



October 2017

BIODEFENSE

Federal Efforts to Develop Biological Threat Awareness

Why GAO Did This Study

Biological threats come from a variety of sources and can pose a catastrophic danger to public health, animal and plant health, and national security. Threat awareness, which consists of activities such as collecting and analyzing intelligence, developing risk assessments, and anticipating future threats, is vital to help federal agencies identify necessary biodefense capabilities and ensure investments are prioritized to make effective use of federal funds.

GAO was asked to review how key federal agencies develop and share threat awareness information, and how that information informs further investments in biodefense. This report describes: (1) the types of actions that key federal agencies have taken to develop biological threat awareness, and how that information is used to support investment decisions; (2) the extent to which these agencies have developed shared threat awareness; and (3) how DHS's NBACC determines what additional threat characterization knowledge to pursue.

GAO analyzed federal policies, directives, and strategies related to biodefense, as well as agency documents such as threat assessments and modeling studies. We identified five key biodefense agencies based on review of the roles designated in these documents. GAO interviewed officials from these agencies about threat awareness activities, and reviewed prior GAO work and related biodefense studies. Each of the key agencies reviewed a draft of this report and provided technical comments that GAO incorporated as appropriate.

View [GAO-18-155](#). For more information, contact Chris Currie at 404-679-1875 or curriec@gao.gov.

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Federal Efforts to Develop Biological Threat Awareness

What GAO Found

Key biodefense agencies—the Departments of Homeland Security (DHS), Defense (DOD), Agriculture (USDA), and Health and Human Services (HHS), and the Environmental Protection Agency—conduct a wide range of activities to develop biological threat awareness for intentional and naturally occurring threats, and reported using that information to support investment decisions.

- **Intelligence gathering:** Agencies use a combination of intelligence gathering on adversaries' capabilities to cause harm with a biological weapon and global disease surveillance to monitor threats from naturally occurring health threats that might impact humans, animals, or plants.
- **Scientific research:** Agencies use traditional laboratory research to help understand the characteristics of various threat agents, including their virulence, stability, and ability to be dispersed through various methods. Scientific research is also performed on emerging pathogens to understand their means of transmission, host susceptibility, and effects of infection.
- **Analysis activities:** Agencies use modeling studies and other analytical work to help determine the scope and impact of possible biological threats.

These three activities help agencies identify and prioritize the most dangerous biological threats, which can then be used to guide biodefense investments. For example, USDA told GAO it uses threat information to determine which foreign animal diseases represent its highest priorities based on the potential of those agents to cause catastrophic harm, and those priorities are used to inform investments. Similarly, HHS said it conducts threat awareness activities to help inform the development and acquisition of human medical countermeasures.

Federal agencies with key roles in biodefense share biological threat information through many different mechanisms designed to facilitate collaboration among government partners, including working groups and interagency agreements. For example, agency officials reported using collaborative mechanisms to coordinate activities and avoid duplication and overlap. However, as GAO and others have noted, opportunities exist to better leverage shared resources and inform budgetary tradeoffs. Recent legislation requires key biodefense agencies to create a national biodefense strategy that has the potential to help address these issues, by, among other things, supporting shared threat awareness. Until the strategy is developed, the extent to which it will meet this need is unknown.

The threat characterization research agenda at DHS's National Biodefense Analysis and Countermeasures Center (NBACC) is based primarily on the results and knowledge gaps identified through the Bioterrorism Risk Assessment (BTRA). According to DHS officials, the knowledge gaps deemed most critical include data about biological agents that have a high impact on BTRA consequence estimates and also a high degree of uncertainty. Each year NBACC produces an annual plan that outlines new research projects intended to address these knowledge gaps, and incorporates additional planning criteria, such as interagency stakeholder input, resource availability, and maintenance of required technical capabilities. According to DHS officials, the results of NBACC research were used to directly enhance the BTRA, including updating data associated with eight biological agents since 2010.

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Abbreviations

ARS	Agricultural Research Service
APHIS	Animal and Plant Health Inspection Service
ASPR	Assistant Secretary for Preparedness and Response
BTCP	Biological Threat Characterization Program
BTRA	Bioterrorism Risk Assessment
CBD	Chemical and Biological Defense
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DIA	Defense Intelligence Agency
DOD	Department of Defense
DTRA	Defense Threat Reduction Agency
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HSPD	Homeland Security Presidential Directive
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JRO	Joint Requirements Office
JSTO	Joint Science and Technology Office
MTA	Material Threat Assessment
NBACC	National Biodefense Analysis and Countermeasures Center
NDA	National Defense Authorization Act
NIH	National Institutes of Health
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PPQ	Plant Protection and Quarantine
RPM	Research Prioritization Matrix
S&T	Science and Technology Directorate
USDA	U.S. Department of Agriculture

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October 11, 2017

The Honorable Ron Johnson
Chairman
The Honorable Claire McCaskill
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Dan Donovan
Chairman
Subcommittee on Emergency Preparedness, Response, and
Communications
Committee on Homeland Security
House of Representatives

Biological threats come from a variety of sources and can pose a catastrophic danger to public health, animal and plant health, and national security.¹ Emerging infectious diseases represent an ongoing threat to the health and livelihoods of people and animals worldwide. According to the World Health Organization, infectious diseases are not only spreading faster, they also appear to be emerging more quickly than ever before. A naturally occurring disease can cross an ocean at the speed of a commercial airliner and cause nationwide fear, as exemplified in 2014 when a traveler infected with Ebola virus returned home to Texas from West Africa. Additionally, our agriculture industry is under constant threat from foreign pathogens and pests that may be introduced via trade. The potential disruption of the agriculture or food production systems represents a serious threat to the U.S. national economy, trade, and human health. Finally, the threat of biological terrorism (bioterrorism) remains, as nonstate actors like The Islamic State of Iraq and the Levant (also known as ISIL and Da'esh) have advocated for the use of biological weapons. For example, several known biological threat agents could be made into aerosolized weapons (i.e., converted into a fine spray or placed in a suspension enabling disease agents to be dispersed through the air) and intentionally released in a transportation hub or other populated urban setting, introduced into the agricultural infrastructure and food

¹Definitions for key biodefense terms, such as threat, can vary among federal agencies due, in part, to their unique mission responsibilities. See the sidebar that follows for a list of key terms and definitions used within this report.

Key Biodefense Terminology

Biodefense—To prevent, protect against, and mitigate biological threats that could have catastrophic consequences to the nation.

Threat—For the purposes of this report, we use the term threat to describe both the intentional use of biological weapons by individuals or entities and naturally occurring biological events that have the potential to have catastrophic biological consequences for the United States including loss of life or national security and economic welfare effects.

Agent—Microorganism (or derived toxin) or pest that causes disease in humans, animals, or plants.

Characterization (of agents, pests and biological events)—Agents and pests can be characterized by applying modern scientific techniques that describe their properties, behaviors, life cycle, or genetic makeup. Biological events can be characterized by evaluating specific disease outbreaks to understand what the outbreak is and how serious it is likely to be by monitoring such things as the cause, speed, duration, and means of transmission.

Surveillance—In the biological context, the ongoing collection, analysis, and interpretation of data to help look for pathogens in plants, animals, and humans; in food supplies; and in the environment.

Detection—In the biological context, involves recognition of signs and signals 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.

Source: GAO analysis of biodefense doctrine, literature, and agency information. | GAO-18-155

supply, or used to contaminate the water supply.² These specific types of threats, whether naturally occurring or deliberate, may contribute to Global Catastrophic Biological Risks, a term of art that represents extraordinary biological disaster beyond the collective capability of national and international governments and the private sector to control.³

In 2004, Homeland Security Presidential Directive (HSPD) 10 identified four key areas—or pillars—of national biodefense.⁴ One of the pillars of biodefense identified in HSPD-10 is threat awareness, which consists of activities such as collecting and analyzing intelligence, developing risk assessments, and anticipating future threats. For example, such information may include assessment about where biological threat agents might come from, how outbreaks may unfold, and the effectiveness of available defenses against them. Threat awareness is vital to help identify necessary biodefense capabilities to help identify, protect against, and respond to National or Global Catastrophic Biological Risks and help ensure investments are prioritized to make effective use of federal funds.

Protecting humans, animals, plants, food, and the environment (air, soil, and water) from potentially catastrophic effects of intentional or natural biological events entails numerous activities carried out within and among multiple federal agencies and their nonfederal partners. The Department of Homeland Security (DHS) plays a lead role in interagency coordination and planning for emergency response to biological incidents in the United States and is responsible for assessing the risks to the civilian population posed by various biological agents. DHS conducts multiple efforts to enhance biological threat awareness, including development of the Bioterrorism Risk Assessment (BTRA) with input from other key federal agencies, such as the Departments of Defense (DOD) and Health and

²Biological threat agents are those that are traditional, emerging, and genetically modified agents. “Traditional” biological threat agents are naturally occurring microorganisms or toxin products with the potential to be disseminated to cause mass casualties. “Emerging agents” are previously unrecognized pathogens that might be naturally occurring and present a serious risk to human populations. “Genetically modified” agents are organisms that have either been artificially modified or developed to bypass traditional countermeasures or produce a more severe or enhanced disease. According to HHS, biological threats may also be due to “re-emerging” agents, which are those once considered conquered by modern medicine that—due to natural genetic shifts or other changes in the organism—are becoming resistant to current antibiotics or antimicrobials.

³Monica Schoch-Spana et al., “Global Catastrophic Biological Risks: Toward a Working Definition,” *Health Security*, vol. 15, no. 4 (2017).

⁴Executive Office of the President, *Biodefense for the 21st Century*, Homeland Security Presidential Directive 10 (Apr. 28, 2004). The four pillars identified in HSPD-10 include threat awareness; prevention and protection; surveillance and detection; and response and recovery.

Human Services (HHS). DHS also operates the National Biodefense Analysis and Countermeasures Center (NBACC), which, among other activities, carries out research to better characterize individual biological agents and provide timely scientific data, knowledge products, and expertise to support threat analyses.

You asked us to review how key biodefense agencies develop and share threat awareness information, and how this information informs further investments in biodefense. This report describes: (1) the types of actions that key federal agencies have taken to develop biological threat awareness and how that information is used to support investment decisions, (2) the extent to which federal agencies have developed shared threat awareness, and (3) how NBACC determines what additional threat characterization knowledge to pursue.

To conduct work related to all three objectives, we analyzed government-wide policies, directives, and strategies related to biodefense, including HSPD-9 (*Defense of United States Agriculture and Food*), HSPD-10 (*Biodefense for the 21st Century*), and the *National Strategy for Countering Biological Threats*, among others.⁵ We analyzed these documents to understand agencies' roles and responsibilities regarding biodefense, specifically those pertaining to threat awareness activities. We identified the key biodefense agencies by reviewing the biodefense policies mentioned above, as well as through interviews with DHS officials who identified the key agencies with which they collaborate on threat awareness activities.⁶ The agencies we identified through these policy reviews and interviews were DHS, DOD, HHS, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).⁷

To describe how these five key agencies conduct their threat awareness activities and use this information to support investment decisions, we

⁵Executive Office of the President, *Defense of United States Agriculture and Food*, Homeland Security Presidential Directive 9 (Jan. 30, 2004); HSPD-10; and National Security Council, *National Strategy for Countering Biological Threats* (Nov. 23, 2009).

⁶We initially focused on DHS, because as the owner of NBACC and the primary agency responsible for the security of the homeland, it has critical roles and responsibilities within the threat awareness pillar. We also engaged with DHS as part of our work addressing another NBACC-related threat awareness activity, bioforensics. See GAO, *Bioforensics: DHS Needs to Conduct a Formal Capability Gap Analysis to Better Identify and Address Gaps*, [GAO-17-177](#) (Washington, D.C.: Jan. 11, 2017).

⁷DHS and other agency officials also described working with the intelligence community in some contexts. We did not engage directly with the intelligence community for this review, but did collect and report information about how the agencies in our review use intelligence inputs.

reviewed agency-specific strategies and plans related to their biodefense activities, including those from NBACC, DOD's Chemical and Biological Defense Program, the multiagency Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), and USDA's Animal and Plant Health Inspection Service (APHIS). We also analyzed information provided by agencies and conducted interviews with agency officials related to agencies' threat awareness activities to determine how threat awareness is conducted and how it informs other biodefense investments. For example, we reviewed documents such as threat assessments, including the 2010 and 2016 BTRAs; scientific reports on biological agent characteristics; modeling studies of the potential impact of various biological threats; and response guidelines informed by biological threat awareness activities. For additional context and support, we also reviewed prior GAO work related to biodefense and reports from other organizations, such as the Congressional Research Service, the Bipartisan Weapons of Mass Destruction Terrorism Research Center, the Blue Ribbon Study Panel on Biodefense, and the National Research Council of the National Academies.⁸

To determine the extent that federal agencies have developed shared threat awareness and how NBACC determines what additional threat characterization knowledge to pursue, we conducted a site visit to NBACC at Fort Detrick, Maryland, to meet with DHS officials and NBACC staff to discuss the collaborative efforts among the key biodefense agencies in conducting and reviewing the BTRA. We interviewed agency officials from DHS, DOD, HHS, USDA, and EPA to understand the types of collaborative activities they engage in, examine the opportunities available to share threat awareness information, and identify any challenges in sharing information across agencies. We compared the activities to leading practices we have identified in prior work to enhance and sustain interagency collaboration.⁹ We also examined existing policy, strategies, and structures that could enable shared threat awareness

⁸Bipartisan Weapons of Mass Destruction Terrorism Research Center, *Bio-Response Report Card: 21st Century Biological Threats* (Washington, D.C.: October 2011); Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* (Washington, D.C.: Hudson Institute, October 2015); and National Research Council of the National Academies, *Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change* (Washington, D.C.: National Academies Press, 2008).

⁹GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005); and *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

activities, including the recent National Defense Authorization Act (NDAA) mandate to create a national biodefense strategy.¹⁰ We analyzed NBACC's strategic plans and annual plans from fiscal year 2011 through fiscal year 2017, as well as funding information, to identify biodefense-related investments. We also met with key DHS officials involved in planning NBACC's threat awareness projects to determine how priorities are set for NBACC's biodefense investments.

We conducted this performance audit from April 2016 to October 2017 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.

Background

Biodefense Doctrine

Several presidential directives and national strategies establish biodefense policy for the federal government. These directives establish overall goals and policies as well as assign specific responsibilities to federal agencies.¹¹ See table 1 for relevant directives and strategies. Among these directives, the White House released HSPD-10 in 2004, which outlines the structure of the biodefense enterprise and discusses various federal efforts and responsibilities that help to support it.¹² The directive organizes biodefense efforts into four key pillars, consisting of threat awareness, prevention and protection, surveillance and detection, and response and recovery. Each of these pillars comprise numerous activities—such as conducting research on emerging pathogens that

¹⁰National Defense Authorization Act for Fiscal Year 2017, Pub. L. No. 114-328, §1086, 130 Stat. 2000, 2423 (Dec. 23, 2016).

