

**Meeting of the States Parties to the Convention
on the Prohibition of the Development,
Production and Stockpiling of Bacteriological
(Biological) and Toxin Weapons and on Their
Destruction**

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Item 7 of the provisional agenda

**Standing agenda item: strengthening
national implementation**

**Key biosecurity-related changes made to the USA select
agent regulations**

Submitted by the United States of America

I. Introduction

1. The United States of America's Federal Select Agent Program,¹ created in 2002, establishes and regulates safety and security measures to prevent unauthorized access to biological select agents and toxins (BSAT). In the United States of America, the Select Agent Regulations restrict possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, as well as animal and plant products. These regulations strengthen the United States of America's national implementation of the Biological Weapons Convention. The United States of America reviews the BSAT list, which currently includes 65 agents and toxins, every two years to determine whether changes are necessary due to developments in areas such as biosafety, infectious disease risk, medical countermeasures, and security developments. Select Agent Regulations apply to all entities that possess, use, or transfer BSAT in the United States of America, including federal, State, and local government laboratories, academic research institutions, pharmaceutical and vaccine companies, and the commercial and manufacturing sectors.

2. In 2010, the Federal Expert Security Advisory Panel (FESAP) was established by Executive Order 13546 to recommend how to optimize and strengthen the security measures in the BSAT regulations.² These recommendations were based on the combined expertise of federal policymakers and the scientific community. On October 5, 2012, the

¹ See www.selectagents.gov and www.cdc.gov/phpr/documents/DSAT_brochure_July2011.pdf.

² FESAP members, or their designees, are subject matter experts representing the federal life sciences, public health, law enforcement, security, and intelligence communities.

Department of Health and Human Services (HHS) and the USA Department of Agriculture (USDA) published an official update amending the Select Agent Regulations.³

3. This paper discusses the following key biosecurity-related changes⁴ made to the Select Agent Regulations in 2012:

- (a) Designation of “Tier 1” BSAT.
- (b) Pre-access personnel suitability assessments for access to Tier 1 BSAT.
- (c) Ongoing assessment of personnel suitability with access to Tier 1 BSAT.
- (d) Training to implement the Tier 1 personnel suitability programs.
- (e) Reporting of incidents to appropriate entity⁵ and law enforcement officials.

II. Designation of “Tier 1” Select Agents and Toxins

4. Executive Order 13546 required the designation of a subset of BSAT (Tier 1 BSAT) that present the “greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, crucial infrastructure, or public confidence.” Of the current 65 select agents and toxins, 13 were designated as Tier 1 BSAT.⁶ BSAT that were determined to have the greatest ability to produce a mass casualty event or devastating effects to the economy, high communicability, low infectious dose, and a history of weaponization were recommended to the Federal Select Agent Program by the FESAP for Tier 1 status. The Federal Select Agent Program then published proposed amendments (including designation of Tier 1 BSAT) to the Select Agent Regulations and solicited public comments. In October 2012, the United States of America published an official update to the Select Agent Regulations which included the designation of Tier 1 BSAT. The Tier 1 designation allows for targeted enhancement of security measures to Tier 1 BSAT entities, while avoiding burdening other entities that do not possess, use, or transfer Tier 1 BSAT.

III. Pre-Access Personnel Suitability Assessments

5. USA law requires that all entities possessing BSAT must be registered, have security plans, and ensure that personnel with access to BSAT receive a Federal Bureau of Investigation (FBI) Security Risk Assessment (SRA).⁷ The 2012 changes to the Select

³ The Federal Register is the official journal of the government of the United States of America that contains routine publications and public notices of government agencies, including proposed and final regulations. Proposed regulations are published in the Federal Register before they take effect to allow interested parties to comment. Final regulations are codified in the USA Code of Federal Regulations.

⁴ While physical security enhancements and information technology security requirements were also included in the amendments to the Select Agent Regulations, they are not discussed in this paper.

⁵ For the purposes of this paper, an entity broadly refers to a place of scientific research. For example, this can include public or private research laboratories, clinical diagnostic facilities, or commercial organizations.

⁶ BSAT list and Tier 1 agents:

<http://www.selectagents.gov/select%20agents%20and%20toxins%20list.html>.

⁷ The SRA is a series of Federal electronic database checks that seek to identify individuals who are legally prohibited or restricted from accessing select agents based upon specific provisions of the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act. The SRA is, by law, limited in scope. Example “prohibitors” include being convicted of a crime

Agent Regulations require—in addition to the SRA—that entities that possess Tier 1 BSAT must establish procedures for conducting “pre-access personnel suitability assessments” for individuals who will access Tier 1 BSAT. While the SRA (performed by the FBI) seeks to identify individuals who are legally prohibited or restricted from accessing BSAT, the pre-access personnel suitability assessment (performed by the entity) seeks to evaluate the ability of an individual to comply with biosafety and security protocols and determine whether he or she displays behaviours that may increase the risk of theft, loss, or release of BSAT. Adequate academic credentials and prior experience may qualify a person to conduct research with Tier 1 BSAT; however, these qualities alone do not constitute suitability. Suitability assessments may include checking public records for derogatory information, verifying official education transcripts and professional certifications/licenses, and conducting phone or in-person interviews with peer or professional references to obtain additional information about the candidate. Entities are encouraged to consider all information, both positive and negative, when making suitability determinations.

