



October 2017

# HIGH- CONTAINMENT LABORATORIES

## Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens

Accessible Version

## Why GAO Did This Study

Safety lapses continue to occur at some of the 276 laboratories in the United States that conduct research on select agents—such as Ebola virus or anthrax bacteria—that may cause serious or lethal infection in humans, animals, or plants, raising concerns about whether oversight is effective.

GAO was asked to review the federal oversight approach for select agents and approaches from other countries or regulatory sectors. This report (1) evaluates the extent to which the Select Agent Program has elements of effective oversight and strategic planning documents to guide it, and (2) identifies approaches selected countries and regulatory sectors have used to promote effective oversight.

GAO convened a meeting of experts with the help of the National Academy of Sciences to discuss oversight of select agents. GAO also reviewed relevant laws, regulations, and guidance, and interviewed officials from the Select Agent Program and laboratories it oversees. GAO also reviewed documents and interviewed officials from two countries and other U.S. sectors selected because they have alternate oversight approaches.

## What GAO Recommends

GAO is making 11 recommendations for the Select Agent Program, including to (1) assess risks from its current structure and the effectiveness of its mechanisms to reduce conflicts of interest and address risks as needed, (2) assess the risk of activities it oversees and target reviews to high-risk activities, and (3) develop a joint workforce plan. HHS and USDA agreed with GAO's recommendations.

View [GAO-18-145](#). For more information, contact Timothy M. Persons at (202) 512-6412 or [personst@gao.gov](mailto:personst@gao.gov) or John Neumann at (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@gao.gov).

# HIGH-CONTAINMENT LABORATORIES

## Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens

### What GAO Found

The Federal Select Agent Program (Select Agent Program)—jointly managed by the Departments of Health and Human Services (HHS) and Agriculture (USDA)—oversees laboratories' handling of certain hazardous pathogens known as select agents, but the program does not fully meet all key elements of effective oversight, as illustrated in the following examples:

- GAO's past work identified independence as a key element of effective oversight. However, the Select Agent Program is not structurally independent from all laboratories it oversees, and it has not assessed risks posed by its current structure or the effectiveness of mechanisms it has to reduce organizational conflicts of interest. Without conducting such assessments and taking actions as needed to address risks, the program may not effectively mitigate impairments to its independence.
- Another key element of effective oversight is the ability to perform reviews. Some experts and laboratory representatives raised concerns that the program's reviews may not target the highest-risk activities, in part because it has not formally assessed which activities pose the highest risk. Without assessing the risk of activities it oversees and targeting its resources appropriately, the program cannot ensure it is balancing its resources against their impact.
- Technical expertise is another key element GAO identified in past work. The Select Agent Program has taken steps to hire additional expert staff and improve training, but workforce and training gaps remain.

Moreover, the program does not have joint strategic planning documents to guide its oversight. Although it began taking steps to develop a joint strategic plan during GAO's review, the program is not developing workforce plans as part of this effort. GAO's past work has found that strategic workforce planning is an essential tool to help agencies align their workforces with their missions and develop long-term strategies for acquiring, developing, and retaining staff. Developing a joint workforce plan that assesses workforce and training needs for the program as a whole would help the program leverage resources to ensure all workforce and training needs are met.

Selected countries and regulatory sectors GAO reviewed promote effective oversight using approaches that differ from the U.S. Select Agent Program's approaches:

- In Great Britain, oversight of laboratories that work with pathogens is under an independent government agency focused on health and safety.
- In both Great Britain and Canada, regulators focus their oversight on (1) biological safety, due to safety incidents which provided the impetus for laboratory oversight in these countries; and (2) regulation of all potentially hazardous pathogens and activities in laboratories.

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## Abbreviations

APHIS	Animal and Plant Health Inspection Service
BSL	biological safety level
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
DEFRA	Department for Environment, Food, and Rural Affairs
DOD	Department of Defense
FBI	Federal Bureau of Investigation
GPRA	Government Performance and Results Act
HHS	Department of Health and Human Services
NAS	National Academy of Sciences
NIH	National Institutes of Health
NRC	Nuclear Regulatory Commission
OIG	Office of Inspector General
OMB	Office of Management and Budget
SARS	severe acute respiratory syndrome
UK	United Kingdom
USDA	United States Department of Agriculture

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October 19, 2017

The Honorable Greg Walden  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Tim Murphy  
Chairman  
The Honorable Diana DeGette  
Ranking Member  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives

The Honorable Fred Upton  
House of Representatives

Safety lapses continue to occur at laboratories in the United States that conduct research on hazardous pathogens—such as the Ebola virus and the bacteria that causes anthrax—and toxins that may pose a serious threat to humans, animals, or plants. These lapses raise concerns about whether federal oversight of these laboratories is effective. For example, in November 2016, the Department of Homeland Security discovered that a private laboratory had inadvertently sent a toxic form of ricin (a potentially lethal poison) to one of its training centers multiple times since 2011, potentially putting training participants at risk. In May 2015, the Department of Defense (DOD) discovered that a DOD laboratory had inadvertently shipped live anthrax bacteria to nearly 200 other laboratories worldwide over the course of 12 years. And in July 2014, the National Institutes of Health (NIH) discovered decades-old vials of smallpox in a storage room of a Food and Drug Administration laboratory on its campus.<sup>1</sup>

Laboratories that conduct research on pathogens fall into one of four biological safety levels (BSL), with those at BSL-3 and -4 referred to as

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<sup>1</sup>According to agency documents, none of these three incidents resulted in human infection, severe illness, or death.

high-containment laboratories for the purpose of this report.<sup>2</sup> We—along with Congress and various federal committees<sup>3</sup>—have, for many years, identified challenges and areas for improvement related to the safety, security, and oversight of high-containment laboratories. In 2008 and 2009, for example, we found a proliferation of high-containment laboratories across the United States, with the number of such laboratories in the government, academic, and private sectors increasing since 2001.<sup>4</sup> We also found that, for the subset of these laboratories subject to federal oversight, the oversight was duplicative, fragmented, and dependent on self-policing.<sup>5</sup> More recently, we found in 2016 that stronger oversight mechanisms for federal high-containment laboratories were needed at the individual federal department and component agency

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<sup>2</sup>Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular agents. BSL-3 laboratories work with indigenous or exotic agents with known potential for airborne transmission or pathogens that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic agents that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available. The designations of animal BSL-3 and -4 are used for laboratories that work with animals infected with indigenous or exotic agents. The term BSL-3 Agriculture is used to describe laboratories where studies are conducted on agents of high consequence to agriculture and that use large or loose-housed animals. For the purpose of this report, we are using the term “high-containment laboratories” to refer to all laboratories at designated safety levels 3 and 4, regardless of whether they are working on human, animal, or plant pathogens.

<sup>3</sup>See, for example, The White House, *Next Steps to Enhance Biosafety and Biosecurity in the United States* (Washington, D.C.: Oct. 29, 2015); *Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax*, Before the Subcomm. on Oversight and Investigations, H. Comm. on Energy and Commerce, 114th Cong. (2015); Federal Experts Security Advisory Panel, *Report of the Federal Experts Security Advisory Panel* (Washington, D.C.: December 2014); and White House, National Science and Technology Council, Committee on Homeland and National Security, Subcommittee on Biological Defense Research and Development, Fast Track Action Committee on the Select Agents Regulations, *Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement* (Washington, D.C.: October 2015).

<sup>4</sup>GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, [GAO-09-574](#) (Washington, D.C.: Sept. 21, 2009) and *High-Containment Biosafety Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, [GAO-08-108T](#) (Washington, D.C.: Oct. 4, 2007).

<sup>5</sup>GAO, *Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program*, [GAO-13-154](#) (Washington, D.C.: Jan. 31, 2014), [GAO-09-574](#), and [GAO-08-108T](#).

levels.<sup>6</sup> We have made numerous recommendations over the years, including that a single entity be identified to determine the number of high-containment laboratories needed to meet national goals, the aggregate risks associated with the proliferation of laboratories, and the type of oversight needed.<sup>7</sup> Federal departments have made some progress in implementing recommendations from our past reports, including addressing issues we identified regarding duplicative oversight.<sup>8</sup>

Certain hazardous pathogens and toxins that may be used in high-containment laboratories are designated as select agents because they have the potential to pose a severe threat to human, animal, or plant health and safety, or to animal or plant products.<sup>9</sup> Laboratories conduct research on select agents for a variety of reasons, including to identify their characteristics and develop vaccines and other measures to help diagnose, prevent, or treat exposure to or infection with these agents. Select agent research is subject to federal oversight and regulations, as well as guided by the principles and practices of biological safety and security. The Federal Select Agent Program (Select Agent Program) was established to regulate the possession, use, and transfer of select agents in response to security concerns following bioterrorism attacks in the 1990s and early 2000s. The Select Agent Program is jointly managed by the Division of Select Agents and Toxins within the Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) and the Agriculture Select Agent Services within the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). Together, these components within CDC and APHIS regulate and oversee all high-containment laboratories in the United

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<sup>6</sup>GAO, *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).

<sup>7</sup>[GAO-09-574](#).

<sup>8</sup>In addition, a 2015 White House memorandum contained recommendations that, if implemented, would have addressed our 2009 recommendation regarding identifying a single entity to determine the number of laboratories needed to effectively meet national goals to counter hazardous pathogens. The White House, *Next Steps to Enhance Biosafety and Biosecurity in the United States*.

<sup>9</sup>As of March 2017, 66 agents and toxins have been designated as “select agents and toxins”—that is, as needing specific types of safeguards and oversight. For the purpose of this report, we use the term “select agents” to encompass both designated agents and toxins.



States that register to work with select agents.<sup>10</sup> Such laboratories are required to follow both biological safety and security practices. According to the *Biosafety in Microbiological and Biomedical Laboratories* manual, biological safety practices are intended to reduce or eliminate exposure of individuals and the environment to potentially hazardous pathogens and biological security practices are intended to prevent the loss, theft, release, or misuse of hazardous pathogens and related information by limiting access to facilities and this information.<sup>11</sup>

Other countries also regulate and oversee hazardous pathogens handled in high-containment laboratories and may take different approaches to this oversight.<sup>12</sup> Moreover, other high-risk sectors in the United States, such as the nuclear industry, in some cases, take different approaches to oversight. In our past work reviewing some of these sectors, we have identified five key elements of effective oversight in areas where low-

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<sup>10</sup>Entities that register with the Select Agent Program may include a single laboratory or multiple laboratories under one registration. For the purpose of this report, we refer to all entities registered with the program as “laboratories.” Some BSL-2 laboratories are registered with the Select Agent Program but most are BSL-3 and -4 high-containment laboratories. For the purpose of this report, we focused on oversight of select agents in high-containment laboratories.

<sup>11</sup>The principles and practices of biological safety and security are outlined in the widely accepted leading guidance for laboratories, *Biosafety in Microbiological and Biomedical Laboratories*, which is also used by Select Agent Program inspectors to guide aspects of their inspections. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: December 2009). Certain laboratory research on pathogens is subject to additional NIH oversight. See Department of Health and Human Services, National Institutes of Health, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (Bethesda, Md.: April 2016). According to the Select Agent Program, the program uses the term “security” rather than “biological security.”

<sup>12</sup>For information on selected countries’ oversight approaches, see, for example, National Academy of Sciences and National Research Council, *Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories* (Washington, D.C.: National Academies Press, 2012) and University of Pittsburgh Medical Center, Center for Health Security, *National Biosafety Systems: Case Studies to Analyze Current Biosafety Approaches and Regulations for Brazil, China, India, Israel, Pakistan, Kenya, Russia, Singapore, the United Kingdom, and the United States* (Pittsburgh, Pa.: July 2016).

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probability adverse events can have significant and far-reaching effects.<sup>13</sup> These elements are as follows:

- **Independence:** The organization conducting oversight should be structurally distinct and separate from the entities it oversees.
- **Ability to perform reviews:** The organization should have the access and working knowledge necessary to review compliance with requirements.
- **Technical expertise:** The organization should have sufficient staff with the expertise to perform sound safety and security assessments.
- **Transparency:** The organization should provide access to key information, as applicable, to those most affected by operations.
- **Enforcement authority:** The organization should have clear and sufficient authority to require that entities achieve compliance with requirements.

In our past work, we have also found that requirements under the Government Performance and Results Act of 1993 (GPRA), as amended,<sup>14</sup> for strategic planning at the agency level can serve as leading practices at lower levels within federal agencies, such as for individual programs.<sup>15</sup> The act requires agencies to develop strategic plans that include documents and planning tools such as mission statements, strategic goals and objectives, and performance measures, which, according to our past work, can help inform agency decision making to address challenges.

You asked us to review the effectiveness of the current approach to overseeing select agents as well as approaches from other countries and

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<sup>13</sup>In particular, we have used these elements for reviews related to oversight of nuclear safety and oil and gas management. See GAO, *Nuclear Safety: Department of Energy Needs to Strengthen Its Independent Oversight of Nuclear Facilities and Operations*, [GAO-09-61](#) (Washington, D.C.: Oct. 23, 2008) and *Oil and Gas Management: Key Elements to Consider for Providing Assurance of Effective Independent Oversight*, [GAO-10-852T](#) (Washington, D.C.: June 17, 2010).

<sup>14</sup>Pub. L. No. 103-62, 107 Stat. 285 (Aug. 3, 1993), amended by GPRA Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866 (Jan. 4, 2011).

<sup>15</sup>GAO, *Homeland Security: Agriculture Inspection Program Has Made Some Improvements, but Management Challenges Persist*, [GAO-12-885](#) (Washington, D.C.: Sept. 27, 2012) and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, [GAO-12-77](#) (Washington, D.C.: Oct. 6, 2011).

regulatory sectors. This report (1) examines the extent to which the Select Agent Program has the elements of effective oversight and has strategic planning documents to guide its oversight efforts, and (2) describes approaches that selected countries and regulatory sectors have used to promote effective oversight.

To evaluate the extent to which the Select Agent Program has the elements of effective oversight, we first identified five key elements of effective oversight we have used in the past for assessing the effectiveness of oversight in other areas where low probability adverse events can have significant and far-reaching effects. We discussed these elements with agency officials, experts, and representatives from nongovernmental organizations to ensure their applicability to the oversight of select agents (see app. I for a description of these elements and our vetting process). We then reviewed relevant laws, select agent regulations, and joint documents from the Select Agent Program, such as program guidance, inspection checklists, memorandums of understanding guiding the program, reports on the program, information on enforcement actions, inspection data, and other documents to determine the extent to which the program performed activities or met requirements in the key elements. We took several steps to determine the reliability of the inspection data, including interviewing agency officials and comparing a subset of the data to information from other sources. We determined that the inspection data were sufficiently reliable for the purpose of this report.

We also reviewed documents from or related to the two components of the program, CDC and APHIS, such as workforce planning documents, agency policies, budget justifications, and internal program reviews. In addition, we contacted the HHS Office of Inspector General (OIG) and USDA Office of General Counsel to obtain their legal views on the departments' authority to impose civil money penalties on federal laboratories. We interviewed officials from CDC and APHIS—including senior agency leadership, senior Select Agent Program officials, and inspectors—to discuss the Select Agent Program's structure, inspections and other oversight responsibilities, technical expertise, and other issues related to the five elements of effective oversight. To gain additional perspectives on the Select Agent Program, we interviewed officials from DOD and the Department of Homeland Security as well as representatives from a nongeneralizable selection of 18 laboratories registered with the Select Agent Program. We selected these laboratories to represent a range of laboratories across various sectors (e.g., federal—including CDC and APHIS—academic, commercial, and state and local government), biological safety levels, and CDC or APHIS

component registration. The views of these representatives are not generalizable to all registered laboratories, but they provide illustrative examples.

To evaluate the extent to which the Select Agent Program has strategic planning documents to guide its oversight efforts, we reviewed relevant laws and our past work in this area. We also reviewed joint program documents and documents from the two components of the program, including mission statements, business plans, performance measures, and other related documents. In our interviews with program officials, we discussed the program's past and ongoing efforts related to strategic planning.

To obtain expert views on the effectiveness of the approaches the Select Agent Program and other selected countries and regulatory sectors have used to promote effective oversight, we worked with the National Academy of Sciences to convene a meeting with 18 experts with combined expertise in biological safety, biological security, microbiology, nuclear safety, worker safety, airline safety, food safety, risk management, organizational change management, and human factor assessments. The experts were evaluated for any conflicts of interest, such as any current or financial or other interest that might conflict with the service of an individual because it (1) could impair objectivity and (2) could create an unfair competitive advantage for any person or organization. The 18 experts were determined to be free of conflicts of interest, and the group as a whole was judged to have no inappropriate biases. (See app. II for a list of the experts that participated and a description of our expert selection methodology.) The 2-day meeting was composed of six sessions covering a range of topics, such as effectiveness of the Select Agent Program's oversight, lessons learned from other oversight approaches, and considerations for the program moving forward.

