

Update: Regulation of Select Agents and Toxins in the U.S.



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Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Evolution of Select Agent and Toxin Regulations



Select Agent Biosafety Policy Issues

“Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the U.S.”

U.S. House of Representatives Committee on
Energy and Commerce

October 4, 2007

Congressional Concerns Discussed at October 2007 Hearing

- Uncoordinated proliferation of BSL-3 and BSL-4 laboratories in the U.S.
- Inadequate federal oversight of BSL-3 and BSL-4 laboratories

Division of Select Agent and Toxins (DSAT) Improvements Discussed at October 2007 Hearing

- Improved oversight:
 - Review additional documents prior to site visit
 - More in-depth interviews of workers
 - From “Trust” to “Trust, but Verify”
- External Review of DSAT
- Better outreach to the regulated community
- Trans-Federal Taskforce Study

2008-2009 Select Agent Biosecurity Reviews

- *Enhancing Personnel Reliability among Individuals with Access to Select Agents.* National Science Advisory Board on Biosecurity
- *Responsible Research with Biological Select Agents and Toxins.* National Research Council
- *Dept. of Defense Biological Safety and Security Program.* Defense Science Board
- *Perimeter Security Assessment of the Nation's five BSL-4 Laboratories.* GAO-08-1092
- *World At Risk.* Weapons of Mass Destruction Commission
- Executive Order (EO) 13486 Working Group on Strengthening Biosecurity in the U.S.

Executive Order 13486: Working Group on Strengthening Biosecurity in the U.S.

- Establish Interagency Working Group to Review the Effectiveness of:
 - Existing Biological Select Agent and Toxins (BSAT) laws, regulations and policies
 - Physical, facility, and personnel security practices
- Establish a report including:
 - Assessment of BSAT laws, regulations, and policies
 - Recommendations for new legislation, regulations or guidance

EO 13486 Working Group Recommendations: Select Agent Regulations

- Review/stratify the Select Agent Lists
- Improve inspection coordination
- Provide Guidance on
 - Inventory management
 - Recordkeeping

EO 13486 Working Group Recommendations: Personnel Security

- Federal Level: Enhance Security Risk Assessment Process
- Local Level: Require continuous monitoring of supervisor accountability; self-peer reporting

EO 13486 Recommendations: Physical Security

- Develop minimum prescriptive security standards for regulated entities

Executive Order 13546: Optimizing the Security of Biological Select Agents and Toxins in the United States

- Tiered/Reduced Select Agent List
- Federal Expert Security Advisory Panel
 - Recommendations on strengthening personal reliability of BSAT workers
 - Recommendations on strengthening physical security at BSAT facilities
- Streamlined Agency/Department BSAT Policies
- Coordinated Inspections

Evolution of the CDC Select Agent Program

- **More rigorous oversight**
 - Enhanced inspections
 - Pre-visit document review
 - Employee interviews
 - Non-routine Inspections
 - Compliance verification
 - Response to concern or complaint
 - Announced or Unannounced
 - Internal entity risk assessment
 - Identifies entities for more extensive oversight
 - Entity Performance Improvement Plan

Evolution of the CDC Select Agent Program

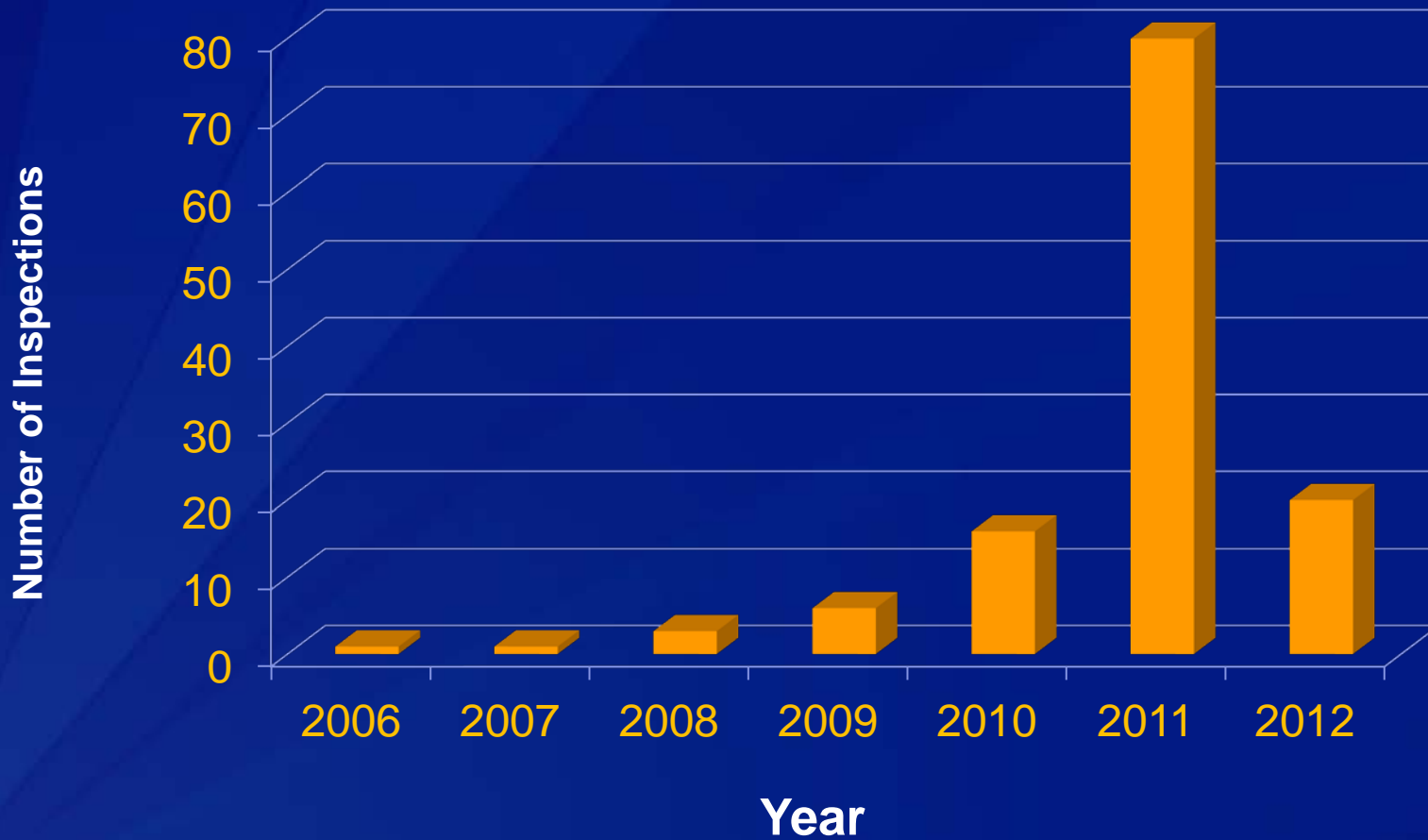
- **More proactive incident response**
 - Active follow-up of theft, loss, release (Form 3) reports
 - Active surveillance of reports of identification of select agents in diagnostic samples (Form 4) reports
- **More outreach**
 - Guidance documents
 - Scientific meeting participation
 - More emphasis on training

