IMPLEMENTATION OF RECOMMENDATIONS OF THE FEDERAL EXPERTS SECURITY ADVISORY PANEL (FESAP) AND THE FAST TRACK ACTION COMMITTEE ON SELECT AGENT REGULATIONS (FTAC-SAR)

October 2015

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Culture of Responsibility

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Develop and incorporate bioethics modules and quality system training into laboratory biosafety and laboratory biosecurity training and/or research design. The training should include discussions of ethical and legal considerations, as well as the social relevance of life science research, and the range of dual-use concerns that arise due to the impact of science and technology on society, health, and national security. **[Action by July 2016]**	IBMWG
	• Promote bioethics and quality system training (creating and implementing quality planning and assurance, as well as quality control and quality improvement) that includes curricula on conduct that incorporates fundamental safety and security responsibilities expected of all life scientists. **[Action by September 2016]**	IBMWG
	• Develop semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar interventions to reduce risk and improve safety in domestic research laboratories housing infectious agents and toxins. **[Action by December 2017]**	Study sponsored by HHS, USDA

Oversight

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Develop an approach to 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. Plan includes: – Approach external organizations including research and biosafety organizations in order to determine whether they have the relevant guidelines that they provide to their membership related to organizational and governance structures. – Compile all such policies and documents in a shared space for access and review for harmonization. **[Actions by March 30, 2016]**	IBMWG
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.	• HHS and USDA will identify or constitute a review entity qualified to validate local policies, laboratory protocols, and mitigation plans involving the inactivation, sterilization, or decontamination of biohazardous materials at research institutions registered with the Federal Select Agent Program. **[Action by September 30, 2016]**	HHS, USDA

Oversight (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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 Federal Select Agent Program (FSAP).	• Convene an interagency group to develop a mechanism for external stakeholders to engage with the FSAP to provide subject matter expertise, including development of recommendations on the specific role/mandate of the mechanism and its relationship with other mechanisms (e.g., FESAP, Interagency Select Agents and Toxins Technical Advisory Committee [ISATTAC]). – Identify pros, cons, and feasibility of options. **[Action by December 2015]** – Obtain feedback from stakeholders and identify preferred option. **[Action by January 2016]** – Develop a plan to institute preferred option. **[Action by March 2016]** – Implement measures to establish preferred option. **[Action by June 2016]**	HHS and USDA lead with participation from FBI, DOI, DOD, DHS, EPA, DOC, and DOS

Outreach and Education

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.**	• FBI has developed a security awareness program that is consistent with the recommendation and will work with interagency partners to assist with implementation - or in developing a program tailored for their use. **[Action by November 30, 2016]** – **FBI recommends inclusion of an additional element:** Incorporate security awareness education as a means to reinforce existing safety, ethics, and other training programs and provide better understanding as to the rationale for the existence of compliance requirements associated with the Select Agent Program.	FBI
FESAP 1.5: Develop and implement strategies to ensure effective communication and awareness of biosafety, biocontainment, and biosecurity.	• Develop a strategic communications plan for biosafety, biocontainment, and biosecurity outreach and education. **[Action by January 2016]** • Support an outreach program to promote effective communication and awareness of biosafety, biocontainment, and laboratory biosecurity; improve biorisk management; and help coordinate interagency outreach activities that deal with biosafety, biocontainment, and laboratory biosecurity. **[Action to be ongoing]**	IBMWG

Outreach and Education (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FTAC 2: Public Release of information: The FTAC recommends that information about biological select agents and toxins (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.	• FSAP will release aggregate information on laboratory incidents on an annual basis. **[Action to be conducted annually beginning in June 2016]**	FSAP
	• Federal BSAT laboratories develop and adopt a policy of transparency, to the maximum extent feasible, regarding both the agents used and laboratory incidents. **[Action to be ongoing]**	Federal D/As with BSAT laboratories
	• Encourage non-Federal BSAT laboratories to adopt a policy of transparency, to the maximum extent feasible and based on federal guidance, regarding both the agents used and laboratory incidents. **[Action to be ongoing]**	Federal D/As with BSAT laboratories
FTAC 3: Sharing Best Practices: The FTAC recommends members of the regulated community establish a mechanism for sharing best practices.	• Consult with relevant stakeholders to identify a mechanism for sharing best practices; and, support establishment of a plan to implement. **[Action by January 2016]**	HHS/CDC and USDA/ARS in collaboration with stakeholders

