



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



Implications of the Food Safety Modernization Act

Warren Stone, MBA
Director of Science Policy,
Compliance & Inspection
Grocery Manufacturers Association

www.gmaonline.org

Agenda

1. GMA Approach to FSMA
2. Some Specifics on FSMA Components
3. Questions

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.

GMA Approach to FSMA

Big Buckets - Priority



GMA



www.gmaonline.org

Food Safety Modernization Task Force Work Streams

- ❖ Guidance Development
- ❖ Rules and Regulations
- ❖ Education and Training
- ❖ International Integration

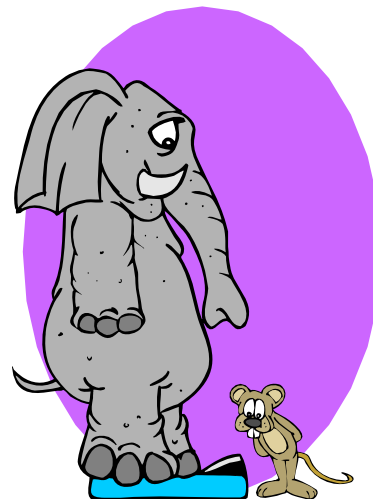
Guidance Development Goals & Objectives

Provide FDA with input and suggestions that will assist with development and implementation of regulations developed from FSMA

Guidance Development Goals & Objectives

❖ Suggestions should be:

- **Appropriate for very small as well as large processors**
- Directional and not prescriptive
- Focused on goals and outcomes as opposed to tasks
- Practical and non-burdensome
- Based on industry leading practices
- Flexible
- Appropriate for domestic and international operations



Rules & Regulations-Preventive Controls & Records Access

- ❖ Hazard analysis and risk-based preventive controls
- ❖ Verification steps and testing
- ❖ Records access
- ❖ Performance standards

Rules & Regulations- Food Defense

- ❖ **Prevention of intentional contamination**
- ❖ **Food defense plans**
- ❖ **Economic adulteration with respect to food safety**

Rules & Regs- Supply Chain Management

- ❖ Foreign and Domestic
 - Foreign Supplier Verification Program
 - Preventive Controls

International integration

- ❖ APEC PTIN integration
- ❖ Trans Pacific Partnership
- ❖ Non-APEC
- ❖ Codex guidance



FSMA ≠ Barrier to Trade



How do I get involved?

❖ GMA Involvement:

- Shannon Cole: scole@gmaonline.org
- Warren Stone: wstone@gmaonline.org

❖ Through your trade organizations

❖ University groups, consumer advocates

❖ Our gracious hosts (**ASTA** has representation on several of GMA's working groups)

DO IT NOW

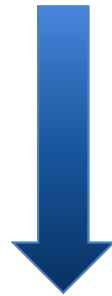
GMA



www.gmaonline.org

The training continuum

Basic, general webinars



Advanced, detailed, specific training



Hands-on, detailed workshops

New training programs

- ❖ Building Blocks webinar March 30
- ❖ Supplier Benchmarking Webinar April 15th,
http://www.gmaonline.org/forms/meeting/Microsite/Supplier_Benchmarking
- ❖ More to come

FSMA Specifics

(as specific as we can be at this time)

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)

New regulatory requirements

- ❖ Facilities required to conduct **hazard analyses** and develop and implement **written preventive controls plans**.
- ❖ Importers required to implement **foreign supplier verification programs**.
- ❖ Facilities must maintain records, including copies of their hazard analyses and preventive controls plans, and additional records.

Hazard Analysis & Preventive Controls

(Section 103)

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).

Preventive Controls May Include the Following:

❖ **Supplier verification activities related to food safety**

- ❖ Sanitation procedures for food contact surfaces and utensils;
- ❖ An environmental monitoring program to verify the effectiveness of pathogen controls
- ❖ A food allergen control program;
- ❖ Good Manufacturing Practices (21 C.F.R. Part 110);
- ❖ Supervisor, manager, and employee hygiene training;

FSMA & Supply Chain Management

- 1. Supplier verification activities related to food safety as part of the preventive controls plan (Section 103)**
- 2. Foreign Supplier Verification Program (Section 301)**
- 3. Voluntary Qualified Import Program (Section 302)**
- 4. Authority to Require Import Certificates (Section 303)**

