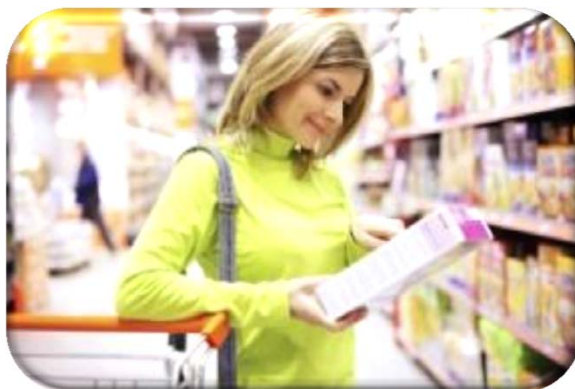


GMA



Representing the Makers of the World's Favorite Food, Beverage and Consumer Products

Food Safety Modernization Act: *A Deeper Dive into Preventive Controls*



Shannon Cole, MS, PMP
Senior Director, Science Program Management

Agenda

1. Overview of GMA's FSMA Program
2. FSMA Preventive Controls Requirements
3. GMA Food Safety Plan Checklist
4. Resources for the Industry
5. Upcoming Training Programs

GMA Member Companies

General Members



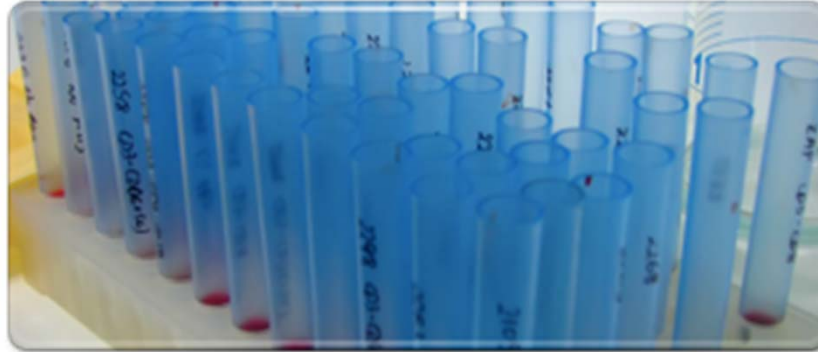
Associate Members



*Represents a sample of GMA members

www.gmaonline.org

GMA Practice Areas



Science

Policy, Service, Education and Research



Government Affairs

Impacts Public Policy



Industry Affairs

Market Growth





GMA FSM Program Organizational Sub-Projects

Monday, December 05, 2011

SRAC Executive Committee

Food Safety Modernization Steering Group

Food Safety Modernization Program

Topic Principal: Leon Bruner

GMA Staff Project Leader: Shannon Cole

Food Safety Modernization Task Force

GMA Staff Lead: S. Cole

Education and Training

Sponsor: D. Mastorocco
WG Chair: H. Mockus
GMA Staff Lead: G. Black

- FSL Educational Programs
- New Training Programs
- New Publications

Rules and Regulations

Co-Sponsor: S. Geisert
Co-Sponsor: TBD
GMA Staff Lead: S. Cole

Guidance Development

Sponsor: P. Barone
WG Chair: R. Reinhard
GMA Staff Lead: TBD

- Guidance Dev. Strategy
- Hazard Analysis Toolbox
- Guidance Document review and comment

International Integration

Sponsor:
WG Chair: B. Eldridge
GMA Staff Lead: P. Rochette

- APEC PTIN Integration
- TPP Integration
- Non-APEC Country Integration
- Codex Guidance Integration

GMA Membership Support

Co-Sponsor: H. Chin
Co-Sponsor: M. Robach
GMA Staff Lead: S. Cole

- Science Forum Strategy
- Big Picture
- Communication Strategy
- Marketing Strategy
- Retail Strategy