Outreach and Education (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Support efforts, including convening and expanding membership of the International Expert Group for Biosafety and Biosecurity Regulation (IEGBBR), an informal ad hoc group consisting of members from several countries for the purpose of sharing the experiences by individuals responsible for development and implementation of biosafety and security regulations governing the possession, importation and use of infectious disease agents and toxins by biological laboratories in accordance with the Biological and Toxin Weapons Convention and the United Nations Security Council Resolution 1540. **[Action by June 2016]** • Initiate one or more international meetings to discuss pathogen security regulations, policies, and practices, and opportunities to strengthen biorisk management on an international basis. **[Action by August 2017]**	FSAP DOS and/or DOD with FSAP and other D/A support

Applied Biosafety Research

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• HHS, USDA, DOD, and DHS to convene a small group to develop an implementation plan, timeline, and resource strategy including potential for consultation with external stakeholders**. [Action by January 30, 2016]** Elements of plan include: – Determine whether any entities maintain an existing database on applied biosafety research. – Support study to develop a national research agenda for applied biosafety with a one health focus to improve the management of biohazard risks. – Develop a sustainable program of applied biosafety research to create additional and update existing evidence based practices and technologies for the laboratory and the field. – Maintain applied biosafety research program.	Lead: HHS, USDA; with support from DHS, DOD

Incident Reporting

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Pilot Incident Reporting System on HHS intranet. **[Action by December 2016]** • Pilot incident reporting system by other Federal D/A, dependent on outcome of pilot. **[Action by December 2017]** • Expand incident reporting system to non-Federal stakeholders, dependent on outcome of pilot. **[Action by December 2018]**	HHS, IBMWG Other Federal D/As Federal D/As

Material Accountability

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FESAP 1.8: Increase awareness of existing material accountability best practices, and support the establishment of material accountability procedures where none currently exist. **and** **FESAP 2.5: Improve guidance regarding working stocks and inventory control.**	• Establish a small group of subject matter experts and implement next steps to enhance inventory control, including mechanisms to ensure biological material ownership and responsibility is transferred when an individual leaves the organization. Plan includes: – Approach external groups for best practices on pathogen inventory. – Develop a best practice guidance for the research	HHS, USDA, DHS, and DOD

Material Accountability (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
	community. - Ask all research entities to develop and adopt a specimen management policy. - Require all D/A to incorporate a select agent annex or other specificity into their scientific collections policies that ensure accountability. - Improve guidance regarding inventory control for working stocks. **[Actions above by January 30, 2016]** - Develop a strategic communication plan to address BSAT material accountability **[Action by March 2016]** - Support outreach efforts to stakeholders (federal and non-federal) to address BSAT material accountability. **[Action to be ongoing]**	IBMWG IBMWG

Material Accountability (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Review, and update if necessary, guidance and training related to inventory management to specifically preclude the quantitative characterization of biological agents (e.g., Guidance on the Inventory of Select Agents and Toxins 7 CFR Part 331, 9 CFR Part 121, 42 CFR Part 73; 16 April 2015). **[Action by January 2016]**	FSAP

Inspection Processes

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Establish an interagency working group to develop a mechanism to solicit input from stakeholders related to inconsistencies and other issues experienced by stakeholders during inspections. Solicit concrete examples of inspection inconsistencies and issues. **[Action by January 2016]** • The FSAP will gather concrete examples of the inconsistencies and issues identified by stakeholders, and develop an approach to improving the consistency of inspections and resolving these issues. **[Action by October 2016]**	FSAP FSAP