We also reviewed relevant documentation and interviewed officials from selected countries and sectors about their oversight approaches. To select countries, we first identified developed countries with high-containment laboratory oversight models based on past reports and recommendations from experts and nongovernmental organizations. We then narrowed our list of countries to those with networks of high-containment laboratories comparable to that of the United States (i.e., with multiple BSL-3 and -4 laboratories across a range of sectors that handle hazardous pathogens similar to select agents) and with key differences in their oversight models compared with that of the United

States. Because of the resources needed to conduct site visits, we selected two countries from that list to visit, the United Kingdom (UK) and Canada. In addition, we interviewed officials from four additional countries—France, Germany, Switzerland, and the Netherlands—to learn about their oversight approaches. We conducted these interviews at a meeting of the European subgroup of the International Expert Group on Biosafety and Biosecurity Regulation in Switzerland. To learn more about other regulatory sectors' oversight approaches, we reviewed documents and interviewed officials from the Nuclear Regulatory Commission (NRC) and Department of Labor's Occupational Safety and Health Administration and collected information from the Department of Transportation's Federal Aviation Administration.

We compared information from federal documents about the Select Agent Program's oversight and strategic planning efforts, interviews with laboratory representatives and agency officials, and our expert meeting against the five elements of effective oversight,<sup>16</sup> federal internal control standards, requirements from the Office of Management and Budget (OMB), and our past work. We also reviewed the Select Agent Program's responses and actions related to recent federal reviews of the program, including CDC and APHIS internal reviews,<sup>17</sup> reviews from the HHS and USDA OIGs,<sup>18</sup> and reports from other federal committees.<sup>19</sup>

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<sup>16</sup>We conducted a qualitative, rather than quantitative, assessment of the extent to which the Select Agent Program met the five elements of effective oversight.

<sup>17</sup>Centers for Disease Control and Prevention, *90 Day Internal Review of the Division of Select Agents and Toxins* (Atlanta, Ga.: Oct. 22, 2015) and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development, Program Assessment and Accountability, *Agriculture Select Agent Services Management Review*, PAA-15-05 (Washington, D.C.: April 2016).

<sup>18</sup>Department of Health and Human Services, Office of Inspector General, *CDC Generally Met Its Inspection Goals for the Federal Select Agent Program; However, Opportunities Exist to Strengthen Oversight*, OEI-04-15-00430 (Washington, D.C.: May 2017) and U.S. Department of Agriculture, Office of Inspector General, *Follow Up on APHIS' Implementation of the Select Agent or Toxin Regulations*, Audit Report 33701-0001-AT (Washington, D.C.: Nov. 6, 2012).

<sup>19</sup>See, for example, Federal Experts Security Advisory Panel, *Report of the Federal Experts Security Advisory Panel*, National Science Advisory Board for Biosecurity, *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility: A Report of the National Science Advisory Board for Biosecurity* (Washington, D.C.: September 2011), and White House, National Science and Technology Council, *Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement*.

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We conducted this performance audit from July 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.

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## Background

This section provides information on select agent regulations and program roles, responsibilities, and requirements; and the history of the Select Agent Program.

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### Select Agent Regulations and Program Roles, Responsibilities, and Requirements

The Select Agent Program is fragmented because oversight responsibility is, by law, split between CDC and APHIS.<sup>20</sup> The two agencies have delineated roles and responsibilities to regulate laboratories—including conducting inspections and other activities—that possess, use, or transfer biological select agents.<sup>21</sup> CDC's Division of Select Agents and Toxins is responsible for the oversight and regulation of select agents that could pose a threat to public health and safety, such as the Ebola virus. APHIS's Agriculture Select Agent Services is responsible for the oversight and regulation of select agents that could pose a threat to animal or plant health or animal or plant products, such as the virus that causes foot-and-mouth disease. Some select agents, such as *Bacillus anthracis* (the bacterium that causes anthrax), are regulated by both agencies because they pose a threat to both human and animal health; these agents are known as overlap agents. As part of their oversight, CDC and APHIS

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<sup>20</sup>According to our past work, fragmentation refers to those circumstances in which more than one federal agency (or more than one organization within an agency) is involved in the same broad area of national need and opportunities exist to improve service delivery. GAO, *2017 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, [GAO-17-491SP](#) (Washington, D.C.: Apr. 26, 2017).

<sup>21</sup>CDC and APHIS were delegated authority by their respective department secretaries to regulate the use, possession, and transfer of select agents.

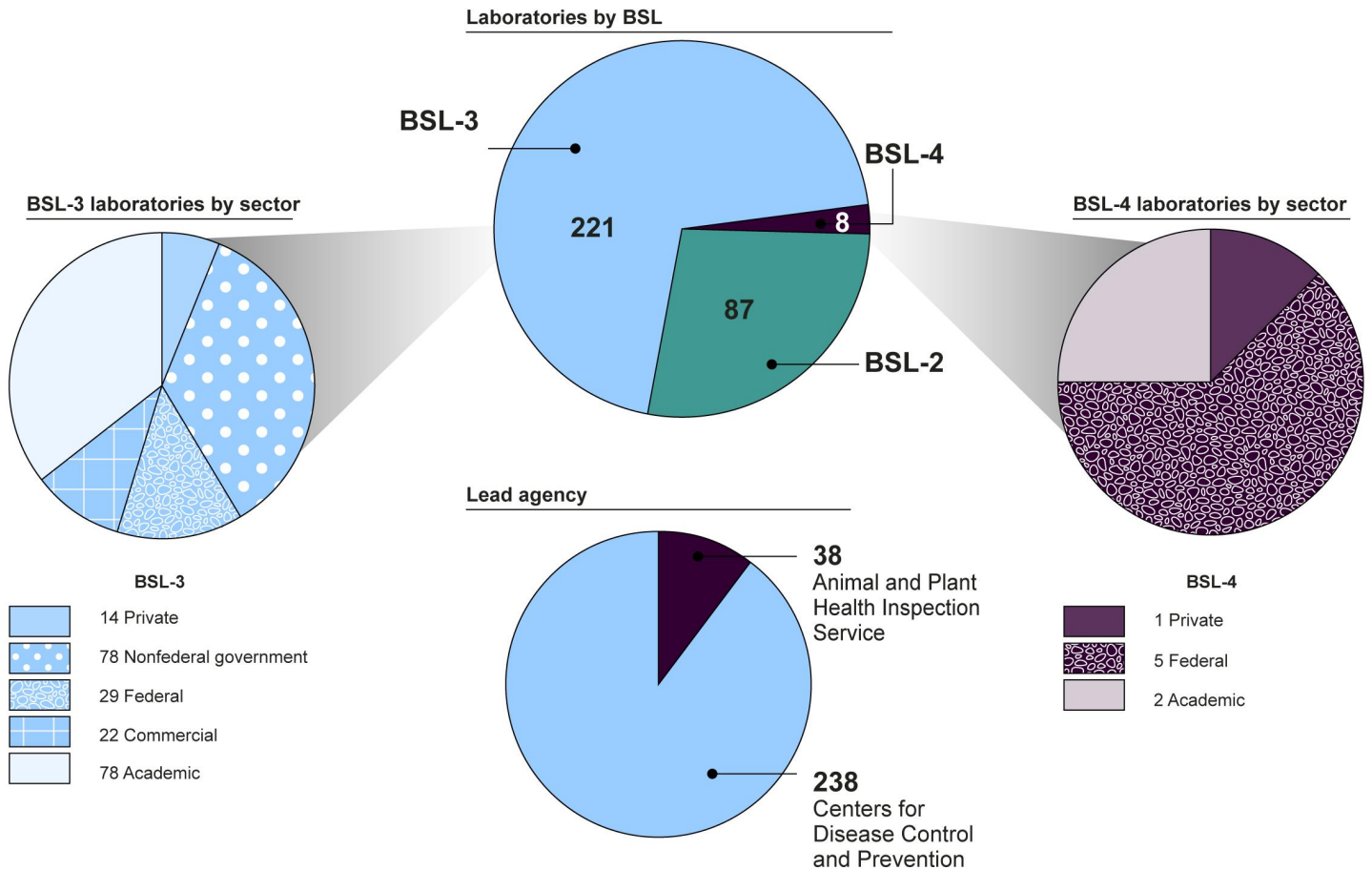
maintain a list of select agents that they are required to review and republish at least every 2 years.<sup>22</sup>

Generally, laboratories (including those at federal agencies and private institutions) and individuals who possess, use, or transfer these select agents must register with CDC or APHIS and renew their registration every 3 years. Most laboratories registered with the Select Agent Program are registered with CDC (238 of 276). (See fig. 1 for information about the laboratories registered with the program.) In fiscal year 2016, CDC's budget to manage its component of the Select Agent Program was about \$21 million and APHIS's was about \$5.5 million.

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<sup>22</sup>In determining whether to include an agent on the HHS select agent list, the HHS Secretary must consider the following criteria: (1) the effect on human health of exposure to the agent or toxin; (2) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans; (3) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and (4) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate. In determining whether to include an agent or toxin on the USDA list, the USDA Secretary must consider the following criteria: (1) the effect of exposure to the agent or toxin on animal and plant health, and on the production and marketability of animal and plant products; (2) the pathogenicity of the agent or toxin and the methods by which the agent or toxin is transferred to animals or plants; (3) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and (4) any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products. Each component of the Select Agent Program has an interagency select agents and toxins technical advisory committee that assists the agencies in their review of the select agent list.

**Figure 1: Laboratories Registered with the Federal Select Agent Program by Biological Safety Level (BSL), Sector, and Lead Agency as of December 2016**



Source: GAO analysis of information from the Federal Select Agent Program. | GAO-18-145

Note: Entities that register with the Federal Select Agent Program may include a single laboratory or multiple laboratories under one registration. For the purpose of this report, we refer to all entities registered with the program as “laboratories.” Because some registered laboratories have multiple facilities at different BSLs, the total number of laboratories by BSL is greater than the total number of registered laboratories. The number of laboratories registered with the program may change over time as new laboratories register and others leave the program.

Select agent regulations govern the possession, use, and transfer of designated select agents.<sup>23</sup> To apply for a certificate of registration, the laboratory must submit an application package to either CDC or APHIS, and laboratory personnel must submit to a security risk assessment

<sup>23</sup>7 C.F.R. Part 331 (APHIS-plant), 9 C.F.R. Part 121 (APHIS-animal), and 42 C.F.R. Part 73 (CDC).



conducted by the Federal Bureau of Investigation (FBI).<sup>24</sup> The Select Agent Program conducts an on-site inspection before issuing a new certificate of registration or renewing an existing registration; both are valid for a maximum of 3 years. Once approved, a laboratory's certification of registration may be amended to reflect changes in circumstances, such as replacement of the responsible official or other personnel changes, changes in ownership or control of the laboratory, changes in the activities involving any select agents, or the addition or removal of any select agents.<sup>25</sup> As a condition of registration, the select agent regulations require each laboratory to designate an individual to be its responsible official, who is responsible for ensuring compliance with the regulations. In addition, the regulations require laboratories to develop various written plans, as well as provide training and maintain records of training and other activities. For example, the regulations require that laboratories registered with the program develop and implement a written security plan sufficient to safeguard each select agent against unauthorized access, theft, loss, or release; develop and implement a written biological safety plan that is commensurate with the risk of the select agent, given its intended use; provide training on biological safety and security for individuals with access to select agents; and maintain records on the activities covered by the select agent regulations.

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## History of the Select Agent Program

Several historical security incidents involving hazardous pathogens resulted in a series of laws and other regulatory activity that served to establish and amend the Select Agent Program. First, Congress passed section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 after an individual in the United States unlawfully obtained *Yersinia pestis*, the bacterium that causes plague, by mail order. Section 511 directed the Secretary of HHS to promulgate regulations identifying a list of biological agents that have the potential to pose a severe threat to public health and safety, providing procedures governing the transfer of those agents, and establishing safeguards to prevent unauthorized access to those agents

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<sup>24</sup>Laboratories seeking to conduct research with human health agents should submit registration applications to CDC, and laboratories seeking to conduct research with plant or animal agents should submit their applications to APHIS. Laboratories seeking to conduct research with overlap agents may submit their applications to either CDC or APHIS.

<sup>25</sup>Prior to any change, the responsible official must apply for an amendment to the certificate of registration.

for purposes of terrorism or other criminal activities.<sup>26</sup> The HHS Secretary delegated the authority to regulate select agents to CDC, thus establishing the Select Agent Program in its initial form. In carrying out this authority, CDC required laboratories transferring select agents to be registered with the program.

After the terrorist events of September 11, 2001, and the subsequent anthrax attacks in October 2001, Congress passed the USA PATRIOT Act of 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.<sup>27</sup> These acts significantly expanded the Select Agent Program by restricting access to select agents and increasing safeguards and security measures for select agents.<sup>28</sup> The 2002 act also expanded the program to include not only the regulation of the transfer but also the use and possession of select agents, and it granted comparable authority to USDA for select agents that pose a threat to animal or plant health, or animal or plant products. The Secretary of Agriculture delegated the authority to regulate select agents that affect animal or plant health to APHIS. The act also required HHS and USDA to coordinate on overlap agents and required the Secretaries of both departments to establish, maintain, and biennially review and republish the select agent list, making revisions as appropriate to protect the public.

On July 2, 2010, the President signed Executive Order 13546, “Optimizing the Security of Biological Select Agents and Toxins in the United States.” The executive order directed HHS and USDA, as a part of their ongoing review, to tier the select agents on the list, consider shortening the list, and establish physical security standards for select agents with the highest risk of misuse; HHS and USDA did so in final

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<sup>26</sup>Pub. L. No. 104-132, 110 Stat. 1214, 1284-85 (Apr. 24, 1996). To implement section 511, HHS promulgated regulations governing the transfer of select agents. 61 Fed. Reg. 55,190 (Oct. 24, 1996). Codified at part 72 of title 42 of the Code of Federal Regulations. HHS removed these regulations in 2008 to eliminate duplication with Department of Transportation regulation of hazardous materials. See 73 Fed. Reg. 3873 (Jan. 23, 2008).

<sup>27</sup>Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Pub. L. No. 107-56, § 817, 115 Stat. 272, 385-86 (Oct. 26, 2001) and Pub. L. No. 107-188, title II, 116 Stat. 594 (June 12, 2002).

<sup>28</sup>For additional detail on the provisions of these acts, see [GAO-09-574](#).

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rules published October 5, 2012.<sup>29</sup> About half of the laboratories registered with the program as of December 2016 were registered to work with tier 1 agents (142 of 276).

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## Select Agent Program Does Not Fully Meet Key Elements of Effective Oversight or Have Joint Strategic Planning Documents to Guide Its Efforts

The Select Agent Program does not fully meet key elements of effective oversight. In particular, the program has oversight shortcomings related to each of the five key elements: independence, performing reviews, technical expertise, transparency, and enforcement. In addition, the program does not have joint strategic planning documents to guide its oversight efforts, such as a joint strategic plan and workforce plan; it did, however, begin taking steps to develop a joint strategic plan over the course of our review.

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## Select Agent Program Does Not Fully Meet Oversight Elements Related to Independence, Performing Reviews, Technical Expertise, Transparency, and Enforcement

The Select Agent Program does not fully meet our key elements of effective oversight. Specifically, the program is not independent from all laboratories it oversees, and it has not formally assessed the potential risks posed by its current organizational structure. In addition, the program regularly performs reviews of laboratories' compliance with regulatory and program requirements, but these reviews may not target the activities that pose the highest risk to biological safety and security. Moreover, even though the program has taken steps to hire additional staff and enhance the technical expertise of its staff, workforce and training gaps remain. The program has increased transparency since

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<sup>29</sup>77 Fed. Reg. 61,084 (HHS) and 77 Fed. Reg. 61,056 (USDA) (Oct. 5, 2012). In their final rules, HHS and USDA designated a subset of select agents—including agents on HHS's and USDA's lists as well as overlap agents—as “tier 1,” which reflects agents that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence. Of the 66 select agents as of March 2017, 13 are designated as tier 1 agents.

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2016, but the information it shares is limited and there is no consensus about what additional information could be shared, given security concerns. Lastly, the Select Agent Program has authority to enforce compliance with program requirements, but is still working to address past concerns about the need for greater consistency and clarity in actions it takes in exercising this authority.

**Independence**

The organization conducting oversight should be structurally distinct and separate from the entities it oversees.

