPS has deployed an indoor monitoring system—Biohazard Detection System—at mail distribution centers nationwide that automatically detects and warns of the presence of the anthrax organism in the air surrounding mail-sorting equipment. DOD has also developed indoor and outdoor monitoring systems to detect airborne chemical, biological, radiological, or nuclear agents in order to protect military interests.

[43]It is beyond the scope of this report to assess the effectiveness of these sensor-based technologies. Previous GAO reports have discussed some of these technologies in more detail. See GAO, *Homeland Security: First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas is Significantly Limited.* GAO-08-180 (Washington, D.C.: June 27, 2008) and Institute of Medicine and National Research Council of the National Academies, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version: Summary* (Washington, D.C.: 2009).

[44]As currently operated, BioWatch filters are collected every 24 hours and delivered to local laboratories, where they are analyzed according to prescribed protocols. If this analysis recognizes one of the biothreat agents that the system is designed to detect, the laboratories report the results to local public health officials, who must then decide how to respond. DHS is developing new detection technology known as Generation 3.0 which would replace the existing technology used by the BioWatch program. This new technology is to provide a fully automated detector which not only collects air samples but also analyzes them for threats.

However, these sensor technologies are limited in their ability to provide early detection because there are constraints on the speed with which the diagnostic testing can be performed. For example, DHS' Biowatch sensor technology depends on air filters which must be collected and transported to a laboratory for diagnostic testing, which can take more than a day.[45] According to senior officials from the Office of Health Affairs and the Science and Technology Directorate at DHS, research and development to eliminate the need for manual collection of samples is underway, but the science needed to do so may not yet be fully mature. Additional information on the USPS, DOD, and DHS biodetection systems can be found in appendix IV.

A National Strategy and a Focal Point Could Help Guide Development of a National Biosurveillance Capability

While some high-level biodefense strategies have been developed, there is no broad, integrated national strategy that encompasses all stakeholders with biosurveillance responsibilities that can be used to guide the systematic identification of risk, assessment of resources needed to address those risks, and the prioritization and allocation of investment across the entire biosurveillance enterprise. Further, while numerous agencies have biosurveillance responsibilities, a single focal point for this effort has not been established. We have reported that developing effective national strategies and establishing a focal point with sufficient time, responsibility, authority, and resources can help ensure successful implementation of complex interagency and intergovernmental undertakings, such as providing a national biosurveillance capability.[46]

A National Biosurveillance Strategy Has Not Yet Been Developed

We reported in 2001 that complex interagency and intergovernmental efforts—for example developing a robust national biosurveillance capability—can benefit from developing a national strategy.[47] In prior work, we identified elements of an effective national strategy including (1) identifying the purpose, scope, and particular national problems and threats the strategy is directed towards; (2) establishing goals, subordinate objectives and activities, priorities, milestones, and performance measures; (3) defining costs, benefits, and resource and investment needs;

[45]See *Biosurveillance: Preliminary Observations on Department of Homeland Security's Biosurveillance Initiatives*, GAO-08-960T (Washington, D.C.: July 16, 2008).

[46]GAO-01-822 and GAO-04-408T.

[47]GAO-01-822.

(4) delineating roles and responsibilities; and (5) integrating and articulating the relationship with related strategies' goals, objectives, and activities.[48]

Although broad national strategies for biodefense have been formulated, there is no national strategy to help guide federal agencies and their partners' efforts to build and maintain the national biosurveillance capability. Two national strategies—the National Security Council's National Strategy for Countering Biological Threats and HHS's National Health Security Strategy—call for further development of biosurveillance strategies and plans to help support their broader biodefense goals. Specifically, the National Strategy for Countering Biological Threats, which is a high-level strategy to provide a framework for future federal efforts to support biological threat preparedness, calls for the development of a strategy for advancing situational awareness and a plan that identifies key elements of information to be shared, critical sensitivities to be protected, and a framework for enabling information exchange. However, this high-level call for additional work does not articulate or assign specific roles and responsibilities; it does not establish specific objectives, activities, milestones, and performance measures; and it does not provide a foundation for determining investment priorities to guide the entire interagency and intergovernmental biosurveillance enterprise.

HHS's Office of the Assistant Secretary for Preparedness and Response issued the National Health Security Strategy (NHSS) in December 2009. The NHSS is designed to achieve two goals: build community resilience and strengthen and sustain health and emergency response systems. One of the strategy's 10 strategic objectives is to ensure the nation has a situational awareness capability. Under this objective, the strategy and its accompanying interim implementation plan emphasize the need for situational awareness obtained through epidemiological and animal disease surveillance as well as monitoring agricultural and food supplies for contamination. This NHSS goal is similar to the call for robust and integrated biosurveillance capabilities in HSPD-21; however, like the National Strategy for Countering Biological Threats, it does not provide a foundation to clarify roles and responsibilities; define specific objectives, activities, and priorities; or guide investment priorities.

[48]GAO-04-408T.

USDA and HHS have drafted strategies for carrying out the missions that support biosurveillance within the animal and human health domains, but these are not intended to support a robust and integrated capability across the entire biosurveillance enterprise.[49] USDA has had a strategic plan for the National Animal Health Surveillance System (NAHSS) since 2005, drafted in part to respond to HSPD-9's call to develop robust, comprehensive, and fully coordinated surveillance and monitoring systems to support timely detection and situational awareness. The plan notes that although consequences of inadequate surveillance could be catastrophic, resources for surveillance activities are limited and have to be judiciously and efficiently allocated. As such, it identifies specific goals and objectives designed to support surveillance mission activities including enhancing timely detection and situational awareness—for example, by encouraging the development and application of new technologies for early and rapid disease detection and data analysis related to foreign and emerging animal diseases. However, this strategy was formulated to help USDA pursue its animal health mission and neither reflects nor provides guidance to help ensure that investments of limited resources to support USDA's mission are aligned with a comprehensive strategy that supports linkages across the biosurveillance enterprise.

Similarly, in response to the same HSPD-9 concept of robust and fully coordinated surveillance, which was reiterated and expanded in HSPD-21, CDC has led the formulation of the National Biosurveillance Strategy for Human Health and an accompanying Concept Plan for Implementation. Noting that the challenges and opportunities for creating a more robust biosurveillance system are substantial and multidimensional, while resources are limited, the strategy outlines six priority areas of focus. Among the priority areas are equipment and systems enhancements to strengthen the way information is used and shared, as well as strategies for addressing workforce issues by helping to ensure the availability of well-trained medical and public health officials. However, this strategy focuses its attention on human health and does not serve the purpose of providing a unified, national biosurveillance strategy to guide the whole biosurveillance enterprise. We spoke with CDC officials responsible for formulating this strategy about its scope, among other things, and they acknowledged that it does not fully address key aspects of biosurveillance

[49]At the time of our review, officials from DOI also said they were in the process of developing a strategic framework to integrate a wildlife disease component in the biosurveillance enterprise but did not yet have a draft they could share with us.

outside of human disease. Further, officials from agencies with key biosurveillance responsibilities, including CDC, DOD, DOI, and USDA, said that efforts to enhance the national biosurveillance capability would benefit from a broader strategic effort that integrated the human health focus with other domains and relevant mission activities.

An Effective National Strategy Could Help Ensure the Development of a National Biosurveillance Capability

Although federal agencies have efforts underway that could provide support for a robust, integrated biosurveillance capability, many challenges remain—looming workforce shortages, providing ongoing training in rapidly evolving fields, information-sharing impediments among systems developed for various purposes, and constraints on environmental monitoring systems. These challenges are complex, inherent to building capabilities that cross mission areas and agencies, and not easily resolved. Having a strategy in place to guide development of a national biosurveillance capability could potentially help agencies address these challenges. A national strategy could define the scope of the problems to be addressed, and in turn could lead to specific objectives and activities for tackling those problems, better allocation and management of resources, clarification of roles and responsibilities, and, finally, to integration of a biosurveillance strategy with other related preparedness and response strategies.

Purpose, Scope and Problems to Be Addressed

A national strategy could help to clarify the purpose and scope of a national biosurveillance capability and the specific problems or risks to be addressed by this capability. While federal agencies have put in place various monitoring programs and systems in pursuit of their agency-specific missions, senior officials we interviewed from agencies with key biosurveillance roles expressed concern that definitional issues, such as the scope of biosurveillance and the range of activities that it should include, are unclear. For example, CDC officials stated that although the National Biosurveillance Strategy for Human Health provides a framework for biosurveillance within the human health domain, questions regarding the scope of this effort remain. Specifically, CDC officials said it is yet to be determined whether human health biosurveillance efforts should be limited to pathogens that directly cause illness in humans or also include events that could indirectly affect the health of humans, such as an agricultural event that causes mass starvation. Other federal officials we interviewed from agencies including USDA, EPA, FDA, and DOD said it was unclear whether the scope of biosurveillance should extend to any event that affects the health of living organisms—humans, plants, and animals—or whether biosurveillance should be limited to detecting and monitoring pathogens that may cause disease. A national strategy for

biosurveillance could allow the federal government to define and agree on key terms, among other things, that could help federal agencies clarify the actions needed to meet their biosurveillance responsibilities.

Goals, Objectives, Activities, and Priorities

A national strategy could help establish goals, objectives, activities, priorities, milestones, and performance measures to help guide the development of a national biosurveillance capability. A national strategy could further clarify the goals of a national biosurveillance capability, building upon the decisions made regarding the scope and purpose of the capability. At the highest level, this could be a description of the ideal "end-state" of what a robust and integrated national biosurveillance capability would be, followed by accountability mechanisms for implementation and ongoing performance monitoring. Federal agencies, such as CDC and USDA, have developed some strategic doctrine that outlines agency priorities in pursuit of their missions, but there is no strategy that outlines national goals, objectives, and priorities for the entire biosurveillance enterprise that would guide the larger federal effort. For example, the National Strategy for Biosurveillance for Human Health, calls for the development of information that would define objectives and funding needs to help mitigate looming workforce shortages. A national strategy could assist in setting priorities, milestones, and desired results across the biosurveillance enterprise—not only for human or animal health—while giving implementing parties flexibility to pursue and achieve those results within a reasonable time frame. In addition, once objectives and priorities are established, outcome-based performance measures could provide information to further refine them over time.

Costs, Benefits, Resources, and Investment Needs

A national strategy could help assess the costs of a robust, integrated, national biosurveillance capability and identify potential benefits of mitigating the problems or risks identified by the strategies' goals and objectives. Currently, limited information is available to develop a reliable, enterprisewide assessment of the costs and benefits of a national biosurveillance capability. According to the Institute of Medicine, the costs of the broader infectious disease-surveillance activities in the public health and health care systems are difficult to determine. The institute reported in 2009 that current budgeting and accounting systems at the local, state, and federal levels do not usually provide this information, and the surveillance costs incurred by the private-sector components of the health

care system are even less readily captured.[50] Similarly, the National Biosurveillance Advisory Subcommittee reported in 2009 that it was unable to establish reliable estimates of the annual cost of U.S. biosurveillance programs, in part because there is no budget activity line for federally funded biosurveillance activities that would allow for tracking total federal spending. The subcommittee noted that although current appropriations do not appear to be sufficient for the tasks at hand, additional cost efficiencies are possible.[51]

In addition, a national strategy could help identify the resources currently being used to support a biosurveillance capability, additional resources that may be needed, and opportunities for leveraging resources. CDC and USDA officials have stated that there is no accurate inventory of resources currently being used to support a biosurveillance capability or of the sources and types of resource investments that would be needed in the future to build a national biosurveillance capability. CDC is developing a National Biosurveillance Registry for Human Health. This registry is to identify existing federal, state, local, and international systems that could support the National Biosurveillance Strategy for Human Health, as well as determine the need for additional systems. According to CDC officials, they have begun to work with FDA in this regard. The CDC officials responsible for the project stated that they have made progress, but also said the registry is complex and will take longer than originally envisioned, in part because the project competes for resources with other projects and duties—including activities to respond to emerging situations like the 2009 H1N1 pandemic—which has affected its progress. Moreover, although CDC's registry is an encouraging step, this registry project does not yet involve all the federal agencies and programs that play a role in biosurveillance and, thus, will not approach a complete picture of the entire biosurveillance enterprise for some time. USDA has also undertaken a separate registry project, known as the U.S. Animal Health and Productivity Surveillance Inventory, for animal health surveillance

[50]See Institute of Medicine and National Research Council of the National Academies, Committee on Effectiveness of National Biosurveillance Systems: BioWatch and the Public Health System, *BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats: Abbreviated Version: Summary* (Washington, D.C.: 2009).

[51]*Improving the Nation's Ability to Detect and Respond to 21st Century Urgent Health Threats: First Report to the National Biosurveillance Advisory Subcommittee,*. Health and Human Services, Centers for Disease Control and Prevention (Washington, D.C.: Apr. 30, 2009).

activities as a mechanism to leverage resources. The USDA project identifies opportunities for efficiencies across programs, such as allowing animal samples to be simultaneously tested for multiple diseases thus eliminating the need for different surveillance programs to undertake multiple sampling campaigns. According to USDA, the Web-based registry contains approximately 300 animal surveillance programs, most at the federal level. A national strategy that identifies the resources associated with the entire biosurveillance enterprise could help further identify efficiencies and opportunities for leveraging resources.

Finally, a national strategy could prioritize where those additional resources and investments should be targeted and guide agencies to allocate resources accordingly. A national strategy could begin to address the difficult but critical issues of who pays and how funding for biosurveillance will be sustained in the future. Federal officials from agencies with key biosurveillance roles that we interviewed noted that there are few guarantees that funding for potentially valuable activities that are not solely devoted to one specific disease surveillance activity will be sustained. For example, CDC developed a program designed to integrate human-health disease information from across the entire agency into daily reports of disease activity to enhance situational awareness for HHS decision makers, as well as federal and nonfederal partners. According to CDC officials, this program was designed as a key supporting activity to achieve the National Biosurveillance Strategy for Human Health priority of "Integrated Biosurveillance Information." However, the program was funded from general funds that compete with other CDC activities for scarce resources, and the CDC director determined that other activities were a higher priority. In another example, officials from USDA's National Surveillance Unit, whose mission is to develop and enhance national animal health surveillance, noted that one of their main challenges involves the limitations of funding mechanisms. For example, these officials told us that the National Surveillance Unit produces evaluations of surveillance systems in order to make recommendations for improvements and cost efficiencies. However, the current funding mechanisms, such as line items and earmarks, make it difficult to efficiently move the funding stream from a program where less surveillance is needed to a new disease area that has need for more intensive testing.

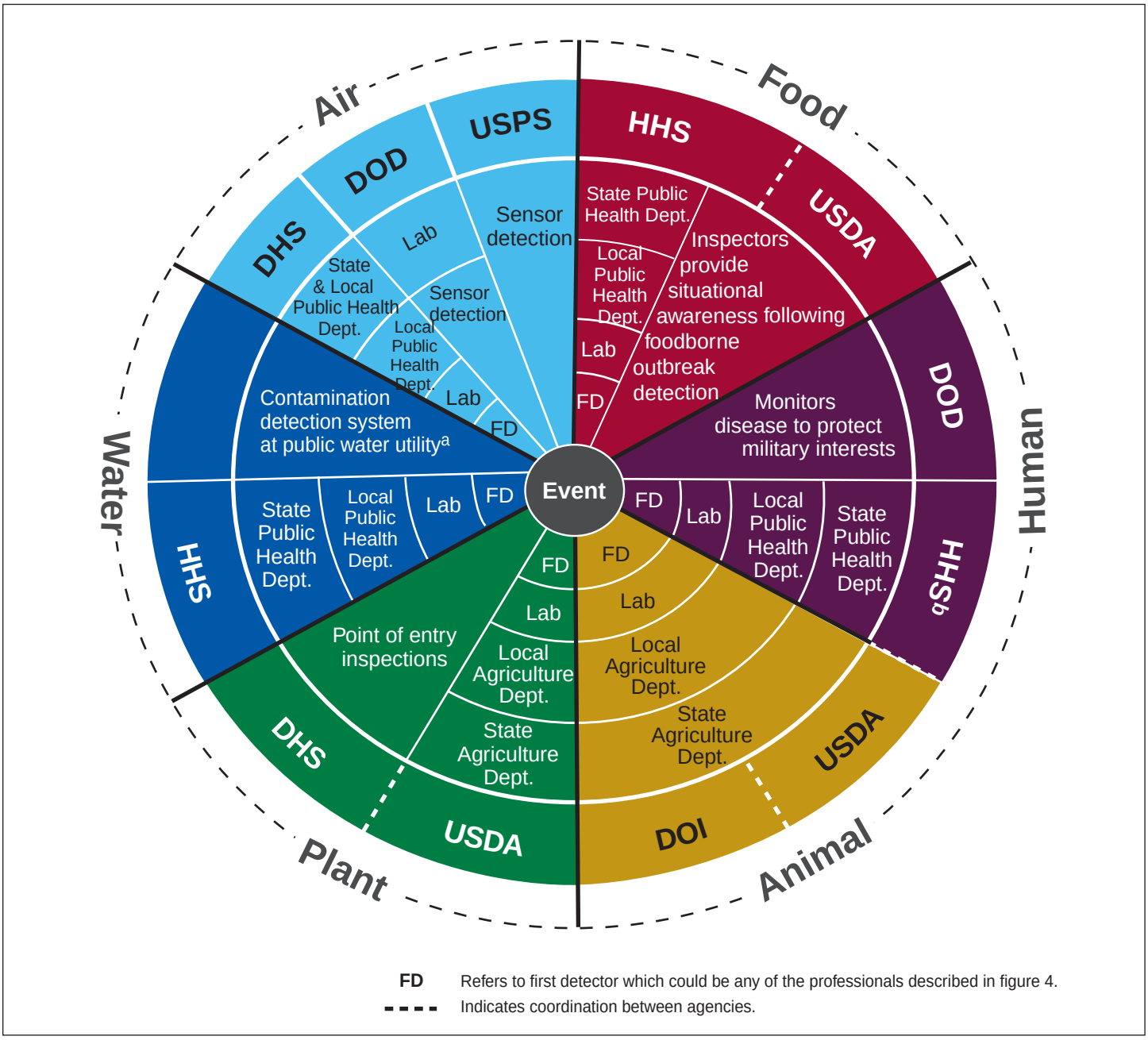
Further, we found in our December 2009 review of NBIC that agencies were skeptical and confused about the value of providing data for the center's integration and analysis efforts. Among the specific reasons federal officials cited for the skepticism was their uncertainty that the

model of biosurveillance integration was the most effective investment for strengthening the nation's biosurveillance capacities. In an environment with competing priorities and limited resources, a strategy could help address these types of challenges where investments must be carefully weighed and considered and sound judgments about targeting investments and using the most cost-effective approaches require information about the cost, benefits, and risks associated with the whole biosurveillance enterprise.