¹¹Although the directives and strategies identified are current as of September 2017, federal biodefense policy will also be informed by the forthcoming National Biodefense Strategy when it is published.

¹²The nation's biodefense enterprise is the whole combination of systems at every level of government and the private sector that can contribute to protecting the nation and its citizens from potentially catastrophic effects of a biological event. It is composed of a complex collection of resources, programs, and initiatives, designed for different purposes and dedicated to mitigating various risks, both natural and intentional.

could pose a threat—that are carried out by multiple federal agencies and generally require coordination across the entire biodefense enterprise.

Table 1: Presidential Directives and Strategies Pertaining to Biodefense

Title	Date issued	Description
HSPD-9— <i>Defense of United States Agriculture and Food</i>	January 30, 2004	Establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies.
HSPD-10— <i>Biodefense for the 21st Century</i>	April 28, 2004	Assigns roles and responsibilities for preventing, protecting against, and mitigating biological events. Describes the four key areas—or pillars—of national biodefense.
HSPD-18— <i>Medical Countermeasures against Weapons of Mass Destruction</i>	January 31, 2007	Establishes policy to address the challenges presented by chemical, biological, radiological, and nuclear weapons of mass destruction and the need for medical countermeasures.
HSPD-21— <i>Public Health and Medical Preparedness</i>	October 18, 2007	Applies and expands the four pillars of biodefense from HSPD-10 to public health preparation.
<i>National Strategy for Countering Biological Threats</i>	November 23, 2009	Provides a framework for future U.S. planning efforts to support HSPD-10, and recognizes that biological threats cannot be addressed by the federal government alone.
PPD-2— <i>Implementation of the National Strategy For Countering Biological Threats</i>	November 23, 2009	Assigns recurring responsibilities to federal agencies for carrying out biodefense strategy.
<i>National Strategy for Biosurveillance</i>	July 31, 2012	Describes the U.S. government’s approach to strengthening biosurveillance.

Legend

HSPD: Homeland Security Presidential Directive

PPD: Presidential Policy Directive

Source: GAO analysis of Executive Office of the President documents. | GAO-18-155

The Challenges of Threat Awareness in a Vast and Evolving Biological Threat Landscape

The biological threat landscape is vast and requires a multidisciplinary approach to developing threat awareness. Synthetic biology, if used to create and combine agents, also poses a significant threat and potentially complicates the ability to assess the biological threat landscape.¹³ Despite ratification of the Biological Weapons Convention in 1975 and the end of the Cold War decades later, the threat of biological warfare persists today.¹⁴ For example, as the Blue Ribbon Study Panel on Biodefense reported, the State Department assessed in 2015 that China, Iran, North Korea, Russia, and Syria continue to engage in dual-use or biological weapons-specific activities and are failing to comply with the convention, to which each of these countries has agreed. Additionally, the revolution in biotechnology presents opportunities to advance the life sciences, yet that same technology in the wrong hands could be used to create biological weapons.¹⁵ For example, nonstate actors such as terrorist organizations, domestic militia groups, and “lone wolves” have both the interest and capacity to develop biological weapons.¹⁶ The intelligence community plays a key role in assessing these types of threats.

¹³Synthetic biology is the engineering of biology: the synthesis of complex, biologically based (or inspired) systems, which display functions that do not exist in nature.

¹⁴Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, April 10, 1972, 1015 U. N. T. S. 163. Signatory nations agree to never “develop, produce, stockpile or otherwise acquire or retain microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.”

¹⁵DHS officials stated that genetic engineering of mosquitos to help prevent the spread of Zika virus (or similar viruses) is an example of a scientific discovery that could also potentially become a threat if used for nefarious purposes.

¹⁶According to the 2015 Blue Ribbon Study Panel report, U.S. domestic militia members have produced ricin (a biological toxin) and sarin (a chemical weapon) on a larger scale than previously reported, demonstrating increasing capabilities. The report also identifies the threat posed by lone wolves, who are individuals that do not operate within the organizational constructs offered by militias, domestic violent extremist groups, or terrorist groups, and are thus more difficult to monitor. A lone wolf who obtains biological agents or weapons should be expected to use them with little hesitation. Additionally, U.S. citizens who sympathize with ISIL and likeminded groups may present an equal or even greater danger than terrorist groups.

The Evolving Biological Threat Landscape

Advances in genetic engineering and “do-it-yourself” biology methods potentially enable the nefarious use of enhanced and advanced biological agents. Dual Use Research of Concern (DURC) is life sciences research that can be reasonably anticipated to provide knowledge, methods, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to human, animal, and plant health, the environment, or national security.

For example, the same methods that can aid researchers in understanding how to combat disease causing agents could also be used to manipulate genetic material for use as a bioweapon. Depicted below is a transgenic cat whose genes were modified using jellyfish genes to help track whether other genetic alterations to combat a virus were successfully transferred to kittens born from the modified embryos



Source: GAO analysis; Photo adapted by permission from Macmillan Publishers Ltd: Nature Methods, copyright 2011. | GAO-18-155

Threat awareness is also challenged by the unpredictable nature of naturally occurring disease, which could affect human and animal health and agricultural security, potentially causing global catastrophic biological risks which could lead to loss of life, and sustained damage to the economy, societal stability, or global security. To assess and develop means to combat these threats, many federal agencies conduct biological threat awareness activities, which may include a combination of risk assessment and key activities to better understand certain characteristics of biological threats. For example, the genetic compositions of some viruses naturally change, as exemplified in 2009, when an H1N1 influenza virus emerged with a new combination of genes, causing a global pandemic. According to the Centers for Disease Control and Prevention (CDC)—an entity within HHS—when these significant genetic changes occur in a virus, most people have little or no immunity to the new virus. Climate change also has the potential to negatively impact human health and the agriculture industry. As we reported in October 2015, climate change may contribute to the spread of vector-borne diseases that are transmitted to humans by animals, including invertebrate animals such as mosquitoes and ticks.¹⁷ Examples of vector-borne diseases that currently pose health risks in some regions of North America include chikungunya disease, dengue fever, Lyme disease, and West Nile virus fever.¹⁸ Additionally, habitat loss and human encroachment on rural and wildlife environments are bringing populations of humans and animals into closer and more frequent contact, increasing the risk of disease transmission among people, pets, livestock, and wildlife.

Finally, the scientific community must safeguard the biological agents it uses to assess threats. Protecting laboratory workers and the population at large from intentional or accidental release of dangerous pathogens during the pursuit of more knowledge about them is also challenging. Recent high-profile events, such as a DOD laboratory inadvertently

¹⁷GAO, *Climate Change: HHS Could Take Further Steps to Enhance Understanding of Public Health Risks*, GAO-16-122 (Washington, D.C.: Oct. 5, 2015.)

¹⁸Chikungunya is a viral disease spread to people by the bite of infected mosquitoes. According to CDC, the first locally acquired cases of chikungunya were reported in Florida in 2014. Dengue is caused by any one of four related viruses transmitted by mosquitoes. According to CDC, dengue is endemic to Puerto Rico and the Pacific Islands, and occurs only infrequently in the United States. Lyme disease is a bacterial disease that is transmitted to humans through the bite of infected blacklegged ticks. Most Lyme disease cases reported to CDC through national surveillance are concentrated heavily in the Northeast and upper Midwest of the United States. West Nile virus is most commonly transmitted to humans by mosquitoes. According to CDC, the West Nile virus has been detected in all of the 48 contiguous United States, but not in Hawaii or Alaska.

shipping incompletely inactivated samples of *Bacillus anthracis*, the bacterium that causes anthrax, to almost 200 laboratories worldwide over the course of 12 years and the unexpected discovery of misplaced vials of smallpox (*variola*) virus at the National Institutes of Health (NIH) campus, also highlight the threat due to improper handling and unknown storage of dangerous biological agents.¹⁹

Federal Roles and Responsibilities

Several federal departments and agencies have responsibilities as part of their mission to assess the threat of biological agents and carry out key biodefense roles as delineated in HSPD-10 and the National Strategy for Countering Biological Threats, among other documents.

National Biodefense Analysis and Countermeasures Center (NBACC)

NBACC consists of two centers:

National Biological Threat Characterization Center

Its mission supports national goals to deter and reduce the impact of current and newly identified biological threats by providing timely scientific data, knowledge products, and expertise required for accurate and informed threat analyses and biodefense planning, preparedness, response, and recovery.

National Bioforensics Analysis Center

It serves as the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials from biocrime and bioterror investigations or those recovered following a biological attack in support of the lead federal agency.

Source: Department of Homeland Security. | GAO-18-155

Department of Homeland Security. DHS is the principal federal department with responsibility for domestic incident management and supports federal efforts to prepare for, respond to, and recover from domestic biological attacks.²⁰ Within DHS, the Science & Technology Directorate's (S&T) Chemical and Biological Defense (CBD) Division leads key efforts related to enhancing threat awareness with a focus on bioterrorism. S&T develops Material Threat Assessments in collaboration with HHS, as well as the BTRA, which includes assessments of the relative risks posed by biological agents based on variable threats, vulnerabilities, and consequences.²¹ S&T also operates NBACC, which conducts scientific research and develops reports and products specifically intended to address identified knowledge gaps associated with current and future biological threats, including the characterization of key attributes of biological attacks by an adversary such as agent

¹⁹GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, [GAO-16-642](#) (Washington, D.C.: Aug. 30, 2016); and *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, [GAO-16-305](#) (Washington, D.C.: Mar. 21, 2016).

²⁰DHS's Office of Health Affairs, headed by the DHS Chief Medical Officer, leads DHS's biodefense activities and provides timely incident specific guidance for the medical consequences of disasters. Among its roles, the Office of Health Affairs operates the National Biosurveillance Integration Center, which serves to consolidate data from multiple surveillance systems maintained by member agencies across human, animal, and plant domains.

²¹The requirements for federal departments to develop such risk assessments are in provisions in the Project BioShield Act of 2004, Pub. L. No. 108-276, § 3, 118 Stat. 835, 844 (July 21, 2004); HSPD-10; HSPD-18; and Executive Office of the President, *Domestic Chemical Defense*, Homeland Security Presidential Directive 22 (2007).

acquisition; agent production; dissemination methods; virulence; and the effectiveness of potential countermeasures.²²

Department of Defense. DOD is responsible for protecting U.S. armed forces from biological threats worldwide and conducts a range of efforts to support research, development, and acquisition of medical countermeasures and other technologies to prevent or mitigate the health effects of biological agents and naturally occurring diseases. Multiple organizations across DOD are responsible for a number of activities, including (1) determining requirements; (2) providing science and technology expertise; (3) conducting research, development, test, and evaluation; and (4) providing oversight.²³ This enterprise is structured to conduct research and develop defenses against chemical and biological threats.

Department of Health and Human Services. HHS is the federal agency primarily responsible for identifying needed medical countermeasures to prevent or mitigate potential health effects from exposure to biological agents for the nation and engaging with industry to develop them.²⁴ In 2006, HHS established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a federal interagency body that is responsible for providing recommendations on medical countermeasure priorities and development and acquisition activities. Within HHS, the Office of the Assistant Secretary for Preparedness and Response (ASPR) leads PHEMCE and the federal medical and public health response to public health emergencies, including strategic planning, medical countermeasure prioritization, medical countermeasure requirements development, and support for developing and procuring

²²The President's fiscal year 2018 budget proposes elimination of NBACC. In the related DHS budget justification, DHS estimated that the NBACC closure would save \$37.6 million in fiscal year 2018; however, DHS requested approximately \$9.3 million to maintain threat characterization program activities that it determined could be performed at other unspecified facilities.

²³Principal DOD organizations with roles in biodefense include the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), which oversees the research, acquisition, life-cycle support, and medical countermeasures of assigned chemical and biological programs; and the Joint Science and Technology Office for Chemical and Biological Defense (JSTO), which oversees science and technology efforts, and is part of the Defense Threat Reduction Agency (DTRA). Several other agencies support these offices, including the Defense Intelligence Agency (DIA) and facilities owned and operated by the U.S. Army that support research, development, test, and evaluation of biological defense capabilities, such as the U.S. Army Edgewood Chemical Biological Center and the U.S. Army Medical Research Institute of Infectious Diseases.

²⁴According to HHS and DOD officials, HHS, through PHEMCE, is responsible for coordinating the development and acquisition of medical countermeasures for the civilian population, whereas DOD has responsibility for military personnel medical countermeasures.

medical countermeasures for the Strategic National Stockpile.²⁵ CDC maintains the Strategic National Stockpile and supports state and local public health departments' efforts to detect and respond to public health emergencies, including providing guidance and recommendations for the mass distribution and use of medical countermeasures, among other activities.²⁶ The agency also engages in laboratory detection of diseases and epidemiological investigation of outbreaks to protect the nation from health, safety, and security threats, both foreign and in the United States. The Food and Drug Administration (FDA) conducts research and performs vulnerability assessments to help prevent adulteration of the food supply.²⁷ NIH conducts and funds basic and applied research to develop new or enhanced medical countermeasures and related medical tools and provides oversight and guidance on biosafety and biosecurity to research laboratories.

U.S. Department of Agriculture. USDA is the lead agency with responsibility to protect and improve the health, quality, and marketability of our nation's agricultural products. Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for working to prevent, control, or eliminate harmful pests, pathogens, and diseases of animals and plants. APHIS consists of multiple component units with key roles in biodefense including Veterinary Services, and the Plant Protection and Quarantine (PPQ) program. These offices are supported by multiple research centers and laboratory networks, as well as the Agricultural Research Service (ARS), which conducts a wide range of research addressing agricultural issues of high national priority.

Environmental Protection Agency. EPA is the lead agency for environmental cleanup and remediation, including indoor cleanups. EPA is also the lead federal agency for protecting drinking water and wastewater infrastructure. In addition, EPA provides technical assistance and operational support for sampling, characterization, decontamination,

²⁵Within ASPR, the Biomedical Advanced Research and Development Authority develops and procures needed medical countermeasures, including vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures, against a broad array of public health threats, including biological agents, whether natural or intentional in origin.

²⁶CDC's Strategic National Stockpile is the nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. The Stockpile also houses medical countermeasures that are not available on the market.

²⁷FDA also assesses the safety and effectiveness of medical countermeasures; regulates their development; and approves, clears, or licenses them.

clearance, and waste-management efforts. According to EPA officials, if there is potential for environmental contamination due to a biological incident, HHS collaborates with EPA in developing and implementing sampling strategies and sharing results.²⁸ EPA's Office of Research and Development's Homeland Security Research Program aims to help increase the capabilities of EPA and communities to prepare for and respond to chemical, biological, and radiological disasters. EPA's Water Security Division also provides resources to monitor incidents and threats.

