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FACT SHEET: Enhancing Biosafety and Biosecurity

The United States Government (USG) today released two sets of recommendations, one from the Federal Experts Security Advisory Panel (FESAP) and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) These recommendations are key elements of progress toward strengthening the government's biosafety and biosecurity practices and the oversight system. The recommendations recognize that work with biological select agents and toxins (BSAT) has public, animal, and plant health and national security benefits. The recommendations of both groups are complementary and will help further ensure that life science efforts which benefit the global community in countering biological threats are carried out safely and securely. The Centers for Disease Control and Prevention (CDC) also released today a 90-day internal review of its select agent program, which oversees the possession, use and transfer of biological select agents and toxins through the Federal Select Agent Program (FSAP).

IMPORTANCE OF LABORATORIES AND EFFORTS TO COUNTER BIOLOGICAL THREATS

Efforts in the life sciences are crucial for ensuring public and agricultural health, including research on hazardous biological agents such as pathogens and toxins that require laboratory containment facilities. These activities contribute significantly to the understanding of human, plant, and animal pathogens and the diseases they cause; the development of new diagnostics, treatments, and preventive measures for protecting human, plant, and animal health; the development of a more robust and nutritious food supply; and the development of medical countermeasures for biodefense. A critical component of the nation's strategy to counter biological threats is the ability to quickly detect, respond to, and mitigate the consequences of a biological incident (whether naturally occurring, accidental, or deliberate). The recent Ebola virus disease, severe acute respiratory syndrome, and Middle East respiratory syndrome outbreaks, and the development of related medical countermeasures, serve as reminders of the importance of laboratory work to counter biological threats to health.

ENHANCING BIOSAFETY AND BIOSECURITY

Laboratories involved in research, development, and diagnostic activities with BSAT play a critical role in response. BSAT are biological pathogens and toxins whose possession, use, and transfer are regulated by the Departments of Health and Human Services (HHS) and Agriculture (USDA). The Federal Select Agent Program has developed regulations and guidance over the last 15 years to ensure security of BSAT while allowing this crucial research to continue.

However, recent reports of lapses in biosafety practices involving federal laboratories have served to remind the scientific community and the nation of the need to continually strengthen biosafety and laboratory biosecurity. As a measure toward preventing future lapses, enhancing biosafety and laboratory biosecurity, as well as promoting stewardship of the life sciences, the USG took immediate action to develop FESAP and FTAC-SAR recommendations to enhance the current U.S. system of biosafety and biosecurity oversight and practice.

The White House National Security Council (NSC) and Office of Science and Technology Policy (OSTP) established parallel federal and broad stakeholder reviews resulting in specific recommendations to strengthen biosafety and biosecurity practices and the government's system of oversight. The federal review was conducted by the FESAP, which was tasked to 1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity,

oversight, and inventory management and control for BSAT; 2) identify actions and any regulatory changes to improve biosafety and biosecurity; and 3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. The review involving broad stakeholder engagement was conducted by the FTAC-SAR. The FTAC-SAR was tasked to conduct a comprehensive review of the impact that the Select Agent Regulations (SAR) have had on science, technology, and national security.

FESAP AND FTAC-SAR RECOMMENDATIONS

The FESAP and FTAC-SAR recommendations are complementary. Collectively they include recommended actions to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT; actions, regulatory changes, and guidance to improve biosafety and biosecurity; an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT; and the identification of areas that need additional analysis.

Recommendations to Optimize Biosafety, Biosecurity, Oversight, and Inventory Management and Control for Biological Select Agents and Toxins

<u>Culture of Responsibility</u>

- FESAP 1.1: Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences. This culture of responsibility should be characterized by individual and institutional compliance with biosafety and laboratory biosecurity regulations, guidelines, standards, policies and procedures, and enhanced by effective training in biorisk management.