Preventive Controls & Records Access

WG Co-Chair: T. Jackson
WG Co-Chair: D. Bresnahan
GMA Staff Lead: E. Mathusa

- Hazard Analysis & Risk Based Prev. Controls
- Verification Steps/ Testing
- Records Access
- Performance Standards

Food Defense

WG Chair: B. Ramsey
WG Co-Chair: S. Mavity
GMA Staff Lead: W. Stone

- Intentional Contamination Prev.
- Food Defense Plans
- Smuggled Foods
- Economic Adulteration

Supply Chain Mngm't (Foreign & Domestic)

WG Chair: B. Welshons
WG Co-Chair: J. Scimeca
GMA Staff Lead: E. Mathusa

- Foreign Supplier Verification Program
- Domestic Supply Chain Mngm't
- Sanitary Transportation
- Regulatory Audits

Inspections & Enforcement

WG Chair: P. Harvey
WG Co-Chair: D. Baldwin
GMA Staff Lead: L. Hontz

- Risk Based Inspections
- Foreign Facility Inspections
- Re-inspection Fees
- Registration & Suspension
- Mandatory Recall & Detention of Food
- Reportable Food Registry

Import Certification

WG Chair: R. DePalma
WG Co-Chair: M. Overland
GMA Staff Lead: E. Mathusa

- Laboratory Accreditation
- Accreditation of 3rd Party Auditors
- Accreditation of Foreign Gov'ts
- Import Certifications
- Voluntary Qualified Importer Program

