

# Preventive Controls for Human Foods & Preventive Controls Qualified Individuals

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Technical Assistance to Enhance Produce Safety



USDA NIFA AWARD NUMBER 2015-70020-24397

## Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

*Margaret A. Hamburg, M.D.,  
Commissioner of Food and Drugs*



# The Law and the Final Rule



## FDA Food Safety Modernization Act (FSMA)

- Passed by 111<sup>th</sup> U.S. Congress (2010)
- Signed into law by President B. Obama (2011)
- Final rules enter development (early 2012)

## Final Rule: Current Good Manufacturing Practices, Hazard Analysis, and Preventive Controls for Human Foods (21 CFR §117)

- Proposed rule released via Federal Register with comment request (Jan. 2013)
- Final rule released (Sep. 2015)
- Rule into effect: Nov. 2015 or Sep. 2018



## FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

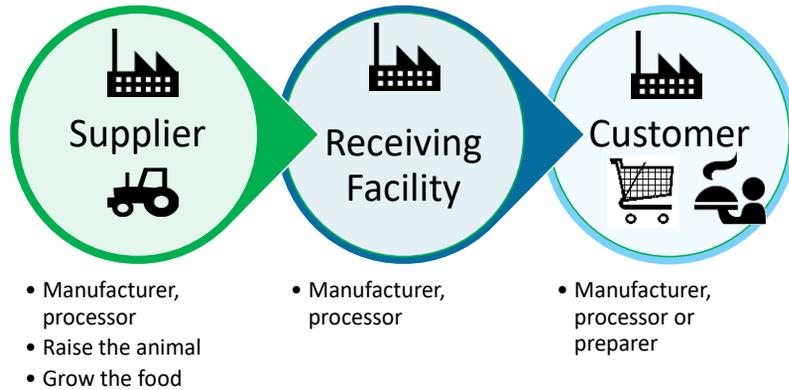
# Who is Impacted?

Those firms required by the U.S. Federal Food, Drug, and Cosmetic Act to be registered with the FDA (§415)

- Some exceptions include:
  - Seafood industry members and processors using HACCP
  - Juice processors using HACCP
  - Low-acid canned/hermetically sealed foods manufacturers adhering to 21 CFR §113
  - Foodservice establishments (restaurants, etc.) – State/municipal law covers
- Food processing establishments in general will register/participate
- Dairy industry members adhering to adopted forms of Pasteurized Milk Ordinance (even those participating under voluntary HACCP program) will register and be covered



## Who is covered by Final Rule? (From FSPCA/FDA)



## Some others who aren't impacted by rule

Farms: FDA defines primary and secondary operations that may be exempt from the Preventive Controls for Human Foods final rule

All food processors subject to USDA-FSIS inspection/jurisdiction

- Meat
- Poultry
- Egg products

Egg producing facilities subject to the Shell Egg/SE Final Rule (FDA regulation, 21 CFR §118)



## Some critical definitions to use in identifying whether you're covered

**Facility** means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities.

(1) *Domestic facility* means any facility located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States.



## Defining farms by FDA (21 CFR §1.227)

**Primary production farm:** an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities: (i) Pack or hold raw agricultural commodities; (ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and (iii) Manufacture/process food, provided that: (A) All food used in such activities is consumed on that farm or another farm under the same management; or (B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of: (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing); (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation);



## Farm definition, Part 2

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**Secondary activities farm:** A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.



## Mixed-type facilities

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*Mixed-type facility* means an establishment that engages in activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act **and** activities that require the establishment to be registered. An example of such a facility is a “farm 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.



