

APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE "A" MILK AND MILK PRODUCTS

Food Safety Plan:

This *Ordinance*, with Appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. The milk plant's food safety plan shall be in writing and shall be prepared, or its preparation overseen by one (1) or more PCQIs. The milk plant's written food safety plan and its contents shall include the following:

1. The written Recall Plan;
2. The written Hazard Analysis;
3. The written Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
4. The written Supply-Chain Program, as appropriate, for hazards not addressed by this *Ordinance*;
5. The written Procedures for Monitoring the Implementation of the Preventive Controls, as appropriate, for hazards not addressed by this *Ordinance*;
6. The written Corrective Action Procedures, as appropriate, for hazards not addressed by this *Ordinance*; and
7. The written Verification Procedures, as appropriate, for hazards not addressed by this *Ordinance*.

The owner, operator or person in charge of the milk plant shall sign and date the food safety plan:

1. Upon initial completion; and
2. Upon any modifications.

A reanalysis of the milk plant's written food safety plan as a whole shall be conducted at least once every three (3) years. A reanalysis of the milk plant's written food safety plan as a whole, or the applicable portion of the food safety plan shall be conducted:

1. Whenever a significant change in activities conducted creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;
2. Whenever the milk plant becomes aware of new information about potential hazards associated with the milk and/or milk products;
3. Whenever appropriate after an unanticipated food safety problem;
4. Whenever the milk plant finds that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective; and
5. When FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

A PCQI shall perform, or oversee, all of the reanalysis cited above.

The milk plant's current written food safety plan is considered a record and shall remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location. The food safety plan shall be retained at the milk plant for at least two (2) years after its use is discontinued.

Recall Plan:

A milk plant shall establish a written recall plan that shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate for the milk plant:

1. Directly notify the direct consignee of the milk and/or milk product(s) being recalled, including how to return or dispose of the affected milk and/or milk product(s);
2. Notify the public about any hazard presented by the milk and/or milk product(s) when appropriate to protect public health;
3. Conduct effectiveness checks to verify that the recall is carried out; and
4. Appropriately dispose of recalled milk and/or milk product(s), i.e. reprocessing or rework if allowed for within this *Ordinance*, diverting to a use that does not present a milk safety concern, or destroying the milk and/or milk product(s).

NOTE: For additional information and guidance from FDA regarding product recalls, milk plants should also refer to the current Guidance for Industry: Product Recalls, Including Removals and Corrections at:

<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

Hazard Analysis:

A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed. A milk plant may group similar types of milk and milk products, or similar types of production methods together, if the hazards and procedures are essentially identical. The hazard identification shall consider:

1. Known or reasonably foreseeable hazards that include:
 - a. Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
 - b. Chemical hazards, including radiological hazards, substances such as pesticides and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
 - c. Physical hazards, such as stones, glass and metal fragments.
2. Known or reasonably foreseeable hazards that may be present in milk and/or milk products for any of the following reasons:
 - a. The hazard occurs naturally;
 - b. The hazard may be unintentionally introduced; or
 - c. The hazard may be intentionally introduced for purposes of economic gain.

Preventive Controls:

A milk plant shall identify and implement written preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the milk and/or milk products processed, packaged or held will not be adulterated under Section 402 of the *FFD&CA* or misbranded under Section 403(w) of the *FFD&CA*. Preventive controls include:

1. Controls at critical control points (CCPs); and
2. Controls, other than those at CCPs, that are also appropriate for food safety.

Preventive controls shall include, as appropriate to the milk plant and the milk and/or milk products:

1. Process controls that include procedures, practices and processes to ensure the control of parameters during operation;
2. Food allergen controls that include procedures, practices and processes to control food allergens as referenced in Item 15p.(C) of this *Ordinance*;
3. Sanitation controls that include procedures, practices and processes to ensure that the milk plant is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee practices and food allergen hazards;
4. Supply-chain controls as referenced in this Appendix;
5. Recall plan; and
6. Other controls, such as employee hygiene training and other current GMPs.

