



# **AFDO Annual Education Conference 2018**

## **Preventive Controls Inspections in Minnesota**

**Presented by Jan Kelly, Manufactured Food Program Manager**  
**Food & Feed Safety Division**

- **Adoption of the Regulation**
- **Staff Training**
- **GMP Inspections (Limited Scope PC Inspections)**
- **Preventive Controls Inspections**
- **Challenges**
- **Key's to Success**
- **Next Steps**

# Adoption of the Regulations

- Minnesota Statute provides for adoption of Federal Regulations by reference

- **117 GMPs**
  - **FDA 117 Modernized GMP Webinar – July 2016**
    - All Manufactured Food Program Staff at that time viewed the webinar
  - **Additional training in-house training conducted Nov 2016**
  - **MFRPS Standard 2 Training – Basic Training Plan**
    - Added review FDA GMP Webinar (July 2016)
    - In-house GMP Training Updated to include 117 references

# Staff Training – Preventive Controls

- **117 Subp C – Preventive Controls Training**
  - **Currently not included in MFRPS Standard 2 (Training)**
  - **MDA -MFP added as Specialized/Advanced Training Course**
    - **FD 254 Preventive Controls for Human Food Regulators Course**
    - **Prerequisite: Preventive Controls for Qualified Individuals**
  - **Added Joint Inspections and Evaluations to Field Training SOP**
    - **2 Joint Inspections**
    - **1 Evaluation**
    - **Conducted by Qualified Trainer**

# Staff Training – Preventive Controls

- **Implementation of 117 Subp C – Preventive Controls Training**
  - All current staff have completed PCQI Training
  - **FD 254 – PC Regulator Training**
    - One MFP lead inspector accepted by FDA to be part of the National Training Cadre
      - completion of FD 254, train the trainer courses, and course instructor
    - Three additional inspectors have completed FD 254
      - In the process of completing Joint Inspections and Evaluations
    - Four additional staff attending FD 254 in June 2018 in Minneapolis
    - Hope to complete Joint inspections and Evaluations for all by Oct 1, 2018

# Staff Training – Future Considerations

## Who should conduct Preventive Controls Inspections?

- **All (trained) staff?**
- **Select staff? Identify skills needed**
  - **Attention to detail**
  - **Systems based thinking**
  - **Problem solving**
  - **Tenacity**

- **Electronic Inspection System updates (USA Food Safety)**

**Added new inspection types and standard orders (based off Turbo citations)**

- **117 GMP Inspection Subp B & F**
- **Add on inspection for 117 Subp C & Subp G**



- **117 GMP Inspections started January 2017**
  - About 160 conducted in 2017
  - Over 250 conducted so far in 2018
- **Preventive Controls Inspections - Full Scope PC (Subp C/G)**
  - started Fall 2017
  - FDA Contract - 6 inspections
    - 5 completed so far, 1 to go
  - State inspections – 1 so far

# SUCCESSSES!

- **Inspectors planned for sufficient time to do it right**
- **Have/use inspectional references provided during PCQI and FD 254 Course**
- **Ensure relevant docs requested of the firm early in the inspection**
- **Do the walk-through and see the food safety plan before the hazard analysis is conducted; may need to do additional walk-throughs**
- **Asking the right questions of the firm**
- **Risk Communication and education at the firm when deficiencies are found**

# SUCCESSSES!

- Many firms were more prepared than expected
  - Firms built on existing HACCP plans or other procedures
- The inspectional approach for PC inspections has value

# Preventive Controls Inspections - Challenges

- **Determining if appropriate controls were in place**
  - Required inspectors to do a lot of independent research
  - Some firms lacked understanding of appropriate allergen controls
- **3 facilities also had products under USDA inspection**
- **Finding additional resources for support – access to national experts**
- **Resource Intensive**
  - Hazard analysis, review of prereq programs

# Preventive Controls Inspections – Challenges: Resource Needs

PC Inspection	In-plant and state report time	Additional FDA Contract reporting	Notes
1	70 hrs	10 hrs	Additional travel time; USDA Products also; Firm was prepared and few regulatory issues encountered
2	65 hrs	10 hrs	Additional travel time; USDA Products also; Firm was prepared and few regulatory issues encountered
3	89 hrs	10 hrs	Additional travel time; firm had incomplete Food Safety Plan; significant regulatory issues; recall
4	60 hrs	NA – State	Additional travel time; Firm was prepared and few regulatory issues encountered
5	64 hrs	8 hrs	Additional travel time; USDA Products also; Firm was prepared and few regulatory issues encountered
6	Not available		Additional travel time; firm had no food safety plan; significant regulatory issues

# Preventive Controls Inspections – Challenges: Resources

- Based on our MFRPS Std 8 Resource Assessment (prior to Prev Controls Inspections)
  - Determined we needed > 20 inspectors (FTE) to conduct the work we're obligated to
  - Based on current inspection procedures, firm risk classification, inspection frequency, etc.
  - Currently assigned only 12 FTEs (14 positions)

***Add new inspection type at hundreds of facilities that takes 75% longer than the average GMP inspection .... RESOURCE CHALLENGE***

# Next Steps - Concerns

- **Determination on staff training for PC Inspections**
  - Did request additional seats for FD 254 in FY 19
  - Training for Supervisors, Managers, Compliance Officers, etc.
- **Program Reassessment**
  - Inspection Procedures
  - Risk Classification
  - Inspection Frequency

# Contact Information

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