Traceability & Produce

WG Chair: S. Mavity
WG Co-Chair: J. Rosen
GMA Staff Lead: C. Balestrini

- Standards for Produce Safety
- Tracking & Tracing
- IFT Pilot Programs

Results Delivered



Conducted
SME Face
to Face
Meetings
with FDA

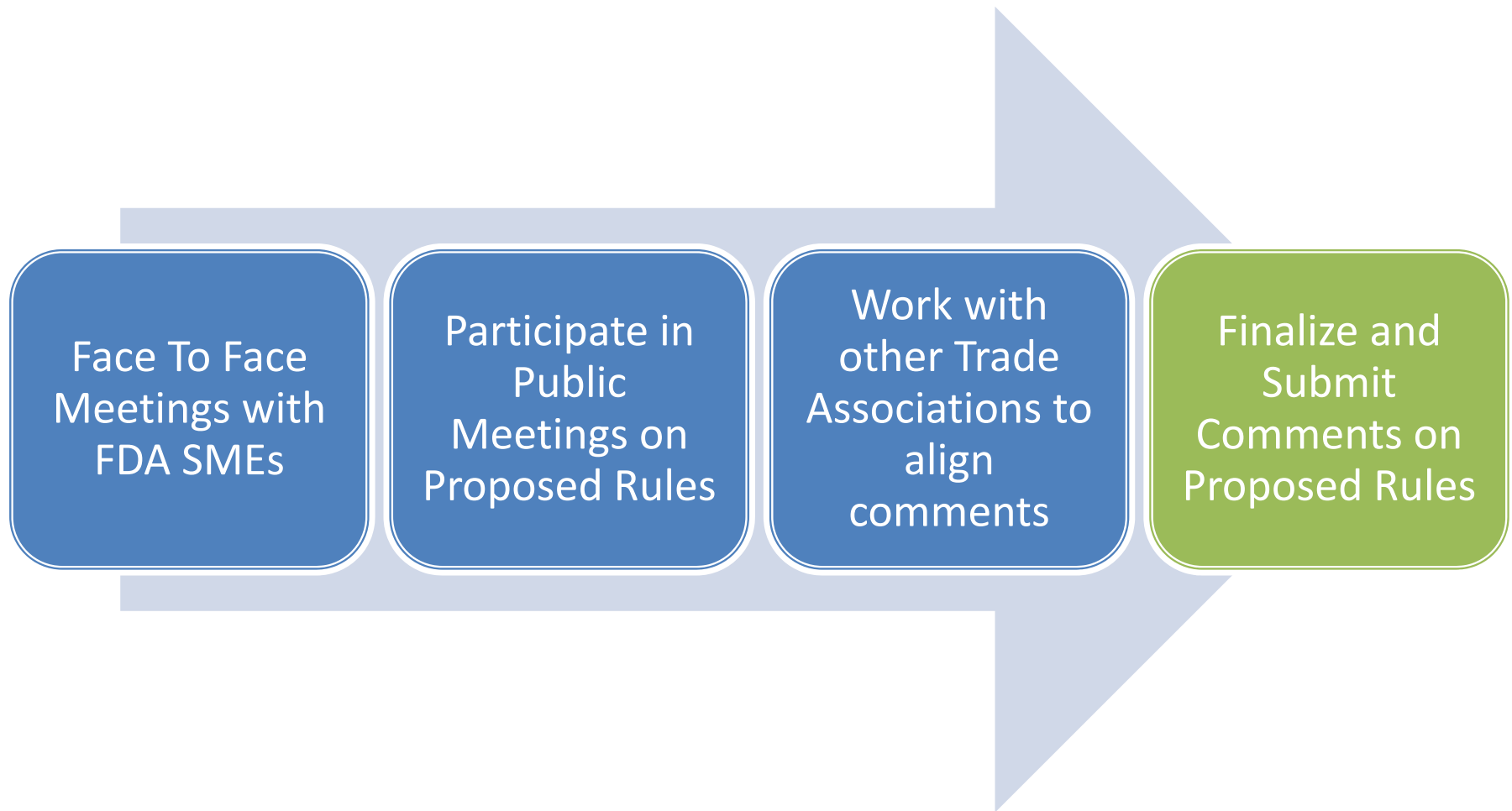
Participated
in all FDA
Public
Meetings

Submitted
Comments
to ALL Public
Dockets

Collaborative
Meetings with
GMA FSMA
Coalition,
Pew/RWJF,
Chamber of
Commerce, IFT,
Foreign
Delegations and
Embassies

**Launched SharePoint site for
access to all FSMA related
materials – includes ~600 users!!**

Upcoming Deliverables



Food Safety Modernization Act (FSMA) Concept

***Preventing production of
contaminated foods is much more
effective than reliance on detection
of contaminated goods in
distribution and corrective actions***

FSMA Requirements

❖ Under FSMA, food facilities are required to:

- Conduct **hazard analyses**
- Develop and implement written **preventive controls (PC) plans**
- **Monitor** the performance of the preventive controls
- Establish **corrective actions** as necessary
- **Verify** the preventive controls are working
- Maintain appropriate **records**
- Make appropriate documents available to FDA during an inspection

FSMA calls for enactment of the Hazard Analysis & PC sections 18 months after the law was put in force (January 4, 2011).



Food Safety Plan

Written Plan
(includes procedures)

Ongoing Documentation
(keep at least 2 years)

Hazard Analysis

- Biological
- Chemical
- Physical
- Radiological
- Natural Toxins
- Pesticides
- Drug Residues
- Decomposition
- Parasites
- Allergens
- Unapproved food or color additives
- Natural hazards
- Unintentional hazards
- Intentionally introduced hazards

Preventive Controls*

* Includes all preventive controls that may be appropriate, including those in cGMPs and CCPs, if any:

- Sanitation
- Hygiene training
- Environmental monitoring
- Allergen control
- Recall plan
- cGMPs
- Supplier verification
- Other controls

Monitoring

- Monitor and document effectiveness of preventive controls

Material Non-conformance

Corrective Actions

- Take action to reduce likelihood of recurrence
- Evaluate affected food for safety
- Prevent affected food from entering commerce if necessary
- Document efficacy

Verification

- Preventive controls are adequate to control hazards
- Monitoring
- Appropriate decisions about corrective actions
- Addressing hazards (including environmental and product testing programs and other appropriate means)
- Periodic reanalysis

Intentional Hazards
(Food Defense)

GMA's Food Safety Plan Checklist

Purpose: Tool to assist companies in developing a new Food Safety Plan or revising their existing plan to be compliant with the requirements in FSMA.

The intent is not to be a comprehensive “how to” document, but to outline the major activities that should take place.



GMA's Food Safety Plan Checklist

❖ The checklist activities are broken down into these main areas:

1. Preliminary Tasks
2. Hazard Analysis and Preventive Controls
3. Monitoring
4. Corrective Actions
5. Verification and Validation
6. Records
7. Training



1. Preliminary Tasks

❖ Assessing current operations:

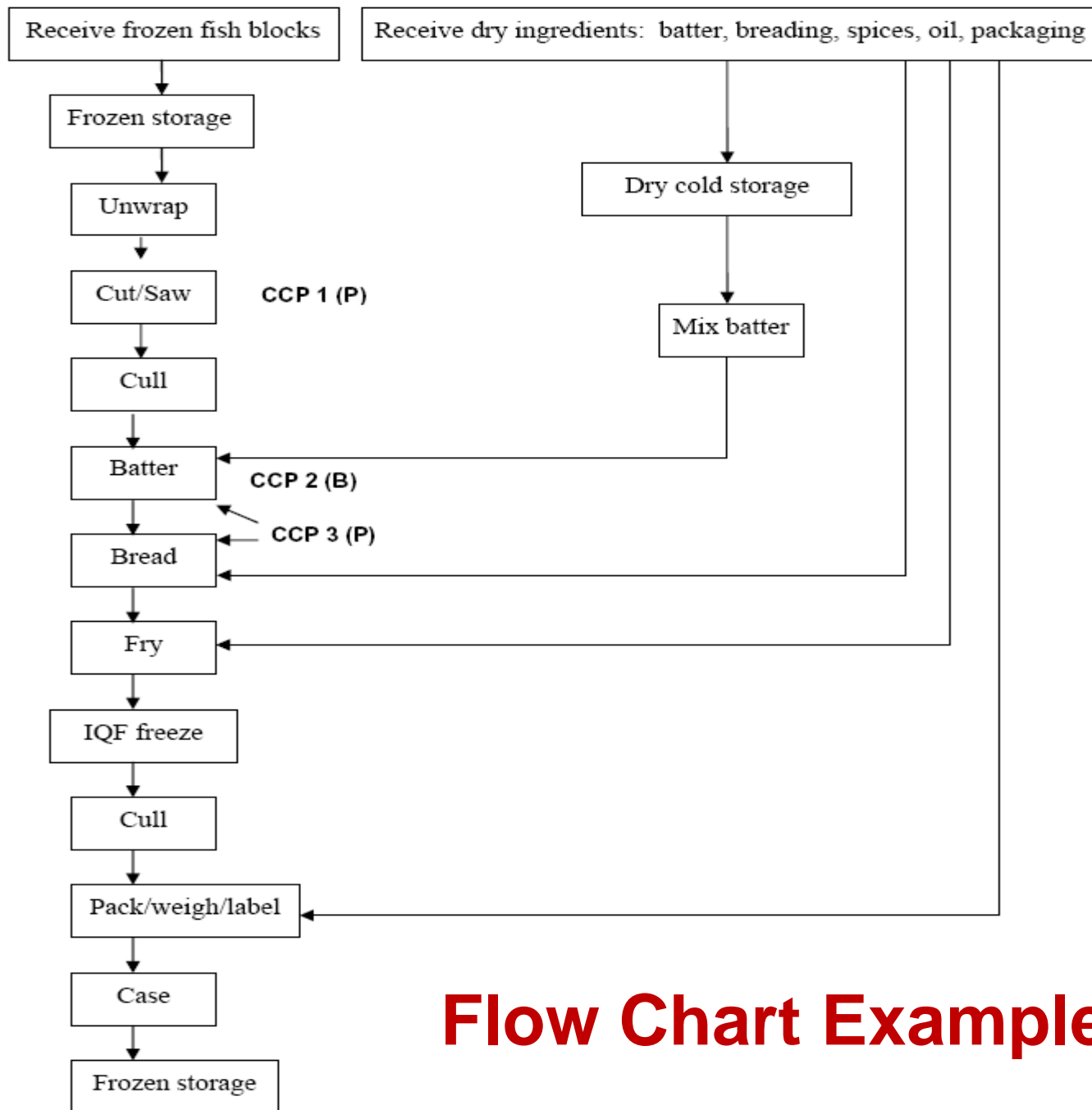
- Establish a cross-functional **Food Safety Plan team**
 - Get the appropriate food safety knowledge/skills at the table
- Describe the product, intended use and customer
 - Ask the right questions (GMA tool box)
 - Develop worksheet to capture information considered
 - Result should be a detailed summary of product and manufacturing systems/conditions