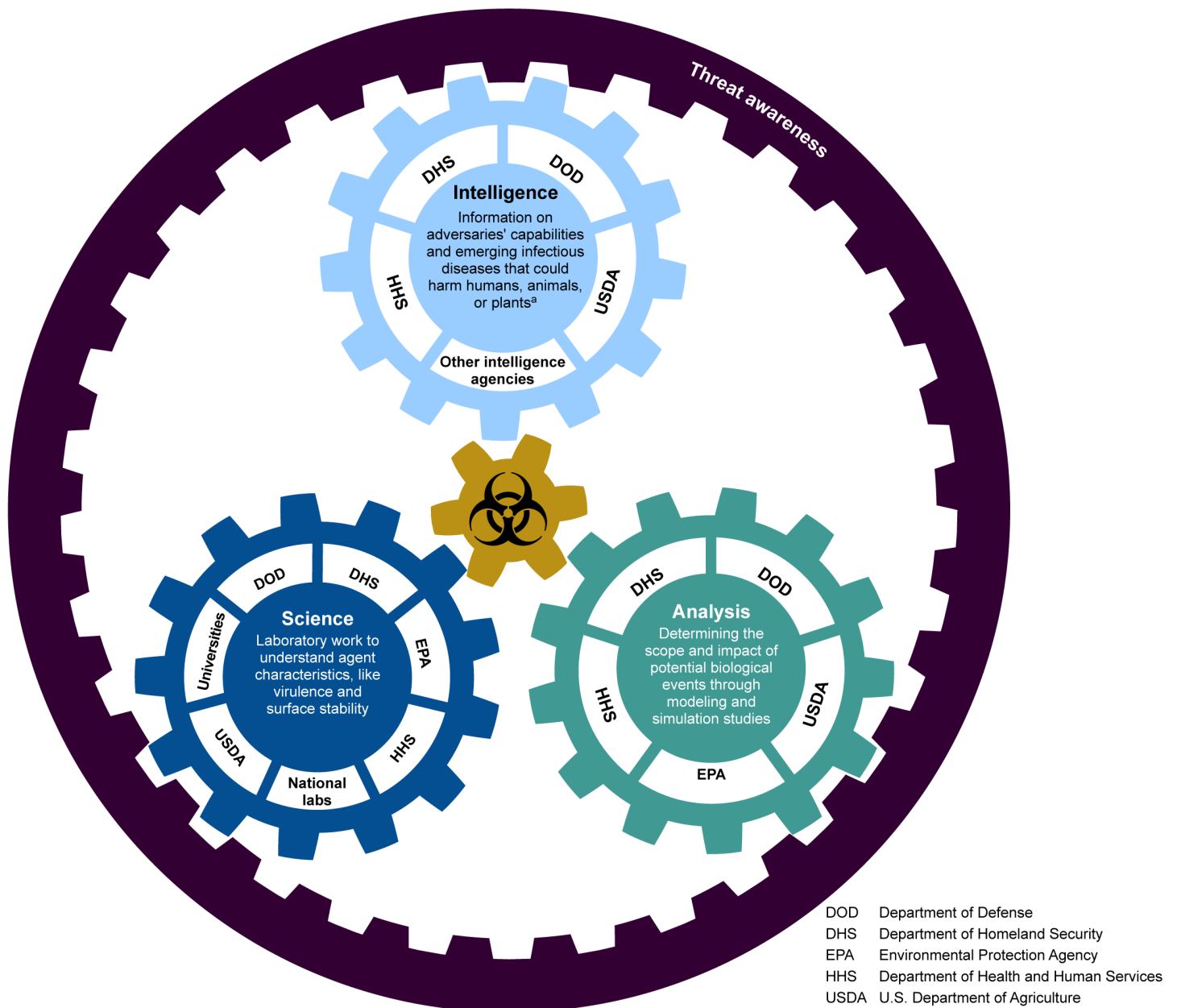
Intelligence Gathering and Global Surveillance, Research, and Analysis Are Designed to Inform Biological Threat Awareness and Investment Decisions

Key biodefense agencies, including DHS, DOD, HHS, USDA, and EPA rely on intelligence and global surveillance information, scientific study of disease agent characteristics, and analysis to better understand threats and help make decisions about biodefense investments.²⁹ Figure 1 depicts the three components of threat awareness described in this report.

²⁸Additionally, the Environmental Response Laboratory Network is a national network of laboratories that can be ramped up as needed to support large-scale environmental responses.

²⁹This section provides selected examples of threat awareness activities and biodefense investments. It is not comprehensive, but rather it represents the range and variety of activities that correspond to agencies' missions.

Figure 1: Three Components of Threat Awareness



Source: GAO analysis of agency information. | GAO-18-155

^aEpidemic intelligence on naturally occurring global disease events—performed by agencies like HHS and USDA—relies on the analysis of open source global disease surveillance information. This is a separate function and mission from the information collection activities by the Intelligence Community on adversaries' capabilities to cause harm using a biological weapon.

Agencies Rely on Intelligence Gathering, Scientific Research, and Analysis Activities to Develop Biological Threat Awareness

Intelligence Collection and Global Disease Surveillance

Key federal biodefense agencies use intelligence to understand adversaries' capabilities to cause harm with a biological weapon and conduct global disease surveillance to monitor threats from naturally occurring agents.³⁰ DHS and DOD rely on information from the intelligence community about adversaries' capabilities to acquire, produce, reengineer, and disseminate a biological agent. For example, DHS solicits information from the intelligence community to create models on nonstate actors' possible target (e.g., a transportation hub), the possible agent and amount used, and the method of attack. DHS also gathers information on terrorist organizations' financial and technical resources to help determine their capabilities in staging an attack. This information is used to develop the BTRA to support DHS's responsibilities to protect against non-state actor intentional acts of bioterrorism. For more information on the BTRA and its development and evolution, see appendix I.

DOD also relies on intelligence information to support its mission to protect the warfighter against acts of biological warfare. Intelligence from the Defense Intelligence Agency (DIA) is generally focused on state actors. However, DOD is also learning about means to address non-state actor threats, because of the changing nature of warfare and more attention directed towards combatting terrorist organizations. The DIA Chemical, Biological, Radiological, and Nuclear (CBRN) Capstone Threat Assessment is the primary analytic foundation for intelligence support to the defense acquisition process regarding biological threats, among other

³⁰Adversaries may include state and nonstate actors.

Predicting the Threat of Zika Virus Spread to the United States Based on Chikungunya and Dengue

Zika virus is a flavivirus that is primarily spread in humans by the same mosquitos that also spread dengue, chikungunya, and other viruses. The first confirmed local transmission of this emerging threat in Brazil occurred in May 2015. Since that time, the Centers for Disease Control and Prevention's (CDC) Global Disease Detection Operations Center has been monitoring the spread of the epidemic from Brazil to other countries in the Americas. By early 2016, the Zika virus had spread to dozens of countries, including local transmission in U.S. territories. At this time, CDC activated its Emergency Operations Center to respond to outbreaks of Zika occurring in the Americas, and enhance disease surveillance and response coordination.

In February 2016, the director of CDC said that recent chikungunya and dengue outbreaks in the United States suggest that Zika outbreaks in the U.S. mainland may be relatively small and localized, which can be attributed to better infrastructure and mosquito control than that found in Latin America. In contrast, he said outbreaks of dengue and chikungunya suggest that Zika virus may spread widely in the U.S. territories.

CDC estimates of Zika virus cases for 2016 support the CDC director's prediction, with 224 locally acquired mosquito-borne cases in the United States (in Florida and Texas) compared to nearly 36,000 locally acquired cases in U.S. territories (largely in Puerto Rico).

Efforts to improve international capacity for virus surveillance support CDC's ability to characterize emerging threats and enhance threat awareness.

Source: CDC. | GAO-18-155

subjects. It projects foreign capabilities in particular warfare areas out 20 years in the future.³¹

Other agencies, such as HHS and USDA, rely on global disease surveillance to identify and characterize naturally occurring disease events that may impact human, animal, or plant health.³² Although surveillance and detection activities constitute an entire separate pillar of the biodefense enterprise, these activities can also help federal agencies enhance threat awareness by providing information about emerging global disease events that might affect the United States. For example, within HHS, CDC's Global Disease Detection program conducts global surveillance on emerging infectious disease events to rapidly detect and monitor the characteristics of the disease event to determine whether and what kind of threat it poses to the U.S. population.³³

Similarly, within USDA, APHIS conducts surveillance of foreign animal diseases and plant pests and pathogens to determine what threat they may pose to the U.S. agriculture industry. APHIS officials said they have a number of relationships and sources they use to gather information on traditional and emerging animal diseases. These include the National Center for Medical Intelligence within DIA, DHS's National Biosurveillance Integration Center, CDC, and the World Organisation for Animal Health. USDA's Risk Identification and Risk Assessment unit conducts open source monitoring globally to identify situations of greatest risk to the animal agriculture community.³⁴ For plant surveillance, USDA's PestLens is an offshore open-source monitoring and analysis function designed to

³¹We reported in November 2016 that the Validated Online Lifecycle Threat report will replace the DIA Capstone Threat Assessment by the end of fiscal year 2017. GAO, *Defense Intelligence: Additional Steps Could Better Integrate Intelligence Input into DOD's Acquisition of Major Weapon Systems*, GAO-17-10 (Washington, D.C.: Nov. 1, 2016).

³²DOD also has infectious disease surveillance efforts, for example, through the DIA's National Center for Medical Intelligence and the Office of the Assistant Secretary of Defense for Health Affairs' Global Emerging Infections Surveillance program of the Armed Forces Health Surveillance Branch.

³³According to CDC officials, CDC also works to build capacity for disease detection overseas to help identify threats before they reach the United States.

³⁴Housed within one of USDA's science centers, the Center for Epidemiology and Animal Health, the Risk Identification and Risk Assessment team uses information from a wide variety of sources to conduct epidemiological, biological, economic, geospatial, and environmental analyses and other assessments of present, future, and emerging threats to animal health, including estimates of the likelihood of a damaging event and the resulting consequences.

identify emerging pests and diseases.³⁵ The PestLens team stationed overseas evaluates these potential threats for their impact on trade and identifies threats to look for at ports. It conducts research to determine whether there are outbreaks of disease or pests in other countries.

Scientific Research

Epidemiology Terms

Virulence is the relative capacity of a pathogen to overcome body defenses.

Pathogenesis is the process by which an infection leads to disease.

Infectious dose is an estimate of the amount of a pathogen required to cause illness.

Zoonotic disease is an infectious disease that is transmissible from animals to humans.

Source: GAO analysis of scientific terminology. | GAO-18-155

Agencies use scientific research to help understand the characteristics of various threat agents, including their virulence, stability, and ability to be dispersed through various methods. Agencies also perform or contract for scientific research on emerging pathogens to understand their means of transmission, host susceptibility, and effects of infection. Research is conducted on agents that may be used intentionally as biological weapons or on disease-causing agents that may exist in nature and contribute to outbreaks or pandemics, such as influenza viruses. One example of DHS-conducted scientific research is NBACC's work to understand properties associated with agent acquisition, production, dissemination, stability, virulence and pathogenesis, and existing medical countermeasure efficacy. A DOD example of scientific research is DTRA's efforts to characterize biological agents (virulence, dissemination, infectious dose, etc.). For instance, DTRA might fund research to determine whether current diagnostic tools would be adequate if the Ebola virus's genetic sequence were to change.

For conducting scientific research to characterize naturally occurring threats, HHS and USDA agencies engage in a spectrum of activities. Within HHS, CDC, NIH, and FDA all conduct various scientific research to characterize biological agents. For example, CDC conducts characterization of infectious diseases, including analyses of pathogenesis, and works to identify uncommon signals of disease and conduct research to assess zoonotic potential. One effort CDC has to characterize an infectious disease is the Influenza Risk Assessment Tool that assesses potential pandemic risk. NIH also conducts characterization research—such as pathogenesis, infectious dosage rates, and potential effects if agents are aerosolized—primarily for known public health threats, which may also be used as inputs into modeling. Additionally, FDA conducts scientific food defense research to understand, among other things, thermal stability and inactivation of biological agents.

³⁵PestLens is the result of the merger of two previously existing Plant Protection and Quarantine systems—Exotic Pest Information Collection and Analysis and the Offshore Pest Information System—intended to result in a more streamlined, efficient, and user-friendly system.

Within USDA, ARS also conducts basic biological research on animal and plant pathogens.³⁶ Because of the sheer volume of animal diseases, ARS takes a strategic approach to research and study families of viruses, rather than a single virus. For example, ARS officials said they were able to leverage ongoing research on flaviviruses when Zika virus, a flavivirus, emerged in the Americas. ARS is also trying to use more predictive biology to anticipate and properly prepare for new and emerging pathogens—such as understanding vector-borne virus adaptability to potentially prevent transmission to humans—to ensure the public and animal health, as 70 percent of new and emerging diseases are zoonotic. ARS researchers also look at pests and pathogens not currently in the United States to help identify countermeasures, should they appear.

Additionally, EPA conducts research to fill science gaps associated with environmental contamination resulting from accidental or intentional releases of biological agents.³⁷ For example, EPA studies the behavior of biological agents in the environment to inform strategies for characterization and remediation. Research includes developing methods for characterization of persistent biological contamination, mitigating its impacts, cleaning it up in the environment, and managing the subsequent waste.

Modeling Studies and Other Analytical Work

All agencies we interviewed described modeling studies and other analytical work they conduct to help determine the scope and impact of possible biological threats. For example, because biological threat agents cannot be released into the air in operational environments due to health risks, programs such as DHS's BioWatch Program rely on computer modeling and attack simulations to assess the performance of biological detection systems.³⁸ DHS also uses the BTRA modeling to assess potential public health impacts and mitigation efforts for potential biological attacks (see app. I). Similarly, according to DOD officials, DTRA develops and employs modeling and simulation tools for consequence assessment of biological attacks within and outside of the United States.

³⁶USDA also funds clinical science research at the Foreign Animal Disease Research Unit at Plum Island Animal Disease Center to use as inputs to modeling.

³⁷EPA uses information on adversary capabilities and tactics to better assess potential environmental countermeasures for attacks on water systems and indoor/outdoor areas. EPA uses DHS's BTRA to understand which biological threats are likely to be released and their potential impacts.

³⁸For an in-depth look at how modeling and simulation studies are used for the BioWatch Program and the associated challenges with those studies, see GAO, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established*, [GAO-16-99](#) (Washington, D.C.: Oct. 23, 2015).

HHS conducts public health consequence modeling for various types of attacks with specific agents, which uses inputs from DHS Material Threat Assessments to help determine the unmitigated medical consequences.³⁹ Unmitigated consequence estimates are modeled based on factors such as projected spread patterns, infectious dose rates, and estimated time frames, which can help inform response efforts that could mitigate these consequences such as needed prophylaxis and medical countermeasures as part of the PHEMCE process. The public health and medical consequence assessment is the first step in developing the documents necessary for the PHEMCE to establish medical countermeasure requirements. This analysis allows PHEMCE to determine how many lives could be saved if a medical countermeasure were developed, procured, and deployed, and informs HHS decisions regarding the development of medical countermeasures that might be needed during an event.

