Preventive Controls and Microbial Food Safety for Fresh Cut Produce

ISHS III International Conference on Fresh-cut Produce 15 September 2015

Preventive Controls and Microbial Food Safety for Fresh Cut Produce

FSMA Final Rule for Preventive Controls for Human Food 1 Sept. 2015

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

A risk-based safety management approach focused on hazard analysis and prevention of problems in order to ensure the production of food products that are safe to consume.

Key components of FSMA Preventive Controls
- Validation and Verification
- Product testing and Environmental Monitoring
- “Preventive Controls” Preharvest
- Wash Water Validation Work Group

Introducing new term to capture FSMA expectations
- HACCP-based — Same seven principles
- HARPC – Hazard Analysis – Risk-based Preventive Controls
  - Sanitation procedures at food surface contact points
  - Sanitation of utensils and equipment
  - Staff hygiene training
  - Environmental monitoring program (for pathogen controls)
  - Pathogen Testing (applicable to fresh-cut produce)
  - Food allergen control program
  - Recall plan
- Current Good Manufacturing Practices (cGMPs)
- Supplier verification activities

Multiple Inter-related Rules
- Standards for Produce Safety Proposed
- Preventive Controls for Human Food
- Preventive Controls for Food for Animals
- Foreign Supplier Verification Programs (FSVP) for Importers
- Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and Issue Certifications
- Sanitary Transportation of Human and Animal Food
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration

Compliance dates by business size

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Preventive Controls for Microbial Safety

**Key Components of PC Final Rule**

- Establish and implement a food safety system
- PC Rule requires a written food safety plan
  - Hazard Analysis - hazard identification of *known or reasonably foreseeable* biological, chemical, and physical hazards
  - Preventive Controls - sourcing, process, food allergen, sanitation controls, *supply-chain controls*, recall plan
- Oversight and management of preventive controls
  - Verification - Validation - Monitoring

**Supply-Chain Controls Program**

- Risk-based supply chain program for those raw material and other ingredients for which it (*the facility*) has identified a hazard requiring a supply-chain applied control
  - Primary Production Farm
  - Secondary Activities Farm
  - Supplier Verification Plan

**Key Preventive Control Training and Compliance Resource Components**

- Establish a Food Safety Plan
- CGMPs and Prerequisite Programs
- Biological Food Safety Hazards
- Chemical, Physical and Economically Motivated Hazards
- Preliminary Steps in Developing a Food Safety Plan
- Process Preventive Controls
- Allergen Preventive Controls
- Sanitation Preventive Controls
- Supplier Preventive Controls
- Recall Plan
- Verification and Validation Procedures
- Record-keeping Procedures
- More…

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**Verification is Highest Level in CODEX/NACMCF**

1a Verification
- Is the plan the right plan?

1b Verification
- Evidence & Data-based
- Entry point for research
- Audit of process

Monitoring
- Validity of FSP
- Operating within FSP parameters
- Confirm efficacy

2a Validation
- Operating within Validation controls
- Corrective actions are effective

**Traditional Definitions are Not Fully Consistent with Current FSMA Use**

Verification is the first step
Validation leads to Verification and Re-Validation

Codex
NACMCF
FSMA

Codex Alimentarius
National Advisory Committee on Microbiological Criteria for Foods
Food Safety Modernization Act - Preventive Controls Rule

**Definitions as applied in FSMA PC**

- **Validation**
  - establishing and documenting the scientific evidence that food safety hazards are being effectively controlled through preventive means

- **Monitoring**
  - procedures designed to provide a record of assurance that preventive controls are consistently performed

- **Verification**
  - ensure that preventive controls are consistently implemented and are effectively carried out
  - environmental monitoring and product testing are verification activities not monitoring

**White Paper Resource**

*Validation and Verification: A Practical, Industry-driven Framework Developed to Support the Requirements of the Food Safety Modernization Act (FSMA) of 2011*

Food Protection Trends November/December 2014

**FSMA PC Expectations: Testing and Microbial Monitoring**

**FSMA View of Validation: Verification Cycles of Continuous Improvement**

Verify, monitor, validate, and re-validate

- Training and Food Safety Culture
- Corporate Food Safety Policy

Brackett et al. FPT, 2014

tvsuslow@ucdavis.edu
FSMA PC Expectations: Implementation will require Guidance

If the facility is processing ready to eat foods where there is no kill step and supply-chain control risks, like salads, then both environmental and product testing are appropriate.

Depending on a facility-specific hazard identification and analysis, the operation may require product testing of each of the raw ingredients mixed in the salad, and general environmental and food contact surface testing.

SO YOU THINK YOU CAN DISCOVER A “KILL STEP”

IFSH Wash Water Work Group: Validation Framework and Standards

Illinois Institute of Technology
FDA
USDA
CDC
United Fresh
PMA
Center for Produce Safety
UC Davis
U of Guelph
U of Florida
WSU

Earthbound Farms
Taylor Farms
Ready Pac
Dole
Fresh Express
Ecolab
SmartWash
Pulse Instruments
KIVAR Chemical Technology

Potential Sources of Listeria Circulation between Farms and Facilities

IFSH Wash Water Work Group
VALIDATING ANTIMICROBIAL WASHES AS PREVENTIVE CONTROLS FOR FRESH-CUT LEAFY VEGETABLES

Rationale for the IFSH WG

FSMA Section 103

“In General...The...[fresh cut]...facility shall identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated...monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.”

