



U.S. Department of Health and Human Services
U.S. Department of Agriculture



Federal Experts Security Advisory Panel Recommendations and Future Activities

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Briefing for the National Science Advisory Board for Biosecurity

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Background on the Federal Experts Security Advisory Panel (FESAP)



- Created in Executive Order 13546
 - Participants from 15 Departments and Agencies

HHS- co-Chair
USDA- co-Chair
DoD
DHS
DOJ/FBI

EPA
DOE
DOT
VA
OSTP

Joint Chiefs
ODNI
State
Commerce
Labor

- Taskings
 - Provide the following consensus recommendations:
 - Designate Tier 1 list of biological select agents and toxins (BSAT)
 - Consider reducing the list of BSAT
 - For entities housing and personnel handling Tier 1 BSAT, make recommendations on appropriate practices for personnel reliability, physical security, and cybersecurity
 - Other relevant policy issues



FESAP Working Groups



- Tiering Working Group
 - Chaired by HHS and USDA
 - 70 participants
 - Sub-groups on animal agents, plant agents, human viruses, human bacteria and fungi, and toxins
- Personnel Reliability Working Group
 - Chaired by HHS and FBI
 - 50 participants
 - Sub-group on issues pertaining to foreign nationals
- Physical Security and Cybersecurity Working Group
 - Chaired by DHS
 - 60 participants



Tiering



Current List and FESAP Approach

- 82 agents with equivalent requirements despite disparity in risk of potential to cause a high consequence event

Goals of the FESAP

- Create a Tier 1 list of those agents and toxins with a documented risk of causing a high consequence event higher than other BSAT
- Eliminate those agents which have little or no evidence of risk of causing a high consequence event



Recommended List of Tier 1 BSAT



- *Bacillus anthracis*
- *Burkholderia mallei*
- *Burkholderia pseudomallei*
- Ebola virus
- Foot-and-mouth disease virus
- *Francisella tularensis*
- Marburg virus
- Variola major virus
- Variola minor virus
- *Yersinia pestis*
- Botulinum toxin, and toxin-producing strains of *C. botulinum*

Criteria for Tier 1 status:

- Ability to produce a mass casualty event or devastating effects to the economy
- Communicability
- Low infectious dose
- History of or current interest in weaponization based on threat reporting



Recommended agents for removal



Human and Overlap Agents

- Cercophithecine herpesvirus 1 (Herpes B virus)
- *Coccidioides posadasii*
- *Coccidioides immitis*
- Eastern Equine encephalitis virus, South American genotypes
- Flexal virus
- Tick-borne encephalitis viruses, European subtypes
- Venezuelan Equine Encephalitis virus, Enzootic subtypes ID and IE

Animal Agents

- Akabane virus
- Bluetongue virus
- Bovine Spongiform Encephalitis
- Camel Pox virus
- *Ehrlichia ruminantium*
- Goat Pox virus
- Japanese Encephalitis virus
- Malignant Catarrhal Fever virus
- Menangle virus
- *Mycoplasma capricolum*, subsp. *capripneumoniae*
- Sheep Pox virus
- Vesicular stomatitis virus

Criteria for removal:

- Low potential for causing mortality
- Endemicity in the U.S. (animal agents)
- Difficulty in producing quantities necessary for high consequence event



Personnel Security

Current Policies and FESAP Approach



Federal Level

- Security Risk Assessment (SRA)
- SRA is database check for existing statutory disqualifiers
- SRA is NOT a background check or a clearance

Local level

- Local pre-employment screens
- Responsible Officials given duty to remove anyone from access for any concern
- No guidance as to what behaviors should be of concern

Goals of FESAP

- Strengthen FBI's ability to assess statutory disqualifiers
- Provide tools and guidance to ROs to adequately assess suitability and reliability of individuals at the local level
- Promote awareness of security risks of those who have access to BSAT and ensure that they have adequate opportunities to report concerns



Personnel Security: Suitability and Reliability



- Suitability statement
 - Personnel with access to BSAT should be reliable, loyal, trustworthy, honest, free from emotional or mental instability, possess sound judgment, free of conflicting allegiances and potential for coercion, and possess a willingness to abide by regulations governing the possession, use, or transfer of select agents.



