

FSMA's Final Rule on *Preventive Controls* for Human Food

❖ Who is Subject to FDA's new FSMA Preventive Controls Rule?

The Food Safety Modernization Act (FSMA), which became law in 2011, requires firms that manufacture, process, pack or hold human food and that must register with FDA under 2002 BT Act to ALSO follow the Preventive Controls (PC) Rule's new food safety requirements found in **21 CFR Part 117**. To learn more about who must register their firms with FDA, visit the FDA website at: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

The Preventive Controls rule is now final, and compliance dates for some businesses begin as early as September 2016. For more information about the FDA's FSMA Final Rule for PC for Human Food, please visit: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

The Pennsylvania Department of Agriculture (PDA) will adopt 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 of the effective compliance date. As Pennsylvania regulation, all PDA registered firms will be expected to comply with the applicable portions of the PC Rules 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.

The new *PC Rule* requires food establishments to follow updated good manufacturing practices (**cGMPs**), and establish and implement a comprehensive Hazard Analysis and Risk-Based Preventive Controls (**HARPC**) plan.

❖ FSMA's Food Safety Plan Requirements

Firms that are subject to the regulations must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. This 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,
 - Food Allergen Controls,
 - Sanitation Controls,
 - 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.
 - Recall Plan—It must include steps and methods to be used to notify the direct recipients of the food about the recall and the public about any hazard, and to verify that the recall is carried out as well as procedures to appropriately dispose of the recalled food in the food establishment and by all recipients.
 - Other Appropriate Controls
- **Oversight and management of preventive controls:**
 - Monitoring: to provide assurance that preventive controls are consistently performed.
 - Corrective Actions and Corrections: to quickly identify and correct a minor isolated problem that occurs during food production.
 - Verification: to ensure that preventive controls are consistently implemented and effective.
- **Recordkeeping:** Documentation of compliance with the food safety plan to include but not limited to monitoring, corrective actions and verification activities. Required records shall be made available to the regulatory authority.

**Pennsylvania Department of Agriculture
Bureau of Food Safety & Laboratory Service**

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❖ **When would Food Establishments need to comply (if not exempted)?**

Business Size	Description	Compliance Date
Very small	<\$1M total annual sales of food (3 year avg.)	September 16, 2018
Small	<500 full-time equivalent employees	September 16, 2017
Large	All other businesses	September 16, 2016



Implementing Supply-Chain Program has differing compliance dates based upon when the food establishments' suppliers must comply with the PC Rule.

❖ **What Food Establishments are exempt from the FSMA's PC rule?**

- Food establishments that manufacture products covered by separate regulations including juice, seafood, dietary supplements, alcoholic beverages, or *Low-acid canned foods*.
- 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.
- 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.*)
- Farms are not covered by the new requirements, unless they trigger the "establishment" definition.

❖ **What Food Establishment is subject to or qualifies for the modified PC requirements?**

(This may apply to most PDA Limited Food Establishments)

- + A very small business not meeting the "on-farm" OR the "low-risk activity" criteria.
- + An establishment that has less than \$500,000 in gross annual sales (3 years average) AND the majority of the food is sold directly to a "qualified end-user," then it must maintain certain records and must certify that:
 - a. It qualifies for modified requirements AND,*
 - b. It is implementing/monitoring preventive controls*
OR, it is complying with applicable State food safety law.
- + An establishment that is solely engaged in the holding of packaged food not exposed to the environment but requires time/temperature control for safety (TCS food); the firm must:
 - a) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens AND,*
 - b) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed AND,*
 - c) Take appropriate corrective actions to correct any loss of temperature control that may impact the safety of the refrigerated packaged food AND,*
 - d) Verify that temperature controls are consistently implemented AND,*
 - e) Establish and maintain records (subject to the requirements of Part 117, subpart F) documenting the above monitoring, corrective actions, and verification activities.*

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❖ **Updated Current Good Manufacturing Practice (cGMP)**

The PC Rule also updates Current Good Manufacturing Practice (cGMP) requirements. Updates include:

- ✓ Clarifications on protections against cross-contact of food by allergens,
- ✓ Deletion of certain nonbinding provisions (language containing recommendations),
- ✓ Some previously nonbinding provisions are now modified to be binding provisions.
(An example is education and training, in which management is now required to ensure that all employees who manufacture, process, pack or hold food are qualified to perform their assigned duties. These employees must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food. Individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and hygiene).

Establishments that are exempt or subject to modified requirements in the new requirements for Hazard Analysis and Risk-Based Preventive Controls (HARPC) would generally be subject to cGMP requirements.

❖ **How does a “preventive controls plan” compare to a HACCP plan?**

The general concepts are very similar. However, these “preventive controls plans” also cover monitoring, records, and corrective actions for items that are considered pre-requisite programs in HACCP, including food allergen controls, sanitation controls, and a recall plan. Preventive controls plans do NOT have a requirement for a Critical Limit as in HACCP plans.