HHS and USDA also conduct disease patterns and pathways analysis to determine the routes by which certain pathogens found overseas might arrive in the United States. For example, CDC conducts modeling to identify modes of transmission, sources and nodes; and to project epidemiological patterns. One such example is a 2015 CDC study to estimate future numbers of Ebola patients needing treatment at any one time in the United States. The model was developed to help public health officials assess the potential risk for Ebola virus infection in individual travelers and the subsequent need for postarrival monitoring. USDA units also use pathways analysis to assess the likelihood and means by which animal diseases and plant pests might arrive in the United States. For example, USDA Plant Protection and Quarantine (PPQ) evaluates the environmental and economic impacts of pest introduction, and the pathways by which certain pests might arrive (e.g., imported commodities via ship or rail).

Additionally, EPA supports water utilities by providing models, tools, and guidance that help harden their infrastructure to respond to and recover from contamination incidents and other disasters, as contamination of drinking water can result from acts of terrorism.

³⁹See GAO, *National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources*, [GAO-12-121](#) (Washington, D.C.: Oct. 26, 2011).

Agencies Reported Using Biological Threat Awareness Information to Help Prioritize Their Various Biodefense Activities and Investments

Agency officials in our review described how their threat awareness activities help identify biological threat agents of concern and broad-based capability needs, which help guide their biodefense investment decisions. For example, agencies use threat information to determine which agents represent their highest priorities based on the potential of those agents to cause catastrophic harm. Officials from HHS and USDA also described properties or criteria against which they evaluate emerging or reemerging biological agents while conducting surveillance activities to determine whether they pose a serious threat, such as:

- health effects after exposure to an agent or toxin,
- degree of contagiousness,
- economic and trade impact, and
- likely transmission routes.

This threat assessment activity allows agencies to characterize and respond to urgent or real-time disease events, such as a Zika virus or an avian influenza outbreak.

In addition to agent-specific approaches, some agencies also reported using threat awareness information as part of efforts to identify and develop broader capabilities that would prepare them to respond to more than one agent. For example, DOD looks at what types of protective equipment are needed to complete the mission in the face of various threats, rather than starting with an individual threat agent. DOD's Joint Requirements Office (JRO) uses a broad capability-based approach by performing operational risk assessments to evaluate current and future capability needs that will translate into military service requirements. Additionally, HHS, through PHEMCE, reported working on broad capabilities-based investments for medical countermeasures that provide more flexible and sustainable capabilities over the long term. In this regard, PHEMCE seeks to promote technologies that have more than one application or are able to be quickly modified to respond to new threats.⁴⁰ For example, according to the PHEMCE Strategy and Implementation Plan, HHS agencies continue to expand their broad-spectrum antimicrobial programs to address both biodefense disease threats, such as plague and tularemia, and the more general public health concern of

⁴⁰These efforts depend on early-stage research and early identification of biotechnologies that may already be applied in routine product development.

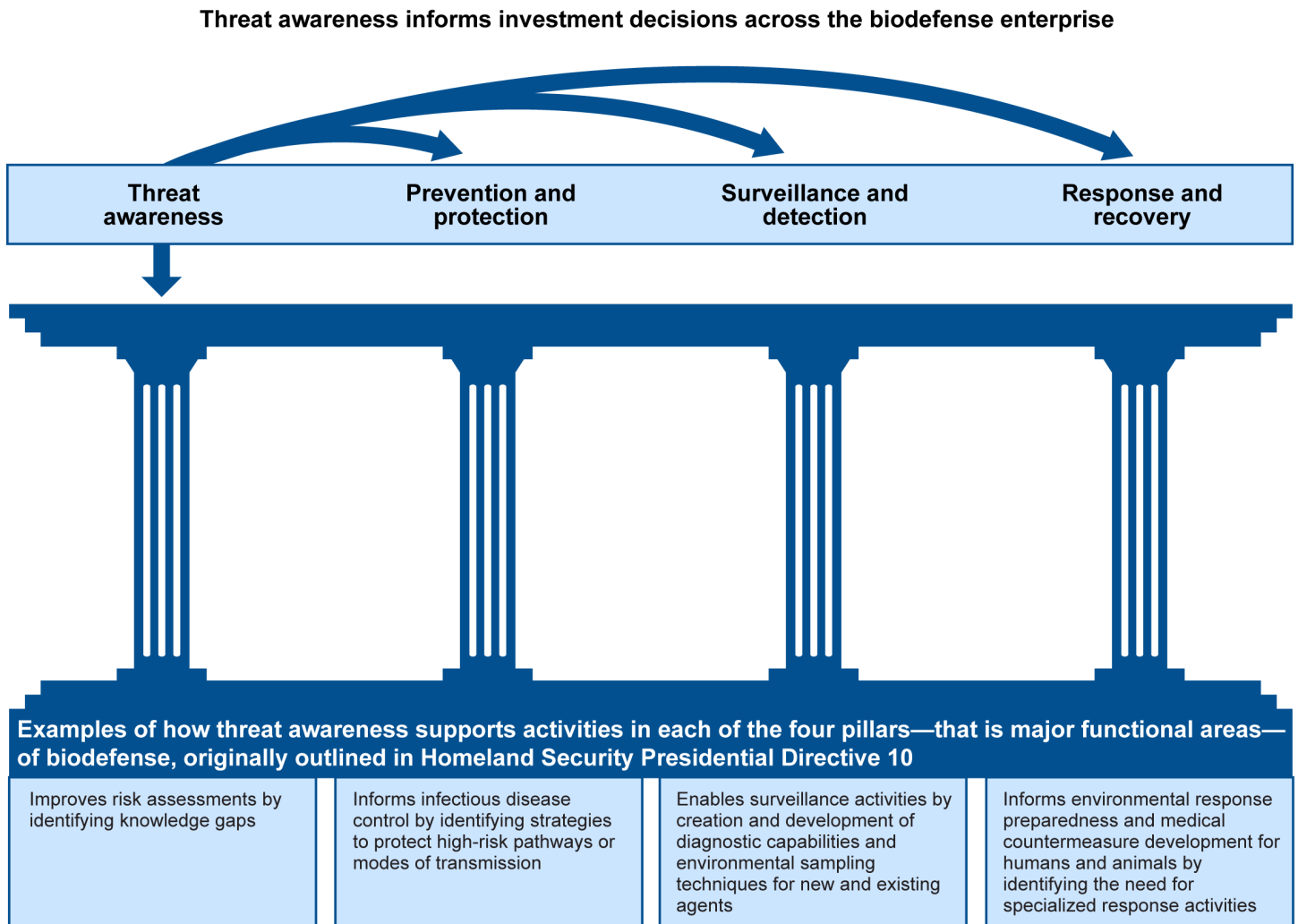
antimicrobial resistance.⁴¹ Investments in multiplex diagnostic tools also represent a move beyond single-agent detection capabilities.⁴²

Once threats have been established and capability gaps have been identified, agencies reported using threat awareness information to help prioritize their investments across various biodefense enterprise activities—threat awareness, prevention and protection, surveillance and detection, and response and recovery—to support their missions (see fig. 2).

⁴¹Tularemia is a disease of animals and humans caused by the bacterium *Francisella tularensis*. Rabbits, hares, and rodents are especially susceptible and often die in large numbers during outbreaks. Humans can become infected through several routes, including tick and deer fly bites, skin contact with infected animals, and inhalation of contaminated aerosols or agricultural dusts.

⁴²NIH along with DOD support the development of a multiplex diagnostic tool to detect infectious disease pathogens associated with acute fevers, including eight viruses (Ebola, Marburg, Lassa, Crimean-Congo Hemorrhagic Fever, chikungunya, dengue, West Nile, and Zika); five bacteria (*Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Salmonella typhi*, and several species of *Leptospira*.); and two parasites (several species of *Plasmodium* and *Leishmania donovani*). We recently issued a report examining multiplex technologies. GAO, *Technology Assessment: Medical devices: Capabilities and challenges of technologies to enable rapid diagnoses of infectious diseases*, [GAO-17-347](#) (Washington, D.C.: Aug. 14, 2017).

Figure 2: Threat Awareness Informs Biodefense Activities




Source: GAO analysis of Homeland Security Presidential Directive 10 and agency information. | GAO-18-155

The following figures present examples, based on our analysis of agency documents and interviews, of how agencies use threat awareness information to help direct resources and investments across the biodefense pillars. This presentation is not a comprehensive catalogue of all biodefense investments in these areas, but rather examples of the diversity of activities agencies conduct to fulfill their biodefense missions for threat awareness, prevention and protection, surveillance and detection, and response and recovery. Appendix II includes information organized by agency.

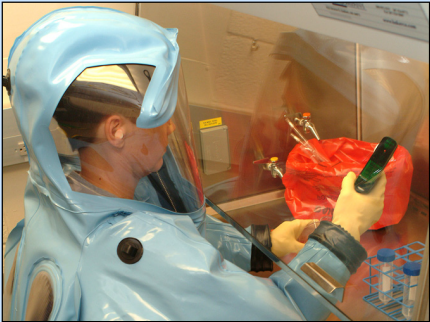
Threat awareness is an ongoing and cyclical process that can be further informed by investments in its key activities—intelligence, science, and analysis. For example, threat agent characterization activities and risk identification analysis identify knowledge gaps, which can then be filled through scientific or analytical work. Figure 3 shows examples of how agencies’ activities in the threat awareness pillar can be applied to further refine threat awareness.

Figure 3: Examples of How Agencies Reported Threat Awareness Can Be Further Refined



Threat awareness

Threat awareness includes assessments of the potential vulnerability and consequences of a biological event, whether naturally occurring or intentional, and evaluation of the capability and intent of actors to use a biological weapon.



National Interagency Biodefense Campus, at Fort Detrick, Maryland

The DOD, the Department of Health and Human Services, the U.S. Department of Agriculture, and DHS share a joint biological research campus, known as the National Interagency Biodefense Campus, at Fort Detrick, Maryland, which has its own governance structure. The campus is intended to maximize resource sharing and facilitate scientific exchange on the study of dangerous biological pathogens. According to DOD officials, the cadre of senior-level scientists and officials involved in research on biological threat agents at the shared campus is relatively small, and allows scientists to share valuable insights and improve collaborative relationships significantly. Colocation on the same campus is intended to help agencies improve understanding of emerging diseases and understand how medical requirements to treat diseases can be defined to support both the military and civilian population.


Based on our analysis of agency documents and interviews, the following examples illustrate how agencies evaluate gaps identified through their threat awareness activities—intelligence, science, and analysis—with the intention to further enhance their threat awareness knowledge.

- The Department of Homeland Security (DHS) identifies scientific knowledge gaps while conducting the Biological Terrorism Risk Assessment (BTRA) and may decide to invest in additional agent characterization work at the National Biodefense Analysis and Countermeasures Center (NBACC) to better understand agent properties and enhance the validity of the BTRA results.
- The Department of Defense (DOD) uses threat awareness information, such as information based on laboratory research, to initiate integrated concept teams. These teams conduct additional threat characterization research to fill a scientific knowledge gap that is needed for a current or future capability. For example, DOD might conduct a toxin study to better understand the toxin’s characteristics, such as its methods of production or dissemination.
- Environmental Protection Agency’s threat awareness activities inform priorities by identifying gaps in environmental sampling and analysis, early warning technologies, agent behavior, decontamination, and personnel safety.

Source: GAO analysis of agency information; DOD (photo). | GAO-18-155


Prevention efforts can involve cooperation with international governments to prevent individuals, groups, and nations from acquiring biological agents, technologies, and abilities to develop and produce the capability to use biological agents as weapons of mass destruction. Protection involves assessing the vulnerability of critical infrastructure—particularly the medical, public health, food, water, energy, agricultural, and transportation sectors—and taking action to improve the resilience of these sectors. Figure 4 shows examples of how agencies reported using threat awareness to inform investments in prevention and protection activities.

Figure 4: Examples of How Agencies Reported Using Threat Awareness to Inform Investments in Prevention and Protection Activities



Prevention and protection

Prevention and protection activities include controlling access to dangerous biological agents used in research and infectious disease control in humans and animals



The Department of Homeland Security (DHS) and USDA working together

The DHS's CBP enforces USDA regulations at ports of entry. CBP agriculture specialists inspect shipments of imported products and ensure that the required permits, sanitary certificates (for animal products), and phytosanitary certificates (for plant products) accompany each shipment.

Based on our analysis of documents and interviews, the following examples illustrate how agencies reported using threat awareness information to inform investments in prevention and protection activities.

- The Department of Defense uses threat awareness information from intelligence agencies, such as the Defense Intelligence Agency, as well as information from the military services and the Combatant Commanders to identify a range of likely threats against the warfighter worldwide. That information is used by the Joint Requirements Office to define and prioritize technology needs and broad-based capabilities such as physical and medical countermeasures needed to protect the warfighter.
- If the U.S. Department of Agriculture (USDA) identifies a disease threat through threat awareness activities, it can propose increased testing of products and guide the international services division at USDA. This division has people stationed all around the world to provide information on disease events overseas in an effort to prevent them from affecting the domestic agriculture industry. USDA can also notify U.S. Customs and Border Protection (CBP) that increased inspections at ports may be warranted.
- The Centers for Disease Control and Prevention regulates the importation of certain animals, items, or things that pose a threat to human health, and provides lifesaving immunobiologics to healthcare facilities to treat ill individuals infected with certain diseases of public health interest.
- The Food and Drug Administration uses its analytical work (which identifies common vulnerabilities and themes across food and agricultural products) and scientific research (e.g., stability of specific agents to production processes) to take measures to help protect food from adulteration.

Source: GAO analysis of agency information; CBP (photo). | GAO-18-155

The early warning, detection, and recognition of an intentional or naturally occurring biological event can enable a timely response to mitigate the event's consequences and is an essential component of biodefense. Recognizing biological events at the earliest possible moment is necessary to permit initiation of a robust response to prevent unnecessary loss of life, economic losses, and social disruption. Biosurveillance involves a coordinated approach that brings together federal, state, local, and tribal governments; the private sector; nongovernmental organizations; and international partners to protect human, animal, and plant health. Figure 5 shows examples of how agencies reported using threat awareness to inform investments in surveillance and detection activities.

Figure 5: Examples of How Agencies Reported Using Threat Awareness to Inform Investments in Surveillance and Detection Activities



Surveillance and detection

Surveillance and detection activities include disease surveillance and environmental monitoring for harmful biological agents



DHS's BioWatch Program

In 2003, DHS created the BioWatch program to provide early warning, detection, or recognition of a biological attack. The BioWatch program uses routine laboratory testing designed to detect an aerosolized (i.e., made into a fine spray or placed in a suspension to allow disease agents to disperse through the air) biological attack for five specific biological agents identified in the BTRA and considered high risk for use as biological weapons.


Based on our analysis of agency documents and interviews, the following examples illustrate how agencies reported using threat information to help design and implement surveillance and detection systems.