Clarifying Roles and Responsibilities for Leading, Partnering, and Supporting

A national strategy could help delineate and clarify roles and responsibilities for developing and supporting a national biosurveillance capability. As figure 6 shows, numerous federal, state, local, and private sector entities have roles and responsibilities for monitoring for pathogens in human, animal, plant, food, and the environment. Federal departments, such as HHS, USDA, DOI, and DHS, play leading biosurveillance roles for some domains such as human and animal health, food, and air, but within these domains also rely on support from state and local authorities or partner with other federal agencies. In other cases federal departments or agencies play supporting roles. In particular, agencies with missions that do not entail health surveillance activities may play a supporting biosurveillance role on an ongoing or ad hoc basis. For example, as demonstrated during the 2009-10 H1N1 pandemic, the Department of Education provided information on school closings which enhanced situational awareness. In another example, although the National Weather Service does not have health surveillance responsibilities, NBIC may at times coordinate with this agency because understanding weather patterns helps predict the course of some outbreaks.

Figure 6: Roles and Responsibilities for Detection across the Intergovernmental, Cross-Domain Biosurveillance Network



Source: GAO analysis of agency information.

[a]This could include the EPA Water Security Initiative program's contamination warning system being piloted in a few states.

[b]While the Department of Veterans Affairs does not have a primary biosurveillance mission, it does participate in interagency biosurveillance activities (e.g., NBIS) and provides health data to CDC for biosurveillance (e.g., BioSense).

Clarifying the numerous governmental and private sector entities' roles and responsibilities for leading, partnering, or supporting biosurveillance activities could help ensure timely disease detection and situational awareness across these multiple domains. Clarifying roles and responsibilities could also help identify gaps or duplications in biosurveillance coverage within and across domains and determine whether they should be addressed. For example, in the water domain, while federal standards for clean drinking water have been established, monitoring the quality of drinking water itself is a local responsibility, a decentralized function that relies on public water utilities. According to EPA, health care practitioners would likely be the first to detect waterborne pathogens by diagnosing people who have become sick from drinking tainted water. A strategy could help determine whether and to what extent local, state, and federal authorities should partner, lead, or support each other to monitor drinking water for elements besides those provided for in federal water quality standards, such as pathogens that could be used in a bioterror attack.

By mapping out clear roles and responsibilities for leading, supporting, and partnering across the biosurveillance enterprise, a national strategy could also help promote better coordination among federal agencies and their public and private sector partners. As noted in legislation, presidential directives, and national and agency strategies, coordination is important because a national biosurveillance capability relies on the ability of this complex interagency and intergovernmental network to work together. We and others have noted that numerous challenges have impeded efforts to coordinate and collaborate across organizational boundaries to integrate biosurveillance activities, including lack of clearly defined roles and responsibilities. As we reported in December 2009, NBIC, which under the 9/11 Commission Act has statutory responsibility and authority for coordinating information sharing across agencies, faced challenges collaborating with its federal partners. These challenges were at least partially attributable to a lack of clarity regarding roles,

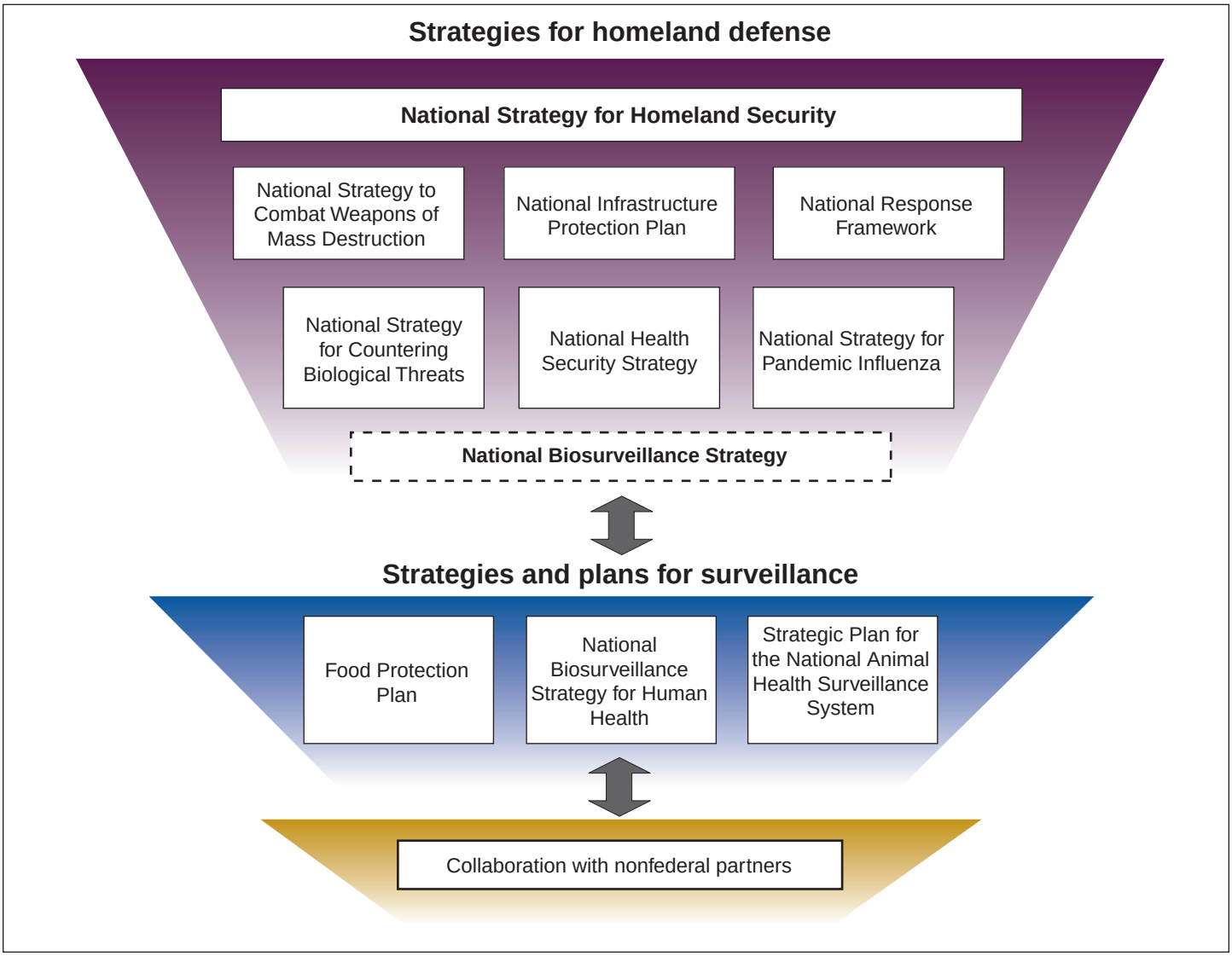
responsibilities, joint strategies, policies, and procedures for operating across agency boundaries.[52]

Integrating National Strategies and Capabilities

A national strategy could help integrate and articulate how the national biosurveillance capability would support and be supported by related biodefense strategies and preparedness capabilities. The final element of a strategy that could help support a national biosurveillance capability is the articulation of how the strategy relates to other strategies' goals, objectives, and activities and associated implementation plans. Clarifying relationships among strategies can help support effective and efficient resource use across a whole range of interrelated activities by helping responsible parties understand their roles and responsibilities, fostering effective implementation, and promoting accountability. Although it is an inherently interagency enterprise facing complex challenges, biosurveillance, as described in HSPD-10, is but one pillar in a biodefense architecture. Similarly, as shown in figure 7, a national biosurveillance capability is a critical element in both the National Strategy for Countering Biological Threats and the National Health Security Strategy. Strategies for countering biological threats and ensuring human health security are in turn a supporting element of the National Strategy for Countering Weapons of Mass Destruction, which is a component of the Homeland Security Strategy. Also, strategies for human and animal health surveillance could draw from and contribute to a national biosurveillance strategy to help ensure that goals and objectives are aligned. In addition to this vertical chain of supporting relationships among strategies, other strategies and plans like the National Strategy for Pandemic Influenza and strategic and operational plans for responding to biological emergencies can inform and be informed by a national surveillance strategy.

[52]GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: December 18, 2009). We recommended that NBIC develop a strategy for collaboration based on key collaboration practices that, among other things, defines roles and responsibilities for its partner agencies. DHS stated it is in the process of implementing this recommendation.

Figure 7: A National Biosurveillance Strategy Would Support Related Strategies at the National, Agency, and Nonfederal Levels



Source: GAO.

Moreover, although the scope of our work is confined to federal domestic biosurveillance efforts, because of the nature of disease and bioterrorism, as the National Strategy for Combating Weapons of Mass Destruction notes, cohesive international efforts are important. The biosurveillance HSPDs each include international surveillance as part of their call for

integrated surveillance systems, and federal agencies like HHS and USDA support global monitoring efforts as part of their mission activities. In addition, the NSC's Strategy for Countering Biological Threats focuses on leading collaborative initiatives across the international community. Moreover, the United States is a signatory of the Biological and Toxin Weapons Convention, which bans the development, production, stockpiling, acquisition, transfer, and retention of microbial or other biological agents or toxins that have no justification for peaceful purposes. The 2010 meeting of experts associated with the convention will focus on biosurveillance and monitoring issues. Clear articulation of mission, scope, purpose, roles, responsibilities, and priorities for the U.S. biosurveillance enterprise could also position the United States to be a more effective leader and partner in international strategies and initiatives.

Establishing a Focal Point Could Help Ensure the Development and Implementation of a National Strategy

We reported in February 2004 that strategies themselves are not endpoints, but rather, starting points, and, as with any strategic planning effort, implementation is the key.[53] This work also reported that the ultimate measure of these strategies' value will be the extent to which they are useful as guidance for policy and decision makers in allocating resources and priorities. However, for an undertaking such as developing a national biosurveillance capability, those policy and decision makers are spread across the interagency and intergovernmental network. In our work related to combating terrorism, we reported that an interagency and intergovernmental undertaking can benefit from the leadership of a single entity with sufficient time, responsibility, authority, and resources needed to provide assurance that the federal programs are based upon a coherent strategy, are well coordinated, and that gaps and duplication in capabilities are avoided.[54]

According to our analysis of requirements in laws and presidential directives related to biosurveillance, a focal point has not been established with responsibility and authority for ensuring the development of a robust, integrated, national biosurveillance capability. The mission responsibilities and resources needed to develop a biosurveillance capability are dispersed across a number of federal agencies, and, according to officials at a number of federal agencies—CDC, USDA, and DHS—chief among them, agencies have capabilities that could be leveraged to support a robust,

[53]GAO-04-408T.

[54]GAO-01-822.

integrated, national biosurveillance capability. However, our analysis indicates that no entity has the responsibility, authority, and accountability for working across agency boundaries to guide and oversee the development and implementation of a national effort that encompasses all stakeholders with biosurveillance responsibilities. For example, CDC has been given the operational lead for developing the vision of HSPD-21 for a human health biosurveillance capability. However, according to CDC officials, responsibility for developing a national biosurveillance capability that includes human as well as animal, plant, food, and environmental surveillance has not been assigned to a single entity such as an intergovernmental council, a federal agency, or an individual official.

Officials in various agencies have taken the lead to fulfill their agencies' biosurveillance missions, but they lack authority to direct other agencies with whom they must partner to take specific action. For example, CDC has undertaken some efforts to coordinate federal efforts relating to human and zoonotic disease surveillance, but according to CDC officials, it has limited authority to ensure the implementation of specific activities at other agencies. According to CDC officials, an overarching organizational mechanism and clearly articulated roles and responsibilities across the separate surveillance programs that serve a range of purposes could help address common surveillance issues within CDC and across the biosurveillance enterprise by coordinating communication and planning.[55] Officials from CDC, DOD, DHS, USDA, and HHS stated that having a focal point would help coordinate federal efforts to develop a national biosurveillance capability. Because the mission responsibilities and resources needed to develop a biosurveillance capability are dispersed across a number of federal agencies, efforts to establish a national biosurveillance capability could benefit from designated leadership—a focal point—that provides leadership for the interagency community.

Conclusions

The report of the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism stated that an attempted biological attack somewhere in the world is likely is likely within the next few years and concluded that the nation was unprepared for such an event. A key component of preparedness is the ability to detect a

[55]CDC has outlined various proposed governance models for human health biosurveillance activities in the *Concept Plan for the Implementation of the National Biosurveillance Strategy for Human Health*, Health and Human Services, Centers for Disease Control and Prevention (Washington, D.C.: January 2010).

dangerous pathogen early and assess its potential spread and effect. Various federal statutes and presidential directives call for biosurveillance actions, culminating with HSPD-2's most recent call for a robust, integrated national biosurveillance system that draws upon and synthesizes the capabilities of multiple existing systems across a number of federal departments and agencies. The challenges in achieving this vision are many and difficult to successfully address, such as acquiring and retaining staff with sophisticated skills and melding disparate information and data systems. Biosurveillance must operate in a complex environment of many players and an evolving threat. Because a biological incident, originating from nature or deliberate acts, could emerge through any number of means—plant, animal, air, and human transmission—it is essential that federal agencies collaborate to leverage their capabilities and find effective and efficient solutions and strategies for detection and analysis. Although efforts like the National Biosurveillance Strategy for Human Health, USDA's Strategy for the National Animal Health Surveillance System, and DHS's National Biosurveillance Integration Center are potentially useful steps in developing a robust, national biosurveillance capability, they do not provide a unifying framework and structure for integrating dispersed capabilities and responsibilities. Further, none of the current players have the authority to guide and oversee the development and implementation of a national effort that encompasses all stakeholders with biosurveillance responsibilities. Without a unifying framework, structure, and an entity with the authority, resources, time, and responsibility for guiding its implementation, it will be very difficult to create an integrated approach to building and sustaining a national biosurveillance capability as envisioned in HSPD-21.

Recommendations for Executive Action

In order to help build and maintain a national biosurveillance capability—an inherently interagency enterprise—we recommend the Homeland Security Council direct the National Security Staff to, in coordination with relevant federal agencies, take the following two actions:

(1) Establish the appropriate leadership mechanism—such as an interagency council or national biosurveillance director—to provide a focal point with authority and accountability for developing a national biosurveillance capability.

(2) Charge this focal point with the responsibility for developing, in conjunction with relevant federal agencies, a national biosurveillance strategy that:

- defines the scope and purpose of a national capability;
- provides goals, objectives and activities, priorities, milestones, and performance measures;
- assesses the costs and benefits associated with supporting and building the capability and identifies the resource and investment needs, including investment priorities;
- clarifies roles and responsibilities of leading, partnering, and supporting a national capability; and
- articulates how the strategy is integrated with and supports other related strategies' goals, objectives, and activities.

Agency Comments and Our Evaluation

We provided a draft of this report for review to the Departments of Homeland Security (DHS), Health and Human Services (HHS), Agriculture (USDA), Commerce (DOC), Defense (DOD), Interior (DOI), Justice (DOJ), State (State), Transportation (DOT), and Veterans Affairs (VA); the Environmental Protection Agency (EPA); the United States Postal Service (USPS); and the National Security Council (NSC). DHS provided written comments on the draft report, which are summarized below and presented in their entirety in appendix V of this report. DOC, DOD, DOI, DOJ, HHS, State, DOT, VA, EPA, USDA, USPS, and the NSC did not provide written comments. We incorporated technical comments from DOC, DOD, DOI, DOJ, HHS, State, DOT, VA, EPA, USDA, and the USPS where appropriate.

In written comments, DHS generally concurred with our findings and recommendations. In particular, DHS noted that it is important to develop a strategy that encompasses all biological domains. Further, DHS stated that the department's National Biosurveillance Integration Center in conjunction with its NBIS partners, have identified strategic planning gaps and could also be helpful in providing leadership for the strategic planning effort. DHS also noted that the statutory responsibilities and expectations assigned to NBIS federal participants could serve as guideposts for any White House Homeland Security Council leadership mechanism.

