

Testimony of

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Subcommittee on Oversight and Investigations
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Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify today about the role of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and its operation of the Federal Select Agent Program (FSAP). APHIS, through its Agriculture Select Agent Services (AgSAS), and the Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins jointly oversee the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products.

As director of the program, I can assure you that this is a mission that we take very seriously. We all recognize the importance of ensuring the safety, security, and proper use of these potentially dangerous agents. Every day, I and our employees, are working directly with laboratories and researchers to ensure they understand our select agent regulations and that they are following all proper protocols. Aside from developing and enforcing the select agent regulations, we provide guidance and clarification to laboratories about best practices and regulatory compliance. We want to make sure that the facilities we regulate are doing things right and that they can safely use and adequately secure these potentially deadly agents.

Over the last few years, we have received a number of recommendations from organizations that have evaluated the efficacy of our biosecurity and biosafety programs, and we have diligently worked to implement as many of those recommendations as we can. Whether it was the Federal Experts Security Advisory Panel (FESAP), the Fast Track Action Committee on the Select Agent Regulations (FTAC-SAR) or any of the recent Government Accountability Office (GAO) reviews, we have taken these recommendations seriously and used them to make the FSAP stronger and more accountable. I can confidently say that biosecurity and biosafety are stronger today than they were when I started.

Current Activities

We appreciate continued support from Congress for the Federal Select Agent Program. An increase in funding in FY 2017 allowed APHIS to strengthen the program's scientific and

technical capabilities. This funding has allowed APHIS to hire eight additional expert personnel who will increase the scientific and technical capabilities of AgSAS. One benefit is that more scientific and technical personnel will be involved in complex inspections, improving both the inspections' efficiency and the technical knowledge and knowledge transfer among our personnel. The additional staff will also allow us to improve our timeliness for registrations and renewals for new and existing facilities and individuals.

With the additional funding, we will also continue working to update and modernize the National Select Agent Registry (NSAR) database – APHIS/CDC's joint FSAP database. The two agencies are creating a new, more efficient and user-friendly platform that allows stakeholders to safely and more securely submit entity information directly. An improved database will also give us better and more real-time data to analyze for any potential risks, allowing us to fix potential problems before issues arise. The database and our other efforts will move us toward the goal of having aligning APHIS and CDC processes so that there is consistency across FSAP.

On the stakeholder front, we now have dedicated staff focused on improving our communication and training with registered entities to ensure that those we regulate fully understand their obligations under the select agent regulations.

The November GAO Audit on High-Containment Laboratories

We appreciate this latest GAO report on our select agent program. This is the most recent in a series of evaluations GAO has conducted of our program, and their past recommendations have helped to make this program stronger. We cooperated fully with this audit, agree with its recommendations, and have already taken steps toward implementing them.

Broadly, the audit determined that APHIS and CDC need to improve our coordination and ensure the independence of our programs within our Departments. We will continue work in carrying out these recommendations in the coming weeks and months.

Specifically, here is an update on what we will do in response to those recommendations for APHIS:

We agree that the independence of the select agent program is important, and think that minimizing any potential conflicts of interest with USDA laboratories is essential. In practice, I regularly meet with the APHIS Administrator's office to provide updates on the select agent program major activities, enforcement actions, and overall administration of the program. We are developing a document that will formally outline this relationship.

We also agree with the recommendation to work with CDC to establish control activities to help ensure each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding. While we have made great strides in aligning our two programs and improving consistency of inspections and operation, updating our joint formal standard operation procedure will greatly improve our ability to meet this goal.

We agree that we 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. We have a track record of both evaluating our own program and working with experts to develop recommendations for strengthening our program. We are considering various options with CDC to review the current structure.

We will work to carry out the recommendation to 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. However, I think it is important to note that the current inspection process does include some risk assessment and analysis activities. This includes establishing a baseline assessment that identifies the safety and security risk based on the work being performed and for which select agents and toxins the entity uses. We also determine the frequency of inspections dependent upon the risks of that facility combined with any incidents or compliance issues we have previously identified.

We have already worked very hard on the recommendation to improve transparency and increased our communications with stakeholders so they better understand the program and how to properly secure and use select agents and toxins.

Our efforts include our work to establish an independent forum to foster peer-to-peer sharing at workshops and webinars on best practices; the development of a formal process to respond to questions and provide guidance and interpretation about the select agent regulations; and the sharing of draft policies, interpretations and guidance documents with industry for feedback and clarification.

Lastly, to improve technical expertise and overcome fragmentation, we have already hired a contractor to help us prepare a joint strategic plan that will incorporate these recommendations, and have held several initial meetings with them.

Conclusion

APHIS and CDC are committed to having the strongest possible FSAP. We will take these GAO recommendations very seriously, as we have previous GAO recommendations and those of the other panels that have reviewed this program.

Our goal is the same as theirs: We want a program that allows our nation's scientists and researchers to be able to safely and securely conduct important work and development with select agent and toxins to advance human, animal, and plant safety.

I appreciate the opportunity to testify. I would be happy to answer any questions you or the members of this subcommittee may have.