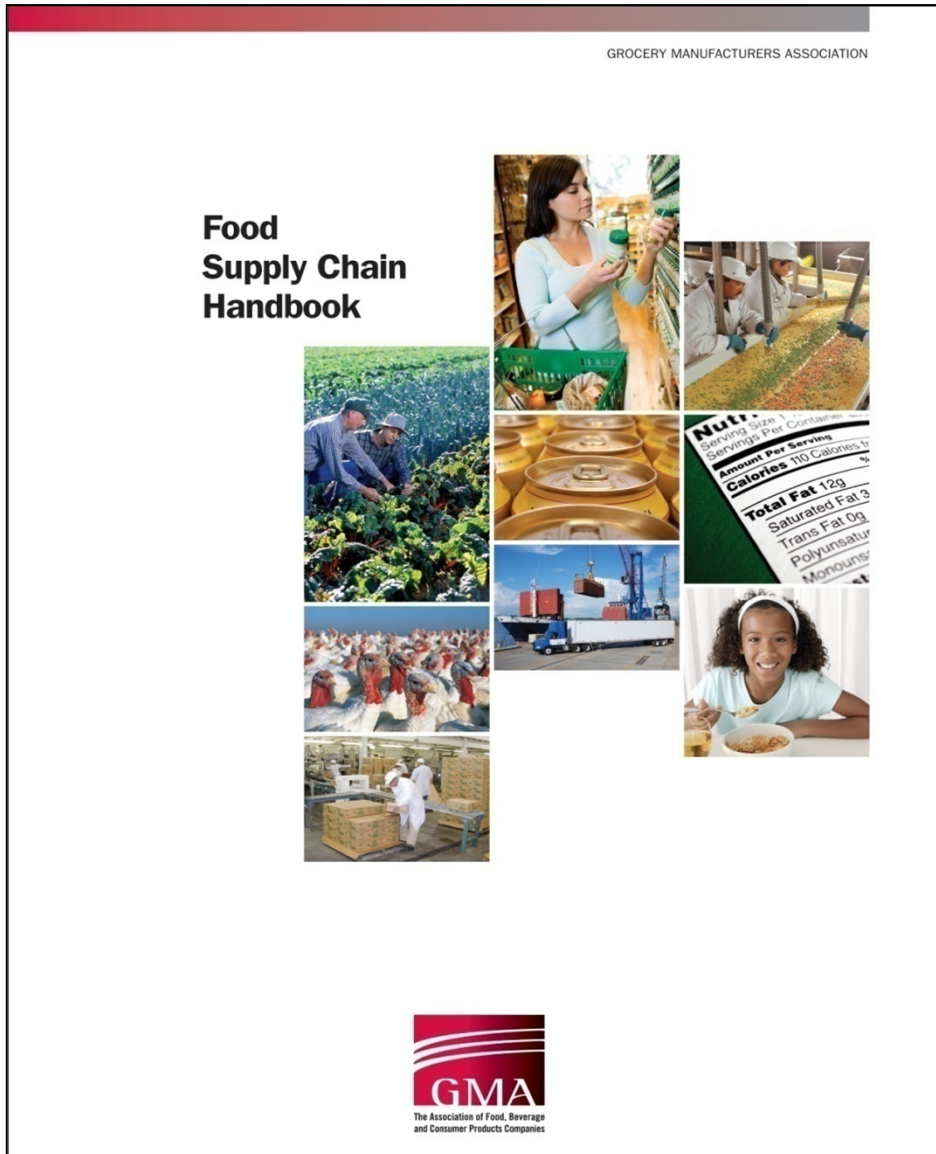
Food Supply Chain Handbook

To aid companies in selecting such valued business partners, the Grocery Manufacturers Association (GMA) has developed a ***Food Supply Chain Handbook***



Available in:

- English
- Spanish
- Mandarin
- French
- Russian
- Japanese (pending)



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

Tools for Supplier Verification

- Supplier Management
- Supplier Pre-assessment & Review
- Change Control
- Documentation & Recordkeeping
- Supplier Documentation (LOGs, COAs etc.)
- Auditing
 - Internal & External
- Regulatory Compliance
- Food Defense
- Sanitation Programs
- Sanitary Design
- Employee Training
- Environmental Monitoring
- Allergen Control

Foreign Supplier Verification Program (Section 301)

- ❖ Requires foreign supplier verification activities to verify that imported food is
 - Not adulterated
 - Produced in compliance with requirements of FSMA hazard analysis and preventive control sections

A Multinational Loaf

- ❖ **Wheat gluten** – France, Poland, Russia, Netherlands, Australia
- ❖ **Honey** – China, Vietnam, Brazil, Uruguay, India, Canada, Mexico, Argentina
- ❖ **Calcium propionate** – Netherlands
- ❖ **Guar gum** – India
- ❖ **Flour enrichments** – China
- ❖ **Beta-carotene** – Switzerland
- ❖ **Vitamin D₃** – China

14 Countries!!

Source: Amy Schoenfeld, New York Times



Source: Sara Lee

FSVP May Include (FSMA*):

