FSMA *Preventive Controls* for Human Food Rule (PCHF)

Guidelines for PA Food Processors, Manufacturers, Packers, Holders & Distributors

The Food Safety Modernization Act (**FSMA**), a federal law enacted in 2011, requires firms that manufacture, process, pack or hold human food, and that must register with FDA, follow the Preventive Controls for Human Food (**PCHF**) rule's new food safety requirements found in 21 CFR Part 117. The PCHF rule is final, and compliance dates are based on business size but all food establishments (regardless of size) are expected to comply with the new regulation either fully or partially as early as September 2018.

The Pennsylvania Department of Agriculture (PDA) adopts the new federal regulations as dictated by the Food Safety Act (3 Pa. C.S.A. §5733(f)) and will enforce all applicable provisions. As Pennsylvania regulation, all PDA registered firms will be expected to comply with the applicable portions of the PC rule regardless of FDA registration status, unless specifically exempted in the rule. During inspection of food establishments, PDA will evaluate the required food safety plans and make sure the plans are being implemented properly.

PCHF requires eligible food establishments to follow the updated good manufacturing practices (*modernized GMPs*), and to establish and implement a comprehensive written Food Safety Plan (FSP).

Food Safety Plan Requirements:

Firms that are subject to the full requirements of PCHF must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. This food safety system includes a **written** food safety plan that covers:

- **Hazard analysis**: What are the known or reasonably foreseeable biological, chemical, and physical hazards that occur naturally, are unintentionally introduced, or are intentionally introduced, that could affect the safety of the food.
- **Preventive controls**: Measures that are required to minimize or prevent the identified hazards, including:
  - Process Controls: procedures, practices, and processes to control parameters during operations. Examples of process controls are cooking and refrigeration, and product formulation.
  - Food Allergen Controls: procedures, practices, and processes to control allergen cross-contact within a facility and procedures to ensure all food allergens are correctly labeled.
  - Sanitation Controls: procedures, practices, and processes to make sure the facility is maintained in a sanitary manner to control hazards such as environmental pathogens. Environmental monitoring is required if contamination of a ready-to-eat food with an environmental pathogen such as *Listeria monocytogenes* is a hazard requiring a preventive control.
  - Supplier-Chain Controls — a risk-based approach to ensure suppliers are not providing food establishments with raw materials or ingredients that pose a significant risk to the final product made by the firm.
  - Other Controls: preventive control procedures that are not process, food allergen, or sanitation controls, but are necessary to ensure that a hazard requiring a preventive control will be significantly minimized or prevented.
- **Oversight & Management of Preventive Controls:**
  - Monitoring*:* to provide assurance that preventive controls are consistently performed.
  - Corrections*:* to quickly identify and correct a minor isolated problem that occurs during food production.
  - Corrective Actions: include actions to identify and correct a problem implementing a preventive control, reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent that food from entering commerce if you cannot ensure that the affected food is not adulterated.
  - Verification: to ensure that preventive controls are consistently implemented and effective.
- **Record-keeping:** Documentation of compliance with the written food safety plan to include but not limited to monitoring, corrective actions, corrections and verification activities. Required records shall be made available to the regulatory authority (which will include PDA andFDA).
- **Recall Plan:** If the hazard analysis identifies a hazard that requires a preventive control, you must have a written recall plan that includes the procedures that describe the steps to perform the recall and at minimum assigns responsibility for:
  - Notifying the direct consignees of the food being recalled, including how to return or dispose of the affected food;
  - Notifying the public about hazards in the food;
  - Conducting effectiveness checks; and
  - Appropriately disposing of the recalled product.

Exemptions *(from Subparts C, G and D)*

- ✓ Food establishments covered by separate regulations including juice, seafood, dietary supplements, alcoholic beverages, or *Low-acid canned foods (for C. botulinum control ONLY as regulated by Part 113).*
- ✓ Establishments such as grain elevators and warehouses that are solely engaged in storing agricultural commodities (other than fruits and vegetables) intended for further processing.
- ✓ Establishments, such as warehouses, that only store packaged foods that are not exposed to the environment and for which refrigeration is not required for safety *(Dry Warehouses).*
- ✓ Establishments that are *Small or Very Small On-Farm* businesses that conduct certain low-risk manufacturing and processing, packing, or holding activities *(e.g., making jams/jellies, honey, maple syrup, candy, soft drinks, etc.);*

NOTE:
A Farm is not covered by the new requirements, unless it is a mixed-type facility which is an establishment that is a Farm, but also conducts activities outside the farm definition that require the establishment to be registered as required under section 415 of the Federal FD&C Act.