We are sending copies of this report to the Special Assistant to the President for National Security Affairs; the Attorney General; the Secretaries of Homeland Security, Health Human and Services, Agriculture, Commerce, Defense, Interior, State, Transportation, and Veterans Affairs; the Administrator of the Environmental Protection Agency; the Postmaster General; and interested congressional committees. The report is also available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report please contact me at (202) 512-8777 or JenkinsWO@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.

William O. Jenkins, Jr.
Director, Homeland Security
and Justice Issues

Appendix I: Objectives, Scope, and Methodology

The Implementing Recommendations of the 9/11 Commission Act of 2007 required GAO to describe the state of federal, state, local, and tribal government biosurveillance efforts, the duplication of biosurveillance efforts, the integration of biosurveillance systems, and the effective use of resources and expertise at these levels of governments.[1] We are addressing these questions in a series of three reports. The first of the series, issued in December 2009, focused on the Department of Homeland Security's (DHS) National Biosurveillance Integration Center (NBIC).[2] This report describes domestic biosurveillance efforts at the federal level; we did not review efforts by the federal government to create or improve on international biosurveillance programs. A third report, which we expect to issue during the Winter of 2011, will describe biosurveillance efforts at the state, local, tribal, and territorial levels of government.

Specifically, this report examines the following: (1) federal agency efforts to provide resources—personnel, training, equipment, and systems—that support a national biosurveillance capability; and (2) the extent to which mechanisms are in place to guide development of a national biosurveillance capability.

To address these objectives, we reviewed key legislation, presidential directives, and agency-issued policies related to biosurveillance. Specifically, we reviewed the Homeland Security Act of 2002,[3] the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,[4] the Pandemic and All Hazards Preparedness Act of 2006,[5] the Implementing Recommendations of the 9/11 Commission Act of 2007,[6] and Homeland Security Presidential Directives (HSPD) 5, 7, 8, 9, 10, and 21. These laws and presidential directives task various federal agencies with specific biosurveillance responsibilities and related mission activities, describe biosurveillance activities that agencies are to perform, and define key terms, among other things. To determine the elements of a capability,

[1]Pub. L. No. 110-53, § 1102, 121 Stat. 266, 379 (2007).

[2]GAO, *Biosurveillance: Developing a Collaboration Strategy Is Essential to Fostering Interagency Data and Resource Sharing*, GAO-10-171 (Washington, D.C.: Dec. 18, 2009).

[3]Pub. L. No. 107-296, 116 Stat. 2135 (2002).

[4]Pub. L. No. 107-188, 116 Stat. 594 (2002).

[5]Pub. L. No. 109-417, 120 Stat. 2831 (2006).

[6]Pub. L. No. 110-53, 121 Stat. 266 (2007).

we reviewed DHS's Target Capability List, which specifies that capabilities are made up of the personnel, training, equipment and systems, planning, and leadership necessary to accomplish a mission. We consulted our prior reports including reports on the public health system, emerging infectious diseases, the use of information technology tools to support homeland security and national security goals, protection of animal health and the agriculture sector, food safety and defense, and combating terrorism. See Related GAO Works for an expansive list.

We used the information in the laws and presidential directives, as well as previous GAO work, to identify federal departments and agencies responsible for biosurveillance. We also considered federal departments and agencies that NBIC had included among its National Biosurveillance Integration System (NBIS) partners. In addition to DHS, NBIC has identified 11 NBIS-partner agencies, which it considers to be part of the NBIS interagency community. Those departments and agencies are the Departments of Agriculture (USDA), Commerce, Defense (DOD), Health and Human Services (HHS), Interior, Justice, State, Transportation, Veterans Affairs, as well as the Environmental Protection Agency (EPA) and the United States Postal Service (USPS). We considered interviews we conducted with officials with responsibilities for participating in the NBIC community, as well as interviews with officials responsible for a number of other biosurveillance-related mission activities to inform the findings and underlying context of this report. Although we conducted interviews at multiple components of 12 federal departments, we focused on information collected at 7 federal departments that have key roles and responsibilities—based on agency mission, statutory responsibilities, presidential directives, or programmatic objectives—for biosurveillance and related mission activities, including protection of public health, agriculture, and national security. These departments are USDA, DOD, DHS, HHS, DOI, EPA, and USPS. Further, as USDA, HHS, and DHS have the larger and more direct mission responsibilities for biosurveillance and related mission activities, we focused most heavily on the contributions of their activities to support a national biosurveillance capability. For the purposes of this review, we limited our evaluation to domestic biosurveillance activities and how these domestic activities may contribute to a national biosurveillance capability. We did not review federal efforts to enhance international disease surveillance.

Specifically, we met with and reviewed documents from officials in the agencies shown in table 1.

Table 2: Departments and Agencies with Which We Met To Discuss Biosurveillance Roles, Responsibilities, and Programs

Department	Component/agency	Unit/program
United States Department of Agriculture (USDA)	Animal and Plant Health Inspection Service	Veterinary Services
	Animal and Plant Health Inspection Service	Plant Protection and Quarantine
	Animal and Plant Health Inspection Service	Wildlife Services
	National Institute of Food and Agriculture	
	Forest Service	
	Food Safety and Inspection Service	
Department of Commerce	National Oceanic and Atmospheric Administration	
Department of Defense	Armed Forces Health Surveillance Center	
	Pentagon Force Protection Agency	Pentagon Shield/Urban Shield
	National Center for Medical Intelligence	
Environmental Protection Agency	Office of Ground Water and Drinking Water	Office of Homeland Security and Division of Water Security
Department of Health And Human Services	Centers for Disease Control and Prevention	Coordinating Center for Health Information and Service: National Center for Public Health Informatics
	Centers for Disease Control and Prevention	Coordinating Center for Infectious Diseases:
	Centers for Disease Control and Prevention	Coordinating Center for Infectious Diseases: National Center for Preparedness, Detection, and Control of Infectious Diseases
	Centers for Disease Control and Prevention	Coordinating Office for Terrorism, Preparedness, and Emergency Response
	Food and Drug Administration	Office of Food Protection
	Food and Drug Administration	Office of Regulatory Affairs
	Food and Drug Administration	Center for Food Safety and Applied Nutrition
	Indian Health Service	
	National Institutes of Health	
Department of Homeland Security (DHS)	Customs and Border Protection	
	Federal Emergency Management Agency	
	Office of Health Affairs	
	Science and Technology Directorate	
Department of the Interior	U.S. Geological Survey	National Water Quality Assessment Program
	U.S. Fish and Wildlife Services	
Department of Justice	Federal Bureau of Investigation	WMD Directorate
Department of State	United States Agency for International Development	
United States Postal Service	Biohazard Detection System	

Department	Component/agency	Unit/program
Department of Transportation	Federal Transit Administration	
Department of Veterans Affairs	Assistant Secretary for Operations, Security and Preparedness	
	Infectious Disease Program Office	
	Office of Public Health and Environmental Hazards	

Source: GAO.

We reviewed publicly available documents, including organizational charts, mission statements, memoranda of understanding, and program descriptions from these agencies to identify programs which may contribute to disease surveillance, early detection of biological events, or improved situation-specific information during a biological event. We also reviewed previously assembled lists of biosurveillance or disease surveillance programs compiled in our prior reports and by other federal agencies. These include a portfolio of biosurveillance programs completed by CDC in October 2008 and the U.S. Animal Health and Productivity Surveillance Inventory assembled by USDA. NBIC has a biosurveillance mission specified in the Implementing Recommendations of the 9/11 Commission Act of 2007,[7] which requires interagency coordination across the federal government to detect and provide warning of biological events of national concern. As such, we reviewed NBIC operational documents that describe the federal agencies that participate in NBIC's biosurveillance activities.

To determine the extent to which mechanisms are in place to support a national biosurveillance capability, we reviewed strategic plans issued for supporting the nation's biodefense goals—which includes biosurveillance—for the extent to which these plans incorporated biosurveillance objectives. These plans included the National Health Security Strategy, the National Security Council's National Strategy for Countering Biological Threats, and the National Response Framework. We also reviewed documents from individual agencies' efforts to pursue their biosurveillance mission, in order to determine the extent to which individual agencies efforts may contribute to a national biosurveillance capability. These documents include: The National Biosurveillance Strategy for Human Health, NBIC's Concept of Operations for the National Biosurveillance Integration System, USDA's National Animal Health

[7]Pub. L. No. 110-53, § 1101, 121 Stat. 266, 375 (2007).

Surveillance System strategic plan, and FDA's Food Protection Plan. We also reviewed reports issued by the National Academies of Science's Institute of Medicine which analyzed the existing capacity of the United States to detect and respond to emerging microbial threats, the limitations of disease surveillance, and costs and benefits of existing biosurveillance programs. We reviewed the approach used and the information provided in the Institute of Medicine studies and found them to be credible for our purposes.

We met with federal officials who had responsibility for specific disease surveillance programs or were directly involved in other federal biosurveillance activities, such as representing the department as part of NBIC activities or having responsibility for implementing the department's responsibilities in relevant HSPDs. We interviewed these officials on the function of the specific disease surveillance program, including the process of detection, information-sharing mechanisms, and time frames in which information is generated and shared. In addition, we interviewed these officials on the degree to which the federal government has built a national biosurveillance capability, how specific programs could contribute to a national capability for early detection or situational awareness of biological events, the degree to which federal programs are integrated with each other, and the limitations of these programs in supporting a national biosurveillance capability. We analyzed this information to determine how individual agencies' programs could contribute to building the personnel, training, and equipment and systems needed for a national biosurveillance capability. We also interviewed agency officials from programs that have responsibilities for carrying out the relevant HSPDs to determine the extent to which individual agencies have created mechanisms for integrating data, information sharing, and implementing new biosurveillance techniques. We also interviewed these officials on the limitations individual agencies have in building this capability and compared it to our previous work on identifying a focal point. These officials included senior officials with CDC's Biosurveillance Coordination Unit, HHS's Office of the Assistant Secretary for Preparedness and Response, DHS's NBIC, USDA's Centers for Epidemiology and Animal Health, and DOD's National Center for Medical Intelligence.

In addition, because public health activities are primarily administered at the state and local levels of government, we met with representatives from nonprofit and public health professional organizations that have biodefense or disease surveillance-related missions, as well as state and local organizations, in order to further identify federal programs or

initiatives that may contribute to biosurveillance. These include the Association of State and Territorial Health Officials, the Council of State and Territorial Health Epidemiologists, and the National Association of County and City Health Officials. These organizations represent state and local epidemiologists, public health organizations, and officials involved in public health at the state and local levels. In particular, the Council of State and Territorial Health Epidemiologists coordinates the development of the National Notifiable Disease List. In addition, we met with experts from research organizations that study biodefense issues, including the University of Pittsburgh Center for Biosecurity, the Congressional Research Service, and the National Academies's Institute of Medicine. These organizations identified biosurveillance efforts at the federal level, discussed the status of the federal government's efforts to build a national biosurveillance capability, and described limitations on the federal government's biosurveillance efforts and efforts to build a robust and integrated national biosurveillance capability.

During our review of documents and interviews with knowledgeable officials, we compiled a list of more than 100 programs from across the federal government which may be relevant to biosurveillance. We also asked federal officials to explain how these programs may contribute to detecting biological events or providing situation-specific information to decision makers during an ongoing event, and to identify other programs to consider for inclusion in our study. For each program identified, we interviewed officials and requested descriptive information on their program, such as the coverage and frequency of populations surveyed; diseases on which data are collected by these biosurveillance efforts and their characteristics; how data are used to conduct biosurveillance; how information is reported to support early detection of a biological event or improved information during an event; the status of these efforts; and costs to operate these efforts. These programs were included in our catalog because they may contribute to biosurveillance in one of the following five ways:

1. Provide information to establish disease baselines, such as infection rates and geographical distribution of disease outbreaks.
2. Provide opportunities for astute clinicians to detect outbreak signals, such as collecting syndromic data that, when analyzed, may indicate an emergent infectious disease.
3. Provide disease-specific information to enhance response; for instance, data which may be used to identify and trace sources of detected outbreaks.

4. Represent a surveillance effort designed to shorten the time to detect disease outbreaks, such as environmental sensors designed to detect specific biological agents.
5. Provide tools to integrate data or coordinate information sharing; for instance, communication platforms on which analysts can discuss biosurveillance issues of concern.

For each agency in our review, we compiled the information on each program into a standard profile and validated this information with program officials. We asked these program officials to verify the accuracy of the information, to add missing information, or make technical comments, which we incorporated as appropriate. We also requested officials to identify additional programs for us to consider including in this review, which we added as appropriate.

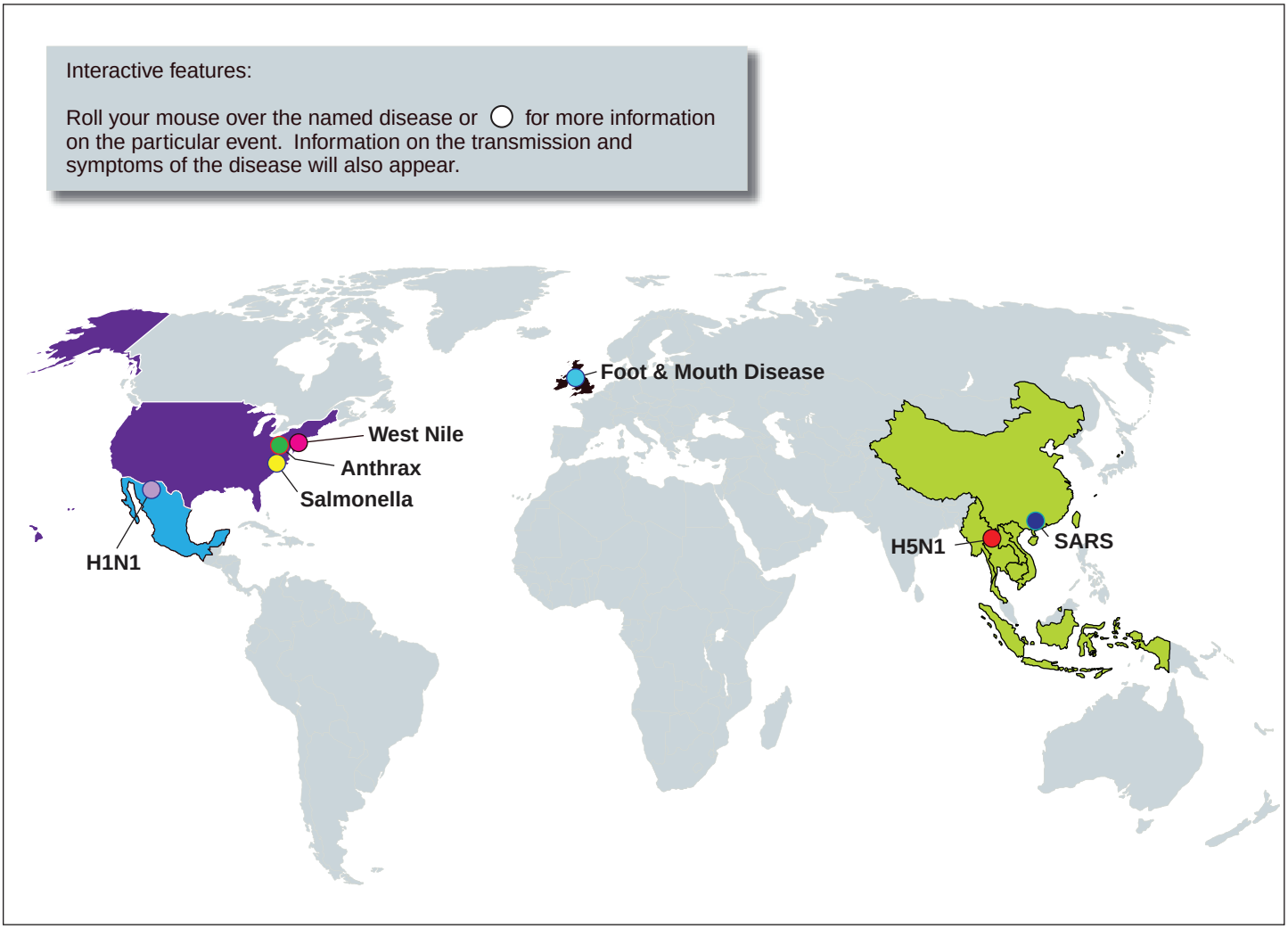
These selected efforts do not represent the total universe of biosurveillance efforts, nor does the catalog represent a statistically representative sample of federal biosurveillance efforts. In addition, we did not include programs or initiatives that are led by state, local, international, or private entities; do not specifically support biosurveillance activities; or are classified systems. Some programs or initiatives may be used to support the nature and purposes of biosurveillance on a case-by-case basis during a biological event, but may not regularly be used to support biosurveillance. For example, some systems we identified track weather patters or map transportation infrastructures, which may be used to estimate the severity of an outbreak or predict a disease's epidemiology. These programs are not included in the selected catalog. Because these efforts are not included in the selected catalog, it does not represent the total universe of biosurveillance capabilities nor does it represent a statistically significant sample of biosurveillance efforts. Finally, we did not evaluate the efficiency or effectiveness of the biosurveillance efforts that we identify in the catalog.

We conducted this work from December 2008 through June 2010 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.

Appendix II: Full Text for Figure 2 Select Worldwide Disease Occurrences in Recent Decades

The following information appears as interactive content in the body of the report when viewed electronically. The content associated with each point on the map describes a disease event and includes information on the transmission and symptoms of the disease. The content appears in print form below in alphabetical order by disease name.

Figure 8: Select Worldwide Disease Occurrences in Recent Decades



Sources: GAO analysis; Map Resources (map).