- The Department of Homeland Security (DHS) uses threat awareness information to help make better informed decisions about research, development, and acquisitions for technologies designed to protect the homeland from biological attacks. Specifically, DHS used information from the Bioterrorism Risk Assessment (BTRA) to determine which biological threat agents pose the greatest threat for use in an aerosolized attack and designed the BioWatch program to detect those agents.
- The Centers for Disease Control and Prevention (CDC) uses threat awareness information to help prioritize investments in developing diagnostic tests and assessment tools. CDC has developed diagnostic tests to detect Zika virus and also developed a test that can detect Ebola virus within a few hours. Having detection tools available to rapidly identify the presence of threatening infectious diseases can help accelerate treatment options and mitigate the effects of a potential outbreak.
- The U.S. Department of Agriculture uses threat awareness information to inform investments in surveillance in the most likely regions or animal populations in the United States where a foreign animal disease might be discovered or inform the development of diagnostic tests. If there is a determination that a new pest presents a threat to U.S. crops or agriculture animals, this assessment would inform domestic surveillance and monitoring programs. For example, the pest might be added to the Cooperative Agricultural Pest Survey or to a specific commodity survey, such as the bundled corn pest survey.

Source: GAO analysis of agency information; DHS (photo). | GAO-18-155


Speed and coordination are essential in mitigating and responding to the lethal, medical, psychological, and economic consequences posed by a catastrophic biological event. Planning and preparedness can prevent loss of life, illness, and psychological trauma, and can contain the spread of potentially contagious diseases through use of medical countermeasures. Recovering from a biological event may also require significant decontamination and remediation activities. Figure 6 shows examples of how agencies reported using threat awareness to inform investments in response and recovery activities.

Figure 6: Examples of How Agencies Reported Using Threat Awareness to Inform Investments in Response and Recovery Activities



Response and recovery

Response and recovery activities include development of medical countermeasures for humans and animals and decontamination practices



Stockpiling

The Centers for Disease Control and Prevention’s (CDC) Strategic National Stockpile is the nation’s largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. The stockpile is designed to ensure the right medicines and supplies are available when and where needed to save lives. The stockpile also houses medical countermeasures that have limited utility in the market because they are specifically designed to counteract threat agents.

USDA manages the National Veterinary Stockpile, which provides the veterinary countermeasure animal vaccines, antivirals, or therapeutic products, supplies, equipment, and response support services that states, tribes, and territories need to respond to damaging animal disease outbreaks.

Based on our analysis of agency documents and interviews, the following examples illustrate how agencies reported using threat information to help identify and procure necessary medical countermeasures and develop decontamination strategies.

- The Department of Health and Human Services (HHS) uses threat awareness information provided by Material Threat Assessments to inform investments in medical countermeasures through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) for the Strategic National Stockpile. HHS officials said that in terms of general research priorities, there are some known pathogens that stand out for potential terrorist activity, such as those that cause anthrax and smallpox. They said while countermeasure development aims to cover a range of potential threats and scenarios—such as development of antimicrobials against anthrax which may help reduce risk of similar or related agents—viral agents, such as the viruses that cause smallpox, generally require specific medical countermeasures.
- The U.S. Department of Agriculture (USDA) developed the High-Consequence Foreign Animal Diseases and Pests List in 2013 to help prioritize investments in medical countermeasures for the National Veterinary Stockpile. Using criteria on factors such as the likelihood or consequence of introducing a foreign animal disease helps prioritize countermeasure development.
- The Department of Defense and Environmental Protection Agency also use threat awareness information to inform the requirements for decontamination equipment and approaches for military operations and communities, respectively.

Source: GAO analysis of agency information; CDC (photo). | GAO-18-155

Multiple Mechanisms Exist to Share Biological Threat Information, and New Biodefense Strategy Could Help Agencies Better Use Threat Information to Leverage Resources across the Enterprise

Federal agencies with key roles in biodefense share biological threat information through many different mechanisms designed to facilitate collaboration among government partners, including working groups and interagency agreements. However, as we and others have observed in recent reports, opportunities remain to enhance threat awareness across the entire biodefense enterprise, leverage shared resources, and inform budgetary tradeoffs among various threats and agency programs.

Federal Partners Share Biological Threat Information through a Combination of Working Groups, Interagency Agreements, and Other Mechanisms

Officials from key federal agencies, including DHS, DOD, EPA, HHS, and USDA, identified multiple mechanisms that facilitated biodefense collaboration and shared awareness of biological threats. These mechanisms often serve multiple purposes; for example, a working group can develop policy and also aid in information sharing, among other benefits. Officials from these key biodefense agencies reported using collaborative mechanisms to share biological threat information, as well as to coordinate activities, avoid duplication and overlap, implement specific programs for addressing biological threats, and assist in policy development at the agency and White House level. The existence of working groups and similar bodies to help promote information sharing, align policies and procedures, and coordinate to leverage resources is consistent with key practices and mechanisms that we have previously reported as useful for enhancing and sustaining interagency collaboration.⁴³ Figure 7 provides examples of collaborative mechanisms identified for biodefense.

⁴³GAO-06-15 and GAO-12-1022.

Figure 7: Examples of Collaboration Mechanisms for Biodefense and Threat Awareness

Collaboration mechanism Description	Federal entity										
	Department of Agriculture	Department of Defense	Department of Energy	Department of Health and Human Services	Department of Homeland Security	Department of Justice	Department of State	Department of Veterans Affairs	Environmental Protection Agency	Executive Office of the President	Intelligence Community
Interagency Bioterrorism Risk Assessment Working Group Interagency group to review and provide direction on Bioterrorism Risk Assessment	●	●	●	●	●	●	●	○	●	●	●
Public Health Emergency Medical Countermeasures Enterprise Interagency group led by agency and department heads	●	●	○	●	●	○	○	●	○	○	○
Combating Terrorism Technical Support Working Subgroup for Chemical, Biological, Radiological, Nuclear, and Explosive Threats Cochairs of interagency group for research and development requirements ^a	○	●	○	○	●	●	○	○	○	○	○
Memorandum of Understanding for Biodefense Interagency agreement clarifying roles for biodefense research, development, and acquisition	○	●	○	○	●	○	○	○	●	○	○
National Interagency Biodefense Campus Physical colocation at Fort Detrick, Maryland	●	●	○	●	●	○	○	○	○	○	○
DHS Science and Technology Directorate research projects Joint funding and research program efforts	●	●	○	○	●	○	○	○	●	○	○

● Participant in collaborative mechanism ○ Not a participant in collaborative mechanism^b

Source: GAO analysis of agency information. | GAO-18-155

^aSubgroup members include senior representatives from the White House and 17 federal entities as well as state and local agencies.

^bFor illustrative purposes only. Nonparticipation is not intended to denote a deficiency.

Officials at key federal agencies reported participating in several types of collaborative mechanisms, including interagency bodies, working groups at the agency and executive level, formalized agreements, colocation, joint projects and funding efforts, and shared expertise. Examples within each mechanism include the following:

Interagency bodies. Key federal agencies reported participating in formal interagency bodies that have their own authority and resources and are established to coordinate activities related to biodefense. One such group is PHEMCE, the federal interagency decision-making body for medical countermeasure development and acquisition.⁴⁴ PHEMCE is led by HHS, and includes both internal HHS partners, such as CDC, FDA, and NIH, and external interagency partners, such as DOD, DHS, USDA, and the Department of Veterans Affairs. In addition, other key agency officials reported participating in interagency bodies coordinated by HHS and USDA to determine additions and removals to the select agent list.⁴⁵

Working groups. Officials in each of the key agencies said they participate in established and ad hoc working groups to provide subject-matter knowledge and expertise, share information, prioritize research, and avoid duplicating efforts. For example, officials from over a dozen agencies and components participate in an Interagency Bioterrorism Working Group through DHS that provides a conduit for interagency review of technical inputs and assumptions for biological agents and other parameters in the BTRA. DHS officials stated that this working group also works to obtain wider interagency understanding and ownership of the DHS BTRA. Officials from DOD's JPEO-CBD also stated that they sit on multiple interagency working groups with DHS officials that focus on combating terrorism, biosurveillance, and research and development, among other topics. Similarly, CDC officials stated they participated on approximately 10 to 20 separate working groups with specialized purposes, such as integrated process teams for specific research programs.

⁴⁴The PHEMCE Implementation Plan is supported by a number of HHS funding streams, and agency officials we interviewed noted that each partner agency within the PHEMCE must use its own resources to pursue priorities.

⁴⁵A select agent is a biological agent or toxin that (1) potentially poses a severe threat to public health and safety, animal or plant health, or animal or plant products and (2) is regulated by select agent rules for possession, use, and transfer (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73). The Federal Select Agent Program is a regulatory program jointly comprised of two offices within CDC and USDA to help enhance laboratory safety and security.

Collaborative mechanisms within the Executive Office of the President. Some working groups and other collaboration mechanisms have been led by the National Security Council and other offices within the Executive Office of the President in order to ensure a comprehensive and coordinated approach to biodefense across agencies.⁴⁶ For example, the Subcommittee on Biological Defense Research and Development was led by the White House Office of Science and Technology Policy and included representatives from 16 agencies and three White House offices. This subcommittee evaluated U.S. biological defense capabilities to identify future priorities and actions. The National Security Council has also led integrated policy committees focused on a particular threat or range of threats, such as genome editing and synthesis and select agents and toxins.

Written interagency agreements. Agencies have executed written agreements in order to define their relationships for a particular aspect of biodefense. For example, in March 2015, DOD, DHS, and EPA renewed a formalized relationship through a memorandum of understanding for chemical and biological defense research, development, and acquisition—all of which require shared threat awareness.⁴⁷ The agreement identifies roles and responsibilities for chemical and biological defense, establishes senior and technical working groups, and establishes cross-agency responsibilities. In particular, DOD, DHS, and EPA agreed to exchange and identify program needs and overlapping interests; establish interagency agreements between parties for joint projects and funding; conduct research and provide data to the partner agencies; and facilitate the establishment of interagency projects and working groups. DOD officials stated that the activities carried out under the memorandum have varied over time, but ongoing collaborative activities included efforts in biosurveillance, wearable sensors, decontamination, and a repository for threat agent data.

⁴⁶The National Security Act of 1947, as amended, established the National Security Council to advise the President with respect to the integration of domestic, foreign, and military policies relating to the national security. There is also a Homeland Security Council—established through Executive Order 13228 on October 8, 2001, and subsequently codified in the Homeland Security Act of 2002—which advises the President on matters pertaining to homeland security. Each council is also responsible for the effective coordination of the security-related activities and functions of the executive departments and agencies.

⁴⁷Memorandum of Understanding between the Department of Defense, the Department of Homeland Security, and the U.S. Environmental Protection Agency on Areas of Cooperation in Chemical and Biological Defense (March 30, 2015).

Joint facility locations. As we reported in 2014, to maximize resource sharing and facilitate scientific exchange on the study of biological threat agents and other pathogens, DOD, HHS, and DHS share a joint biological campus, known as the National Interagency Biodefense Campus, located at Fort Detrick, Maryland.⁴⁸ DHS officials said that, in addition to gaining efficiencies by sharing biosecurity and infrastructure requirements among all three facilities (U.S. Army Medical Research Institute of Infectious Diseases, DHS's NBACC, and NIH's Integrated Research Facility), personnel at the three laboratories can communicate more regularly than would otherwise be possible with different locations. The agencies represented on the National Interagency Biodefense Campus also conduct a research consortium to coordinate projects.

Joint funding and program efforts. Key federal biodefense agencies have provided funding to partner organizations and agencies in order to obtain technical assistance or expertise for individual projects. DOD and EPA officials stated that DHS's S&T Directorate often funds subject-matter experts to perform research and testing to assist in the development of answers to technical questions. For example, DHS funded staff at the U.S. Army Medical Research Institute of Infectious Diseases to research the characteristics of a particular agent in an aerosolized environment.

Leveraging expertise. Agency officials also stated how more informal mechanisms, such as relationships between key personnel and soliciting input for research projects, provide the opportunity to leverage expertise to share threat awareness information and can increase collaboration and positive results between agencies. For example, DHS holds interagency stakeholder panels and outreach events (separate from existing working groups) to gather expertise during development of several biodefense products, including the BTRA. DHS officials said that DOD personnel from DTRA and DHS's Biological Threat Characterization Program also conduct joint program reviews, and DHS personnel contribute expertise to DTRA's contract evaluation teams.

⁴⁸See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, [GAO-14-442](#) (Washington, D.C.: May 15, 2014). The USDA Agricultural Research Service (ARS) is also a member of the National Interagency Biodefense Campus and participates in the federal interagency governance structure.

Biodefense Strategy Provides an Opportunity to Use Enterprise-Wide Threat Awareness to Help Leverage Resources and Inform Resource Tradeoffs

The collaborative mechanisms in which the key agencies in our review participate may facilitate information sharing in support of specific federal activities and in individual programs, or in response to specific biological events after they begin to unfold, but there is no mechanism in place to develop enterprise-wide threat awareness and assess the relative risks. For example, the BTRA is a dedicated effort to identify and assess the risk of biological events that stem from nonstate actors intentionally seeking to harm U.S. interests using biological agents. By design, it is focused on the consequences and likelihood of terrorist events threatening human health, and does not assess the risk from other types of biological threats. However, there is no similar comprehensive mechanism in place that integrates threat awareness information for all sources of intentional biological threats, as well as naturally occurring events that could harm or destabilize U.S. interests by catastrophically affecting humans, animals, and plants. Similarly, HHS officials stated that PHEMCE is a primary mechanism used to communicate threat awareness and other information on biodefense. However, the primary purpose of PHEMCE is to make decisions about human health countermeasures to be acquired for the Strategic National Stockpile. As a result, biological threat information pertaining to other domains, such as plant or animal health, may not be discussed and shared within this venue without a connection to human health.

In addition, there is no existing mechanism that can leverage threat awareness information to direct resources and set budgetary priorities across all agencies for biodefense. Agencies use threat awareness mechanisms for resource planning according to the individual agency's mission. For example, DOD guidance states that budgeting and planning for biodefense relies, in part, on DIA's CBRN Warfare Capstone Threat Assessment. Similarly, DHS officials stated they use the BTRA to help plan DHS investments in future research or to help inform domestic biodefense preparations. According to DOD officials, because the DOD mission is different, they only use the BTRA indirectly and do not specifically rely on it for prioritizing activities or planning efforts.

HSPD-10 requires the development of periodic assessments of the evolving biological weapons threats. DHS officials stated that the BTRA was created, in part, to fulfill the need for an assessment of the risk of intentional use of biological weapons by nonstate terrorists. However, the nation faces other biological threats, including naturally occurring diseases that affect human, animal, and plant health, and biological weapons used by state actors. Without a mechanism that is able to

assess the relative risk from biological threats across all sources and domains, the nation may be unable to prioritize resources, defenses, and countermeasures against the most pressing threats.

