HACCP Capacity Building in the Caribbean

The Online Follow-up Workshop

11-12 July, 2016
St Lucia

www.gmaonline.org
Who We Are

The GMA Science and Education Foundation

- Non-profit organization established in 2007
- Affiliated with the Grocery Manufacturers Association

Mission:
- Training – HACCP, BPCS, FSMA, domestic and international
- Education – food safety for middle school children
- Research – food processing
Grocery Manufacturers Association

- A trade association that represents world’s leading food, beverage and consumer products companies
- Promotes sound public policy
- Champions initiatives for productivity and growth
- Helps to protect safety and security of the food supply through scientific excellence
Basic and Advanced HACCP Workshops are accredited by the International HACCP Alliance.

The International HACCP Alliance uses our manual for training.

GMA is the sole provider of HACCP Train-the-Trainer workshops for the International HACCP Alliance.
Rules of the Course

- Informal – Few rules
  - Everyone should participate
- Agenda
- Logistics
- Cell phones
- Breaks & Lunch
- Sign in Sheet
Course Materials

❖ Books & Notebooks
  ○ HACCP Manual
  ○ Notebook
    • Working group instructions and forms
    • Supplemental information
    • Presentation slides
Objectives of the Course

- Review Key Points of HACCP Principles
  - Hazard analysis and CCPs
  - CLs, monitoring and CAs
  - Verification and Record-keeping
- Learn to apply the principles – work through a “mock” HACCP plan
  - NOT to develop a HACCP plan
- Discuss current regulatory situation
Who Are You?

- Name?
- Organization?
- Questions about HACCP based on the online course and/or experience
Agenda - HACCP training

- Hazard Analysis & CCPs
- Working Group Exercise – Task A
- Critical Limits, Monitoring & Corrective Actions
- Working Group Exercise – Task B
- Verification, Validation & Recordkeeping
- Working Group Exercise – Task C
- Regulations
What do you want to learn?
Initial Tasks in Developing HACCP Plans
Gain Management Support

Upper management must make a commitment to support HACCP – both financially and in spirit.
Implement Well-Designed Prerequisite Programs First
Five Initial Tasks
1. Assemble HACCP Team

- HACCP coordinator
- Multi-disciplinary unit
- Consultants (if necessary)
- Ad hoc groups
2. Describe the Food and Its Distribution

- Common name and ingredients
- Nature of the product and shelf life
- General description of the process
- Type of storage and distribution
- Parameters related to food safety: pH, $a_w$, packaging, preservatives, etc.
3. Describe the Intended Use & Consumers

- Intended use, e.g., retail, foodservice, further manufacturing
- Potential for mishandling
- Preparation procedures, e.g., heat-and-serve, Ready-to-eat (RTE), reconstitute
- Intended for at-risk individuals, e.g., infants, immunocompromised, elderly
4. Develop a Flow Diagram

- A simple (block) flow diagram showing the locations where specific ingredients are added, and where storage, preparation and processing steps occur.
Example: Apple Juice in Glass Bottle, Shelf Stable

- Receive Apple Juice Concentrate
- Blend Tank
- Hold Tank
- Pasteurize
- Hot Fill
- Close
- Invert
- Cool
- Code/Label
- Palletize
- Storage/Ship

- Receive and Store Packaging Materials
- Bottle Inversion/Air Cleaning
- Caps

Water
Description of Product and Process

- The block flow diagram should be supplemented with a description of the product and process flow.

