

# GMA

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



## Food Safety Modernization Act Update – Jan 2013

**FDA FOOD SAFETY  
MODERNIZATION ACT**



# Agenda

- Introduction and Overview
- 10 Key Takeaways
- Highlights from Major Provisions
- Key Points from the Produce Safety Proposed Rule
- FSMA Program Structure & Path Forward
- Question and Answer Session

# About the Grocery Manufacturers Association

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day.

The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.



# What is the Grocery Manufacturers Association?

- GMA represents the world's leading food, beverage and consumer product companies involved in global sourcing
- GMA provides leadership to the industry in food safety through promotion of scientific excellence
  - State of art research and analytical laboratory
  - Training in regulatory and food safety issues
  - Collaboration with U.S. government on food issues
  - GMA is a founding member of the APEC FSCF PTIN Steering Group

# GMA Member Companies



## General Members



## Associate Members

\*Represents a sample of GMA members

[www.gmaonline.org](http://www.gmaonline.org)

# Industry's Goal: Safety, Quality & Brand Protection

**The primary goal of a food company is to deliver safe, quality products to our customers & consumers while promoting & protecting our brands & trademarks.**

**We would like to work with regulating bodies to foster transparency from both sides.**

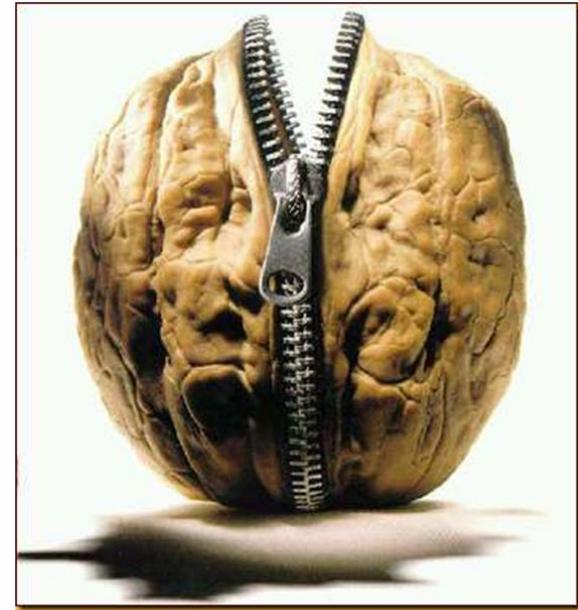
*It is in this spirit that we offer policy recommendations ...*

# Food Safety Modernization Act

- Food Safety Modernization Act
  - **January 4th , 2013: Two proposed rules released**
    - **Preventive Controls for Human Food**
      - Food Defense and Intentional Contamination to come later
    - **Produce Safety**
  - **120 day Comment Period – Due May 16<sup>th</sup> of 2013**
- FDA says that more proposed rules are forthcoming

# Overview of Preventive Controls Proposal

- Implements the Hazard Analysis and Risk-Based Preventive Controls provision of FSMA
- Updates and revises the cGMPs in Part 110
- Includes several exemptions and modified requirements
- Includes a subpart on recordkeeping
- Would place everything in a new Part 117



# 10 Key Takeaways

## 1. Proposed rule generally tracks the statute



# 10 Key Takeaways (continued...)

## 2. FDA generally provides industry flexibility

- Each facility to tailor food safety plan to its own circumstances

## 3. FDA generally aligned proposal with HACCP

## 4. Testing/supplier verification not required (yet)

- Cost implications and Economic analysis assumptions
- Requests comment on inclusion in final rule



HACCP  
HACCP  
HACCP



# 10 Key Takeaways (continued...)

## 5. Validation of preventive controls key issue

- FDA expects high level of scientific justification

## 6. High emphasis on recordkeeping/FDA access

- Always keep food safety plan on-site at least 6 months
- Facility profiles & remote access (requested comment)
- Electronic records (Part 11)

## 7. Updates to cGMPs

- Outgrowth of cGMP Modernization Initiative
- Would replace Part 110 in its entirety