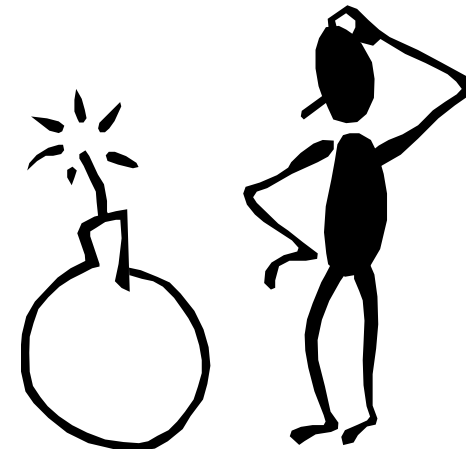
- ❖ Monitoring records of shipments*
- ❖ Lot-by-lot certification*
- ❖ Annual on-site inspections of foreign suppliers*
- ❖ Checking the hazard analysis and prevent controls plans of foreign suppliers*
- ❖ Periodic sampling and testing of shipments*
- ❖ Other tools from *GMA Food Supply Chain Handbook*

“Certification”

❖ Lots of confusion!!



❖ All imports will require certification =
FALSE !!!!



Though certification may
play a key role in other
FSMA components



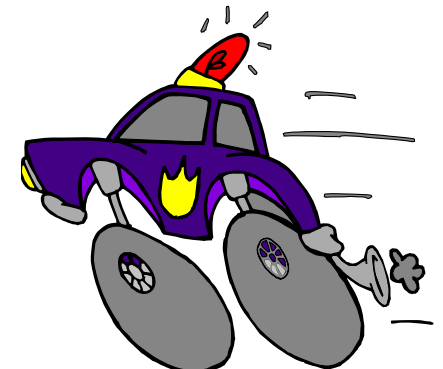
Voluntary Qualified Importer Program

Section (302)

- ❖ FDA to establish ... a VQIP to expedite movement of food through the import process
- ❖ VQIP is basically a fast lane through various import requirements



GMA

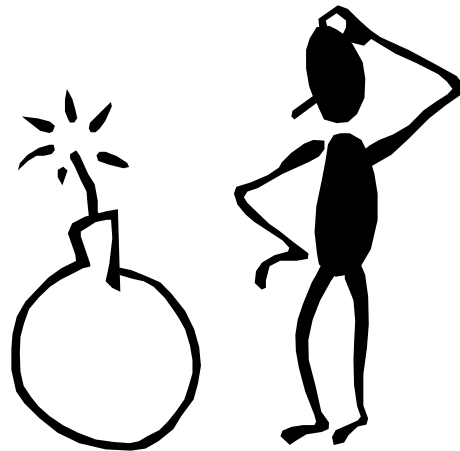


www.gmaonline.org

VQIP - Eligibility

Must be importing food from a facility that has been **certified** by an **accredited third-party auditor** under FSMA accreditation procedures (TBD)

Not to be confused with...



Import Certification

(Section 303)

- ❖ FDA authorized to require, as a condition of granting admission to an article of food,
 - An agency or representative of the government of the country from which the food originates, or an accredited third-party auditor, provide a **certification**, ... that the food complies with FD&C Act requirements.
- ❖ FDA may refuse to accept an **import certificate**
- ❖ FDA may require renewal of a certificate at any time.



FDA considerations

- ❖ Known safety risks of the food
- ❖ Known safety risks of the source country, territory, or region
- ❖ Findings by FDA that the food safety programs, systems, and standards in the region of origin are inadequate



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

- ❖ Section 106: Protection Against Intentional Adulteration
 - Plus hazard analysis mandated under section 103 (Preventive Controls) must include analysis of hazards involving **intentional adulteration**
- ❖ Section 108: National Agriculture and Food Defense
- ❖ Section 109: Food & Agriculture Coordinating Council

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)

“... Allied Bakeries has been hit with...deliberate cases of **malicious tampering** of its bakery products. The company reported ... 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...”

Company recalls nutrition bars

❖ Because an external manufacturer sourced peanuts from the Plainview, Texas plant of PCA

❖ **Food defense or food safety??**



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 emergency access to records provision of the law will also apply to security and food defense records such as security reports, access control records and CCTV.
- ❖ Are you prepared to turn over, support and explain these records to FDA?

Recordkeeping & Records Access

- ❖ The facility is required to maintain a copy of the facility's written preventive controls plan.
- ❖ Such records **must be made available to FDA** promptly upon oral or written request.

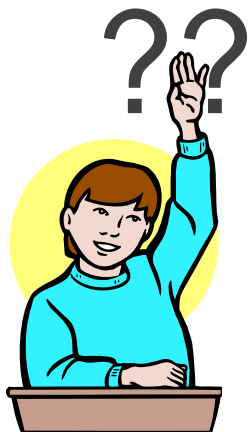
Summary

- ❖ 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.



¿Preguntas?

❖ QUESTIONS?



GMA

www.gmaonline.org