Emerging Select Agent Issues and Regulations

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Key Issues in 2015: A Tumultuous Year

- Investigation of two major release incidents
- Larger and more complex select agent facilities
- Prepared the Notice of Proposed Rulemaking for the Biennial review of the select agents and toxins list
- Federal Select Agent Program (FSAP) reviews
- Issued policies and guidance
- Convened subject matter experts
- Published studies of FSAP data on transfers and restricted experiment requests
Key Issues in 2016: Program Improvement

- Address recommendations from FSAP reviews
  - Improving entity oversight
  - Improving incident response
  - Improving engagement with the regulated community
  - Increasing transparency and public understanding

- Develop and Implement the Final Rule for the Select Agent Regulations
In Oct. 2015, three sets of reviews and recommendations were released, all designed to strengthen the federal government’s biosafety and biosecurity practices and oversight:

- Internal CDC 90-day review
- Two USG-wide reports ordered by the White House:
  - External experts - “Fast Track Action Committee on Select Agent Regulations” (FTAC)
Emphasis on:

- Improving entity oversight
- Improving incident response
- Improving engagement with the regulated community
- Increasing transparency and public understanding
Key Progress

- Oversight
  - Enhanced training to departures requiring most judgment
  - Tracking timeliness quarterly with intent to release annual reports; issuing interim reports
  - Auditing inspection reports
  - Involving a technical editor
  - Studying violations to align with risk and consequences
  - Piloting risk scoring of inspections
  - Implementing a dispute resolution process for inspection reports
  - Commissioned study on biosafety risk assessment and alternative regulatory models
  - Convening experts regarding high-risk procedures
Key Progress

- **Incident Response**
  - Emergency operations
  - Form 3 update to clarify theft/loss/release reporting requirements
  - Reporting results and clarifying terminology

- **Entity Engagement**
  - Regulatory interpretations
  - Comment period preceding issuance of new policy
  - Post-inspection survey
  - RO Training

- **Public Transparency**
  - Annual public report (aggregate data)
  - Deliberative security review process for information release
Key Progress

- Also working on:
  - New electronic information system to improve the customer experience, increase efficiency of inspection staff, and support quality improvement through routine analysis and reporting of performance metrics
  - Creating an analytic database from past three years of inspections and incident reports to identify risk associations and improve program effectiveness
  - International engagement to encourage related programs
  - Priority issues: inactivation and exclusions; inventory management; culture of safety/security and incident reporting
“Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements”

- Proposes reductions to the list of select agents and toxins
- Proposes enhanced biosafety and biosecurity requirements
- Aligns language in USDA with HHS regulations

Public Comment Period January 19-March 21, 2016

Available at https://federalregister.gov/a/2016-00758
Reductions to the List

- Based upon recommendations of the Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) and public comments received during the Advanced Notice of Proposed Rulemaking (ANRPM) in 2015

- CDC is proposing to amend the HHS list of select agents and toxins by removing 6 agents/1 toxin set:
  - *Coxiella burnetii*
  - *Rickettsia prowazekii*
  - *Bacillus anthracis* Pasteur strain
  - *Brucella abortus, B. melitensis, and B. suis*
  - *Short, paralytic alpha-conotoxins*
Changes to Toxin Requirements

- Based upon recommendations of the 2015 Intragovernmental Toxin Working Group
  - Due Diligence
  - Increase Regulatory Exclusion Limits
  - Exclusion of original food samples, clinical samples, byproducts
  - Notification of identification (specimen provider and Form 4)
Remove:

Peronosclerospora philippinensis
(Peronosclerospora sacchari)
Sclerophthora rayssiae
Phoma glycinicola (formerly Pyrenochaeta glycines)
Remove:

Bacillus anthracis (Pasteur strain)
Brucella abortus
Brucella suis

Retain:

Brucella melitensis
Inactivation.
A method to render a select agent non-viable but retain characteristic of interest for future use, or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Kill curve.
The results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable, or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.
Enhanced Biosafety and Biosecurity

- Rulemaking also proposes:
  - New requirements to address the inactivation of select agents
  - Adds specific biosafety provisions
  - Clarifies regulatory language concerning security, training, incident response, and records

- Addresses recent recommendations of the two parallel USG-wide biosafety and biosecurity reviews, the White House’s Fast Track Action Committee (FTAC) and the Federal Experts Security Advisory Panel (FESAP)
NPRM Next Steps

- Invite further comments on proposed reductions to the list of select agents and toxins, as well as the enhanced biosafety and biosecurity requirements
  Available at https://federalregister.gov/a/2016-00758

- Following opportunity for the public comment on the proposed changes (60 days), input received will be considered during the finalization of the regulations
Looking Forward

- **Nature of work means evolving program responsibilities and challenges**

- **Priorities in 2016:**
  - Implement recommendations from reviews
  - Use data to guide program improvements
  - Increasing internal and external training
  - Improve IT systems
  - Increase capacity of the program
Discussion

www.selectagents.gov

For more information please contact Centers for Disease Control and Prevention

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