Suitability for Access- Federal



- Enhance and clarify the Security Risk Assessment (SRA) process to better assess disqualifiers
- Vet foreign nationals
- Explain information requested on the FD-961
- Call for consistent statutory authority between the Secretaries of USDA and HHS.



Suitability for Access to BSAT



- Provide guidance on pre-access suitability assessments of personnel to assist the entity in identifying qualities of suitability for being granted access to BSAT.

May include:

- Credit checks
 - Professional and peer references
 - Credential verification
 - Criminal records check
 - History of violent behavior
 - History of adherence to biosafety or other security programs
- Require a process for pre-access suitability assessment in the security plans of entities housing Tier 1 BSAT.
 - As part of its continuing work, the FESAP will further explore the utility of behavioral assessments to identify indicators of potential for violent behaviors, criminal behaviors, or other behaviors that pose a national security risk.



On-going reliability assessments



- After the granting of initial access to BSAT, ongoing monitoring of an employee's reliability is critical.
- The SAP should provide guidance to entities regarding self- and peer- reporting of circumstances, conditions, activities, actions, or behaviors that may be of a safety or security concern.
 - In addition, the SAP should provide guidance to ensure that local Responsible Officials have the tools necessary to assess reliability, remove personnel from access temporarily or permanently, and to contact the local FBI Weapons of Mass Destruction Coordinator in the event of knowledge of a local threat to security.



Physical Security



Current Policies and FESAP Approach

Current Regulations

- Performance-based measures based on level of risk of individual entities
 - Concern that there are no consistent standards for risk assessment
 - Concern that moving to more prescriptive standards may cause excessive burden to smaller facilities, like state public health labs

Goals of FESAP

- create minimum prescriptive standards where possible
- allow for flexibility where prudent
- provide facilities with tools to accurately assess risk



Physical Security



- A risk management tool should be developed to facilitate uniform, comprehensive risk assessments at all BSAT facilities.
- For all facilities housing BSAT, standards to ensure comprehensive cybersecurity should be met
- Codify current guidance for securing items upon receipt at a facility
- Current threats that are known to the security and intelligence communities should be shared with BSAT facility managers, when appropriate.
- The SAP should establish or refine standards in regulation for Tier 1 BSAT to allow for layered protection of assets to include: security barriers, intrusion detection and monitoring, delay/response force, access control, and cybersecurity.



Physical Security Standards



The SAP should establish or refine standards in regulation for Tier 1 BSAT to allow for layered protection of assets as follows:

Security Barriers	The entity has a robust security and monitoring system that enables the facility to thwart adversary penetrations.
Intrusion Detection and Monitoring	The entity can demonstrate a reasonable probability that unauthorized adversary actions would be detected and access would be denied, and that unauthorized actions by individuals with authorized access would be detected.
Delay/ Response Force	The entity is able to detect and initiate a response to intruders resulting in the intruders being interdicted before they reach a restricted area.
Access Control	The entity can demonstrate a reasonable probability of detecting and preventing fraudulent entry and has a system for the timely reporting of such attempts to law enforcement.
Cybersecurity	The entity provide backup power and energy sources to power lighting, networks and integrated access controls during emergencies.



Caveat for smaller laboratories



- The FESAP recognizes that there are unique facilities such as diagnostic, public health, animal health, and environmental laboratories, such as the laboratories of the Laboratory Response Network, which perform a vital national security function and may require different methods of implementation of the recommended standards.
- FESAP encourages the Select Agent Program, through their authority in E.O. 13546, to permit tailored risk management practices based upon relevant contextual factors



Future Activities of the FESAP



- Behavioral Assessment Working Group
- Risk Assessment Tool Working Group
- Assistance to SAP in developing suitability and reliability assessment guidance to entities
 - Credit checks
 - Reference vetting
 - Self- and Peer- reporting mechanism



Development of new Rules and Guidance

