FDA Program Alignment
Tobacco
FY 2016 Action Plan

Specifics of Action Plan

The following Action Plan between the Office of Regulatory Affairs (ORA) and the Center for Tobacco Products (CTP) is intended to facilitate increased operational and program alignment as FDA transitions to distinct commodity-based and vertically-integrated regulatory programs with well-defined leads, coherent policy and strategy development, and well-designed and coordinated implementation.

This Action Plan is the agreed upon framework of mutually-shared strategic, policy and operational changes that will occur as part of a multi-year change management initiative. As initiated in FY15, ORA and the CTP will continue establishing specific action items for implementation during FY16. Where possible, Action Plans will also include target dates agreed on by ORA and the CTP. Senior managers in both ORA and the CTP will be assigned responsibility for specified implementation activities. The annual implementation plan will be reviewed throughout the year by the Center Director and ACRA to assess progress and make any necessary adjustments to the broader multi-year Action Plan.

CTP and ORA will continue to enter into an Annual Performance Agreement. This Performance Agreement outlines the number of full-time employees (FTEs) needed, a description of services and tasks performed, the basis for reimbursement, financial arrangements, and responsibilities between CTP and ORA for the reimbursement of direct costs, indirect costs, overhead in support of tobacco regulatory activities, and justification and documentation for those activities. The Performance Agreement also includes the annual workplan for ORA and it details the CTP priorities and the roles and responsibilities of the various ORA Offices who perform tobacco-related activities for CTP (e.g., OO, OPRM, OCI, SRL, FCC).

The Annual Performance Agreement will not prohibit multi-year strategic planning between ORA and CTP for prioritization of work, incorporate policy, operations, and strategy.

A. Transition to Commodity-Based and Vertically Integrated Regulatory Programs.

In May 2014, five individuals were selected to start the new Tobacco Inspection Cadre for ORA. These product-specific investigators will be trained and dedicated to do tobacco-related work, including inspections of registered tobacco manufacturing facilities, investigations of smokeless tobacco free sample events, internet surveillance to ensure tobacco products that are in violation of the law are not sold to U.S. consumers, including minors, and other tobacco investigative activities.

For future years, ORA and CTP will work to build longer term plans for inspectional resource needs to prepare for new regulation and guidance implementation and to ensure continuing investments in training and building of the specialization program.

1. ORA will refine and implement an overarching transition plan covering the transition from geographic management to program-based management developed in FY15 and provide regular progress updates.

- Lead Organization: ORA
- Due Date: September 30, 2016
- Acceptance Criteria: Implementation of the transition plan evidenced by stand up plans for operations, new programmatic SOPs, alignment of ORA staff, etc. and updates on the status of the transition
- Deliverable Format: Updates to the Steering Committee

2. In **FY 16**, CTP/OCE staff will accompany tobacco cadre investigators on certain inspections of tobacco manufacturers as SMEs, where appropriate.
    - Lead Organization(s): CTP; ORA
    - Due Date: 9/30/2016
    - Acceptance Criteria: Annual schedule or plan that CTP produces
    - Deliverable Format: Annual schedule or plan

3. In **FY16**, ORA will work with CTP on selection criteria that reflect Tobacco program interests and to include CTP participation in selection process for key manager positions related to the Tobacco program. CTP will involve ORA in key hires of program managers that regularly interact with ORA.
    - Lead Organization(s): CTP; ORA
    - Due Date: 9/30/2016
    - Acceptance criteria: Key position descriptions; forming the selection team and criteria
    - Deliverable Format: Key position descriptions and selection criteria

4. In future years, once deeming is published and effective, it is anticipated that there will be an increase in inspectional obligations. A plan will be developed to increase the cadre to meet these increases. Specifically, depending on what the needs are, the plan may need to address classification of the Tobacco Investigator PD at different grades. ORA may need to consider hiring lower graded entry level positions beyond the GS-13 currently classified.

B. Training

ORA and CTP developed a list of training and educational needs for the Cadre and other impacted components in ORA (tobacco workforce). ORA and CTP will continue to work together to develop materials for training needs, i.e., Deeming and TPMP Regulations.