- May include information associated with ingredient storage, preparation, equipment, processing, packaging, storage and distribution, etc.
FSIS requires a flow chart as part of the hazard analysis for meat and poultry products

- Include designation of CCP(s) on the flow chart
The flow diagram should be verified for accuracy and completeness by an on-site inspection of the facility, equipment and operations.
Summary – Initial Tasks

1. Assemble HACCP Team
2. Describe the Food and Its Distribution
3. Identify Intended Use and Consumers
4. Develop a Flow Diagram
5. Verify the Flow Diagram
Any Questions?
Hazard Analysis and CCPs
HACCP PRINCIPLE 1

Conduct a Hazard Analysis
Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. (Codex, 2003)

E. coli O157:H7 Image from CDC
Hazard Analysis

The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.
Hazard reasonably likely to occur:

- One for which a prudent processor would establish controls
  - Experience
  - Illness data - World Health Organization (WHO), US Food and Drug Administration (FDA)
  - Scientific reports
  - Consumer comments/trends

- Reasonable possibility hazard will occur in the absence of the controls
If the hazard analysis is not conducted correctly:

- Hazards warranting control within the Food Safety Plan will not be identified
- The Plan will not be effective in protecting consumers, regardless of how well it is followed
Evaluation for Hazards to Include:

1. Biological contamination
2. Chemical contamination
3. Physical hazards
Hazard Analysis

Two Stages:

1. Hazard identification
   - List of potential hazards (one step)

2. Hazard evaluation
   - Based on severity and likelihood of occurrence (three steps)
Example - evaluation for almonds in chocolates

Stage 1: hazard identification
Determine potential hazards associated with product

B - Salmonella in incoming raw almonds
Stage 2: Hazard evaluation

Step (1): Assess severity of health consequences if potential hazard is not properly controlled

*Salmonella* in raw almonds may result in salmonellosis, an infection with moderate to severe consequences.
Stage 2: Hazard evaluation

Step (2): Determine likely occurrence of potential hazard.

Raw almonds have been known to contain Salmonella.
Stage 2: Hazard evaluation

Step (3): Decide if this potential hazard is to be addressed in the HACCP plan.

Yes;
If *Salmonella* from raw almonds is not properly controlled, consuming this product presents a significant risk.
Example – Blending step

Stage 1: hazard identification
Determine potential hazards associated with product

C- Residual sanitizers in the blend tank
Stage 2: Hazard evaluation

Step (1): Assess severity of health consequences if potential hazard is not properly controlled

Sanitizer residues would be diluted with product, therefore unlikely to have severe public health impact
Stage 2: Hazard evaluation

Step (2): Determine likely occurrence of potential hazard.

Residual sanitizers are Not Reasonably Likely to Occur due to SSOP XXX.1, which includes a pH check of the final rinse.
Stage 2: Hazard evaluation

Step (3): Decide if this potential hazard is to be addressed in the HACCP plan.

No;
Residual sanitizers not likely to occur and levels unlikely to pose health risk.
Justifications for Not Including Potential Hazard in Food Safety Plan

Not Reasonably Likely to Occur…

- Even in absence of control
- At levels likely to cause illness or injury
- In finished product due to system design
- Due to the presence of specific SOP or prerequisite program
Hazard Analysis Hints

- Do not determine hazards based on controls the operation has in place.
- Be specific in listing the potential hazard
Be specific about the hazard!

- Potential hazard: foreign objects
- Potential hazard: glass, metal, wood

Different hazards require different controls
Be specific about the hazard!

- **Potential hazard:**
  - Bacteria

- **Potential hazard:**
  - Enteric pathogens such as *Salmonella* and *E. coli* O157:H7
  - Pathogenic sporeformers such as *C. botulinum*
  - Growth of pathogens such as *C. botulinum*
  - Recontamination with *L. monocytogenes*

**Different hazards require different controls**
Thorough hazard analysis vital to effective HACCP Plan.

Identify hazards using two-stage process (hazard identification and hazard evaluation).

Evaluation of hazards based on likelihood of occurrence and severity.

Identify control measures for hazards to be addressed in the HACCP plan.
HACCP PRINCIPLE 2

Determine the Critical Control Points
**Critical Control Point (CCP)**

A step at which control can be applied and is **essential** to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

(CODEX, 2003)
Important considerations

- Use the output of the hazard analysis – do not base CCPs on where you have controls!
- A subsequent step in the process may be more effective for controlling a hazard.
## Prerequisite Program or HACCP?

