FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

FSMA: Impact on Food Manufacturers and the Path Forward

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Agenda

- Key parts to pay attention to in FSMA to be in compliance
- Understanding what FSMA means to you
- Combining HACCP and HARPC programs
- Best practice methods to meet these requirements
- Unresolved Issues / Challenges

Setting Up For Success

Existing HACCP Programs	*Internal/External Audit Programs*	*Existing Cross Functional Collaboration*	*3rd Party Certification Journey (e.g. FSSC 22K vs. FSMA)*

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Key parts to pay attention to in FSMA to be in compliance

Food Companies Need To:

- Know their Rights
- Adapt to these changes
- Be prepared

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Seven Pillars of FSMA - http://www.fda.gov/fsma

PCHF	*PCAF*	*Produce Safety*	*FSVP*	*3rd Party Certification*	*Food Defense*	*Sanitary Transport*

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Compliance dates (large businesses)

- **CGMPs and PCs for human food**
  - GMPs and preventive controls: **9/19/16**
  - Supply-chain program: **3/17/17**
- **CGMPs and PCs for animal food**
  - GMPs: **9/19/16**
  - Preventive controls: **9/18/17**
  - Supply-chain program: **9/18/17**
- **Sanitary Transportation**: **4/6/17**
- **Produce safety**: **1/28/18** (most activities)
- **FSVP**: **5/27/17**
- **Intentional adulteration**: **7/28/19**

Preventive Controls (21 CFR 117.135; 507.34)

Purpose: To provide assurance that hazards will be significantly minimized or prevented

– Measures include:
  - •Process controls
  - •Food allergen controls
  - •Sanitation controls
  - •Supply-chain controls
  - •Recall plan

- In some cases, an aspect of GMP compliance may serve as a preventive control for a hazard. Where this is the case, the GMP/PRP becomes part of the HARPC plan, and associated requirements such as monitoring, corrective actions, etc. attach to implementation of that requirement.

Understanding what FSMA means to you

Some New Items to highlight:

- Verbiage/Language such as Significant Hazard to Hazard requiring Preventive Control (HrPC)
- Expanded Hazard Analysis:
  - Further justify all decisions in writing such as Likelihood, Severity, Acceptable level, etc.
- If it was not documented, it did not happen.
- About accountability
- Covers the entire food chain internationally

Introduction to a Food Safety Plan (HARPC)

Requires a written Food Safety Plan containing:

- Written Hazard Analysis
- Written and validated preventive controls
- Written corrective action procedures
- Written verification procedures

Hazard Analysis & Risk-based Preventive Controls

- Written supplier approval and verification program
- Written recall plan

Key Elements of the Food Safety Plan

Supplier Approval and Verification Program

- To approve suppliers and determine appropriate supplier verification activities consider:
  - Risk posed by the food (hazard analysis)
  - Entities controlling hazards or verifying control
  - Supplier characteristics (procedures, processes, and practices; FDA compliance; food safety history)
- Determine appropriate verification activities (and frequency) based on food and supplier evaluation
  - Activities may include: onsite auditing; sampling and testing; review of supplier records; other appropriate measures
- Written procedures to ensure food is obtained from approved suppliers
- May use unapproved suppliers on temporary basis when subject food to verification
- Written procedures for verification activities
- Annual onsite auditing is the default approach when a food has a reasonable probability that exposure to the hazard will result in Serious Adverse Health Consequences or Death to Humans (SAHCODH)

Validated Recall Plan

- A written recall plan (for food with a hazard that is reasonably likely to occur based on possible failure of a preventive control and its respective corrective action).
- It must include:
  - ✓ Steps and methods to be used to notify the direct recipients of the food about the recall
  - ✓ Steps and methods to notify the public about any hazard
  - ✓ Method to verify that the recall is carried out
  - ✓ Procedures to appropriately dispose of the recalled food in the food facility and by all recipients
- Validate this through Mock Recall Drills

Comparison of HARPC and HACCP

HACCP

1. Conduct Hazard Analysis
2. Identify CCPs
3. Establish Critical Limits
4. Establish Monitoring Actions
5. Establish corrective Actions
6. Establish Verification Procedures
7. Establish a Record-Keeping System