## Qualified exempt facility

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Very small businesses (average less than \$1M) are qualified facilities exempt from the requirements for hazard analysis and risk-based preventive controls, but have some modified requirements

- Attestation the facility is a qualified facility; AND
- Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored;

OR

- Attestation that facility is in compliance with an applicable non-Federal food safety law



## Key Components of the Rule; What's required...

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Use of GMPs

Food safety plan

Hazard analysis

Preventive controls development (as needed)

Verification and monitoring systems

Corrective actions

Recall plan (a type of preventive control)

Supplier management plan



## Current GMPs (21 CFR §117.10-110)

Operation within helps prevent food *adulteration*, and produce food in wholesome and sanitary manner

Re-codifies/applies GMPs from 21 CFR §110

- Personnel
- Plant and grounds
- Sanitary operation
- Sanitary facilities & controls
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
- **Holding and distribution of human food byproducts used for animal food (Newly incorporated – focuses on byproducts not subject to additional processing, labeling of byproducts, and sanitary condition maintenance of shipping containers)**
- Defect action levels



What's Wrong with this Picture?

### White and Brown Sugar at a Bakery



Improper storage of chemicals

Even when properly labeled, these chemicals do not belong in a food preparation area to prevent accidental use

*Adapted from FSPCA PCHF Training Curriculum*



# Hazards Analysis (21 CFR §117.130)

**MUST** be conducted for covered facilities to identify *known and/or reasonably foreseeable hazards* to determine needs for food safety preventive controls (PC)

- Not all food processes will require a PC – some may require a Mac...
- Hazard classes:
  - Biological (Microbial pathogens and toxins)
  - Physical
  - Chemical (Including allergen and radiological hazards)
- Hazard evaluation must include determination of environmental pathogens in cases of RTE food exposure (*L. monocytogenes*, etc.)

Regardless of PC identification, a WRITTEN Hazard Analysis is required (117.130)

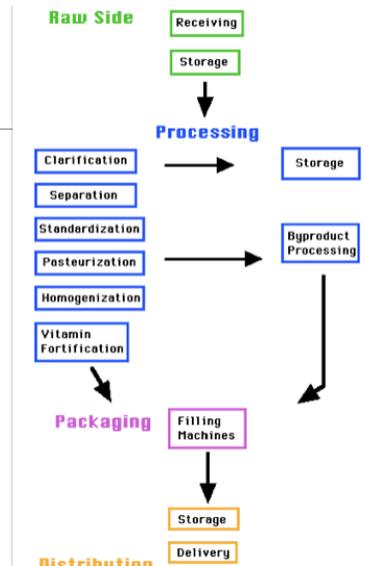
Must consider likelihood of disease/harm to consumer absent controls, and severity (risk assessment)



## Hazards Analysis: Flow Diagram

Not required by the rule, but still a really good idea!

Training curriculum by FSPCA makes point of recommending completion



# Food Safety Preventive Controls

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“Those risk-based, reasonably appropriate procedures, practices, and processes that a **person knowledgeable about the safe manufacturing, processing, packing, or holding of food** would employ to **significantly minimize or prevent the hazards identified under the hazard analysis** that are consistent with the current scientific understand of safe food manufacturing, processing, packaging, or holding at the time of the analysis.”

- An assessment of PC needs is completed following hazards analysis
- *Not all processes will require a PC (Hazard analysis still required to define no need)*



## No PC Required Scenarios

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Not covered by the rule (covered by other FSMA rules like Produce Safety Rule), covered by other food safety rules (HACCP), or USDA-FSIS-regulated

*You produce foods that cannot be consumed without a preventive control (e.g., coffee beans, grains)*

You sell to other processors who document hazard control and you HAVE the documents

- Your customer may not be subject to the rule, but must document appropriate control no matter what
- Your direct customer sells to another who then controls



## Recall Plan (§117.139)

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Required for food products identified to require a PC

- Written plan on file

Includes:

- Direct customer notification
- Public notification when appropriate
- Efficacy checks for recall plan progress
- Disposition of impacted/recalled foods

Not the same as a market withdrawal (risk-based decision)



## Process Monitoring (§117.145)

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Preventive controls implementation **must be monitored** in appropriate fashion