1. By **2nd quarter FY16**, ORA and CTP will monitor training, awareness, and communication inventory developed for the ORA tobacco workforce and assess the items identified in FY15 to ensure staff will be trained to conduct tobacco work.
    - Lead Organization(s): CTP; ORA
    - Due Date: 3/31/2016
    - Acceptance criteria: Updated training/education list
    - Deliverable Format: Training list

2. By **3rd quarter FY16,** ORA and CTP will develop a training/communication/education implementation plan for the tobacco workforce, focusing on the Cadre, BIMO inspectors, and deeming topics. The plan will consider the prioritization and timing of trainings, the level of content based on the employee's job responsibilities, and use of materials.
    - Lead Organization(s): CTP; ORA
    - Due Date: 6/30/2016
    - Acceptance criteria: Implementation Plan
    - Deliverable Format: Implementation plan

3. In the future, ORA and CTP will:

    a) Develop a dynamic multi-year plan for training as new rules are finalized. This plan will include requirements for any relevant or yet to be developed certification, required and suggested continuing education or training, continual review frequencies, etc.
    b) Establish and charter a Training Curriculum Committee:

        i. To act as an advisory board for ORA and CTP to provide guidance for ORA Tobacco workforce training and collaboratively serve the needs of the employee development for the tobacco workforce.

        ii. Establish a charter, ground rules, general operating processes for the group, and select and task a project manager with appropriate education and training related knowledge and skill to manage the Committee's work.

        iii. Collaborate to build consensus for the analysis; design; development; delivery; and evaluation of training curricula per jobs and/or specializations and/or sub-specializations that meet FDA training policy for the tobacco workforce roles. This may include:

            1. Establishing a curriculum for defined specialized jobs that includes need supported by policy; purpose, goals, and that includes supporting analyses; design; development; delivery of learning content, quality standards; and evaluations
            2. Reviewing learning events and or curriculum annually, at a minimum, for sufficient administration of learning events to address planned work and other evaluative metrics as needed for the tobacco workforce
            3. Recommend changes and enhancements to learning events based on training analytics to demonstrate successful administration of the learning event.

        iv. Establish a process for the development of FDA courses that defines the membership, roles, and responsibilities of the Content Advisory Groups (CAGs).

        v. Assess, develop, and obtain resources for the administration of learning events for the tobacco workforce.

vi. Develop and deliver a quarterly learning event administration report that lists the physical classroom course(s) administered during that quarter, student distribution per organization and a list of attendees.

vii. Task the project manager with creating a report to track and trend the number of trainings and attendee capacity of each learning event training session and learning event effectiveness using learning event evaluation data for the course advisory group to use towards measuring the effectiveness of the training.

C. Agency Work Planning and Performance agreement

ORA and CTP will establish a program-based work planning regime that improves FDA's targeting and utilization of compliance-related resources that is based on Center priorities, public health outcomes, past inspectional history, and operation experience, and that is reported through performance-based metrics clearly demonstrating public health and compliance outcomes.

1. ORA and CTP will continue to establish an annual Performance Agreement to outline expectations and deliverables. In **3rd quarter FY16,** ORA will provide CTP with their FTE estimates and operating expenses needed to complete the work plan and other tobacco specific operations.
    - Lead Organization(s): CTP; ORA
    - Due Date: 6/30/2016
    - Acceptance criteria: Performance Agreement
    - Deliverable Format: Performance Agreement

2. ORA and CTP leadership will:
    a) Use and assess the process developed to estimate FTE resource needs and operating expenses to support and complete the work plan and other tobacco specific operations in **3rd quarter FY16**.
        - Lead Organization(s): CTP; ORA
        - Due Date: 6/30/2016
        - Acceptance criteria: Draft work plan
        - Deliverable Format: Draft work plan
    b) Implement the 2-year work plan process developed in FY15 to determine the increase of work based on implementation of new rules, completing FY17 milestones by **4th quarter FY16**.
        - Lead Organization(s): CTP; ORA
        - Due Date: 9/30/2016
        - Acceptance criteria: Draft work plan and performance agreement
        - Deliverable Format: Draft work plan and performance agreement

3. Throughout FY16, the Tobacco Cadre Program Manager (or designee) will work with CTP to monitor adherence and coordinate on a regular basis to ensure the performance agreement is accomplished.
    - Lead Organization(s): ORA
    - Due Date: 9/30/2016
    - Acceptance Criteria: Tracking and reporting progress
    - Deliverable Format: TBD

D. Compliance Policy and Enforcement Strategy

As tobacco regulations are developed, clear, outcome-based and effectively communicated compliance policies and enforcement strategies should be established. CTP has the lead on establishing enforcement strategies, implementing enforcement actions, compliance programs and compliance policy, in partnership and consultation with ORA.

