

FDA Program Alignment
Food and Feed Program
FY2015 Action Plan

I. General Information: Program Alignment ORA/Center Negotiated Action Plans

The Food and Feed Program Action Plan (the Action Plan or Plan) is the agreed upon framework for shared strategic, policy and operational changes that will occur as part of the Program Alignment multi-year change management initiative to be carried out under the auspices of the Food and Veterinary Medicine (FVM) Governance Board.

Each fiscal year, beginning with FY 2015, the Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM) and the Office of International Programs (OIP) will identify specific deliverables under select Program Alignment initiative target areas as identified by the Commissioner and senior FDA leaders to be accomplished during that fiscal year. Accountability for developing the Action Plan and accomplishing the deliverables will be achieved through FDA's performance management system. ORA, CFSAN, CVM and OIP managers responsible for FDA's Food and Feed Program will be assigned responsibility for specific deliverables and subsequent implementation activities. Where possible, deliverables in the Action Plan will include target dates for completion as agreed on by ORA CFSAN, CVM and OIP leadership. Where appropriate, deliverables include streamlined business processes with clearly delineated roles and responsibilities. The FVM Governance Board will review the Action Plan and its deliverables on a quarterly basis to assess progress and make any necessary adjustments.

The FVM Governance Board is the cross-organizational joint governance body created by the Office of Global Regulatory Operations and Policy (GO) and the Office of Foods and Veterinary Medicine (OFVM) to ensure the proper coordination and vertical integration of the inspection, compliance, enforcement and other field-based activities of the FVM Program carried out by ORA, OIP, CFSAN, and CVM. The FVM Governance Board is the highest decision-making body of the Program, with direct accountability to the Commissioner and a focus on significant strategic priority setting and resource allocation decision-making. [Its authority is described in the FVM Governance Charter.] The FVM Governance Board is ultimately responsible for this action plan. In concert with the FVM Governance Board and the FVM Executive Council, ORA, OIP, CFSAN and CVM management teams will implement the Action Plan and the Senior Leadership of each of the organization will be accountable for the Action Plan's success. In the course of carrying out the Action Plan presented below, deliverables and recommendations that include significant change and/or require significant redirection or investment of resources will be vetted and decided through the FVM Governance Board.

II. Objectives of the FY 2015 Food and Feed Program Action Plan

The objectives and deliverables in the FY2015 Food and Feed Program Action Plan align with and promote the FDA food Safety Modernization Act (FSMA) post final rule implementation strategies and guiding principles in the May 2014 *Operational Strategy for Implementing FSMA* document.

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The FY 2015 Action Plan is intended to:

1. Address the target areas identified in the Commissioner's February 2014 memo including transitioning to a specialized vertically integrated Food and Feed Program with cross-organizational decision-making and transparency in resource planning and allocation.
2. Facilitate the development of an implementation plan for the transition to a commodity-based and vertically integrated Food and Feed Program.
3. Align with and support current Food Safety Modernization Act (FSMA) implementation efforts and other Food and Veterinary Medicine Program priorities.
4. For each of the areas mentioned in the Commissioner's February 2014 memorandum and in this Action Plan and in other areas that the FVM Governance Board identifies, the FVM Governance Board will define decision rights and processes.
5. Ensure that clear, current, outcome-based and effectively communicated compliance policies and enforcement strategies are available, with CFSAN/ CVM taking the lead for establishing the compliance policy, compliance programs and enforcement strategies, with ORA collaboration and with ORA taking the lead for execution of the strategies and policies, with CFSAN and CVM collaboration.
6. Serve as the foundation for the communication strategy.

In addition, the FVM Governance Board will develop outcome-oriented performance and public health metrics for the Food and Feed Program that align with the FSMA Operational Strategy and that pertain to PAG target areas. The metrics will include internal performance metrics for FDA managers and external performance metrics that enable FDA stakeholders and the general public to assess progress. Existing performance goals will be evaluated and work will be initiated to reduce or eliminate those that are not adequately outcome oriented, i.e., field exams. A concerted effort will be made to remove or modify existing performance goals that do not align with any outcome-oriented metrics agreed upon as part of this deliverable.

III. The FY 2015 Food and Feed Program Action Plan

Unless otherwise noted, all items will be accomplished in fiscal year 2015.

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

1. ORA will develop plans for transitioning operational resources within ORA to commodity-specific structures. In developing the Food and Feed Program plan, ORA will collaborate with the FVM Governance Board.
2. ORA will establish the Senior Executive Food and Feed Program Director position and launch recruitment. ORA will engage OFVM, CFSAN and CVM as participants in the selection process for this position.
3. ORA will develop a baseline of program specialization of its current workforce through a survey. Once the survey is completed and existing data are analyzed, ORA will conduct a workforce analysis to overlay the workplan and the Official Establishment Inventory (OEI), identify gaps and develop a hiring plan by programmatic specialty. ORA will collaborate and share results with CFSAN and CVM.
4. CFSAN and CVM will develop and/or share workforce reports and hiring strategies that align with ORA's survey elements.
5. OIP will develop and share a baseline workforce report of its staff involved in planning and conducting food and feed foreign inspection activities. OIP will then share its hiring strategy for foreign posts as it pertains to the Food and Feed Program.
6. ORA, CFSAN and CVM will develop and implement a process to routinely share information about organizational changes, hiring plans and current points of contact.
7. CFSAN and CVM continue to share plans with ORA for hiring and allocating resources to align with Food and Feed Program priorities and agreed upon operating models and give ORA an opportunity for comment and input. CFSAN and CVM will work with ORA to establish plans for prioritization of hiring/resource allocation to align with and support ORA's transition process.
8. ORA, CFSAN and CVM will establish recommendations and prioritization for the specialization of investigators, compliance officers and first-line managers within the Food and Feed Program.¹ CFSAN, CVM, ORA and OIP will adjust hiring strategies in future years to align with the specialization model.

¹ The recommendations will address investigators, compliance officers, and first line managers at a minimum. Other positions may also be included in the recommendations for sub-specialization.

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9. CFSAN, CVM and ORA will initiate discussions on how specialization will affect states and state contract alignment. CFSAN, CVM, ORA and OIP will adjust state contracts in future years to align with the specialization model.

B. Training²

1. ORA, CFSAN, CVM and OIP will share their inventories of training currently offered and how it has been developed, delivered, evaluated and updated. ORA will conduct an analysis of any overlap between existing trainings to determine where leveraging opportunities exist.
2. ORA, CFSAN, CVM and OIP (when appropriate) will:
 - a. Identify current staff and skillsets involved in training, coordination, development and delivery and contracts available.
 - b. Establish documented roles and responsibilities for course development, delivery, evaluation and continuing education of the food and feed food safety staff training and development program.
3. ORA, CFSAN and CVM will develop options and recommendations to meet future training needs of the Food and Feed Program. This includes training for local, state, tribal, territorial, and other regulatory partners.
4. ORA, CFSAN and CVM, with input from the FSMA Preventive Controls (PC) Workgroup, will develop and begin implementation of a multi-year training plan for the PC rules for human and animal food.

In future years, ORA, CFSAN, CVM, and when appropriate, OIP will:

- Begin to develop outcome metrics to assess training effectiveness and consistency in application of the training.
- Identify gaps in skillsets needed to update and implement the food and feed training program.
- Evaluate how best to fill the gaps considering both internal and external sources, such as industry and academia.

² Training includes conferences, details to other organizations or positions, on the job training, developmental assignments, and classroom training (both in-person and virtual formats).

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C. Food and Feed Program Workplanning

1. ORA will work with CFSAN and CVM to:
 - a. Map business processes and develop data strategies to improve the accuracy of the OEI, taking into account the data transferred from the registration database;
 - b. Develop training for all involved including contractors in the OEI and data input; and.
 - c. Update references (e.g., FMD 130, “OEI Development and Maintenance Procedures”) as appropriate.
2. ORA, CFSAN, CVM and OIP will design and agree upon a multi-year workplanning model and its contents for the Food and Feed Program, with the intention of piloting the new model in FY 2016. The model will:
 - a. Align with strategic priorities and build upon risk-based prioritization models currently in use.
 - b. Consider future priorities and activities to allow CFSAN, CVM, ORA and OIP to adjust resources to meet future program needs.
 - c. Include more detailed operational activities for cooperative programs.
3. ORA, CFSAN, CVM and OIP will establish a documented protocol for tracking accomplishments toward the workplan, approving changes to the planned portion of the workplan and updating jointly held goals.
 - a. ORA will establish a workplan dashboard.
 - b. CFSAN, CVM and OIP will provide feedback on the dashboard and ORA, CFSAN, CVM and OIP will reach agreement on any proposed changes.
 - c. CFSAN, CVM, ORA and OIP will meet regularly to discuss accomplishment of the workplan to date and any proposed changes.
 - d. ORA, CFSAN, CVM and OIP will fully implement the workplan dashboard and the ORA Food and Feed Program Executive or designee will be responsible for carrying out the planned portion of the workplan.
4. ORA, CFSAN and CVM will develop a process for keeping each other informed and making decisions relative to state contracts, grants, cooperative agreements and training that affect the workplan
 - a. ORA will provide an annual update to CFSAN and CVM on current contracts, grants, and cooperative agreements including, to the extent the information is available, the number of state inspectors available or the capacity of the states to do this contract work in the future.

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- b. CFSAN and CVM will provide an annual update to ORA on each of their current contracts, grants and cooperative agreements and share best practices for handling.
 - c. ORA, with Office of Acquisitions and Grants and State input, will explore the feasibility of transitioning all state contracts, grants and cooperative agreements to the federal fiscal year cycle and include language changes toward the specialization model.
- 5. ORA, CFSAN, CVM and OIP will work to improve the current foreign inspection program. Specifically:
 - a. ORA will share its map of the foreign inspection process with CFSAN, CVM and OIP and complete the map with input from CFSAN, CVM and OIP.
 - b. ORA will identify opportunities for streamlining the logistics of trip planning.
 - c. CFSAN and CVM will enhance current foreign site selection using an improved risk-based approach.
 - d. CFSAN and CVM will ensure early assignment of viable firms to facilitate accomplishment of the foreign inspection portion of the workplan.
 - e. ORA, CFSAN, CVM and OIP work to integrate investigators stationed at foreign posts into the annual Food and Feed Program workplan and accomplishment reports.

D. Compliance Policy and Enforcement Strategies

- 1. ORA, CFSAN and CVM will develop practical approaches and scenarios for using the new FSMA administrative enforcement tools; i.e., administrative detention, suspension of registration, mandatory recall.
- 2. ORA, CFSAN and CVM will work with OCC to determine the feasibility of issuing deficiency letters to firms within a few days of identifying noncompliance during an inspection which, if not corrected quickly could affect public health and, if deemed feasible, begin to delineate the process/plan for implementation.
- 3. ORA, CFSAN and CVM will identify opportunities for expansion of direct reference Warning Letter authority to ORA. ORA, CFSAN and CVM will periodically audit use of such direct reference authorities to ensure consistency.
- 4. CFSAN and CVM, with ORA participation, will:

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- a. Identify and assess gaps in compliance policy and enforcement strategies and where existing compliance policies and enforcement strategies need to be updated.
 - b. Prioritize gaps and need for updates in policy based on public health risks, develop a project management plan, and initiate related policy and strategy development work.
 - c. With OCC, establish a streamlined process for clearance of compliance policy.
5. ORA, CFSAN and CVM will establish a process/standard operating procedure to establish, use and document new and innovative strategies for novel or unique situations that may set precedents and/or establish new policy to handle compliance-related issues. OFVM CORE will implement the process as established. CFSAN and CVM will establish a process to ensure the routine review of such decisions for trends and consistency and to identify where new national policy/procedures need to be established.
6. ORA, CFSAN and CVM will develop strategic recommendations and plans for prioritizing, implementing and communicating the use of rational questionnaires and other streamlined approaches in the Food and Feed Program to document inspections and support compliance and enforcement activities.
7. ORA, CFSAN and CVM, with OFVM CORE input where appropriate, will establish and begin implementation of a new streamlined/delayed, effective, and time efficient process for the development and clearance of field assignments. This process will include re-envisioning enforcement strategies developed as part of assignments.
8. CFSAN and CVM offices of compliance will better integrate and leverage CFSAN and CVM compliance activities and experts. More specifically, CFSAN and CVM will:
 - a. Share risk informed targeting protocols and models for designating firms/facilities as high risk and non-high risk; create and execute statistically-based sampling models; and develop a risk- based workplan and associated field assignments.
 - b. Establish a documented process for identifying compliance policies to be developed jointly by CFSAN and CVM and/or policies that should align across the two Centers.
 - c. Compare business processes and timeframes for regulatory actions and align where appropriate.
9. ORA, CFSAN and CVM will begin to transition No Action Indicated (NAI) and Voluntary Action Indicated (VAI) foreign inspection review and classification to a process similar to the domestic inspection review and classification.

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In future years, ORA, CFSAN, CVM, and when appropriate, OIP will:

- Define a standard process for foreign OEI maintenance, and consumer complaints related to foreign facilities.
- Establish a streamlined process for establishing and clearing of compliance programs. ORA, CFSAN and CVM will begin to transition compliance programs to a format that improves organization, consistency and usability.
- Share and integrate quality system activities across the Food and Feed Program as they relate to compliance and enforcement activities, to promote harmonization.
- Map the processes, including OCC, for advisory actions (domestic and foreign warning letters). In subsequent years, CFSAN, CVM and ORA will address administrative actions, judicial actions and recalls.
- Define a standard process for recall coordination related to foreign facilities.

E. Imports Operations

1. ORA, CFSAN and CVM, including OCC, will map the business processes to improve collaboration, while reducing duplication of efforts and streamlining decision-making for import alerts. In subsequent years, ORA, CFSAN and CVM will address other import compliance actions.
2. ORA, CFSAN and CVM will establish a process to address the establishment, use and documentation of new and innovative strategies for novel or unique situations that may set precedents and/or establish policy to handle import related issues. OFVM CORE will implement the process as established. CFSAN and CVM will routinely review decisions for trends and consistency and the need to develop new national policy/ procedures.
3. ORA, CFSAN and CVM will create a cross-organizational workgroup to develop a plan to retool food related import alerts and begin to implement the plan to assure success in Foreign Supplier Verification Program (FSVP) and Voluntary Qualified Importer Program (VQIP) implementation.
4. CFSAN will begin to provide information on the inherent risk of various cosmetics and dietary supplements to ORA and work to establish PREDICT business rules around these categories of regulated products.
5. CVM will provide information on the inherent risk of food for animals.
6. ORA will share operational findings, recommendations, and decisions made as a result of the Centralized Entry Review Pilot.

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In future years, ORA, CFSAN, CVM, and when appropriate, OIP will:

- Identify opportunities for expansion of direct reference authority in the imports program to ORA. ORA, CFSAN and CVM will periodically audit use of direct reference authorities to ensure consistency.
- Review the current structure/staff involved in governance of the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting system (PREDICT) and the decision-making processes for food and feed entries; provide recommendations for any necessary changes to the governance structure and resources/staff dedicated to PREDICT; evaluate PREDICT business rules for alignment with the workplan, sampling models, and priorities, and FSMA import programs; and, where there is not alignment, develop a strategy to address and establish a procedure for regular review and update of the business rules.
- Review and update the inherent risks associated with conventional foods and provide the information to ORA to ensure that business rules reflect the most current information available.

F. Laboratory Optimization

1. ORA will brief CFSAN and CVM on the current lab optimization plan, ORA lab operations and use of Food Emergency Response Network (FERN) laboratories. CFSAN and CVM will brief ORA on their current and future lab operations (i.e. microbiology and chemistry future state pilots).
2. ORA, CFSAN and CVM will establish a process to set strategic direction for Food and Feed Program analytical resources including assessment of laboratory optimization, plan work for upcoming and future years, and explore additional areas of lab efficiency and regulatory science competency development.
3. OFVM, ORA, CFSAN and CVM will establish a process to ensure that all food/feed-related research is captured in CARTS, and establish a system of accountability to ensure this happens.

G. IT

OFVM, ORA, CFSAN and CVM will develop an IT-focused program to enhance information-sharing and collaboration and to facilitate risk- based activities. Goals include end-to-end data system analysis to assess how to improve integration of CFSAN, CVM, and ORA information needs for making risk- based regulatory decisions.

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1. ORA, CFSAN and CVM will develop a process to routinely share information about Food and Feed Program-related IT investments and jointly prioritize the development of new systems and changes to existing systems to facilitate business processes.
2. ORA will enhance IT systems related to corrective actions, update procedures and inform staff, to better capture information on corrective actions taken by firms during or after an inspection.
3. ORA and CFSAN will advance the utilization of tablets or lightweight computers and rational questionnaires for the collection of data during inspections and investigations to promote consistency, efficiency and trending.