Anthrax

Anthrax, United States: In 2001 anthrax was intentionally spread through the postal system by sending letters with powder containing anthrax to the U.S. Capitol. Of the 22 infected persons, 5 died. EPA spent $27million for clean up of Capitol Hill and the U.S. Postal Service was appropriated hundreds of millions of dollars to clean up affected facilities.

Transmission and Symptoms: Symptoms vary depending on the type of disease. Cutaneous symptoms include a small sore that develops into a blister, and later becomes a skin ulcer with a black area in the center. Gastrointestinal symptoms are nausea, loss of appetite, bloody diarrhea, fever, and bad stomach pain. Inhalation symptoms are like cold or flu symptoms and can include a sore throat, mild fever and muscle aches, cough, chest discomfort, shortness of breath, tiredness, and muscle aches. All warm-blooded animals are also susceptible to anthrax, but cattle, horses, sheep, and goats are most commonly affected. Anthrax spores that occur naturally in the soil can be ingested by animals or spread by horse flies which spread the disease when they feed on infected carcasses.

Source: EPA.

Foot and Mouth Disease

Foot and Mouth Disease (FMD), United Kingdom, 2001: Resulted in mass slaughtering and burial of animals and a loss of about $4 billion.

Transmission and Symptoms: FMD is a highly contagious viral disease which infects cloven-hoofed animals, such as cattle, swine, and sheep. Infected animals develop a fever and painful blisters between their hooves and on their tongue and lips, making it difficult to feed. This is a debilitating disease that leads to severe losses in the production of milk and meat. Many native wildlife species, including white tail deer, are susceptible to FMD and move readily from farm to farm. According to officials at DOI, if free ranging deer populations in the United States become infected, controlling the spread of FMD will likely become much more challenging and expensive. Because of its rapid spread and potential economic losses, producers greatly fear contraction of FMD among their livestock. FMD is not a threat to people and no human health risks are associated with the disease.

Source: USDA.

H1N1

H1N1, Worldwide, 2009: Initially detected in North America, the virus spread to more than 213 countries, overseas territories, or communities with millions of confirmed cases, including over 17,700 deaths. The World Health Organization declared a pandemic in June 2009.

Transmission and Symptoms: H1N1 spreads like other influenza viruses through person-to-person contact through respiratory droplets produced when an infected person coughs or sneezes. It can also spread when a person touches a surface or object contaminated with infectious droplets and then touches his or her mouth or nose. Symptoms may include: a fever or feeling feverish/chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, fatigue, vomiting, or diarrhea. The 2009 H1N1 has genes derived from flu viruses from pigs, birds, and humans. Swine are susceptible to infection with the Novel H1N1 2009 Virus.

Source: CDC; Cade Martin.

H5N1

H5N1 (commonly known as Avian influenza), Worldwide: Avian influenza spread from China to nearly 60 countries) beginning in early 2000s reaching a peak in 2006. Nearly 500 human cases have been reported, with almost 300 fatalities. H5N1 has also resulted in the death and destruction of millions of wild and domestic birds throughout Asia, Europe, Africa, and the Middle East.

Transmission and Symptoms: Influenza A, H5N1 (avian influenza) is a type of influenza that infects birds and may be transmitted to humans. Although primarily an avian disease, this virus has also infected humans-most of whom had close contact with infected poultry. Symptoms of avian influenza in humans range from typical influenza-like symptoms to pneumonia, acute respiratory distress, and other severe and life-threatening complications. In bird populations, avian influenza is highly contagious, transmitted by direct contact between healthy and infected birds by fecal excretions as well as by nose, mouth, and eye secretions. Indirect contact can also occur via contaminated equipment and materials. Clinical signs in birds vary and can range from inapparent or mild clinical signs to 100 percent mortality. Serious concerns exist that H5N1 could reach North America at any time via migrating birds or smuggled imports of diseased birds and bird products. Health experts are concerned that a pandemic could occur should highly pathogenic H5N1 (or another subtype), to which humans have no immunity, develop the capacity to spread easily from person to person.

Source: CDC.

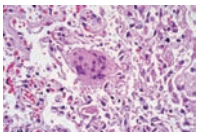
Salmonella

Salmonella, United States, 2008: Outbreak occurred in 43 states and DC; 1,500 persons reported ill with the outbreak strain. The initial investigations identified tomatoes as the likely source. As the outbreak continued, additional investigations showed much of the outbreak was due to jalapeno and Serrano peppers grown and packed in Mexico and distributed in the United States. According to the USDA *Rural Cooperative*, the tomato industry sustained an estimated $100 million or more loss.

Transmission and Symptoms: Transmission to humans usually occurs by eating foods contaminated with animal feces. Contaminated foods are often of animal origin, such as beef, poultry, milk, or eggs, but any food, including vegetables, may become contaminated. Symptoms of Salmonella develop 12-72 hours after infection and can include diarrhea, fever, and abdominal cramps. Salmonella can also be transferred from animal to animal through contact with newly acquired farm animals, the use of contaminated food and water sources, and stress and overcrowded conditions can increase the spread of the bacteria.

Source: GAO.

SARS



Severe Acute Respiratory Syndrome (SARS): Worldwide (with highest concentration in Southeast Asia) 2003: Over 8,000 infected and over 750 deaths. Economic losses due to lack of tourism and consumer spending in Asia were estimated at $20 billion.

Transmission and Symptoms: SARS seems to spread by close person-to-person contact through respiratory droplets produced when an infected person coughs or sneezes. It can also spread when a person touches a surface or object contaminated with infectious droplets and then touches his or her mouth, nose, or eye(s). SARS causes flu-like symptoms which may progress to pneumonia. Symptoms include fever, headache, body ache, coughing, difficulty breathing, and diarrhea. Multiple mammalian species have been proven to be susceptible to the SARS virus, including the civet. To date, scientists have not been able to confirm the origin of SARS in humans. Some public health officials hypothesize that SARS virus was transmitted from an animal to human thereby sparking the 2003 outbreak.

Source: CDC.

West Nile

West Nile Virus (WNV), United States, 1999: First detected in New York, 62 cases were reported in 1999 with 7 fatalities. The virus has since been reported in the lower 48 states. In 2009, over 700 cases were reported with over 30 fatalities.

Transmission and Symptoms: The virus is spread by mosquitoes who bite birds containing the virus and then pass it to humans through bites. While most people infected do not experience any symptoms, they can range from mild (e.g., headache, nausea, or rash) to severe (e.g., high fever, muscle weakness, or paralysis). Birds serve as a reservoir for this virus; over 170 species have tested positive for WNV in the United States. Mortality rates for birds with WNV are high. Death usually occurs within 3 weeks of infection. Clinical signs prior to death include uncoordinated walking, weakness, lethargy, tremors, and head tilt caused by encephalitis or meningitis. Horses are also susceptible to infections.

Source: CDC; Jim Gathany.

Appendix III: Traditional Monitoring Systems Provide Important but Limited Contributions to a National Biosurveillance Capability

National Notifiable Disease List

The Council of State and Territorial Epidemiologists, in consultation with CDC, updates the list of notifiable conditions and national surveillance case definitions every year. The list includes those diseases that CDC and state public health officials have identified as posing a serious public health risk for which case reports would help inform prevention and control efforts. State public health departments verify cases of notifiable diseases, monitor disease incidence, and identify possible outbreaks within their states. States voluntarily report their notifiable disease data to CDC to support the National Notifiable Diseases Surveillance System. The agency publishes current data on notifiable diseases in its *Morbidity and Mortality Weekly Report*.

Source: GAO.

CDC's Influenza Portfolio

The influenza surveillance system is one of the largest and most timely surveillance systems at CDC. The system consists of seven complementary surveillance components. These components include reports from more than 120 laboratories, 2,000 sentinel health care providers, vital statistics offices in 122 cities, research and health care personnel at the Emerging Infections Program and New Vaccine Surveillance Network sites, and influenza surveillance coordinators and state epidemiologists from all 50 state health departments and the New York City and District of Columbia health departments. Influenza surveillance data collection is based on a reporting week that starts on Sunday and ends on Saturday of each week. Each surveillance participant is requested to summarize weekly data and submit them to CDC by Tuesday afternoon of the following week. The data are then downloaded, compiled, and analyzed at CDC each Wednesday. The compiled data are interpreted and checked for anomalies which are resolved before the report is written and submitted for clearance at CDC. On Friday, the report is approved, distributed, and posted to the Internet. CDC collects data year-round and reports on influenza (flu) activity in the United States each week from October through May.

Source: GAO.

Traditional disease surveillance systems designed to collect information on the health of humans, animals, and plants support biosurveillance efforts by recording national health and disease trends and providing specific information about the scope and projection of outbreaks to inform response. Traditional systems, however, rely on time-intensive testing and confirmation practices as well as data not owned by the federal government, which present challenges that limit their ability to provide timely detection and situational awareness.

Monitoring for disease at the national level establishes a baseline understanding of disease characteristics that enables officials to recognize anomalous disease occurrences within the United States. Detecting a signal that warns of a potential or imminent biological threat of national concern requires the ability to discern whether disease occurrence is abnormal based on its general characteristics, as well as where, when, and how severely the disease has historically occurred. This information is also useful for projecting how an outbreak may progress during response to a potentially catastrophic biological event.

The U.S. government has a long history of monitoring human, animal, and plant health—in some cases for more than a century—to help limit malady, loss of life, and economic impact. Disease surveillance for human health at the national level was established to assess the status of the public's health, develop policy to define public health priorities, and provide assurance of the prevention and control of disease. The federal government uses a nationally notifiable disease List as the foundation of its human health surveillance efforts.

Fifty-seven jurisdictions, including state and local health departments, voluntarily report cases of certain diseases named on the list of nationally notifiable diseases to the CDC. CDC uses these reports from the states to monitor national health trends, formulate and implement prevention strategies, and evaluate state and federal disease prevention efforts. In addition to the National Notifiable Disease Surveillance System, CDC maintains programs aimed at detecting and preventing specific diseases, such as influenza. (For more information on specific programs, see app. IV.) In general, these programs rely on participating health providers to send case reports to CDC on a periodic basis. According to CDC, the timeliest of these disease-specific surveillance programs have participants report the data weekly. Other programs may send information to the CDC on a monthly or annual basis. CDC compiles the data, checks for accuracy, clarifies inconsistencies, and reports national level data at regular intervals. Information that is collected through the National Notifiable

Disease Surveillance System and other public health surveillance programs can be applied to determine the scope and forecast the course of an outbreak to enhance situational awareness to guide decision makers' response efforts.

National Animal Health Reporting System

The National Animal Health Reporting System was designed to provide data from chief state animal health officials on the presence or absence of confirmed World Organization for Animal Health reportable diseases in specific commercial livestock, poultry, and aquaculture species in the United States. Within a state, data about animal disease occurrence are gathered from as many verifiable sources as possible and consolidated into a monthly report submitted to the National Surveillance Unit, where the information is verified, summarized, and compiled into a national report. The commodities currently covered are cattle, sheep, goats, equine, swine, commercial poultry, and commercial food fish. The system is a joint effort of the U.S. Animal Health Association, American Association of Veterinary Laboratory Diagnosticians, and USDA's Animal and Plant Health Inspection Service.

Source: GAO.

Similarly, to help protect the nation's agricultural sector, USDA has routine reporting systems and disease-specific surveillance programs for domesticated animals and some wildlife that can provide information to support the early detection goal of biosurveillance. Information gathered through these efforts can also help characterize and project the nature and scope of an outbreak—for example, by providing the number of infected animals and where they are located—to enhance situational awareness. For instance, state animal health officials obtain information on the presence of specific, confirmed clinical diseases in livestock, poultry, and aquaculture in the United States from multiple sources—including veterinary laboratories, public health laboratories, and veterinarians—and report this information to the USDA's National Animal Health Reporting System (for more information, see app. IV). USDA has also developed control and eradication programs of specific diseases that threaten the health of animals to reduce the incidence of disease and to provide timely detection of some foreign animal diseases, resulting in smaller outbreaks. These programs are carried out in targeted high-risk populations of various animal and aquaculture species to identify cases of the disease, stem the spread of disease, and take measures to ensure certain diseases that are no longer common in the United States do not reemerge.

In addition, USDA coordinates with state departments of agriculture, state foresters, universities, and industry partners to conduct pest detection surveys of agricultural plants and forests annually. By working with states to identify and prioritize pest threats of national interest and coordinate pest surveys, USDA's Pest Detection Program provides nationwide information about the presence of select plant pests.

According to officials at DOI, currently there is no national reporting system for diseases of wildlife, making it difficult to track national trends in wildlife disease. DOI's U.S. Geological Survey's National Wildlife Health Center is changed with addressing wildlife disease throughout the U.S. This center provides disease diagnosis, field investigation, disease management and research, and training. It also maintains a database on disease findings in wild animals and on wildlife mortality events.

For foodborne illness, CDC, USDA, and FDA can partner to use their traditional surveillance activities to enhance situational awareness during

outbreaks. First, CDC identifies an outbreak of foodborne illnesses based on reports from state and local health care providers. Then, it works with the other federal partners to characterize the extent of the illness and identify its source, using a system called OutbreakNet (see app. IV for more information). While CDC works with its external partners to collect additional information about identified cases—such as characteristics of the people affected, the types of food consumed, and the possible location of the consumption—FDA and USDA work with state and local food safety agencies to gather additional information about the source by conducting inspections and testing food samples.

Although information provided by traditional surveillance activities is essential for biosurveillance purposes, the nature of those systems presents inherent challenges that prevent them from being wholly sufficient as tools for timely detection and enhanced situational awareness. We and others have reported that traditional disease reporting has generally been slow and incomplete, and, therefore, not well suited to provide early detection and warning of a disease outbreak or pest infestation.[1] For example, federal agencies collecting data from state, local, and private-sector entities generally rely on voluntary participation, which limits the federal government's ability to institute controls at the initial collection and data entry points to help ensure accuracy, completeness, or timely reporting. As we reported in 2004, most states maintain a modified version of the national notifiable disease list that reflects the public health priorities of the particular state, but do not consistently reflect CDC's list of notifiable diseases. Therefore, some local health care providers are not obligated to report diseases on the national notifiable disease list. For instance, five states, including Alabama, Nevada, New Hampshire, Oregon, and Washington do not require local health care providers to report cases of smallpox—which could be used by terrorists as a biological weapon—even though CDC requests this information.[2]

We also previously reported that state officials have experienced significant underreporting by health care providers in their efforts to

[1]See GAO, *Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Ability to Respond to Public Health Emergencies*, GAO-03-139 (Washington, D.C.: May 30, 2003).

[2]See GAO, *Emerging Infectious Diseases: Review of State and Federal Disease Surveillance Efforts*, GAO-04-877 (Washington, D.C.: Sept. 30, 2004).

collect disease data and underreporting can adversely affect public health efforts by leading to erroneous conclusions about trends in incidence, risk factors for contracting a disease, appropriate prevention and control measures, and treatment effectiveness.[3] According to the Institute of Medicine, many health care providers do not fully understand their role in infectious disease surveillance, including their role as a source of data.[4] Furthermore, despite the existence of state notifiable disease lists and related laws, some providers may be unaware of basic reporting requirements.

Also posing a challenge to timely detection and situational awareness is the need for laboratory confirmation. Although mechanisms exist for reporting suspected cases of disease, traditional public health systems rely on laboratory-confirmed cases. Laboratory confirmation, while important to establishing accurate information, adds up to 2 weeks to the reporting process, as results are analyzed and communicated at the state and local levels before they are reported to federal health officials. Officials from CDC and USDA attribute this delay to the inability of labs to communicate test results electronically.

Timely detection and situational awareness are also problems for livestock biosurveillance. For example, we reported in 2005 that USDA does not always use rapid diagnostic tools to test animals at the site of an outbreak. Although, according to experts, on-site use of rapid diagnostic tools is critical to speeding diagnosis, containing the disease, and minimizing the number of animals that need to be slaughtered, USDA employd them only within selected laboratories. DOD used rapid diagnostic tools to identify disease agents on the battlefield, but USDA officials considered the technology to be still under development.[5] A 2002 USDA exercise estimated that, under the current approach, a foreign animal disease such as Foot and Mouth Disease would spread rapidly, necessitating the

[3]See GAO, *Infectious Diseases: Gaps Remain in Surveillance Capabilities of State and Local Agencies*, GAO-03-1176T (Washington, D.C.: Sept. 24, 2003) and *Emerging Infectious Disease: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance*, GAO/HEHS-99-26 (Washington, D.C.: Feb.5, 1999).

[4]See Institute of Medicine and National Research Council of the National Academies, Committee on Emerging Microbial Threats to Health in the 21st Century, *Microbial Threats To Health: Emergence, Detection, and Response* (Washington, D.C.: 2003).

[5]See GAO, *Homeland Security: Much Is Being Done to Protect Agriculture from a Terrorist Attack, but Important Challenges Remain*, GAO-05-214 (Washington, D.C.: Mar. 8, 2005).

slaughter of millions of animals and cause staggering financial losses—precisely the type of high-visibility destruction some experts told us terrorists seek.[6] In response to our recommendation, USDA is in the process of evaluating the costs and benefits of using penside rapid diagnostic tools. In addition, we reported that animal numbers and locations are generally not known, and without a national animal identification program, surveillance, trace back, and disease containment is a challenge.[7]

[6]GAO-05-214.

