Are You Ready for FSMA ?

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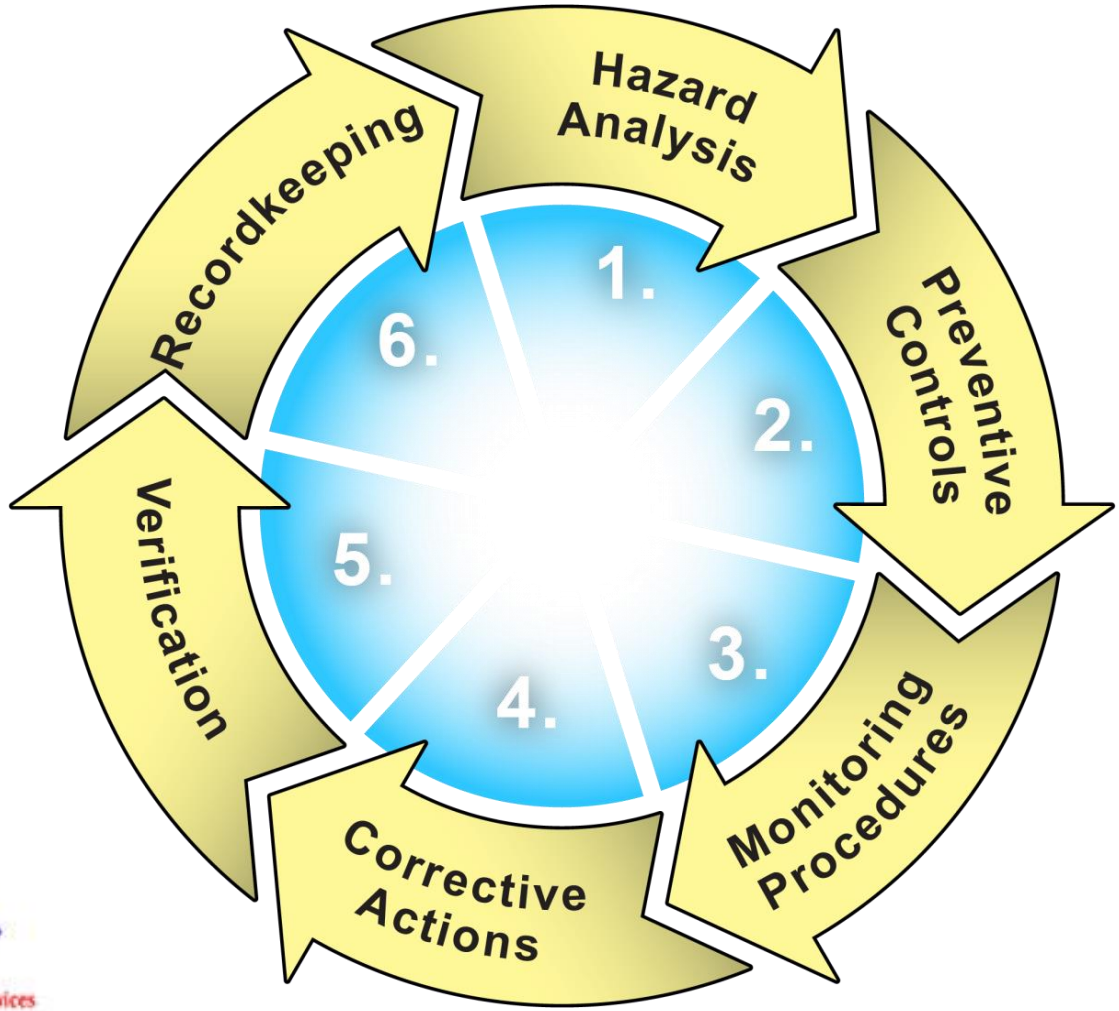

U.S. Department of Health and Human Services
Food and Drug Administration

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New Responsibilities for Food Companies

Impacting daily operations in all registered facilities, domestic and foreign:

- Food Safety Plans / Preventive Controls
- Supply Chain Management (?)
- Records Maintenance and Access
- GMPs

