

CDC Division of Select Agents and Toxins

Program Improvement Initiatives

The information below is designed to extract and summarize the recommendations relevant to CDC's role within the Federal Select Agent Program (FSAP), collect them in one place, outline actions that have been identified to address each, and provide an update on progress towards implementation. The Division of Select Agents and Toxins (DSAT), in conjunction with its Agriculture Select Agent Service (AgSAS) colleagues, continues to work diligently to implement these improvements to the FSAP and will provide periodic updates, located at http://www.cdc.gov/phpr/dsat/review_progress.htm.

IMPROVING INSPECTIONS

Improving Facility Inspections

Area of Focus	Action Identified	Status	Addresses
Improve quality and consistency of FSAP inspections, inspection teams, and inspectors	Identify violations that require greater inspector judgment and establish an inspector training plan to address knowledge gaps and increase standardization so that registered entities have clear, consistent information	In progress; observations requiring greater inspector judgment have been identified, and internal efforts to develop trainings, as well as train inspectors, on these issues are underway.	CDC 90-Day #1: Reduce potential variability of inspections FTAC #7: Improve consistency of inspections
	Create an inspection tool to categorize violations along a spectrum of severity and ensure enforcement actions are appropriate given the violation severity; this will serve to increase compliance by reducing ambiguity and providing more precise and transparent information to the regulated community on how performance and violations are graded	In progress; violations are currently being categorized according to a range (or spectrum) of severity, along with enforcement options for each; once list is developed, DSAT will convene a panel of experts for feedback	CDC 90-Day #1: Reduce potential variability of inspections CDC 90-Day #4: Better characterize severity of inspection findings CDC 90-Day #5: Prioritize and strengthen enforcement actions to highest risk violations FTAC #9:

			Categorize inspection findings
Analyze inspection data and risk assessments to prioritize oversight activities	Examine and convey trends and associations between inspection findings and risk in order to better understand and anticipate actions most strongly and most often associated with poor outcomes; use this information to improve biosafety and biosecurity practices across regulated entities and improve the inspection process	In progress; data analysis is underway	CDC 90-Day #7: Analyze trends and associations between inspection findings and risk
	Review the science and practice of risk assessment in modern select agent laboratories to identify the highest risk activities; this will inform additional recommendations to implement standardized risk assessment activities and improve the effectiveness and timeliness of the inspection process	In progress; convening an independent group for external input	CDC 90-Day #3: Review and implement options for standardized risk assessment
Increase inspection capacity	Develop a staffing and retention plan for inspectors to improve the FSAP's ability to effectively conduct an increased volume of inspections, as well as limit turnover of trained, experienced staff	In progress	CDC 90-Day #2C: Present staffing and retention plans
Address inventory control concerns	Clarify current FSAP policy regarding the monitoring of inventories, to ensure clear and consistent understanding of the policy across inspectors and entities	Completed and communicated policy to registered entities on 2/23/16	FTAC #6: Retain inventory control requirements

Improving Inspection Reporting

Area of Focus	Action Identified	Status	Addresses
Improve content and clarity of inspection reports	Design and implement an inspection scoring system to better characterize the severity of inspection findings to reduce ambiguity and increase understanding in the regulated community on how performance and violations are graded	In progress; an internal pilot program of the scoring system is underway and the tool will be further refined in response to lessons learned during this period.	<p>CDC 90-Day #4: Better characterize severity of inspection findings</p> <p>CDC 90-Day #5: Prioritize and strengthen enforcement actions to highest risk violations</p> <p>CDC 90-Day #7: Analyze trends and associations between inspection findings and risk</p> <p>FTAC #9: Categorize inspection findings</p>
	Establish an inspection report auditing process to assess the overall quality and tone of inspection reports to improve content and consistency on a sample of inspection reports	In progress; lessons learned will help to inform additional program efforts	CDC 90-Day #1: Reduce potential variability of inspections
	Assess the range of terminology currently used in inspection reports in order to develop clear and consistent standard language for use	In progress; review of new inspection reports is underway	CDC 90-Day #1: Reduce potential variability of inspections
Improve the timeliness of inspection reports	Implement a process to issue interim inspection reports to entities to provide timely feedback after an inspection, particularly when a final inspection report will not be completed within 30 business days. These	In progress; pilot testing of both types of reports is underway	<p>CDC 90-Day #2B: Provision of interim inspection reports</p> <p>FTAC #8: Improve customer service</p>

	can be one of two types: 1). Routine preliminary reports that are for an entity's information only, and 2). Immediate action preliminary reports that highlight serious violations needing urgent action		
	Initiate routine analysis and reporting of inspection report timeliness data to identify opportunities to improve issuance of final reports within 30 days after an inspection	In progress; data analysis is underway and DSAT is developing an external report analyzing inspection report timeliness throughout 2015 with the intent to issue these reports on an annual basis moving forward	CDC 90-Day #2A: Increase timeliness of inspection reports FTAC #8: Improve customer service