[7]See GAO, *Avian Influenza: USDA Has Taken Important Steps to Prepare for Outbreaks, but Better Planning Could Improve Response*, GAO-07-652 (Washington, D.C.: June 11, 2009) and *National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback*, GAO-07-592 (Washington, D.C.: July 6, 2009) and *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, GAO-09-178 (Washington, D.C.: Feb. 4, 2009).

Appendix IV: Selected Systems Used in Federal Early Detection and Situational Awareness Activities

Below we describe selected systems owned or developed by federal agencies which may be used to detect or provide enhanced information about outbreaks relating to human, animal, and plant health, as well as monitoring food and the environment. This list encompasses information reported by federal agencies on electronic communications and surveillance systems as well as networks of laboratories and health officials engaged in disease surveillance.

Integrated Consortium of Laboratory Networks

DHS	Domain:
Science and Technology Directorate	Human Health, Animal, Plant, Food, Air, Water

Description

The Integrated Consortium of Laboratory Networks is to facilitate the development and maintenance of a system of laboratory networks that is built upon established laboratory networks such as the Food Emergency Response Network; the Laboratory Response Network; the National Animal Health Laboratory Network; the National Plant Diagnostic Network; the Environmental Response Laboratory Network; and other emerging networks within the federal government with responsibilities and authorities for laboratory preparedness and response. These networks are to provide timely, high-quality, and interpretable results for the early detection and effective consequence management of acts of terrorism and other events requiring an integrated laboratory response. The Integrated Consortium of Laboratory Networks has created a capabilities assessment of member network laboratories and established working groups to address deficiencies identified by member lab networks. Additionally, the Integrated Consortium of Laboratory Networks provides a forum for laboratory network representatives to provide assistance in the event of a biological, chemical, or radiological contamination emergency.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Homeland Security, Interior, Justice, State, and the Environmental Protection Agency are ICLN members	Members provide information to leverage expertise	In development since 2005 and will be transitioned to the Office of Health Affairs once operational (currently targeted for fiscal year 2011)	$1,500

Diseases of Concern

Diseases resulting from an act of terrorism involving a biological or chemical agent or toxin, radiological contamination, or a naturally occurring outbreak of an infectious disease that may result in a national epidemic.

Disease Information

Laboratory networks have modeled threats posed by chemical, biological, and radiological agents and are developing the capability to support characterization, containment, and recovery from such attacks.

BioWatch

DHS	Domain:
Office of Health Affairs (OHA)	Air

Description

The Department of Homeland Security's BioWatch Program is an early warning system comprised of collectors capable of detecting aerosol releases of select biological agents, natural and man-made. The Program develops and disseminates guidance and other documents geared toward the public health community, which provide information necessary to prepare for and respond to the detection of an agent of interest. The rogram also evaluates state and local implementation of guidance documents through an active exercise program which serves to assure that BioWatch coverage areas have the capability to respond to a detection. According to DHS, the combination of early warning and rapid public health response can substantially minimize the potentially catastrophic impact on the population.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Local public health officials and Department of Homeland Security officials	State and local laboratories conduct testing on air samples	System is operational. BioWatch sensors were first deployed to major urban areas across the United States in 2003	$116,000

Diseases of Concern

Aerosolized biological agents

Disease Information

DHS has identified scenarios involving the release of biological materials in urban areas that could result in significant casualties and economic disruption.

National Biosurveillance Integration Center

DHS	Domain:
Office of Health Affairs	Human Health, Animal, Plant, Food, Air, Water

Description

The Implementing Recommendations of the 9/11 Commission Act (9/11 Commission Act) established, within the Department of Homeland Security, the National Biosurveillance Integration Center. The center is tasked with enhancing the capability of the federal government to rapidly identify, characterize, localize, and track biological events of national concern by integrating and analyzing data related to human health, animal, plant, food, and environmental monitoring systems, and to disseminate alerts if any such events are detected. A central responsibility is to develop and oversee the National Biosurveillance Integration System, a federal interagency consortium and information management concept that was established to integrate and analyze biosurveillance-relevant information to achieve earlier detection and enhanced situational awareness.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal agencies	NBIC has identified the following federal agencies as potential partners: The Departments of Agriculture, Commerce, Defense, Education, Energy, Health and Human Services, Interior, Justice, Labor, State, Transportation, and Veterans Affairs, as well as the US Postal Service, and the Environmental Protection Agency. State, Local, Tribal and Territorial Agencies will also be provided access to information and analysis as well as be allowed to contribute data	NBIC has been operational since 2007	$8,000

Diseases of Concern

Any bio-event involving the intentional use of biological agents as well as emergent biohazards, such as accidental release of biological agents or natural disease outbreaks.

Disease Information

A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.

Airbase/Port Detector System (Portal Shield)			
DOD		Domain:	
Joint Portal Shield		Human Health, Air	
Description			
The Portal Shield sensor system was developed to provide early warning of biological threats for high-value, fixed-site assets, such as air bases and port facilities. Portal Shield can detect and identify up to 10 biological warfare agents simultaneously, within 25 minutes of release.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Military commanders and health personnel at fixed asset sites (e.g., air bases and port facilities)	CBRNE operative personnel managing the system	System is operational	$22,000
Diseases of Concern			
Potential biological warfare agents			
Disease Information			
Biological agents could pose a threat to soldiers on the battlefield			

Electronic Surveillance System for the Early Notification of Community-based Epidemics (ESSENCE)			
DOD		Domain:	
TRICARE Management Activity		Human Health	
Description			
ESSENCE is used in the early detection of infectious disease outbreak and provides epidemiological tools that can be used to investigate disease oubreaks. It utilizes ambulatory data from hospitals and clinics. Epidemiologists can track, in near real time, symptoms being reported in a region through a daily feed of reported data (such as working diagnoses indicated by codes assigned by local health care staff). ESSENCE uses the daily data downloads, along with traditional epidemiological analyses that use historical data, for baseline comparisons in order to improve detection			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Military and veterans' public health and preventive medicine officials	Military health care providers	System is operational	$2,676
Diseases of Concern			
Infectious diseases affecting humans			
Disease Information			
Health surveillance is critical to medical readiness and force health protection.			

Armed Forces Health Surveillance Center

DOD	Domain:
US Army Public Health Command (formerly known as US Army Center for Health Promotion and Preventative Medicine)	Human Health

Description

The mission of the Armed Forces Health Surveillance center is to analyze, interpret, and disseminate information related to the status, trends, and determinants of the health of the U.S. military service members and military-associated populations. The center identifies obstacles to medical readiness by linking various databases that communicate information relevant to service member health and fitness. The Armed Forces Health Surveillance Center maintains the Defense Medical Surveillance System, a database containing up-to-date and historical data on disease and medical events as well as longitudinal data on personnel and deployments. The Defense Medical Surveillance System provides the data supporting the Department of Defense Serum Repository which as of Spring 2010 includes over 50 million serum specimens drawn from servicemembers (since the late 1980s) and used to perform longitudinal analyses of service member health. The system also also supports the Defense Medical Epidemiology Database, an application that provides remote user access to selected deidentified data (i.e., data with patient identifying characteristics removed). The Armed Forces Health Surveillance Center also operates the Global Emerging Infectious Surveillance and Response System, a program that conducts laboratory-based surveillance for emerging infectious diseases within the U.S. military and in foreign civilian populations through leveraging a network of research and clinical laboratory partners in the United States and overseas.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
DOD officials for health surveillance information on military and military-associated populations	The Armed Forces Health Surveillance Center gathers data from a variety of existing health surveillance sources maintained by other military units	System is operational	Defense Medical Surveillance System/DOD Serum Repository/ Defense Medical Epidemiology Database: $6,000 Global Emerging Infectious Surveillance and Response System: $52,000

Diseases of Concern

All health threats to U.S. military personnel, including trauma, psychological stress, environmental hazards, and infectious diseases. Laboratory network surveillance is focused on infectious diseases affecting humans, including some animal diseases that also affect humans, as well as some pathogens that could contaminate food.

Disease Information

Health surveillance is critical to medical readiness and Force Health Protection.

Division of Migratory Bird Management			
DOI		Domain:	
Fish and Wildlife Service		Animal	
Description			
The Division of Migratory Bird Management is largely responsible for monitoring the health of migratory bird populations and issuing guidelines for conservation and sustainable harvest. The Division of Migratory Bird Management program activities are restricted to sampling migratory bird populations and testing those populations for indicators of diseases affecting birds or zoonotic diseases that could affect human populations, such as avian (H5N1) influenza. The United States Geological Survey laboratory in Madison, Wisconsin conducts laboratory analysis of submitted samples. The Division of Migratory Bird Management also collaborates with USDA's Animal and Plant Health Inspection Service to test bird samples and to survey bird populations.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Fish and Wildlife and U.S. Department of Agriculture officials	Fish and Wildlife inspectors and inspection programs active in foreign countries provide information	System is operational	Not available
Diseases of Concern			
Infectious diseases affecting migratory birds			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Fish and Wildlife Service Inspections			
DOI		Domain:	
Fish and Wildlife Service (FWS)		Animal	
Description			
Fish and Wildlife Service inspectors work with public health officials and other federal inspectors at ports of entry to enforce wildlife regulations and ensure compliance with international wildlife laws as they pertain to wild animal imports. Some inspections consist of examinations of import paperwork, while others may consist of physical inspections of the animals being imported to confirm that the shipment contents match corresponding documents. The decision to physically inspect a shipment could depend on the type of commodity, country of origin, or importer history. Random physical inspections are also conducted.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Fish and Wildlife officials	FWS inspectors stationed at ports of entry	System is operational	$687
Diseases of Concern			
Diseases affecting animal populations are not the primary focus of the wildlife inspection program; although, if wildlife inspectors note the presence or suspected presence of disease, they will notify the appropriate federal agency.			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

National Wild Fish Health Survey			
DOI		Domain:	
Fish and Wildlife Service		Animal	
Description			
The National Wild Fish Health Survey is an ongoing effort to sample and test wild fish for both specific diseases identified as key threats and for emerging infectious diseases. Fish samples are collected by state and tribal governments for testing at one of Fish and Wildlife Service's nine regional laboratories. A national database collects and maintains all laboratory test results. Fish and Wildlife Service inspectors also examine all federal fish hatcheries at least annually and some are examined biannually. States may also request testing in the event of a major fish die-off or apparent disease outbreak.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Incidences of notifiable diseases are reported to USDA's Animal and Plant Health Inspection Service	Data is primarily provided by state and local wildlife inspectors	System is operational	Not available
Diseases of Concern			
Infectious diseases affecting fish populations			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Water Security Initiative

EPA	Domain:
Office of Ground Water and Drinking Water	Water

Description

The Water Security Initiative addresses the risk of intentional contamination of drinking water distribution systems by promoting the voluntary adoption of online water quality monitoring, sampling and analysis, enhanced security monitoring, consumer complaint surveillance, public health surveillance, and a consequence management plan at local water utilities. EPA is implementing the Water Security Initiative by developing the conceptual design of a system for detection of and response to a contamination event; demonstrating the viability of such a system through pilots in five cities; and developing guidance and outreach to promote voluntary adoption of drinking water contamination warning systems. EPA has implemented a pilot drinking water contamination warning system with the Cincinnati Water Works in Cincinnati, Ohio, and has funded pilots in San Francisco, New York City, Philadelphia, and Dallas, all of which are underway.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Local water utilities that implement Water Security Initiative in their distribution network.	EPA provides guidance and best practice standards to facilitate the implementation of a contamination warning system in a drinking water utility, and local water utilities operate the system and respond to threats.	System is a pilot.	$13,870

Diseases of Concern

Chemical, biological, and radiological agents which could be present in drinking water

Disease Information

Drinking water utilities have been recognized as being potentially vulnerable to physical disruption, bioterrorism, chemical contamination, and cyber attack. Damage or destruction of a water network could disrupt not only the availability of safe drinking water but also the delivery of vital services that depend on these water supplies, like fire suppression.

Environmental Response Laboratory Network			
EPA		Domain: Water	
Description: The Environmental Response Laboratory Network serves as a ntaional network of labs that can be accessed as needed to support large scal environmental responses by providing consistent analytical capabilities, capacities, and quality data in a systematic, coordinated response.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal, state, and local decision makers	Contributors to the Environmental Response Laboratory Network include CDC, DOD, USDA, FDA; state environmental, agricultural, and public health organizations; and commercial laboratories	System can be accessed as needed to support large-scale environmental responses	Not available
Diseases of Concern: Chemical, biological, and radiological agents present in air or water that can cause diseases resulting from a large-scale environmental disaster			
Disease Information: A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

122 Cities Mortality Reporting System

HHS	Domain:
CDC	Human Health

Description

As part of its national influenza surveillance effort, CDC receives weekly mortality reports from 122 cities and metropolitan areas in the United States within 2-3 weeks from the date of death. These reports summarize the total number of deaths occurring in these cities/areas each week due to pneumonia and influenza. This system provides CDC with the preliminary information with which to evaluate the impact of influenza on mortality in the United States and the severity of the currently circulating virus strains.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC epidemiologists	122 cities and metropolitan areas contribute data to the system	System is operational	Not available

Diseases of Concern

Pneumonia and influenza

Disease Information

Influenza viruses are found in human and many different animals, including ducks, chickens, pigs, whales, horses and seals. Seasonal Flu is a contagious respiratory illness caused by flu viruses. It can cause mild to severe illness, and at times can lead to death. Pneumonia is an infection of the lungs that is usually caused by bacteria or viruses. Globally, pneumonia causes more deaths than any other infectious disease, such as AIDS, malaria, or tuberculosis. However, it can often be prevented with vaccines and can usually be treated with antibiotics or antiviral drugs.

Arboviral Surveillance System (ArboNet)			
HHS		Domain:	
CDC		Human Health	
Description			
ArboNet is an internet-based national arboviral surveillance system developed by state health departments and CDC in 2000. ArboNet collects reports of arboviral diseases and other data from all states and three local districts (New York City, Washington D.C, and Puerto Rico). Data are reported by local health departments weekly for routine analysis and dissemination. These data are summarized periodically in the Morbidity and Mortality Weekly Report and yearly in the MMWR Summary of Notifiable Diseases.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Public health officials at CDC. esearchers, pharmaceutical companies, the media, and the general public may access limited use data sets	State and local health departments	System is operational since 2000	Not available
Diseases of Concern			
Arboviruses, such as West Nile Virus, encephalitis, and yellow fever viruses			
Disease Information			
West Nile virus is a mosquito-borne viral disease that is transmitted to humans through infected mosquitoes. Many people infected with the virus do not become ill or show symptoms. Symptoms that do appear may be limited to headache, sore throat, backache, or fatigue. There is no vaccine for the West Nile virus, and no specific treatment besides supportive therapies. The disease occurs in Africa, Eastern Europe, West Asia, and the Middle East. This disease appeared for the first time in the United States in 1999. Yellow fever is a mosquito-borne viral disease that occurs in tropical and subtropical areas. The yellow fever virus is transmitted to humans through a specific mosquito. Symptoms include fever, muscle pain, headache, loss of appetite, and nausea. There is no treatment for yellow fever beyond supportive therapies. A vaccine for yellow fever is available.			

BioSense

HHS	Domain:
CDC	Human Health

Description

BioSense is a national program intended to improve capabilities for rapid disease detection, monitoring, and real-time situation awareness through access to specific health care data from participating organizations, including more than 500 acute-care hospitals, commercial laboratories, as well as Department of Defense and Veterans Affairs health care facilities. BioSense enables local and state public health departments to share and access data, providing a more complete picture of potential and actual health events both locally and across jurisdictional boundaries. Data received into the system are available simultaneously to state and local health departments, participating hospitals, and CDC through a Web-based application. BioSense securely processes, analyzes, and visualizes data to help characterize and monitor outbreaks and enable appropriate and timely public health interventions. Based on user feedback, BioSense is undergoing revision to deemphasize collection of detailed clinical data from hospitals at CDC and emphasize greater dependence on collection of data from existing automated surveillance systems operated by state and local health departments. The BioSense program also funds applied and developmental projects including Regional Surveillance collaboratives, state-based health information exchanges, Centers of Excellence in Public Health Informatics, and BioSense evaluations.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Public health staff at state and local health departments, CDC program staff (e.g., influenza, environmental health, injury), CDC's Emergency Operations Center, International Society for Disease Surveillance, VA's Office of Public Health and Environmental Hazards, VA's Infectious Disease Program Office	580 acute-care hospitals; 1,300 DOD and VA hospitals and health care facilities; 2 large national commercial laboratories; national retail pharmacy database representing 27,000 retail pharmacies	BioSense is operational across the current participating health care facilities, health systems, and health department surveillance systems. A contract solicitation is underway to support BioSense redesign to enhance population coverage and stakeholder engagement.	$27,656

Diseases of Concern

All-hazards (with a focus on infectious diseases) affecting human health

Disease Information

The BioSense program monitors 90 concepts (syndromes and sub-syndromes) that encompass infections, injuries, chronic diseases, exposures, miscellaneous conditions, and specified codes, and free-text search terms corresponding to these concepts. In addition to these health outcome data, patient demographics (age group, sex), date of diagnosis, and geographic location information is reported.

