GMP/Preventive Controls for Human Food

Record Keeping: An FDA Perspective

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FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

Relevance of Recordkeeping
Presentation Overview

- General information on records
- Required Records
- Implementation records
- Salsa Processor Example
- Record retention and availability

General Requirements
Records

- Form
  - Original, true copies or electronic
- Content
  - Actual values or observations
  - Accurate, permanent and legible
  - Real time recording
  - Adequate detail
- Computerized records – Part 11 like…..

General Requirements
Records

- Name of Record
- Name and location of facility
- Date and time of activity
- Actual measurements or observations
- Product identification – if applicable
- Signature or initials of person doing monitoring
- Reviews signature or initials and date

GMP/PC – Training Records

- Individual must be qualified by education, training, or experience to manufacture, process, pack or hold food
- Individuals must receive food hygiene and food safety, including the importance of employee health and personal hygiene as appropriate
- Training must be documented

Food Safety Plan - Components

- Written Hazard Analysis
- Written Preventive Controls
  - Process
  - Allergen
  - Sanitation
- Written Supply-Chain Program
- Written Recall Plan
- Written Procedures
  - Monitoring / Corrective Actions / Verification

FSP & Records - Acidified

Salsa Processor

- Product and Hazard Analysis
  - Shelf-stable chopped mix veg salsa (Acidified)
  - HA identifies pathogens & non health spoilage organisms capable of growth at room temp
- Process Design & Description
  - Hot fill and hold using steam-jacketed kettle
  - Batch directly acidified (formulation)
  - PCQI also Process Authority (onsite)
    - Files scheduled process – time/temp/pH/formula

Process Determined

- Review of literature
- pH is set to ensure:
  - No pathogen growth (i.e. *C bot*)
  - Specific spoilage concerns are addressed
- Process Temp – Time:
  - Adequate for vegetative pathogens
  - Shelf stability
  - Uniform heating established - agitation

Monitoring Records

- Facility must have written procedures, including frequency performed, for monitoring preventive controls
- Monitoring must be documented in records
  - Records are subject to general record keeping requirements
  - Records must be reviewed
  - Expanded for AF/LACF
    - i.e. sanitation for allergen cross contact

Measured Data

- Subpart B: GMP's 21 CFR 117.40:
  - (f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.
  - 110 has similar language

Salsa Processor Monitors:

- Ingredient specifications
- Temperature in cook kettle*
- Time at or above process temperature*
- Temperature in filling surge tank (if used)
- Conveyor belt speeds for control of inversion time

Note: Monitoring completed per batch* or shift

Corrective Actions Records

- Facility must have written procedures for steps to be taken when preventive controls are not properly implemented
  - Prevent adulterated food from entering commerce
  - Evaluate food for safety
  - Identify and correct a problem
  - Reduce likelihood of occurrence

Salsa Corrective Actions

- pH exceeds maximum
  - Rework for different product
  - Investigate root cause / correct
  - Evaluate for shelf stability and/or reprocess
- Temp and/or Time fails to meet minimum
  - Product held for PCQI / PA evaluation
  - Investigate root cause / correct
  - Employees retrained (if applicable)

Verification Records

- Includes (as appropriate to the facility, food and nature of the preventive control):
  - Validation studies
  - Accuracy check and calibration records
  - Product testing records
  - Environmental monitoring records
  - FSP reassessment

Calibration & Records

- Subpart C: Verification of implementation and effectiveness 21 CFR 117.165:

  Conduct activities that include the following, as appropriate……..

  – (1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy)

  – 21 CFR 117.190 Implementation records……

    - Calibration of process monitoring and verification instruments

Salsa Processor Verification

- Outside calibration service – annually for critical process measurements – PCQI reviews & signs
- QA Manager reviews belt speed logs for inversion periodically – PCQI reviews & signs
- Critical production data reviewed by PCQI daily:
  - Time / Temp / pH
  - Surge tank & jar fill temp
  - Belt speed
  - Corrective Actions reviewed weekly

Supply-Chain Records

- Appropriate supplier verification activities records can include:
  - Onsite audits records
  - Sampling and testing records
  - Review of relevant food safety records - record
  - Other records as appropriate
    - e.g. Suppliers compliance with FSVP requirements

Recall Plan

- Written recall plan
  - Define roles and responsibilities
  - Contact list for external notification
    - Regulators, customers, public
  - Lot identification
  - Effectiveness check procedures
  - Product disposition procedures

- Expanded documentation requirements

What about LACF?

- Things for consideration:
  - FSP for Chemical / Physical
  - Run order for allergen management
  - Sanitation for cross contact of allergens
  - Insipient spoilage and potential for toxin
  - Exempt from Supply Chain requirements
  - Failed chart recorders with non-Part 11 digital records

Record Retention and Availability

- Retained 2 years
- Available upon oral or written request
- Process validation – at least 2 years after use is discontinued

Questions?

Discussion….