HARPC

- Written Hazard Analysis
- Written and validated preventive controls
- Written corrective action procedures
- Written verification procedures
- Written supplier approval and verification program
- Written recall plan

- **Written by a "qualified" individual**
- **Updated every 3 years or whenever there is a change**
- **Historical records to demonstrate implementation and continued usage**

Hazard Analysis (HA) and Preventive Controls (PC)

- **HA**
  - Identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held to determine if they require a control
  - Biological, chemical (including radiological), and physical hazards
  - Naturally occurring, unintentionally introduced, or intentionally introduced for economic gain (ex. Olive oil, milk ingredients, etc.)
- **PC**
  - Identify and implement PC to provide assurance that the hazard is significantly minimized or prevented to avoid adulteration. May be CCPs or Other Controls as needed (hygiene training and cGMPs)
  - May be Process Controls including the nature of the process control & the maximum or minimum value to which the parameter should be controlled
  - May be Allergen Controls: protection against cross contact contamination & Labeling
  - May be Sanitation Controls for microbial and allergen risks, including transportation
  - May be Supply Chain Controls
  - Must include a Recall Plan
  - Must be written

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Best practice methods to meet these requirements

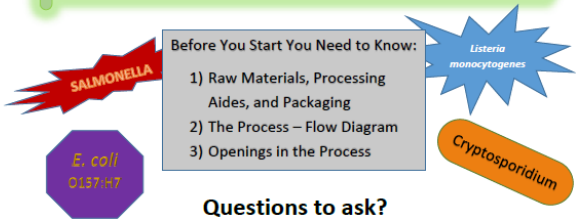
- Standardized Forms
- Guides and Tools
- Practice Storytelling
- Effective training at all levels
- Train employees on what to do if an investigator shows up
- Top Management must be involved and understand all aspects
- Adding a FSMA module to your next audit

Hazard Analysis Is, Arguably, The Most Important Component of the PC Rules

WHAT TO THINK ABOUT WHEN IDENTIFYING MICROBIOLOGICAL HAZARDS

Hazard – Will cause illness or death when product is consumed

Microbiological - Pathogenic Bacteria or its toxin, Parasites, Viruses



Before You Start You Need to Know:

1) Raw Materials, Processing Aides, and Packaging
2) The Process – Flow Diagram
3) Openings in the Process

Questions to ask?

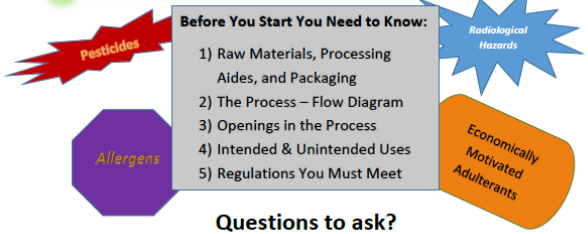
1. Are there pathogenic Microorganisms known to be associated with any of the Raw Materials, Processing Aides, or Packaging?
2. Are there any Raw Materials, Processing Aides, or Packaging capable of supporting growth of pathogenic Microorganisms?
3. Are there any Raw Materials, Processing Aides, or Packaging susceptible to pathogenic Microorganisms due to mishandling or contamination?
4. Are there any situations that may allow pathogens to multiply?
5. Are there any situations where pathogens may enter the product stream?
6. Are there any situations where microbiological hazards may be created or made worse by mishandling?
7. At what point or points may the identified pathogen enter the process?
8. What is the likelihood?
9. Are there controls points downstream to mitigate the hazard?

List all identified Microbiological Hazards in the Hazard Analysis at the point where it enters the process.

WHAT TO THINK ABOUT WHEN IDENTIFYING CHEMICAL HAZARDS

Hazard – Will cause illness or death when product is consumed

Chemicals – Toxic substances that may render a food unsafe



Before You Start You Need to Know:

1) Raw Materials, Processing Aides, and Packaging
2) The Process – Flow Diagram
3) Openings in the Process
4) Intended & Unintended Uses
5) Regulations You Must Meet

Questions to ask?