Food Safety Plan ≠ HACCP

Based Largely on HACCP Principles

* To highlight differences

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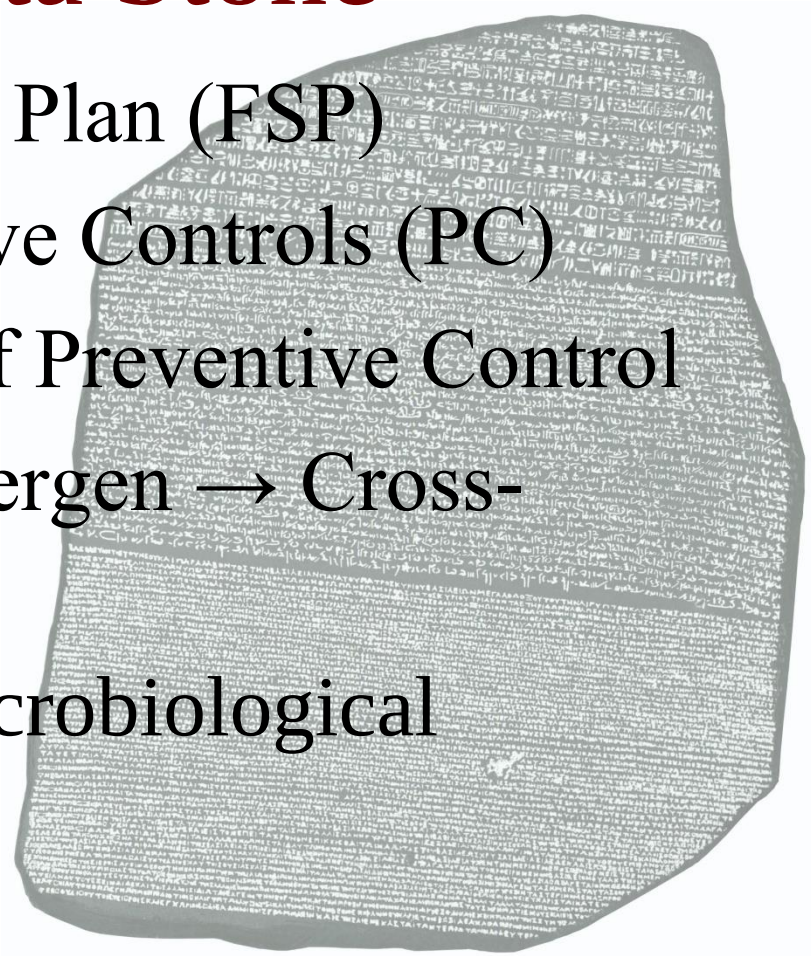
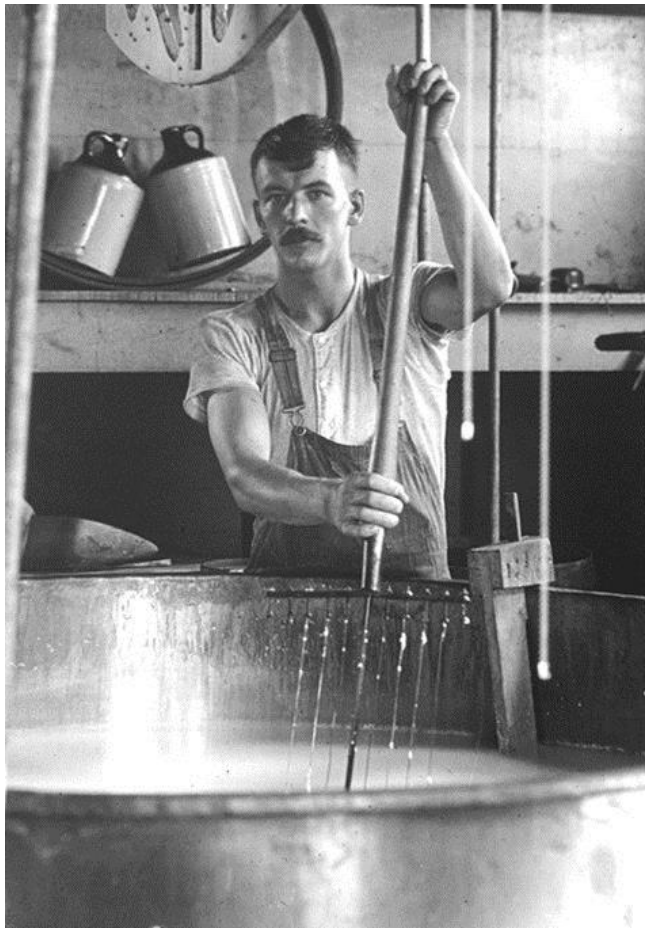
FSMA Rosetta Stone