WG Assumption – Critical process controls, critical limits, and validated surrogates are not known and must be standardized
No “kill-step’ for contaminated product is likely in near-term

- Preventive Controls must include
  - Verification of Produce Rule standards and metrics
  - Supply Chain Control Program
  - Must define practical controls of raw material contamination
- Practical validation must focus on prevention of cross-contamination

Why Focus on Preventive Controls of Cross-Contamination?

A Practical Application of the Research

- How likely is sporadic contamination, following a series of “process” hurdles, to result in a foodborne illness “outbreak”?
  - 5 large Iceberg Lettuce fields
    - ~10 acres
    - ~40,000 lbs/acre
  - 50X the product testing background level of 0.00025 CFU/pound
  - Foodborne “outbreak” for this model is defined as 5 or more people.

Adapted by courtesy of J. Brennan - SmartWash Solutions

Current IFSH WG Focus is Limited to HOCl:OCI

- Preventive Controls & Outbreak Mitigation
  - What is the probability that at least 1 lot would result in an outbreak?

Validation System Framework

1. Demonstrate lethality under most challenging operational conditions
   i. Challenge-inoculation using a suitable surrogate
2. Demonstrate efficacy of operational conditions to deliver critical-limit lethality using integrated water quality and C, parameters established for the microbial target
3. Demonstrate that minimum microbial control limits are achieved under challenging critical wash water parameters
4. Current approach focuses on a 3-tier approach

Level 1 – Self-Validation

- Performed in-plant with the actual process equipment under most challenging operational conditions.
  - Standardized amount of product is inoculated with a standardized amount of a validated surrogate
  - Safely used in the facility
  - No cross-reactivity to pathogen tests
  - Comparable sensitivity to sanitizer/antimicrobial under the operational conditions
  - Dose and function can be accurately monitored during validation
  - Performance is measured by the level of cross-contamination from inoculated to un-inoculated product
Unresolved Obstacles to Validation

- Inoculation Studies (Level 1)
  - How do you select a surrogate?
    - Scientific relevance vs. commercial practicality
  - What is a reasonable inoculation level?
    - How much to inoculate?
    - What level of inoculum?
  - How do you inoculate?
    - Uniformity of population on product
    - Acclimation period – attachment; reduced metabolism
  - What constitutes a most challenging operation?
    - Range and extent of operations
  - What is a statistically valid sampling scheme?
    - Process variables
    - Microbial detection/recovery performance – What is your ‘zero’?

Unresolved Obstacles to Hybrid Validation: Verification

- Process Control Studies (Level 2)
  - What constitutes a most challenging operation?
    - Range and extent of operations
  - What is a statistically valid sampling scheme?
    - Process variables
    - Microbial performance
  - How do you establish your control parameters?
    - Variable process conditions
    - Lower and Upper limits – function of precision vs. accuracy
    - Variability of raw materials – must replicate over time

Level 2 – Hybrid External Validation & In-House Verification

- Fundamental validation performed on sanitizer efficacy
- In-plant verification with actual process equipment under most challenging case operational conditions.
  - Sensors or real-time measurement of validated dose and conditions
    - Knowledge of process location(s) where dose may be at its lowest when operating under most challenging case conditions.
  - Performance is measured by verification that the minimum level of antimicrobial necessary to prevent cross-contamination is maintained at all times and at all points of water contact to conform with the related independent scientific study that established the process conditions.

Next Steps: Define the Typical Process Capability

- Define the typical Process Capability

Process Capabilities Determine Risk Potential

- Lower Limit – deviation beyond this limit will likely results in outbreak if contamination is present
- Upper Limit: generally applies to corrosion, product quality impacts, worker safety/comfort

Minimally, Wash Lines “Process Capabilities” are affected by:

- Wash Line equipment – flumes, jacuzzi, single tanks, double tanks, etc...
- Water Management – single-use, re-circulation/conditioning, fresh water exchange
- Poundage – rates
- Products – shred, spring mixes, carrots, etc...
- Monitoring and Control systems –
Even in well managed wash systems, pH control can fluctuate outside of the desired control range for minutes at a time.

Validation must account for the dynamic nature of the wash system process design and controls and its variable water chemistry.

Courtesy: J. Brennan - SmartWash Solutions

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**Level 3 – Process Authority**

- Validation of antimicrobial monitoring rather than direct prevention of cross-contamination.
- External validation of critical limits for target pathogen control
- Validation of sensors function, position, calibration
- Establishment of “safe harbor” conditions
- No longer accepted as practical for fresh-cut

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**Thank you for your attention**

*Eat More Produce*

The harder we work, the further away from a solution we seem to always be.