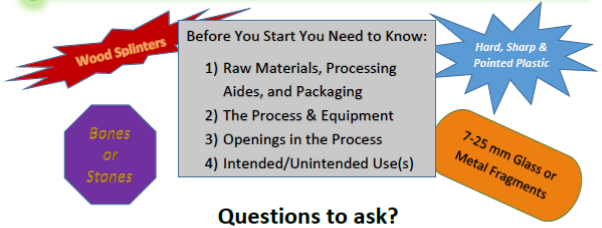
1. Are there hazardous chemicals known to be associated with any of the Raw Materials (e.g. mycotoxins, pesticides, etc.), Processing Aides (e.g. allergens, sulfites, etc.), or Packaging (e.g. approved for intended use)?
2. Are all of the food additive ingredients approved for their intended uses?
3. Would any chemical pose a significant safety risk if used inappropriately?
4. Are there labeling requirements associated with any food additive (e.g. sulfites, color additives, priority allergens)?
5. Are food contact surfaces free of toxic substances (e.g. sanitation compounds)?
6. Are there any situations where chemical hazards may be created or made worse by mishandling (e.g. misuse of shop, non-food grade, cleaning/sanitizing, pest control chemicals, adding too much)?
7. Are all chemicals labeled, stored and secured appropriately?
8. What is the likelihood of exposure?
9. Are there controls points downstream to mitigate the hazard?

List all identified Chemical Hazards in the Hazard Analysis at the point where it enters the process.

WHAT TO THINK ABOUT WHEN IDENTIFYING PHYSICAL HAZARDS

Hazard – Will cause illness or injury when product is consumed

Physical – Foreign objects that are capable of injury: size & shape matter



Before You Start You Need to Know:

1) Raw Materials, Processing Aides, and Packaging
2) The Process & Equipment
3) Openings in the Process
4) Intended/Unintended Use(s)

Questions to ask?

1. Are there hard or sharp foreign objects capable of causing injury or choking associated with any of the Raw Materials, Processing Aides, or Packaging?
2. Are there environmental sources of physical hazards in and around product storage and processing areas (e.g. unprotected light fixtures, wood pallets, loose nuts, bolts, and/or screws, corroded metal fixtures, employees, implements, etc.)?
3. Is any equipment capable of generating physical hazards (e.g. splinters from wood materials, metal fragments from metal-to-metal operations, glass fragments from unprotected thermometers and/or guages, etc.)?
4. Are potential physical hazards such as glass, bones, tools, PPE, etc. adequately addressed in prerequisite programs (PRPs) to prevent or decrease contamination?
5. What is the likelihood of exposure in the finished product?
6. Are there control points downstream to mitigate the hazard (e.g. screens, metal detectors, etc.)?

List all identified Physical Hazards in the Hazard Analysis at the point where it enters the process. Don't forget to follow your definitions of Risk when assessing.

Use of Qualified Individuals

- Must use a qualified individual to perform all required tasks
  - *Must have education, training, or experience (or combination thereof) necessary to perform the activity*
  - Must be able to read and understand the language of any records reviewed in performing an activity
- FDA can reject a Food Safety Plan based on the qualification of the Author(s)
  - Rejected plan is an actionable offense
    - ***Fines and imprisonment of Food Company officials!!***

Standardizing Documentation Will be Very Important

Supply Chain Documentation

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PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL (PCQI)/QUALIFIED INDIVIDUAL (QI)

Employee information			
Name	Click here to enter text.	Department	Click here to enter text.
Current Position	Click here to enter text.	Cargill Experience	Choose an item.

Food Safety Experience (please provide a detailed description including years of experience and current food safety duties)

Click here to enter text.