Monitoring:

The milk plant shall establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive controls and shall monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. The milk plant shall document the monitoring of preventive controls to verify that monitoring is being conducted as required and that the required monitoring records are being reviewed within seven (7) working days after the records are created.

Corrective Actions:

The milk plant shall establish and implement written corrective action procedures that shall be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

1. The presence of a pathogen or appropriate indicator organism detected as a result of product testing; and
2. The presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring.

The corrective action procedures shall describe the steps to be taken to ensure that:

1. Appropriate action is taken to identify and correct a problem that has occurred with the implementation of a preventive control;
2. Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;
3. All affected milk and/or milk products are evaluated for safety; and
4. All affected milk and/or milk products are prevented from entering into commerce, if the milk plant cannot ensure that the affected milk and/or milk products are not adulterated under Section 402 of the *FFD&CA* or misbranded under Section 403(w) of the *FFD&CA*.

The milk plant shall document all corrective actions and, when appropriate, corrections taken and that the required corrective action and corrections records are being reviewed within seven (7) working days after the records are created.

Verification:

Verification activities shall include, as appropriate to the nature of the preventive control and its role in the milk plant's food safety system:

1. Validation;
2. Verification that monitoring is being conducted as required;
3. Verification that appropriate decisions about corrective actions are being made as required;
4. Verification that the preventive controls are consistently implemented and are effective and significantly minimizing or preventing the hazards; and
5. Reanalysis.

The milk plant shall conduct finished milk and milk product testing as appropriate to the milk plant, the milk and/or milk products, and the nature of the preventive control and its role in the milk plant's food safety system for a pathogen or appropriate indicator organism or other hazard. The milk plant shall establish and implement written procedures for finished milk and milk product testing as appropriate and the procedure shall:

1. Be scientifically valid;
2. Identify the test microorganism(s) or other analyte(s);
3. Specify the procedures for identifying samples, including their relationship to specific lots of milk and/or milk products;
4. Include the procedures for sampling, including the number of samples and the sampling frequency;
5. Identify the test(s) conducted, including the analytical method(s) used;
6. Identify the laboratory conducting the testing; and
7. Include the corrective action procedures for the presence of a pathogen or appropriate indicator organism detected as a result of product testing.

The milk plant shall document all verification activities that are conducted in their records.

Validation:

The milk plant shall validate that the preventive controls identified and implemented are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the milk plant's food safety system. The validation of the preventive controls shall be performed by or under the oversight of a PCQI:

1. Prior to the implementation of the food safety plan;
2. When necessary, to demonstrate the control measures can be implemented as designed within ninety (90) days after production of the applicable milk or milk product first begins;
3. Whenever a change to the control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazard; and
4. Whenever a reanalysis of the food safety plan reveals the need to do so.

The milk plant does not need to validate the following:

1. The food allergen controls;
2. The sanitation controls;
3. The recall plan;
4. The supply-chain program; and
5. Pasteurization as defined in Item 16p of this *Ordinance*.

The milk plant shall document in their records all validation activities that are conducted.

Records:

The milk plant shall establish and maintain the following records documenting the implementation of the food safety plan:

1. The food safety plan;
2. Records that document the monitoring of preventive controls;
3. Records that document corrective actions;
4. Records that document verification, including, as applicable, those related to:
 - a. Validation;
 - b. Verification of monitoring;
 - c. Verification of corrective actions;
 - d. Calibration of process monitoring and verification instruments;
 - e. Product testing as appropriate;
 - f. Environmental monitoring;
 - g. Records review; and
 - h. Reanalysis;
5. Records that document the supply-chain program; and
6. Records that document the applicable training for milk plant employees and the PCQI(s), including the date of training, the type of training and the person(s) trained.

Records that are required in the milk plant's food safety plan shall be:

1. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;
2. Onsite and available for review by the Regulatory Agency. Electronic records are considered to be onsite if they are accessible from an onsite location; and
3. Retained for at least two (2) years after the date they were created. Offsite storage of these records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

Monitoring and corrective action records shall be reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records were created.