# 10 Key Takeaways (continued . . .)

## 8. Defines small and very small businesses

## 9. Compliance dates

- 1 year for large businesses
- 2 years for small businesses
- 3 years for very small businesses

## 10. Warehouse exemption

- Non-refrigerated warehouses – exempt
- Refrigerated & Frozen warehouses – modified controls

**\*\* All from date of publication of Final regulation**

# Food Safety Plan

- Prepared (or preparation overseen) by “qualified individual”
- Signed and dated by owner, operator, or agent in charge initially and each time modified
- Would need to include:
  - Hazard analysis
  - Preventive controls
  - Procedures for monitoring (including frequency), corrective actions, and verification
  - Recall plan
- Would need to be written



# Hazard Analysis

- Identify and evaluate “known or reasonably foreseeable hazards” for each type of food
  - Proposal specifies categories of hazards to consider during identification
  - Proposal specifies factors to consider during evaluation, including:
    - Severity of illness
    - Environmental pathogens in RTE foods exposed to the environment
    - Foreseeable consumer use
- Determine which hazards are “reasonably likely to occur”
- Include a justification for conclusions reached



# Preventive Controls

- Identify and implement preventive controls for those hazards reasonably likely to occur
- Preventive controls must include, as appropriate:
  - Process controls
  - Allergen controls
  - Sanitation controls
  - Other controls
  - Recall plan
- Although FSMA identified cGMPs, s and employee hygiene as preventive controls, the proposed rule does not



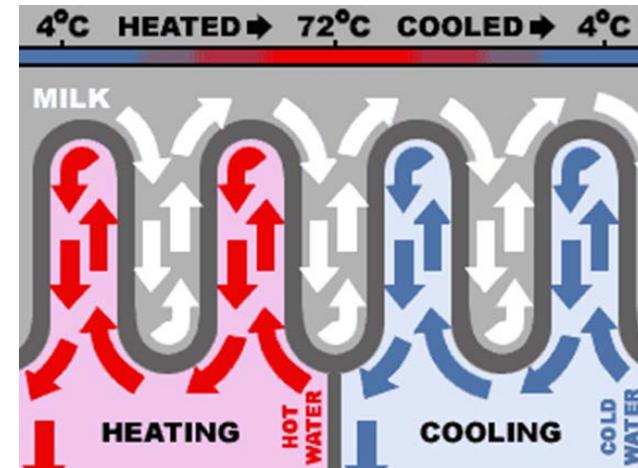
# Preventive Controls continued . . .

- Process controls: procedures, practices, and processes performed on food
  - Cooking, cooling, drying, acidifying, etc.
- Sanitation controls
  - Would be required in certain situations
  - Would need to include procedures for the cleanliness of food contact surfaces and the prevention of cross contact and cross contamination
- Allergen controls: procedures, practices, and processes to
  - Protect food from cross contact during storage and use
  - Ensure proper labeling



# Preventive Controls continued . . .

- Preventive controls may be implemented at critical control points (CCPs), and also may be implemented at points other than CCPs
- Parameters associated with the control (the factors that must be controlled) would be required
  - The maximum or minimum value or combination of values to which the parameter must be controlled
  - **This is similar to requiring critical limits at critical control points, but would apply to all preventive controls, whether at a CCP or another point**



# Recall Plan

- A written recall plan would be required
- Would be required to contain procedures for:
  - Notifying consignees
  - Notifying the public
  - Conducting effectiveness checks
  - Disposing of recalled product
- FDA is requesting comment on whether it should require:
  - A recall plan to include procedures for notifying FDA
  - Mock recalls as a verification activity



# Monitoring

- Establish and implement written procedures for monitoring preventive controls
  - Would include frequency of monitoring activities
    - FDA does not specify monitoring frequency, but states that monitoring must be performed at sufficient frequency to ensure that the preventive controls are being performed consistently
- Monitoring activities would be:
  - Documented
  - Subject to verification activities, including records review by a qualified individual within a week after the records are created

