# Written Testimony
# House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

## Oversight of Hazardous Pathogens under the Federal Select Agent Program

***Statement of***


## Samuel S. Edwin, PhD

*Director, Division of Select Agents and Toxins*
*Office of Public Health Preparedness and Response*
*Centers for Disease Control and Prevention*
*Department of Health and Human Services*


**For Release upon Delivery**
**Expected at 10:15 a.m.**
**Thursday November 2, 2017**

Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Samuel S. Edwin, Director of the Division of Select Agents and Toxins (DSAT), which resides within the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention (CDC). I -- along with my counterpart at the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service/Agriculture Select Agent Services (AgSAS), Dr. Freeda Isaac -- direct the Federal Select Agent Program (FSAP or program). I have held this position for just over one year, and welcome this opportunity to testify before you. I appreciate the Subcommittee's continued interest in improving oversight of laboratories that work with select agents and toxins to ensure that this important work is done in as safe and secure a manner as possible.

Laboratory research on biological select agents and toxins plays a critical role in saving lives and protecting Americans. It is also an important part of our nation's contribution to support preparedness and defense against naturally occurring diseases and potential bioterrorism events. However, the nature of scientific laboratory work with these materials means that some risk is always present. Our goal is to reduce risk to the maximum extent possible.

I will provide a brief background of our program and CDC's role and responsibilities implementing the FSAP, followed by a discussion of steps taken to strengthen the FSAP and enhance the safety and security of high-containment laboratories regulated under this program.

**Background on the Federal Select Agent Program**

The regulation of select agents and toxins is a shared federal responsibility involving the Department of Health and Human Services (HHS), Department of Agriculture, and Department of Justice (DOJ). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) authorizes HHS to regulate the possession, use, and

transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The Secretary of HHS delegated this authority to CDC. USDA was given similar authority to regulate select agents and toxins that have the potential to pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting security risk assessments of entities and individuals prior to their possession, use, or transfer of select agents or toxins. DOJ delegated this authority to the Federal Bureau of Investigation (FBI). This oversight helps prevent access to these pathogens and toxins by terrorists or others who may wish to misuse them.

The FSAP promotes laboratory biosafety and security through: (1) promulgating, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR 331); (2) providing guidance to the regulated community; and (3) inspecting facilities that work with select agents and toxins to verify that the laboratories meet safety, security and record-keeping requirements. Under these regulations, entities must undergo a rigorous registration process and obtain approval before they can possess and work with select agents and toxins. At the end of 2016, 276 entities -- including academic, non-federal government, federal government, and private laboratories -- were registered with the FSAP to possess select agents and toxins. The program currently regulates 66 select agents and toxins. The list of biological select agents and toxins is reviewed at least once every two years to determine if agents or toxins need to be added to or deleted from the list.

Key functions and activities of the FSAP include:

- Maintaining a national database of entities and individuals authorized to work with select agents and toxins. This database serves several functions, including: allowing the program to proactively reach out to entities in advance of and following natural disasters

or other events to ensure all select agents and toxins are properly secured; and enabling the federal government to quickly identify those authorized to have access to particular agents, when needed, in connection with an investigation;

- Establishing requirements to prevent unauthorized access to, or theft, loss, or release of, select agents and toxins, and assessing compliance of registered entities with these requirements;
- Receiving reports of theft, loss, or release, following up with each entity to ensure appropriate actions are taken to prevent similar incidents from happening in the future, and notifying appropriate authorities;
- Taking appropriate enforcement action when deficiencies in biosafety or security measures are identified, including referring a matter to the HHS Inspector General (HHS IG) or the FBI, to address the risk and increase compliance with regulations in the future; and
- Serving as a resource on the regulations by providing guidance to those working with select agents and toxins, interpreting the regulations to help entities follow the requirements, and conducting training and outreach to increase knowledge of and compliance with the regulations.

**Strengthening Oversight under the FSAP Program**

Maximizing safety and security through oversight at the FSAP-regulated laboratories is an unending endeavor, not something that can be checked off a list. I would like to acknowledge the important contribution that the Government Accountability Office's (GAO) continued engagement and recommendations for FSAP have made in our work to improve the program.

DSAT accepts and will implement all of GAO's recommendations in its current report. Below I will highlight some steps that DSAT, in partnership with USDA, has taken to strengthen oversight of facilities registered to work with select agents and toxins. And you have my commitment to continue efforts to improve the system for oversight of these facilities.

*Independence*:

To ensure our independence in regard to our role in regulating laboratories, DSAT entered into a Memorandum of Understanding (MOU) with AgSAS in 2012, under which AgSAS leads all select agent inspections of CDC laboratories. AgSAS and DSAT recently modified the MOU by strengthening procedures to delineate roles and responsibilities to ensure each component of the FSAP carries out its inspection responsibilities as outlined in the MOU. The MOU supplements structural safeguards that have been in place since 2003: DSAT is located within the Office of Public Health Preparedness and Response (OPHPR), a part of CDC that does not include any laboratories and has a separate reporting line to the CDC Director. We believe that the MOU designating AgSAS as the lead inspector for CDC laboratories, and the organizational separation between DSAT and CDC's regulated laboratories, provide strong protections against any actual or perceived conflict of interest.

*Ability to Perform Reviews: Risk-Based Oversight*:

The FSAP has taken a number of steps to identify the highest risk activities conducted at registered entities and ensure that these activities are targeted in inspections.