Qualification of Individuals:

1. The owner, operator or person-in-charge of a milk plant shall ensure that all individuals who receive, handle, process, package, etc. milk and/or milk products are qualified to perform their assigned duties.
2. Each individual engaged in the receiving, handling, processing, packaging, etc. of milk and/or milk products, including temporary and seasonal personnel, or in the supervision thereof shall:
 - a. Have the education, training, or experience or combination thereof necessary to receive, handle, process, packaging, etc. milk and/or milk products as appropriate to the individual's assigned duties; and
 - b. Receive training in the principles of food hygiene and food safety, including the importance of employee health and personnel hygiene, as appropriate to the milk and/or milk products, the milk plant and the individual's assigned duties.
3. Responsibility for ensuring compliance by individuals with the requirements shall be clearly assigned to supervisory personnel who have the education, training, or experience or combination thereof, necessary to supervise the production of clean and safe milk and milk products.
4. Records that document training shall be established, maintained and retained at the milk plant for at least two (2) years after the date they were prepared.

The following milk plant's food safety plan activities are required to be performed or overseen by one (1) or more PCQIs:

1. Preparation of the food safety plan;
2. Validation that the preventive controls identified and implemented are adequate to control the hazards appropriate to the nature of the preventive control and its role in the milk plant's food safety system;
3. Review of records; and
4. The reanalysis of the food safety plan;

Environmental Monitoring:

A milk plant shall have a written environmental monitoring program that is implemented and supported by records for ready-to-eat milk and/or milk products exposed to the environment prior to packaging and the packaged milk and/or milk products do not subsequently receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:

1. Be scientifically valid;
2. Identify the test microorganism(s);
3. Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites shall be adequate to determine whether preventive controls are effective;
4. Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples shall be adequate to determine whether preventive controls are effective;
5. Identify the test(s) conducted, including the analytical method used;

6. Identify the laboratory conducting the testing; and
7. Include the corrective action procedures for the presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring.

Supply-Chain Program:

A milk plant shall establish and implement a written risk-based supply-chain program for those raw materials and other ingredients for which the milk plant has identified a hazard requiring a supply-chain-applied control. The supply-chain program shall, at a minimum:

1. Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly minimize hazards for all milk and/or milk product ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.
2. Document that a supplier of non-milk and/or milk product ingredients utilized in the milk plant's Grade "A" milk and/or milk products has a functional and written food safety program that provides assurances that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented and also includes food allergen management.
3. A supply-chain program shall include:
 - a. Using approved suppliers. The milk plant shall approve suppliers, and document that approval, before receiving raw materials and other ingredients;
 - b. Determine appropriate supplier verification activities to include determining the frequency of conducting the activity;
 - c. Conducting and documenting supplier verification activities before using raw materials and other ingredients. One (1) or more of the following are appropriate supplier verification activities for raw materials and other ingredients:
 - (i) Onsite audits annually for serious hazards unless there is a written determination that other verification activities and/or less frequent on-site auditing provide adequate assurance that the hazards are controlled;
 - (ii) Sampling and testing of the raw material or other ingredient;
 - (iii) Review of the supplier's relevant food safety records; and
 - (iv) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.
 - d. When applicable, verifying a supply-chain-applied control applied by an entity other than the milk plant's supplier and documenting that verification; and
 - e. Include written procedures for receiving raw materials and other ingredients and document that those procedures are being followed.

If the milk plant determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or other relevant food safety information that the supplier is not controlling hazards that the milk plant has identified as requiring a supply-chain-applied control, the milk plant shall take and document prompt action to ensure that raw materials or other ingredients from the supplier do not cause milk and/or milk products that are manufactured or processed to be adulterated under Section 402 or misbranded under section 403(w) of the *FFD&CA*.

NOTE: A very small business is exempt from this Appendix.