<table>
<thead>
<tr>
<th>Prerequisite Programs</th>
<th>HACCP Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deal <em>indirectly</em> with food safety issues</td>
<td>Deal <em>solely</em> with food safety issues</td>
</tr>
<tr>
<td>Cross multiple product lines</td>
<td>Specific to product &amp; line</td>
</tr>
<tr>
<td>Failures seldom result in food safety hazards</td>
<td>Deviations must be considered potential food safety hazards</td>
</tr>
</tbody>
</table>
Hazards CANNOT be **CONTROLLED** by prerequisite programs

- Successful, thorough, & comprehensive PPs can create situations where potential hazards are not reasonably likely to occur (NRLTO).
- When doing the hazard analysis, all concerns are considered “potential” hazards – some become hazards that need to be controlled with CCPs, some become NRLTO due to PPs.
How many CCPs should we have?
It depends on...

- Hazard analysis
  - type of product
  - ingredients
  - processing methods
  - existing prerequisite programs

- Regulatory concerns or issues
Critical Control Points

Any Questions?
<table>
<thead>
<tr>
<th>Hazard Analysis Stage</th>
<th>Frozen cooked beef patties produced in a manufacturing establishment</th>
<th>Product containing eggs prepared for foodservice</th>
<th>Commercial frozen pre-cooked, boned chicken for further processing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage 1</strong> &lt;br&gt; <strong>Hazard Identification</strong></td>
<td>Determine potential hazards associated with product.</td>
<td>Enteric pathogens e.g., <em>E. coli</em> O157:H7 and <em>Salmonella</em></td>
<td><em>Staphylococcus aureus</em> enterotoxin</td>
</tr>
<tr>
<td><strong>Stage 2</strong> &lt;br&gt; <strong>Hazard Evaluation</strong></td>
<td>Assess severity of health consequences if potential hazard is not properly controlled.</td>
<td>Epidemiological evidence indicates these pathogens cause severe health effects, including death among children and the elderly. Undercooked beef patties have been linked to disease from these pathogens.</td>
<td>Salmonellosis is a foodborne infection causing a moderate to severe illness that can be caused by ingestion of only a few cells of <em>Salmonella</em>. Certain strains of <em>S. aureus</em> produce an enterotoxin, which can cause a moderate foodborne illness.</td>
</tr>
<tr>
<td></td>
<td>Likely occurrence of <em>E. coli</em> O157:H7 is low to remote while the likelihood of salmonellae is moderate in raw beef trimmings.</td>
<td>Product is made with liquid eggs, which have been associated with outbreaks of salmonellosis. Recent problems with <em>Salmonella</em> in eggs. Probability of <em>Salmonella</em> in raw eggs cannot be ruled out. If not effectively controlled, some consumers are likely to be exposed to <em>Salmonella</em> from this food.</td>
<td>Contamination with <em>S. aureus</em> due to human handling Enterotoxin capable of causing illness will only occur if <em>S. aureus</em> multiplies to about 1X10⁶/g. Operating procedures and subsequent freezing are unlikely to permit growth of <em>S. aureus</em>, thus potential for toxin formation is very low.</td>
</tr>
<tr>
<td></td>
<td>Using information above, determine if this potential hazard is to be addressed in the HACCP plan</td>
<td>The food safety team decides that enteric pathogens are hazards for this product</td>
<td>Food safety team determines the potential for enterotoxin formation is very low due to normal good operating practices. While still desirable to keep the number of <em>S. aureus</em> organisms low, this does not require control in the HACCP plan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Food safety team determines that uninterrupted control is needed to prevent an unacceptable health risk.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Hazards must be addressed in the HACCP plan.</strong></td>
<td><strong>Hazard must be addressed in the HACCP plan.</strong></td>
</tr>
</tbody>
</table>
Critical Limits, Monitoring & Corrective Actions

HACCP Principles 3, 4 & 5
Establish
Critical Limits (CLs)

HACCP PRINCIPLE 3
Critical Limit

The maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. (NACMCF, 1997)
Critical Limit
Codex Definition

