

CATHY McMORRIS RODGERS, WASHINGTON
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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6115

Majority (202) 225-3641

Minority (202) 225-2927

September 15, 2023

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

The Honorable Tom Vilsack
Secretary
Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Dr. Cohen and Secretary Vilsack,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the safety and security of federal high-containment laboratories. We are writing to obtain further details about the performance and enforcement of the federal select agent program (FSAP), jointly managed by the CDC/Center for Preparedness and Response/Division of Select Agents and Toxins (DSAT), and the U.S. Department of Agriculture (USDA)/Animal Plant Health Inspection Service (APHIS)/Veterinary Services/Agriculture Select Agent Services.

This Committee has a continuing oversight interest in the FSAP and compliance with the Select Agent Regulations (SAR). For example, on April 27, 2023, the Subcommittee on Oversight and Investigations held a hearing on biosafety and risky research, including discussion about the FSAP. According to the seven published FSAP Annual Reports from 2015 - 2021¹:

- The FSAP conducted 1,316 inspections: 173 by the Agriculture Select Agent Services, 857 by the Division of Select Agents and Toxins, and 286 joint inspections by CDC's DSAT and USDA's APHIS;

¹ The FSAP has not yet published its annual report for 2022.

- The FSAP conducted 46 compliance inspections;²
- 17 entities participated in the FSAP Corrective Action Plan program;
- The FSAP made 20 referrals to the HHS OIG and/or the Animal and Plant Health Inspection Service Investigative and Enforcement Services.

To assist the Committee's oversight of FSAP, please provide further details and related documents by September 29, 2023:

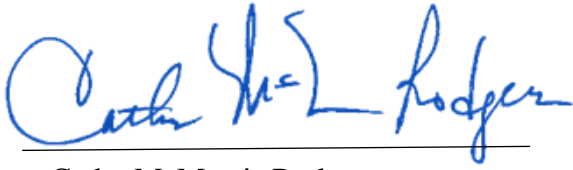
1. Please provide copies of all referrals the FSAP has made to the Department of Health and Human Services (HHS) Office of Inspector General and/or APHIS Investigative and Enforcement Services since January 1, 2015. Please provide the outcomes of these referrals.
2. According to the 2020 Annual Report, FSAP received one report involving a complaint about transportation issues that were unrelated to the SAR. FSAP referred this complaint to the Food and Drug Administration and the Department of Transportation. Please provide a copy of this referral. Please provide the outcome of this referral.
3. According to the 2020 Annual Report, FSAP referred an entity to the FDA for issues related to vaccine development. Please provide a copy of this referral. Please provide the outcome of this referral.
4. Please provide copies, if any, of all notifications to FSAP of SAR violations from FDA, CDC, or NIH. Please provide all documents related to the site visits conducted in response to these notifications.
5. Please provide copies of all FSAP compliance inspections conducted at laboratories at FDA, NIH, and CDC since January 1, 2015.
6. Since January 1, 2015, please list all entities levied civil money penalties as a result of FSAP enforcement actions, the nature of the violations, the kinds of pathogens involved, amount of the penalties, and the total amount of civil money penalties collected. Did any federal government entity have SAR violations that would have subjected a non-federal entity to civil money penalties? If so, which ones, and why were civil money penalties not levied?
7. Since January 1, 2015, please list all entities that have withdrawn from the FSAP, the reasons the entity withdrew from the FSAP, and whether the withdrawal was voluntary.

² The 2015 Annual Report did not include a specific number for compliance inspections.

8. How many entities are or were suspended from doing any select agent research? Please list the entities and explain why each of these entities was suspended, the period of suspension, and the reason for reinstatement.
9. Since January 1, 2015, please list the federal government entities participating in the FSAP Corrective Action Plan (CAP) program, and provide documents related to their participation.
10. Is the FSAP Performance Improvement Plan the same as the FSAP CAP program? If not, please explain the differences, and list the federal government entities participating in FSAP Performance Improvement Plans since January 1, 2015, and provide documents related to their participation.
11. For 2015-2021, the FSAP reported conducting 1,316 inspections. How many of those inspections were unannounced inspections?
12. Since December 22, 2022, has there been a release, loss, or theft of an agent or toxin listed as a federal select agent from or within a laboratory facility owned or operated by the HHS, or any other Federal laboratory facility?
 - (a) If so, was there a notification to this committee or the Committee on Health, Education, Labor and Pensions of the Senate no later than 72 hours after such event was reported to the HHS Secretary, including (1) the Federal laboratory facility in which such release, loss, or theft occurred; (2) the circumstances of such release, loss, or theft? If not, why not?
 - (b) Not later than 14 days after such notification to the committees, was an update provided to the committees on (1) any actions taken or planned by the HHS Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and (2) any actions taken or planned by the HHS Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.
13. Is an annual report being prepared on the number and nature of notifications, actions taken to address incidents, and description of gaps in safety and security practices to be submitted to the committees?

If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-3641. Thank you for your attention to this request.

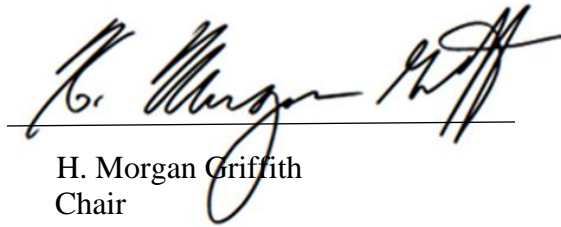
Sincerely,

A handwritten signature in blue ink, reading "Cathy McMorris Rodgers", written over a horizontal line.

Cathy McMorris Rodgers
Chair
Energy and Commerce Committee

A handwritten signature in blue ink, reading "Brett Guthrie", written over a horizontal line.

Brett Guthrie
Chair
Subcommittee on Health

A handwritten signature in blue ink, reading "H. Morgan Griffith", written over a horizontal line.

H. Morgan Griffith
Chair
Subcommittee on Oversight and Investigations

cc: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee
Anna Eshoo, Ranking Member, Subcommittee on Health
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations