

GMA



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

Implications of the Food Safety Modernization Act

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Summary

Things that might have seemed like just a good idea before, are now going to be mandatory, require records to support compliance, and those records are going to be available to FDA.

- **FSMA included identification and evaluation of intentionally introduced hazards**
- Preventive controls are not restricted to implementation at CCPs

Food Defense

- ❖ Having measures in place to reduce the chances of **intentional** adulteration of the food supply
- ❖ The FSMA mentions deterrence of **intentional** adulteration eleven times in five separate sections

FSMA and Food Defense Items (Sections 103, 105, 106, 108, 109)

- ❖ Section 105: Produce Safety
- ❖ Section 106: Protection Against Intentional Adulteration
- ❖ Hazard analysis mandated under Section 103 (Preventive Controls) must address hazards involving **intentional adulteration**
- ❖ Section 108: National Agriculture and Food Defense
- ❖ Section 109: Food & Agriculture Coordinating Council

Food Defense vs. Food Safety

Food Defense

- Contamination is intentional
- Vulnerability assessments identify sites where hazards could be introduced
- Has potential to result in many deaths

Food Safety

- Contamination is unintentional (or neglect??)
- Risk assessments identify severity of adverse health outcome
- May involve many illnesses but few deaths

Milk Tampering Incident

- ❖ In April 2002, there were 14 reported cases of apparent milk tampering in western New York.
- ❖ **More than 48,000 gallons of milk were destroyed, costing farmers tens of thousands of dollars.**
- ❖ Upon investigation it became apparent that antibiotics had been added to milk storage tanks. In some cases, cows were injected with the antibiotics.

DELIBERATE SABOTAGE OF PRODUCT IS A PLANT MANAGER'S NIGHTMARE

(FoodQualityNews.com, 17 Oct 2006)

“Over the past 12 months Allied Bakeries has been hit with...deliberate cases of **malicious tampering** of its bakery products. The company reported that ... it has received...complaints involving fragments of glass or sewing needles in its...sliced bread...

The company believes the objects are inserted into the packaging after the baking process, but police have so far not determined whether the tampering is happening inside the factory or in the supply chain.”

Industry, Supplier Food Defense Issues

- While food safety enjoys significant infrastructure and staffing at appropriate levels within the industry:
 - There are few security professionals present in the industry
 - Food defense responsibilities are usually handled by those who have little or no background in security
 - Such as food scientists and/or other food safety professionals
 - Especially true among small to mid size companies

Industry, Supplier Food Defense Issues

- Food defense issues, which will come out of FSMA legislation, and into regulation and/or guidelines from FDA may very well turn out to be the most expensive part of food safety compliance.
 - Especially for companies which have done little or nothing thus far to develop food defense measures.
 - For small/mids, this could be very expensive if not handled well.

Industry, Supplier Food Defense Issues

- ❖ The records access to provision of the law will also apply to security and food defense records such as security reports, access control records and CCTV.

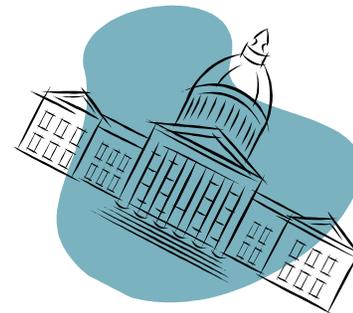
Foreign Supplier Verification Program (Section 301)

- ❖ The FSMA requires every U.S. importer to:
 - Perform risk-based foreign supplier verification activities to verify that the food it imports is
 - Not adulterated
 - Produced in compliance with the requirements of FSMA hazard analysis and preventive control sections
 - This would include the intentional adulteration (food defense) provisions

- FSMA included identification and evaluation of intentionally introduced hazards
- **Preventive controls are not restricted to implementation at CCPs**

Changes from FSMA??

- ❖ Validation requirements may need to address the entire food safety system, not just the critical limits (CLs) that support CCPs
 - Prerequisite programs (PPs) to support hazard not reasonably likely to occur
 - PPs are foundation for a food safety plan, such as HACCP to operate effectively



PPs – PAS 220

- ❖ Layout of premises and workspace
- ❖ Utilities – air, water, energy
- ❖ Equipment suitability, cleaning and maintenance
- ❖ Management of purchased materials
- ❖ Measures for prevention of cross contamination
- ❖ Cleaning and sanitizing
- ❖ Pest management
- ❖ Environmental monitoring
- ❖ Food defence, biovigilance and bioterrorism
- ❖ Personnel hygiene and employee facilities
- ❖ Rework
- ❖ Product recall procedures
- ❖ Warehousing
- ❖ Product information/consumer awareness
- ❖ Waste disposal
- ❖ Allergen Control

Specialized PPs for certain applications

- ❖ Moisture control (war on water) for low moisture foods
- ❖ Environmental monitoring for post lethality exposed RTE foods

**The hazard is not reasonably likely
to occur (NRLTO) due to the
presence of one or more
prerequisite programs**

The justification why a hazard is NRLTO
may also be viewed as a form of validation

Review of Prerequisite Programs

Periodic review of the SOPs and audit reports to ensure that the programs are operating in a manner that **should not require a change in the hazard analysis or HACCP plan.**

Validation of prerequisite programs in support of food safety plans

- ❖ PPs often don't lend themselves to traditional validation protocols
 - Microbial elimination validation: Inoculate with target organism and measure survival
 - Pest management: similar approach would not be practical. Cannot release a population of pests into a facility and see if they are eradicated
- ❖ “**Validation**” of PPs may have to be against best standards available
 - E.g., GMPs validate against 21 CFR Part 110
 - Food defense: validate against best industry practices

Verification of Prerequisite Programs

- ❖ Is the SOP performed in the manner intended?
- ❖ Is the procedure monitored?
- ❖ Are instruments (pH meters, thermometers) used in verification activities routinely calibrated?
- ❖ Are appropriate records kept?
- ❖ Is there an independent observation and/or audit?
- ❖ Are programs revised as necessary?
- ❖ Does the PP/SOP conform to best industry practices?

Validation of Prerequisite Programs

Determine whether the program is effective.

Validation is a component of verification. Not all procedures need to be, or can be, validated.

Environmental monitoring (EM) for pathogen control - validation

~~Inoculate equipment with pathogens and see if the EM program identifies them, and if corrective actions eliminate the harborages~~



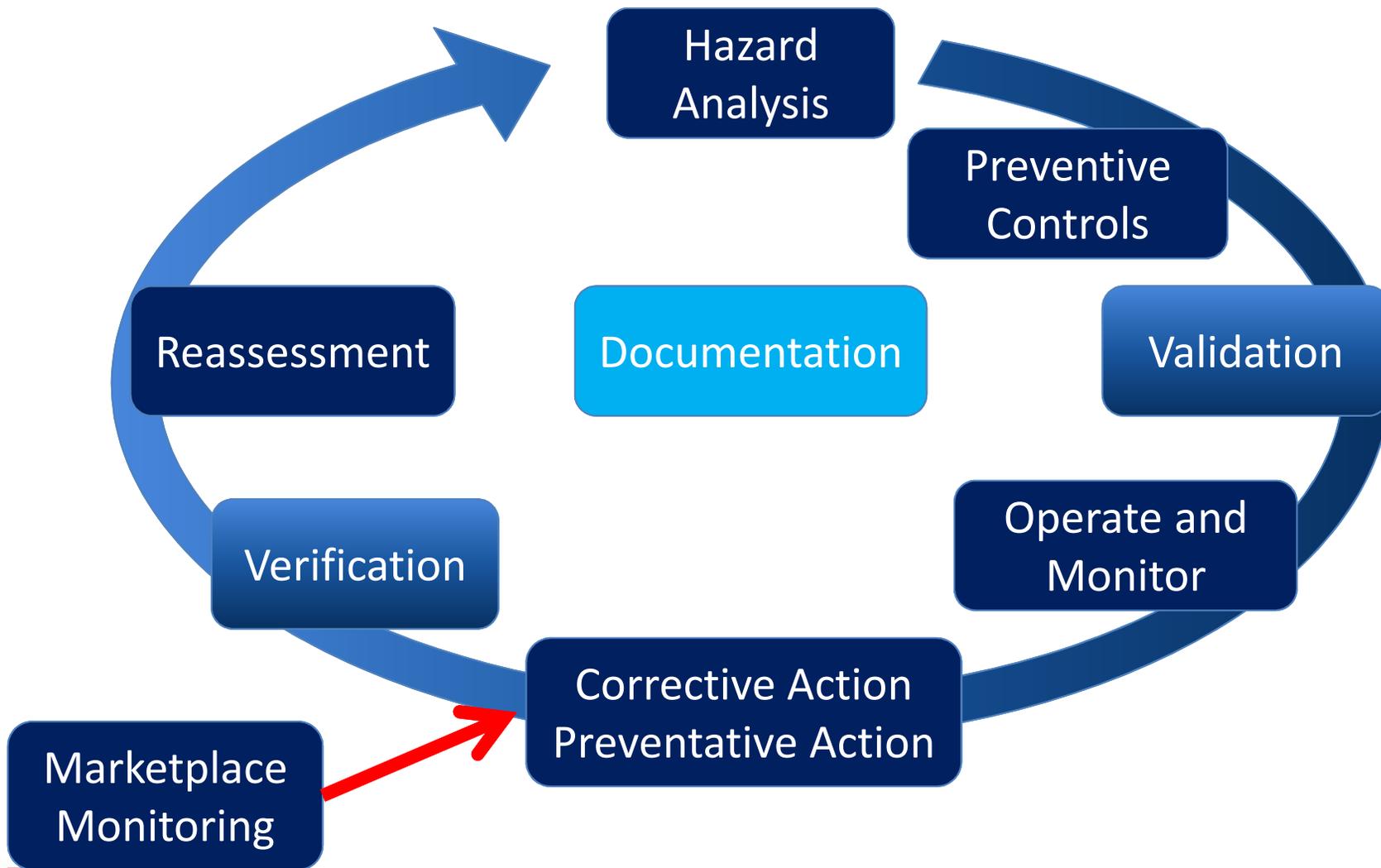
EM for pathogen control – “validation”

