



**U.S. FOOD & DRUG
ADMINISTRATION**

Moving Towards a Public Health Systems Approach

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW

Association for Food & Drug Officials (AFDO)

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FSMA Implementation

- Goal of FSMA is to move food safety system from a reactive to a preventive mode.
- FSMA's success depends on bringing about high rates of compliance.
- FDA is committed to educating before and while we regulate.
- FDA will engage and communicate to international community that is consistent with domestic efforts.

2017 Operational Field Activities

- Inspections by FDA cadre
 - Preventive controls for human food (full requirements, domestic and foreign).
- Inspections by FDA and state
 - Preventive controls for human food and animal food CGMPs.
- Record reviews of importers (FSVP).
- Inspections of Sprout Producers and Seed Suppliers.
- Other inspectional and sampling obligations as directed by Centers through directed assignments.



2018 Operational Field Activities

- Continue PC Human Food, Animal Food (CGMP), Sprouts, FSVP Record Reviews.
- Begin Sanitary Transportation Inspectional Components relative to large businesses (153 surveillance activities).
- Obtain stability from Program Alignment Initiative.
- Continue inspections as outlined in FDA's Food Safety Work Plan.

2018 Operational Field Activities

- Continue engagement with state regulatory partners to leverage resources.
- Continue training of food safety staff through internal webinars and outreach.
- Increase training of food safety staff in FDA's Regulators Training Course.

2019 Operational Field Activities

Intentional Adulteration

- Two Level Inspectional Approach
 - High level review for required sections
 - Trained investigators for full requirements

- Training and Assistance
 - Online courses
 - Webinars
 - FSMA Technical Assistance Network (TAN)

Operational Field Activities

Lessons Learned

- Clear communication of purpose of inspection.
- Industry not understanding ORA's policy on taking photographs.
- Longer inspection times and more participants on inspections, partly due to OJE.
- Consider feedback from industry, consumers, and state partners.
- Obtaining copies of Food Safety Plans and other documents as informational rather than supporting evidence of violation or significant observation.

What's Next?

- FDA's primary focus will continue to be on education, training and technical assistance to help companies comply with the new requirements.
- FDA recently issued draft guidance documents and will continue collaboration with regulated industry to ensure everyone understands and engages their respective roles in food safety.
- Inspection approach will focus on assessing the progress a company has made towards compliance and whether it is taking appropriate steps necessary to protect public health.
- Work with the food industry to create a culture of food safety, with procedures, processes, and practices that we know will achieve high rates of compliance with the rule and minimize the risk of foodborne illness.

Thank You

