

ADPI Center for Excellence & Center for Food Safety & Regulatory Solutions (CFSRS)

The “REAL” Story on FSMA Preventive Controls – Dairy Plant Primer

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With the September 17th, 2015 formal release by the US Food & Drug Administration of the final requirements for the FSMA “Preventive Controls for Human Foods (PCHF),” the life of dairy processing plants, brokers of dairy ingredients and importers of dairy ingredients was changed forever.

The regulation is 928 pages long, but the actual requirements that directly impact dairy plants is much shorter (approximately 40 pages), still resulting in many of us going cross-eyed while trying to read and understand it. In addition, there were significant new or modified requirements compared to the January 2013 proposed regulation and its September 2014 update.

In order to demystify this regulation and its impact on dairy processing plants, we have created a “Primer” that in a few pages summarizes the September 17, 2015 PCHF regulation. FDA has committed to publishing a “Guideline” sometime in 2016 to also provide added clarity, but its availability may be too late for dairy plants that have to be in compliance by September 17, 2016. It is strongly recommended that dairy plants conduct a thorough review of this “Primer”

For more information on how to modify your plant’s food safety operations to become FSMA PCHF compliant, please contact Allen Saylor with the ADPI Center for Excellence (asaylor@cfsrs.com), or call Dan Meyer, Technical Director for ADPI at (630) 530-8700 x224). Begin this process as soon as possible to ensure your plant is ready when the FDA investigator walks in to enforce the PCHF.

TIMELINES:

The enforcement date by FDA for the various sizes and types of dairy plants is listed below:

1. September 17, 2016 – plants owned by companies with more than 500 total processing employees
2. September 17, 2017 – small plants owned by companies with less than 500 total processing employees
3. September 17, 2018
 - a. Very small plants averaging less than \$1 million in gross food sales are “qualified facilities” which need to provide supporting records to FDA by December 17, 2018, every year after and then every two (2) years starting October 1, 2020.
 - b. Grade “A” dairy plants – note that only the Grade “A” products receive this extension so a Grade “A” dairy plant making non-Grade “A” products will have to be ready for an FDA enforcement inspection based on #1, #2 or #3a above.

DAIRY PLANT’S FOOD SAFETY PLAN: The PCHF regulation requires that each dairy plant have a written food safety plan available at all times for an FDA inspection. Other written requirements and their records can be produced within twenty-four (24) hours of the beginning of the FDA PCHF inspection. The dairy plant’s food safety program must contain:

1. The written hazard analysis
2. The written preventive controls program with written procedures for implementation
3. The written supply-chain program

4. The written recall plan
5. The written corrective action procedures
6. The written verification procedures
7. Records supporting food safety plan

PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI):

All dairy plants having to comply with the FSMA Preventive Controls for Human Foods (PCHF) will have to have their food safety plan managed by a “Preventive Controls Qualified Individual (PCQI).” The PCQI does not have to work full-time at the dairy plant - so a corporate PCQI that serves more than one dairy plant would be acceptable. However, this is not recommended since the PCQI must be on-site during the FDA inspection to explain various parts of the dairy plant’s food safety plan. The PCQI can become qualified by being trained or through personal experience and knowledge of the FSMA PCHF regulation. It is strongly recommended that each dairy plant send at least two individuals to the “PCQI” training sponsored by the FDA Food Safety Preventive Controls Alliance (FSPCA). FSPCA has been conducting specialized training for “Lead Instructors” that are then recognized by FDA as being qualified to train the PCQIs. It is important that as dairy plants evaluate available training for PCQIs, they ensure that the specific trainer has a certificate from FSPCA identifying him/her as having passed the “Lead Instructor” training.

