Implementation of the Preventive Controls for Human Foods Rule

New York State Department of Agriculture and Markets
Division of Food Safety and Inspection
Adoption of Regulation

• The Department elected to adopt the entire regulation (21 CFR 117) with the exemption of subparts D & E, through the consensus rule making process
• We received no objections
• Regulation was published in the State Register on June 21, 2017
• Adoption of the rule enables the Department to conduct inspections covered by the Preventive Control for Human Food rule under New York State jurisdiction
Implementation

• Devised a ‘information collection’ worksheet for inspectors to:
  • Understand the size of the universe i.e. how many facilities in New York are affected by the rule
  • As a mechanism to create awareness around the new rule
  • To provide outreach on the rule (FDA PC ‘At-A-Glance’ document)
  • To understand the ‘gap’ between current processes/practices and actual regulation

• Additional resources are needed to bring small/medium facilities into compliance – Cornell University Institute for Food Safety
Implementation *cGMP only*

- Using FDA GMP ‘cross-walk’ document - reviewed and compared differences between existing reg (21 CFR 110) and current reg (21 CFR 117 subpart B)
- Devised a training presentation as a mechanism to train inspectors on the differences
- Provided this training in-person to all inspectors across the state
- Prior to in-person training required all inspectors to complete online class (FD-8000r)
- Updated and rolled out inspection worksheet to include new requirements
- Updated inspection database to include new requirements
- Using FDA ‘citations’ draft document – updated enforcement/compliance tools
Implementation *Next Steps*

- **Training**
  - Provide PC regulator training to inspectors across the state
  - Devise a list of PC – SMEs. SMEs will supplement PC regulator training by providing training to all remaining staff and providing hands-on on the job ‘experience’ training

- Create a specialty inspection worksheet to include all PCHF requirements
- Update inspection database to include new specialty PCHF inspection requirements
- Identify high-risk facilities and determine based on risk, compliance history and recalls, etc what the appropriate frequency will be to perform full PC inspection
- Determine what additional resources are needed (staff, IT, etc)
- Timeframe? *Years...*
Challenges

**Infrastructure**
- Funding is unavailable
- Training is limited
- Guidance is lacking
- Enforcement tools are unavailable
- Do we have skilled people?
- Do we have people?

**Uniformity**
- No coordination for implementation of PC rule
- Working groups have not been formed
- No forum to learn from each other
- 50 different methods of conducting PCHF inspections, compliance, etc.
NY-CA-FDA Training Pilot (FD-180/FD152)

**Problem**

- Model was in-person training only
- Limited seats available
  - Did not allow for long-term sustainability or training consistency among inspectors
- State travel restrictions
- Student waivers received (to avoid seasoned inspectors having to take the course) were inconsistent

**Solution**

- Offer FDA classes at New York academic institute
- Create process for states to designate their own trainer and offer training themselves
- FDA classes hosted at NYS offices
- Create a process for a student to receive a ‘waiver’ from taking the class
- Exploring waivers for (state) training class equivalents
- Virtual hosting of training
Infrastructure

• Availability of funding
• Expand training pilot to all courses
• Insight into creation of guidance
• Formation of working groups to aid in the *uniform* implementation of the rule

Uniformity

• MFRPS alliance to form forum for working groups to report into
• Forum to be the conduit that works and communicates *with/between* States and FDA
• Forum to provide higher level feedback to AFDO and NASDA
Questions?

Thank You!

Andrew M. Cuomo
Governor

Richard A. Ball
Commissioner