Source: GAO. | GAO-18-145

**Program Is Not Independent and Has Not Formally Assessed All Risks Posed by Its Current Structure**

According to our key elements of effective oversight, to be independent, the organization conducting oversight should be structurally distinct and separate from the entities it oversees. The Select Agent Program is not structurally distinct and separate from all of the laboratories it oversees but has taken some steps to reduce conflicts of interest potentially posed by its current structure within CDC and APHIS. The two components of the Select Agent Program are located in CDC and APHIS, both of which also have high-containment laboratories registered with the program. Many experts at our meeting raised concerns that the Select Agent Program cannot be entirely independent in its oversight of CDC and APHIS laboratories because the Select Agent Program is composed of divisions of those agencies. In particular, one expert stated that to be independent, the agencies cannot regulate themselves, and others said that the agencies' oversight of their own laboratories may present a conflict of interest. However, laboratories owned by CDC and APHIS are not generally located within the same agency divisions and thus are not in the same chain of command as the Select Agent Program. The one exception is an APHIS-owned complex of laboratories in the same division as the APHIS component of the program, but that complex is registered with CDC, which means that CDC leads its inspections and oversight.<sup>30</sup>

Senior program officials, many laboratory representatives, and some experts cited a number of benefits to the Select Agent Program's current structure within CDC and APHIS, including the ability for inspectors to have access to experts and other support from their respective divisions. For example, program officials said that the Select Agent Program had reached out to CDC scientists for assistance in developing guidance

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<sup>30</sup>APHIS has other laboratories registered with the Select Agent Program, but they are not in the same agency division as the APHIS component of the program.

documents for the program. In addition, inspectors sometimes obtain technical assistance from experts in CDC and APHIS, such as in cases where the inspectors are not familiar with certain techniques or equipment being used in a registered laboratory. However, program officials also said that they have tried to limit the extent that they rely on CDC and APHIS scientists from outside the program, so as not to raise concerns about conflicts of interest. Senior program officials from CDC and APHIS also said that the Select Agent Program's current locations within the two agencies allow for access to additional support as needed, including additional funds and administrative services. Senior program officials from CDC further stated that being located in an office focused on preparedness and response is advantageous because the Select Agent Program can quickly pivot into incident response mode, allowing for rapid response and assessment of incidents that occur in registered laboratories. They noted that this location proved advantageous during an incident in 2015, for example, when the program responded to the discovery that a DOD laboratory had inadvertently sent live *Bacillus anthracis*, the bacterium that causes anthrax, to nearly 200 laboratories.

The location of the program has also raised some concerns in the past, which the Select Agent Program has taken some steps to address. In response to past concerns about conflicts of interest and separation of duties raised by HHS OIG, APHIS, and us, both CDC and APHIS made structural changes to increase the Select Agent Program's independence within their respective agencies.<sup>31</sup> In particular, in 2003, in response to concerns from HHS OIG and us, CDC moved its component of the Select Agent Program into the agency's Office of Public Health Preparedness and Response because that office did not have any laboratories registered with the program.<sup>32</sup> (See fig. 2 for HHS's organizational chart, including a depiction of where CDC's Select Agent Program component currently sits in relation to other agency divisions.) According to CDC

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<sup>31</sup>GAO, *Homeland Security: CDC's Oversight of the Select Agent Program*, [GAO-03-315R](#) (Washington, D.C.: Nov. 22, 2002).

<sup>32</sup>In 2003, at the time of the reorganization, CDC's Division of Select Agents and Toxins was moved to the Coordinating Office for Terrorism Preparedness and Response, which is now the Office of Public Health Preparedness and Response.

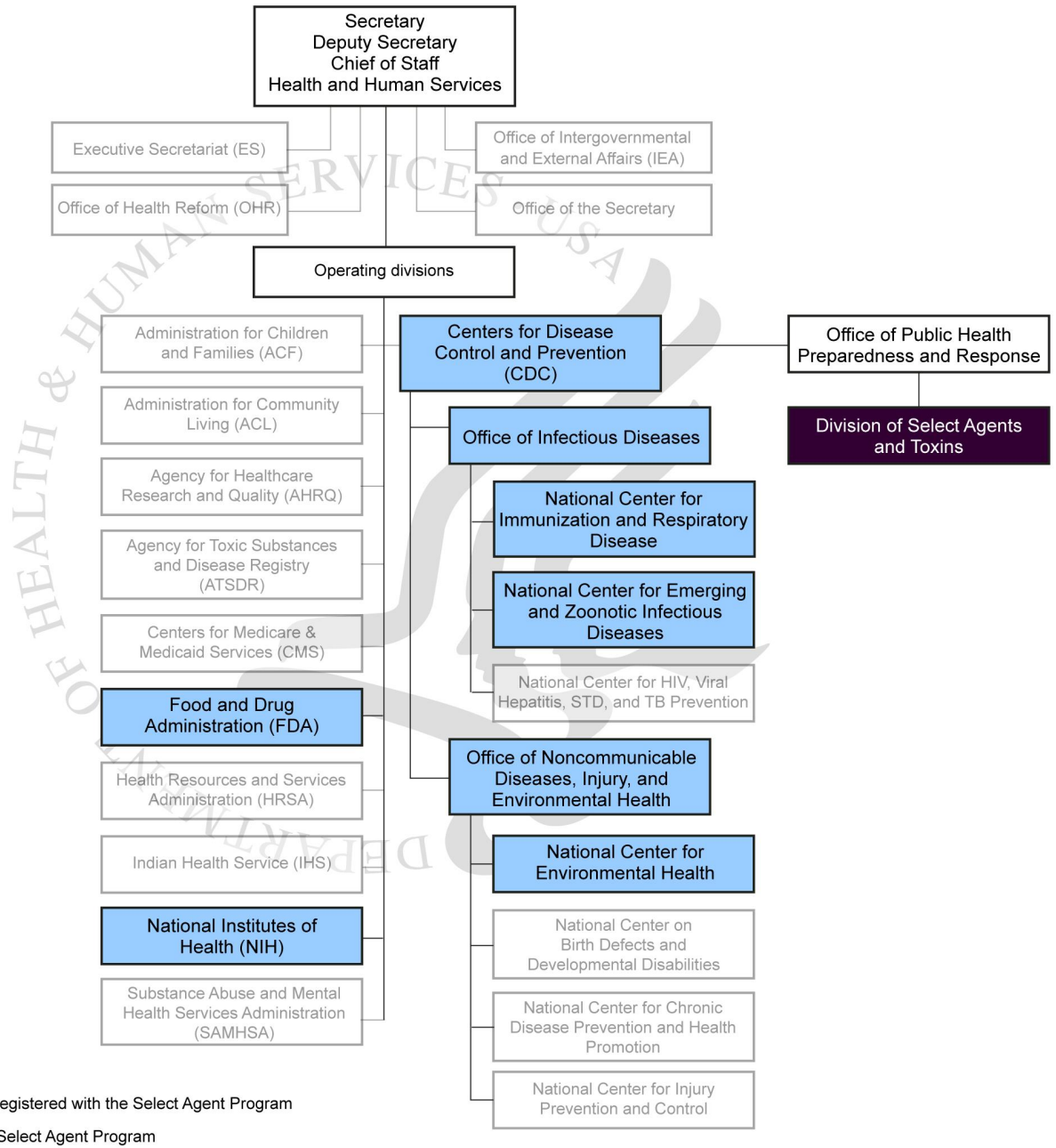
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officials, the director of the CDC component of the Select Agent Program has access to senior leadership at CDC as needed.<sup>33</sup>

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<sup>33</sup>As shown in fig. 2, the director of the CDC component of the Select Agent Program reports to the director of the Office of Public Health Preparedness and Response who reports to the CDC director.

**Figure 2: Location of the Division of Select Agents and Toxins and Laboratories Registered with the Federal Select Agent Program (Select Agent Program) within the Department of Health and Human Services**



Source: GAO analysis of information from the Department of Health and Human Services. | GAO-18-145

Similarly, since 2013, APHIS has also made some organizational changes, including realigning supervisory responsibilities for the program

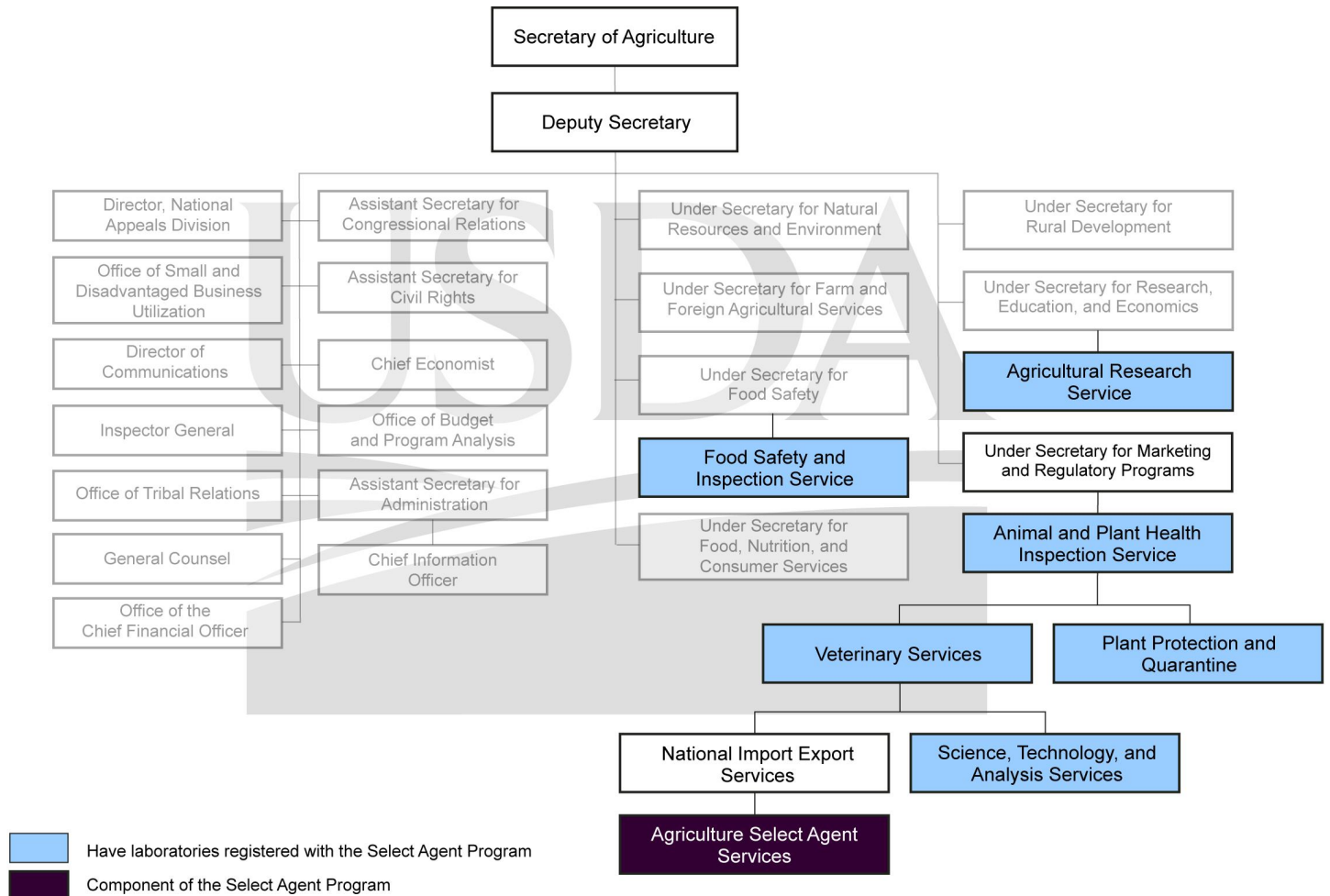
and creating a direct line of communication from the director of the APHIS component of the Select Agent Program to the APHIS administrator. Previously, the program reported to a director whose division had a suite of laboratories that the program inspects. Now it is managed through APHIS's National Import Export Services, which has different senior-level managers that report directly to the Office of the Administrator rather than the managers who oversee registered laboratories. According to agency officials, these changes increased the level of independence between the Select Agent Program and APHIS-owned laboratories but did not fully address the appearance of a lack of independence within APHIS, since the agency's organizational chart still places the APHIS component of the Select Agent Program under Veterinary Services. (See fig. 3 for USDA's organizational chart, including a depiction of where APHIS's Select Agent Program component currently sits in relation to other agency divisions). The APHIS director of the Select Agent Program and the Associate Administrator of APHIS meet regularly to discuss incidents involving select agents, enforcement actions, and operation of the Select Agent Program, among other issues, according to agency officials, but this reporting structure is not documented. According to federal standards for internal control, management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives and should develop and maintain documentation of its internal control system.<sup>34</sup> Until APHIS formally documents the reporting structure for its component of the Select Agent Program from the APHIS director of the program to the administrator of APHIS, it will continue to appear to have conflicts of interest in its oversight of APHIS-owned laboratories.

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<sup>34</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999), and *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014). [GAO/AIMD-00-21.3.1](#) was effective through the end of fiscal year 2015 (Sept. 30, 2015). [GAO-14-704G](#) is the 2014 revision of [GAO/AIMD-00-21.3.1](#) and became effective the first day of fiscal year 2016 (Oct. 1, 2015).



**Figure 3: Location of the Agriculture Select Agent Services and Laboratories Registered with the Federal Select Agent Program (Select Agent Program) within the U.S. Department of Agriculture**



Source: GAO analysis of information from the U.S. Department of Agriculture. | GAO-18-145

In addition to these structural changes, the program has put mechanisms in place to reduce organizational conflicts of interest, but the agencies do not always follow a key mechanism. In particular, CDC and APHIS signed a memorandum of understanding in 2012 that stated that APHIS would provide the lead inspector for all inspections of registered laboratories owned by CDC. However, in practice, CDC inspectors still participate in inspection activities because of their expertise in human agents.<sup>35</sup> In

<sup>35</sup>APHIS inspectors may also participate in inspections of USDA- and APHIS-owned laboratories because of their expertise in animal and plant agents.

March 2015, the memorandum was amended to state that CDC would lead inspections of all USDA-owned laboratories.<sup>36</sup>

However, since the memorandum was amended, the APHIS component of the Select Agent Program has led at least three inspections of USDA-owned or operated laboratories. In particular, APHIS led an inspection of a laboratory owned by another USDA agency, the Agricultural Research Service, in November 2015; one run by the Agricultural Research Service and APHIS scientists in May 2015; and one owned by APHIS in December 2015. APHIS officials we interviewed said that they had overlooked this amendment to the memorandum of understanding and the program does not have a process in place to help ensure the memorandum is followed. According to federal standards for internal control, management should design control activities to achieve objectives and respond to risk.<sup>37</sup> Such internal control activities help ensure that management directives such as those outlined in the memorandum of understanding are carried out, and should be effective and efficient in accomplishing the program's control objectives. One example of a control activity would be establishing a process to ensure APHIS and CDC comply with the memorandum to help ensure APHIS does not inspect its own laboratories. Without establishing control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding, the Select Agent Program cannot have reasonable assurance that its key mechanism to reduce conflicts of interest is implemented.

Although the Select Agent Program has taken steps to help reduce conflicts of interest, it has generally done so in response to concerns raised by others. The program itself has not formally assessed all potential risks posed by its current structure and the effectiveness of its mechanisms to address those risks. For example, the program did not identify all of the areas noted above that may present conflicts of interest and has not considered whether there may be additional areas of

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<sup>36</sup>The amended memorandum of understanding did not expand APHIS's responsibilities to lead inspections of all HHS-owned laboratories because, according to CDC officials, there is no perceived conflict of interest regarding CDC leading inspections of HHS laboratories outside of CDC. According to CDC officials, as of July 2017, the Select Agent Program is planning to update the memorandum of understanding to state that CDC will lead inspections of APHIS-owned laboratories but not all USDA-owned laboratories.

<sup>37</sup>[GAO/AIMD-00-21.3.1](#) and [GAO-14-704G](#).

concern. An expert in our meeting identified benefits of an independent, third-party review of the Select Agent Program. For example, we and other audit organizations are subject to an external peer review at least once every 3 years that includes a review of documentation related to independence, among other issues.<sup>38</sup> According to senior program officials we interviewed, the program as a whole has not engaged in comprehensive risk management activities but they would be willing to do so in the future.<sup>39</sup>

OMB's Circular A-123 requires federal agencies to integrate risk management activities into their program management to help ensure they are effectively managing risks that could affect the achievement of agency objectives.<sup>40</sup> According to the circular, once initial risks are identified, it is important for agencies to regularly re-examine risks to identify new risks or changes to existing risks. In addition, federal internal control standards state that management should identify, analyze, and respond to risks related to achieving defined objectives.<sup>41</sup> Without (1) regularly assessing the potential risks posed by the program's current structure and the effectiveness of its mechanisms to address them, such as by commissioning external reviews, and (2) taking actions as necessary to ensure any identified risks are addressed, the program may not be aware of or effectively mitigate impairments to its independence that could affect its ability to achieve its objectives.

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<sup>38</sup>GAO, *Government Auditing Standards, 2011 Revision*, [GAO-12-331G](#) (Washington, D.C.: December 2011).

<sup>39</sup>According to CDC officials, while the Select Agent Program has not engaged in comprehensive risk management activities, CDC has done such an assessment as part of its agency-wide risk management activities and has not identified structural independence as a key concern for the CDC component of the program.

<sup>40</sup>Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*.

<sup>41</sup>[GAO/AIMD-00-21.3.1](#) and [GAO-14-704G](#).

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## Reviews May Not Target the Highest-Risk Activities

### Ability to perform reviews

The organization should have the access and working knowledge necessary to review compliance with requirements.