“A criterion which separates acceptability from unacceptability”
CL parameters

❖ Measurable
  o Temperature
  o pH
  o A maximum or minimum value (not an average)

❖ Observable
  o “on and functioning”
  o “in place and intact”
Setting Critical Limits

First, determine the food safety criterion that must be met at the CCP to control the hazard, for example:

- Prevention of growth of *C. botulinum*.
- Destruction of vegetative cells of pathogens.
- Absence of metal pieces that could cause injury.
Setting Critical Limits

- Base on science - publications
- May require consultation with experts
- May require research
- May be established by regulatory standards and guidelines – e.g., action levels, performance standards
Time and temperature used for pasteurization of certain juices (Example)

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>min. 72ºC</td>
<td>min. 3 sec</td>
</tr>
</tbody>
</table>

Parameters obtained from scientific literature or in-house studies
Flow rate and temperature used for pasteurization of juices
(Example)

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Flow rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>min. 72ºC</td>
<td>max. 42 L/min</td>
</tr>
</tbody>
</table>

Obtain parameters from scientific literature (time/temp) and in-house studies (flow rate to deliver appropriate time)
Examples of Critical Limits

**GOAL:** Achieving an Internal Temperature of 67°C for 41s in Meat Patties

- **Product related** - Internal temperature of product $\geq 67^\circ C$ for $\geq 41$ seconds.

  or

- **Process parameter related** - Oven temperature $\geq 150^\circ C$, belt speed $< 2.5$ m/min, initial temperature $\geq 0^\circ C$, and patty thickness $< 15$ mm.
Be Practical

- Absence of metal

versus

- Metal detector on and properly functioning
HACCP PRINCIPLE 4

Establishing Monitoring Procedures
Monitor

⚠️ The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. (Codex, 2003)
Monitoring

- **What** - CL parameter
- **How** – measurements/observations
- **When (frequency)** – continuous or periodically
- **Who** – trained personnel
Considerations for periodic monitoring

- Interval must be short enough to detect possible deviations
- Frequency should not be overly burdensome
- Consider the amount of variability in the parameter
- Consider how close the operating parameter is to the CL
- Consider how much product you are willing to sacrifice
Example: Screen

- What is monitored?
  - status: screen intact
- How is it monitored?
  - visually
- When is it monitored?
  - at start up, at end of operation
- Who monitors it?
  - production employee
Reviewing monitoring records

- observe trends
- adjust processes/operating range
- avoid a deviation

May reveal discrepancies from normal operations
May indicate need for equipment maintenance
HACCP PRINCIPLE 5

Establish Corrective Actions
Corrective Actions - main components

- Correct cause of deviation
- Identify affected product and determine its disposition
- Create a record of all actions taken
- Determine if there are actions that will prevent reoccurrence of the deviation
- Determine if HACCP plan needs to be modified
Process adjustments

- Actions taken in response to make adjustments of an operating limit are not corrective actions if CL is not violated.
Continuous application of the same CA indicates a HACCP plan not in control

- **Good:** Deviation from CL → Implementation of CA
  - No potentially harmful product in commerce

- **However,** routinely repeating this sequence for the same deviation (not meeting the same CL) indicates:
  - HACCP plan is not controlling the particular hazard
  - Unsuccessful root cause analysis
  - Plan needs to be reassessed

- No definition for how much is too much
Verification (Validation) & Recordkeeping
HACCP PRINCIPLE 6

Establish Verification [and Validation] Procedures
Verification

The application of methods, procedures, test and other evaluations, in addition to monitoring to determine compliance with the HACCP plan. (Codex, 2003)
VERIFICATION PYRAMID

- Regulatory Audit
- HACCP Plan Validation and Reassessment
- HACCP Plan Verification (HACCP System Audit)
- Verification of Prerequisite Programs
- “Routine” Verification at CCPs

INCREASING COMPLEXITY
INCREASING FREQUENCY
Components of CCP Verification

- **Calibration** of all instruments used in monitoring, corrective actions and verification.
- **Review of records** (monitoring, corrective actions and verification).
- **Independent check** on the effectiveness of the CCP to control the identified hazard.
Verification activities include:

- Review of consumer complaints
- Calibration of monitoring instruments
- Record review by a trained individual
  - monitoring and corrective action records within 1 week
  - calibration records and process/product testing records at reasonable times.

