

GAO Highlights

Highlights of [GAO-16-642](#), a report to congressional committees

Why GAO Did This Study

Several incidents involving the shipment of live pathogens, thought to be inactivated, have recently occurred, potentially exposing people to dangerous pathogens that cause infectious diseases, such as the bacterium that causes anthrax.

GAO was asked to evaluate issues related to inactivation of pathogens in high-containment laboratories. This report examines (1) the extent to which incidents involving incomplete inactivation occurred from 2003 through 2015, (2) any challenges that may affect the implementation of inactivation in high-containment laboratories, and (3) the extent to which the Select Agent Program referred violations and enforced regulations related to incidents involving incomplete inactivation. GAO convened an expert meeting with the assistance of the National Academy of Sciences to discuss various issues surrounding inactivation. GAO also reviewed relevant laws, regulations, and guidance, and interviewed officials at laboratories that conduct inactivation.

What GAO Recommends

GAO is making six recommendations to HHS and USDA to, among other things, improve the Select Agent Program's oversight of inactivation by revising reporting forms, improving guidance for development and validation of inactivation protocols, and developing consistent criteria for enforcement of incidents involving incomplete inactivation. HHS and USDA agreed with GAO's recommendations.

View [GAO-16-642](#). For more information, contact Timothy M. Persons, Ph.D. at (202) 512-6412 or personst@gao.gov or John Neumann at (202) 512-3841 or neumannj@gao.gov.

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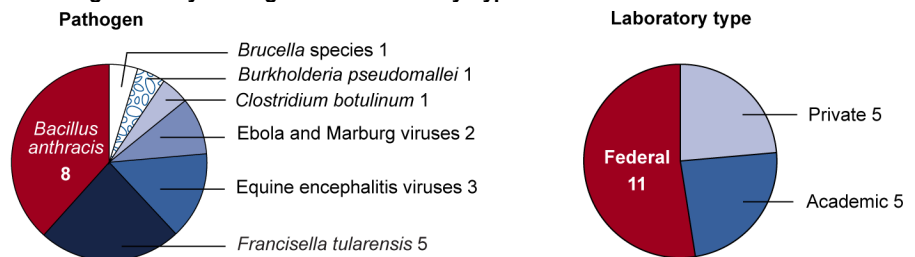
HIGH-CONTAINMENT LABORATORIES

Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk

What GAO Found

The total number of incidents involving incomplete inactivation—a process to destroy the hazardous effects of pathogens while retaining characteristics for future use—that occurred from 2003 through 2015 is unknown for several reasons. One key reason is that the Select Agent Program—operated by the Departments of Health and Human Services (HHS) and Agriculture (USDA) to oversee certain dangerous pathogens, known as select agents—does not require laboratories to identify such incidents on reporting forms. According to the program, 10 incidents occurred from 2003 through 2015. However, GAO identified an additional 11 incidents that the program did not initially identify. Because the program cannot easily identify incidents involving incomplete inactivation, it does not know the frequency or reason they occur, making it difficult to develop guidance to help mitigate future incidents. The 21 identified incidents involved a variety of pathogens and laboratories, as shown below.

Figure: Twenty-one Identified Incidents Involving Incomplete Inactivation that Occurred from 2003 through 2015 by Pathogen and Laboratory Type



Source: GAO analysis of information from the Federal Select Agent Program. | GAO-16-642

Several challenges affect the implementation of inactivation in high-containment laboratories, including gaps in scientific knowledge and limited guidance. For example, there is limited federal guidance for researchers on the development and validation of inactivation protocols. Validation helps ensure protocols are scientifically sound and produce consistent results. Due to limited guidance, laboratories varied in their interpretation of validated methods of inactivation, resulting in researchers applying differing levels of rigor. Without more comprehensive guidance, as called for by experts, protocols will vary in their scientific soundness, increasing the risk of incomplete inactivation.

The Select Agent Program did not consistently refer incidents involving incomplete inactivation for further investigation and enforcement for violations of select agent regulations. For example, the program referred incidents involving incomplete inactivation at various laboratories, but did not refer two incidents in 2014 that occurred at HHS. A memorandum of understanding between HHS and USDA states that the program should handle incidents consistently. GAO found, however, that the program does not have a consistent, written set of criteria for handling incidents. Without such criteria, the program risks inconsistent enforcement of select agent regulations. This further highlights GAO's previous finding that existing federal oversight of high-containment laboratories is fragmented and self-policing.