1. Preliminary Tasks

❖ Assessing current operations (cont'):

- Describe plant operational practices
- Develop a flow diagram including receipt of raw materials, process steps, processing equipment, rework steps, packaging, storage, and shipping, etc.
 - Details!! Should list each and every process step starting with receiving through finished product shipping
- Identify existing regulatory requirements being addressed
 - E.g. Current Good Manufacturing Practices (cGMPs), Juice HACCP, Seafood HACCP, LACF, Allergen Labeling, etc.
 - What are you already doing?

Frozen Breaded Fish Sticks



Flow Chart Example

2. Hazard Analysis and Preventive Controls

❖ Conduct a hazard analysis

▪ Two important parts:

1. Brainstorming foreseeable hazards (**hazard identification**)
2. Determining level of risk (**hazard evaluation**)



2. Hazard Analysis and Preventive Controls

❖ Conduct a hazard analysis

- **Hazard identification** - Food facilities must identify known or reasonably foreseeable hazards that may be associated with the facility, FSMA **mandates** consideration of the following hazards:

1. Biological contamination
2. Chemical contamination
3. Physical hazards
4. Unlawful pesticide residues
5. Decomposition (if a food hazard exists)
6. Radiological hazards
7. Natural Toxins
8. Unapproved use of food or color additives
9. Parasites
10. Hazards that may be intentionally introduced
11. Drug residues
12. Undeclared allergens

2. Hazard Analysis and Preventive Controls

- ❖ Conduct a hazard analysis
 - ❖ **Hazard evaluation** - In this step of the hazard analysis, the team decides which potential hazards must be addressed. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence.
 - ❖ Determine Critical Control Points (CCPs), if any

2. Hazard Analysis and Preventive Controls

❖ Determine appropriate preventive controls

▪ For example:

- Sanitation procedures
- Hygiene training
- Environmental monitoring program
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices (cGMPs)
- Supplier verification activities related to food safety

2. Hazard Analysis and Preventive Controls

- ❖ Consideration of plant/equipment design modifications that could assist in managing/mitigation potential hazards
- ❖ Develop a program that addresses the requirement to verify that **suppliers** (both domestic and foreign) have Food Safety Plans in place that provide for production of food and ingredients in accordance with US requirements

3. Monitoring

- ❖ Identify monitoring activities associated with preventive controls, as appropriate, to assure that identified hazards will be significantly minimized or prevented
 - SMOPing 😊
- ❖ Define and determine critical limits for any CCPs

4. Corrective Actions

- ❖ Identify procedures to be taken when preventive controls are not properly implemented or are found to be ineffective
- ❖ Establish procedures for documenting corrective actions
 - *E.g.* A corrective actions form, need to show that you carried out the appropriate corrective action through documentation