[21 CFR 120.11(a)]
Record reviews

- Necessary to ensure that all HACCP plan requirements have been met and are accurately documented
- Conducted by a designated, qualified individual
- Documented by signing and dating the record
- Useful to detect deficiencies
When to Verify CCP?

- Calibration of instruments
  - Weekly, quarterly?
- Review of records (monitoring, corrective actions and verification)
  - Daily?
- Independent check

Less Frequent than Monitoring Activities
HACCP System Verification

Compliance Audit of HACCP System

- Records review (including review of HACCP plan, monitoring, corrective action, verification records)
- On-site observations (including flow chart, monitoring activities, employee training, selected verification activities)
Validation

Obtaining evidence that elements of the HACCP plan are effective.

(Codex, 2003)
Initial Validation

• Assure that the plan is adequate for controlling food safety hazards.
• Verify that the plan is being implemented properly.
Pasteurization

- Critical limit: minimum 3 sec at minimum 72°C
  - Delivers at least 5-log reduction (Mazzotta, 2001)
  - Heat-exchanger delivers target temperature and time

- Critical limit: minimum XX L/min at minimum 72°C
  - Heat exchanger delivers target temperature and flow rate equivalent to 3 sec residence time
Validation Examples

▶ Critical limit: rocks/pits not to exceed 7 mm
  ○ FDA CPG 555.425: evidence for sizes of hard and sharp objects capable of causing injury
  ○ Challenge screen to make sure that it traps objects with 7mm or larger
Validation

… shall be performed by trained individual(s).

… records subject to record-keeping requirements.
Changes → Plan Validation

- Raw materials or source of raw materials;
- Product formulation;
- Processing methods or systems, including computers and their software;
- Packaging;
- Finished product distribution systems; or
- The intended use or consumers of the finished product.

[21 CFR 120.11(b)]
Other Reasons to Re-validate Plan

- HACCP Plan is Found Inadequate
- Compliance to Plan is Difficult
- New Pathogen Linked to Product Type
- Recalls on Similar Foods, Ingredients
- Significant Increase in Production Volume
- Consumer Complaints
Any Questions?
Principle No. 7

Establish Record-Keeping and Documentation Procedures
Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

Codex Rev. 4-2003
Typical HACCP Records

- SSOP implementation records
- Written hazard analysis
- Written HACCP plan
- Monitoring and corrective action records
- Verification and validation records

Note: The above HACCP records are required in the United States: [21 CFR 120.12(a)]
Records for HACCP System

- Hazard analysis summary
- Written HACCP plan
  - List of the HACCP team and assigned responsibilities
  - Description of the food, its distribution, intended use, and consumers
  - Verified flow diagram with CCPs
  - HACCP Plan Summary Table

(NACMCF)
Support Documentation
(The rationale behind the HACCP plan)

- Establishment of CCPs
- Establishment of critical limits
- Establishment of monitoring procedures
- Establishment of corrective actions
- Establishment of verification procedures
- Summary of prerequisite programs that support the HACCP system
Good Record Keeping Records Include:

- Name and location of processor or importer
- Date and time of activity
- Signature or initials of responsible individual
- Identity of product and production code, where appropriate.