EMPLOYEE TRAINING & QUALIFICATIONS: It is important to recognize that each processing employee and supervisor engaged in manufacturing, processing, packing, or holding food must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual’s assigned duties; and receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual’s assigned duties. In addition, each plant must have “Qualified Individuals” (QIs) that are directly responsible for specific tasks. The regulation does not require specialized training for QIs, but they must demonstrate they are qualified for the task they are assigned to perform. Specific QI tasks identified in the regulation include:

- Conducting internal audits
- Plant processing and supervisory staff responsible for manufacturing, processing, packing, or holding food
- Any other activity required by the Preventive Controls for Human Foods not specifically assigned to a “Preventive Controls Qualified Individual”

SPECIFIC PREVENTIVE CONTROLS REQUIREMENTS FOR DAIRY PLANTS:

One of the more confusing parts of the PCHF regulation is the requirement that all dairy plants are required to have “preventive controls.” The dairy industry has used prerequisite programs, GMP-based programs and critical control points to control food safety hazards for ingredients and processing steps to build an effective food safety program. Now we have to also identify hazards that are required to use “preventive controls” as well. The question is what are preventive controls? The best answer is not to use the formal definition, which is long and lacks specificity, but to use the PCHF regulation details (21 CFR 117.135). See below for practical preventive control details:

1. **Process Controls (Practical Definition):** Any step where there is a hazard that, if not controlled at that step, will result in a food safety compromise of the finished product. Examples include:
 - a. Pasteurization processing step – biological hazard controlled by a CCP.
 - b. Packaging processing step – biological hazard controlled by a set of prerequisite programs, i.e. equipment sanitation, employee hygiene, etc.)
 - c. Ingredient Blending processing step - biological and physical hazards controlled by a set of prerequisite programs, i.e. equipment sanitation, employee hygiene, etc.)
 - d. Temperature Controls where failing to maintain raw material, ingredient, in-process or finished product temperature could be expected to create a food safety problem.

2. **Food Allergen Controls.** A dairy plant’s entire written “Allergen Management Program” would be a preventive control with a number of parts that include segregation of ingredients at receiving, ingredient storage, product processing, product packaging and a label review and verification program.
3. **Sanitation Controls.** A dairy plant’s “Sanitation” preventive controls are mostly focused on biological pathogens that could cause foodborne illness through dairy product consumption. “Sanitation” preventive controls need to be applied to primary hazards in the following areas:
 - a. Processing Equipment & Utensil Cleaning & Sanitation Program
 - b. Facility Cleaning Program
 - c. Integrated Pest Management Program
 - d. Processing area ventilation to eliminate overhead condensate and air-borne contamination. The use of pressurized air to “push” ingredients and product through the production system must also be addressed.
4. **Supply-Chain Controls.** A dairy plant’s Supply-chain preventive control program needs to address hazard(s) in a raw material or ingredient when that specific hazard(s) must be controlled prior to receipt by the dairy plant. If the hazard of concern is controlled by the dairy plant, then the PCHF does not require a supply-chain control program to address that supplier. Also, if the hazard associated with a raw material or ingredient comes from a foreign supplier and the supplier has qualified itself under FSMA’s Foreign Supplier Verification Program, the dairy plant is not required to have a supply-chain control program for that supplier. Any written supply chain preventive control program needs to include:
 - a. List of approved suppliers
 - b. Sampling and testing program for the raw material or other ingredient;
 - c. Annual onsite audit (see 21 CFR 117.435 for audit requirement details) if there is a reasonable probability that exposure to a hazard will result in serious adverse health consequences or death to humans (SAHCDH). Such an audit needs to be conducted by a “qualified auditor” and contain the following information:
 - 1) The name of the supplier;
 - 2) Documentation of audit procedures;
 - 3) The date(s) of the audit;
 - 4) Audit conclusions;
 - 5) Corrective actions taken by the supplier or dairy plant in response to significant deficiencies identified during the audit.
 - d. Imported Raw Materials: A Supply Chain program for imported raw materials and ingredients needs to include documentation that the foreign supply plant is in compliance with the FSMA Foreign Supplier Verification Program or have the following information available for an FDA inspection:
 - 1) Documentation of the approval of a supplier;
 - 2) Written procedures for receiving raw materials and other ingredients;
 - 3) Records supporting the written procedures for receiving raw materials and other ingredients;
 - 4) Records verifying the supplier’s verification activities for raw materials and other ingredients;
 - 5) Records of the on-site audit of the foreign supplier must document:
 - The name of the supplier;
 - Audit procedures;
 - Date(s) of the audit;
 - Audit conclusions;
 - Corrective actions taken by the supplier or dairy plant in response to significant deficiencies identified during the audit;