- HACCP → Food Safety Plan (FSP)
- Some PRPs → Preventive Controls (PC)
- CCP → Critical Limit of Preventive Control
- Cross-contamination allergen → Cross-contact
- Cross-contamination microbiological →Cross-contamination



Requirements for a FS Plan
§117.126

- Responsibility
- Contents
- Qualified Individual



Responsibility

- Owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written Food Safety Plan*
- Required to sign and date upon completion and upon any modification

Qualified Individual*

- Food Safety Plan must be prepared by a qualified individual
  - Or its preparation overseen by a qualified individual
- Also responsible for:
  - Validation of Preventive Controls
  - Review of Records for implementation & effectiveness of PCs and appropriateness of Corrective Action
  - Reanalysis of FSP

Qualified Individual*

- Successfully completed training in the development and application of risk-based preventive controls
  - Recognized as adequate by FDA
  - Training must be documented
- Or qualified through job experience to develop and apply a food safety system

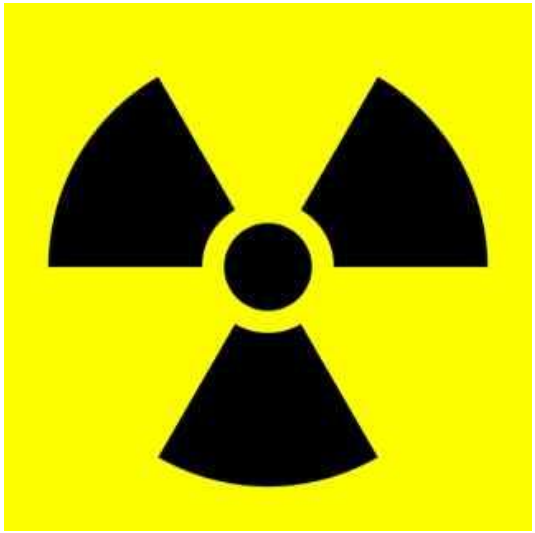
Note: FDA has funded FSPCA to develop training curriculum

Contents of FS Plan

1. Written Hazard Analysis
2. Written Preventive Controls*
3. Written Procedures for monitoring the implementation of Preventive Controls
   - including frequency that they are to be performed
4. Written Corrective Action Procedures
5. Written Verification Procedures
6. Written Recall Plan*

FS Plan Contents: Hazard Analysis - Identification

- Hazard identification must consider hazards that may occur naturally or be unintentionally introduced
  - Biological
  - Chemical
  - Physical
  - Radiological*



FS Plan Contents: Hazard Analysis - Evaluation

1. Determine likeliness to occur and assess the severity of the illness or injury if hazard were to occur
2. Evaluate environmental pathogens likeliness to occur whenever a RTE food is exposed to the environment*

FS Plan Contents: Hazard Analysis - Evaluation

3. Must consider the effect of the following on the safety of the Finished Product for the intended consumer
   i. Formulation
   ii. Condition, function, and design of equipment and facility*
   iii. Incoming materials / ingredients
   iv. Transportation practices*

More Effects on FP to Consider

v. Manufacturing / processing procedures
vi. Packaging & labeling activities
vii. Storage & distribution
viii. Intended or reasonably foreseeable use*
ix. Sanitation; including employee hygiene
x. Any other relevant factors

FS Plan Contents: Preventive Controls*

- Preventive controls significantly broader than HACCP CCPs
- Preventive controls may or may not include critical limits
- Preventive controls include programs that we have called Prerequisite Programs (PRP) under HACCP

FS Plan Contents: Preventive Controls*

- Parameters associated with the control of a hazard and the values to which any parameter must be controlled (CCPs)
- Process controls – include procedures, practices, and processes performed on food during manufacture (cooking, cooling, acidifying, etc.)