Due to the nature of the industry and the constantly evolving legal interpretations of the Tobacco Control Act, all compliance and enforcement activities resulting from manufacturing inspections and the smokeless tobacco free sampling investigations are conducted at CTP, in collaboration with ORA. In future years, ORA will work with CTP to jointly develop enforcement actions.

In FY16, CTP will partner with ORA in the development of rules, guidance or policy statements that affect tobacco program staff.

1. ORA/OPRM and CTP will collaborate in developing policy.
    - Lead Organization(s): CTP; ORA
    - Due Date: 9/30/2016
    - Acceptance criteria: Monthly meetings or as scheduled
    - Deliverable Format: Meeting minutes

2. By **4th quarter FY16**, ORA/OPRM and CTP will develop a preliminary communication strategy for internal dissemination of tobacco policy.
    - Lead Organization(s): CTP; ORA
    - Due Date: 9/30/2016
    - Acceptance criteria: Draft communications plan
    - Deliverable Format: Draft communications plan

E. Imports

1. By **4th quarter FY16**, ORA and CTP will assess and use the process developed in FY15 to conduct import work by commodity/product.
    - Lead Organization(s): ORA; CTP
    - Due Date: 9/30/2016
    - Acceptance criteria: Implement SOP, develop checklist, and report on the implementation

Deliverable Format: Checklist and reporting

F. Laboratory Optimization

CTP and ORA have worked together to create a centralized laboratory within ORA. ORA utilizes SRL as a centralized laboratory to perform all tobacco-related laboratory testing and analysis to support CTP's tobacco product review and enforcement activities. ORA/FCC also performs tobacco-related laboratory activities to support OCI work. All ORA laboratory activities are based on CTP priorities and they are detailed in its annual Performance Agreement with ORA.

CTP has a dedicated laboratory liaison, located in Atlanta, GA, who coordinates laboratory activities between CTP, SRL, FCC, and CDC regarding CTP priorities, staffing levels, equipment and training needs to accomplish the annual Performance Agreement actions. CTP and ORA work with the CTP laboratory liaison to streamline the communication process between CTP and SRL and to ensure the laboratories are not conducting duplicative efforts.

1. ORA and CTP will implement the lab optimization plan developed in FY15, completing all FY16 milestones by **4th quarter FY16**.
    - Lead Organization(s): ORA; CTP
    - Due Date: 9/30/2016
    - Acceptance criteria: Demonstrate implementing milestones: quarterly meetings, final report
    - Deliverable Format: Final report

2. ORA and CTP will begin implementation of the multi-year strategic plan developed in FY15, completing all FY16 milestones by **4th quarter FY16**.
    - Lead Organization(s): ORA; CTP
    - Due Date: 9/30/2016
    - Acceptance criteria: Demonstrate implementing milestones: quarterly meetings, final report
    - Deliverable Format: Meeting minutes; final report

3. ORA and CTP will meet annually to reassess the laboratory work plan for the upcoming year, completing by **4th quarter FY16**.
    - Lead Organization(s): ORA; CTP
    - Due Date: 9/30/2016
    - Acceptance criteria: Demonstrate implementing milestones: annual meeting; additional meetings throughout the year to monitor progress
    - Deliverable Format: Meeting minutes

G. IT

1. By **4th quarter FY16**, ORA and CTP will develop requirements for IT enhancements and identify the IT systems to enhance and accommodate tobacco program needs.
    - Lead Organization(s): ORA; CTP
    - Due Date: 9/30/2016
    - Acceptance criteria: Prioritize IT efforts and begin development of requirements
    - Deliverable Format: Draft requirements document