

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 or John Neumann at (202) 512-3841 or 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.