Biosurveillance Coordination			
HHS		Domain:	
CDC		Human Health, Animal, Plant, Food, Air, Water as it relates to human health	
Description			
The mission of the Biosurveillance Coordination is to coordinate the development and support the implementation of an integrated, national biosurveillance plan for human health. The plan, a requirement outlined in Homeland Security Presidential Directive 21, includes the capacity to generate timely, comprehensive, and accessible information with proper context for public health decision making. Biosurveillance Coordination has developed the National Biosurveillance Strategy for Human Health and a companion document titled Concept Plan for Implementation of the National Biosurveillance Strategy for Human Health. Biosurveillance Coordination has begun to compile an inventory of biosurveillance systems, tools, collaboratives, programs, and registries within CDC. More information about these activities and final documents can be found at http://www.cdc.gov/osels/ph_surveillance/bc.html			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Decision makers in federal, state, local, tribal, and territorial public health agencies	Not applicable	CDC established the BCU in early 2008	$2,400
Diseases of Concern			
All hazards			
Disease Information			
Not applicable			

Biosurveillance Indications and Warning Analytic Community (BIWAC)			
Collaborative effort among BIWAC partners		Domain: Human Health, Animal, Plant, Food, Air, Water	
Description The Mission of the Biosurveillance Indications and Warning Analytic Community (BIWAC) is to provide a secure, interagency forum for timely collaborative exchange of critical information regarding Indications and Warning (I&W) of Biological events that may threaten U.S. National Interests. The BIWAC will conduct the collaborative exchange of critical Biosurveillance information through an encrypted information-sharing portal called “Wildfire,” and also through meetings and teleconferences.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
BIWAC partners include the intelligence community and the Departments of Agriculture, Defense, Health and Human Services, Homeland Security, and State	BIWAC partners contribute data to the system and share information via an online portal	System is operational	$801 (with additional in-kind support from partners)
Diseases of Concern Diseases of concern to BIWAC members, including foreign animal and plant diseases and pathogens of national significance (priority 1 and 2), and zoonotic diseases, particularly those with pandemic potential.			
Disease Information Not applicable			

Border Infectious Disease Surveillance Project			
HHS		Domain:	
CDC		Human Health	
Description			
The Border Infectious Disease Surveillance Project serves as a binational early warning and active syndromic illness and disease monitoring network operating in the United States (U.S.)-Mexico Border Region and targets approximately 12 million people. The project conducts surveillance among residents of border states who visit participating clinics and hospitals. Using Web-based data entry, the project provides timely data sharing through data system and Epi-X notifications dependent on state health department and Mexican national policies.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State and local public health epidemiologists at the U.S.-Mexico border	Data are contributed by local, state, and federal public health officials from the United States and Mexico	The Web-based system has been operational since 2006	$728
Diseases of Concern			
Infectious diseases affecting humans of mutual interest to the United States and Mexico including syndroms compatible with bioterrorism agents			
Disease Information			
The Border Infectious Disease Surveillance Project conducts surveillance for viral hepatitis (A,B,C,D,E); fever and rash syndromes (measles, rubella, dengue, flea-borne typhus, tick-borne ehrlichiosis); fever and neurologic illness/West Nile Virus; influenza; undifferentiated fever/dengue/rickettsial disease; severe acute vesicular rash/varicella; community acquired pneumonica/Coccioidomycosis; animal rabies; brucellosis; and foodborne infections such as Salmonella and E.coli 0157:H7.			

Early Aberration Reporting System			
HHS		Domain:	
CDC		Human Health	
Description			
The Early Aberration Reporting System provides a free-to-end-user analysis tool that allows state and local public health officials as well as disaster and response agencies and organizations to quickly detect syndromes that might indicate a public health emergency and to monitor progression and control. The Early Aberration Reporting System allows users to add anything that can be counted into the software, and it will detect trends indicating something out of the ordinary. The tool may be downloaded from CDC's Web site. Unless a user initiates a submission, there is no link alerting CDC to investigate a potential public health emergency, and the user is responsible for initiating investigation and incident response. According to CDC, a new version of the system is scheduled for release in Summer 2010 and a version geared for local disaster management and monitoring organizations, both domestic and foreign, will be developed and fielded prior to 2011.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State and local public health officials, federal government public health officials at other agencies, universities, and nongovernmental agencies and organizations. This system, or portions of its software, has been used widely across the United States, as well as by government entities in Japan, China, New Zealand and elsewhere.	Users contribute and may analyze only their own data. CDC does not currently receive data from the system, and the data from end users vary according to state regulations and the data-sharing agreements set up with data reporters	System is operational	$350
Diseases of Concern			
Diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause hundreds of thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security. Being able to monitor extent and impact is valuable for response coordinators.			

Early Warning Infectious Disease Surveillance			
HHS		Domain:	
CDC		Human Health	
Description			
The Early Warning Infectious Disease Program is a collaboration of state, federal and international partners who are working to provide rapid and effective laboratory confirmation of urgent infectious disease case reports in the border regions of the United States, Canada, and Mexico. Activities include assessing surveillance and laboratory capacity on each side of the international border, improving electronic sharing of laboratory information, maintaining a database of all sentinel/clinical labs, and working to develop and agree on a list of notifiable conditions. The program was established in 2003 in order to enhance coordination between the United States, Canada, and Mexico to provide early warning and cross-border capability in the event of a disease outbreak.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Not applicable	Not applicable	The program was established in 2003	Not available
Diseases of Concern			
Diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Electronic Disease Notification System

HHS	Domain:
CDC	Human Health

Description

The Electronic Disease Notification System is an electronic system used to notify state and local public health jurisdictions about diseases and disease outbreaks occurring among refugees and immigrants entering the United States. The system has a module to track tuberculosis and other quarantinable diseases in refugees and immigrants. CDC uses the system to electronically notify health departments of arriving refugees and immigrants with Class A and Class B quarantinable conditions, provide an electronic communication system for health departments to notify each other of persons with tuberculosis conditions who change jurisdictions, and provide health departments with an electronic system to record and evaluate the outcome of domestic follow-up examinations.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC officials as well as state and local public health officials	Panel Physicians using required Department of State medical examination forms	System is operational	$1,183

Diseases of Concern

Quarantinable Diseases, as defined by executive order 13295, include cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers (such as Marburg, Ebola and Congo-Crimean disease), SARS (severe acute respiratory syndrome), and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic.

Disease Information

Tuberculosis is a bacterial disease that is usually transmitted by contact with an infected person. People with healthy immune systems can become infected but not ill. Symptoms include a bad cough, coughing up blood, pain in the chest, fatigue, weight loss, fever, and chills. Several drugs can be used to treat tuberculosis, but the disease is becoming increasingly drug resistant.

Emerging Infections Program (EIP)			
HHS		Domain:	
CDC		Human Health	
Description			
The Emerging Infections Program is a network of CDC and 10 state health departments working with collaborators, including academic institutions and other federal agencies. The network conducts active population-based surveillance and research for emerging infectious diseases of public health importance. Examples of programs included in the Emerging Infections Program network include Active Bacteria Core Surveillance (a program conducting laboratory-based surveillance for bacterial pathogens), FoodNet (a program to monitor the incidence of foodborne and waterborne diseases), and Influenza Projects (a program that tracks trends and characterizes outbreaks of severe influenza).			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
EIP data collection and surveillance activities are conducted by participating state health departments	Reports generated from EIP data are shared with public health officials, scientists and policy makers at CDC and federal agencies, and the public	System was established in 1995 and is operational	$30,000
Diseases of Concern			
A variety of diseases affecting humans			
Disease Information			
Not applicable			

Epidemic Information Exchange, Epi-X			
HHS		Domain:	
CDC		Human Health	
Description			
Epi-X connects state and local public health officials so that they can share information about outbreaks and other acute health events, including those possibly related to bioterrorism. It is intended to provide epidemiologists and others with a secure, Web-based platform that can be used to instant emergency notification of outbreaks and requests for CDC assistance. Epi-X provides tools for searching, tracking, and reporting on diseases.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC epidemiologists, veterinarians, and other relevant public health professionals	Epi-X has over 5,000 users who have the capability to provide data, including all state epidemiologists and local health officers from more than 150 major metropolitan cities or counties that can post data to the system. Epi-X scientific staff are available 24 hours a day, 7 days a week to post reports and notify users of urgent health events.	System is operational	Not available
Diseases of Concern			
Diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Foodborne Disease Active Surveillance Network (FoodNet)			
HHS		Domain:	
CDC		Human Health	
Description			
As part of CDC's Emerging Infections Program, FoodNet provides a network for responding to new and emerging foodborne diseases of national importance, monitoring the burden of foodborne disease, and identifying the sources of specific foodborne diseases. It consists of active surveillance and related epidemiological studies, which help public health officials better understand the epidemiology of foodborne diseases in the United States. Participating FoodNet sites may also be employed to coordinate enhanced surveillance and epidemiologic investigation if a novel foodborne disease threat is suspected in order to more rapidly identify the source and extent of the threat.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC epidemiologists and public health officials	Public health and food safety officials in the 10 FoodNet sites	System is operational	$5,900
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Foodborne illness harms human health, and outbreaks undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance, the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Global Disease Detection			
HHS		Domain:	
CDC		Human Health	
Description			
The Global Disease Detection program focuses on gathering, analyzing, and sharing global information to identify and respond to emerging health threats. The program has three mechanisms to accomplish this focus: regional centers that are placed around the world and are concerned with the detection and control of emerging infectious disease; CDC staff placed overseas to support CDC's mission; and the Global Disease Detection program operations center, which serves as the central clearinghouse focused on early detection of international events to which CDC may be asked to respond.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC and other federal government decision makers and public health subject matter experts	Staff in the Global Disease Detection unit	The program began operating in 2004	Not available
Diseases of Concern			
Infectious diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Global Emerging Infections Sentinel Network (GeoSentinel)			
HHS		Domain:	
CDC		Human Health	
Description			
GeoSentinel is a Web- and provider-based sentinel network. It consists of travel/tropical medical clinics around the world that participate in surveillance to monitor geographic and temporal trends in morbidity among travelers and other globally mobile populations. Passive surveillance and response capabilities are also extended to a broader network of GeoSentinel Network members.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Physicians in travel/tropical medicine clinics	Travel and tropical medical clinics that are users of the system	GeoSentinel was established in 1995 and is operational	$685
Diseases of Concern			
Infectious diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Health Alert Network			
HHS		Domain:	
CDC		Human Health	
Description			
The Health Alert Network is a nationwide system serving as a platform for the distribution of health alerts, dissemination of prevention guidelines and other information, distance learning, national disease surveillance, and electronic laboratory reporting, as well as for CDC's bioterrorism and related initiatives to strengthen preparedness at the local and state levels. Among other things, the Health Alert Network is to provide early warning alerts and to secure capability to securely transmit surveillance, laboratory, and other sensitive data.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State public health officials	Not available	System is operational	Not available
Diseases of Concern			
Not applicable			
Disease Information			
Not applicable			

Influenza Surveillance Portfolio			
HHS		Domain:	
CDC		Human Health	
Description			
The objective of influenza surveillance is to monitor the timing, geographic extent, and severity of influenza activity in the United States and its impact on the U.S. population over time. The system consists of nine complementary surveillance components, which include data on laboratory-based data describing the number and percentage of positive tests from laboratories across the country; the percentage of doctor visits for flu-like symptoms; the percentage of deaths reported to be caused by pneumonia and influenza in 122 U.S. cities; state and territorial epidemiologist reports of influenza activity; influenza-associated pediatric mortality; and reported pediatric influenza hospitalizations.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC public health officials and the public	Data on influenza are contributed by more than 120 laboratories, more than 2,400 sentinel health care providers, vital statistics in 122 cities, research and health care personnel at the Emerging Infections Program and influenza surveillance coordinators and state epidemiologists for 50 state health departments, New York City and the District of Columbia	System is operational	Not available
Diseases of Concern			
Influenza affecting humans			
Disease Information			
Influenza viruses are found in human and many different animals, including ducks, chickens, pigs, whales, horses, and seals. Seasonal flu is a contagious respiratory illness caused by flu viruses. It can cause mild to severe illness, and at times can lead to death.			

Laboratory Response Network			
HHS		Domain:	
CDC		Human Health, Air	
Description			
The Laboratory Response Network is an integrated network of 165 public health and clinical laboratories that provide laboratory diagnostics and disseminated testing capability for public health preparedness and response. It ensures that all member laboratories collectively maintain current biological detection and diagnostic capabilities, as well as surge capacity for all biological and chemical agents likely to be used by terrorists. The network is based on the use of standard protocols and reagents, integrated data management, and secure communications.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State and local public health officials	Members share data with each other	System is operational	$7,594
Diseases of Concern			
Infectious diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Morbidity and Mortality Weekly Report			
HHS		Domain:	
CDC		Human Health	
Description			
The Morbidity and Mortality Weekly Report is the nation's leading public health bulletin and the flagship publication of CDC. The Morbidity and Mortality Weekly Report includes reports on disease epidemics, trends, prevention and control of illness, injuries, and deaths. This information represents the primary manner that state and local public health officials, the media, and the public are informed of public health issues from CDC. The Morbidity and Mortality Weekly Report publishes data from the National Notifiable Disease Surveillance System each week and in an annual Summary of Notifiable Diseases. These data are the official statistics, in tabular and graphic form, for the reported occurrence of nationally notifiable infectious diseases in the United States.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Physicians and scientists, public health officials, public information officers, associations, and the general public.	International and U.S. public health officials and scientists submit epidemiological and surveillance data about outbreaks or other health events. Other federal agencies, such as USDA, FDA, and EPA produce public health information for publication. The publication is also integrated with the Epi-X and National Notifiable Diseases Surveillance System, both of which contribute data for publication.	The Morbidity and Mortality Weekly Report published its first issue in 1961. The publication is updated weekly and monthly.	Not available
Diseases of Concern			
Not applicable			
Disease Information			
Not applicable			

National Botulism Surveillance			
HHS		Domain:	
CDC		Human Health	
Description			
The National Botulism Surveillance System compiles information on botulism cases that occur in the United States. CDC provides clinical, epidemiological, and laboratory consultation and testing services for suspected botulism cases 24 hours a day and is the only source for antitoxin in the US. CDC alerts other federal agencies concerning botulism outbreaks associated with commercially produced and distributed food products. Also, CDC conducts a yearly survey of state and territorial epidemiologists and of state public health laboratory directors to identify and compile all botulism cases that occurred in the previous year.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Clinicians, laboratory professionals, and epidemiologists involved in diagnosing botulism	Federal public health officials; annual report is compiled from data provided by state health departments	System is operational	$250
Diseases of Concern			
Botulism			
Disease Information			
Botulism is a rare but serious paralytic illness caused by a nerve toxin that is produced by theneurotoxin producing Clostridia. There are four types of botulism. Foodborne botulism is caused by eating foods that contain the botulinum toxin. Wound botulism is caused by toxin produced from a wound infected with Clostridium botulinum. Infant botulism is caused by consuming the spores of the botulinum bacteria, which then grow in the intestines and release toxin. Finally, Adult Colonization is a rare form of botulism, similar to Infant Botulism, and results from ingestion of spores by susceptable persons and subsequent growth and toxin production in the intestines. All forms of botulism can be fatal and are considered medical emergencies. Foodborne botulism can be especially dangerous because many people can be poisoned by eating a contaminated food.			

National Notifiable Diseases Surveillance System

HHS	Domain:
CDC	Human Health

Description

CDC has responsibility for the collection and publication of data concerning nationally notifiable diseases. All 50 states, 5 territories, the District of Columbia, and New York City participate in the National Notifiable Diseases Surveillance System. The Council of State and Territorial Epidemiologists, with input from CDC, makes recommendations annually for additions and deletions to the list of nationally notifiable diseases. Reporting of nationally notifiable diseases to CDC by the states is voluntary. Reporting is currently mandated (i.e., by state legislation or regulation) only at the state level. The list of diseases that are considered notifiable, therefore, varies slightly by state. All states generally report the internationally quarantinable diseases (i.e., cholera, plague, and yellow fever) in compliance with the World Health Organization's International Health Regulations.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State and local public health officials and CDC officials	Public health officials in 50 states, 5 territories, the District of Columbia and New York City	System is operational	Not available

Diseases of Concern

Diseases affecting humans

Disease Information

Most states have a list of notifiable diseases that approximates a national list of notifiable diseases maintained by the Council of State and Territorial Epidemiologists. This national list is reviewed and revised annually with input from CDC. States may modify their list of notifiable diseases to reflect the public health needs of their region.

National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet)			
HHS		Domain:	
CDC		Human Health	
Description			
PulseNet is an early warning system for outbreaks of foodborne diseases. The network has participants from public health laboratories in all 50 states, federal regulatory agencies, and some state agricultural laboratories and is coordinated by CDC. PulseNet contributes to the identification and investigation of outbreaks of foodborne and bacterial diseases through comparison of the molecular "fingerprints" of foodborne pathogens from patients and their food, water, and animal sources. Once an outbreak is detected, PulseNet identifies patients who are infected with isolates that have the outbreak DNA "fingerprint" and thus are likely to be part of the outbreak. If a foodborne pathogen is isolated from a suspected vehicle, PulseNet also links it to the outbreak if it displays the outbreak "fingerprint." Finally, PulseNet provides leadership, expertise, training, and education in the field of foodborne and bacterial diseases.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
PulseNet participants include the state public health laboratories in all 50 states as well as other city, county, agricultural, and other federal food safety laboratories	PulseNet participants enter data into the system using standardized equipment and methods	System is operational	$4,400
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For example, the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

National Outbreak Reporting System			
HHS		Domain:	
CDC		Human Health, Animals, Food, Water	
Description			
The National Outbreak Reporting System is a Web-based application for states to report foodborne, waterborne, and other outbreaks electronically. Information collected includes the number ill, dates and places of outbreak, percent of cases by age group and gender, symptoms, incubation period and duration of illness, implicated food or water item, contributing factors leading to food or water contamination, source of implicated food or water, and food recall or other public health response. Data are used for annual summary reports of foodborne illness as well as for the monitoring of multistate outbreaks. The National Outbreak Reporting System was developed by CDC as a successor system to the Electronic Foodborne Outbreak Reporting System.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State public health, CDC, USDA, FDA, and EPA officials	50 state and 15 territorial reporting areas provide information on the number and characteristics of foodborne, waterborne and other enteric disease outbreaks in their area	System is operational	$600
Diseases of Concern			
Foodborne, waterborne and other enteric disease outbreaks			
Disease Information			
Foodborne, waterborne and other enteric disease outbreaks have myriad causes (e.g., bacteria, viruses, parasites, toxins and chemicals). These agents cause a range of human illnesses through toxicity (toxins or chemicals) or by infection (pathogens).			