- Frequency of monitoring
- Methods of monitoring (direct/in-line, indirect); officers responsible for monitoring (line operations, QC)
- Generate monitoring records that are subject to verification procedures/checks

Aids in determining when a process deviation has occurred, loss of process control

Identify trending to or away from control



# Corrective Actions & Corrections

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Like monitoring systems, are mandated for PCs to assist return to process control

- Written procedures to address pathogen presence in RTE foods
- Presence of pathogen or indicator in environment via testing
- Addresses all impacted food, root cause of deviation, and reduces likelihood of problem re-occurrence
- May result in food re-processing, destruction, or other disposition decision

*Corrections:* Do not require corrective actions development/implementation when correction is made in manner that food safety not impacted

- Identify wrong labels selected for allergen-containing food before food is packaged and leaves facility
- Determine incorrect sanitizer preparation before sanitation occurs, so new batch properly prepared is made, documented, and used



# Verification

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Required, including validation of process preventive controls, for processes including PCs

- Written documents verification and storage with food safety plan
- Corrective actions use verified
- Validation of efficacy of process PCs
  - Within 90 days of implementation of process PC or appropriate time (as approved by request to FDA)
  - Change to process
- Verification documents must be reviewed by PCQI within 7 days or longer if written justification is produced



# Food Safety Plan Re-Analysis (§117.170)

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Comprehensively completed at least once every 3 years

Comprehensive, or partial reanalysis:

- Significant changes at facility (new equipment, new formulation, new ingredient suppliers)
- Newly identified hazards become known (new transmission routes of *E. coli* via flours)
- Following unanticipated food safety hazard detection
- Following identification of preventive controls or GMPs inadequacy
- Following recall
- Newly implemented process PCs must be validated as outlined in verification requirements
- **Must** be completed by PCQI



## PCQI – What’s this?

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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 is otherwise qualified through job experience to develop and apply a food safety system.

- 21 CFR 117.3
- Has a great deal of responsibility for food safety plan development, implementation/execution, oversight, and re-analysis!
- Process PC validation design/completion
- Does not have to be a company employee! (Probably will be though in many/most cases)



# Facility Food Safety Plan

**Required** for covered facilities (117.126) – written plan

- Hazard analysis
- Preventive controls used for hazards control (all types)
- Supply chain program
- Recall plan
- Monitoring records methods for PC monitoring
- Corrective actions
- Verification procedures

Required when PCs are identified as required

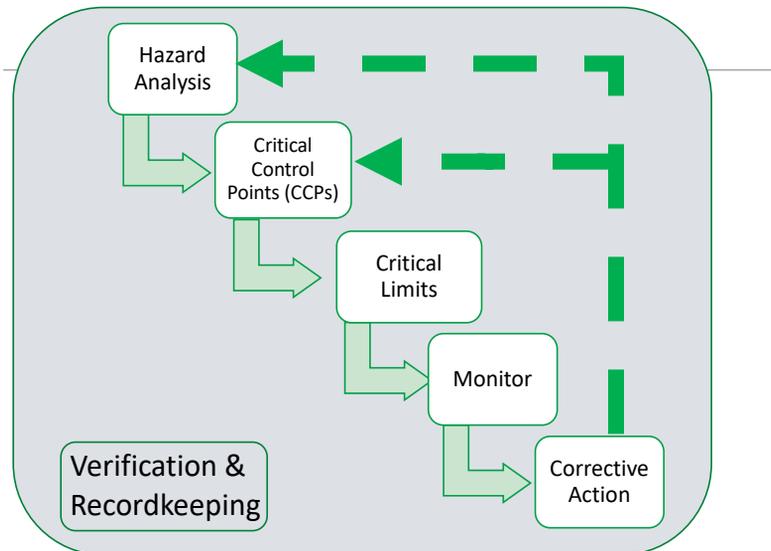
Other components, documents may be included to support/demonstrate food safety protection