Unannounced Select Agent Inspections

- Authorized under 42 CFR Part 73.18
- Shorter duration, focused on:
 - Previous inspection findings
 - Specific security or safety areas
 - “Real time” regulatory compliance

DSAT Unannounced Select Agent Inspections

(as of April 30, 2012)



October 2012 HHS Select Agent and Toxin Final Rule

- Tiered Select Agent List
- Specific physical and cyber security requirements for Tier 1 BSAT
- Personal Suitability Programs for Tier 1 BSAT
- Occupational Health Programs for Tier 1 BSAT
- Broader definition of Restricted Experiments

Additions to & Deletions from the HHS Select Agent List

Additions

- SARS-associated coronavirus (SARS-CoV)
- Lujo virus
- Chapare virus

Removals

- Cercopithecine Herpesvirus 1 (Herpes B virus)
- *Clostridium perfringens* epsilon toxin
- *Coccidioides posadasii*/*Coccidioides immitis*
- Eastern Equine Encephalitis virus (South American type only)
- Flexal virus
- West African clade of Monkeypox viruses
- *Rickettsia rickettsii*

Proposed Additions to & Deletions from the HHS Select Agent List

Removals

- **Conotoxins, except short, paralytic alpha conotoxins containing the following nucleic acid sequence**
- **Shigatoxins**
- **Shiga-like ribosome inactivating proteins**
- **Staphylococcal Enterotoxins, except A, B, C, D, and E subtypes**
- **Tick-borne encephalitis complex viruses (Central European subtype)**

Deletions from the Overlap Select Agent List

- Deletions: Venezuelan Equine Encephalitis virus (subtypes 1D and 1E). All other subtypes to remain regulated.

Tier 1 Select Agents and Toxins

- Ebola and Marburg viruses
- Variola minor and Variola major viruses
- *Francisella tularensis*
- *Yersinia pestis*
- *Bacillus anthracis***
- *Burkholderia mallei* and *B. pseudomallei*
- Botulinum neurotoxin and neurotoxin-producing strains of *Clostridium botulinum*
- Foot-and-Mouth Disease virus*
- Rinderpest virus*

***USDA-regulated**

****Pasteur strain exempt**

Specific security requirements for Tier 1 Select Agent Possessors

Suitability assessments

- Pre-access suitability assessments
- On-going assessment of the suitability of personnel

Physical security standards: access control

- Minimum of three security barriers to reach space that contains Tier 1 BSAT
- Intrusion Detection System

Occupational Health Programs for Tier 1 BSAT

The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

Broader definition of Restricted Experiments

(a) An individual or entity may not conduct or possess products resulting from a restricted experiment with a select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary

(b)(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(b)(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight.

Development of Guidance Documents (www.selectagents.gov)

- Incident Response
- Information Systems Security Control
- Inventory Requirements
- Occupational Health Program
- Physical Security Control
- Responsible Official
- Suitability Assessment

Exemptions for Diagnostic Laboratories (42 CFR § 73.5)

- General Diagnostic Exemption (42 CFR 73.5(a))
- Proficiency Testing (42 CFR 73.5 (b))
- Possession of products licensed or cleared as an investigational drug by the FDA (42 CFR 73.5 (c)(d))
- Public health emergency (42 CFR 73.5 (e))

Impact on Laboratory Response Network

QA/QC strains	Tier 1	Select agent status
<i>Bacillus anthracis</i> Pasteur	No	regulated
<i>Bacillus anthracis</i> Sterne	No	excluded
<i>Brucella suis</i> 1330 positive control strain	No	regulated
<i>Brucella melitensis</i> 16 M strain	No	regulated
<i>Francisella tularensis</i> LVS	No	excluded
<i>Yersinia pestis</i> A1122	No	excluded

www.selectagents.gov



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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



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