Source: GAO. | GAO-18-145

According to our key elements of effective oversight, the organization conducting oversight should have the ability to perform reviews, including access to facilities and working knowledge necessary to review compliance with requirements. The Select Agent Program performs several types of reviews to ensure compliance with regulatory and program requirements, including registration inspections for laboratories seeking certification to use select agents, renewal inspections for laboratories seeking to renew their registration, and verification inspections. (See fig. 4 for additional information on these inspections). The program has the ability to access any registered laboratory for inspection, including without prior notification.<sup>42</sup> Inspections typically include review of registration and other documents—such as biological safety and security plans and inventory and personnel training records—as well as physical inspections of laboratory workspace and interviews with laboratory representatives, among other inspection activities. During inspections, Select Agent Program inspectors go through checklists that are based on the select agent regulations, the *Biosafety in Microbiological and Biomedical Laboratories* manual,<sup>43</sup> and guidelines from NIH.<sup>44</sup> The inspections cover a variety of topics—such as facility design and operation, incident response, security, training, records management, and biological safety—and may last anywhere from 1 day with 1 or 2 inspectors for simpler laboratories, to a couple of weeks with up to 10 inspectors for larger and more complex laboratories. Most laboratory representatives we spoke with said that the inspectors generally had the working knowledge necessary to review compliance and that the inspections and resulting reports were in-depth and generally fair and accurate.

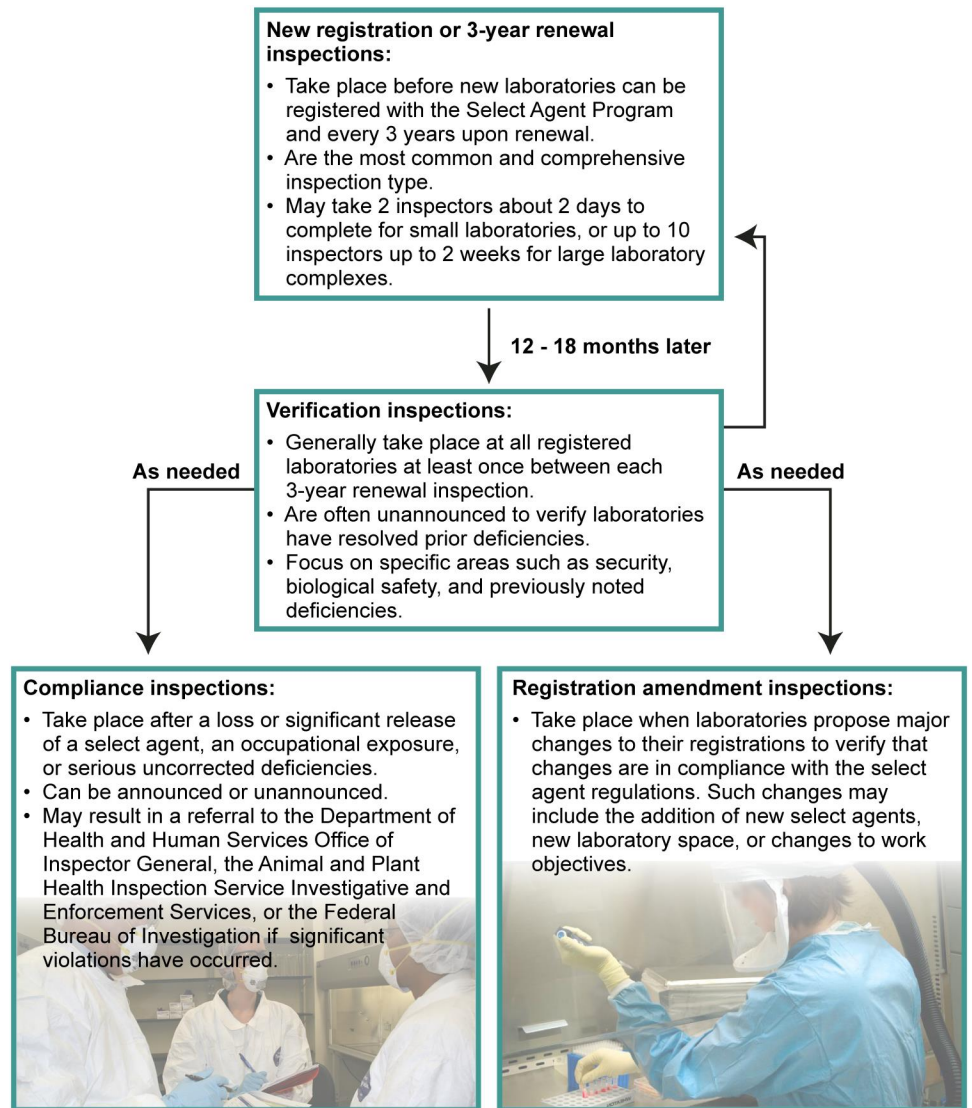
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<sup>42</sup>42 C.F.R. § 73.18(a) (CDC); 7 C.F.R. § 331.18(a) (APHIS-plants); 9 C.F.R. § 121.18(a) (APHIS-animals).

<sup>43</sup>Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*.

<sup>44</sup>Department of Health and Human Services, National Institutes of Health, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

**Figure 4: Types of Federal Select Agent Program (Select Agent Program) Inspections**



Source: GAO analysis of Centers for Disease Control and Prevention and Animal and Plant Health Inspection Service documents and officials. | GAO-18-145

Note: The Select Agent Program aims to conduct annual inspections of those registered laboratories at the highest biological safety level (BSL), BSL-4. Select Agent Program officials noted that they decided in February 2017 to conduct all verification inspections as unannounced inspections.

However, the program may not target the highest-risk activities in its inspections, in part because it has not formally assessed which activities

pose the highest risk to biological safety and security.<sup>45</sup> According to Select Agent Program officials, the program's policy is to conduct at least one verification inspection of all registered laboratories—regardless of their past history or performance—between each 3-year renewal inspection, and the program may consider additional inspections at laboratories that pose a higher risk. Specifically, the program scores laboratories' risk based on a number of factors, such as past inspection findings. However, a 2017 HHS OIG report found that the CDC component of the Select Agent Program had evaluated some, but not all, variables that could inform the risk a laboratory poses to health and safety and concluded that CDC may wish to enhance its risk assessment by considering additional factors, such as whether a laboratory has previously reported losses or releases of a select agent, to better inform a laboratory's level of risk over time.<sup>46</sup> In addition, some experts at our meeting and laboratory representatives we interviewed raised concerns that the program's inspections do not target resources to the highest-risk activities. For example, some experts said that the program has historically not put enough emphasis on verifying that certain laboratory procedures are safe and effective, which some said may have contributed to high-profile incidents in 2014 and 2015 in which select agents were inadvertently released from high-containment laboratories.<sup>47</sup> However, according to the Select Agent Program, the program does not validate or verify laboratory procedures as it is the responsibility of the laboratories themselves to do so. Further, many experts at our meeting and laboratory representatives we interviewed raised concerns about the amount of time inspectors spend assessing compliance with inventory controls (e.g., by counting and examining vials containing select agents) and reviewing inventory records during the inspection process, which takes time away

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<sup>45</sup>We found in our past work that, according to experts and CDC officials, there is a baseline risk associated with any high-containment laboratory and that the risks from accidental exposure or release can never be completely eliminated. GAO, *High-Containment Laboratories: Recent Incidents of Biosafety Lapses*, [GAO-14-785T](#) (Washington, D.C.: July 16, 2014).

<sup>46</sup>Department of Health and Human Services, Office of Inspector General, *CDC Generally Met Its Inspection Goals for the Federal Select Agent Program; However, Opportunities Exist to Strengthen Oversight*. The OIG report did not include any recommendations to CDC.

<sup>47</sup>For more information on some of these incidents, including the 2015 DOD incident, see GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, [GAO-16-642](#) (Washington, D.C.: Aug. 30, 2016). The revised select agent regulations, issued in January 2017, include new requirements on the validation of inactivation procedures.

from inspecting other aspects of biological safety and security. Experts at our meeting said that these activities do little to reduce the risk of theft of select agents because samples could be clandestinely removed from vials and replicated without being detected by the inventory controls currently in place. Finally, other laboratory representatives told us that activities to assess compliance with certain program requirements did little to reduce risk and were unnecessarily burdensome, such as time-consuming reviews of records so that nicknames such as “Rob” match up to registered names, such as “Robert.” These inspection activities are generally intended to address biological security concerns, such as theft; however, recent high-profile incidents at registered laboratories have been related to biological safety rather than security, and no thefts have been reported since 2003, when notification requirements were first implemented, according to program officials and documents.

Experts at our meeting generally agreed that the Select Agent Program has historically put more focus on security than on biological safety in its reviews, given that the program was established in response to terrorist incidents. For example, some experts said that the program has not focused enough on ensuring the health and safety of researchers and reducing the potential for their exposure to select agents, which some noted are more likely to occur than thefts due to security issues. Many experts questioned if the focus on security continues to be appropriate, in light of recent biological safety incidents. According to senior APHIS officials we interviewed, the Select Agent Program has been mandated to focus on security and if they move the program’s focus too far from security to biological safety, they may lose the goals established when the program was formed. They also noted that, according to the select agent regulations, laboratories are responsible for developing and implementing a written biological safety plan,<sup>48</sup> and therefore a balance should be maintained between the laboratories’ execution of these plans and the level of oversight from the Select Agent Program.<sup>49</sup> In addition, these officials stated that, during inspections, it is much easier for inspectors to ensure laboratories are meeting security requirements than carrying out their biological safety plans. For example, inspectors can easily check to make sure laboratories have required security barriers in place, such as

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<sup>48</sup>42 C.F.R. § 73.12 (CDC); 7 C.F.R. § 331.12 (APHIS-plants; called a biocontainment plan); 9 C.F.R. § 121.12 (APHIS-animals).

<sup>49</sup>Some experts at our meeting also noted the importance of laboratory leadership instilling a strong safety culture in their laboratories, which they noted may go beyond ensuring compliance with the select agent regulations.

locks on doors, but it is harder to measure whether laboratories are carrying out laboratory procedures safely. They also noted that the program does not want to be prescriptive with respect to biological safety so that laboratories can implement those biological safety practices that are most appropriate for their facility.

A 2015 internal review of the CDC component of the Select Agent Program acknowledged uncertainties and gaps in understanding how best to balance laboratories' ability to conduct critical research using select agents with the program's need to ensure the safety and security of the public and laboratory workers.<sup>50</sup> The resulting report recommended that the CDC and APHIS components of the program work together to analyze inspection and investigation data to identify trends and associations between inspection findings and risk and to improve the inspection process. According to program officials we interviewed, the Select Agent Program has not yet addressed the recommendation because the program does not currently have adequate tools to do so. They noted that the program is transitioning to a new database that will enhance their ability to analyze program data to identify such trends and associations and thereby guide improvements to the inspection process.<sup>51</sup> However, the program did not provide a plan for when or how the program will carry out these analyses or use the information to improve the inspection process. Federal internal control standards state that management should identify, analyze, and respond to risks related to achieving defined objectives.<sup>52</sup> In addition, the Project Management Institute's Standard for Program Management calls for program scheduling planning as a leading practice to ensure organizational activities are completed.<sup>53</sup> Without developing and implementing a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and

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<sup>50</sup>Centers for Disease Control and Prevention, *90 Day Internal Review of the Division of Select Agents and Toxins*.

<sup>51</sup>According to program officials, the new database will replace the program's National Select Agent Registry and will include information on registered laboratories, inspections, and other information.

<sup>52</sup>[GAO/AIMD-00-21.3.1](#) and [GAO-14-704G](#).

<sup>53</sup>See Project Management Institute, *The Standard for Program Management*, 3<sup>rd</sup> ed. (Newtown Square, Pa.: 2013). The Project Management Institute is a not-for-profit association that provides global standards for, among other things, project and program management. These standards are used worldwide and provide guidance on how to manage various aspects of projects, programs, and portfolios.



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other oversight efforts to target those activities, the Select Agent Program will not have assurance that it is effectively balancing the potential safety and security gains from its oversight efforts against the use of program resources and the effect on laboratories' research.

Select Agent Program Has Taken Steps to Hire Additional Expert Staff and Improve Technical Expertise, but Gaps in Workforce and Training Remain

According to our key elements of effective oversight, the organization conducting oversight should have sufficient staff with the expertise to perform sound safety and security assessments. CDC and APHIS have hired additional staff for the program and improved training to enhance expertise, but workforce and training gaps remain.

**Technical expertise**

The organization should have sufficient staff with the expertise to perform sound safety and security assessments.

Source: GAO. | GAO-18-145

**Workforce Sufficiency**

The CDC and APHIS components of the Select Agent Program increased the number of full-time federal inspectors in 2016 and 2017, but have faced challenges in hiring and retaining sufficient staff with the requisite expertise to perform the necessary work in a timely manner. According to agency reports, agency officials, and laboratory representatives, Select Agent Program inspectors are subject to a large workload with an intensive travel schedule. Inspectors perform a variety of tasks, including conducting on-site inspections of laboratories, developing written reports of inspection results, processing requests for amendments to laboratory registrations, and communicating program requirements to laboratory representatives.

According to agency reports and inspectors we spoke with, inspectors often travel 30 percent to 50 percent or more of their time in performing their duties.<sup>54</sup> This intensive workload and travel schedule has led to delays in both the issuing of inspection reports and processing of registration amendments. According to a 2017 CDC report, the time to process CDC's inspection reports in 2016 ranged from 4 to 224 business days, with about 27 percent of reports exceeding the Select Agent

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<sup>54</sup>The frequency of travel is a particular challenge for inspectors from the APHIS component of the program, who noted that they generally travel 50 percent to 75 percent of their time. CDC inspectors' travel time is capped at 40 percent, according to agency officials. APHIS does not have a travel cap.

Program's 30-day target for issuance.<sup>55</sup> Workload issues were cited as one of the key reasons for delays.<sup>56</sup> A 2016 APHIS internal report also identified delays in issuing inspection reports.<sup>57</sup> According to the 2016 report, the time to process APHIS's inspection reports in 2014 averaged 36 days, but some reports were issued more than 100 days from the date the inspection concluded. Similarly, the processing time for amendments to registrations, which the program has not routinely tracked in the past, generally varies from a couple of weeks or months to approve simpler amendments (such as personnel changes) to a year or more to approve major changes to facilities (such as adding new laboratory space), according to laboratory representatives. Delays in issuing inspection reports or processing amendments may hamper the implementation of corrective measures to address safety issues identified in inspections or impede laboratories' research on select agents, according to agency reports and laboratory representatives. For example, representatives from one laboratory told us that they lost grant funding because it took over a year for the Select Agent Program to review and approve an amendment to its registration to allow the proposed research to be conducted.

Workload issues have also created problems with retention, according to agency documents and program officials we interviewed, and have sometimes resulted in staff from the APHIS component of the Select Agent Program being assigned responsibilities outside their areas of expertise. For example, at the time of our review, an APHIS security specialist was given the additional responsibility of conducting reviews not related to his area of expertise, such as inspecting ventilation systems, which are critical to ensuring select agents are not released into the environment.<sup>58</sup> According to the 2016 internal APHIS report, the APHIS

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<sup>55</sup>Centers for Disease Control and Prevention, Office of Public Health Preparedness and Response, Division of Select Agents and Toxins, *2016 Inspection Report Processing Annual Summary* (Atlanta, Ga.: May 2017). CDC began analyzing inspection report processing data in 2016, in response to a 2015 CDC internal review that recommended that CDC analyze the data to identify reasons for delays in the issuance of inspection reports. According to the report, in 2015, 36 percent of inspection reports exceeded the 30-day target for issuance.

<sup>56</sup>Other reasons for delays in issuing inspection reports cited in the CDC report included, among others, the need to address severe compliance issues and inspection scheduling.

<sup>57</sup>U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development, Program Assessment and Accountability, *Agriculture Select Agent Services Management Review*.

<sup>58</sup>In August 2017, APHIS hired a facilities specialist for the APHIS component of the Select Agent Program.

component of the program has historically struggled with resource deficiencies and has had to implement strategies to fulfill its legal mandates and meet basic goals and objectives within its limited resources.

Both the CDC and APHIS components of the Select Agent Program have individually taken steps to identify and address gaps in their workforce but have not coordinated these actions to manage fragmentation across the program. CDC developed a formal workforce plan for its component of the Select Agent Program in 2016, identified and secured the necessary resources to implement the plan, and is working to fill needed positions.<sup>59</sup> As of August 2017, the CDC component of the program had 7 vacancies out of its 51 total inspector positions. APHIS also identified additional needed positions, through development of its 5-year business plan, and has used money from an APHIS contingency fund to fill them. APHIS hired additional inspectors in 2016 and 2017 and now has 11 inspector positions, up from 7 in 2015. APHIS also added several other new positions in the first half of 2017, including a scientific officer, a security manager, and a program analyst, among others.

However, according to program officials we interviewed, even with the additional recently hired inspectors, the program may not have adequate staff to handle surges in workload. For example, if there is a need to respond to critical incidents similar to those that occurred at CDC and DOD in 2014 and 2015,<sup>60</sup> the program may find it challenging to respond to those incidents in addition to meeting its annual inspection schedule. Moreover, according to the 2016 APHIS internal review and CDC and APHIS officials we interviewed, the complexity of laboratories that work with select agents, the select agent regulations, and inspections have continued to increase, which may continue to contribute to workload issues in the future. Program officials we interviewed said they are hopeful that the new database the program is implementing will allow the

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<sup>59</sup>In addition, according to CDC officials, as of May 2017, CDC's Office of Public Health Preparedness and Response was in the process of conducting another analysis of workforce needs across the CDC component of the Select Agent Program.