<u>Oversight</u>

- FESAP 1.2: Require that all research institutions in which human, plant, and/or animal infectious agents and toxins research is conducted have an appropriate organizational and governance structure to ensure compliance with biosafety, biocontainment, and laboratory biosecurity regulations and guidelines.
- FESAP 1.3: Require that an appropriately constituted and qualified review entity validate local policies, laboratory protocols, and mitigation plans involving the inactivation, sterilization, or decontamination of biohazardous materials at research institutions.
- FTAC 11 Peer Advisory Mechanism: The FTAC recommends creating an expert panel or Federal Advisory Committee to serve as an external group that could share best practices or make recommendations to the FSAP.

<u>Outreach and Education</u>

- FESAP 1.4: Support the development and implementation of security awareness education programs/curriculum that: underscore personal responsibility for safeguarding potentially hazardous biological agents; share information about security breaches that have occurred involving infectious or toxic materials; emphasize the need for self and peer reporting; discuss material protection strategies; and explain exploitation of life sciences research.
- FESAP 1.5: Develop and implement strategies to ensure effective communication and awareness of biosafety, biocontainment, and biosecurity.
- FTAC 2 Public Release of Information: The FTAC recommends that information about BSAT research, including laboratory incidents, be periodically provided to the public, and that federal BSAT laboratories adopt, to the maximum extent feasible, a policy of transparency regarding both the agents used and laboratory incidents.
- FTAC 3 Sharing Best Practices: The FTAC recommends members of the regulated community establish a mechanism for sharing best practices.

- FTAC 12 International Engagement: The FTAC recommends international engagement to explore harmonization of pathogen security standards and ensure understanding of the rationale for, and implementation of, the SAR-equivalent standards by collaborating foreign governments.

Applied Biosafety Research

- FESAP 1.6: Develop and maintain a robust federally supported program of applied biosafety research to create additional evidence-based practices and technologies, and to update existing practices and operations.

Incident Reporting

- FESAP 1.7: Establish a new voluntary, anonymous, non-punitive incident-reporting system for research laboratories that would ensure the protection of sensitive and private information, as necessary.

Material Accountability

- FESAP 1.8: Increase awareness of existing material accountability best practices, and support the establishment of material accountability procedures where none currently exist.
- FESAP 2.5: Improve guidance regarding working stocks and inventory control. *(Also see section on guidance below.)*
- FTAC 6 Inventory Control Requirements: The FTAC recommends retaining requirements to maintain inventories of samples containing biological select agents and toxins, while ensuring that BSAT institutions are not requested to characterize biological agents quantitatively.

Inspection Processes

- FTAC 7 Consistency of Inspections: The FTAC recommends development of an approach to improve the consistency of the inspection process across inspectors, inspecting agencies, and inspected sites.
- FTAC 8 Improve Customer Service in Communicating with Regulated Entities: The FTAC recommends improving communication before and after site inspections and improving the timeliness of inspection reports.
- FTAC 9 Categorize Inspection Findings: The FTAC recommends developing a system to categorize findings on inspection reports.
- FTAC 10 Appeals Process: The FTAC recommends expanding the appeals process for institutions to adjudicate disputed findings in inspection reports.

Identification of Actions and any Regulatory Changes and Guidance to Improve Biosafety and Biosecurity

- FESAP 2.1: Add a specific requirement for the documentation of the drills and exercises required in sections 11 (Security), 12 (Biosafety), and 14 (Incident Response) of the current SAR.
- FESAP 2.2: Add a specific requirement to section 15 (Training) to include how a trainee can access the HHS and USDA Office of the Inspector General (OIG) Hotline to anonymously report a safety or security concern.
- FESAP 2.3: Optimize guidance to address integration of the Responsible Official with entity's biosafety and biosecurity oversight committee(s).
- FESAP 2.4: Modify guidance documents to recommend that the composition of the local oversight committee(s) represent the breadth of stakeholders involved in developing and implementing institutional biosafety and biocontainment programs.
- FESAP 2.5: Improve guidance regarding working stocks and inventory control.
- FESAP 2.6: Improve guidance for biosafety plans.
- FESAP 2.7: Amend guidance documents to suggest that entities consider establishing policies on maximum work hours for high containment workers.
- FESAP 2.8: Support U.S. Occupational Safety and Health Administration Infectious Diseases Standard.
- FTAC 1 Regulation Interpretations: The FTAC recommends developing a formal mechanism for issuing, publicizing, and accepting requests for interpretations of the SAR.