6. It is important to recognize that the SRA conducted by the FBI is not a background investigation and does not serve as the sole tool for determining an individual’s suitability for access to BSAT. Derogatory information that does not fall within the federally mandated scope of the SRA (e.g., violations of some state and local laws) is not considered during the SRA but may still impact an individual’s suitability. This underscores the importance of BSAT entities conducting suitability checks to identify potential derogatory information about candidates that falls short of federal SRA prohibitors.

IV. Ongoing Assessment of Personnel Suitability

7. With the 2012 changes in Select Agent Regulations, entities that possess Tier 1 BSAT must include in their security plans procedures for conducting ongoing suitability assessments for individuals that have access to Tier 1 BSAT. For instance, entities often conduct annual staff reviews to assess employee performance, and some entities may also conduct periodic public records checks (e.g., state and local criminal records, civil orders, driving records, etc.) to assist in determining staff suitability. However, behavioural changes can arise at any time in the laboratory, so ongoing assessment is necessary. There must be an additional specific program in place (e.g., peer and self-reporting) to allow for the continuous assessment of behavioural indicators and help ensure the ongoing reliability of staff.

8. A key objective of ongoing personnel suitability assessments is to empower individuals to recognize and detect any threats to themselves or others. Insiders with access to select agents can pose a significant threat because they have the ability to bypass many security measures. Within select agent laboratories, behavioural indicators comprise a broad range of scenarios, from data falsification or manipulation, research sabotage or espionage, and unapproved experimentation, to more serious incidents of theft or violence. An ongoing personnel suitability assessment process can help to identify and mitigate such insider threats.

9. To supplement the new pre-access and ongoing personnel suitability requirements for Tier 1 BSAT entities, HHS and USDA developed a personnel suitability guidance document,⁸ which incorporates recommendations from the FESAP and FBI. The guidance document addresses topics such as:

exceeding one year in prison, an unlawful user of controlled substances, or a fugitive from justice.

⁸ See http://www.selectagents.gov/Guidance_for_Suitability_Assessments.html.

- (a) The potential for insider threats and the need for personnel suitability assessments.
- (b) The concurrent but separate process of the FBI Security Risk Assessment and the entity's pre-access suitability assessment.
- (c) Delineating the roles and responsibilities of entity leadership and personnel.
- (d) Information that might be collected and verified when conducting a personnel suitability assessment.
- (e) Reportable conditions or behaviours for ongoing self and/or peer review.
- (f) The development of a threat reporting mechanism.
- (g) Responding to reports in a consistent, prompt, and confidential manner.
- (h) Comprehensive staff training in areas such as insider threat awareness, behaviours of concern, self and peer review procedures, and entity policies regarding ongoing assessment and monitoring procedures.

V. Suitability Training

10. With the 2012 changes in the Select Agent Regulations, entities that possess Tier 1 BSAT must provide procedures for training employees with access to Tier 1 BSAT on policies and procedures for reporting and evaluating concerns and identifying corrective actions that may be taken. Training is an important component of security, since awareness helps foster compliance with personnel suitability and reliability measures. Annual refresher training must also be provided for all individuals with access to BSAT. The Federal Select Agent Program's supplemental BSAT guidance⁹ recommends designation of an employee to manage the assessment of laboratory personnel. If a concern is reported, it is recommended that laboratory personnel (and not just security personnel) are included during the threat evaluation process.

VI. Reporting Incidents to Appropriate Entity and Law Enforcement Officials

11. With the 2012 updates to the Select Agent Regulations, entities that possess BSAT must include procedures for how the Responsible Official¹⁰ will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its BSAT material. Such security plans must include procedures for how the entity will notify the appropriate federal, State, or local law enforcement agencies of such activity, so as to facilitate the involvement of law enforcement to evaluate suspicious activity. Each of the 56 FBI field offices across the United States of America has a WMD Coordinator who can assist local BSAT entities by providing resources, expertise, and local threat updates.

⁹ BSAT guidance documents are found at: <http://www.selectagents.gov/Resources.html>.

¹⁰ A Responsible Official (RO) is the individual designated by the entity with the authority and responsibility to act on behalf of the entity to ensure compliance with the BSAT regulations.

VII. Empowering Compliance

12. The periodic review process for the Select Agent Regulations highlights shared security responsibilities between the federal government and regulated entities. Entity personnel have a role in protecting BSAT, but they must be trained and empowered to do so. Key to their success is the support provided by the leadership of the entity in funding security programs, including making resources for personnel available from institutional areas such as employee assistance programs, campus security, human resources, and legal counsel. The FBI is positioned to assist entities possessing BSAT for the purpose of biosecurity without undue burden or hindrance to scientific research.