- Sampling and testing conducted as a supplier verification activity
 - Review of the supplier’s relevant food safety records that list the name of the supplier whose records were reviewed, the date(s) of review, the general nature of the records reviewed and the conclusions of the review; and corrective actions taken in response to significant deficiencies identified during the review;
5. **Recall Plan.** The dairy plant’s recall program is a preventive control under PCHF.
 6. **Other controls.** A preventive control is also any other control necessary to deliver food safety and could include establishing segregated hygiene areas, employee hygiene training, employee traffic management, proper employee hygiene, captive shoe program and/or foot baths or foamers, etc.

Monitoring Preventive Controls: The dairy plant must have a written program on how preventive controls will be monitored that addresses the name of the monitor record and the frequency of monitoring.

Corrective Action and Correction Procedures: The dairy plant needs a written program to address what happens when a preventive control is not implemented, implemented improperly or cannot be verified by supporting records. At a minimum, a dairy plant’s corrective action plan should include the following steps:

- a. Segregate and hold the affected product.
- b. Determine the acceptability of the product for distribution.
- c. Take corrective action to assure that injurious or adulterated product does not enter commerce.
- d. Correct the cause of the deviation.
- e. Determine whether modification of the HACCP plan is necessary

Verification of Preventive Controls: A dairy plant’s food safety program that includes the preventive controls must be verified internally. The PCHF regulation states that verification includes as appropriate:

- a. Calibration of process monitoring instruments and verification instruments (or checking them for accuracy) that includes the method and frequency of the calibration activity.
- b. Product testing, for a pathogen (or appropriate indicator organism) or other hazard;
 - 1) Be scientifically valid;
 - 2) Identify the test microorganism(s) or other analyte(s);
 - 3) Specify the procedures for sample identification and linkage to the source lot;
 - 4) Sampling schedule that includes the number of samples, what is to be sampled and the sampling frequency;
 - 5) Specific test(s) to be conducted, including the reference analytical method(s) used;
 - 6) Identity of the laboratory conducting the test; and
 - 7) Corrective action if a test results indicates a problem.
- c. Environmental monitoring for an environmental pathogen or indicator organism is required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control. The amount of samples, sample locations, and frequency must be adequate to determine whether preventive controls are effective. If conducted by a dairy plant, an environmental monitoring program must address the following:
 - 1) Be scientifically valid;
 - 2) Identify the test microorganism(s), the test(s) conducted, the analytical method(s) used and the laboratory conducting the testing
 - 3) Have a map of the facility with sampling locations or a list that identifies all sample locations.
 - 4) Schedule that includes the number of samples, what is to be sampled and the sampling frequency.
 - 5) Have corrective action procedures if a environmental sampling test result comes back “positive”
- d. **Records Review** under the oversight of a PCQI to ensure that the records for the food safety plan and preventive controls are complete, effective, and the corrective actions are preventing food safety hazards from getting into finished product. At a minimum, a dairy plant’s records review program frequency needs to be:

- 1) 7 days after the records were created for records supporting the dairy plant's food safety. If more than 7 working days is needed, written justification must exist from the PCQI.
- 2) "Reasonable time" for records of calibration, testing (*e.g.*, product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities

Validation of Preventive Controls: The PCQI is the only party at the dairy plant that will be recognized by FDA as having the qualifications, training and knowledge to validate any identified preventive control. Fortunately, the PCHF states that the food allergen controls, sanitation controls, the recall plan, the supply-chain program and the "Other Controls" programs do not require validation.