National Respiratory and Enteric Virus Surveillance System			
HHS		Domain:	
CDC		Human Health	
Description			
The National Respiratory and Enteric Virus Surveillance System is a laboratory-based system that monitors temporal and geographic patterns associated with the detection of respiratory viruses including respiratory synctial virus, human parainfluenza viruses, respiratory and enteric adenoviruses, and rotaviruses. Influenza detections are also reported to the system, but are integrated with CDC influenza surveillance. Users upload data to the National Respiratory and Enteric Virus Surveillance System through a Web-based or telephone dial-in system.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
State public health officials and professionals	Commercial, public health, and clinical laboratories	System is operational	$131
Diseases of Concern			
Respiratory and enteric viruses			
Disease Information			
Respiratory viruses tracked in the system are generally transmitted through direct or close contact with contaminated secretions that are spread through droplets in the air or by contact with contaminated environmental surfaces. Enteric infections tracked in the system enter the body through the mouth and intestinal tract and are usually spread through contaminated food and water or by contact with vomit or feces.			

OutbreakNet			
HHS		Domain:	
CDC		Human Health, Food	
Description			
OutbreakNet is a national network of epidemiologists and other public health officials coordinated by CDC who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States. OutbreakNet ensures rapid, coordinated detection and response to multistate outbreaks of foodborne illness and to promote more comprehensive outbreak surveillance. OutbreakNet seeks to improve the collaboration and partnership among officials in local, state, and federal agencies who work with foodborne and diarrheal disease outbreak surveillance and response. OutbreakNet works in partnership with U.S. state and local health departments, USDA, FDA, and PulseNet (a national surveillance network made up of state and local public health laboratories and federal food regulatory agency laboratories).			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Public health and food safety officials at FDA, USDA, CDC, and state and local health departments	Local, state and federal officials with responsibility for investigating and reporting foodborne, waterborne and other enteric diseases outbreaks	System is operational	$1,500
Diseases of Concern			
Foodborne, waterborne and other enteric diseases			
Disease Information			
Foodborne, waterborne and other enteric disease outbreaks have myriad causes (e.g., bacteria, viruses, parasites, toxins and chemicals). These agents cause a range of human illnesses through toxicity (toxins or chemicals) or by infection (pathogens).			

Public Health Information Network			
HHS		Domain:	
CDC		Human Health	
Description			
The Public Health Information Network is an effort initiated by CDC to provide interoperability across public health functions and organizations, such as state and federal agencies, local health departments, public health labs, vaccine clinics, clinical care, and first responders. It is intended to, among other things, (1) deliver industry standard data to public health, (2) investigate bioterrorism detection, (3) provide disease tracking analysis and response, and (4) support local, state, and national data needs. It builds on existing CDC investments in other surveillance systems. The Public Health Information Network will not replace any of these systems but will provide an “umbrella” to support the interoperability of existing CDC surveillance, communications, and reporting systems.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Other federal agencies, national public health organizations, and state and local public health agencies	Information standards are contributed by CDC	Network is operational	Not available
Diseases of Concern			
Not applicable			
Disease Information			
Not applicable			

Quarantine Activity Reporting System			
HHS		Domain:	
CDC		Human Health	
Description			
CDC'S United States Quarantine Stations seek to limit the importation of infectious diseases into the United States by working with key partners to identify ill persons and potentially infectious items. Quarantine Stations enter reports into the Quarantine Activity Reporting System in real time to CDC-Atlanta that summarizes port activities at 20 ports of entry and land-border crossings where international travelers arrive. The reports are analyzed and evaluated daily and relevant information is captured and disseminated as part of a Disease and Activity Report which is sent to CDC leadership and relevant external partners. During 2009 Quarantine Station staff reported 3, 847 illnesses and 125 deaths, conducted 122 airline contact investigations involving 95 index cases, forwarded 9,778 migrant packets, processed 205 non-human primate shipments, released 125 drug shipments, and participated in 1,510 activities with external partners.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CDC personnel	CDC's Quarantine Stations report data gathered from airline staff, state and local health departments, Customs and Border Protection personnel, emergency responders, and other first responders to infectious disease outbreaks	System is operational	$568
Diseases of Concern			
Infectious diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Unexplained Deaths and Critical Illnesses Surveillance System			
HHS		Domain:	
CDC		Human Health	
Description			
As part of CDC's Emerging Infections Program, the Unexplained Deaths and Critical Illnesses Surveillance System is expected to contain limited epidemiological and clinical information on previously healthy persons aged 1 to 49 years who have illnesses with possible infectious causes. It is also expected to provide active population-based surveillance through coroners and medical examiners at limited sites. National and international surveillance will be passive for clusters of unexplained deaths and illnesses.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Epidemiologists at CDC	Not available	System is in development	Not available
Diseases of Concern			
Diseases affecting humans			
Disease Information			
A catastrophic biological event, such as a terrorist attack with a weapon of mass destruction or a naturally occurring pandemic could cause thousands of casualties or more, weaken the economy, damage public morale and confidence, and threaten national security.			

Electronic Laboratory Exchange Network, (eLEXNET)			
HHS		Domain:	
Food and Drug Administration (FDA)		Human Health, Food	
Description			
eLEXNET provides a Web-based system for real-time sharing of food safety laboratory data among federal, state, and local agencies. It allows public health officials at multiple government agencies engaged in food safety activities to compare and coordinate laboratory analysis findings in a secure setting. eLEXNET captures food safety sample and test result data from participating laboratories and uses them for risk assessment and decision support purposes, improving the early detection of problem products.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Public health and agricultural food safety officials	FDA's Center for Food Safety and Applied Nutrition manages eLEXNET, which has 1,800 users including 203 participating labs, 150 of which are FERN labs	System is operational	$1,097
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance, the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Food Emergency Response Network			
HHS and USDA		Domain:	
FDA and the Food Safety and Inspection Service at USDA		Food	
Description			
The Food Emergency Response Network is a coordinated initiative between USDA's Food Safety and Inspection Service and FDA to develop an integrated laboratory network capable of responding to national emergences. Laboratories participating in the network are responsible for detecting and identifying biological, chemical, and radiological agents in food. The primary objectives of the Food Emergency Response Network are to prevent attacks on the food supply through surveillance; to prepare for emergencies by strengthening lab capabilities; to respond to threats, attacks, and emergencies in the food supply; and to assist in recovery. Participating laboratories conduct investigations of terrorism-related events involving food and play a major role in method development and validation for detecting foodborne contamination.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Officials at FDA and USDA's Food Safety and Inspection Service	State food testing laboratories are the primary providers of data. Some federal, local, and county food testing laboratories also provide data	System is operational	USDA: $10,223 HHS: $18,758
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance, the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Center for Animal Health Information and Analysis			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animal	
Description			
The Center for Animal Health Information and Analysis analyzes biosurveillance data on animal diseases by conducting all-source intelligence and issue assessment of threats, identification of the hazards posed by animal diseases, analysis of risk and modeling of the spread of an animal disease, and the issuance of recommendations to target surveillance resources to animal threats. The center is organized into three teams: Global Intelligence and Forecasting focuses on improving animal health through intelligence and analysis; Risk Analysis identifies methods and approaches for estimating risks of animal disease outbreaks; and Spatial Epidemiology develops geospatial methods to collect and analyze data on farm animal locations and livestock concentration.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Alerts and advisories are issued to selected federal agencies and international organizations, including USDA, DHS, the United Nations Food and Agriculture Organization, and the World Organization for Animal Health	Officials from the center analyze data from a variety of sources and issue alerts	Operational	$4,586
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Emergency Management Response System			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animals	
Description			
The Emergency Management Response System is used to manage investigations of outbreaks of animal diseases in the United States. This Web-based task management system was designed to automate many of the tasks that are routinely associated with disease outbreaks and animal emergencies. The Emergency Management Response System is used for routine reporting of foreign investigations of animal disease, state-specific disease outbreaks or control programs, national responses, or natural disasters involving animals. The system also has a mapping feature, which allows for real-time identification of outbreaks to enable responders to respond more quickly by providing high-resolution maps to decision makers, government agencies, and the public. The system interfaces with state and federal diagnostic laboratories for reporting test results.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal and state animal health agencies	State and federal animal health officials	System is operational	$463
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

The emerging Veterinary event database			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animals	
Description			
The emerging Veterinary event database stores syndromic surveillance information regarding adverse animal health events. USDA's Center for Animal Health Information and Analysis uses publicly available information sources to gather information on these events. The database is used to establish a baseline for animal disease and catalog reports of adverse animal health events. Analysts use this information to produce reports on emerging disease. Access to the database is not restricted to personnel from the Center for Animal Health Information and Analysis.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USDA Center for Emerging Issues officials and Veterinary Services staff	Open source material is collected from electronic sources, such as newspapers, Web sites, and listervs	System has been operational since 1999	Minimal costs associated with employee time for maintenance
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

National Agriculture Pest Information System			
USDA		Domain:	
Animal and Plant Health Inspection Service		Plants	
Description			
The National Agricultural Pest Information System is a database for collection, summarization, and standardized information on plant pests such as insects, diseases, weeds, and nematodes. Data are gathered by each of the states and by USDA's Plant Protection and Quarantine. Emphasis is given to surveys for exotic pests, pests that may impact export of U.S. agricultural products, as well as pest and biological control agents identified by Plant Protection and Quarantine progam officials. The National Agricultural Pest Information System facilitates data management coordination for the plant pest survey data gathered on a national, regional, and/or state scale as part of the Cooperative Agricultural Pest Survey program sponsored by USDA.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Plant health officials administering the Cooperative Agricultural Pest Survey program	States participating in the Cooperaive Agricultural Pest Survey enter data into the system	System is operational	$499.91
Diseases of Concern			
Exotic pests affecting plants			
Disease Information			
Plant resources in the United States, inlcluding crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

National Animal Health Laboratories Network

USDA	Domain:
Animal and Plant Health Inspection Service	Animal
National Institute of Food and Agriculture	

Description

The National Animal Health Laboratories Network was established as part of a strategy to coordinate and network the diagnostic testing capabilities of federal veterinary diagnostic laboratories with state and university diagnostic laboratories to improve early detection of, response to, and recovery from animal health emergencies, including bioterrorist events, newly emerging diseases, and foreign animal disease agents. The network is composed of 58 laboratories in 45 states. Current activities include a training program for technicians who test for certain high-risk diseases such as food and mouth disease and conducting surveillance for animal diseases, such as swine influenza virus and pseudorabies.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Program managers and state and federal animal health officials	State and university veterinary diagnostic labs	Operational since 2002	$8,125 (excludes funding provided to labs for testing, sample collection, or training)

Diseases of Concern

Infectious diseases affecting animals

Disease Information

Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.

National Animal Health Monitoring System			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animal	
Description			
The mission of the National Animal Health Monitoring System is to deliver information and knowledge about animal health by conducting studies that generally focus on food animals, dairy, livestock, and poultry commodities. The studies are designed to gather information about industry practices, biosecurity, and prevalence of endemic diseases. The studies are conducted about every 5 years or more depending on budget/resources and needs of commodity stakeholders, and the results are published in an annual Animal Health Report. This information is used for surveillance planning to identify risk factors, so that surveillance can be targeted to key areas of concern.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Data are used by animal health officials within USDA and other federal agencies, state and local partners such as state veterinarians and animal health agencies, and international partners such as the World Organization for Animal Health	Data is provided by industries that are selected through the National Agricultural Statistics Service	System is operational	$4,157
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

National Animal Health Reporting System

USDA	Domain:
Animal and Plant Health Inspection Service	Animal

Description

The National Animal Health Reporting System was designed to provide data from chief State animal health officials on the presence or absence of confirmed World Organization for Animal Health reportable diseases in specific commercial livestock, poultry, and aquaculture species in the United States. Within a state, data about animal disease occurrence are gathered from as many verifiable sources as possible and consolidated into a monthly report submitted to the National Surveillance Unit, where the information is verified, summarized, and compiled into a national report. The commodities currently covered are cattle, sheep, goats, equine, swine, commercial poultry, and commercial food fish. The National Animal Health Reporting System is a joint effort of the U.S. Animal Health Association, American Association of Veterinary Laboratory Diagnosticians, and USDA's Animal and Plant Health Inspection Service.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Epidemiology and veterinary health officials at USDA	State personnel utilize multiple data sources (i.e., program disease information, Foreign Animal Disease investigations, veterinarians, veterinary labs, public health labs, and other agencies) in completion of monthly reports	System is operational	Federal cost is a portion of the overall budget of the National Surveillance Unit

Diseases of Concern

Infectious disease affecting animals

Disease Information

Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.

National Surveillance Unit			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animal	
Description			
The objective of the National Surveillance Unit includes developing and improving methods for surveillance and analysis of animal health related data; analyze surveillance data to provide actionable information; designing and evaluating national animal health surveillance systems; and communicating surveillance information to key partners. The National Surveillance Unit is the coordinating entity for the National Animal Health Surveillance System. The goal of the unit is to create a comprehensive, integrated national surveillance system for animal health. The National Surveillance Unit has created an inventory of biosurveillance systems focused on animal health which allows users to search for animal health surveillance systems by species, disease, source of data, sample type, category of system, and agency administering the system.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
The National Surveillance Unit's reports are used by officials within USDA, state regulators, researchers and the public. The Surveillance Unit also reports the presence of confirmed disease outbreaks to the World Organization for Animal Health. Strategic surveillance planning and analysis are used by federal regulators for decision making.	States, National Animal Laboratory Network Laboratories, and USDA animal disease programs report data to the National Surveillance Unit	NSU was founded in 2003 and is operational	$2,418
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Offshore Pest Information System

USDA	Domain:
Animal and Plant Health Inspection Service	Plants

Description

The Offshore Pest Information System is a Web-based information-sharing tool that allows users to communicate in an organized manner about offshore animal and plant health events and issues. The system is a key instrument used to meet the goals of the International Safeguarding Information Program. This program is risk-focused and designed to collect, synthesize/analyze, communicate, and utilize relevant offshore animal and plant disease or pest information. The Offshore Pest Information System is secure and enables multiple users to access, respond to, and act upon information about international events that affect animal and plant health. Weekly reports are generated from events in the system's database that are distributed to the system's users and stakeholders.

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Officials at USDA, DHS's Customs and Border Protection, and state Departments of Agriculture. Other users interested in plant pests may also subscribe to alerts.	Officials in select components of USDA's Animal and Plant Health Inspection Service	System is operational	$1,750

Diseases of Concern

Animal and plant emerging diseases and pests

Disease Information

Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies. Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.