❖ **Assistance to Industry**

The FDA FSMA Technical Assistance Network (TAN) is now operational and providing technical assistance to industry regarding FSMA implementation. Inquiries may be submitted through a web form accessible at www.fda.gov/fsma select “Contact FDA about FSMA” and then Submit Inquiry.

The FDA is developing several guidance documents on subjects that include:

- *Hazard Analysis & Preventive Controls,*
- *Environmental Monitoring,*
- *Food Allergen Controls,*
- *Validation of Process Controls,*
- *A Small Entity Compliance Guide that explains the actions a small or very small firm must take to comply with the rule.*

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

REMEMBER

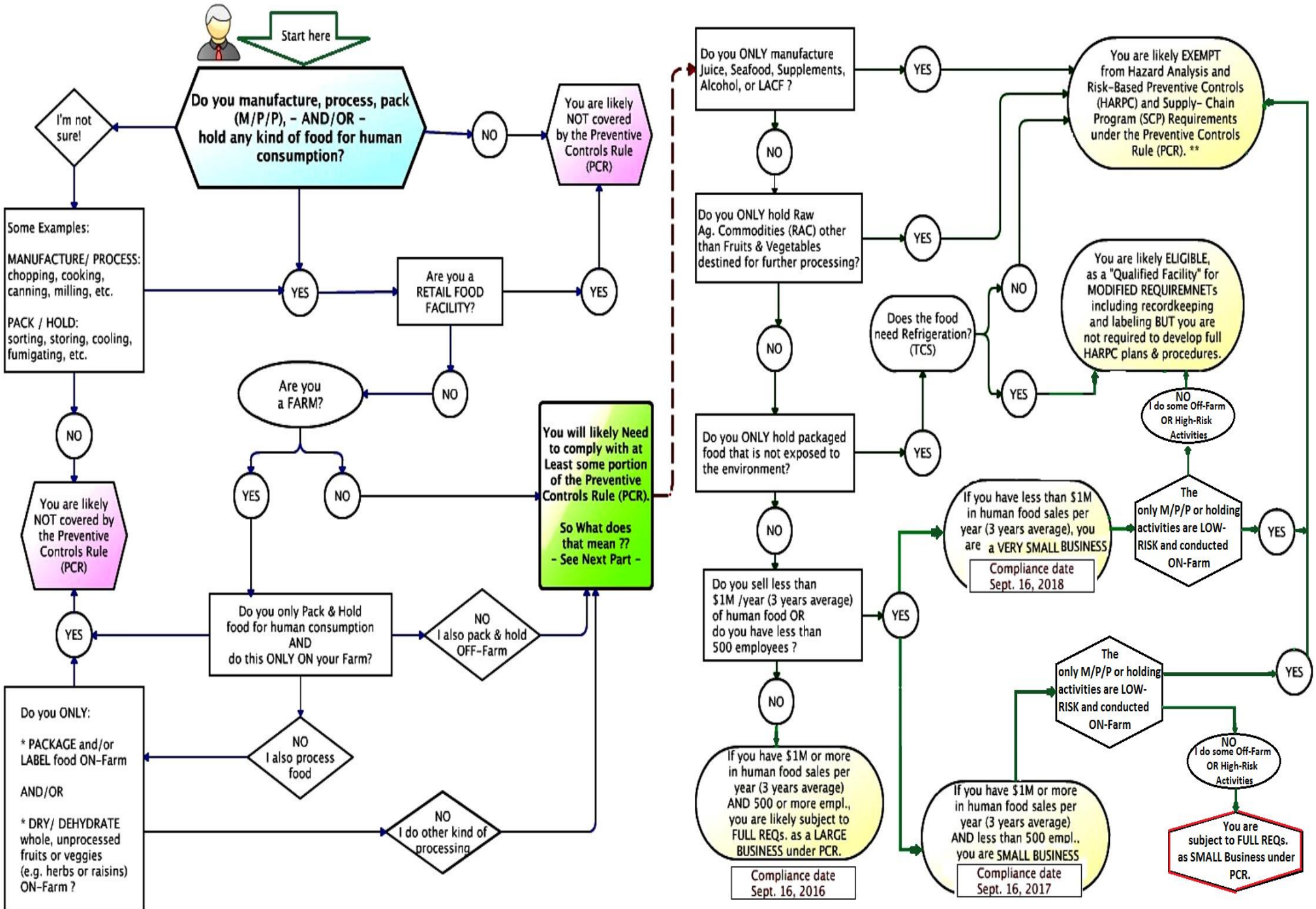
**Regardless of your status under FSMA rules, food safety is everyone’s responsibility
-- From field to fork --**



See the Flow Chart in the back of this sheet to determine whether you are affected by the FSMA PC Rule.



AM I AFFECTED BY THE FSMA PREVENTIVE CONTROLS RULE ?



** Establishments exempt from HARPC and SCP Requirements MUST still comply with already-existing rules and practices (cGMPs, Part 120, 123, etc.), but DO NOT need to develop HARPC plans and SCP procedures.