Qualified Individual Questionnaire	
I have an education in food science or other science-related discipline (e.g. biology, chemistry, toxicology, etc.)	Choose an item.
I have knowledge and experience in developing and carrying out a food safety plan appropriate for this manufacturing facility	Choose an item.
I have had experience and/or training in applying/implementing Cargill-specific food safety programs which are based on globally-recognized standards	Choose an item.
I have had experience and/or training in applying HACCP- and HARPC-based principles to a food safety plan	Choose an item.
I have experience and/or training in hazard identification and update, as appropriate, our facility's food safety plan to properly mitigate these hazards	Choose an item.
I have experience and training in developing validation, verification, and monitoring programs to mitigate identified hazards within our facility	Choose an item.
I have experience and training in implementing corrective actions, as appropriate, in a timely manner to prevent food safety events	Choose an item.

Specific Education, Training, and Certifications

Click here to enter text.

Record Keeping Is, by Far, the Biggest Challenge

Supply Chain Management

- ***Preventive Control (PC) Communication***
- Who's ultimately ***responsible?***

Hazard Analysis

- ***When does a hazard need a Preventive Control?***
- ***Programs vs. Parameters***
- "Known or ***reasonably*** foreseeable"

Food Safety Activities

- ***Monitoring***
- ***Verification***
- ***Validation***
- ***SOPs***
- ***SSOPs***
- ***Environmental Monitoring Programs***

If you didn't document it, it didn't happen
How you documented it - is exactly how it happened

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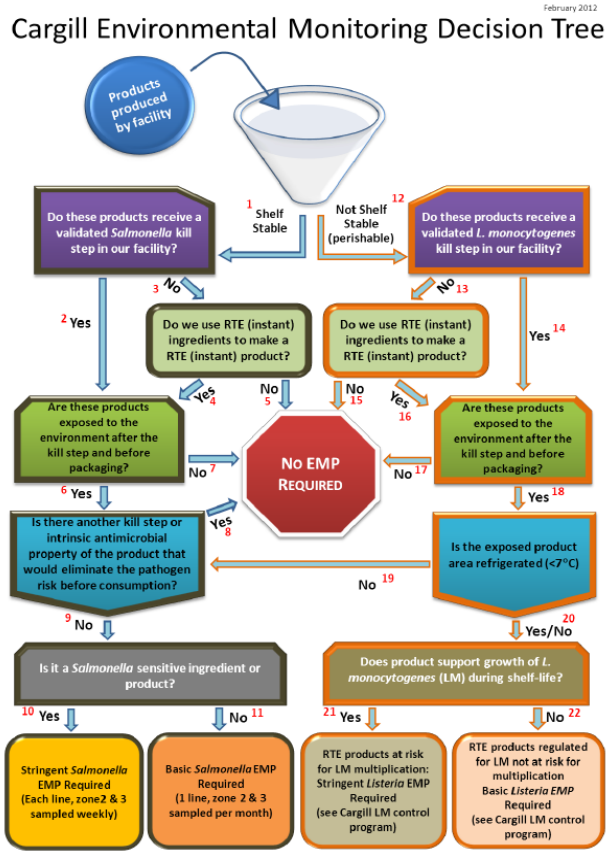
Providing Direction is Essential for FSMA Compliance

cGMPs

- Gap assessments/closures
- Regulatory non-compliances?
- Sanitation deviations?

Docs/Records

- Prepared, easily-found, standardized
- "Story telling"



