



Division of Select Agents and Toxins

# Program Improvement Initiatives

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Centers for Disease  
Control and Prevention  
Office of Public Health  
Preparedness and Response

# 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](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<br><br>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<br><br>CDC 90-Day #4: Better characterize severity of inspection findings<br><br>CDC 90-Day #5: Prioritize and strengthen enforcement actions to highest risk violations<br><br>FTAC #9: Categorize inspection findings |

| <b>Area of Focus</b>  | <b>Action Identified</b>  | <b>Status</b>   | <b>Addresses</b>  |
|---|---|---|---|
| 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>  |

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|               | can be one of two types:<br>1). <b>Routine preliminary reports</b> that are for an entity's information only, and 2). <b>Immediate action preliminary reports</b> 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  | Completed; An external report analyzing inspection report timeliness throughout 2015 was published on 4/20/2016 (available <a href="#">here</a> ) and DSAT intends to issue these reports on an annual basis moving forward | CDC 90-Day #2A:<br>Increase timeliness of inspection reports<br><br>FTAC #8:<br>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:<br>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:<br>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:<br>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:<br>Improve customer service<br><br>FTAC #10:<br>Expand appeals |

| Area of Focus  | Action Identified  | Status   | Addresses  |
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|  |  |  | 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"> <li>• 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</li> <li>• Improved guidance for biosafety plans is in development</li> <li>• Message was sent to regulated entities to communicate the</li> </ul> | FESAP #2.1: Add requirements for drills and exercises<br><br>FESAP #2.6: Improve guidance for biosafety plans<br><br>FESAP #2.7: Amend guidance documents to consider maximum work hour policies |

| Area of Focus   | Action Identified   | Status  | Addresses  |
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|   |   | importance of entities<br>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:<br>Improve material accountability practices and procedures<br><br>FESAP #2.5:<br>Improve guidance regarding working stocks and inventory control<br><br>FTAC #6:<br>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:<br>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:<br>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  | In progress; conducted a case-study analysis of one organism ( <i>F. tularensis</i> ) in order to inform discussions  | CDC 90-Day #9:<br>Keep pace with scientific advances through incorporation of  |

| Area of Focus   | Action Identified   | Status   | Addresses   |
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|   | molecular diagnostic methods in addition to traditional culture-based methods, to keep pace with the current state of the science   | regarding these changes and found that non-culture methods are not used with this organism; now considering non-culture methods for other viruses.                                     | molecular diagnostics   |
| 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  | Completed March 2016; the HHS Biosafety and Biosecurity Council reviewed and concluded that current waiver authorities are adequate; FSAP will continue to be | FTAC #5: Develop mechanism for response to emergency situations                 |

| Area of Focus | Action Identified   | Status  | Addresses |
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|               | public health emergencies involving select agents or toxins | attentive for potential scenarios where current authorities might fall short. |           |

## 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. | CDC 90-Day #10: Increase public reporting of inspection processes and findings<br><br>FTAC #2: Support public release of information |
| 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  |