<sup>60</sup>For information on incidents that occurred at CDC, see Centers for Disease Control and Prevention, *Report on the Potential Exposure to Anthrax* (Atlanta, Ga.: July 11, 2014), *Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1* (Atlanta, Ga., Aug. 15, 2014), and *Report on the Potential Exposure to Ebola Virus* (Atlanta, Ga.: Feb. 4, 2015).

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program to gain efficiencies in amendment processing and other areas, which may reduce workload issues in the future.

### **Training to Improve or Maintain Expertise**

Most laboratory representatives we interviewed said that, in their experience, Select Agent Program inspectors generally had appropriate expertise to perform reviews. According to agency documents, the vast majority of the program's inspectors have advanced degrees, including many inspectors from CDC with doctoral degrees in microbiology or related fields and many inspectors from APHIS with doctoral degrees in veterinary medicine. However, CDC and APHIS internal reviews from 2015 and 2016,<sup>61</sup> respectively, as well as some laboratory representatives we interviewed, identified some shortcomings and inconsistencies in inspectors' expertise and approach related to their regulatory responsibilities. In particular, the reports found that inspectors had inconsistent knowledge about the select agent regulations, variabilities in skill level, and divergent approaches to inspections, both within and across the two components of the Select Agent Program. In addition, several laboratory representatives said that some inspectors imposed requirements on laboratories that the inspectors considered to be best practices rather than requirements of the select agent regulations or items on inspection checklists.

Both CDC and APHIS officials in the program identified gaps in the training available to maintain their expertise. CDC inspectors we interviewed told us they need additional training opportunities to keep up with scientific changes in the field, such as advances in laboratory techniques and equipment. APHIS officials we interviewed also identified areas where they need additional training, including in facilities and engineering aspects of laboratories; decontamination; and new laboratory techniques, technologies, and equipment. In addition, some APHIS inspectors we interviewed said that they sometimes do not have the necessary knowledge to effectively perform all aspects of inspections and, in some cases, depend on inspectors from CDC to address gaps in expertise. Relying on CDC inspectors when APHIS is inspecting CDC-owned laboratories raises conflict of interest concerns. Furthermore,

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<sup>61</sup>Centers for Disease Control and Prevention, *90 Day Internal Review of the Division of Select Agents and Toxins*, and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development, Program Assessment and Accountability, *Agriculture Select Agent Services Management Review*.

according to inspectors from both CDC and APHIS, they are rarely able to attend external conferences or other external training because of their intensive workload and travel schedules and because they must compete for training funds with CDC or APHIS scientists who are not assigned to the program. Priority is given to those scientists presenting information at conferences, which Select Agent Program staff rarely do because their inspection work is not the type of information shared at conferences, according to program officials.

In response to these concerns, both the CDC and APHIS components of the Select Agent Program have individually taken steps to improve training for program staff, including inspectors, but have not always coordinated steps to manage fragmentation across the program. For example, in 2016, APHIS increased training opportunities for two inspectors to better enable them to inspect BSL-4 laboratories. In addition, CDC developed a training strategy that identified various areas in its training program that needed improvement, including the need to provide funding support for existing training activities and enhanced professional development opportunities.

According to CDC's training strategy, the complexity of the inspector position and evolving science on select agents demand ongoing training and professional development opportunities for staff. Among other recommendations, the strategy identified the need for three additional full-time-equivalent positions in the training area—in addition to the one the CDC component of the program currently has; as of August 2017, CDC was in the process of hiring one additional training specialist.<sup>62</sup> APHIS has not developed a similar formal training strategy, but during the course of our review, APHIS sought and received approval and funds to hire a full-time training coordinator, which it was in the process of filling as of July 2017. Because APHIS has not had a training coordinator dedicated to the Select Agent Program in the past, the APHIS component of the program has generally relied on CDC to address training needs, although APHIS does provide its own training to its inspectors and has coordinated with CDC to develop some training, according to APHIS officials. A senior APHIS official noted that having its own training coordinator moving forward will help ensure APHIS's training needs are met, as animal inspection needs have not explicitly been addressed in the past when CDC has taken the lead on training.

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<sup>62</sup>According to CDC officials, the additional positions will be filled through a contract.

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## Security Concerns Have Limited the Program's Transparency

### Transparency

The organization should provide access to key information, as applicable, to those most affected by operations.

Source: GAO. | GAO-18-145

According to our key elements of effective oversight, the organization conducting oversight should provide access to key information, as applicable, to those most affected by operations. Past White House and other reports, as well as experts at our meeting, also emphasized the importance of transparency, including the sharing of information on incidents and lessons learned, in the Select Agent Program.<sup>63</sup> However, the program limits the information it shares about registered laboratories and violations of the select agent regulations, mainly because of security concerns.<sup>64</sup> For example, the program does not disclose to the public or other laboratories the locations of laboratories registered with the program, the agents that laboratories work with, or details on violations of select agent regulations.

The Select Agent Program has recently increased the transparency of high-level laboratory and program information it shares with the public and registered laboratories, partly in response to recent federal reports. For example, in 2016, the Select Agent Program issued its first annual public report on the program.<sup>65</sup> The report provided a variety of information, such as background information on the program, statistics about registered laboratories, and aggregated information on the potential losses and releases reported to the program. In 2015, the program developed a mechanism for laboratories to request interpretation of the select agent regulations from the program and has since published

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<sup>63</sup>Federal Experts Security Advisory Panel, *Report of the Federal Experts Security Advisory Panel*; National Science Advisory Board for Biosecurity, *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility: A Report of the National Science Advisory Board for Biosecurity* (Washington, D.C.: September 2011); and White House, National Science and Technology Council, *Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement*.

<sup>64</sup>There are statutory restrictions on the information the Select Agent Program can be forced to release in response to requests made under the Freedom of Information Act. 42 U.S.C. § 262a(h) (HHS); 7 U.S.C. § 8401(h) (USDA).

<sup>65</sup>Department of Health and Human Services, Centers for Disease Control and Prevention, and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, *2015 Annual Report of the Federal Select Agent Program* (Washington, D.C.: June 2016).

several regulatory interpretations on its website.<sup>66</sup> In addition, starting in summer 2016, the Select Agent Program worked with a nongovernmental organization, the American Biological Safety Association International,<sup>67</sup> to develop an online forum for registered laboratories to share information with one another, which laboratory representatives told us has been very helpful. The Select Agent Program also held a workshop for responsible officials from registered laboratories in December 2016 to disseminate program information; the workshop also provided the opportunity for attendees to interact. Many laboratory representatives told us that this was very helpful, and some noted that they had not had an opportunity to communicate and share lessons learned with responsible officials from other registered laboratories in the past.

Even so, some experts, agency officials, and laboratory representatives we interviewed said there needs to be more transparency to the public about select agent research and incidents in order to increase public trust concerning the activities conducted at high-containment laboratories. For example, several laboratory representatives noted that the media has incorrectly described their laboratories as conducting “bioterror” research, when the research they conduct is to mitigate the consequences of a bioterrorist attack—for example, by developing vaccines and other measures to help diagnose, prevent, or treat exposure to or infection with select agents. On the other hand, many laboratory representatives told us that the program was already sharing an appropriate amount of information with the public. According to officials from HHS and USDA, this issue has been examined and discussed extensively within their departments, partly in response to recent federal reports. CDC officials pointed out that laboratories themselves could share additional information about their select agent research and any incidents. For example, the U.S. Army Medical Research Institute for Infectious Diseases and the National Biodefense Analysis and Countermeasures Center, both at Fort Detrick in Maryland, and the Galveston National

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<sup>66</sup>The Select Agent Program developed this mechanism in response to a 2015 White House report that recommended development of a formal mechanism for laboratories to request interpretations of the select agent regulations. White House, National Science and Technology Council, *Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement*.

<sup>67</sup>The American Biological Safety Association International is a professional organization that represents the interests and needs of biological safety professionals and provides a forum for the continued and timely exchange of biological safety information.

Laboratory in Galveston, Texas, voluntarily share information about their select agent research and incidents with the public via their websites.

In addition, many laboratory representatives we interviewed said the program needs to be more transparent for registered laboratories. In particular, some said that it would be helpful for the program to share more information among laboratories about select agent research and incidents to enhance the sharing of lessons learned to improve biological safety and security. According to experts at our meeting, it is important for information, such as lessons learned from incidents, to be shared among laboratories so that they can learn from one another's experiences to improve their own operations.<sup>68</sup> Some laboratory representatives also said that it would be helpful for the Select Agent Program to provide additional guidance in certain areas, such as regarding the use and storage of toxins. Federal internal control standards state that management should internally and externally communicate the necessary quality information to achieve the entity's objectives.<sup>69</sup> However, there is no consensus about what additional information should be shared with laboratories. Without determining what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the Select Agent Program to share with registered laboratories, the program may be missing opportunities to provide key information that ultimately could help improve biological safety and security.

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<sup>68</sup>We previously noted that one way to share such information is through safety reporting systems, which we found can be key tools for safety improvement efforts in high-containment laboratories, including through the sharing of information and lessons learned. See GAO, *Biological Laboratories: Design and Implementation Considerations for Safety Reporting Systems*, GAO-10-850 (Washington, D.C.: Sept. 10, 2010).

<sup>69</sup>GAO/AIMD-00-21.3.1 and GAO-14-704G. According to federal internal control standards, external parties include, among others, regulators, government entities, and the general public. Federal internal control standards state that management should select appropriate methods to communicate externally considering a variety of factors, such as the intended recipients of the communication, the purpose and type of information being communicated, and requirements in laws and regulations that may affect communication.



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Program Has Authority to Enforce Compliance with Requirements and Is Working to Address Concerns about Clarity and Consistency of Enforcement Actions

According to our key elements of effective oversight, the organization conducting oversight should have clear and sufficient authority to require entities to achieve compliance with requirements. The Select Agent Program has the authority to and takes a range of enforcement actions for violations of the select agent regulations and is working to address concerns about the clarity and consistency of enforcement actions. When the Select Agent Program identifies a possible violation of the select agent regulations, the program may take several types of compliance or enforcement actions, as follows:

**Enforcement authority**

The organization should have clear and sufficient authority to require that entities achieve compliance with requirements.

Source: GAO. | GAO-18-145

- **Administrative actions:** The Select Agent Program can propose a corrective action plan;<sup>70</sup> suspend or revoke a registered laboratory's registration; or deny a laboratory's application to possess, use, or transfer select agents.
- **Referrals to HHS OIG or APHIS's Investigative and Enforcement Services:** The Select Agent Program may refer violations to HHS OIG or APHIS's Investigative and Enforcement Services, both of which can levy civil money penalties, issue a Notice of Violation letter, or close the case.<sup>71</sup>
- **Referral to the FBI:** The Select Agent Program can refer possible violations involving criminal negligence, criminal intent, or suspicious activity or person to the FBI for further investigation. Criminal enforcement may include imprisonment for up to 5 years, a fine, or both.

The Select Agent Program has taken enforcement actions against laboratories but did not always do so consistently or according to any available criteria. The Select Agent Program has taken a range of

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<sup>70</sup>The Select Agent Program may propose that a laboratory with serious or repeated violations of the select agent regulations participate in a corrective action plan. Such plans allow laboratories to take steps to address violations while the program monitors the progress. Laboratories may choose to not participate in a corrective action plan, in which case the program may take stronger enforcement actions, such as suspending or revoking the laboratory's registration.

<sup>71</sup>HHS OIG and APHIS's Investigative and Enforcement Services can levy civil money penalties of up to \$250,000 per individual employee for each violation and up to \$500,000 for a registered laboratory for each violation.

enforcement actions for violations of the select agent regulations—including suspending or revoking registrations or proposing corrective action plans—as well as referring violations to HHS OIG or APHIS’s Investigative and Enforcement Services for further investigation. Following investigation, HHS OIG and APHIS’s Investigative and Enforcement Services have taken other enforcement actions, including levying civil money penalties and issuing Notice of Violation letters. However, we previously found in 2016 that the Select Agent Program did not consistently refer laboratories to investigative entities for violations of the select agent regulations or enforce regulations related to incidents involving incomplete inactivation, and we found that this appears to be true beyond incidents involving incomplete inactivation as well.<sup>72</sup> For example, from 2003 through 2016, the program suspended or revoked 10 laboratories’ registrations in response to violations of the select agent regulations, only 1 of which was a federal laboratory, and neither HHS OIG nor APHIS’s Investigative and Enforcement Services have levied a civil money penalty against a federal laboratory.<sup>73</sup> Moreover, we previously found that the program referred various laboratories to HHS OIG for incidents involving incomplete inactivation but did not refer HHS laboratories for two incidents in 2014. We recommended in 2016 that the Select Agent Program develop and implement consistent criteria and documentation requirements for referring laboratories to investigative entities and enforcing regulations.

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<sup>72</sup>[GAO-16-642](#). This report and related recommendations were focused on incidents involving incomplete inactivation, but the steps the agencies are taking in response apply to enforcement more broadly. In that report, we also recommended that the Select Agent Program revise reporting forms to help identify when incidents involving incomplete inactivation occur.

<sup>73</sup>The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides HHS and USDA with the authority to impose civil money penalties on any person who violates the select agent regulations, with the term “person” including federal, state, and local governmental entities. According to HHS, HHS OIG has determined that it will not impose civil money penalties on federal laboratories because (1) there would be no net receipt of money to the federal government and levying a civil money penalty may result in costs related to negotiating or disputing the penalty, and (2) HHS OIG believes that civil money penalties are less effective than other enforcement actions, such as imposing corrective action plans, at improving compliance. According to USDA, APHIS would consider levying a civil money penalty against a federal laboratory, taking into consideration whether the penalty would be more effective at achieving compliance with the select agent regulations and deterring future violations than other enforcement actions, such as suspending or revoking a laboratory’s registration.

The Select Agent Program is taking steps to address such past concerns about the need for greater consistency and clarity in enforcement actions and implement our recommendation. In particular, in September 2017, the program finalized a document that provides guidance on when to refer laboratories for violations and options for enforcement. This document categorizes regulatory departures along a spectrum of severity with associated enforcement options, so that inspectors and laboratories have a clear understanding of what to expect during and as a result of inspections, regardless of which Select Agent Program component conducts them. In addition, the CDC component of the program worked with HHS OIG to develop criteria to guide referrals to OIG, which CDC finalized and implemented in June 2017. APHIS is not developing a similar document at this time because APHIS officials believe the guidance on when to refer laboratories for violations and options for enforcement actions described above provides sufficient guidance on referrals for the Select Agent Program. The program's development of guidance with criteria is a positive step and the program continues to develop associated documentation requirements for referring violations to investigative entities and enforcing regulations, according to a senior program official.

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### Select Agent Program Does Not Have Joint Strategic Planning Documents to Guide Oversight

As of August 2017, the Select Agent Program does not have joint strategic planning documents to guide its shared oversight efforts across CDC and APHIS.<sup>74</sup> For example, the program does not have a joint mission statement to collectively define what the program seeks to accomplish through its oversight. It also does not yet have a strategic plan, although it is taking steps to develop one. Agencies can use strategic plans to set goals and identify performance measures for gauging progress towards those goals. Strategic plans can also outline how agencies plan to collaborate with each other to help achieve goals

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<sup>74</sup>For the purpose of this report, "joint" activities refer to the coordination between CDC and APHIS in developing plans that take into consideration the resources and needs of both components of the Select Agent Program.

and objectives, as well as describe the strategies and resources required to achieve the goals and objectives.<sup>75</sup>

**Mission statements for the two components of the Federal Select Agent Program**

The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins reduces the risks for thefts, losses, and releases of biological agents by ensuring regulated laboratories or importers are safe and select agents are secure through its monitoring of facilities and enforcement of regulations.

The Animal and Plant Health Inspection Service's (APHIS) Agriculture Select Agent Services is a team of Agriculture Health Professionals dedicated to providing superior customer service to safeguard the health of domestic animals, plants, and their products from agricultural biological agents and toxins.

Source: CDC and APHIS. | GAO-18-145

Each component of the program has conducted some strategic planning—each has an individual mission statement, some strategic planning documents, and performance measures—but the components differ in what they seek to achieve and how they measure the effectiveness of their efforts. For example, according to CDC officials, in the past, the CDC component has developed yearly strategic goals, such as to improve regulatory oversight through inspections and the biological safety and security of laboratories. In contrast, APHIS developed a 5-year business plan for its component of the Select Agent Program in 2014, which it updated in July 2017. In addition, it identified a number of annual goals in 2015, 2016, and 2017, such as developing additional BSL-4 training and filling vacancies in existing and new positions. CDC's and APHIS's performance measures also differ. For example, CDC has a range of performance measures, such as tracking the number of laboratory-acquired infections and the timeliness of inspection reports, whereas APHIS's performance measures address the number of thefts, losses, and releases involving select agents and the processing of amendments.

