

Why GAO Did This Study

Between 2009 and 2011, there were roughly 374 entities across the United States conducting research with select agents such as anthrax, which have the potential to threaten health and safety. Inspections are one means of ensuring safety and compliance with regulations. However, several federal agencies—CDC, APHIS, DOT, DHS, and DOD—conduct such inspections, creating significant potential for overlap and duplication of effort. In this context, GAO was asked to assess (1) the extent of overlap and potential duplication in federal inspections of select agent entities, (2) the costs of such overlap and effects on laboratory operations, and (3) actions to reduce the costs and negative effects of any overlap. To answer these objectives, GAO analyzed agency data, surveyed entities, held focus groups with lab staff, and interviewed agency officials.

What GAO Recommends

GAO recommends that CDC and APHIS work with DHS and DOD to coordinate inspections and ensure consistent application of inspection standards.

HHS, USDA, DHS, and DOD generally agreed with our recommendations and noted various actions they have already taken, or plan to take, to coordinate inspection efforts.

OVERLAP AND DUPLICATION

Federal Inspections of Entities Registered with the Select Agent Program

What GAO Found

About 15 percent of entities registered to work with select agents were subject to inspection overlap (multiple federal agencies inspecting within a 2-year period). Entities experiencing overlap tended to be larger ones, with more laboratories, principal investigators, and staff. Although there was overlap between Department of Transportation (DOT) inspections and those of the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), they were generally not duplicative because specific inspection activities tended to differ, according to GAO's survey of entities experiencing overlap. For example, DOT inspections tended to focus on transportation issues, such as checking hazardous materials and transportation security plans, rather than general biosafety issues. The Department of Homeland Security (DHS) and Department of Defense (DOD) inspections, however, tended to be more duplicative with those of CDC and APHIS. For example, both review the same documents, require safety and security demonstrations, conduct inventory inspections and personnel interviews, and provide corrective action plans. While inspections are important for safety and compliance, there is no value added when federal agencies are expending resources to conduct the same work and, in some cases, reinspecting before entities have had time to respond to findings from a previous inspection.

The costs of overlapping federal inspections and effects on lab operations are difficult to quantify because agencies and entities generally do not track them and some costs are not quantifiable. Although GAO could not quantify the portion of federal and entity costs directly attributable to overlap, it could quantify the costs of inspections in general. According to agency data, the approximate overall federal cost for fiscal years 2010 and 2011 inspections was \$2.1 million dollars. On average, the entity costs per inspection were nearly \$15,000, and staff time per inspection was 380 hours, according to the GAO survey. While surveyed entities reported that inspections can help correct deficiencies and improve accountability, most reported moderate to significant nonquantifiable costs of inspections due to loss of productivity and delays in research. In addition, according to surveyed entities, overlapping inspections negatively affected lab productivity, staff morale, available time to complete research, and the research schedule. Because many of these entities are federal laboratories or are funded through federal grants, these costs are passed on to the federal government.

Actions to reduce the costs of overlapping and duplicative inspections include better coordination among federal agencies and greater consistency in the application of standards, according to various experts and surveyed entities. CDC has taken actions to better coordinate inspections with other agencies, for example, by increasing the use of joint inspections. But such actions, including joint inspections, do not fully address the negative effects of multiple inspections if agencies apply inconsistent standards and develop separate reports of findings. Well-trained inspectors, who apply consistent standards, are also needed. Collectively, these actions would reduce the negative effects of overlap and duplication and could increase agencies' acceptance of each other's inspection results.