We previously reported in 2011 that the overarching biodefense enterprise would benefit from strategic oversight mechanisms, including a national strategy, to ensure efficient, effective, and accountable results.⁴⁹ We noted that the complexity and fragmentation of roles and responsibilities across numerous federal and nonfederal entities presents challenges to ensuring efficiency and effectiveness across the entire biodefense enterprise. In light of that complexity and fragmentation, we observed that a national biodefense strategy could help address the key fragmentation issues across the biodefense enterprise, such as ensuring strong linkage and identifying gaps in investments across the four pillars. In response to our observations, National Security Council staff in December 2014 identified three presidential policy documents—the National Strategy for Countering Biological Threats, the National Biosurveillance Strategy, and Presidential Policy Directive 8—they reported work in concert to provide comprehensive strategic guidance. However, none of these documents comprehensively addresses all four pillars of biodefense, and, even when taken together, they do not fully address the fragmentation issues we have previously identified.

Other independent observers have also commented on challenges presented by fragmentation and complexity across the biodefense enterprise. For example, in October 2015, the Blue Ribbon Study Panel on Biodefense reported that the United States lacked strategic leadership to promote collaboration within the federal government and other biodefense partners and achieve innovation throughout the enterprise. The study panel also recommended that the federal government develop, implement, and update a comprehensive national biodefense strategy that would define all organizational structures, future plans, and resource requirements along with unified budgetary authority.

We testified in 2016 that several high-level biodefense strategies had been created in the past.⁵⁰ However, there is no broad, integrated strategy that can be used to identify risk, assess resources, and prioritize

⁴⁹GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, [GAO-11-318SP](#) (Washington, D.C.: Mar. 1, 2011).

⁵⁰GAO, *Biodefense: The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance*, [GAO-16-547T](#) (Washington, D.C.: Apr. 14, 2016).

investments. For example, the National Security Council's *National Strategy for Countering Biological Threats* is focused solely on outlining the federal government's approach to reducing the risks of biological weapons proliferation and terrorism, while the *National Health Security Strategy* authored by the Assistant Secretary for Preparedness and Response (ASPR) seeks to strengthen communities' abilities to protect against and respond to any incidents with negative health consequences. While these and other strategies, such as the *National Strategy for Biosurveillance*, address aspects of biodefense, no single strategy provides a comprehensive approach for the nation to prepare and plan for biological threats. In addition, as we reported in 2016, the individual strategies related to pieces of the biodefense enterprise do not currently address the need for prioritization and tradeoffs among approaches when faced with limited resources and expansive threat.⁵¹

In addition, there is no individual or entity with responsibility, authority, and accountability for overseeing the entire biodefense enterprise. White House officials have previously told us that the National Security Council and the Homeland Security Council act together as focal points for federal biodefense efforts. As noted above, many federal departments and agencies participate in National Security Council groups and mechanisms, and biodefense efforts at the White House level are recognized collaboration mechanisms. However, as described in the Blue Ribbon Study Panel report and reported to us by HHS and DHS officials, these mechanisms may not persist from one presidential administration to the next. As a result, any mechanism located within bodies such as the National Security Council and Homeland Security Council may not provide the continuity and leadership needed to address persistent biological threats. The absence of mechanisms to develop shared threat awareness across the full set of biological threats and use that information to identify opportunities for leveraging resources to mitigate risk across the enterprise is another example of the fragmentation we have previously identified.⁵²

However, opportunities exist to enhance shared threat awareness across the biodefense enterprise. Enacted on December 23, 2016, the National Defense Authorization Act (NDAA) for Fiscal Year 2017 required DOD, HHS, DHS, and USDA to jointly develop a national biodefense strategy

⁵¹GAO, *Biosurveillance: Ongoing Challenges and Future Considerations for DHS Biosurveillance Efforts*, [GAO-16-413T](#) (Washington, D.C.: Feb. 11, 2016).

⁵² [GAO-16-413T](#).

and associated implementation plan.⁵³ The law requires the strategy and implementation plan to:

- inventory and assess all existing strategies, plans, policies, laws, and interagency agreements related to biodefense;
- describe biological threats from warfare, terrorism, naturally occurring infectious disease, and accidental exposure;
- describe current federal efforts preventing the proliferation and use of biological weapons, preventing accidental or naturally occurring outbreaks, and mitigating the effects of an epidemic;
- describe roles and responsibilities of the agencies for biodefense;
- describe interagency capabilities required to support the national biodefense strategy; and
- recommend actions for strengthening current biodefense capabilities and structures, and for improving interagency coordination.

According to DHS officials, as of September 2017, the White House National Security Council is currently overseeing an interagency workgroup to develop that strategy. DOD officials confirmed that the process to create such a strategy is under way, and the effort may include revising or consolidating existing guidance in addition to developing a new national biodefense strategy.

As the departments fulfill their obligations under the NDAA for 2017, key federal organizations have the opportunity to institutionalize mechanisms to help the nation make the best use of limited biodefense resources, to include broader shared threat awareness to inform opportunities to leverage resources. However, until the strategy is developed, we will not know the extent it will address shared threat awareness, if at all. The NDAA for 2017 requires the strategy to be submitted to Congress not later than 275 days after enactment (September 2017) and requires us to review it 180 days after the date of submittal.⁵⁴ We will continue to monitor progress toward developing strategic mechanisms to help confront fragmentation and complexity across the biodefense enterprise.

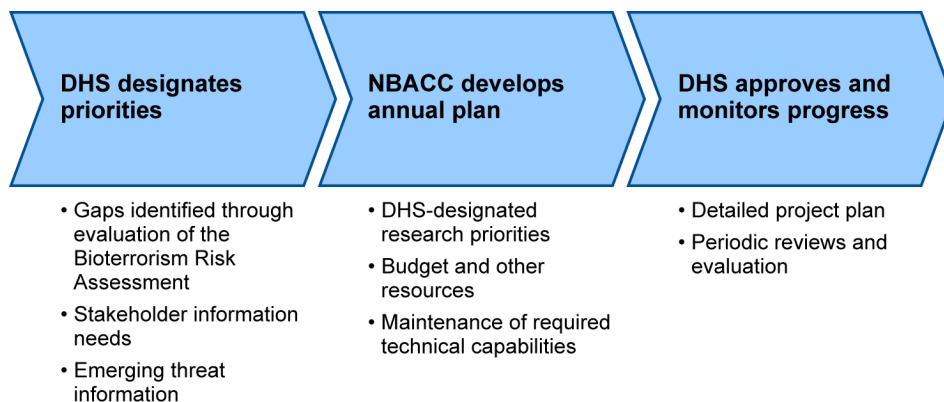
⁵³National Defense Authorization Act for Fiscal Year 2017, Pub. L. No. 114-328, §1086, 130 Stat. 2000, 2423 (Dec. 23, 2016).

⁵⁴According to agency officials, as of September 27, 2017, the strategy was still under development and not yet submitted to Congress.

NBACC Threat Characterization Research Is Largely Driven by Knowledge Gaps Identified through the BTRA Process

According to DHS officials, the threat characterization research agenda at NBACC is based primarily on the results and knowledge gaps identified through evaluation of the BTRA. Each year NBACC produces an annual plan that, among other elements, outlines new research projects intended to address priority knowledge gaps for identified biological threat agents.⁵⁵ These projects are identified through a multistep process that incorporates a combination of DHS-designated priorities, interagency stakeholder input, and additional planning criteria, such as resource availability and ongoing maintenance of required technical capabilities. (See fig. 8.)

Figure 8: Department of Homeland Security (DHS) Process for Selecting and Monitoring the National Biodefense Analysis and Countermeasures Center (NBACC) Research Priorities



Source: GAO analysis of DHS information. | GAO-18-155

⁵⁵The NBACC Annual Plan also addresses DHS priorities and planned activities for the National Bioforensics Analysis Center. For the purposes of this section, we use NBACC to describe the threat characterization research carried out by the National Biological Threat Characterization Center.

Priority Knowledge Gaps and Research Needs

The first step in the project selection process is the identification of knowledge gaps by officials within DHS's Biological Threat Characterization Program (BTCP) based on their evaluation of the BTRA. According to these officials, identification of the most critical knowledge gaps involves determining which inputs have a relatively high impact on BTRA consequence estimates and have a relatively high degree of uncertainty, for example, because data about agent attributes are limited. The officials said they aim to enhance the value of BTRA conclusions by increasing the accuracy and completeness of the data used as modeling inputs through the work of NBACC. DHS has historically relied on the opinions of subject-matter experts to review the BTRA and support determinations regarding data quality but has also recently developed more quantitative methods to integrate BTRA results into the research planning and prioritization process for NBACC.⁵⁶

Using data from the 2010 BTRA, DHS identified a total of 22 priority knowledge gaps that it is currently working to address through NBACC research and plans to complete within 6 to 10 years.⁵⁷ BTCP program officials reported that although research priorities generally target Tier 1 Select Agents, they also seek to advance research projects that broadly encompass (1) a variety of biological threat agents (e.g., bacteria, viruses, and toxins); (2) agents representing different characteristics that affect threat (e.g., means of acquisition or production, dissemination and exposure attributes, and expected medical consequences), and (3) a selection of traditional, emerging, enhanced, and advanced biological threat agents.⁵⁸

In addition to the identification of BTRA-related knowledge gaps, BTCP officials stated that emerging events and specific stakeholder needs could

⁵⁶DHS has also deployed a new software tool—the Research Prioritization Matrix (RPM) Tool—to support evaluation of the impact of individual data inputs and help identify research areas that will be of greatest benefit to inform future iterations of the BTRA. The RPM tool uses sensitivity analysis to compute a score that reflects a level of confidence in the available information about each biological agent used to populate the BTRA models. According to S&T officials, 2017 was the first year that the tool was fully functional and used to inform NBACC research priorities identified in the annual plan. See app. I for more information on the BTRA and RPM tool.

⁵⁷The 2010 BTRA was the last full version of the assessment developed until the most recent iteration, which was released in May 2017 (see app. I for additional information on the BTRA).

⁵⁸Tier 1 agents are a subset of biological agents on the federal Select Agents and Toxins List that are deemed to pose the greatest risk of deliberate misuse with significant potential for mass casualties or other catastrophic impacts.

also influence research priorities.⁵⁹ For example, during the 2014 Ebola outbreak, BTCP officials directed NBACC to perform research to better understand the risk factors associated with disease transmission, such as the persistence of the virus on various surfaces, and the efficacy of common disinfectants to inform decontamination and public health response efforts. DHS officials also noted that the needs of the Federal Bureau of Investigation, particularly through its casework at the National Bioforensics Analysis Center, may drive some of NBACC's research priorities.⁶⁰

Proposed Annual Research Plan

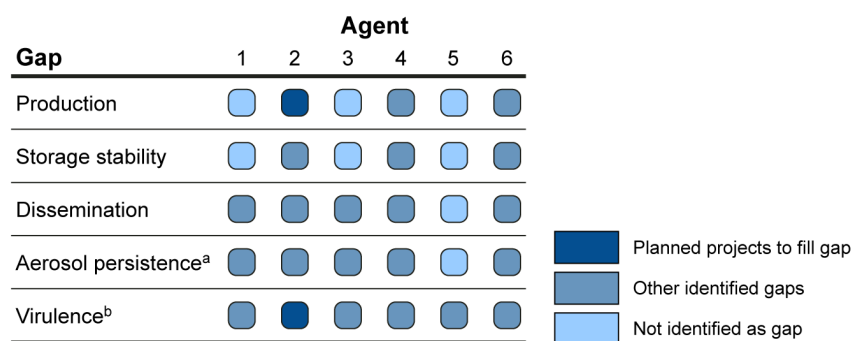
The second step in the process for identifying NBACC threat characterization research projects includes the development of a proposed annual research plan. The annual plan is developed using a combination of inputs including DHS's research priorities, annual NBACC budgetary resources, and technical capability and staff development needs. Although the plan documents the DHS knowledge gaps that serve as a key driver for developing specific project proposals, in some cases these gaps are identified only as general areas of research, such as the virulence of specified threat agents, which could require a broad scope of research to address. As the plan notes, these priority knowledge gaps exceed the resources available for threat characterization each year. For this reason, NBACC uses a combination of additional criteria to further refine research priorities and select projects for inclusion in the new scope of work, such as consideration of the time and resources required and which knowledge gaps are most likely to provide clear and compelling answers through experimentation. Other factors that may influence final project selection include addressing the knowledge gaps that could be completed reasonably comprehensively in 3 to 4 years or may have potential to provide a framework to better understand other priority agents or emerging threats, such as the Ebola virus or other

⁵⁹According to the BTCP Program Manager, research needs are informed by numerous other sources, including national and international events involving potential biological threat agents, current intelligence assessments of bioterrorist threats, other scientific and technical publications, and the needs communicated by other stakeholders and partners.

⁶⁰Analysis of evidentiary samples may result in evidence that will be admissible in court or used as an investigative lead for biocrime or bioterrorism investigations. For additional information on this center and federal bioforensic activities, see [GAO-17-177](#).

infectious diseases (see fig. 9).⁶¹ In developing the annual research plan, NBACC also sets aside a small portion of its threat characterization budget to respond to emerging requests, and the plan notes that project plans may be readjusted due to any emerging requirements.⁶²

Figure 9: Example of the National Biodefense Analysis and Countermeasures Center's (NBACC) Short-Term Research Projects



Source: NBACC. | GAO-18-155

^aAerosol persistence is the ability of an agent to remain viable over time when dispersed through the air.

^bVirulence is the relative capacity of a pathogen to overcome body defenses.

The annual plan also identifies priorities needed to maintain four core technical capabilities (aerobiology, bacteriology, virology, and comparative medicine) and accreditation standards required to perform ongoing threat characterization research on potential threat agents in a maximum security national biocontainment laboratory.⁶³ For example, one of the priorities identified within the 2016 annual plan includes the installation and verification of new equipment intended to enhance aerobiology capabilities. Each annual plan includes a crosswalk between

⁶¹S&T officials said that this time frame allows research to be pursued with a more manageable scope and takes into account an annual budgetary cycle that may impact longer term resource planning. One senior official also noted that broad knowledge gaps often can be addressed through discrete phases of research conducted incrementally over many years if those information needs remain a priority.

⁶²In the 2016 plan year, approximately \$292,000 was allocated to respond to emerging requirements as part of a total budget of about \$8 million dedicated to NBACC threat characterization studies.

⁶³Aerobiology is the study of the dispersion of airborne biological materials, such as pollen, spores, microorganisms, or viruses. Bacteriology is a branch of microbiology dealing with the identification, study, and cultivation of bacteria. Virology is the study of viruses and the diseases caused by them. Comparative Medicine involves the use of animals to evaluate the properties of certain biological agents, because humans are not allowed to be used for such testing.

the proposed projects and the associated capabilities that will be utilized. For example, the 2016 NBACC annual plan outlines a scope of work that includes seven research studies that collectively cover all four of the core technical capabilities. Examples of some of the research conducted in recent years include assessment of the decay rates of aerosolized Tier 1 agents and the virulence of select agents based on particle size and production methods.