The Select Agent Program also does not have a joint workforce plan that collectively identifies workforce and training needs to ensure the program as a whole has the appropriate workforce with sufficient expertise to carry out its responsibilities and that resources are being leveraged appropriately across the two components of the program. According to our past work, strategic workforce planning is an essential tool to help agencies align their workforces with their current and emerging missions and develop long-term strategies for acquiring, developing, and retaining staff.<sup>76</sup> Moreover, the Select Agent Program has not collectively determined its training needs. The APHIS component of the program has

<sup>75</sup>As noted, we have previously found that requirements under GPRA for strategic planning can also serve as leading practices for strategic planning at lower levels within federal agencies, such as planning for individual programs. [GAO-12-885](#) and [GAO-12-77](#).

<sup>76</sup>GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, [GAO-15-183](#) (Washington, D.C.: Jan. 30, 2015), *Workforce Planning: Interior, EPA, and the Forest Service Should Strengthen Linkages to Their Strategic Plans and Improve Evaluation*, [GAO-10-413](#) (Washington, D.C.: Mar. 31, 2010), and *Human Capital: Key Principles for Effective Strategic Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003). [GAO-04-39](#) describes five key principles that strategic workforce planning should address.

generally relied on CDC to help meet its ongoing training needs, as noted, but we found through our review of CDC's training strategy that it did not specifically address APHIS's training needs. According to program officials, joint training provided in the past has not always explicitly addressed animal inspection needs, as noted. Program officials noted that the program has taken some steps to coordinate training, such as holding joint inspector training and webinars.

Senior program officials told us that, even without joint strategic planning documents, the CDC and APHIS components of the Select Agent Program manage fragmentation by collaborating on many aspects of the program, such as through maintaining frequent communication at the director level. They also said that the program had not developed a joint mission statement or strategic planning tools in the past because they prioritized other efforts in recent years, including responding to incidents that occurred in 2014 and 2015, addressing recommendations from recent reports, and developing a new database for the Select Agent Program. In addition, each component of the program has generally focused on its own agency's needs when conducting workforce planning. One senior CDC official said that the Select Agent Program had always been in "reactive mode" and noted that the program could improve its oversight if it took a more strategic view.

During the course of our review, senior program officials told us that they were taking steps to develop a joint strategic plan for the Select Agent Program and, in August 2017, the program began soliciting bids from contractors for the plan's development. The statement of work for the contract states that the contractor shall develop guiding principles for the Select Agent Program along with a mission statement, strategic goals and objectives, and performance measures, among other requirements. However, the statement of work for the contract does not have any requirements related to development of a joint workforce plan. We have found in the past that agencies' strategic workforce planning should be clearly linked to the agency's mission and long-term goals developed during the strategic planning process.<sup>77</sup> Developing a joint workforce plan that assesses workforce and training needs for the program as a whole would help the program to better manage fragmentation by improving how it leverages resources to ensure all workforce and training needs are met; this assessment should be done in conjunction with the development

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<sup>77</sup> [GAO-04-39](#).

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of the strategic plan. Leveraging of resources is especially important given fiscal constraints and the uneven level of resources across the two components of the program.

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## Selected Countries and Regulatory Sectors Employ Other Approaches to Promote Effective Oversight

Selected countries and regulatory sectors employ approaches to promote effective oversight that, in some cases, differ from those of the Select Agent Program. For example, other countries and sectors have regulatory bodies that are structurally independent from the entities they oversee, take a risk-based approach to performing reviews, rely on scientists and other laboratory personnel to have requisite technical expertise on the pathogens and activities in their laboratories, share incident information on their public websites, and have prosecutorial authority when incidents occur.

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### Structural Independence of Oversight Bodies

Some countries and sectors we reviewed have regulatory bodies that are structurally independent from the entities they oversee.<sup>78</sup> For example, Great Britain's Health and Safety Executive, whose mission is to protect worker and public health and safety and who oversees laboratories that work with pathogens, is an independent central government agency, according to officials. It has a chief executive accountable to the UK government's Department of Work and Pensions and a public-private board composed of representatives from a range of industries, including trade unions. Officials noted that this structure, an independent agency with direct access to a departmental head, allows the Health and Safety Executive to have control over defining its own budget and staffing needs. According to officials from the Health and Safety Executive and laboratory

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<sup>78</sup>Some countries, such as Canada and Switzerland, have regulatory structures that are similar to the Select Agent Program in that the regulator is in the same department as some regulated laboratories. According to officials, the Public Health Agency of Canada is cognizant of this issue and tries to ensure laboratories under the Health Minister are following the same rules as other laboratories. According to officials, in Switzerland, inspection responsibility for the laboratory within the same hierarchy as the regulatory agency was permanently transferred to another jurisdiction to address any independence or conflict-of-interest issues.

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representatives we interviewed, one strength of this approach is that it avoids potential organizational conflicts of interest because none of the laboratories that the Health and Safety Executive oversees are part of the same agency.

### Great Britain's Health and Safety Executive

The Health and Safety Executive is an independent regulator in Great Britain whose mission is to prevent death, injury, and illness in the workplace. It was originally established following a government review of the health and safety system in the country in 1974.

One division within the Health and Safety Executive—the Chemical, Explosives and Microbiological Hazards Division—regulates sectors that have the potential for low-probability, high-consequence incidents, including work in high-containment laboratories. It began overseeing laboratories following a smallpox outbreak in 1978.

Great Britain reviewed the regulations for animal pathogens and rewrote them to make them more aligned with the human pathogen and genetically modified organism frameworks after a 2007 safety incident in which a Great Britain laboratory inadvertently released foot and mouth disease into the environment. The Health and Safety Executive is responsible for safety oversight of pathogens that present a risk to human health as well as animal pathogens.

A separate entity, the National Counter Terrorism Security Office, is responsible for security oversight of a subset of pathogens that pose biological security concerns, similar to the United States' select agents. The Health and Safety Executive and the National Counter Terrorism Security Office work closely together in providing oversight, according to officials.

As of July 2017, Great Britain had a total of 434 registered high-containment laboratories across the government, academic, and private sectors.

Source: GAO analysis of information provided by Great Britain's Health and Safety Executive. Image: Courtesy of Health and Safety Executive. | GAO-18-145

Some other regulatory sectors in the United States are also structurally independent from regulated facilities as a mechanism to ensure independence. For example, prior to the creation of NRC in 1974, the U.S. Atomic Energy Commission was responsible for both promotion and oversight of the nuclear industry. The Energy Reorganization Act of 1974 established NRC as a separate, independent entity. According to a relevant Senate committee report, this was a response to growing criticism that there was a basic conflict between the U.S. Atomic Energy Commission's regulation of the nuclear power industry and its development and promotion of new technology for the industry.<sup>79</sup> Independence is one of NRC's "Principles of Good Regulation" that the commission seeks to follow in carrying out its regulatory activities.<sup>80</sup> NRC's Office of Nuclear Reactor Regulation uses performance metrics associated with these principles—including measures of the objectivity and independence of its inspectors—to annually evaluate the effectiveness of its Reactor Oversight Process in meeting its pre-established goals and intended outcomes.<sup>81</sup> This office reports the results of this analysis to NRC in an annual report on the self-assessment of the Reactor Oversight Process.

<sup>79</sup>S. Rep. No. 93-980 at 2 (1974).

<sup>80</sup>NRC's "Principles of Good Regulation" include independence, openness, efficiency, clarity, and reliability. According to NRC, these principles help to focus the commission on ensuring safety and security while appropriately balancing the interests of NRC's stakeholders, including the public and licensees.

<sup>81</sup>The staff conducts performance metric analysis annually in accordance with the recently revised Inspection Manual Chapter (IMC) 0307, "Reactor Oversight Process Self-Assessment Program," and IMC 0307 Appendix A, "Reactor Oversight Process Self-Assessment Metrics," dated November 23, 2015.



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## Risk-Based Approaches to Performing Reviews

Other countries and sectors we reviewed have adopted risk-based approaches to reviewing compliance with regulatory requirements. In particular, regulators in some countries, including Great Britain and Canada, apply a risk-based approach to target their reviews to laboratories with a documented history of performance issues or those conducting higher-risk activities. Great Britain's Health and Safety Executive prioritizes which laboratories to inspect during the year by assessing the level of risk a specific laboratory or program may have on worker or public health and safety or the environment, according to officials. This assessment takes into consideration factors such as which pathogens pose a greater risk, how these pathogens are used in the laboratory, and the potential consequences of an incident.<sup>82</sup> For example, officials noted that a laboratory complex that works with many pathogens that may pose a significant risk to the country—such as animal pathogens that affect livestock and the food supply—may be subject to more oversight and additional inspections from regulators, based on the associated risk assessment, than a diagnostic laboratory that may destroy samples after testing.

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<sup>82</sup>Great Britain's Health and Safety Executive inspects all U.S. BSL-4 equivalent laboratories at least once every year, but may conduct multiple visits each year. According to officials from the Health and Safety Executive, because they do not have the resources to visit all laboratories, they prioritize which U.S. BSL-3 equivalent laboratories to visit each year based on risk. Canada and Great Britain use different terminology for the classification of pathogens and containment laboratories but they are essentially equivalent to the four biological safety levels used in the United States and are referred to as BSL-3 and BSL-4 equivalent in this report for consistency.

**Public Health Agency of Canada**

Public Health Agency of Canada Agence de la santé publique du Canada

The Public Health Agency of Canada is responsible for promoting and protecting the health of Canadians through various public health initiatives. It was established in 2004, partly in response to an outbreak of severe acute respiratory syndrome (SARS) in 2003, when it became evident that Canada had no legal requirements for domestic laboratories to report information such as whether they were working with SARS samples, and therefore officials could not determine the potential scope of the problem.

The agency sits under Canada's Minister of Health and its Centre for Biosecurity is responsible for administering and enforcing Canada's Human Pathogens and Toxins Act to oversee the safe and secure handling of human pathogens and toxins. The act came into full force in December 2015, following an extensive consultation process with stakeholders.

The Centre for Biosecurity has authority to license and oversee laboratory activities involving human pathogens and toxins, some animal pathogens, and a subset of human pathogens that have additional biological security concerns.

Oversight responsibility for the other animal pathogens rests with the Canadian Food Inspection Agency.

As of June 2017, Canada had a total of 63 licensed high-containment laboratories across the government, academic, and private sectors.

Source: GAO analysis of information provided by the Public Health Agency of Canada. Image: Courtesy of the Public Health Agency of Canada. | GAO-18-145

Similarly, officials from the Public Health Agency of Canada's Centre for Biosecurity, whose mission is to protect the health and safety of the public against the risks posed by human pathogens and toxins, stated that their division for the oversight of laboratories that work with pathogens also has a risk-based licensing and inspection scheme. Under this scheme, the stringency of licensing and inspection requirements largely depends on the pathogen's risk level.<sup>83</sup> In addition, the Public Health Agency of Canada places different requirements on activities carried out in laboratories depending on their sector (e.g., public health or research) because it determined that activities in certain sectors present a higher risk than others, with the research sector having the highest associated risks. As such, the Public Health Agency of Canada places additional requirements on research scientists conducting certain activities with pathogens than it does with respect to personnel conducting activities in other types of laboratories. For example, the agency requires research scientists to develop and submit documentation that demonstrates a reasonable plan to manage risk and promote compliance with requirements. Officials noted that this approach helps the agency to understand where best to focus its efforts to achieve the desired risk mitigation results. According to officials from both Great Britain and Canada, this risk-based approach helps the oversight bodies in both countries focus their limited resources on laboratories they have identified as having the highest risks.

In addition, Great Britain's Health and Safety Executive and the Public Health Agency of Canada apply a risk-based approach in determining the focus of their inspections. For example, according to agency officials in Great Britain and Canada, because they have not found stringent inventory requirements to be effective in reducing biological safety risks in the laboratory, neither country places as much focus, time, or resources on inventory management as the Select Agent Program does. For

<sup>83</sup>The Public Health Agency of Canada generally licenses activities involving risk-level 4 pathogens (the equivalent of those worked with in U.S. BSL-4 laboratories) for 1 year and inspects those laboratories at least once in that year. Activities involving pathogens handled in BSL-3-equivalent laboratories are generally licensed for 3 years, and the agency aims to inspect those laboratories at least once within that period. In addition to the pathogens handled in BSL-3 and -4-equivalent laboratories, the Public Health Agency of Canada also oversees activities involving pathogens handled in BSL-2-equivalent laboratories because, according to officials, it allows the agency to have a solid foundation for understanding all the relevant biological work happening in the country. Activities in these laboratories are generally licensed for 5 years, and the agency may or may not inspect these laboratories during that period, based on a prioritization of the risks involved with the various activities.

example, neither country spends time during every inspection counting and examining vials and comparing them to inventory logs, according to officials. Instead, Great Britain's Health and Safety Executive's approach is to sample laboratories' biological safety measures and assess whether they have mechanisms in place to mitigate the consequences of incidents should they occur. Similarly, in Canada, the Canadian Biosafety Standard requires that laboratories working with pathogens in high-containment have an inventory tracking system that is based on the risks internally identified by the laboratory, in order to allow for timely identification of missing vials if necessary.<sup>84</sup>

In addition to having less prescriptive inventory requirements than the Select Agent Program, both Great Britain's Health and Safety Executive and the Public Health Agency of Canada generally focus their oversight on (1) biological safety, and (2) regulation of all potentially hazardous pathogens in laboratories. In contrast, the Select Agent Program originated from security-related concerns and regulates only those pathogens identified on the U.S. select agent list and no other pathogens, such as West Nile virus, that may be handled in high-containment but are not select agents. In both Great Britain and Canada, specific biological safety incidents provided the impetus for establishing oversight for laboratories that work with pathogens and, as a result, their regulatory agencies generally focus on biological safety.<sup>85</sup> Both Great Britain and Canada have additional oversight requirements, such as security clearances for personnel, for a limited number of pathogens for which they have heightened security concerns, similar to the security requirements for working with select agents in the U.S. For example, in

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<sup>84</sup>Public Health Agency of Canada officials noted that the Canadian Biosafety Standard is the documented standard that all licensed laboratories in Canada must follow. Laboratories are not required to file their inventories with the agency, except for initial licensing, but must produce them on request during an inspection. Officials also noted that inspectors can verify compliance with this requirement through on-site inspections or targeted document review, but not every inspection may involve an inventory review component. Government of Canada, *Canadian Biosafety Standard*, 2<sup>nd</sup> ed. (Ottawa, ON, Canada: 2015).

<sup>85</sup>Great Britain's Health and Safety Executive was originally established in response to a government review of the country's health and safety system in 1974, with oversight of laboratories that work with pathogens added in 1978 following a smallpox outbreak. The Public Health Agency of Canada was established in 2004, in part as a response to an outbreak of severe acute respiratory syndrome (SARS) in 2003. Although biological safety is the primary focus of oversight in Great Britain and Canada, officials from both countries noted that by addressing biological safety, many biological security issues will be addressed as well.

Great Britain, the Health and Safety Executive focuses on only biological safety in its oversight of high-containment laboratories and works with the National Counter Terrorism Security Office for oversight of pathogens with biological security concerns.<sup>86</sup> In addition, to ensure compliance with biological safety regulations, officials we interviewed in Great Britain and Canada told us it was beneficial for their programs to have oversight over all hazardous pathogens that present biological safety risks to laboratory workers and the public, regardless of their containment level and their potential to pose biological security concerns.<sup>87</sup> For example, the Public Health Agency of Canada regulates any pathogens with characteristics that require handling in laboratories equivalent to U.S. BSL-2, -3, or -4, which currently covers thousands of pathogens, according to officials, as opposed to the 66 agents on the U.S.'s select agent list.

NRC also considers risk in its oversight of nuclear reactors, fuel cycle facilities, and radioactive materials.<sup>88</sup> In particular, for facilities that work with nuclear materials, NRC conducts inspections of a fraction of these facilities each year because, according to officials, there is a lower risk associated with nuclear materials than there is with nuclear power plants. There are no resident inspectors at these facilities; instead, the frequency of inspections for nuclear materials is based on the risk associated with,

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<sup>86</sup>In Great Britain, the Anti-Terrorism, Crime & Security Act 2001 applies to the biological security of specific human and animal pathogens. Security for these pathogens is coordinated by the National Counter Terrorism and Security Office, which provides oversight and enforcement through warranted officers in UK Police Forces, known as Counter Terrorism Security Advisors. According to officials, the National Counter Terrorism Security Office conducts periodic inspections, less frequently than the Health and Safety Executive, and does not have a set inspection schedule. The Health and Safety Executive shares information with this office on regulated pathogens, provides training for the Counter Terrorism Security Advisors responsible for inspecting laboratories, and undertakes joint inspections with advisors as required.

<sup>87</sup>The feasibility of taking a similar approach to biological safety and security oversight in the United States by focusing on the risks associated with pathogens was addressed in a January 2017 White House report. This report noted that oversight systems that focus on the inherent risks in an activity are common across many other industries in the United States in which high-consequence incidents can occur, such as the chemical, nuclear, and airline industries. According to the report, these industries have achieved significant reductions in the number and severity of incidents through this focus on risk. White House, National Science and Technology Council, Committee on Homeland and National Security, Subcommittee on Biological Defense Research and Development, *Fast Track Action Committee on Biosafety and Biosecurity, Fast Track Action Committee Report: Biosafety and Biosecurity* (Washington, D.C.: January 2017).