As part of the initial inspection to determine whether to approve an entity's application for FSAP registration, which authorizes the entity to conduct specified work with select agents and toxins, the FSAP establishes a baseline that identifies the biological safety and security risk of the work to be done with each select agent or toxin the entity will possess. The program can

then, based on findings in the course of follow-up inspections, reassess the baseline risk, the mitigation factors in place to reduce the risk, and the residual risk such as any identified departures from the biosafety and security requirements of the select agent regulations. FSAP can determine the frequency of verification inspections at an entity based on the initial risk assessment, in conjunction with any findings or assessments from subsequent inspections or reassessments, incidents or compliance matters. In addition, FSAP identifies inspection findings as having a low, moderate, or high severity, based on the risk they pose. This contributes to the assessment of risk at an individual facility and enhances our ability to identify and address across the regulated community recurring violations that pose the greatest risk.

Also at a programmatic level, when FSAP identifies processes that present a high risk, the FSAP works to reduce that risk across registered entities, as applicable. Such was the case in response to incidents in 2014 – 2015 involving incomplete inactivation of *Bacillus anthracis* spores that are produced by the bacteria that causes anthrax. FSAP requested that registered entities observe a voluntary moratorium on the transfer and use of anthrax samples that had undergone inactivation, and subsequently amended the select agent regulations to specifically address inactivation. On January 19, 2017, FSAP published the Final Rule "Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements" that included additional biosafety requirements and specific provisions for the inactivation of select agents. In conjunction with publication of the new regulatory provisions, FSAP published a guidance document on the inactivation or removal of select agents and toxins for future use.

In addition, FSAP is in the process of transitioning to a new electronic information system, eFSAP. This system will allow the regulated community to interact with the program more

efficiently and allow for better and faster reporting of issues of potential public health concern. After eFSAP is implemented, FSAP will have greater real-time access to programmatic data such as registration amendments to change the number of select agents used at a facility, changes in personnel authorized to work with select agents and toxins, transfers of select agents to other facilities, and inspection reports. This access will expedite and enhance the ability of FSAP to monitor and analyze the data and identify potential risk, and thereby continually enhance oversight of biosafety and security.

*Technical Expertise*:

FSAP inspectors have the practical experience and advanced professional degrees (e.g., microbiology and veterinary medicine) necessary to perform reviews of select agent laboratories. That said, continued training of inspection staff is a key priority for the FSAP, and we have a robust training program for inspectors that we continually refine to address unmet training needs. FSAP training initiatives include sending staff to a multi-day in-person training course on biosafety level -3 (BSL-3) safety training and expanded opportunities for intensive BSL-4 training. In addition, FSAP holds regularly scheduled inspector training opportunities, occurring monthly or more frequently depending on the topic covered. Topics for these sessions include natural disaster response, facility reviews, facility security, and biosafety issues of interest. FSAP also organizes annual inspector trainings for both DSAT and AgSAS inspectors. The annual FSAP inspector training for 2017 is scheduled for this week (November 1-3, 2017). In addition, the FSAP is in the early stages of developing a joint DSAT (public health) and AgSAS (agriculture) strategic plan that includes assessment of workforce and training needs for staff across the program.

*Transparency:*

The FSAP has taken a number of steps to increase transparency and collaboration with the regulated community, including:

- Developing a formal process to publicly respond to requests for clarification regarding the select agent regulations (i.e., provide regulatory interpretations).
- As appropriate, sharing draft regulatory policies and interpretations, guidance documents, and intended actions with the regulated community before these efforts are finalized. This builds credibility and allows our stakeholders to provide valuable input into those issues that will affect their work.
- Implementing a formal dispute resolution process, which allows registered entities to dispute specific inspection findings.
- Hosting a three-day, in-person Responsible Officials training workshop in December 2016, which included the opportunity for peer-to-peer engagement of the regulated community with the FSAP, as well as networking between colleagues. The FSAP will host another Responsible Official workshop at the end of this month (November 2017).
- Establishing an independent forum, through the American Biological Safety Association (ABSA) International, to encourage routine peer-to-peer sharing regarding best practices among those working with select agents and toxins. ABSA International has supported online discussions, an in-person workshop, and webinars, thereby allowing the regulated community to share information and best practices with each other independent of the FSAP.

- Developing a post-inspection survey that allows registered entities the opportunity to provide feedback on their inspection experience.
- Continuing to create other opportunities to engage stakeholders through analysis and reporting of our program's findings, such as the reporting of aggregate program data via the *FSAP Annual Report* and the annual analysis of data related to the timeliness of inspection report processing via publication of the *DSAT Inspection Report Processing Annual Summaries*.

We also are exploring avenues for disseminating further information regarding common deficiencies identified during inspections, and an analysis of data related to potential occupational exposures to select agents and toxins, from which we are able to identify common causes and provide recommendations for prevention.

*Enforcement Authority*:

FSAP recently finalized the *Severity Spectrum of Inspection Departures and Enforcement Actions*, which outlines categories of noncompliance with regulations related to biosafety and security, grouped according to the level of severity, as well as related enforcement options that may be applied. The document provides awareness of how FSAP considers the severity of inspection findings. As I mentioned earlier, regulatory violations (departures) are now grouped into a three-tier risk scoring system in the categories of low, moderate, and serious severity levels. We provided the regulated community an opportunity for input and feedback during the development process, and posted the final version on the FSAP website. FSAP is also using this information to help ensure consistency between inspections. For example, analysis of this data informed training initiatives to reduce variability between inspectors. The training will be completed at our joint inspection training November 1-3, 2017.

**Conclusion**

FSAP is committed to further strengthening oversight of laboratories that handle select agents and toxins, and appreciates the input of GAO and other entities that have provided recommendations toward that end. We have and will continue to work diligently, thoughtfully, and collaboratively with our federal partners and others who share in our commitment to protect Americans from biological threats. We value the Subcommittee's input as we continue to improve our oversight and enhance the safety and security of laboratories working with select agents and toxins.

Thank you for the opportunity to testify. I would be glad to answer to any questions you may have.