IMPROVING CUSTOMER SERVICE

Area of Focus	Action Identified	Status	Addresses
Provide opportunity for entities to give inspection feedback	Develop survey so that registered entities can provide feedback on the inspection process, including on the consistency of inspections	In progress	FTAC #8: Improve customer service
Provide opportunity for entities to request interpretations of the select agent regulations	Establish a formal mechanism for issuing, publicizing, and accepting entities' requests for FSAP to answer questions regarding the select agent regulations	Completed and communicated the process to regulated entities on 12/29/15	FTAC #1: Accept requests for regulation interpretation
Increase opportunities for the select agent community to provide program input	Share draft FSAP policies and guidance before these items are finalized (as appropriate) to allow the community to provide input into issues that will affect their work	Implemented as of January 2016	FTAC #8: Improve customer service
Provide opportunity for entities to dispute findings in inspection reports	Develop a formal mechanism for entities to dispute findings in inspection reports and come to a resolution	Completed and communicated the process to regulated entities on 3/31/16.	FTAC #8: Improve customer service FTAC #10: Expand appeals process for

			disputed inspection findings
Provide additional training and guidance to the select agent community	Develop guidance for Customs and Border Protection (CBP) inspectors that process shipments of select agent and toxins coming into the U.S. to increase awareness of the applicable regulations	Guidance completed on 1/14/16; currently working with CBP on implementation.	FTAC #13: Develop training and guidance for customs inspectors
	Establish a training program for entities' Responsible Officials (ROs) in order to increase education and build community	In progress	FTAC #3: Peer-sharing of best practices
	Strengthen guidance for ROs to encourage participation in their entities' biosafety and biosecurity oversight committees so that the ROs are engaged in discussions affecting the work	In progress	FESAP #2.3: Optimize guidance for ROs
	Establish and update guidance for entities on biosafety and biosecurity plan development to provide additional details and clarity on what is needed to comply with the select agent regulations and increase biosafety and biosecurity measures	In progress: <ul style="list-style-type: none"> • Language addressing requirements for drills and exercises is included as part of the Notice of Proposed Rulemaking published in January 2016; changes are dependent upon the Final Rule • Improved guidance for biosafety plans is in development • Message was sent to regulated entities to communicate the importance of entities 	FESAP #2.1: Add requirements for drills and exercises FESAP #2.6: Improve guidance for biosafety plans FESAP #2.7: Amend guidance documents to consider maximum work hour policies

		establishing policies on maximum work hours for those in high containment laboratories (FESAP #2.7; Completed on 4/5/16)	
	Update and improve guidance for entities on inventory management best practices	In progress	FESAP #1.8: Improve material accountability practices and procedures FESAP #2.5: Improve guidance regarding working stocks and inventory control FTAC #6: Retain inventory control requirements
	Increase awareness of the OIG hotline so that staff at registered entities know how to anonymously report a safety or security concern	Added hotline information to the FSAP website; a proposal requiring entities to provide staff training on how to access the hotline is also included as part of the Notice of Proposed Rulemaking published in January 2016	FESAP #2.2: Add OIG hotline training requirement
Improve information systems	Develop a new electronic information system that will increase efficiency, accuracy, and speed of interactions between FSAP and registered entities	In progress	FTAC #8: Improve customer service
Keep pace with scientific advances in the area of diagnostics	Research diagnostic options used to confirm the presence of a select agent, including the incorporation of molecular diagnostic methods in addition to traditional culture-based	In progress; conducted a case-study analysis of one organism (<i>F. tularensis</i>) in order to inform discussions regarding these changes and found that non-culture methods are not	CDC 90-Day #9: Keep pace with scientific advances through incorporation of molecular diagnostics

	methods, to keep pace with the current state of the science	used with this organism; now considering non-culture methods for other viruses.	
Maintain close communication and coordination with AgSAS colleagues	In conjunction with AgSAS colleagues, develop joint FSAP plans and policies for program improvements, including efforts such as joint inspection reports, regulatory interpretations, the inspection dispute resolution process, and aggregate reporting of data, among others, to ensure collaboration and consistency across the FSAP	Routine communication and coordination between agencies continues to take place, including regularly scheduled in-depth discussions each week to discuss issues affecting the program.	Multiple recommendations across the CDC 90-Day, FTAC, and FESAP reviews

IMPROVING INCIDENT RESPONSE

Area of Focus	Action Identified	Status	Addresses
Improve entity incident reporting and data collection	Update Form 3 so that incident reporting is more informative about the actual and potential risk of reported theft, loss, and release incidents. This includes identifying the most common categories of incident reports and additional subcategories that are needed to collect a greater level of detail on each reported event in a more consistent fashion.	In progress	CDC 90-Day #8: Make reporting more informative about risk of reported incidents
Ensure adequate emergency response capabilities	Review existing regulations to ensure that the emergency authorities of the HHS Secretary are adequate for timely response to domestic or foreign public health emergencies involving select agents or toxins	Completed March 2016; the HHS Biosafety and Biosecurity Council reviewed and concluded that current waiver authorities are adequate; FSAP will continue to be attentive for potential scenarios where current authorities might fall short.	FTAC #5: Develop mechanism for response to emergency situations

IMPROVING TRANSPARENCY AND ENGAGEMENT

Area of Focus	Action Identified	Status	Addresses
Public release of annual data reports	Assess the feasibility of releasing a public report containing FSAP aggregate data on registered entities, inspection findings, and other key statistics. This includes creating a deliberative process to consider the security implications of such information disclosures.	In progress; a report template has been created and a full report containing aggregate data is being developed. The security community will continue to be engaged to assess potential security concerns as this process moves forward.	<p>CDC 90-Day #10: Increase public reporting of inspection processes and findings</p> <p>FTAC #2: Support public release of information</p>
Engagement with the international community	DSAT should support the International Expert Group for Biosafety and Biosecurity Regulation and, through this group, collaborate on related biosafety and biosecurity issues with foreign governments	Completed; DSAT already supports this group, as well as other global work, through its international program efforts	FTAC #12: Engagement with international community
Identify regulatory process alternatives	Research enforcement options used by other U.S. regulatory programs (e.g. aviation, food industry)	In progress; convening an independent group for external input	CDC 90-Day #6: Report on other approaches to increase regulation compliance
Support information-sharing among peers	Establish a forum to encourage routine peer-to-peer sharing regarding best practices among those working with select agents and toxins	In progress; identifying possible forums to support this effort	FTAC #3: Peer-sharing of best practices