<sup>88</sup>Fuel cycle facilities produce nuclear fuel for commercial nuclear reactors or manufacture specialty nuclear materials for the U.S. Navy's nuclear fleet.

among other things, the specific material and each facility's past performance. Sites with past issues will receive more attention, while sites with a history of good performance will generally be subject to the minimum frequency of inspections applicable to that type of site. In contrast, as part of its Reactor Oversight Process,<sup>89</sup> NRC places at least two resident inspectors at each of the country's commercial nuclear power plants because they pose a higher risk.<sup>90</sup> For nuclear power plants, potential incidents can have high-consequences and far-reaching effects, such as the effects of the 2011 nuclear accident at the Fukushima Daiichi reactor in Japan. To ensure that each nuclear power plant is complying with federal safety requirements, these inspectors oversee a variety of activities on a daily basis, including by visiting control rooms, reviewing logbooks, performing visual assessments, and observing tests and repairs.

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### Drawing on Technical Expertise of Advisory Panels and Laboratories

Other countries have adopted various approaches to help ensure they have access to individuals with the appropriate expertise to perform sound safety and security assessments. According to officials in Great Britain, regulators at the Health and Safety Executive have access to external expert advisory committees to advise on issues related to new or emerging pathogens, diseases, or other scientific issues that inspectors may encounter during inspections or when developing policy. Health and Safety Executive officials noted that they generally go to the committees with questions of science and not regulation, as the inspectors are expected to be experts in biological safety and Great Britain regulations. Both France and Germany also have expert advisory committees that regulators can consult on scientific and technical issues, according to officials from these countries.

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<sup>89</sup>The Reactor Oversight Process is NRC's program to inspect, measure, and assess the safety and security performance of operating commercial nuclear power plants and to respond to any decline in their performance.

<sup>90</sup>NRC also places one resident inspector at each high-enriched uranium fuel fabrication facility. These facilities produce fuel for the U.S. Naval Reactors program and down-blend highly-enriched uranium with other uranium to create low-enriched uranium reactor fuel. Inspectors at these facilities ensure compliance with federal safety requirements by overseeing a variety of activities on a daily basis.

### Merging Oversight of Human and Animal Pathogens in Great Britain and Canada

Great Britain merged the inspection and oversight responsibilities for human and animal pathogens into one oversight body, the Health and Safety Executive, in 2008, following the 2007 accidental release of foot and mouth disease into the environment. Oversight of animal pathogens was originally under the United Kingdom's Department for Environment, Food, and Rural Affairs (DEFRA). When oversight of animal pathogens was first transferred to the Health and Safety Executive, DEFRA initially retained the licensing of sites with animal pathogens. In 2015, DEFRA transferred all oversight responsibilities, including licensing, to the Health and Safety Executive, but retained responsibilities for policy matters. According to agency officials and laboratory representatives in Great Britain, this change had a number of benefits, including creating a single agency contact for laboratories that work with regulated pathogens, strengthening the oversight of animal pathogens, and improving the logistics and ease of the system.

Similarly, in 2013, Canada transferred the oversight responsibility for a subset of animal pathogens from the Canadian Food Inspection Agency (CFIA) to the Public Health Agency of Canada to strengthen and harmonize its biological safety oversight framework and reduce the regulatory and administrative burden on researchers and laboratory officials. CFIA continues to issue permits for other animal pathogens, such as emerging animal diseases, which, according to officials, only make up a small number of pathogens.

Source: GAO analysis of information provided by Great Britain's Health and Safety Executive and Public Health Agency of Canada. | GAO-18-145

Officials from the Public Health Agency of Canada noted that they address the issue of technical expertise in part by placing substantial responsibility on the scientists and other personnel in each laboratory to understand and address the risks associated with their specific work, such as the equipment and procedures used in that laboratory. Officials from the Public Health Agency of Canada noted that personnel working in licensed laboratories are the ones most at risk if a safety lapse or other incident occurs, so the agency expects the responsible individuals at the laboratories to reinforce the requirements and help ensure everyone works safely and is in compliance with requirements. Under this approach, the main responsibility is with the laboratory officials to understand and manage the risks inherent in the work being performed at their facility, while the role of the inspector is to verify that they have taken appropriate steps to identify and address the risks.

According to officials in the Netherlands, regulators place responsibility for laboratory biological safety on biological safety officers at each of the laboratories by accrediting them for the oversight of biological safety.<sup>91</sup> Regulators conduct the accreditation process, which includes a review of personnel credentials, before individuals can be accredited. A 2-day course on the laws—such as details of biological safety requirements, case studies, review of transportation rules, and incident examples—is offered to each new accredited biological safety officer. Biological safety officers usually first seek accreditation for the equivalent of U.S. BSL-1 or -2 laboratories and must request additional reviews to receive accreditation for higher levels after acquiring the requisite knowledge and applied laboratory experience for the levels for which they are requesting accreditation. Officials from the Netherlands noted that it is important to have biological safety officers in laboratories as these individuals are versed in biological safety and can convey to researchers what they

<sup>91</sup>Biological safety officers in the Netherlands are accredited for biological safety issues concerning genetically modified organisms (GMO), but not “wild type” pathogens that could be found in nature. The accreditation is currently for an indefinite length of time, and the biological safety officer does not have to complete any additional training once accredited, provided the individual is actively supervising GMO activities. However, officials from the Netherlands noted that they would like to develop updated training for accredited biological safety officers to ensure individuals are applying the most up-to-date practices. Although the accreditation is strictly limited to GMOs, laboratories often combine the responsibilities for GMO and non-GMO activities.

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should be doing to ensure safety, as the regulator cannot be on-site every day.<sup>92</sup>

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## Transparency through Sharing Information on Agency Websites and Other Means

Some countries and regulatory sectors have approaches that provide transparency to entities and the public in a number of ways. For example, in Great Britain, the Health and Safety Executive shares information on licensing, enforcement actions, and prosecutions, among other information, through its website and the public register. Health and Safety Executive officials noted that the agency also issues information to licensed laboratories when there are safety alerts, lessons learned, or key decisions that it feels are pertinent to the regulated community. However, officials limit the sharing of any information that is sensitive or has security concerns, such as the names of individuals cleared to work with pathogens, which poses additional security concerns. Regulators in the Netherlands stated that they are also authorized to share a great deal of information related to some regulated pathogens, such as laboratory risk assessments, with the public and individuals who request the information. Similarly, in Switzerland, the public can request some information about laboratory licenses and the types of activities that occur at laboratories, but regulators do not share information on laboratory exposures because, according to a Swiss official, the public is not generally affected by them so the officials do not feel a need to share such information.<sup>93</sup>

NRC shares safety-related information on nuclear facilities with the public, including by posting the locations of nuclear facilities, inspection reports, and policies on its website. According to NRC officials, NRC believes transparency is important because, otherwise, secrecy can lead to distrust and negatively affect NRC's relationship with industry and the public. In addition, NRC has written policies available on its website that

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<sup>92</sup>A January 2017 White House report provided some options to supplement current oversight mechanisms, such as expanding the use of institutional biological safety committees or accreditation from outside groups. The report noted that accreditation can demonstrate an institutional commitment to biological safety and accountability for compliance and provide help in ensuring that the risk mitigation measures in place address all research risks. White House, National Science and Technology Council, *Fast Track Action Committee Report: Biosafety and Biosecurity*.

<sup>93</sup>Swiss officials noted that they regularly work with their lawyers to discuss the extent to which information can be shared as part of Switzerland's public rights ordinance.

detail what information it shares with registered facilities and the public, as well as guidance for NRC staff on what they can and cannot share. NRC officials stated that NRC strives for a balance between openness and security and that, because the nuclear sector's needs and the public's concerns are constantly changing, it is important to reassess policies as the necessity arises. For example, after the September 11, 2001, terrorist attacks, NRC decided to remove some information from the public sphere in response to concerns that such information could be misused and exploited for future terrorist attacks.

The Federal Aviation Administration also shares information with the public through its Aviation Safety Information Analysis and Sharing System, which collects information from multiple databases, including voluntarily reported near-miss data and accident information. This system is intended to promote an open exchange of safety information to continuously improve aviation safety, and it allows users to perform integrated queries, search safety data, and review incident investigations conducted by the National Transportation Safety Board. For example, analysts from the Federal Aviation Administration analyzed data from the Aviation Safety Information Analysis and Sharing System to determine which weather-related factors posed the biggest threats to pilots and aircraft. In addition, the Federal Aviation Administration provides public access to a library of lessons learned from historically significant, policy-shaping accidents to share key knowledge across the industry to improve aviation safety through the application of such lessons and to understand how the current safety regime has been influenced by past accidents. For example, the library discusses how two similar high-terrain crashes in the 1990s led to a requirement in 2000 to install a warning system in aircraft to reduce the incidence of such terrain accidents.

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## Mechanisms of Enforcement and Nonpunitive Reporting Systems

Countries and regulatory sectors we reviewed employ a range of mechanisms to take enforcement actions against entities or to encourage incident reporting. For example, Great Britain, Canada, France, and Switzerland all have the ability to pursue criminal prosecution in response to serious violations of their laws or regulations governing high-containment laboratories, in addition to the ability to suspend work or shut



down laboratories.<sup>94</sup> In Canada, penalties for the most serious violations can include up to 10 years in prison. Officials from the Public Health Agency of Canada and representatives from laboratories we spoke with noted that laboratory personnel are still encouraged to report incidents in laboratories, such as laboratory-acquired infections, regardless of the potentially heavy penalties, because certain information that is voluntarily provided during the course of an incident cannot then be used in any subsequent criminal proceedings against that individual.<sup>95</sup> In addition, experts from our meeting noted that the nonpunitive nature of airline reporting systems also encourages people to report incidents, which in turn provides valuable information to regulators, pilots, airlines, and the public that has been used to improve airline safety, as noted.

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## Conclusions

In their joint management of the Select Agent Program, CDC and APHIS share a critical role in ensuring that important research on select agents can be conducted in high-containment laboratories in a safe and secure manner. This role is especially important given the significant risks that pathogens handled in high-containment laboratories may pose to laboratory workers and the public. The Select Agent Program has made a number of improvements over the past few years, such as hiring additional staff and sharing more information with the public and registered laboratories. Nevertheless, the program does not fully meet all key elements of effective oversight. For example, the program is not independent in that it is not structurally distinct and separate from all of the laboratories it oversees. Both CDC and APHIS have individually made structural changes and put mechanisms in place to reduce conflicts of interest, but the APHIS component of the program has not documented the reporting process it developed to reduce conflicts of interest. Until APHIS formally documents the reporting structure for its component of

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<sup>94</sup>Great Britain's Health and Safety Executive cannot fine or prosecute other Crown Bodies, although it can impose other enforcement actions, similar to the Select Agent Program choosing not to fine federal laboratories, in part because there would be no net gain for the government.

<sup>95</sup>Section 16 of the Human Pathogens and Toxins Act states that information regarding an inadvertent release, inadvertent production, an incident that has caused a disease, or a missing or stolen pathogen or toxin provided by a license holder or a person conducting activities under the authority of a license may not be used against that person in any criminal proceedings that are subsequently instituted against them, unless the information reported was false or misleading. S.C. 2009, c. 24.

the program from the APHIS director of the program to the administrator of APHIS, it will continue to appear to have conflicts of interest in its oversight of APHIS-owned laboratories. Moreover, APHIS has, on at least three occasions, inspected its own or other USDA laboratories, which is not in keeping with the memorandum of understanding it signed with the CDC component of the program. Without establishing control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding, the Select Agent Program cannot have reasonable assurance that its key mechanism to reduce conflicts of interest is implemented.

In addition, the program has not formally assessed all potential risks posed by its current structure and the effectiveness of its mechanisms to address those risks. For example, the program did not identify some areas that may present conflicts of interest, such as APHIS carrying out inspections of its own laboratories, and has not considered whether there may be additional areas of concern. Without (1) regularly assessing the potential risks posed by the program's current structure and the effectiveness of its mechanisms to address them, such as by commissioning external reviews, and (2) taking actions as necessary to ensure any identified risks are addressed, the program may not be aware of or effectively mitigate impairments to its independence that could affect its ability to achieve its objectives.

Further, regarding the ability to perform reviews, the program may not be targeting the highest-risk laboratory activities in its inspections and other oversight efforts. Without developing and implementing a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities, the program will not have assurance that it is effectively balancing the potential safety and security gains from its oversight efforts against the use of program resources and the effect on laboratories' research. Moreover, the program is not fully transparent because it shares only limited information about lessons learned and other matters with registered laboratories, and there is no consensus about what additional information should be shared. Without determining what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the Select Agent Program to share with registered laboratories, the program may be missing opportunities to provide key information that ultimately could help improve biological safety and security. In addition, the program has not had clarity and consistency in

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its enforcement actions and is taking steps to address our past recommendation.

Further, regarding technical expertise, the two components of the Select Agent Program have individually hired additional staff for the program and improved training to enhance expertise, but workforce and training gaps remain. Although the program has begun to take steps towards development of a joint strategic plan to collectively guide oversight efforts, it does not have a joint workforce plan. Developing a joint workforce plan that assesses workforce and training needs for the program as a whole would help the program to better manage fragmentation by improving how it leverages resources to ensure all workforce and training needs are met; this assessment should be done in conjunction with the development of the strategic plan. Leveraging of resources is especially important given fiscal constraints and the uneven level of resources across the two components of the program.

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## Recommendations for Executive Action

We are making 11 recommendations to the agencies that manage the Select Agent Program, including 6 to APHIS and 5 to CDC:

To improve independence, the Administrator of APHIS should formally document the reporting structure for the APHIS component of the Select Agent Program from the APHIS director of the program to the Administrator of APHIS. (Recommendation 1)

To improve independence, the CDC director of the Select Agent Program should work with APHIS to establish control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding. (Recommendation 2)

To improve independence, the APHIS director of the Select Agent Program should work with CDC to establish control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding. (Recommendation 3)

To improve independence, the CDC director of the Select Agent Program should regularly assess the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks,

such as by commissioning external reviews, and take actions as necessary to ensure that any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives. (Recommendation 4)

To improve independence, the APHIS director of the Select Agent Program should regularly assess the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks, such as by commissioning external reviews, and take actions as necessary to ensure any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives. (Recommendation 5)

To improve the ability to perform reviews, the CDC director of the Select Agent Program should work with APHIS to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities. (Recommendation 6)

To improve the ability to perform reviews, the APHIS director of the Select Agent Program should work with CDC to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities. (Recommendation 7)

To improve transparency, the CDC director of the Select Agent Program should work with APHIS to determine what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the program to share with registered laboratories. (Recommendation 8)

To improve transparency, the APHIS director of the Select Agent Program should work with CDC to determine what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the program to share with registered laboratories. (Recommendation 9)

To improve technical expertise and overcome fragmentation, the CDC director of the Select Agent Program should work with APHIS to develop a joint workforce plan that assesses workforce and training needs for the program as a whole. This assessment should be done in conjunction with the development of the strategic plan. (Recommendation 10)

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To improve technical expertise and overcome fragmentation, the APHIS director of the Select Agent Program should work with CDC to develop a joint workforce plan that assesses workforce and training needs for the program as a whole. This assessment should be done in conjunction with the development of the strategic plan. (Recommendation 11)

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## Agency Comments and Third-Party Views

We provided a draft of this report for review and comment to DOD, HHS, the Department of Homeland Security, NRC, the Department of Transportation, and USDA. We also provided copies to officials from Great Britain, Canada, and the Netherlands, as well as experts who participated in our expert meeting at the National Academy of Sciences.

HHS and USDA—the agencies to whose components our recommendations are directed—both provided written comments agreeing with all of our recommendations. These comments are reprinted in appendixes III and IV, respectively. In their comments, HHS and USDA provided additional information about steps they are taking, or planning to take, to improve their oversight of select agents and to address our recommendations. For example, HHS and USDA stated that the Select Agent Program will explore options to improve independence, including reexamining previous reviews and assessing the need for additional reviews to ensure potential risks posed by the program’s structure are adequately assessed and addressed. In addition, to improve the ability to perform reviews, HHS and USDA stated that the Select Agent Program is transitioning to a new secure information system that will allow the program to develop analytical tools and procedures to analyze risk-related data to improve the inspection process. Further, to enhance transparency, HHS and USDA said the program is exploring ways to disseminate information regarding common deficiencies identified during inspections. Finally, to improve technical expertise and overcome fragmentation, HHS and USDA said that the program has initiated contract support for development of a joint strategic plan that will include the assessment of workforce and training needs.

HHS and USDA also provided technical comments, as did the Department of Homeland Security; officials from Great Britain, Canada, and the Netherlands; and a number of experts who participated in our expert meeting at the National Academy of Sciences. We incorporated these comments as appropriate. DOD, NRC, and the Department of Transportation did not comment on this report.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees; the Secretaries of Agriculture, Defense, Health and Human Services, Homeland Security, and Transportation; the Chairman of NRC; the Director of CDC; the Administrator of APHIS; and other interested parties. In addition, the report will be 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 Timothy M. Persons, Chief Scientist, at (202) 512-6412 or [personst@gao.gov](mailto:personst@gao.gov) or John Neumann, Director, Natural Resources and Environment, at (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@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 V.



