FDA Program Alignment
Tobacco
FY 2015 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. Each year starting with FY15, ORA and the CTP will establish specific action items for implementation during that fiscal year. 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 quarterly 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, 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 This section is about specialization.

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.

CTP/OCE staff will work closely with these tobacco cadre investigators to provide them with the training and education needed to ensure their knowledge and understanding of the industry, unique legal issues involved in the implementation of the Tobacco Control Act, CTP priorities for investigation and enforcement, and the importance of continuous communication with CTP/OCE staff to promote Center and ORA collaboration.

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. CTP will establish a baseline of its staff involved in various activities (such as cigarettes, cigarette tobacco, roll your own tobacco, smokeless, deeming: e-cigs, cigars, state work, modified risk claims, and civil money penalties, etc.) so ORA can appropriately mirror sub specialties as needed.

2. ORA will establish the Senior Executive Tobacco Program Director and launch recruitment by December 31, 2014.

3. In FY 15, CTP/OCE staff will accompany tobacco cadre investigators on certain inspections of tobacco manufactures as SMEs, where appropriate.

4. ORA will work with CTP on selection criteria that reflect Tobacco program interests and to include CTP participation in selection process for senior manager positions related to the tobacco program. CTP will involve ORA in key hires of senior program managers that regularly interact with ORA.

5. Currently, CTP has limited needs for BIMO inspections. The current tobacco cadre members can perform these inspections. As the deeming rule is finalized and becomes effective and the premarket applications that need inspections prior to granting marketing authorizations by CTP, ORA will hire additional members to the tobacco cadre that can conduct these inspections.

B. Training: ORA and CTP must jointly invest for training to be effective.

CTP has taken the lead on training ORA CSO's in conducting tobacco inspections by holding 3 briefing sessions over the past 3 years. This is an excellent introduction to the tobacco regulations and the firms ORA is to inspect. Furthermore prior to each inspection CTP provides a binder of firm information such as registration, labeling, preapprovals to the CSO. CTP has also accompanied CSO's on these inspections. This provides not only CTP SME input but also provides ORA expertise to CTP in conducting EI's.

Tobacco Cadre Implementation Group is a working group made up of Tobacco Field Committee members and CTP. Currently this working group is developing competency requirements. For example background reading materials and 2 week orientation details have been developed.

1. In FY 15, ORA and CTP will develop inventories of trainings offered or conferences attended.
2. In FY 15, all training including scope and curricula for the tobacco cadre will be developed jointly with ORA and CTP/OCE staff.

3. In FY 15, for all other tobacco related work in the districts (ex: complaint handling, imports, recalls, OEI coordination, FOIA requests) CTP/OCE will work with ORA to identify training and education needed to perform tobacco-related activities that are not completed by the ORA tobacco cadre.
4. In the future, ORA and CTP will develop a dynamic multi-year plan for training as new rules come out. 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.

C. Agency Work Planning: 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. ORA will provide CTP with their FTE estimates and operating expenses needed to complete the work plan and other tobacco specific operations.
2. ORA and CTP leadership will work together to formulate a process over time to ensure that resources are allocated to shared strategic priorities and work plan goals.
3. ORA and CTP will work to develop a 2-year workplan plan (FY 16 -17) for the increase of work and implementation of new rules.
4. Tobacco Cadre Program Manager (or designee) will work with CTP to monitor adherence and coordinate on a regular basis to ensure the work plan is accomplished.

D. Compliance Policy and Enforcement Strategy: Clear, current, 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, with ORA participation.

Due to the nature of the industry and the constantly evolving policy and 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.

After Tobacco Product Manufacturing Practice (TPMP) regulations are final and effective, ORA will work with CTP to jointly develop enforcement actions. ORA will be involved in the development of compliance and enforcement policies and guides. In FY 15, CTP will involve the Tobacco Cadre supervisor in the review of EIRs and any resulting enforcement action. CTP will identify areas of training for ORA in working jointly to develop enforcement actions after TPMP regulations are effective.

CTP with ORA participation will collaborate to develop processes for commodity-specific policy development, appropriate policies and programs, and communication and outreach approaches to accomplish the enforcement strategy when CTP policies are changed or developed and six months prior to when new rules will become effective. CTP, working with ORA, will establish a recurring review of established compliance programs and policy guides.

E. Imports:

1. ORA will identify a liaison for imports for CTP. The liaison and the Center will hold regular meetings.

2. ORA and CTP assess import program data and establish a strategic plan for imports by commodity/product.

3. Where needed, CTP and ORA will clarify how import screening strategies, policies and decision-making will be executed
    i. CTP will identify any new import strategies on an on-going basis as new charge codes are developed and implemented.
    ii. CTP will identify clearance process to address any political and diplomatic considerations that may influence specific import strategies.

F. Laboratory Optimization

CTP and ORA have worked together to create of 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. Because laboratory needs are currently based on regulation development and compliance actions, ORA and CTP will coordinate on the lab optimization plan and will discuss the need for further lab specialization. ORA will develop transition plans as required

2. ORA and CTP will work to establish a multi-year strategic plan for ORA scientific work to appropriately hire and train analysts, purchase and use equipment, and allocate resources and facilities.
3. ORA and CTP will meet at least annually to reassess laboratory work plan for upcoming year. Due to the nature of the changes in CTP regarding various efforts and new authorities, ORA and CTP will coordinate frequently to ensure the labs will be able to support upcoming CTP needs

G. IT: ORA and CTP will develop an IT-focused program to enhance information sharing and collaboration to facilitate risk based inspection management. An objective is to integrate real-time visibility into ORA and CTP databases including information on inventory, applications, facilities, adverse events, and risk information that allows for rapid analytics capability.

ORA will identify an ORA IT-expert to assist CTP with specific IT needs as they relate to ORA's existing and future IT systems. For example, both RES and FACTS need modifications to include fields relating to tobacco.