# Corrective Actions

- Establish and implement written corrective action procedures to be used if the preventive controls are not properly implemented, including procedures to:
  - Identify and correct a problem to reduce the likelihood it will recur
  - Evaluate all affected food for safety
  - Prevent affected food from entering commerce if its safety cannot be assured
- Take the same steps AND reanalyze the food safety plan if either specific corrective action procedures have not been established or a preventive control is ineffective
- Corrective actions would need to be documented and subject to verification and records review

# Recordkeeping

- New requirements would apply to all records required by new Part 117
- FDA is proposing to require facilities to establish and maintain records documenting
  - Written food safety plan
  - Monitoring of preventive controls
  - Corrective actions
  - Verification activities
  - Training for qualified individuals



# Records Access

- Records would be required to be made “promptly available to a duly authorized representative” “upon oral or written request”
  - FDA states this is consistent with its HACCP regulations, which require records be available for review and copying
  - FDA seeks comment on whether to explicitly require facilities to send records to the agency and whether they should be required to be submitted electronically
- FDA seeks comment on whether to require the submission of “facility profiles” (products, hazards, and preventive controls)



# Warehouses

- Exempt: Facilities solely engaged in the storage of
  - Non-refrigerated packaged food not exposed to the environment
  - Raw agricultural commodities (other than fruits or vegetables) intended for further distribution or processing
- Modified Requirements:
  - Facilities that store refrigerated packaged food that requires time/temperature control for safety (TCS)



# Refrigerated Warehouses

- FDA expects the warehouse to learn whether a particular food requires time/temperature control for safety from the manufacturer, the label, or the scientific/technical literature
  - Rare for a frozen food to be a TCS food
- Modified requirements:
  - Establish and implement temperature controls
  - Monitor temperature controls
  - Take corrective actions
  - Verify that temperature controls are implemented consistently (through calibrating devices and reviewing records)
  - Document monitoring, corrective actions, verification activities

# Other Exemptions/Modified Requirements

- “Qualified facilities”
- Very small businesses
- Certain low-risk on-farm activities
- Dietary supplements
- Alcoholic beverages
- Foods subject to seafood or juice HACCP
- Farms
- Microbiological hazards addressed by the LACF regulation

# Produce Safety Proposed Rule

- The proposed rule would apply to **almost all produce**
- Exemptions:
  - Specific commodities rarely consumed raw  
(e.g., potatoes)
  - Produce subject to a kill step through commercial processing, so long as documentation kept (e.g., oranges for juice)
  - Produce that is not a raw agricultural commodity
    - Subject to Preventive Controls



# Produce Safety Proposed Rule (continued...)

- Would set standards to control for 6 specific hazards
  - Worker Training and Health and Hygiene
  - Agricultural Water
  - Biological Soil Amendments
  - Domesticated and Wild Animals
  - Equipment, Tools, and Buildings
  - Sprouts
- Generally, more like cGMPs than HACCP



# Emerging issues

- Preventive Controls
  - Environmental monitoring requirements
  - Finished Product testing requirements
  - Supplier verification requirements
  - Record keeping: Compliance with Title 21 CFR Part 11
    - Defines criteria to ensure electronic records and electronic signatures are trustworthy, reliable and equivalent to paper records
    - Requires regulated organizations to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data that are used to maintain and document compliance with FDA regulations