Note: The above HACCP records are required in the United States: 21 CFR 120.12(b)
HACCP Documentation
Examples Include:

- Hazard Analysis
- Critical Control Point Determination
HACCP Record Examples:

- **CCP Monitoring activities**
  - All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

- **Deviations and association Corrective Actions**
  - Deviation and product disposition procedures must be documented

- **Verification procedures performed**

- **Modifications to the HACCP plan**
HACCP & Food Safety Regulations
“Hazard Analysis and Critical Control Point (HACCP) Systems” for Meat and Poultry products

9 CFR Part 417
“Hazard Analysis and Critical Control Point (HACCP) Systems” for *Juice*
21 CFR Part 120

“Procedures for the Safe and Sanitary Processing and Importing of *Fish and Fishery Products*”
21 CFR Part 123
Importing Foods into the United States

- Regulatory requirements apply to imported products
- FSIS has specific approvals for countries to export to US based on equivalency of inspection system
- FDA - defines responsibilities (verification) for importers, requires evidence of compliance
- FSMA: Foreign Supplier Verification Program
Codex

- General Principles of Food Hygiene (GPFH)
- Developed by the Codex Committee on Food Hygiene (CCFH)
- The Codex HACCP Guidelines were adopted as an Annex to the GPFH in 1997
  - “HACCP system and guidelines for its application”
- CCFH is currently revising the GPFH and the HACCP Annex
- Link to CCFH page

Application of the HACCP system
Referred to as “preliminary or initial tasks”

1. Assemble the HACCP Team
2. Describe the product
3. Identify the intended use
4. Construct flow diagram
5. Onsite confirmation of the flow diagram
HACCP Plan

Principles of the system:

- Principle 1: Conduct a hazard analysis
- Principle 2: Determine the CCPs
- Principle 3: Establish Critical Limit(s)
- Principle 4: Establish monitoring procedures
- Principle 5: Establish Corrective Actions
- Principle 6: Establish verification procedures
- Principle 7: Establish documentation procedures
Training

- Training is essential for effective implementation
- Inspectors may ask for date, location and provider of training course (KEEP YOUR CERTIFICATES)
ISO

- ISO 22000:2005 is based on Codex Principles
- Addresses prerequisite programs, HACCP and management system requirements
- Food establishments can gain 3rd party certification
Identifying Hazards To Be Considered

- **FDA**
  - Fish & Fishery Products Hazards & Controls Guide
  - Juice Products Hazards & Controls Guide

- **FSIS**
  - Hazard Identification Guide
  - *E. coli* O157:H7 in raw ground beef
  - *Listeria monocytogenes* in RTE products
  - Control the use and declaration of the ingredients identified by FALCPA
Inspection findings

- Inadequate documentation
  - Justification for hazard analysis
  - Support for critical limits
- Inaccurate flow diagrams (FSIS)
- Missing CCPs
- CLs at CCPs not validated
- Record-keeping errors
Common Problems: Hazard Analysis

- Does not address all steps in the process
- Does not identify hazards from all sources (rework, returns, salvage, water)
- Does not identify all pathogens of concern, or is not specific as to pathogen
- “Controlling” hazards with Prerequisite Programs
Common Problems: Hazard Analysis

- Inadequate justification for Not Reasonably Likely to Occur (NRLTO)
- NRLTO based on presence of a control program (control through GMPs, SSOPs, prerequisite program)
- Inadequate written hazard analysis with supporting documentation
- Hazards without controls
Advice

- Stay on top of the regulatory issues – regulations, FSMA, FSIS Directives, notices, guidance documents
- Read FDA Warning Letters
- Review any regulator training available on the web, e.g., Juice HACCP Regulator training
FSMA: Main Elements of New Law

- Placed New Responsibilities on Companies
- New Controls over *Imported Food*
- Enhanced Enforcement Powers
- Created New Fees on Companies and Importers
Food Safety Modernization Act (FSMA)

- Most significant food safety reform in the United States in 70 years!
  - Some 50 new regulations are expected in total
    - To date: 6 Final Rules under FSMA Published
  - GMA took the lead and continues to take the lead on FSMA implementation of private sector AND regulatory aspects of FSMA
Preventing production of unsafe food is much more effective than reliance on detection of contaminated goods in distribution and corrective actions after safety events have occurred.
Food Safety Modernization Act (FSMA)

- Hazard Analysis & Preventive Controls (Section 103)
- FSMA added a new section to the FD&C Act, requiring facilities to perform a hazard analysis and implement a preventive controls plan.

