

How the Federal Select Agent Program Addresses Serious Biosafety or Security Concerns

Options May Include:

Corrective Action Plan

- Addresses serious and recurrent concerns that do not present an imminent risk to public health and safety
- Participation is voluntary; if entity chooses not to participate, they must successfully resolve the regulatory departures identified within 30 days
- Entity submits a detailed plan to the Federal Select Agent Program (FSAP), including target completion dates and the specifics of how the entity will correct identified regulatory deficiencies
- Allows FSAP to monitor an entity's progress, as well as provide any needed technical assistance



Referral for Civil Penalties

- May include referral to the Department of Health and Human Services Office of Inspector General or the Animal and Plant Health Inspection Service Office of Investigative and Enforcement Services
- Reflects serious violations of the regulations (e.g., if a suspension is issued, false information is knowingly submitted, or in case of continued failure to resolve regulatory concerns)
- Referred for further investigation and may take place concurrently with other enforcement actions
- Can lead to civil monetary penalties levied by these agencies (up to \$250,000 for an individual for each violation and up to \$500,000 for an entity for each violation)



Notification to the Federal Bureau of Investigation

- Used when there may have been a violation of federal criminal law (e.g., in the case of security-related concerns, unauthorized possession, or reports of theft of a select agent or toxin)
- In addition, FBI is automatically informed of any reported loss for awareness and potential investigation
- May take place concurrently with other enforcement actions
- Can lead to criminal penalties



Suspension

- Used when FSAP has significant concerns for the health and safety of humans, animals, or plants because of the entity's failure to comply with the regulations
- Can be a complete or partial suspension of work
- Registration remains suspended until concerns are properly addressed



Revocation

- In the most serious of circumstances, or in the case of repeated failures to maintain compliance with the regulations, FSAP has the authority to revoke an entity's registration to work with select agents and toxins (e.g., if the entity is unwilling or unable to meet the requirements of the regulations)