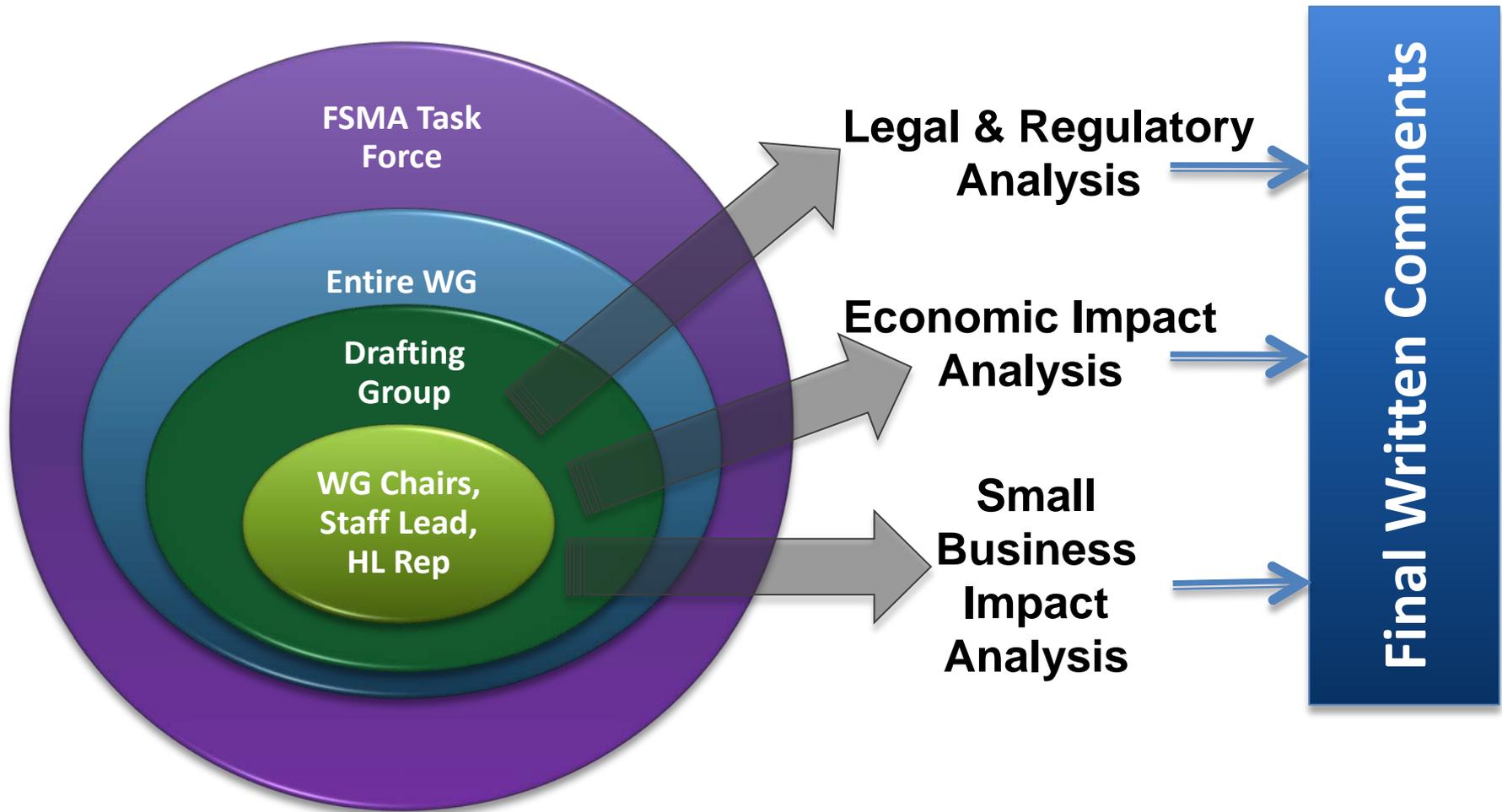
# Emerging issues

- Produce Safety
  - FDA did not apply a high risk/low risk approach to the rule therefore ANYTHING consumed raw is subject to this rule
  - Produce that has NOT been associated with an outbreak are included in the requirements
  - Potential for un-necessary costs to farmers who grow low risk products
  - United Fresh will be leading the development of comments and GMA will participate and determine if we need to submit our own comments

# Other points to consider

- Reading the tea leaves: moving the food industry closer to pharma and medical devices...
- Implementation issues to be aware of:
  - Validation: high level of scientific rigor
  - Focus will be on risk to public health
  - Verification, record keeping requirements and records availability will be taken to a new level...
- Potential trade implications within the *Tester Amendment* to exempt small and very small farms can create trade disputes for foreign facilities