4. Corrective Actions

- ❖ Establish procedures to ensure appropriate actions are taken to reduce the likelihood of a reoccurrence of the deviation
- ❖ Establish procedures to evaluate all affected food for safety and prevent it from entering commerce if its safety cannot be established
- ❖ Establish a recall plan

5. Verification and Validation

- ❖ Establish the scientific or other basis, as appropriate, that documents the **validity** of the preventive control measure(s) and that hazards are adequately prevented, eliminated or reduced to a level that ensures food safety
- ❖ Implement an initial audit that **verifies** the Food Safety Plan is designed properly to control potential hazards

5. Verification and Validation

- ❖ Establish documented, periodic reanalysis of the plan to ensure it is still relevant when
 1. **Significant changes** that create a reasonable potential to affect food safety occur
 - OR**
 2. **Every three years**, whichever is earlier
- ❖ As appropriate, establish environmental monitoring and product testing programs as verification activities

6. Records

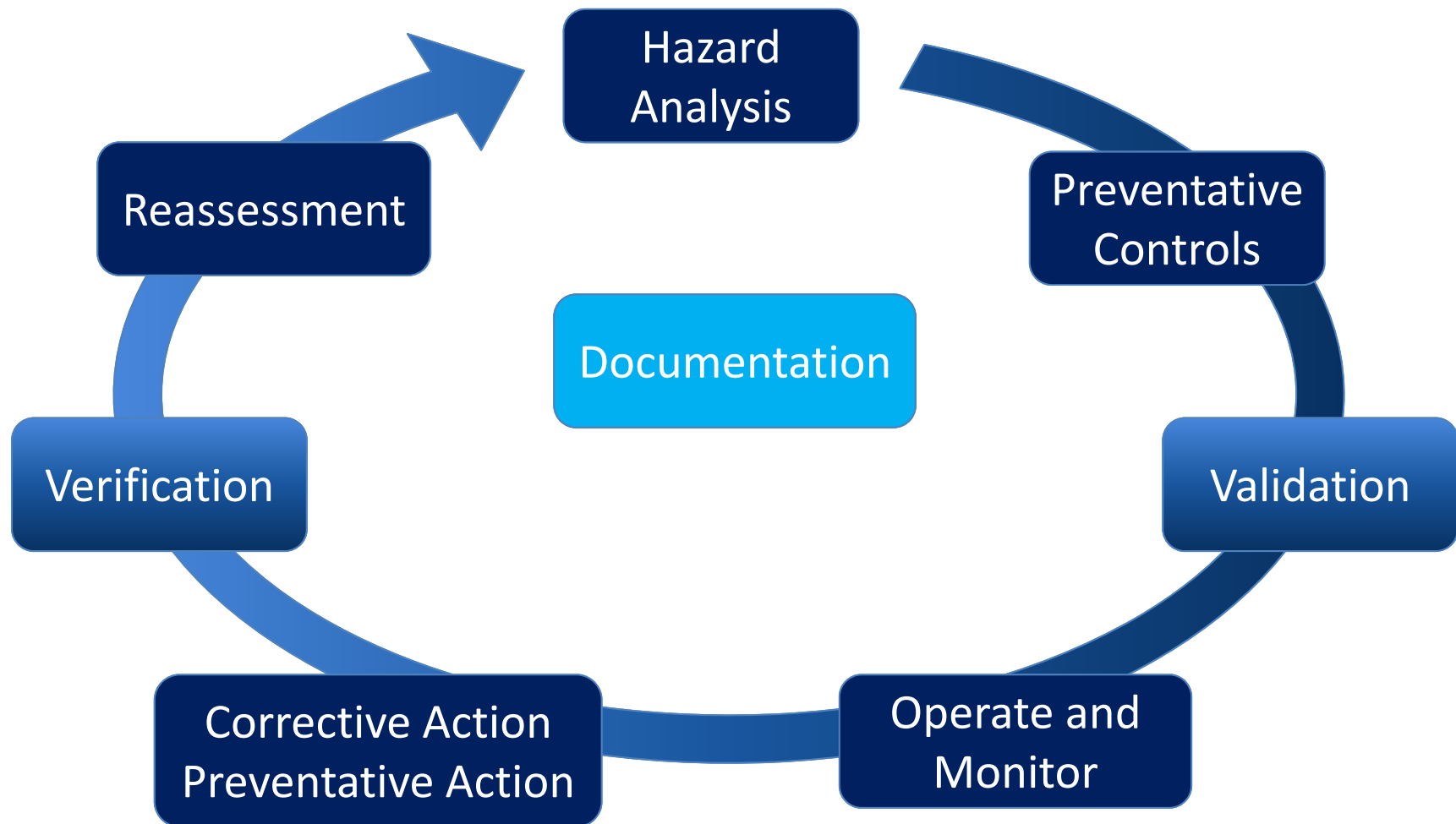
- ❖ Identify record keeping requirements
 - *E.g.* FSMA, Bioterrorism Act, HACCP, LACF

