Written Food Safety Plan: FSMA vs. HACCP
WAFP
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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!