

2018 MFRP Alliance Meeting

What's After Conformance?

Clinton Priestley
on behalf of Ellen Buchanan
CSO Auditor

Clinton.Priestley@fda.hhs.gov
FDA/ORO/OHAFO/Audit Staff

Wait, am I conformed or integrated?

Terminology:

- Conformance
- Socialization
- Operationalization (op-er-a-tional-iza-tion)
- Mutual Reliance (MR)
- Integrated Food Safety System (IFSS)

What is the scope of conformance?

- How does conformance affect my regulatory program operations?
- How does conformance affect my relationship with FDA?
- How does conformance affect my relationship with other state agencies (intra- and interstate) and other federal agencies?

OIG: Oversight of State Food Firm Inspections

Template For Effective FDA Oversight of State Food Firm Inspections

- ✓ **Equivalency:** Equivalency among Federal and State food safety standards, inspection programs, and enforcement practices.
- ✓ **On-site Audits:** An effective on-site mechanism for evaluating State inspection performance.
- ✓ **Inspection Information:** Routine submission of standardized inspection information.
- ✓ **External Sources:** Information from varied external sources on State inspection performance.
- ✓ **Feedback to States:** Substantive and timely FDA feedback to States on inspection performance.
- ✓ **Internal Capacities:** Enhanced FDA capacities to conduct effective oversight.
- ✓ **Public Information:** Proactive public disclosure of FDA's reliance upon and oversight of State inspections.

Stronger Partnerships for Safer Food

An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System

- A vision for an integrated national food safety system that operates as a full partnership among federal, state, and local agencies. The functional attributes of such a system include:
 - Placing first priority on protecting public health and preventing FBI;
 - Addressing food safety risks all across the farm-to-table spectrum of food production, processing, distribution, retailing, and home preparation;
 - Making efficient use of all available public resources by closely coordinating federal, state, and local efforts and targeting those efforts on the basis of risk and opportunities to reduce risk across the system;
 - Implementing as much as possible nationally uniform food safety standards and mounting an integrated, federal-state-local effort to enforce standards, with respect to both domestic and imported foods, through coordinated inspection programs and compliance strategies;
 - Working effectively to detect and contain outbreaks of foodborne illness through robust federal-state-local systems of illness surveillance and outbreak response; and,
 - Systematically collecting and disseminating the information that government officials and the private sector need to manage an integrated, science-based food safety system and prevent foodborne illness.

Ellen's trip down memory lane

- We endorsed the Manufactured Standards and allocated ORA budget to states to enroll in the program.
- We endorsed the Animal Feed Standards and allocated ORA budget to states to enroll in the program.
- We allocated ORA budget dollars for state lab ISO accreditation.
- We endorsed Rapid Response Teams and allocate ORA budget dollars to states to enroll in the program.
- ORA budget dollars were allocated for states to strategize how to handle produce and to develop training for the produce industry.
- OTED developed a training needs survey for states to help identify what training is needed by the states and then allocated seats for state partners in FDA training courses.
- FDA funds the states to attend these FDA trainings.
- We endorsed the development of IFPTI in Battle Creek and fund trainings there.
- We created a training summit to try and understand the whole universe of training and competencies needed for an integrated food safety system.
- We hired state liaisons.
- We hired emergency response coordinators.
- We hired OEI coordinators.
- We dedicated resources in the co-operative programs, for state training and supplies and technical support (this is not new since 2010, but is the model for successful integration).
- Funding and human resources for IT development.



Ellen's trip down memory lane

- DFSR/OP has hired at least 12 employees from state regulatory programs to assist FDA with working with state standards programs and FDA contracts and grants.
- We created PFP to work on common strategic goals.
- We have funded states to the PFP meetings every other year, two individuals per state (plus all of the FDA employees that participate and attend).
- We created an integration branch with OP to assist with integration pilots to find best practices for an integrated food safety system.
- We committed to the same auditors evaluating all third parties (SR, food and feed standards, TPA) so the same people are evaluating everyone the same.
- We certified our auditors, helping to ensure an objective assessment of third party stakeholders.
- We included state employees in all the FSMA working groups. And then held quarterly calls so the state representatives from the FSMA workgroups could brief all 50 states on FSMA workgroup progress, and take questions and provide input.
- We invited states to the FSMA chats, designed to be internal communication from HQ to the field on current and emerging trends and thoughts while we worked on rolling out all the FSMA regulations.
- We created a state strategy working group to receive input from states on FSMA policy considerations, this group eventually merged into PFP.
- We support all the associations states participate in by attending their meetings and speaking from the podium.
- We give out small conference grants to help states pay their way to meetings when the state cannot afford to send them with their own budget dollars.

FDA Initiatives (Current/ Future)

- Mutual Reliance Pilot Project (3 states)
- National Food Safety Data Exchange
- Integration Project Objectives
 - Division Assessments to MFRPS
 - Mutual Reliance – define and establish framework
 - ISO-style Standard? Pros/ Cons
 - Strategic Plans
 - And more.... Talk to Alan Tart

I've been conformed. Rejoice!

Some ideas on what changes may occur:

- Culture change: State/ FDA Division relationships
- Standardization of how work is conducted
- Recognition of work/ data acceptance
- Using data to leverage resources
 - Work Planning for inspection and sampling work
 - Using the most logical resource to achieve public health goals
- IFSS/ MR

*With a little help
from
our friends*



**REGULAR
MAINTENANCE**

**Political Considerations
& Regulatory Changes**

**Information
sharing**

**Innovative
Methods**

Best Practices

**Administrative
Changes**



MFRPAlliance



Welcome to the MFRPA Portal

MFRPA Index of Shared Documents

MFRPA

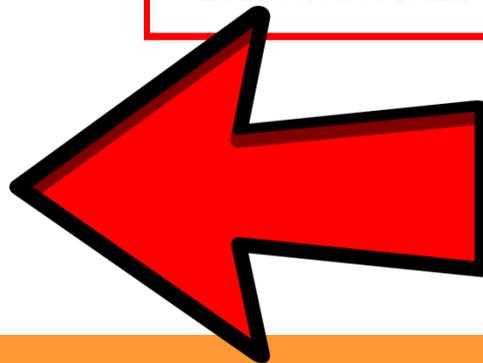
- Board of Directors
- Board Meeting Minutes
- By-laws of the Alliance
- Resource Binder (Jan. 2018)

MFRPS

- 2016 Standards
- 2013 Standards
- MFRPS Exit Strategy Sustainment (ESS)
- MFRPS Standards Enhancement Projects (SEPs)
- MFRPS Document Control

Quick Links

- [7th Manufactured Food Regulatory Program Alliance\(MFRPA\) Meeting & 4th Governmental Food and Feed Laboratories Accreditation Meeting](#)
- [Board of Directors](#)
- [2016 Manufactured Food Regulatory Program Standards \(MFRPS\) and Corresponding Documents](#)
- [Resource Binder](#)
- [MFRPA Document Control](#)
- [2016 MFRPS and PC For Human Food Training](#)
- [2018 MFRPA & Lab Presentations](#)



About the Alliance



Sharing Information in a Useful Way



Integrated Food Safety System



Contact Information

Natalie Adan

Food Safety Division Director

Georgia Department of Agriculture

Natalie.Adan@agr.georgia.gov

Clint Priestley

*Auditor, Office of Human & Animal Food
Operations*

U.S. Food and Drug Administration

Clinton.Priestley@fda.hhs.gov