- ❖ Develop means to establish and maintain essential Food Safety Plan records, and decide where records will be kept
 - *E.g.* At a corporate location or at a particular facility

7. Training

- ❖ Provide training for management and staff who will design and oversee the Food Safety Plan
- ❖ Establish a line-worker training program for operators that will carry out the Food Safety Plan
- ❖ Document training was received and assess its effectiveness

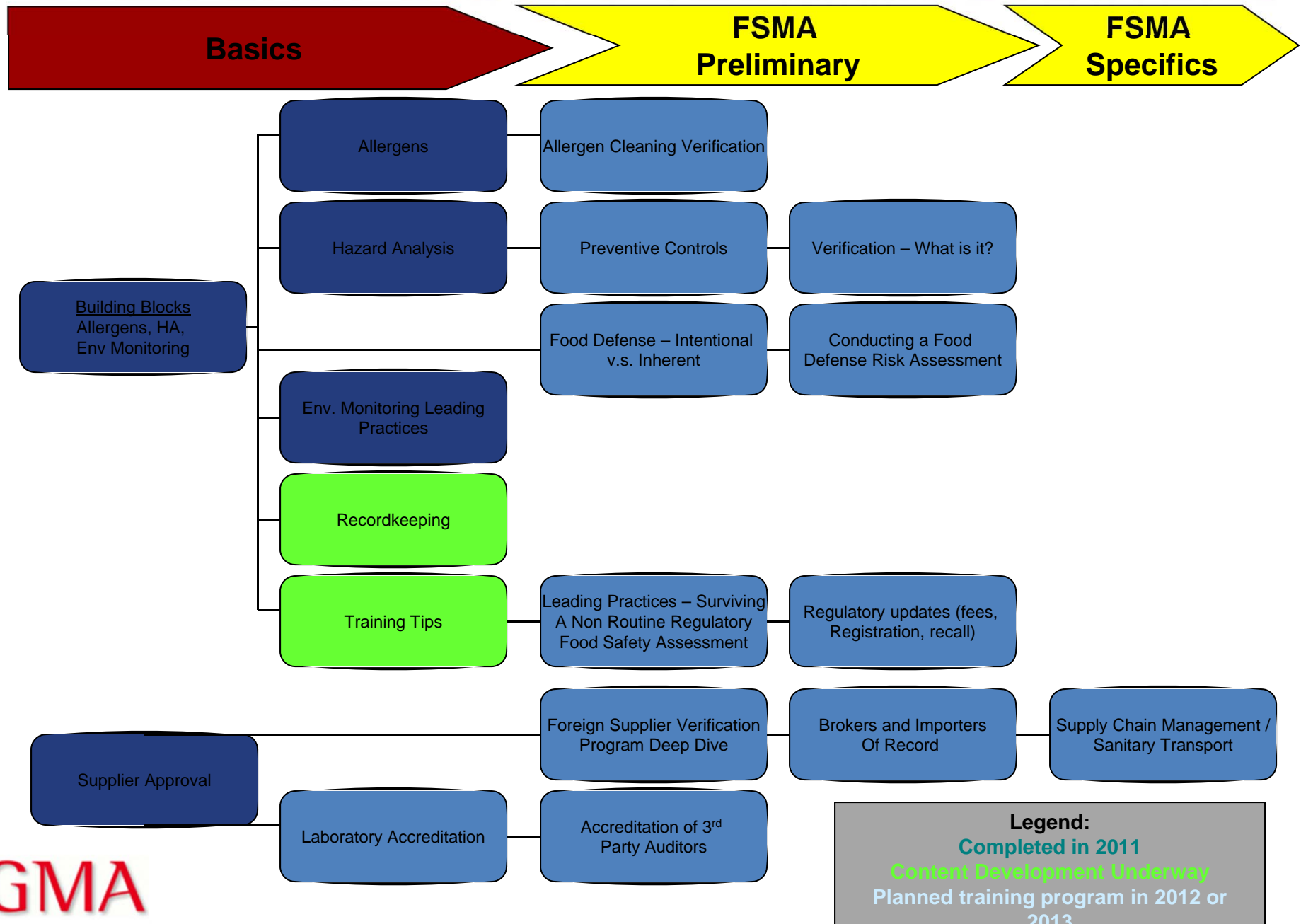
In Summary - Food Safety Planning Process