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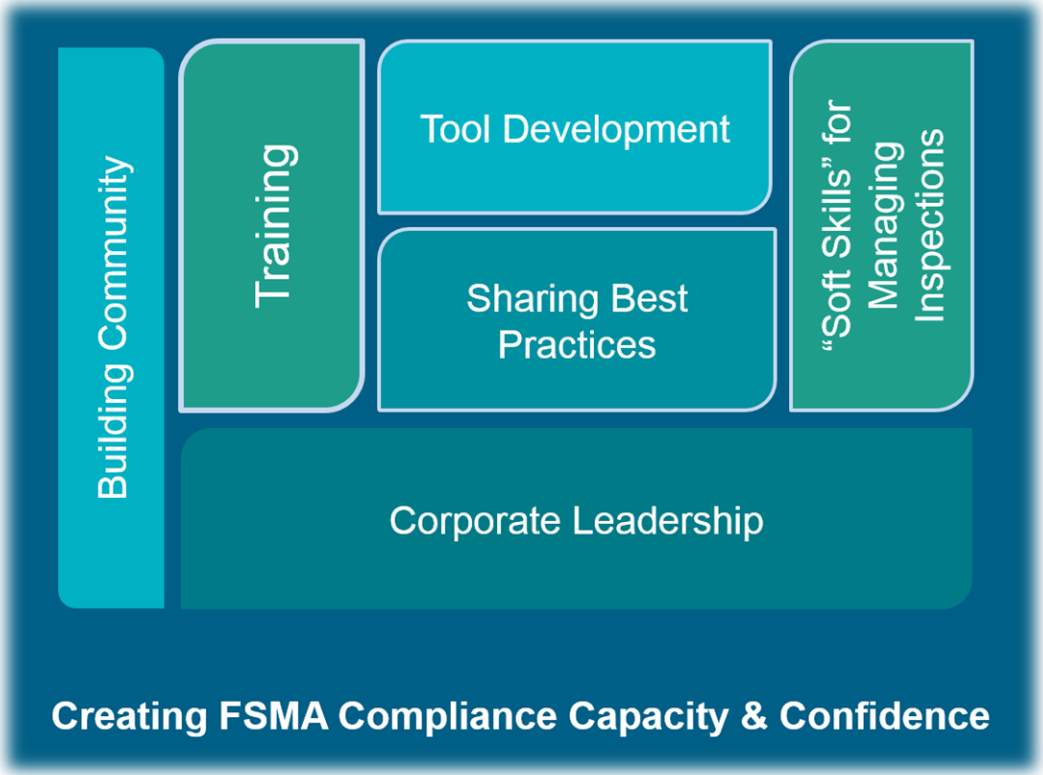
Tools for Success – Continuous Improvement Principles

Cargill is Providing Internal Guidance, Globally, Via Guidance Documents, Tools, and FSMA-Readiness Audits



Internal FSMA-Readiness Audits Provide Great Opportunities for Learning and Preparation

Gaps:

Where Are There Opportunities?

Document/Record Keeping:

What do I need?

HACCP to HARPC:

Are you Speaking the Right Language?

Qualifications:

Is Everyone Qualified to Carry Out Their Job?

Hazards and Preventive Controls:

Have you ID'd ***All PCs*** and ***Are They Effective?***

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Unresolved Issues / Challenges

Inspectional Challenges –

- How will investigators/FDA HQ approach review of Hazard Analyses and HACCP Programs
  - **Be sure to review FDA's PC Guidance – Appendix 1 & 3 Hazards and Inactivation**
  - ***Review FDA Warning Letters to level set with current FDA Practice***
- Initial PC inspections that have brought "swabbing" teams result in 7-10 FDA officials in a facility at one time – difficult to manage for any facility
- FDA "Swabathons" – building the WGS databases, FDA has over 500 facility target on environmental swabbing, as practical matter becoming routine
- **"Educate while regulate"** – some positive signs so far

Unresolved Issues / Challenges

- FDA definition for Ready to Eat (RTE) – “reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.”
  - So basically, everything
  - Combined with heightened concerns around *Listeria monocytogenes* – particularly in frozen vegetables and ice cream, at the moment, there is no clear line between Not RTE and RTE
- Allergens – in context of Hazard Analysis and cGMPs; risk assessment practice at FDA

Unresolved Issues / Challenges

Notifications and Assurances

- ***21 CFR 117.136 - Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.***

- ***Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food*** is "not processed to ***control [***identified hazard]"; ***and***

- ***Annually obtain from your customer written assurance, subject to the requirements of117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.***

In Summary

- Know your Rights & Obligations
- Adapt to these changes
- Be prepared as things happen when you are not prepared

Must be diligent at corrective actions and justifying your decisions - all must be documented.

Are the correct people involved in daily decisions?

Do not be afraid to challenge the FDA investigator or contact the FDA when the rule is not being followed during a visit.

Guidance Documents are nonbinding and in draft form, BUT will be inspected against the guidance from the day it is released. It can stay in draft form forever and comments are accepted at any time.

Putting adulterated food in commerce puts you in a criminal situation

Thank you! Questions?

150 years of helping the world *thrive*