- FTAC 4 Individual-based Security Risk Assessments: The FTAC recommends that in the absence of specific information indicating otherwise, individuals who have been granted access to select agents or toxins at one BSAT institution be able to move to another BSAT institution without having to wait for a new Security Risk Assessment.
- FTAC 5 Emergency Situations: The FTAC recommends development of a mechanism to expedite approvals or to relax FSAP requirements in response to time-urgent emergency situations.
- FTAC 13 Guidance for Customs Inspectors: The FTAC recommends providing better training and guidance for customs inspectors who process BSAT shipments.

Need for Additional Analysis

The FTAC-SAR also identified more complex issues that will require additional definition and analysis before specific proposals can be developed and evaluated. Agency implementation efforts will initially be focused on the recommendations. However, NSC and OSTP, working with federal departments and agencies, will develop a plan for how the FTAC-SAR issues can be addressed, including prioritizing among them.

Identification of an Approach to Determine the Appropriate Number of High-Containment U.S. Laboratories Required to Possess, Use, or Transfer Biological Select Agents and Toxins

The FESAP also identified an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. The FESAP recommended a three-phase process characterized by federal assessment (Phase I), external review (Phase II), and consideration of the recommendations of the external non-federal review by the USG (Phase III). The proposed three-phase process will include the development of a 'best practices checklist' for departments and agencies to follow when they are considering the need to modify or augment existing high and maximum containment laboratory space capacity.

KEY ISSUES

In the USG's consideration of the FESAP and FTAC-SAR recommended actions, the importance of fully addressing specific issues, especially in light of recent incidents, was recognized. These key issues include the transparency of the Nation's laboratory system for public safety and security; incident reporting and accountability to the public; material stewardship; and applicability of these principles to other biological agents that could pose a serious threat to public health or agriculture.

IMPLEMENTATION OF THE RECOMMENDATIONS

The USG has developed a plan to implement the FESAP's and FTAC-SAR's recommended actions. The plan includes concrete actions to optimize biosafety and biosecurity policies and practices, as well as oversight. Steps will be taken to enhance the culture of responsibility; strengthen oversight; promote outreach and education; conduct applied biosafety research; develop an incident reporting system; enhance material accountability and inspection processes; and update regulations and guidance. An approach will be implemented to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT. The USG expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities. The Administration is committed to fostering progress in the life

sciences, including peaceful research involving BSAT as well as non-BSAT, while at the same time ensuring that work is conducted in a safe and secure manner.

CDC 90 DAY INTERNAL REVIEW OF THE DIVISION OF SELECT AGENTS AND TOXINS

CDC also released today a 90-day internal review of its select agent program, which oversees the possession, use and transfer of biological select agents and toxins through the FSAP. A workgroup of CDC experts reviewed areas of the FSAP overseen by DSAT and made recommendations regarding inspections, incident reporting and transparency. The CDC participated in developing and endorsing the FESAP and FTAC-SAR reports also published today, and the 90-day internal review complements these reports with additional specificity relevant to the CDC select agent and toxin regulatory program.

MORE INFORMATION

Information about biosafety and biosecurity in general can be found at the HHS Science, Safety and Security (S3) website. Specific details about the recommendations of the FESAP and the FTAC-SAR are available on the S3 website at Biosafety Stewardship. More information about the FESAP report is available on the Federal Experts Security Advisory Panel webpage.