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
Contact Information

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