NYS ASSOCIATION FOR FOOD PROTECTION ANNUAL CONFERENCE 2019 APPENDIX T

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DETERMINATION IF VERY SMALL BUSINESS (VSB) EXEMPTION APPLIES.

- Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

DEFINITION OF QUALIFIED FACILITY UNDER PART 117

- Part 117 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than **$1,000,000**, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). See the definition of "very small business" in 21 CFR 117.3.

FORM USED TO REGISTER AS A QUALIFIED FACILITY

- FDA Form 3942a, Qualified Facility Attestation for Human Food Facility

APPENDIX T EVALUATION

Request the following

Is the Food Safety Plan documented in writing?

WRITTEN FOOD SAFETY PLAN (FSP) DOCUMENTS

- Written recall plan;
- Written hazard analysis (HA) for each kind or group of Grade "A" milk or milk products processed;
- Written preventive control(s);
- Written monitoring procedures for the implementation of the preventive control(s);

WRITTEN FOOD SAFETY PLAN (FSP) DOCUMENTS

- Written verification procedures for the preventive control(s);
- Written corrective action (CA) procedures for the preventive control(s); and
- Written supply-chain program (if applicable).

DETERMINE

- Qualifications of PCQI (education, training, experience or combination)
- Was the Food Safety Plan prepared/overseen by one or more PCQI's
- Was any re-analysis of the milk plant's Food Safety Plan performed or overseen by a PCQI.

DETERMINE

- Has the owner, operator or person in charge of the milk plant has signed and dated the FSP.

DETERMINE

- If a reanalysis of the applicable portion of the milk plant's Food Safety Plan is conducted due to a change in a hazard; new information of a hazard; an unanticipated food safety problem; or ineffective preventive control(s)

REQUEST

- Request information on all non-milk ingredients utilized in Grade “A” products and Non-Grade “A”.

REQUEST

- Request information on process steps, i.e., process narrative and/or flow diagram.

REQUEST

- Review information on all non-milk ingredients and process steps.

WALK THROUGH

- Brief walk-through of milk plant to verify the process steps and product flow.

REVIEW THE HAZARD ANALYSIS

- Review the HA to determine:
  - If all process steps are listed;
  - If all potential hazards are identified and evaluated; and
  - What preventive control(s) have been identified.

EVALUATE THE PREVENTIVE CONTROLS FOR THE FOLLOWING MANAGEMENT COMPONENTS:

- Evaluate the preventive controls for the following management components:
  - Written monitoring procedures are adequate;
  - Written verification procedures (to include written validation procedures for any process preventive control(s)) is/are adequate; and
  - Written corrective action procedures are adequate.

REQUEST AND REVIEW OF PREVENTIVE CONTROL(S)

- Monitoring, Verification (includes validation when applicable) and corrective action records to determine if the preventive control(s) have been properly implemented and are in control.

POSSIBLE PREVENTIVE CONTROLS

- Pasteurization Process Preventive Control(s)
- Allergen Preventive Control(s)
- Sanitation Preventive Control(s)
- Supply-chain Program

FOR EXAMPLE:

- **Pasteurization Process Preventive Control(s)** – Review of monitoring and verification (to include validation) records such as pasteurization recording charts, last quarter of equipment checks, broken seal reports, and written corrective action report(s) if there were any corrective action(s).

FOR EXAMPLE:

- **Allergen Preventive Control(s)** – Minimum review for a milk plant that only has a 'milk' allergen will include labels ('milk' will need to be properly declared on Grade "A" milk and milk product labels). If the plant has other 'Big 8' allergens, additional label review will be needed. When two or more allergens are present in the milk plant, review of cross-contact control monitoring and verification records such as production scheduling records, cleaning records for shared equipment, protein swabbing records (i.e., ATP, ELISA, others), and filler production records. Written correction and/or corrective action report(s) if milk plant has chosen to use these.

FOR EXAMPLE:

- **Sanitation Preventive Control(s)** when applicable – records for allergen cross contact (see above) if milk plant has chosen to handle this as a sanitation preventive control instead of an allergen preventive control. Review of sanitation control monitoring and verification records such as CIP charts, environmental cleaning and sanitizing records, and environmental swab testing results. Written correction and/or corrective action report(s) if milk plant has chosen to use these.

NOTE:

- Only those records that **directly support the preventive controls will initially be requested and reviewed.** Records not supporting the preventive control(s), i.e., records supporting a pre-requisite program, will normally be evaluated as part of the Appendix N evaluation (unless the firm has determined that drug residue testing is a preventive control) and sanitation portion (PMO 'p' items and applicable appendices) of the inspection.

SUPPLY-CHAIN PROGRAM

- **Supply-chain Program** when the supplier is controlling a **significant hazard** (SAHCDH) **in an ingredient that is not controlled in this milk plant** – Review of records such as the supplier's program documentation, this milk plant's procedures for receiving of this particular non-milk ingredient(s) which is/are being used in Grade "A" milk and/or milk products, and documentation that this is an approved supplier(s). Review of supplier verification activities such as documentation of sampling and testing conducted (i.e., COA), on-site audit(s) reports conducted by a qualified auditor, complies with FSVP requirements if the milk plant is an importer, documentation of the review of the supplier's relevant food safety records, written corrective action reports taken in response to significant deficiencies identified during a supplier review, and/or documentation of an alternative verification activity.

RECALL PLAN

- Review recall plan for:
  - Written procedures, assignments, responsibility, and steps to complete the plan
  - How is the public notified
  - Procedures to conduct effectiveness checks
  - How is the product disposed of.

HAZARD ANALYSIS FOR EACH KIND OF MILK PRODUCT

- Can be group together or kept separate:
  - White Milks
  - Flavored Milks
  - Cultured
  - Cottage cheese
  - Yogurts

PREVENTIVE CONTROLS

- Written for hazards not addressed by the PMO

SUPPLY CHAIN PROGRAM

- Approved suppliers
- Supplier verification activities
- Receiving procedures
- Are the procedures being followed

MONITORING PROCEDURES

- Established
- Implemented
- Performed
- Frequency
- Records

CORRECTIVE ACTIONS

- Established
- Implemented
- Written
- Records
- Reviewed, dated and signed by or with PCQI oversight within 7 days

VERIFICATION AND VALIDATION

- Verification of Preventative Controls consistently implemented and effective
- Validation of Preventive Controls identified and implemented are adequate to control the hazard
- Performed by or overseen by the PCQI

QUALIFICATIONS OF PERSONNEL

- Qualified to perform assigned duties
- Training received in principles of food safety and food hygiene
- Supervisors have the necessary education, training, experience or combination
- Employee Training Records (training and experience)

RECORDS

- Records kept at least two (2) years after the date they were created/ prepared

FSMA TOOLS

- **Pasteurized Milk Ordinance (PMO) 2017 or newer**
- **FDA websites on Industry Resources "Industry Resources on Third-Party Audit Standards and FSMA Supplier Verification Requirements"**
- **Food Safety Plan Builder "**https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder**"**
  - **Helps organize the plan**
- **FSMA Technical Assistance Network (TAN)** "https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan"

QUESTIONS