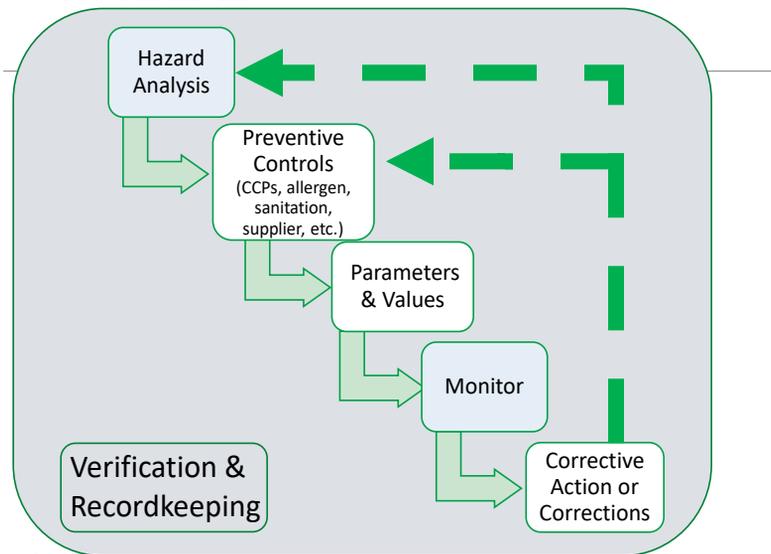
## What's New in a Food Safety Plan

| Element                           | HACCP Plan                     | Added in Food Safety Plan  |
|-----------------------------------|--------------------------------|--|
| Hazard analysis                   | Biological, chemical, physical | Chemical hazards to include radiological; consider economically motivated hazards                          |
| Preventive controls               | CCPs for processes             | Process CCPs + controls at other points that are not CCPs  |
| Parameters and values             | Critical limits                | Parameters and minimum/maximum values (= critical limits for process controls)                             |
| Monitoring                        | Required for CCPs              | Required as appropriate for other preventive controls  |
| Corrective actions or corrections | Corrective actions             | Corrective actions or corrections, as appropriate  |
| Verification                      | For process controls           | As appropriate for all preventive controls; supplier verification required when supplier controls a hazard |
| Records                           | For process controls           | As appropriate for all preventive controls   |
| Recall plan                       | Not required in the plan       | Required when a hazard requiring a preventive control is identified  |

## HACCP Focuses on the Process



## Preventive Controls Include More Than HACCP



## HACCP vs. FSPPCs

### How do these systems differ?

- Some have called FSPPCs and the HARPC (Hazard Analysis and Risk-based Preventive Controls) as “HACCP 2.0,” “HACCP on Steroids,” or “HACCP: The Next Generation.”
- In practice, there probably is not a GREAT deal of day-to-day difference for those already operating with HACCP



## Key Implementation/Enforcement Dates

| Facility Category   | Enforcement/Compliance Starts  |
|---|--|
| Very Small Business (\$1 million/year average sales + value of product manufactured without sale) | 3 years from release for compliance, except records to verify status as Very Small |
| Dairy products processors, milk pasteurizers, others subject to PMO                               | Under extension to allow new PMO to be harmonized with PC Final Rule (9/17/2018)   |
| Small Business (<500 full time employees)   | 2 years post-release (9/2017)  |
| All other covered facilities  | 1 year post-release (Sept. 2016)   |
| Those importing foods subject to the FSVP   | Earliest: May 28, 2019   |





## Summary

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FSMA really is one of the most comprehensive food safety regulatory reforms in many decades in U.S.

Preventive controls adopts and implements many core principles and practices from HACCP and other food safety protection systems

Food safety plans by covered facilities must be written and contain at minimum a hazards analysis

Recall authority now rests with FDA in addition to processor

PCQIs have great responsibility in processor for plan development, implementation, verification, validation, and reanalysis!

The FSPCA is the entity developing a recognized curriculum and aiding training completion globally



# Thanks!

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¿PREGUNTAS?