GMA Resources for Industry

- ❖ Training – GMA FSMA Webinars and Workshops
 - On GMA's website: <http://www.gmaonline.org/file-manager/Events/Workshops-Webinars.pdf>
- ❖ GMA Food Safety Plan Hazard Analysis “Tool Box”
 - On the GMA FSMA SharePoint site: <http://fsma.gmaonline.org>
- ❖ GMA Food Safety Plan Checklist
 - On the GMA FSMA SharePoint site: <http://fsma.gmaonline.org>
- ❖ Supplier verification – GMA's Supply Chain Handbook
 - On GMA's website: http://www.gmaonline.org/downloads/technical-guidance-and-tools/GMA_SupplyChain2.pdf

FSMA EDUCATION & TRAINING STRATEGY



GMA Recorded Webinars & 2012 Upcoming Training Programs

Recorded Webinars Available for Purchase:

- ❖ Building Blocks of an effective Food Safety Plan
- ❖ Allergens: Successful Factory Management Strategies
- ❖ Supplier Benchmarking: Does your supplier make the grade?
- ❖ Hazard Analysis & Food Safety Control: Learning by Example
- ❖ Documentation and Recordkeeping:
"From the Plant Floor to the File Drawer...and Beyond"

Upcoming Workshops/Webinars

- ❖ Apr 25, 2012 Aggressive Control Measures for a Wily Pathogen: Salmonella in Low-Moisture Products
- ❖ End of May Training Tips
- ❖ June 27, 2012 Food Defense Fundamentals: Food Safety Modernization and Economically Motivated Adulteration
- ❖ July 25, 2012 Planning for a Regulatory Inspection



Contact Audrey Rubio for more information:
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www.gmaonline.org

What to expect going forward

- ❖ The level of outside scrutiny of food production processes is going to increase
 - FDA has a long history of GMP and management systems auditing
 - The audit processes are rigorous
 - Manufacturers will need to demonstrate safety management systems are suitable, effective and operating in control
 - Documented processes and procedures
 - Validated controls
 - Verification
 - Records that document actions

Through GMA's Leadership. . .

- The industry will be ready!
- The other trade associations are aligned!
- FDA has received science based information that will be used to shape the regulations!
- The relationship between FDA & GMA is stronger than ever!
- But, we still have our work cut out for us when the rules are published!



Thank you for your time!

Contact Information:

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Grocery Manufacturers Association

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scole@gmaonline.org