Rapid Syndrome Validation Project for Animals (RSVP-A)			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animal	
Description			
Rapid Syndrome Validation Project for Animals is a syndromic surveillance system to facilitate the early detection, reporting, and response to an infectious disease outbreak in animals. Veterinarians collect syndromic data on animals—such as neurologic dysfunction, birth defects, or unexpected death—on hand-held computers and send the data to a central database. USDA officials and other practitioners analyze the data and create alerts of a disease outbreak or summarize normal disease occurrence.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USDA officials and state and local animal health practitioners	Data is contributed by participating practicing veterinarians	Operational in pilot project phase	$334
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Integrated Pest Management Pest Information Platform for Extension and Education			
USDA		Domain:	
National Institute of Food and Agriculture		Plants	
Description			
The Integrated Pest Management Pest Information Platform for Extension and Education is a system to analyze threats to plant health. The system utilizes modeling technology that allows stakeholders to access data online for the location of plant threats, as well as their severity, distribution, forecasting, and state-specific control recommendations. Data included are all hazards, and include weather patterns, observations of plant disease occurrences, and the results of sample testing that are contributed by the system's users. The system is active in 41 states, 5 Canadian provinces, and Mexico.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
ipmPIPE members include international federal, and local officials involved in agricultural health as well as land grant university	Cooperative Extension System	System has been operating since 2005	$150
Diseases of Concern			
Plant pests and pathogens			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong liklihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

National Plant Diagnostic Network			
USDA		Domain:	
National Institute of Food and Agriculture		Plants	
Description			
The mission of the National Plant Diagnostic Network is to safeguard U.S. plant agriculture against introduced pests and pathogens by enhancing diagnostic and detection capabilities; improving communication among federal, state, and local agencies involved in monitoring for plant pests and pathogens; and delivering educational programs regarding the threats posed by their introduction. A single database captures data from voluntary information given to laboratories, such as from grower samples, bugs brought into laboratories, or from citizen complaints. The network, for example, funds diagnostic labs in all 50 states and sponsors training for individuals in the plant industry (from nursery owners to home gardeners). The National Plant Diagnostic Network also maintains a national database with plant disease reports, charts, and mapping tools.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal, state, local, and tribal officials involved in plant health	University diagnostic laboratories	System has been operating since 2002	$4,400
Diseases of Concern			
Plant pests and pathogens			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong liklihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

Automated Import Information System			
USDA		Domain:	
Food Safety and Inspection Service		Food	
Description			
Upon arrival at a U.S. port-of-entry, all meat and poultry shipments must be reinspected by a Food Safety and Inspection Service import inspector before they are allowed into this country. Every lot of product is given a visual inspection for appearance and condition, and checked for certification and label compliance. In addition, the Automated Import Information System assigns various other types of inspection including product examinations and microbial and chemical laboratory analysis based on statistical and trend analysis of the product's origin.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Food Safety and Inspection Service officials	Importers of meat and poultry products submit reports to the system	System is operational	$104
Diseases of Concern			
Biological agents that can contaminate meat and poultry products			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Food Safety and Inspection Service Incident Management System			
USDA		Domain:	
Food Safety and Inspection Service		Food	
Description			
The Food Safety and Inspection Service's Incident Management System is a web-based common operating platform that, according to USDA officials, allows program managers and users to rapidly identify, respond to, and track the agency's response to significant incidents such as suspected tampering of products, threats to facilities, natural disasters, and Class 1 recalls with illness.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Food Safety and Inspection Service officials	Food Safety and Insepction Service Emergency Management Committee members and personnel granted access to the system	System is operational	$548
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Import Alerts Tracking System			
USDA		Domain:	
Food Safety and Inspection Service		Animal, Food	
Description			
In April 2008, the Food Safety and Inspection Service implemented the Import Alert Tracking System, an automated data system that allows field employees to record information related to ineligible, illegal, or smuggled shipments of imported meat, poultry, or egg products found in commerce. The system enables better coordination in enforcement actions through quicker access to information collected on illegal entries. The system has been designed to automate the processes of incident notifications between Food Safety and Inspection Service program areas and creation of an incident report when appropriate.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Food Safety and Inspection Service officials in the Office of International Affairs	Data are contributed by Import Surveillance Liaison Officers at U.S. points of entry	System is operational since 2005.	No direct costs - costs are included under the Food Safety and Inspection Service's Incident Management System
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Laboratory Electronic Application for Results Notification			
USDA		Domain:	
Food Safety and Inspection Service		Food	
Description			
The Laboratory Electronic Application for Results Notification program provides Food Safety and Inspection Service personnel, establishments, and state officials with reports on the status of meat, poultry, and egg product test samples. The application is an automated process that tracks each sample as it is received, analyzed, and results are reported. The Laboratory Electronic Application for Results Notification program allows field inspectors and agency staff to check on the status of individual samples or view circuit, district, and management summaries of results. Establishment and state officials will not have access to the intranet site, but they may receive e-mail reports on the status of individual samples.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Sample collectors at USDA	Food Safety and Insepction Service Laboratories	System is operational	$25
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Microbiological and Residue Computer Information System			
USDA		Domain:	
Food Safety and Inspection Service		Food	
Description			
The Microbiological and Residue Computer Information System contains sample identification information and results for analyses submitted by inspection personnel to laboratories. These samples consist of meat, poultry, and egg products; and they are analyzed to ensure that they are safe, wholesome, unadulterated, and properly labeled. The samples are tested because they bear or contain residues of drugs, pesticides, other chemicals, or microbiological pathogens. Test results are used to alert agency personnel and the industry of contaminations and threats to consumer health and the need for protective actions such as product recalls. The Microbiological and Residue Computer Information System is also used for risk assessment and decision support purposes, improving early detection of problem products, enabling active food safety surveillance, and evaluating potential threats to the food supply.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Food Safety and Inspection Service officials	Food Safety and Insepction Service Laboratories	System is operational	$32
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Pathogen Reduction Enforcement Program			
USDA		Domain:	
Food Safety and Inspection Service		Food	
Description			
The Pathogen Reduction Enforcement Program schedules tests, tracks food samples, and generates a series of reports concerning food testing eligibility and the status of food sample testing results. It collects and stores food manufacturing establishment addresses and product information, as well as the establishment's performance in previous food safety tests. It uses this information to schedule and request the collection of food samples for testing. These tests results are used to alert agency personnel and the industry of contaminations, so an appropriate response can be issued. The Pathogen Reduction Enforcement Program is also used for risk assessment and decision support purposes, improving early detection of problem products, enabling active food safety surveillance, and evaluating potential threats to the U.S. food supply.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USDA's Data Administration Branch, Office of Program Evaluation, Enforcement and Review	Food Safety and Insepction Service Laboratories	System is operational	$25
Diseases of Concern			
Foodborne illnesses			
Disease Information			
Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Agriculture Quarantine Inspection Program			
USDA		Domain:	
Plant Protection and Quarantine		Plants	
Description			
The Agriculture Quarantine Inspection Program partners with Customs and Border Protection to conduct hands-on inspection of agricultural commodities entering the United States to confirm that imports are free of pests and disease. Specifically, Customs and Border Protection officers inspect any incoming agricultural commodities, including plants, animals, food, or other miscellaneous goods—such as automobile parts where pests might hide and enter the United States—for the presence of pests. The Agriculture Quarantine Inspection Program operates Plant Inspection Stations, which process the pest interceptions made by Customs and Border Protection officers at ports, and identify pests and diseases on imported goods. This information is also filtered into USDA's Plant Protection and Quarantine databases.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USDA and CBP officials	USDA and CBP officials enter data into the system	The system is planned to be replaced by a more user-friendly system in the next five years	$1100
Diseases of Concern			
Plant pests			
Animal diseases			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years. Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.Outbreaks of foodborne illness can harm human health, undermine consumer confidence in the safety of the nation's food supply, and have serious economic consequences. For instance the 2006 outbreak of E. coli O157:H7 linked to bagged spinach, resulted in 205 confirmed illnesses, 3 deaths, and an estimated $100 million loss to industry.			

Cooperative Agricultural Pest Survey			
USDA		Domain:	
Plant Protection and Quarantine		Plants	
Description			
The mission of the Cooperative Agricultural Pest Survey program is to identify exotic plant pests in the United States deemed to be of regulatory significance to USDA, state departments of agriculture, tribal governments, and cooperators. It facilitates this mission by working to confirm the presence or absence of environmentally and/or economically harmful plant pests. These pests can impact agriculture or the environment. The Cooperative Agricultural Pest Survey program also establishes and maintains a comprehensive network of cooperators and stakeholders to facilitate a plant protection mission.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
CAPS has established partnerships with all 50 states and some U.S. territories.	States provide information on plant pests and deliver samples for testing to USDA's Plant Protection and Quarantine for further analysis. Results are disseminated back to participating states after testing has concluded.	System is operational	$9,098 was allocated to support pest detection activities. Of this, approximately $8,453.50 was given to the states via cooperative agreements to conduct pest detection activities.
Diseases of Concern			
Plant pests			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

Exotic Pest Information Collection and Analysis

USDA	Domain:
Plant Protection and Quarantine	Plants

Description

The purpose of Exotic Pest Information Collection and Analysis is to conduct plant pest biosurveillance for USDA's Plant Protection and Quarantine. The program continuously gathers, evaluates, and communicates open-source information on quarantine-significant plant pests worldwide. The program also produces concise articles about relevant pieces of pest news, placing the news into a safeguarding context and providing important background information. The articles are distributed weekly in an e-mail notification and are archived in a Web-accessible, fully-searchable database (known as the Global pest and Disease Database).

Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USDA Plant Protection and Quarantine officials	The Exotic Pest Information Collection and Analysis program team gathers publicly available information from the World Wide Web, including scientific journals, Web sites, listervs, and blogs	System is operational	$231

Diseases of Concern

Plant pests such as arthropods, nematodes, pathogens, mollusks, and weeds

Disease Information

Plant resources in the United States, including crops, rangelands, and forests, are threateneded by exotic plant pests. Globalization and international trade increase the likelihood of exotic pest introduction into the United States. According to USDA, up-to-date pest information is essential for preparedness and early response.

Global Pest and Disease Database			
USDA		Domain:	
Plant Protection and Quarantine		Plants	
Description			
The Global Pest and Disease Database is an archive of exotic pest information specific to Plant Protection Quarantine needs, for uses including the prioritization of pest threats to the United States, conducting risk assessments of plant pests, and completing domestic exotic pest surveys. The Exotic Pest Information Collection and Analysis program contains information on over 600 plant and animal plant pests not native to the United States. The Exotic Pest Information Collection and Analysis program is primarily intended for use within USDA but DHS officials, other federal agencies, and state agricultural agencies also have access to the system.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Users include APHIS, state agricultural agencies, and other federal agencies such as DHS	Other USDA biosurveillance systems, such as the Exotic Pest Information Collection and Analysis system, the Offshore Pest Information System, and the New Pest Advisory Group	System is operational	$399
Diseases of Concern			
Plant pests not known to occur in the United States or in limited distribution in the United States			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

National Animal Health Surveillance System			
USDA		Domain:	
Animal and Plant Health Inspection Service		Animal	
Description			
The National Animal Health Surveillance System is a USDA initiative to integrate existing animal health monitoring programs and surveillance activities into a national, comprehensive, and coordinated system and develop new surveillance systems, methodology, and approaches. The system is an interdisciplinary network of partners working together to protect animal health and promote free trade through surveillance, control, and prevention of foreign, emerging, and endemic diseases.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal and state animal health agencies, as well as industry	State and federal officials involved in surveillance programs, accredited private veterinarians, and livestock producers	The system is a multicomponent network. Many components are functional, others are under development	Federal cost is a portion of the overall budget of the National Surveillance Unit
Diseases of Concern			
Exotic and endemic infectious diseases affecting animals and public health			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

National Wildlife Health Center Wildlife Mortality Database (EPIZOO)			
DOI		Domain:	
U.S. Geological Survey National Wildlife Health Center		Human, Animal	
Description			
The USGS National Wildlife Center's EPIZOO database is a data set that documents information on epidemics in wildlife. EPIZOO tracks die-offs throughout the United States and territories, primarily in migratory birds and endangered species. Data include locations, dates, species involved, history, population numbers, total sick and dead, and diagnostic information. The data are collected from a reporting network developed at the National Wildlife Health Center as well as from collaborators across the North American continent.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Officials at NWHC, as well as natural resource managers, regulators, the scientific community, and state and local environmental protection officials	NWHC partners	Regular data are available from 1975 to the present; some data sets are available from earlier years	Not available
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Wildlife Health Diagnostic Database			
DOI		Domain:	
U.S. Geolgocial Survey National Wildlife Health Center		Human, Animal	
Description			
The Wildlife Health Diagnostic Database is a computerized record of specimens sent to the National Wildlife Health Center for processing and diagnostic testing. Data include history and recordkeeping information, types of tests run, and some initial diagnostic and testing results. Data from the system cannot be used as a representative sample of animal health diseases that exist in the wild, but it may be used to determine if a disease or animal health syndrome has occurred in the wild.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Officials at U.S. Geological Survey's National Wildlife Heatlh Center	Data is provided by National Wildlife Health Center personnel and others involved with gathering samples of wild animals for diagnostic testing	Data have been available since 1975	Not available
Diseases of Concern			
Infectious diseases affecting animals			
Disease Information			
Animal diseases can affect wildlife as well as livestock, pets, and companion animals. Some of these diseases may affect humans. Animal disease outbreaks can cause significant and potentially disruptive losses for animal producers, put financial strain on response systems, and affect regional and national economies.			

Forest Health Protection Program			
USDA		Domain:	
US Forest Service		Plants	
Description			
The U.S. Forest Service Forest Health Protection program is responsible for detection and monitoring of forest health conditions on all forested lands in the United States. The program annually conducts aerial surveys of nearly 500 million acres of forested lands for unusual activities of forest insects and pathogens. The Forest Health Protection Program has developed a suite of forest health indicators that are to monitor forest health and facilitate the detection of the introduction of foreign pests. Pest risk assessments are used to target detection surveys in areas that are particularly vulnerable to invasion and establishment of invasive pests. Annual reports at the state, regional, and national levels assess trends in forest condition and highlight new or expanding outbreaks of forest pests.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
Federal, state, tribal, and private landowners; as well as officials from the Departments of Agriculture, Defense, and Interior	Officals from the Forest Health Protection Program, as well as state agencies such as state Departments of Natural Resources	System is operational.	$14,000
Diseases of Concern			
Invasive pests			
Disease Information			
Plant resources in the United States, including crops, rangelands, and forests, are vulnerable to endemic, introduced, and emerging pathogens. More than 50,000 plant diseases occur in the United States, caused by a variety of pathogens. Increasing globalization and international trade activities create a strong likelihood that many other exotic plant pathogens will arrive in the United States in the coming years.			

Biohazard Detection System			
USPS		Domain: Air	
Description: The Biohazard Detection System deployed by the USPS is a decentralized locally networked automated collection and identification system and is used to detect the biological agent causing anthrax that could be present in first-class mail. The system is installed in mail processing facilities nationwide. The system is integrated with mail processing and letters are automatically fed into the system where it detects the presence of anthrax. The detecting process runs continuously and alerts system operators if a presumptive positive case of anthrax is detected.			
Primary Users	Primary Providers of Data	Status	FY 2009 Costs (thousands)
USPS mail processing facilities	Automated Screening and Detection	System has been deployed since November 2005	Annual Operation and Maintenance Costs: $73.5M
Diseases of Concern: Anthrax			
Disease Information: Anthrax is an acute infectious disease caused by a bacterium commonly found in the soil. Although anthrax can infect humans, it occurs most commonly in plant-eating animals. Human anthrax infections have usually resulted from occupational exposure to infected animals or from contaminated animal products. Anthrax infection can take one of three forms: coetaneous, usually through a cut or abrasion; gastrointestinal, usually by ingesting undercooked contaminated meat; or inhalation, by breathing airborne anthrax spores into the lungs. The symptoms are different for each form and usually occur within 7 days of exposure. Anthrax can be treated with antibiotics and a vaccine is available. In 2001, U.S. Postal Service employees and customers contracted anthrax after a domestic bioterrorism incident that spread anthrax spores through the U.S. mail and resulted in five deaths.			

Appendix V: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528

Homeland Security

June 21, 2010

William O. Jenkins, Jr.
Director, Homeland Security and Justice Issues
U.S. Government Accountability Office
441 G St., N.W.
Washington, D.C. 20548

Dear Mr. Jenkins:

The Department of Homeland Security (DHS) appreciates the opportunity to review and provide comments on the Government Accountability Office's (GAO) draft report titled, *Biosurveillance Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader* (GAO-10-645).

DHS has reviewed the draft report and concurs with its observations regarding the need for a national strategy for biosurveillance that encompasses all biological domains as well as generally concurring with its comments regarding the National Biosurveillance Integration System (NBIS) and the National Biosurveillance Integration Center (NBIC).

Under the direction of the DHS Assistant Secretary and Chief Medical Officer, the NBIC has been leading an NBIS interagency review to revise and refine the collaborative activities associated with our shared biosurveillance mission responsibilities. The results of this review will help to improve the value of NBIS interaction with federal, state, local, tribal and territorial departments and agencies. As a part of the ongoing interagency review, the NBIS participants have now also recognized critical strategic planning gaps. These gaps such as multi-agency program procurement / management efforts or interagency analyst training initiatives were also identified among the recommendations presented by the 9/11 Commission and the 2010 bipartisan Congressional Commission on the Prevention of Weapons of Mass Destruction, Proliferation and Terrorism. However, NBIC and NBIS enabling legislation such as Public Law 110-53 or associated Executive Directives (such as Homeland Security Presidential Directives (HSPD) 9, 10, and 21) did not require either NBIC or NBIS to address such gaps and accordingly, during these initial years of both NBIC's and NBIS's development, no strategies to close gaps were developed.

In the report, GAO recommended the "White House Homeland Security Council" (WHHSC) task the National Security Staff to "establish the appropriate leadership mechanism to provide a focal point with authority and accountability for developing a national biosurveillance capability" and that focal point be charged with "the responsibility for developing, in conjunction with relevant federal agencies, a national biosurveillance strategy." Public Law 110-53 assigns specific responsibilities to the NBIC Director and details seven legislative and executive branch expectations cited as responsibilities of the NBIS federal participants. These responsibilities and expectations can serve as guideposts to any WHHSC established "leadership mechanism." As the NBIC is acknowledged in documents such as the Department of Health and Human Services authored *National Biosurveillance Strategy for Human Health* for its integrative cross-domain leadership role, NBIC along with other federal NBIS participants look forward to serving as active participants in producing a national biosurveillance strategy.

The DHS Office of Health Affairs, specifically NBIC, agree on the need to develop a national strategy for biosurveillance. This strategy will likely serve as a keystone to the long-term success of the shared federal biosurveillance mission.

We appreciate the opportunity to review and provide comments on this draft report and we look forward to working with you on future homeland security issues.

Sincerely,

Jerald E. Levine
Director
Departmental GAO/OIG Liaison

Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contact

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Acknowledgments

In addition to the contact named above, Anne Laffoon, Assistant Director; Michelle Cooper; Kathryn Godfrey; Amanda Krause,;Steven Banovac; and Susanna Kuebler made significant contributions to the work. Keira Dembowski, Jessica Gerrard-Gough, and Patrick Peterson also provided support. Tina Cheng assisted with graphic design. Amanda Miller and Russ Burnett assisted with design, methodology, and analysis. Tracey King provided legal support. Linda Miller provided communications expertise.

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