- ❖ Validation, general:
 - Use approved methodology, BAM, AOAC etc
 - Employee training
 - Use approved techniques
 - Thorough recordkeeping reviewed by trained employees
 - Identify appropriate sampling sites
 - “Seek & destroy” program
 - Finished product testing
 - Records show corrective actions effectively established control
- ❖ In cases such as these, validation is a tool that enables processes to be more predictable. Enables management to have confidence in the results

SSOP Validation

- ❖ State the validation objective, for example...
 - Allergen clean
 - Microbially clean
- ❖ Achieve a visibly clean standard
- ❖ Possibly test with microbial swabs, allergen test kits or other methods to see that target contaminant has been removed (residual allergenic proteins, microbes etc.)
 - Surface swabs
 - Testing of final rinse waters
 - Product testing
- ❖ Repeat often enough to gain confidence in the results

Food Safety Planning Process



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
 - Sanitary design
 - Hygiene training
 - Environmental monitoring
 - Allergen control
 - Recall plan
 - cGMPs
 - Supplier verification
 - Pest management
 - 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
- NRLTO supported
- Appropriate decisions about corrective actions
- Addressing hazards (including environmental and product testing programs and other appropriate means)
- Periodic reanalysis

Intentional Hazards (Food Defense)





Available in:

- English
- Spanish
- Mandarin
- French
- Russian
- Japanese

GROCERY MANUFACTURERS ASSOCIATION

Food Supply Chain Handbook

Nutr.	
Serving Size 1	
Servings Per Container 1	
Amount Per Serving	
Calories	100 Calories
Total Fat	12g
Saturated Fat	3g
Trans Fat	0g
Polyunsatur	
Monounsatur	

<http://www.gmaonline.org/publications/index.cfm>

GMA HACCP Courses

Workshop	Descriptions
HACCP Online course*	This online workshop provides flexible, affordable and effective training for food safety personnel who need to learn and apply the principles of HACCP in plan development and implementation.
GMA Online HACCP Follow-up Workshop	This course complements the online HACCP training by providing hands-on experience with the development of a "mock" HACCP plan to facilitate understanding of the online material. Completion of the online course is prerequisite to this 1-day certificate workshop. The online course plus this 1-day follow-up workshop meet the educational requirements cited in the FDA & USDA HACCP regulations.
Advanced HACCP, Verification & Validation	This workshop, accredited by the International HACCP Alliance, concentrates on verification activities included in the sixth principle of HACCP. It explores activities in-depth and how to implement them in a successful HACCP system.
HACCP Train the trainer	The HACCP Train the Trainer workshop is designed to prepare and qualify candidates as International HACCP Alliance Lead Instructors. In addition to providing a greater understanding of the 7 HACCP principles, the workshop covers adult learning styles and delivery techniques to more effectively present HACCP course material. Hands-on working group exercises facilitate the learning process.
Basic HACCP (Meat, Poultry, Juice, Seafood and other products as needed)	This introductory workshop, accredited by the International HACCP Alliance, is composed of lectures and group exercises.. Each of the seven HACCP principles is discussed. The workshop focuses on strategies for HACCP plan development and implementation. GMA instructors can accommodate and provide lectures for specific areas of interest based upon the participants' needs.

*[http://www.gmatraining.com/HACCP Purchase Info.html](http://www.gmatraining.com/HACCP_Purchase_Info.html)

GMA HACCP Resources

Textbooks

- HACCP: A Systematic Approach to Food Safety - English http://www.fpa-food.org/store_product.asp?inve_id=221
- HACCP: A Systematic Approach to Food Safety - Spanish http://www.fpa-food.org/store_product.asp?inve_id=66
- HACCP Verification and Validation: An Advanced HACCP Workshop
 - English: http://www.fpa-food.org/store_product.asp?inve_id=118
 - Spanish: http://www.fpa-food.org/store_product.asp?inve_id=69

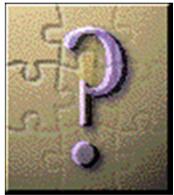
Other Materials

- PowerPoint slide sets to accompany the above HACCP manuals:
 - English: http://www.fpa-food.org/store_product.asp?inve_id=64
 - Spanish: http://www.fpa-food.org/store_product.asp?inve_id=196

Other Courses Offered by GMA

- ❖ **Thermal Process Development**
- ❖ **Thermal Process Deviations**
- ❖ **Better Process Control School**
- ❖ **Aseptic Better Process Control School**
- ❖ **Food Labeling**

❖ Contact Audrey Rubio at: arubio@gmaonline.org



¿Preguntas?

❖ QUESTIONS?

