



The Long Road to FSMA

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Outline

- Adoption of FSMA
- Now What? (implementation approach)
- What we know so far
- Next Steps, or what we don't know so far

Early Adoption of FSMA

- WA State Adoption by reference.
- December 1, 2016

BENEFITS

Continued FDA/WSDA mutual reliance providing contract inspectional services without credentialing or need to use FDA forms

Implementation Approach

- Staff Training – GMPs and Preventive Controls
- Inspection Systems Updates
- Industry Outreach – very small to large

Staff Training

- GMPs and Preventive Controls
 - 32 Field Inspection Staff
 - + 3 Regional Managers
 - + Olympia Management Team
 - = a lot of training!**
- All staff are PC Qualified Individuals
- PC for Regulators Training (FD254) has started

Preventive Controls Inspections

- Instructor development opportunity
 - PC for Regulators Cadre
- First inspectors to course
 - 3 now with 8 more in FY18
- First PC inspections just starting (more later)

Inspection Systems

- New regulations means new systems to support the inspection process.
 - Updated inspection report – includes GMPs and PC related subparts
 - Database enhancements

Outreach

- WSU - PCQI Courses for small processors
- Trade and professional groups
- Fact Sheets – General FSMA and Very Small Firm specific

Inspections

- Modernized GMP Inspections – Oct, 2017
- PC Inspections – Jan, 2018
 - Starting with 4 under FDA Contract
 - State Inspections coming this year with a focus on Technical Assistance

What do we know?

- Small firms are not ready
 - Experience with industry indicates they are trying but not there yet
 - Challenges with hazard analysis and determining controls

What do we know?

- Firms that have never implemented a comprehensive food safety plan are **now** working on it.
- Outreach and technical assistance is critical for success (educate before regulate)

PC Inspection Time

- Not a floors/walls/ceiling inspection
- Significant time involved
 - prep, inspection, write-up, technical assistance
 - 50 hours PLUS for small lower risk firms such as bakeries (allergens!) Prep & Write-up = 16-20 hours
 - Currently two inspectors on each inspection for training to ensure consistency
 - Anticipate this number decreasing as industry and regulators learn

Next Steps

- Modernized GMP inspections for all state inspection work by end of 2018.
- PC for Grade 'A' dairy products end of 2018
 - PC for Dairy Regulators Course – end of 2018
- Further Database Enhancements
 - Electronic inspections, work flow, online license renewal

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