FS Plan Contents: Preventive Controls*

- Food allergen controls
  - Ensuring protection from cross-contact
  - Ensuring proper labeling
- Sanitation controls
  - To minimize or prevent hazards that are reasonably likely to occur
  - Required where RTE food is exposed to environment

Note: Allergen & Sanitation controls have typically been PRPs

FS Plan Contents: Preventive Controls*

- Sanitation controls must include procedures for:
  - Cleanliness of food-contact surfaces
  - Prevention of cross-contact and cross-contamination
  - The owner, operator, or agent in charge of a facility must take action to correct, in a timely manner, conditions and practices not consistent with procedures and document

FS Plan Contents: Preventive Controls*

- Recall Plan that includes procedures with responsibility assigned for the following:
  - Notification of direct consignees
  - Notification of the public when appropriate to protect public health
  - Conducting effectiveness checks
  - Disposal of recalled product

FS Plan Contents: Preventive Controls*

- Other Controls necessary to assure that product is not misbranded or adulterated
  - Temperature control during transportation of refrigerated foods
  - PRPs may fall under this
- FDA is seeking comments on supplier approval and verification programs

Supplier Approval & Verification

- Know who your suppliers are (not just distributors)
- Have a plan for assuring adherence to food safety requirements
- Appropriate to make plan risk-based according to product type and facility history
- Goal is to assure product not adulterated or misbranded

Preventive Controls Summary

- Process Controls (CCPs)
- Food Allergen
- Sanitation
- Recall Plan
- Supplier Approval & Verification (TBD)
- Other

Preventive Controls are Subject to:

- Monitoring
- Corrective Action
- Verification

Preventive Controls Monitoring

- Establish and implement written procedures
- Done with sufficient frequency
- Documented in records
- Subject to verification activities, including records review by qualified individual within a week after record created

Preventive Controls Corrective Action

- Predetermined procedures to be taken
- Procedures must describe steps to ensure
  - Appropriate action is taken to identify and correct a problem and reduce the likelihood that problem will recur
  - Affected food is evaluated for safety
  - Affected food is prevented from entering commerce if facility cannot ensure food is not adulterated or misbranded

Preventive Controls Corrective Action

- In the event of an unanticipated problem
  - Same procedure as predetermined CA
  - Additionally, reanalyze the FS plan to determine whether modification is required
- All Corrective Actions must be documented
- Subject to verification & records review

Preventive Controls Verification

- Validation
  - Prior to implementing FSP or 1st 6 weeks
- Monitoring
- Corrective Actions
- Implementation and effectiveness
  - Calibration of process monitoring equipment*
- Written procedures for verification activities
- Reanalysis
- Documentation

Preventive Controls Verification May Also Include:

- Consumer Complaint Reviews
- Environmental Pathogen Testing
- Finished Product Pathogen Testing

FDA is seeking comment on these verification activities

Preventive Controls Verification - Validation

- Required for:
  - Process Controls (CCPs)
  - Other Preventive Controls
- Not required for:
  - Food allergen controls
  - Sanitation controls
  - Recall plan
    (also exempt from Monitoring and CA)

Food Safety Plan Reanalysis

- At least once every 3 years
- When a significant change creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is not properly implemented, ineffective, or there was no established CA procedure

Start Preparing for FSMA:

- ✓Hazard Analysis
  - Add Radiological Risk to Risk Assessment
  - Assure we address natural toxins, pesticides, drug residues, decomposition, and parasites
  - Severity of illness
  - Foreseeable consumer use/misuse
  - Environmental pathogens probability of cross-contamination in RTE foods
  - Transportation practices