Inspection Processes (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• Develop policies and practices to communicate inspection reports to registered entities within 60 days of the completion of the inspection. **[Action to be ongoing]** • Explore the feasibility of the establishment of an electronic mechanism for communication of information between the registered entities and the FSAP related to inspections and identify elements of the mechanism. **[Action by June 2016]** • If feasible, make progress toward establishment of an electronic mechanism (e.g., Electronic National Select Agent Registry [E-NSAR]) for communication of information between the registered entities and the FSAP related to inspections. **[Action by September 2016]**	FSAP FSAP FSAP
FTAC 9: Categorize Inspection Findings: The FTAC recommends developing a system to categorize findings on inspection reports.	• Develop definitions for categories of findings on inspection reports (e.g., administrative, important, critical). **[Action by February 2016]**	FSAP
FTAC 10: Appeals Process: The FTAC recommends expanding the appeals process for institutions to adjudicate disputed findings in inspection reports.	• Develop a formal mechanism for entities to appeal inspection findings which are disputed by an entity. [**Action by February 2016]**	FSAP

Regulations and Guidelines

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
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.	• The Federal Select Agent Program is incorporating this regulatory change in the biennial review Notice of Proposed Rule. In practice, many registered entities already conduct this activity but the regulation change will ensure this occurs with all registered entities**. [Proposed publication in Summer 2016]**	FSAP
FESAP 2.2: Add a specific requirement to section 15 (Training) to include how a trainee can access the U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) Office of the Inspector General (OIG) Hotline to anonymously report a safety or security concern.	• The Federal Select Agent Program is incorporating this regulatory change in the biennial review Notice of Proposed Rule**. [Proposed publication in Summer 2016]**	FSAP
FESAP 2.3: Optimize guidance to address integration of the Responsible Official (RO) with entity's biosafety and biosecurity oversight committee(s).	• The Federal Select Agent Program will incorporate this guidance into the Responsible Official Resource Manual. **[Target completion by November 2015]**	FSAP

Regulations and Guidelines (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(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.	• Convene interagency group to review the requirements for various oversight committees in institutions that work with BSAT and recommend modification of these guidelines to: – Ensure that committee membership includes appropriate expertise and represents the breadth of stakeholders responsible for the execution of the biosafety and biocontainment programs at an institution, with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* as a model. – Ensure that effective communication and coordination exists between these institutional committees, so that the biocontainment labs have uniform and effective oversight. – Consider incorporating community engagement. **[Action by November 30, 2015]**	Lead: HHS; with support from DOD, USDA, DHS
FESAP 2.5: Improve guidance regarding working stocks and inventory control.	*See Material Accountability section*	

Regulations and Guidelines (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FESAP 2.6: Improve guidance for biosafety plans	• The Federal Select Agent Program has developed a template for biosafety plans and will move forward to develop guidance for creation of biosafety plans. In addition, the biosafety section of the select agent regulations will be expanded to specify required components of biosafety plans for registered entities. Target completion date of the guidance March 2016. **[Target publication of proposed rule in Summer 2016]**	FSAP
FESAP 2.7: Amend guidance documents to suggest that entities consider establishing policies on maximum work hours for high containment workers.	• The Federal Select Agent Program will incorporate this recommendation into its guidance for biosafety plans, which is under development. **[Target completion of the biosafety plan guidance is March 2016]** • HHS to coordinate with USDA, DOD, DHS and other D/A to determine next steps to update the *Biosafety in Microbiological and Biomedical Laboratories*. **[Action by April 2016]**	FSAP Lead: HHS with USDA, DOD, DHS, and other D/A

Regulations and Guidelines (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FESAP 2.8: Support U.S. Occupational Safety and Health Administration (OSHA) Infectious Diseases (ID) Standard.	• Discuss and identify awareness-raising activities and needs related to OSHA's proposed and final ID rules. **[Action by January 2016]** • Discuss development of an interagency listserv on infectious disease topics relevant to the ID Rulemaking and discuss a list of potential members to invite to join this ID listserv. **[Action by January 2016]** • If recommended by the IBMWG, develop a strategic communications and outreach plan. **[Action by July 2016]** • If recommended by the IBMWG, develop outreach materials (e.g., Frequently Asked Questions, fact sheet, etc.). **[Action by November 2016]** • Promote stakeholder awareness related to the publication of the proposed rule related to the OSHA ID standard. **[Action by December 2016]** • Promote stakeholder awareness related to the publication of the OSHA ID standard final rule. **[Action anticipated by December 2018]**	IBMWG