Plan Approval and Oversight

Once NBACC develops a proposed annual research plan, stakeholders review it before the plan goes for S&T approval.⁶⁴ According to S&T officials we interviewed, the BTCP program solicits input and feedback on the draft annual plan from interagency stakeholders within DOD, HHS, and the Intelligence Community, among others. According to these officials, the community of practice for conducting this type of research is small and is generally well coordinated to avoid potential duplication of work. Once S&T officials approve the plan, it then undergoes a final approval process through DHS's Compliance Review Group to ensure adherence with the Biological Weapons Convention.⁶⁵

According to S&T officials, they also participate in periodic project reviews to maintain oversight regarding the extent to which each research study is achieving its objectives, and an overall assessment is performed as part of the annual evaluation process of the NBACC contract performer. The purpose of these periodic reviews is to help identify any changes to the project plan that may be required and help ensure that the research is making progress toward addressing identified knowledge gaps. S&T officials stated that although some projects have been modified based on preliminary results, they rely much more heavily on advance review of the experimental methodology by technical subject-matter experts before a project is initiated to help ensure the research will address identified gaps and help inform future iterations of the BTRA.

⁶⁴For all approved research studies, NBACC develops an individual project plan that provides more details regarding the scope of work, resource estimates, project schedule, and performance goals, among other components. Each study undergoes periodic technical and management review, and is subject to established change control processes—practices consistent with standard project management criteria. See, Project Management Institute, *A Guide to the Project Management Body of Knowledge* (PMBOK Guide), 5th ed. (Newtown Square, Pa.: 2013).

⁶⁵According to S&T officials, this compliance review process has resulted in modifications or delays to proposed NBACC research projects and generally provides incentives for the scope of projects to be more narrowly focused and executed within relatively short time frames, to help reduce the potential for compliance concerns.

NBACC Impacts

Consistent with its strategic goals, S&T officials reported that NBACC research has directly contributed to the closing of identified knowledge gaps and the development of capabilities that are used to respond to emerging threat characterization needs. According to these officials, NBACC products have improved BTRA consequence and hazard modeling by reducing the uncertainty associated with key data inputs. Specifically, officials cited that significant changes were made to the underlying risk models as a result of NBACC research conducted since the completion of the 2010 BTRA, including updates to 62 individual data points associated with eight biological hazards. As noted in the 2016 NBACC annual plan, the limited research available on authentic threat agents has historically entailed the use of data from surrogate or unrelated biological agents to evaluate the threat and consequences of a biological attack on the homeland. According to S&T officials, the use of authentic threat agents at NBACC addresses this shortcoming and has enhanced confidence in estimates of risk and operational response planning. Although NBACC research currently remains focused on closing specific knowledge gaps, officials noted that this research is also intended to lay a foundation for more predictive modeling, such as using the data to identify shared characteristics among a class of agents.

Although the focus of NBACC threat characterization research is generally on the intentional use of Tier 1 biological agents, S&T officials stated that NBACC capabilities could also be employed to address challenges associated with emerging infectious diseases. They further noted that, because many of the high-priority biological threat agents that affect humans also may affect livestock, NBACC's studies could also be useful for informing risk associated with animal health.

NBACC expertise has also been leveraged by other DHS components. For example, S&T officials reported that the U.S. Coast Guard requested information from NBACC to help inform its global vaccine program for its workforce, and DHS's National Protection and Programs Directorate and the Secret Service have requested NBACC to review their own biological risk assessments. Within S&T, CBD officials stated that NBACC-produced products were used to inform the development of new biological sensor technologies. In addition to sharing NBACC research findings through briefings and reports, NBACC officials also reported that they are currently pursuing efforts to establish an electronic repository for NBACC scientific products at the Unclassified/ For Official Use Only, Secret, and Top Secret levels. The goal of this repository site is to facilitate the ability

of end users to search, view, and download documents according to their approved access.

Agency Comments and Our Evaluation

We provided a draft of this report to DHS, DOD, EPA, HHS, and USDA for review and comment. Each of these departments provided technical comments that we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees; the Secretaries of Agriculture, Defense, Health and Human Services, and Homeland Security; and the EPA Administrator. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (404) 679-1875 or curriec@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 key contributions to this report are listed in appendix III.



Chris Currie
Director, Homeland Security and Justice

Appendix I: Bioterrorism Risk Assessment

The Department of Homeland Security (DHS) is responsible for assessing the risks posed by biological agents as directed by the Project BioShield Act of 2004 and Homeland Security Presidential Directives 10—*Biodefense for the 21st Century*, and 18—*Medical Countermeasures against Weapons of Mass Destruction*. To this end, DHS’s Science & Technology Directorate (S&T) has developed four Bioterrorism Risk Assessments (BTRA) since 2006 to assess the relative risks posed by various biological agents based on estimates of likelihood and consequence parameters for a number of potential attack scenarios.¹

BTRA Scope and Methodology

The BTRA is a probabilistic risk assessment intended to quantify risk for rare yet potentially catastrophic intentional attacks using biological agents by nonstate actors.² Results are based on risk modeling for a vast number of potential scenarios derived from multiple event trees representing specific decisions or actions an adversary may pursue.³ The most recent iteration issued in 2017, called the BTRA 5.0, includes over 600,000 scenarios with predicted impacts on human health, fatalities, and economic costs. These consequence estimates are based in part on inputs provided or validated by the Intelligence Community, various estimates of likelihood, and applicable consequence parameters, such as specific agent attributes and threat characterization research results from the National Biodefense Analysis and Countermeasures Center (NBACC).⁴

¹DHS also develops terrorism risk assessments pertaining to chemical, radiological, and nuclear agents, as well as an Integrated Terrorism Risk Assessment combining the results of each of these individual products.

²The *DHS Risk Lexicon* defines risk as the potential for an adverse outcome assessed as a function of threats, vulnerabilities, and consequences associated with an incident, event, or occurrence. Risk assessment is defined as the product or process that collects information and assigns values to risks for the purpose of informing priorities, developing or comparing courses of action, and informing decision making. According to DHS, risk information is usually one of many factors—and not necessarily the sole factor—that decision makers consider when deciding which strategy to pursue to manage risk.

³According to S&T officials, the latest BTRA incorporates over 5 billion scenarios (600,000 with predicted impacts), three categories of terrorist organizations, 37 biological agents, two routes of exposure, 28 targets, and 13 modes of dissemination, among other variables. Consequence estimates for each scenario are calculated 10,000 times to account for potential variability in the model results.

⁴Key consequence metrics identified by DHS Science and Technology Directorate (S&T) include illnesses, fatalities, and estimated economic costs (e.g., remediation, public avoidance, business disruption).

The BTRA incorporates a number of different models related to the various attack scenarios being assessed. For example, DHS utilizes unique models to assess risk for indoor attacks (in 12 different target categories, such as transportation hubs and sporting events), outdoor attacks (including the top 100 most populated U.S. cities and their associated weather patterns), and potential dissemination via food or water systems, as well as a model that estimates the ability for the public health system to mitigate potential illnesses or fatalities based on disease progression, response timelines, and available medical countermeasures. According to S&T officials, one of the key updates in the BTRA 5.0 is the introduction of adversary-decision models, which allow BTRA program officials to incorporate inputs from subject-matter experts and other data sources regarding the likelihood of various attack scenarios.⁵ Selected factors that are considered to help identify potential agents or dissemination methods chosen by an adversary include data on agent acquisition or the means of production in various countries, as well as the likelihood of interdiction during transport.

BTRA 5.0 Updates and Prior Recommendations

According to S&T officials, the BTRA 5.0 is intended to address previous recommendations of the National Research Council of the National Academies (National Academies) and provide additional information regarding data and intelligence inputs provided by subject-matter experts.⁶ The BTRA 5.0 was released in May 2017 and represents the first full BTRA product since 2010.⁷ According to BTRA program officials, a series of limited reports were issued in 2012, but S&T management instructed the division to address previous criticisms of the BTRA, including the National Academies' recommendations, before developing another full report. S&T program officials reported taking action on 12 of the 13 National Academies' recommendations, and determined, after subsequent review by DHS, that no action was required to address the

⁵An adversary-decision model assumes an intelligent adversary that will select the best attack strategy to maximize their strategic objectives. For example, the model allows the evaluation of different variations on an adversary's preferences and capabilities. For example, the model might explore the likelihood of different outcomes depending on an adversary's chosen target (indoor or outdoor location), the chosen biological agent, or the adversary's ability to acquire or produce the agent, among other variables.

⁶National Research Council of the National Academies, *Department of Homeland Security Bioterrorism Risk Assessment: A Call for Change* (Washington, D.C.: National Academies Press, 2008). The National Academies report was an assessment of the 2006 BTRA.

⁷Other BTRA assessments were produced in 2006 and 2008.

final recommendation.⁸ Some notable changes that DHS reported making in response to the National Academies' recommendations include:

- Officials reported implementing adversary-decision models to assess the probabilities of terrorist decisions for transporting materials and selecting targets to respond to National Academies' criticism that the BTRA methodology may not fully consider adversaries' efforts to maximize their chance of success.
- Officials reported publishing models and methodology reports and sending biological data for interagency review to respond to the National Academies' recommendation to improve transparency. In addition, officials said that DHS had made this information available to stakeholders on a secured electronic site for those with access.
- Officials reported developing additional tools and methods to assess consequences and probabilities of changing threats to address the National Academies' concern that the BTRA did not allow for incorporation of newly recognized threats or those that may not yet be well understood.
- Officials reported developing an economic consequence model and beginning to incorporate assessments of agricultural risk in addition to human mortality and morbidity to respond to the National Academies' recommendation that DHS add economic and agricultural effects, among other losses, to its consequence modeling.

According to S&T officials, another change implemented in the BTRA 5.0 is an effort to collect more detailed information about the sources and confidence level of the data inputs provided by subject-matter experts. These officials reported that they obtained expertise by survey primarily from terrorism subject matter experts, including members of the Intelligence Community.⁹ Data results now indicate whether inputs are based upon official reporting or the contributor's opinion based upon subject knowledge.

⁸That recommendation called for eliminating the assessment of probability distributions of event outcomes; however, DHS chose to continue the practice of incorporating subject-matter confidence values into the data inputs. We did not independently assess whether the changes made to the 2017 BTRA addressed the National Academies' recommendations made in 2008.

⁹The BTRA 5.0 included responses from 15 subject matter experts coordinated and selected by DHS officials. According to NBACC officials, they would like to see increased participation in this process and believe because it is voluntary, senior-level officials could help incentivize participation.

Additional BTRA Tools and Model Development

DHS also reported working on additional tools and models that officials expected would enhance the BTRA and make the results more useful to stakeholders. The following are examples of new developments identified to us by S&T officials:

- **Research Prioritization Matrix (RPM) Tool.** The RPM tool is intended to help identify areas of research that will be of greatest benefit to further inform future iterations of the BTRA. The RPM Tool uses a mathematical formula to develop a score based on numerous factors including (1) estimates of likelihood and consequences calculated by the BTRA, (2) the results of a sensitivity analysis of individual data parameters, and (3) an estimate of the confidence in the underlying and supporting data. According to officials, the result is a parameter and agent-specific score that can be used to support decisions regarding research prioritization in a structured, transparent manner that can be tracked over time to demonstrate progress. For example, a specific parameter in the RPM tool may include the decay rate of an agent in a particular substance (for example, in food items), and another parameter might be how much of a certain agent can likely be produced by certain adversaries. According to S&T officials, the RPM tool was recently updated with the latest data and results from the BTRA 5.0 and is expected to be more influential on the development of the research plan for fiscal year 2018. S&T program officials also said that the RPM tool will be made available to other federal entities so that they may use it for their own research prioritization needs, as well as customize the results, such as restricting the model to include only indoor attacks.
- **Agricultural Terrorism Modeling.** S&T officials have initiated efforts to develop additional modeling of potential agricultural impacts of a biological attack. Although a risk assessment of agricultural terrorism was completed in 2012 that assessed potential impacts from five animal diseases and two plant pathogens, officials reported that it was criticized for having substandard modeling and employing limited scenarios. The current effort includes representatives from the U.S. Department of Agriculture, the Food and Drug Administration, and the Federal Bureau of Investigation, and is focused on development of modeling for biological attacks on agriculture that may occur pre-harvest (before food processing begins) to differentiate it from attacks on the food system itself. DHS and stakeholders are currently evaluating available modeling tools and they plan to include the new modeling within the BTRA 6.0.



Appendix II: Summary of Biodefense Activities by Key Federal Agency

Department of Agriculture



Biodefense Responsibilities

- Develop awareness and early warning capabilities to recognize foreign animal diseases and plant pests
- Implement screening and inspection procedures for domestic and imported products
- Develop, with other entities, a National Veterinary Stockpile of animal vaccine, antiviral, or therapeutic products
- Conduct vulnerability assessments of the agricultural and food sectors
- Develop and implement strategies to protect vulnerable nodes of production or processing from introduction of diseases, pests, or poisonous agents
- Develop countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases

Primary Entities Implementing Threat Awareness Activities

- Animal and Plant Health Inspection Service
 - Veterinary Services—Center for Epidemiology and Animal Health
 - Plant Protection and Quarantine—Plant Epidemiology and Risk Analysis Laboratory
- Food Safety and Inspection Service
- Agricultural Research Service

Source: GAO analysis of USDA information; USDA (photo). | GAO-18-155

Key threat awareness activities identified by the agency

The U.S. Department of Agriculture (USDA) operates numerous programs designed to help prevent the entry and spread of agricultural pests and diseases, and protect the health of U.S. agricultural resources by addressing zoonotic diseases (transmissible from animals to humans) and implementing surveillance, preparedness and response, and control efforts. Examples of program activities include the following:

- **High Consequence List.** A three-tier classification system of foreign animal diseases determined to pose a significant threat to animal health if introduced into the United States. The list was developed in 2013 to help prioritize investments in the National Veterinary Stockpile.
- **Global Surveillance and Detection.** The Animal and Plant Health Inspection Service (APHIS) conducts multiple efforts in conjunction with international partners to identify and monitor emerging pests and diseases that could impact agricultural trade or pose a threat to domestic livestock.
- **Risk Assessment and Analysis.** Entities within APHIS support assessment of risk by conducting modeling and analyses of disease pathways and the potential for environmental and economic impacts of emerging pests and diseases. Officials reported using these results to prioritize the most likely threats for additional surveillance or countermeasures, which they say is important given finite resources, and a significant number of potential threats, particularly pests.
- **New Pest Response Guidelines.** Approximately 10—12 reports are produced annually to provide an assessment of pests deemed most important in terms of likelihood or potential consequence. These guidelines define the procedures that stakeholders are to use to identify, characterize, survey, and respond to a particular pest if detected in the United States.
- **Vulnerability Assessments.** The Food Safety and Inspection Service conducts vulnerability assessments that, among other things, can inform the development of countermeasures to help prevent or mitigate the impacts of an intentional attack on the food supply.
- **Scientific Research.** The Agricultural Research Service conducts research to help characterize the status of diseases worldwide and assess their spread patterns. This work can also include basic research on various biological agents, as well as identification of specific scientific and technology gaps related to effective preparedness and response efforts.