Firms subject to the modified requirements *(Subpart D)*

- ✓ Very Small businesses as defined in *21 CFR 117.3*
- ✓ Qualified facilities as defined in *21 CFR 117.3* to which both of the following apply:

1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers;

AND

2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(See modified requirements that apply to qualified facilities in §117.201)

NOTE:
To be eligible for modified requirements, a qualified facility is required to notify FDA about its status and submit an attestation. Please click HERE for more information.

A qualified facility must submit these notifications to FDA during the same two-year timeframe that the facility is required to update its facility registration. An otherwise Qualified Facility that does NOT notify FDA may be subject to the requirements for Hazard Analysis and Preventive Controls.

- ✓ Establishments that are solely engaged in the storage of refrigerated unexposed packaged foods when temperature controls are necessary to prevent pathogen growth. These firms must:
(See complete requirements in §117.206)

1) Establish and implement temperature controls adequate to significantly minimize or prevent pathogen growth, and toxin formation,
2) Monitor the temperature controls at adequate frequency,
3) Take appropriate corrective actions when there is loss of temperature control,
4) Verify temperature controls,
5) Establish and maintain records.

NOTE:
Warehouse and distribution establishments engaged in the storage of any exposed food products and/or engaged in any processing/ manufacturing activities or "value added services" (e.g. blast freezing, roasting, tempering, labeling, repacking), may be subject to the PC rule requirements where they need to conduct a hazard analysis and may need to implement preventive controls.

Updated Good Manufacturing Practices (modernized GMPs)

The PCHF *Rule* also updates the current Good Manufacturing Practice requirements. All food establishments (regardless of exemption status) are subject to modernized GMP regulations. The new updates include:

- ✓ **Training:** Management is required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. The employees must be trained in the principles of food hygiene and food safety, including the importance of employee health and hygiene as appropriate to the food, the facility, and the individual's assigned duties. Records of training must be maintained.
- ✓ **Allergen cross-contact:** Allergen cross-contact is now explicit in the regulatory text. You are required to employ practices and procedures to control allergen cross-contact.
- ✓ **Human food by-products used for animal foods**: The updated CGMPs contain provisions for holding and distributing human food by-products that are used for animal food.

RESOURCES

Assistance to Industry

The PDA will continue to communicate and work with firms, especially small and very small businesses, to understand and comply with the new *PC Rules,* including during routine inspections. PDA will also communicate available training opportunities as they are available.

- Please visit our FSMA website for more information: http://www.agriculture.pa.gov/consumer_protection/FoodSafety/Pages/FSMA-Preventative-Controls.aspx
- All available guidance documents and other FSMA related information can now be found at: *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm*
- FDA has developed a Food Safety Plan Builder (FSPB) which is a tool designed to assist owners/operators of food facilities with the development of food safety plans that are specific to their facilities and meet the requirements of the PCHF regulation (21 CFR Part 117).

  For more information about this tool and other supporting training materials, visit: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm
- The FDA FSMA Technical Assistance Network (TAN) is now operational and providing technical assistance regarding overall FSMA regulatory aspects. Inquiries may be submitted through a web form accessible at: *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm*
- For technical assistance to industry, academia and others regarding training and scientific/ technical questions related specifically to FDA's PC for Human Food and Animal Food regulations, the Food Safety Preventive Controls Alliance (FSPCA) Technical Assistance Network (TAN) is now operational and inquiries can be submitted online at: *https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network*

Training Opportunities

If you are a facility subject to the CGMP & PC rule and no exemptions from Subparts C (Hazard Analysis and Risk-based Preventive Controls) and G (Supply-Chain Program) apply to you, then you are required to have a Preventive Controls Qualified Individual (PCQI) develop and implement your facility's food safety plan (21 CFR 117.180(a)). A PCQI is a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum (21 CFR 117.180(c)(1)).

FSPCA has developed a standardized curriculum recognized by FDA; and successfully completing this course is one way to meet the requirements for a PCQI.

These courses are taught by Lead Instructors trained by the FSPCA, who have been instructed in how to teach the FDA-recognized standardized curriculum.

RESOURCES (Cont.)

- List of upcoming courses and registration information can be accessed at: *https://fspca.force.com/FSPCA/s/course_registration/Course_Registration__c/00B36000007edjpEAA?language=en_US*
- For more information about FSPCA Alliance Training opportunities, visit: *https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food*
- A copy of the FSPCA PC for Human Food Participant manual can found at: https://ifpti.absorbtraining.com/Files/Instructor%20Resource%20Portal/FSPCA%20PC%20Course%20Participant%20Manual_V1.2_2016.02.23.pdf
- Other training opportunities can be found on the Penn State Extension website: *https://extension.psu.edu/preventive-controls-for-human-food-rule*

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REGION 6E/6W (Adams, Cumberland, Dauphin, Franklin, Lebanon, Lancaster, Perry, Schuylkill, and York)
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