Timothy M. Persons, Ph.D.  
Chief Scientist



John Neumann  
Director, Natural Resources and Environment

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## Appendix I: Key Elements of Effective Oversight

This appendix describes the steps we took to confirm the applicability of five elements of effective oversight we have used in the past for our evaluation of the Federal Select Agent Program (Select Agent Program). We have used these key elements in the past for assessing the effectiveness of oversight in other areas where low probability adverse events can have significant and far-reaching effects.<sup>1</sup> These elements are as follows:

- **Independence:** The organization conducting oversight should be structurally distinct and separate from the entities it oversees.
- **Ability to perform reviews:** The organization should have the access and working knowledge necessary to review compliance with requirements.
- **Technical expertise:** The organization should have sufficient staff with the expertise to perform sound safety and security assessments.
- **Transparency:** The organization should provide access to key information, as applicable, to those most affected by operations.
- **Enforcement authority:** The organization should have clear and sufficient authority to require that entities achieve compliance with requirements.

We took several steps to confirm the applicability of these elements for our examination of the Select Agent Program. First, we discussed the applicability of the criteria with senior officials from both components of the Select Agent Program, within the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). Second, we discussed the elements with representatives from the American Society of Microbiology and American Biological Safety Association International, which were selected because of their focus on

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<sup>1</sup>In particular, we have used these elements for reviews related to oversight of nuclear safety and oil and gas management. See GAO, *Nuclear Safety: Department of Energy Needs to Strengthen Its Independent Oversight of Nuclear Facilities and Operations*, [GAO-09-61](#) (Washington, D.C.: Oct. 23, 2008) and *Oil and Gas Management: Key Elements to Consider for Providing Assurance of Effective Independent Oversight*, [GAO-10-852T](#) (Washington, D.C.: June 17, 2010).

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microbiology and biological safety, respectively.<sup>2</sup> Finally, we discussed the elements with experts during our National Academy of Sciences meeting (see app. II for information on this meeting). The officials, representatives, and experts generally agreed that the five elements were appropriate for our examination of the Select Agent Program. We compared information from federal documents about the Select Agent Program's oversight, interviews with laboratory representatives and agency officials, and our expert meeting against the five elements of effective oversight.

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<sup>2</sup>The American Society of Microbiology is the largest single life science society, according to its website. Its mission is to promote and advance the microbial sciences. The American Biological Safety Association International is a professional organization that represents the interests and needs of biological safety professionals and provides a forum for the continued and timely exchange of biological safety information.



## Appendix II: List of Experts and Selection Methodology

The names and affiliations of the experts who participated in the group discussion held at the National Academy of Sciences (NAS) in Washington, D.C. are as follows:

- Kavita Berger, Ph.D., Scientist, Gryphon Scientific
- Lawrence Blyn, Ph.D., Senior Director, Ibis Biosciences, Abbott
- Bob Buchanan, Ph.D., Professor and Director of Center for Food Safety and Security Systems, University of Maryland
- Andrew Cottam, Ph.D., Head of the Microbiology and Biotechnology Unit, Health and Safety Executive, United Kingdom
- John Eakin, Principal Investigator, Air Data Research
- David Franz, DVM and Ph.D., Former Commander, United States Army Medical Research Institute for Infectious Diseases
- Gigi Kwik Gronvall, Ph.D., Senior Associate, Johns Hopkins Center for Health Security
- Marianne Heisz, Ph.D., Director, Office of Biosafety Programs and Planning, Public Health Agency of Canada
- Ruthanne Huising, Ph.D., Associate Professor, McGill University
- Gavin Huntley-Fenner, Ph.D., Principal Consultant, Huntley-Fenner Advisors
- Joseph Kanabrocki, Ph.D. and NRCM(SM), Associate Vice-President for Research Safety, Professor of Microbiology, University of Chicago
- Paul Keim, Ph.D., Regents Professor and Cowden Chair, Northern Arizona University
- James LeDuc, Ph.D., Director, Galveston National Laboratory, University of Texas Medical Branch
- Carol Linden, Ph.D., Director, Office of Regulatory Science and Innovation, Food and Drug Administration
- Allison MacFarlane, Ph.D., Professor and Director, Center for International Science and Technology Policy, George Washington University
- Brian O'Shea, Ph.D., Senior Biological Safety Officer, Battelle Memorial Institute
- Karlene Roberts, Ph.D., Professor Emeritus, Haas School of Business, University of California, Berkeley

- Jonathan Rosen, Principal Industrial Hygiene Safety and Health Consultant, AJ Rosen and Associates, LLC

The comments of these experts generally represented the views of the experts themselves and not the agency, university, or company with which they are affiliated. The meeting with these experts was held at NAS in January 2017. To identify experts to participate in the meeting, we worked iteratively with NAS staff to identify and review biographical information and relevant qualifications of experts, as well as factors such as representation from academia, industry, and federal government and expertise in a range of areas. The Board on Life Sciences of NAS solicited nominations for the expert panel from its extensive contacts in laboratory safety, biological security, and other regulatory sectors, such as occupational safety and health, airline safety, food safety, and chemical safety. These contacts included current and former committee members, current and former members of the Board on Life Sciences, and select members of NAS. NAS received responses from approximately 45 nominees. From this initial list, NAS selected experts based on their knowledge and expertise in the above-mentioned areas as well as their ability to attend the meeting on the chosen dates and obtained our approval of its selections. In order to facilitate discussion among participants, NAS did not include any federal employees or contractors of the Select Agent Program. The final list of 18 experts was then evaluated for any conflicts of interest. A conflict of interest was considered to be any current or financial or other interest that might conflict with the service of an individual because it (1) could impair objectivity and (2) could create an unfair competitive advantage for any person or organization. The 18 experts were determined to be free of conflicts of interest, and the group as a whole was judged to have no inappropriate biases.

We developed the session topics for the 2-day meeting based on our researchable objectives and issues that we identified in our audit work, including our analysis of agency documents and interviews with agency officials and representatives from registered laboratories. The meeting was recorded and transcribed to ensure that we accurately captured the experts' statements, and we reviewed and analyzed the transcripts as a source of evidence. Although the expert meeting was not designed to reach formal consensus on the issues, a number of themes emerged from the group's discussion to which there was general agreement.

## Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

SEP 21 2017

Timothy M. Persons  
Director, Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Persons:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*" (GAO-17-770).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark  
Acting Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COORDINATED ACTIONS NEEDED TO ENHANCE THE SELECT AGENT PROGRAM'S OVERSIGHT OF HAZARDOUS PATHOGENS (GAO-17-770)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

**Recommendation 2**

To improve independence, the Centers for Disease Control and Prevention (CDC) director of the Select Agent Program should work with Animal and Plant Health Inspection Service (APHIS) to establish control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding.

**HHS Response**

HHS concurs with GAO's recommendation.

The Federal Select Agent Program (FSAP), which is jointly managed by HHS and Department of Agriculture (USDA), will establish a standard operating procedure to establish control activities to help ensure that each component of FSAP carries out its inspection responsibilities as outlined in the interagency memorandum of understanding.

**Recommendation 4**

To improve independence, the CDC director of the Select Agent Program should regularly assess, such as through an external review, the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks; and take actions as necessary to ensure that any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives.

**HHS Response**

HHS concurs with GAO's recommendation.

FSAP will explore options, including re-examining previous reviews, and assess the need for additional review to ensure potential risks posed by the program's structures are adequately assessed and addressed.

**Recommendation 6**

To improve the ability to perform reviews, the CDC director of the Select Agent Program should work with APHIS to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities.

**HHS Response**

HHS concurs with GAO's recommendation.

As part of the initial inspection for an entity to obtain its registration, FSAP establishes an entity baseline that identifies the biological safety and security risk based on the work being performed with each select agent or toxin which the entity will be registered to possess. Follow-up inspections (periodic monitoring) and any departures from the regulations identified during these inspections

**GENERAL COMMENTS OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: COORDINATED ACTIONS NEEDED TO ENHANCE THE SELECT AGENT PROGRAM'S OVERSIGHT OF HAZARDOUS PATHOGENS (GAO-17-770)**

are used to reassess the baseline risk, mitigation factors in place and the residual risk. The frequency of verification inspections at an entity is dependent on this risk assessment in conjunction with any incidents or compliance matters that have been identified with the entity. FSAP is transitioning to a new secure information system. With the new system, FSAP plans to develop analytical tools and procedures to analyze the data for risk to improve the inspection process.

**Recommendation 8**

To improve transparency, the CDC director of the Select Agent Program should work with APHIS to determine what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the program to share with registered laboratories.

**HHS Response**

HHS concurs with GAO's recommendation.

FSAP is currently exploring avenues for disseminating information regarding common deficiencies identified during inspections and an analysis of data related to potential occupational exposures to select agents and toxins that identify common causes and provide recommendations for prevention. It should be noted that the HHS-Office of Inspector General already posts information on their website regarding select agent violations that results in civil monetary penalties being assessed.

**Recommendation 10**


To improve technical expertise and overcome fragmentation, the CDC director of Select Agent Program should work with APHIS to develop a joint workforce plan that assesses workforce and training needs for the program as a whole. This assessment should be done in conjunctions with the development of the strategic plan.

**HHS Response**

HHS concurs with GAO's recommendation.

FSAP has initiated contract support to guide us through the development of a joint strategic plan that will include the assessment of workforce and training needs for staff.

## Appendix IV: Comments from the Department of Agriculture

 United States Department of Agriculture	
<p>Animal and Plant Health Inspection Service</p> <p>Office of the Administrator</p> <p>1400 Independence Avenue SW Washington, DC 20250</p>	<p style="text-align: right;">SEP 21 2017</p> <p>Mr. John Neumann, Director Natural Resources and Environment Government Accountability Office 441 G Street NW Washington, DC 20548</p> <p>Dear Mr. Neumann:</p> <p>Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens" (17-770). We have addressed the six Recommendations made to the Animal and Plant Health Inspection Service (APHIS).</p> <p><b><u>Recommendation #1</u></b> <b>To improve independence, the Administrator of APHIS should formally document the reporting structure for the APHIS component of the Select Agent Program from the APHIS director of the program to the Administrator of APHIS.</b></p> <p><b><u>USDA Response</u></b> USDA agrees with this Recommendation. APHIS will develop a document which clearly outlines the communication, reporting and oversight activities of the APHIS Administrator and the select agent program Director.</p> <p><b><u>Recommendation #3</u></b> <b>To improve independence, the APHIS director of the Select Agent Program should work with CDC to establish control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding.</b></p> <p><b><u>USDA Response</u></b> USDA agrees with this Recommendation. The Federal Select Agent Program (FSAP), which is jointly managed by USDA and the U.S. Department of Health and Human Services (HHS), will establish a standard operating procedure (SOP) to establish control activities to help ensure that each component of FSAP carries out its inspection responsibilities as outlined in the interagency memorandum of understanding.</p>
<small>An Equal Opportunity Provider and Employer</small>	

**Recommendation #5**

**To improve independence, the APHIS director of the Select Agent Program should regularly assess, such as through an external review, the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks; and take actions as necessary to ensure any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives.**

**USDA Response**

USDA agrees with this Recommendation. FSAP will explore options, including re-examining previous reviews, and assess the need for additional review to ensure potential risks posed by the program's structures are adequately assessed.

**Recommendation #7**

**To improve the ability to perform reviews, the APHIS director of the Select Agent Program should work with CDC to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities.**

**USDA Response**

USDA agrees with this Recommendation. As part of the initial inspection for an entity to obtain its registration, FSAP establishes an entity baseline that identifies the biological safety and security risk based on the work being performed with each select agent or toxin for which the entity will be registered to possess. Follow-up inspections (periodic monitoring) and the departures of the regulations identified during these inspections are used to reassess the baseline risk, mitigation factors in place and the residual risk. The frequency of verification inspections at an entity is dependent on this risk assessment in conjunction with any incidents or compliance matters that have been identified with the entity. FSAP is transitioning to a new secure information system. With the new system, FSAP plans to develop procedures to analyze the data for risk to improve the inspection process.

**Recommendation #9**

**To improve transparency, the APHIS director of the Select Agent Program should work with CDC to determine what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the program to share with registered laboratories.**

**USDA Response**

USDA agrees with this Recommendation. FSAP is currently exploring avenues for disseminating information regarding common deficiencies identified during inspections and an analysis of data related to potential occupational exposures to select agents and toxins that identify common causes and provide recommendations for prevention.

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**Recommendation #11**

To improve technical expertise and overcome fragmentation, the APHIS director of the Select Agent Program should work with CDC to develop a joint workforce plan that assesses workforce and training needs for the program as a whole. This assessment should be done in conjunction with the development of the strategic plan.

**USDA Response**

USDA agrees with this Recommendation. FSAP has initiated contract support to guide us through the development of a joint strategic plan that will include the assessment of workforce and training needs for staff.

Sincerely,



Kevin Shea  
Acting Deputy Under Secretary  
Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer



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## Appendix V: GAO Contacts and Staff Acknowledgments

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### GAO Contacts

Timothy M. Persons, (202) 512-6412 or [personst@gao.gov](mailto:personst@gao.gov)

John Neumann, (202) 512-3841 or [neumannj@gao.gov](mailto:neumannj@gao.gov)

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### Staff Acknowledgments

In addition to the individuals named above, Mary Denigan-Macauley (Assistant Director), Sushil Sharma (Assistant Director), Amy Bowser, William Carrigg, Marcia Crosse, Caitlin Dardenne, Shana Deitch, Karen Doran, Jack Melling, Cynthia Norris, Lesley Rinner, Sara Sullivan, Walter Vance, and Elizabeth Wood made key contributions to this report.

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# Appendix VI: Accessible Data

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## Data Tables

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**Data Table for Figure 1: Laboratories Registered with the Federal Select Agent Program by Biological Safety Level (BSL), Sector, and Lead Agency as of December 2016**

### BSL3

Sector	Number of Labs
Academic	78
Commercial	22
Federal	29
Nonfederal government	78
Private	14
Total	221

### BSL4

Sector	Number of Labs
Academic	2
Federal	5
Private	1
Total;	8

**BSL 2 Total Labs = 87**

### Labs by Lead Agency

Lead Agency	Number of laboratories
CDC	238
APHIS	38

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**Data Table for Figure 4: Types of Federal Select Agent Program (Select Agent Program) Inspections**

New registration or 3-year renewal inspections:

- Take place before new laboratories can be registered with the Select Agent Program and every 3 years upon renewal.
- Are the most common and comprehensive inspection type.
- May take 2 inspectors about 2 days to complete for small laboratories, or up to 10 inspectors up to 2 weeks for large laboratory complexes.

12 - 18 months later

**Verification inspections:**

- Generally take place at all registered laboratories at least once between each 3-year renewal inspection.
- Are often unannounced to verify laboratories have resolved prior deficiencies.
- Focus on specific areas such as security, biological safety, and previously noted deficiencies.

As needed

**Compliance inspections:**

- Take place after a loss or significant release of a select agent, an occupational exposure, or serious uncorrected deficiencies.
- Can be announced or unannounced.
- May result in a referral to the Department of Health and Human Services Office of Inspector General, the Animal and Plant Health Inspection Service Investigative and Enforcement Services, or the Federal Bureau of Investigation if significant violations have occurred.

Registration amendment inspections:

- Take place when laboratories propose major changes to their registrations to verify that changes are in compliance with the select agent regulations. Such changes may include the addition of new select agents, new laboratory space, or changes to work objectives.

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## Agency Comment Letters

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### Text of Appendix III: Comments from the Department of Health and Human Services

#### Page 1

SEP. 21, 2017

Timothy M. Persons

Director, Natural Resources and Environment

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548 Dear Mr. Persons:

Attached are comments on the U.S. Government Accountability Office ' s (GAO) report entitled, "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens" (GAO-17-770).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

#### Page 2

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## **Recommendation 2**

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### **HHS Response: HHS concurs with GAO's recommendation.**

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## **Recommendation 4**

To improve independence, the CDC director of the Select Agent Program should regularly assess, such as through an external review, the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks; and take actions as necessary to ensure that any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives.

### **HHS Response: HHS concurs with GAO's recommendation.**

FSAP will explore options, including re-examining previous reviews, and assess the need for additional review to ensure potential risks posed by the program's structures are adequately assessed and addressed.

## **Recommendation 6**

To improve the ability to perform reviews, the CDC director of the Select Agent Program should work with APHIS to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities.

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**HHS Response: HHS concurs with GAO' s recommendation.**

FSAP has initiated contract support to guide us through the development of a joint strategic plan that will include the assessment of workforce and training needs for staff.

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**Text of Appendix IV: Comments from the Department of Agriculture**

Page 1

SEP. 21, 2017

Mr. John Neumann, Director Natural Resources and Environment  
Government Accountability Office 441 G Street NW

Washington, DC 20548 Dear Mr. Neumann:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens" (17- 770). We have addressed the six Recommendations made to the Animal and Plant Health Inspection Service (APHIS).

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Sincerely,

Kevin Shea

Acting Deputy Under Secretary Marketing and Regulatory Programs

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