Start Preparing for FSMA:

- ✓CCPs (Critical Limit) with scientific validation documented
- ✓Hazard Analysis and HACCP Plan in place before manufacture begins
- ✓Change management process to initiate a new hazard analysis and HACCP(FSP) review
- ✓Expansion of HACCP training

Start Preparing for FSMA:

- ✓Review/update SOPs for monitoring PCs
  - ✓Frequency
  - ✓Documentation
- ✓Verify PCs all have predetermined Corrective Actions
- ✓Review/update Recall Plan

Records Maintenance and Access

- FDA will have legal access to see and copy (?) records related to FS Plan:
  - FS Plan, Hazard Analysis, Preventive Controls, Monitoring SOPs, Corrective Action SOPs, Verification SOPs, Recall Plan, and All Associated Records
  - Could include:
    - environmental and finished product testing
    - customer/consumer complaints related to food safety
    - monitoring of supply chain

Good documentation practices will be critical!

Records Must:

- Be kept as original true copies or electronic
- Contain actual values and observations
- Be accurate, indelible, and legible
- Be created concurrently with performance of activity
- Be as detailed as necessary to provide a history of work performed

Records Must Include:

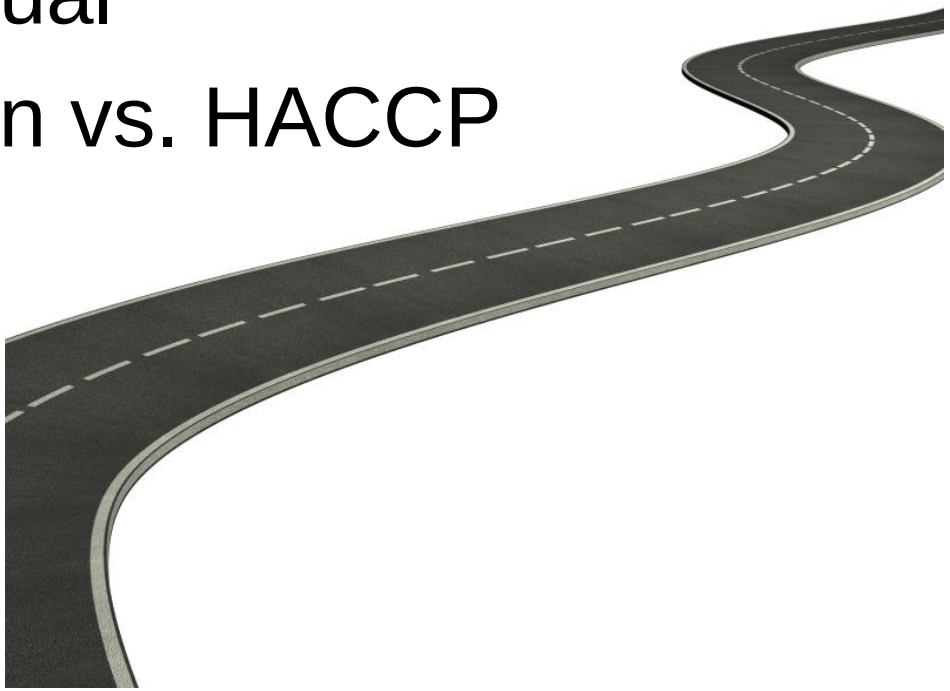
- The name and location of the plant or facility
- The date and time of activity documented
- The signature or initials of the person performing the activity
- Where appropriate, the identity of the product and the production code , if any

Start Preparing for FSMA:

- ✓Review record creation practices
- ✓Review existing records
  - Food Safety Plan or Quality?
  - ‘Return to Control’ documented
  - Consistency
- ✓Record retention – 3 to 2 years?
- ✓Establish marking protocol for documents FDA may copy

Summary

- Responsibility
- Qualified Individual
- Food Safety Plan vs. HACCP
- Records
- Action Items



Questions ?

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