# FSMA Team Structure & Process





# Preventive Controls Proposed Rule Organizational Structure

Thursday, January 17, 2013

## SRAC Executive Committee

**Food Safety Modernization Steering Group**  
Topic Principal: Leon Bruner  
GMA Staff Project Leader: Shannon Cole

- Overarching Issues
- Approve Comments

**Education and Training**  
Sponsor: D. Mastrococco  
WG Chair: R. Petran & K. Kastrop  
GMA Staff Lead: G. Black

- FSPCA Curriculum
- New Training Programs
- New Publications

**Rules and Regulations**  
Co-Sponsor: S. Geisert  
Co-Sponsor: O. Mignot  
GMA Staff Lead: S. Cole

**International Integration**  
WG Chair: B. Eldridge  
GMA Staff Lead: C. Stacy

- Embassy Briefings
- Mitigate Trade Implications

**Preventive Controls**  
WG Co-Chair: T. Jackson  
WG Co-Chair: D. Bresnahan  
GMA Staff Lead: W. Stone

- Hazard Analysis & Risk Based Prev. Controls
- Testing – Env & finished products
- GMPs

**Supply Chain Mngm't**  
WG Chair: B. Welshons  
WG Co-Chair: J. Scimeca  
GMA Staff Lead: F. Ataei & J. Dages

- Domestic Supplier Verification

**Inspections & Enforcement**  
WG Chair: P. Harvey  
WG Co-Chair: D. Baldwin  
GMA Staff Lead: L. Hontz

- Records Access
- Paperwork Reduction Act
- Facility Profiles

**Economic Impact**  
WG Chair: T. Borneman  
GMA Staff Lead: S. Cole & J. Downey

- Review FDA calculations
- Analyze SCV and testing costs
- Assist technical comments with economic impact

**Allergen Committee**  
WG Chair: C. Llewellyn  
WG Co-Chair: S. Estes  
GMA Staff Lead: S. Cole

- Allergen Preventive Controls
- Allergen Thresholds

# Active public dialog



Feb 15, 2013

SME Face to Face Meetings with FDA

Feb 28, 2013

FDA Public Meetings

May 16, 2013

Comments to Public Dockets

Jan 22, 2013

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

Update & Maintain SharePoint site for access to all FSMA related materials

# Additional Results to be Delivered

- **New Publications**

- Industry Food Safety Practices – Informing the FDA FSMA Rule Making Process (Pre-rule making FSMA book with copy of PR)
- Part I and Part II FSMA Manuals (mid year 2013)
- Potential additional publications:
  - Work with FSPCA to identify gaps
  - Comprehensive regulation guide (red-lined and reorganized PC proposed rule)
  - Side by side HACCP analysis (USDA HACCP, Seafood HACCP, Juice HACCP, Codex HACCP & FSMA HACCP)
  - Domestic and Foreign Supplier Verification
  - Compliance with 3<sup>rd</sup> party certification/accreditation rule
  - Others as needed

# Upcoming Proposed Rules

- Round I – Published Jan 16<sup>th</sup>, 2013
  - Preventive Controls for Human Food
  - Produce Safety
- Round II ... Date???....
  - Foreign Supplier Verification Program
  - 3<sup>rd</sup> Party Accreditation/Certification
  - Preventive Controls for Feed
- Round III
  - Safe Food Transport
  - Intentional Adulteration



**Enforcement dates to be specified in final rules  
and we anticipate final rules in 1 - 1½ years**

# Conclusion

- FDA responded in part to several of industry's concerns in the Proposed Rules
  - However, the proposed preventive controls requirements warrant close review
  - The absence of proposed requirements for testing and supplier verification pose special challenges
- FSMA Program is in full speed
- International Program to address trade concerns
- Economic assessment will be very important

**→ Lots of work ahead!**