Department of Defense



Biodefense Responsibilities

- Ensure that military forces can operate effectively and are protected against biological weapons attacks
- Support the consequence management of terrorist incidents outside the United States
- Prevent biological weapons attacks
- Support mass casualty care
- Develop medical countermeasures against biological threats

Primary Entities Implementing Threat Awareness Activities

- Joint Program Executive Office for Chemical and Biological Defense
- Joint Requirements Office
- Joint Science and Technology Office for Chemical and Biological Defense
- United States Army Medical Research Institute of Infectious Diseases
- United States Army Edgewood Chemical Biological Center
- Defense Intelligence Agency
- Office of the Assistant Secretary of Defense for Health Affairs

Source: GAO analysis of DOD information; DOD (photo). | GAO-18-155

Key threat awareness activities identified by the agency

The mission of the Chemical and Biological Defense Program within the Department of Defense (DOD) is to “enable the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear threats and effects as part of a layered, integrated defense.” Examples of program activities include the following:

- **Requirements development.** The Joint Requirements Office conducts risk assessments and reviews information on threat and vulnerabilities, including those from new and emerging biological agents. This information supports the development of recommendations from the Joint Chiefs of Staff to the Secretary of Defense regarding requirements to develop operational capabilities for combatant commanders’ chemical and biological needs.
- **Scientific research.** The Joint Science and Technology Office for Chemical and Biological Defense, part of the Defense Threat Reduction Agency, coordinates research on biological threats, including research that supports the requirements for acquisition programs and other scientific knowledge that can be used to develop new military capabilities. This research is conducted by contractors as well as at several facilities owned and operated by the U.S. Army, including U.S. Army Edgewood Chemical Biological Center and U.S. Army Medical Research Institute of Infectious Diseases carry out the research and development activities.
- **Technology development.** The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) manages the development and acquisition of different technologies and prototypes in order to provide biological defense products to the military services. The technologies can include biological detection systems and laboratory equipment, medical countermeasures, protective equipment for individual warfighters to provide deployed units detection and protection capabilities against different types of biological weapons.
- **Threat assessment.** The Defense Intelligence Agency produces the Chemical, Biological, Radiological, and Nuclear Warfare Capstone Threat Assessment, a report on chemical and biological programs of countries and technology that could be used by adversaries in a threat environment. DOD officials said that JPEO-CBD uses the report to identify biological warfare threats against military and civilian populations and help prioritize resources and investments into research and development.



Environmental Protection Agency



Biodefense Responsibilities

- Support the local, state, and federal consequence management response to a biological attack
- As Sector Specific Agency for water infrastructure, provide resources and guidance to nearly 53,000 drinking water systems to detect and protect against intentional biological contamination of drinking water distribution systems
- Conduct research and analysis to characterize the properties of selected biological agents and the efficacy of various decontamination and waste management methods
- Conduct exercises and training on operational aspects of a biological incident response

Primary Entities Implementing Threat Awareness Activities

- Consequence Management Advisory Division (CMAD), Office of Emergency Management
- Water Security Division, Office of Groundwater and Drinking Water
- National Homeland Security Research Center, Office of Research and Development

Source: Environmental Protection Agency. | GAO-18-155

Key threat awareness activities identified by the agency

The mission of the Environmental Protection Agency's (EPA) Homeland Security Program is to protect human health and safeguard the environment. EPA has primary responsibility for a biological incident response (characterization, decontamination, and waste management), drinking water / waste water infrastructure protection, and the underlying scientific and technical support.

- **Biological Incident Response.** According to EPA, the Office of Emergency Management Chemical, Biological, Radiological, and Nuclear Consequence Management Advisory Division provides 24/7 scientific and technical expertise for all phases of consequence management, including sampling, decontamination, and clearance. According to EPA, threat awareness activities, such as operational tests and simulations to understand the behavior of biological agents in the environment, help inform strategies for characterization and remediation, such as screening, sampling and analysis, decontamination, and waste management.
- **Risk and Vulnerability Assessments.** EPA develops risk assessments of potential impacts to water systems and the environment in the event of a biological incident. EPA officials said EPA relies on the Department of Homeland Security's Bioterrorism Risk Assessment and information on adversary capabilities and tactics to better assess potential environmental countermeasures for attacks on water systems and indoor/outdoor areas, to steer research resources, and to support responders who may need to address the consequences of an attack. EPA Water Security Division officials said they develop tools, training, and programs to address intentional contamination, detection in distribution networks, vulnerability assessments, emergency response capabilities, and how to monitor incidents and threats.
- **Research and Development.** The Office of Research and Development's Homeland Security Research Program aims to help increase the capabilities of EPA and communities to prepare for and respond to chemical, biological, and radiological disasters. EPA relies on information from the BTRA in addition to its own research to inform preparedness activities and its research agenda. EPA's homeland security research is organized into three topic areas that support these objectives: (1) characterizing contamination and assessing exposure; (2) water system security and resilience; and (3) remediating wide areas.



Department of Health and Human Services



Biodefense Responsibilities

- Coordinate all federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events
- Lead efforts to research, develop, evaluate, and acquire public health emergency medical countermeasures to prevent or mitigate illness and death in the event of a biological weapons attack
- Conduct research to understand the potential for novel or genetically engineered biological weapon agents and possible scenarios that require coverage against a range of possible future biological threats to prevent illness even after exposure
- Develop and strengthen an operational national epidemiologic surveillance system for human health
- Conduct vulnerability assessments of the food sector, and develop and implement, as appropriate, mitigation strategies to protect vulnerable critical nodes of production or processing from the introduction of diseases, pests, or poisonous agents

Primary Entities Implementing Threat Awareness Activities

- Assistant Secretary for Preparedness and Response
- Centers for Disease Control and Prevention
- Food and Drug Administration (FDA)
- National Institutes of Health

Source: GAO analysis of HHS information; CDC/ CDC Connects (photo). | GAO-18-155

Key threat awareness activities identified by the agency

The Department of Health and Human Services (HHS) is tasked to lead the federal public health and medical response to potential biological threats and emerging infectious diseases. Under the Project BioShield Act of 2004, HHS is required to assess, on an ongoing basis, the potential public health consequences of any biological agents that the Department of Homeland Security (DHS) determines pose a threat sufficient to affect national security.¹

- **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).** Includes various HHS agencies and other federal departments, such as the Department of Defense (DOD), DHS, and the U.S. Department of Agriculture, to advise the Secretary of HHS on medical countermeasure priorities and approaches to the development, acquisition, stockpiling, and distribution of medical countermeasures for biological weapons attack agents, pandemic influenza, and other emerging infectious diseases.
- **Global disease surveillance.** Helps identify and respond to emerging infections, including pathogenic avian influenza, which remains an urgent global infectious disease threat.
- **Medical and Public Health Consequence Modeling.** HHS's medical and public health consequence modeling reports use the exposure information from DHS's material threat assessments (MTA) to calculate the number of individuals who may become ill, be hospitalized, or die based on the MTA scenario with and without medical countermeasures. HHS reported using the modeling reports as part of an assessment process to establish requirements for medical countermeasures that need to be developed and acquired to respond to a biological incident.
- **Vulnerability Assessments.** FDA conducts vulnerability assessments aimed at reducing large public health consequences of attacks on the food supply. FDA assesses public health and economic impact of an attack, the accessibility of a target and ease of an attack, the ability to recover, the loss of production due to an attack, and target selection. FDA also said it considers the health, economic, and psychological impacts of an attack on the food industry.
- **Scientific Research.** Studies include thermal stability of microbial agents and ability to inactivate biological agents in the food supply, and studies of pathogenic properties of viruses to help understand the epidemiology, transmission, evolution and origin of an outbreak.

¹HHS also has responsibility to respond to potential chemical, radiological, and nuclear threats.



Department of Homeland Security



Biodefense Responsibilities

- Conduct biological risk assessments and make determinations of material threats to national security
- Conduct screening and enforce applicable regulations related to plants and animals entering the United States
- Develop and oversee biosurveillance system and information sharing
- Support prioritization and development of countermeasures to address the intentional introduction or natural occurrence of biological agents or diseases impacting human, animal or plant health
- Conduct research and analysis to improve biological threat awareness and characterize the properties of selected biological agents

Primary Entities Implementing Threat Awareness Activities

- Science and Technology Directorate: Chemical and Biological Defense Division; National Biodefense Analysis and Countermeasures Center
- Office of Health Affairs

Source: GAO analysis of DHS information; DHS (photo). | GAO-18-155

Key threat awareness activities identified by the agency

The Department of Homeland Security (DHS) is the principal department responsible for coordinating domestic federal operations to prepare for, respond to, and recover from biological weapons attacks. Under the Project BioShield Act of 2004 and applicable presidential directives, DHS is required to assess current and emerging biological threats and support ongoing assessment of capabilities to help guide prioritization of investments in biodefense-related research, development, planning, and preparedness. Examples of program activities include:

- **Risk Assessment.** With input from others, DHS develops Material Threat Assessments (MTA) and the Bioterrorism Risk Assessment (BTRA) to quantify relative risks posed by biological agents based on variable threats, vulnerabilities, and consequences. According to officials, these assessments also help identify potential knowledge or capability gaps, and the MTAs inform the development and acquisition of medical countermeasures.
- **Surveillance and Detection.** DHS manages the BioWatch program, which is a system of environmental monitoring intended to provide early warning and detection of a biological attack. DHS also houses and supports the National Biosurveillance Integration Center—a collaboration of 14 federal partners intended to integrate information about threats to human, animal, plant, and environmental health from thousands of sources to develop a more comprehensive picture of the threat landscape.
- **Research and Analysis.** DHS operates the National Biodefense Analysis and Countermeasures Center, which conducts scientific research and develops reports and products intended to address identified knowledge gaps associated with current and future biological threats, including the effectiveness of potential countermeasures and the characterization of key attributes of biological attacks by an adversary such as agent acquisition; agent production; dissemination methods; and virulence. Additional research and analysis efforts are supported by the Biodefense Knowledge Center and multiple National Laboratories.

Appendix III: GAO Contact and Staff Acknowledgments

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Staff Acknowledgements

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Related GAO Products

Biological Defense: Additional Information That Congress May Find Useful as It Considers DOD's Advanced Development and Manufacturing Capability. [GAO-17-701](#). Washington, D.C.: July 17, 2017.

Chemical and Biological Defense: DOD Has Identified an Infrastructure Manager and Is Developing the Position's Roles and Responsibilities. [GAO-17-522R](#). Washington, D.C.: July 7, 2017.

Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks. [GAO-17-445](#). Washington, D.C.: May 23, 2017.

Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts. [GAO-17-360](#). Washington, D.C.: April 13, 2017.

Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness. [GAO-17-150](#). Washington, D.C.: February 10, 2017.

Bioforensics: DHS Needs to Conduct a Formal Capability Gap Analysis to Better Identify and Address Gaps. [GAO-17-177](#). Washington, D.C.: January 11, 2017.

Defense Intelligence: Additional Steps Could Better Integrate Intelligence Input into DOD's Acquisition of Major Weapon Systems. [GAO-17-10](#). Washington, D.C.: November 1, 2016.

High-Containment Laboratories: Actions Needed to Mitigate Risk of Potential Exposure and Release of Dangerous Pathogens. [GAO-16-871T](#). Washington, D.C.: September 23, 2016.

High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk. [GAO-16-642](#). Washington, D.C.: August 30, 2016.

Biodefense: The Nation Faces Multiple Challenges in Building and Maintaining Biodefense and Biosurveillance. [GAO-16-547T](#). Washington, D.C.: April 14, 2016.

Emerging Infectious Diseases: Preliminary Observations on the Zika Virus Outbreak. [GAO-16-470T](#). Washington, D.C.: March 2, 2016.

Air Travel and Communicable Diseases: Comprehensive Federal Plan Needed for U.S. Aviation System's Preparedness. [GAO-16-127](#). Washington, D.C.: December 16, 2015.

Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks. [GAO-16-132](#). Washington, D.C.: December 15, 2015.

Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities Are Established. [GAO-16-99](#). Washington, D.C.: October 23, 2015.

Climate Change: HHS Could Take Further Steps to Enhance Understanding of Public Health Risks. [GAO-16-122](#). Washington, D.C.: October 5, 2015.

Biosurveillance: Challenges and Options for the National Biosurveillance Integration Center. [GAO-15-793](#). Washington, D.C.: September 24, 2015.

Chemical and Biological Defense: Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure. [GAO-15-257](#). Washington, D.C.: June 25, 2015.

Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization. [GAO-14-442](#). Washington, D.C.: May 15, 2014.

National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates. [GAO-14-90](#). Washington, D.C.: December 27, 2013.

Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry. [GAO-13-424](#). Washington, D.C.: May 21, 2013.

Influenza: Progress Made in Responding to Seasonal and Pandemic Outbreaks. [GAO-13-374T](#). Washington, D.C.: February 13, 2013.

Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms. [GAO-12-1022](#). Washington, D.C.: September 27, 2012.

Biosurveillance: DHS Should Reevaluate Mission Need and Alternatives before Proceeding with BioWatch Generation-3 Acquisition. [GAO-12-810](#). Washington, D.C.: September 10, 2012.

Chemical, Biological, Radiological, and Nuclear Risk Assessments: DHS Should Establish More Specific Guidance for Their Use. [GAO-12-272](#). Washington, D.C.: January 25, 2012.

Biosurveillance: Nonfederal Capabilities Should Be Considered in Creating a National Biosurveillance Strategy. [GAO-12-55](#). Washington, D.C.: October 31, 2011.

National Preparedness: Improvements Needed for Acquiring Medical Countermeasures to Threats from Terrorism and Other Sources. [GAO-12-121](#). Washington, D.C.: October 26, 2011.

Homeland Security: Challenges for the Food and Agriculture Sector in Responding to Potential Terrorist Attacks and Natural Disasters. [GAO-11-946T](#). Washington, D.C.: September 13, 2011.

Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture. [GAO-11-652](#). Washington, D.C.: August 19, 2011.

National Preparedness: DHS and HHS Can Further Strengthen Coordination for Chemical, Biological, Radiological, and Nuclear Risk Assessments. [GAO-11-606](#). Washington, D.C.: June 21, 2011.

Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases. [GAO-11-9](#). Washington, D.C.: November 8, 2010.

Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and a Designated Leader. [GAO-10-645](#). Washington, D.C.: June 30, 2010.

Agricultural Quarantine Inspection Program: Management Problems May Increase Vulnerability of U.S. Agriculture to Foreign Pests and Diseases. [GAO-08-96T](#). Washington, D.C.: October 3, 2007.

Global Health: U.S. Agencies Support Programs to Build Overseas Capacity for Infectious Disease Surveillance. [GAO-07-1186](#). Washington, D.C.: September 28, 2007.

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