Regulations and Guidelines (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FTAC 1: Regulation Interpretations: The FTAC recommends developing a formal mechanism for issuing, publicizing, and accepting requests for interpretations of the Select Agent Regulations (SAR).	• Consider development of a formal mechanism for accepting and responding to requests related to interpretations of the select agent regulations (SAR). **[Action by January 2016]**	FSAP
	• Implement formal mechanism, if supported, for accepting and responding to requests related to interpretations of the SAR. **[Action by June 2016]**	FSAP
	• FSAP will publish interpretations of the SAR based on requests, as is necessary and appropriate. **[Action to be ongoing]**	FSAP
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.	• Convene a working group to examine the desirability and feasibility of transferring the Security Risk Assessment or SRA determination from one entity to another entity in the absence of disqualifying information and to craft language for Notice of Proposed Rulemaking. **[Action by September 2016]**	Lead: FBI; with support from and HHS, USDA
	• If desirable and determined to be feasible, the FSAP will publish Notice of Proposed Rulemaking (NPRM) that proposes specific change to the regulations.	FSAP
FTAC 5: Emergency Situations: The FTAC recommends development of a mechanism to expedite approvals or to relax Federal Select Agent Program (FSAP) requirements in response to time-urgent emergency situations.	• Convene a working group to examine the need for additional exemption processes in emergency situations. **[Action by November 2016]**	FSAP
	• Determine what statutory adjustments may be needed to provide more flexibility in the emergency exemptions. **[Action by January 2016]**	FSAP

Regulations and Guidelines (cont'd.)

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FTAC 13: Guidance for Customs Inspectors: The FTAC recommends providing better training and guidance for customs inspectors who process BSAT shipments.	• Develop guidance targeted for customs inspectors related to the select agent regulations. **[Action by January 2016]** • Train customs inspectors. **[Action to be ongoing]**	DHS , FSAP DHS

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

RECOMMENDATION	IMPLEMENTATION PATHWAY AND PROJECTED TIMELINE	D/A LEAD(s)
FESAP: The approach recommended is 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 U.S. Government (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 existing high and maximum containment laboratory space capacity.	• The IPC endorsed the approach recommended by the FESAP to determine the appropriate number of high containment U.S. laboratories required to possess, use, or transfer BSAT. The IPC approved implementation for all three phases of the recommended approach, including an external review that involves public stakeholders. The IPC discussed next steps to develop criteria for a review, which will take into account preparedness, safety, security, and research needs, as well as the U.S. international posture on this issue. – The FESAP will determine timeline to begin Phase One. [**Action by October 1, 2015]** – HHS, USDA, and DHS, in conjunction with OSTP and NSC staff, will convene a working group to oversee next steps and schedule first meeting. **[Action by October 1, 2015]** State/ISN will factor in best practices from the U.S. policy, "Guiding Principles and Assessment Process Related to the Provision of Biocontainment Facilities to Foreign Countries."	 FESAP HHS, USDA, DHS, OSTP, NSC State/ISN

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October 2015

LEGEND:

ARS	Agricultural Research Service
BSAT	Biological Select Agents and Toxins
CDC	Centers for Disease Control and Prevention
D/A	Department and Agency (federal)
DHS	Department of Homeland Security
DOC	Department of Commerce
DOD	Department of Defense
DOI	Department of Interior
DOS	Department of State
E-NSAR	Electronic National Select Agent Registry
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FESAP	Federal Experts Security Advisory Panel
FSAP	Federal Select Agent Program
HHS	Department of Health and Human Services
IBMWG	Interagency Biorisk Management Working Group
ID	Infectious Diseases
IPC	Interagency Policy Committee
ISN	Bureau of International Security and Nonproliferation
ISATTAC	Interagency Select Agents and Toxins Technical Advisory Committee
NPRM	Notice of Proposed Rulemaking
NSC	National Security Council
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy (White House)
RO	Responsible Official
SAR	Select agent regulations
USDA	U.S. Department of Agriculture