- Each facility is required to conduct a hazard analysis and develop and implement a written preventive controls plan to ensure that food is not adulterated under or misbranded (allergen control/labeling).
FSMA Final Rules Published Already

- Preventive Controls for Human Food
- Preventive Controls for Animal Feed
- Produce Safety
- Foreign Supplier Verification Program (FSVP)
- 3rd Party Accreditation Rule
- Sanitary Transportation of Food Rule
- Intentional Adulteration (Food Defense) - Coming Soon!
Who is Covered by Preventive Controls for *Human Food* (FSMA)?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the Food Drug & Cosmetic Act
  - Not farms or retail food establishments
- Applies to domestic and *imported food*
- Some exemptions and modified requirements apply
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 21 CFR Part 117

- Subpart A-General Provisions
- Subpart B-Current Good Manufacturing Practices
- Subpart C-Hazard Analysis and Risk-based Preventive Controls
- Subpart D-Modified Requirements
- Subpart E-Withdrawal of a Qualified Facility Exemption
- Subpart F Requirements Applying to Records that Must be Established and Maintained
- Subpart G Supply-chain program

* Highlighted subparts are areas of key focus
Preventive Controls for Human Food (FSMA Key Points)

- Updated and revised Good Manufacturing Practices (GMPs) - Subpart B
- Food Safety Plan – Subpart C – Hazard Analysis and Risk Based Preventive Controls
- Supplier Controls – Subpart G
- Modified Requirements - storage of unexposed packaged food
- Records, records and more records
The written Food Safety Plan must include the following elements:

- **Hazard analysis**, including the potential for economically motivated adulteration (EMA) as part of the hazard analysis.
- **Preventive controls** (including **preventive controls** at critical control points, if any)
- **Monitoring**
- **Verification**, including **validation** (required only for process preventive controls)
- **Corrective action**
- **Recordkeeping**
Hazard Analysis (FSMA)

- Identify and evaluate known or reasonably foreseeable hazards* to determine whether there are any “hazards requiring a preventive control”
  - “a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility’s food safety system.”

- Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
Under Preventive Controls for Human Food, facilities are required to consider economically motivated adulteration (EMA) as part of their hazard analysis.

Hazard identification must consider “… hazards that may be intentionally introduced for purposes of economic gain.”

FDA suggests it is practicable to determine whether EMA is reasonably foreseeable by focusing on circumstances where there has been a pattern of adulteration in the past.

Examples of EMA-Melamine in Infant Formula
Implementing Preventive Controls

- Preventive controls need to be implemented to significantly minimize or prevent significant hazards.

- The regulations explicitly provide that:
  - Preventive controls include controls other than those at critical control points (CCPs).
  - Parameters (max/min values) only needed for process controls.
The facility must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented:

- Process controls (CCPs)
- Food allergen controls
- Sanitation controls
- Supply-chain controls
- Recall plan
- Other controls
Based on the Hazard Analysis Preventive Controls, *May* include the following (FSMA):

- **Sanitation procedures** for food contact surfaces and utensils;
- **Hygienic zoning**
- **A food allergen control program**
- **Supplier Chain Controls**
- **Supervisor, manager, and employee hygiene training**
The facility is required to maintain a copy of the facility’s written Food Safety Plan on site.

Such records **must be made available to FDA** promptly upon oral or written request.
Must prepare or oversee certain preventive controls functions, such as preparing the food safety plan and conducting or overseeing validation and verification activities.
FSMA Compliance Dates for Businesses

- **Very small businesses** (less than $1 million in annual food sales): Three years (*Fall 2018*)
- **Businesses subject to the Pasteurized Milk Ordinance**: Three years (*Fall 2018*)
- **Small businesses** (a business with fewer than 500 full-time equivalent employees): (*Fall 2017*)
- **All other businesses**: One year (*Fall 2016*)
FSMA: For More Information

- Web site: http://www.fda.gov/fsma
  - Subscription feature available
- To contact FDA about FSMA and find the new online form for submitting questions: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
¿Preguntas?

❖ QUESTIONS?