

Written Food Safety Plan:

FSMA vs. HACCP

WAFP

November 4, 2015

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Opening Comments

- FSMA preventive control regulations are objective based, not prescriptive – more flexible but higher responsibility on manufacturers to show their systems work as intended
- Elements that are different than HACCP Approach*

Subpart C - Food Safety Plan

- Owner, Operator, or Agent in Charge of the facility must prepare, or have prepared, and implement a written FS Plan*
- Preparation by, or overseen by PCQI(s)
- Owner, Operator, or Agent in Charge of the facility must sign and date the Food Safety Plan*
- Reanalysis every 3 years or certain events occur

Contents of FS Plan

1. Written Hazard Analysis
2. Written Preventive Controls*
3. Written Supply-Chain Program
4. Written Recall Plan*
5. Written Procedures for monitoring the implementation of Preventive Controls
6. Written Corrective Action Procedures
7. Written Verification Procedures

Hazard Identification

- Identify all microbiological, chemical, and physical hazards that would be present without any controls
- Also includes hazards that may be present:
 - Naturally occurring
 - Unintentionally introduced
 - Intentionally introduced EMA that causes FS issue* (e.g., melamine, Sudan Red)

Hazard Evaluation

- Assess the severity of the illness or injury if hazard were to occur and probability that hazard will occur in the absence of PC
- Evaluate environmental pathogens whenever a RTE food is exposed to the environment prior to packaging and packaged food does not receive a treatment or control measure*

Hazard Evaluation

- Must consider the effect of the following on the safety of the Finished Product for the intended consumer:
 - Formulation
 - Condition, function, and design of equipment and facility*
 - Raw materials / ingredients
 - Transportation practices*

Hazard Evaluation

- Must consider:
 - Manufacturing / processing procedures
 - Packaging & labeling activities
 - Storage & distribution
 - Intended or reasonably foreseeable use*
 - Sanitation; including employee hygiene
 - Any other relevant factors

Preventive Controls*

- Implement controls to provide assurance that hazards are significantly minimized or prevented
- Preventive controls significantly broader than HACCP CCPs
- Preventive controls include programs that we have called Prerequisite Programs (PRP) under HACCP
- Preventive controls may or may not include critical limits

Preventive Controls*

- Controls at CCPs, if there are any CCPs
- Process Controls with min and max values
- Food Allergen Controls
- Sanitation Controls*
- Supply-Chain Controls*
- Recall Plan*
- Other Controls – hygiene training, CGMPs

Circumstances Where PC Not Required*

- Food could not be consumed w/o application of appropriate control (e.g., cocoa beans)
- You rely on customer to ensure that identified hazard will be significantly minimized or prevented
 - Customer who is subject to HARPC
 - Customer who is not subject to HARPC
 - By entity in distribution chain subsequent to customer

Rely on Customer Requirement*

- Disclose in documents “not processed to control (identified hazard); and
- Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements

Preventive Control Management

- Monitoring
- Corrective Actions and Corrections*
- Verification



Monitoring

- Written procedures including frequency
- Records
- Exception Records*
- Subject to verification activities including records review within specified timeframe by PCQI*

Corrective Actions

- A needs to be commensurate with deviation and documented
- Must establish for:
 - Presence of pathogen / appropriate indicator organism in a RTE product*
 - Presence of environmental pathogen / appropriate indicator organism*
- Predetermined CAs vs. Unanticipated*

Corrective Action Procedures

- Identify and correct problem
- Reduce likelihood that problem will recur
- All affected food is evaluated for safety*
- All affected food is prevented from entering into commerce*
- Unanticipated FS problem may require reanalysis of FS Plan

Corrections*

- Action taken in a timely manner to identify and correct conditions and practices that are not consistent with food allergen controls and sanitation controls
- Does not directly impact product safety
- No documented CA required

Verification Activities

- Validation
 - Prior to implementation of FSP or w/in 90 days after first production*
- Verification that monitoring is being conducted as required*
- Verification that appropriate decisions about CAs are being made*
- Verification of implementation and effectiveness*
- Reanalysis

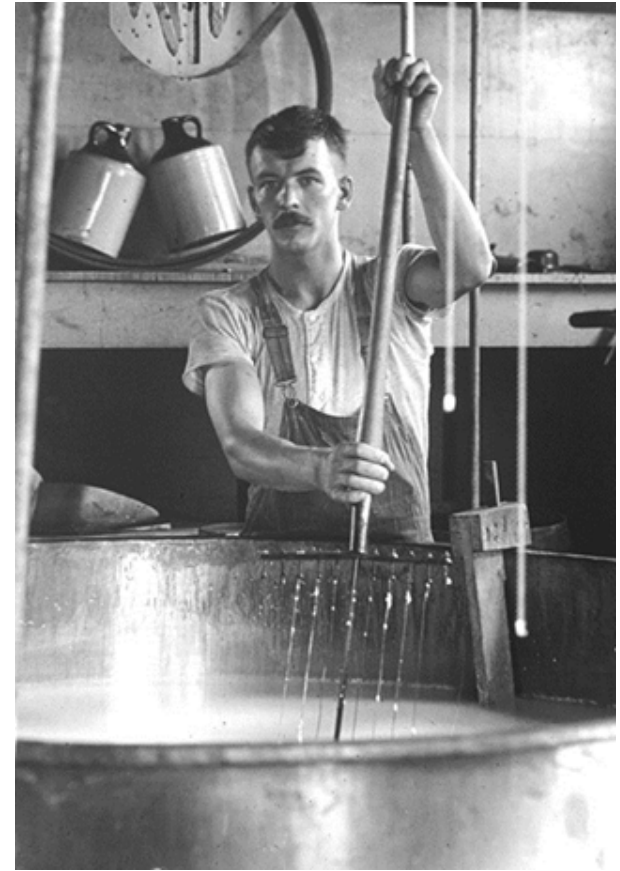
Verification of implementation and effectiveness*

- Calibration or accuracy check of process monitoring and verification instruments
- Product testing – pathogen or indicator
- Environmental monitoring if contamination of an RTE food with an env pathogen is a hazard requiring a PC
- Review of records within specified timeframes

Verification of implementation and effectiveness*

- Written Procedures:
 - Calibration/Accuracy Check
 - Product Testing
 - Environmental Monitoring

- Questions?
- Comments!



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