

November 25, 2019

FSMA & PMO APPENDIX T 1ST YEAR INSIGHTS

Eastern Milk Seminar 2019

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OVERVIEW

- Background
- Qualified Facilities
- National Metrics
- FD378 Training
- Top 5 Issues
- Resources & Tools

BACKGROUND

Preventative Controls Inspections:

- Conducted by FDA Milk Specialists during plant check ratings
- Frequency of not more than 36 months
- If *not* in compliance with Appendix T, follow up & re-rating by SRO within 60 days

NATIONAL METRICS

2019 National Totals	
Appendix T Check Ratings	71
Appendix T Qualified (Exempt) Evaluations	5
Appendix T Re-inspections	4

TOP 5 ISSUES

1. Recall Plans
2. Hazard Analysis
3. Use of modified HACCP and SQF plans
4. Lack of Corrective Actions
5. Food Safety Plan not signed by “Owner, Operator, Person in Charge”

TOP 5 ISSUES

1. Recall Plans

- Incomplete or insufficient
- Lacks info about public notification
- Lacks info about product disposition
- Corporate template not specific to individual facility - generic
- “Mock Recalls” most often used rather than the required “Efficiency Checks”

TOP 5 ISSUES

2. Hazard Analysis

Often missing or not accounted for in Hazard Analysis:

- Milk as an allergen (Label)
- Other allergens in plant
- CIP chemicals, glycol, boiler compounds
- Finished product labeling
- Aflatoxin
- Sanitation hazards not identified post-pasteurization

TOP 5 ISSUES

3. Use of modified HACCP/SQF plans

- FSP modeled to meet 3rd party audits
- HACCP terminology such as “prerequisite program” and “critical control point” in place of “preventative control”
- Programs and SOP’s referenced are in a HACCP Plan or SQF Program – adds time to extract relevant information

TOP 5 ISSUES

4. Lack of Corrective Actions

- Missing entirely, incomplete, insufficient
- Not documented properly
- Often no Environmental Monitoring Program
- What records need PCQI review?

TOP 5 ISSUES

5. Not signed by “Owner, Operator, Person in Charge”

- Plans are in draft form and not yet finalized
- Plan is signed by internal PCQI who is **NOT** Owner, Operator, Person in Charge
- Plan is signed by off-site or consultant PCQI
- Plan is updated or changed and not re-signed

QUALIFIED FACILITIES

Very Small Businesses (VSB) are considered Qualified Facilities and are exempt from PMO Appendix T

- 21 CFR 117.3 - definition of “very small business”
- Must register using FDA Form 3942a

QUALIFIED FACILITIES

VSB Exemption:

- A business, *including any subsidiaries and affiliates*, averaging < \$1 million per year during the preceding 3-year period.
- Includes sales of human food + market value of food manufactured, processed, packed, or held without sale

FD378 PMO PC TRAINING

FY 2020 Course:

July 27 – 30, 2020 in Seattle, WA

- Funding by AFDO grant process
- Target audience is still SRO's (P), Milk Managers, future SRO's

RESOURCES & TOOLS

- Pasteurized Milk Ordinance (PMO) 2017 or newer
- Food Safety Plan Builder
<https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder>
- FSMA Technical Assistance Network (TAN)
<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

QUESTIONS?
