

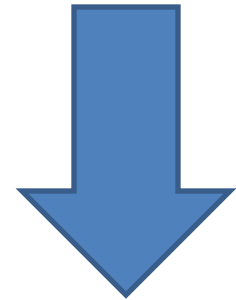


Microbiological Approaches for the Food Safety Modernization Act

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What is FSMA?

- Signed into law in 2011
- Most comprehensive overhaul of the food safety system since 1938
- Focus on **Prevention** and **Risk based Systems** approach
- Its anticipated that close to **45** documents will be released by the FDA in support of FSMA



**FDA FOOD SAFETY
MODERNIZATION ACT**

Seven Proposed Rules

- Preventive Controls for Human Food ✓
- Preventive Controls for Animal Food
- Produce Safety
- Foreign Supplier Verification Program
- 3rd Party Accreditation
- Food Defense
- Sanitary Transportation

✓ Cover Today

Proposed Regulations Dates

To date 7 proposed rules have been published

Proposed Rule	Final Rules Release	Compliance Dates
Preventive Controls for Human Food	Aug 30 2015	Aug 30 2016
Preventive Controls for Animal Food	Aug 30 2015	Aug 30 2016
Foreign Supplier Verification Program	Oct 31 2015	Oct 31 2016
Intentional Adulteration	May 31 2016	May 21 2017
Sanitary Transportation for Food	Jul 31 2016	Jul 31 2017



**Looks OK
to me.**

Pat Racimura 3/11/09

Preventive Controls for Human Food

- Establishment of Food Safety Plans (Not just HACCP)
 - Hazard Analysis
 - Preventive Controls
 - Monitoring
 - Corrective Actions
 - Validation
 - Verification
- Records and Retention
- Qualified Individuals
- Recall
- Testing (Product and Environmental)
- Supplier Controls

Validate

Verify

Validation and Verification

Validate (Scientific Proof)

1. to confirm or corroborate
2. to give legal force or official confirmation to; declare legally valid

Verify (Audit Process)

1. to prove the truth of, as by evidence or testimony; confirm; substantiate

Verification Challenges

- How extensive will requirements be for verification activities?
- EMP good enough?
- Finished Product testing?



Legacy Processes

- Extruded products
 - Cereals
 - Snacks
- Baked products
 - Cookies
 - Breads
- Hot Fill
- Cold formed bars



Verification Challenges

- Low Moisture Foods (cereal)
 - Validation studies confirming kill step
 - Verification to include:
 - Option 1: A good environmental monitoring plan
 - Option 2: Monitoring records for moisture, extrusion temp, oven temperature (zones), belt speed, etc.



Verification Challenges

- Cold formed bars
 - Verification to include:
 - Option 1: Ingredient testing (micro) + environmental monitoring
 - Option 2: Finished product testing



Verification Challenges

- Snacks (seasonings applied post kill step)
 - Verification to include:
 - Option 1: Ingredient inactivation (supplier) + ingredient testing (micro)
 - Option 2: Finished product testing



How to Create a Successful Verification Plan

FSMA Plant Survey

- Hazard analysis
- Allergens
- Sanitation
- Recall procedures
- cGMP's
- Corrective actions
- Preventive actions
- Supplier programs
- Internal audits
- Verification activities
- Record keeping and
- Training

How to Create a Successful Verification Plan

- 3rd Party Audits
 - GFSI
 - BRC
 - SQF
 - FSSC 22000
 - AIBI
 - FSMA Compliance
 - Consolidated Standard
 - Suppliers
 - Global Gap



FSSC 22000 Comparison

	FSSC 22000	FDA Preventive Controls	FDA GMPs
Overarching policy statement	Yes (Exceeds)	No	No
Written Plan	Yes (Comparable)	Yes	
Experienced individual	Yes	Yes	No
Trained Staff	Yes (Exceeds)	No	Yes
Prerequisite programs	Yes (Exceeds)	No	Yes
Raw material assurance	Yes (Exceeds)	No	No
Supplier Verification	Yes (Exceeds)	No pending comment	No
Allergen Management	Yes (Comparable)	Yes	Yes
Validation of Controls	Yes (Comparable)	Yes	No
Finished product testing	No	No pending comment	No
Sanitation Control	Yes (Exceeds)	Yes	Yes
Environmental monitoring	No	No Pending comment	No
Corrective Actions	Yes (Comparable)	Yes	No
Traceability	Yes (Comparable)	No	No
Recall	Yes (Comparable)	Yes	No
Record retention	Yes (Different)	Yes	No
Food defense	Yes (Exceeds)	No	No
Internal Audit	Yes (Exceeds)	No	No

How to Create a Successful Verification Plan

Critical Factors Form

- Aseptic
- Low Acid
- Juice
- Low moisture foods
- High acid beverages
 - ESL
 - Aseptic



Validation / Verification Do's

- Separate verification and validation tasks.
- Validation = Scientific proof
- Verification = audit process
- Used science based information to support the initial validation.
- Use lessons from near misses to adjust the FSP.
- Management must be involved in verification

Validation / Verification Don'ts

- Confuse verification with routine monitoring.
- Rely on literature only to prove controls are valid.
- Conduct audits and then not review the results.
- Perform corrective actions without determining if the FSP must be adjusted.
- Reanalysis is done every 3 years or sooner.

Don't forget to look outside the CCP

- Most recalls are caused by hazards which are not CCP's
- Include prerequisites in your Food Safety Plan.

Examples

- Sanitation
- Spoilage
- Supplier Issues
- Allergens
- Foreign material



Closing Remarks

- Records – Absence of records means it didn't happen.
- Validate legacy processes
 - Don't make assumptions on how the FDA will interpret the effectiveness
- Don't forget to look outside the CCP
 - Most recalls are caused by hazards which are not CCP's
 - Include prerequisites in your Food Safety Plan.
- GFSI Certification scheme