

# FDA Food Safety Modernization Act

Presentation for Peanut and Tree Nut Processors Association

Joseph A. Levitt, Partner

January 17, 2011



# Agenda

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- How we got here
- Overview:
  1. New Responsibilities on Food Companies
  2. New Controls on Imports
  3. New or Enhanced FDA Enforcement Powers
  4. New Fees on Food Companies and Importers
- Implementation Timeline
- How to Prepare
- Key Issues for the nut industry

# How We Got Here

- Series of high profile food safety outbreaks
- Food safety standards in the FFDCA date back to 1906
- Strong support from the Obama Administration



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		DATE OF INSPECTION
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202 Industry Information: www.fda.gov/oc/industry		01/09/2009 - 01/27/2009*
NAME AND TITLE OF AGENCY TO WHOM REPORT ISSUED TO: Sammy L. Lightsey, Plant Operations Manager		FEDERAL NUMBER 1036857
FIRMS NAME Peanut Corporation Of America	STREET ADDRESS 14075 Magnolia St	
CITY, STATE, ZIP CODE, COUNTRY Blakely, GA 39823-1881	TYPE ESTABLISHMENT INSPECTED Peanut Roaster/Peanut Butter and Paste Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.		
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:		
<b>OBSERVATION 1</b>		
Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.		
Specifically, the firm's own internal microbiological testing found the following:		
Salmonella Typhimurium: Peanut paste under lot # 8278 was found contaminated with Salmonella Typhimurium by private laboratory testing conducted by the firm. After the firm retested the product and received a negative status, the firm shipped (b)(4) lb. of the product in interstate commerce. Additionally, this peanut paste was manufactured on 9/26/08 from (b)(4) lb. totes of roasted peanuts received on 9/25/08. The lots of roasted peanuts received on 9/25/08 were also used to produce the following products that were also shipped in interstate commerce: (b)(4) totes were used to manufacture (b)(4) peanut butter under lot # 8276; one tote was used to manufacture peanut butter for (b)(4) under lot # 8277 and (b)(4) under lot # 8277.		
Salmonella Anatum: Peanut Butter manufactured on 8/11/08 under lot # 8220 and # 8224 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.		
Salmonella Anatum: Peanut Meal and Medium Chopped Granules manufactured on September 24, 2008 under lot # 8268 tested positive for Salmonella Anatum by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.		
Salmonella (no strain identified): Medium Chopped Granules manufactured on June 16, 2008 under lot # 8168 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce.		
Salmonella (no strain identified): Small Chopped Granules manufactured on June 9, 2008 under lot # 8161 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped		
SEE REVERSE OF THIS PAGE	EMPLOYEE SIGNATURES Janet B Gray, Investigator <i>JBG</i> Darcy E. Brillhart, Microbiologist Sandra I. Gual, Investigator Robert P. Naligan, Investigator <i>RPN</i> Lesley K. Satterwhite, Microbiologist Theresa L. Stewart, Investigator <i>TLS</i>	DATE ISSUED 01/27/2009
	FORM FDA 482 (04/07) INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES	

# Legislative History

- July 2009, the U.S. House of Representatives passed H.R. 2749, the Food Safety Enhancement Act of 2009
- November 2009, Senate HELP Committee passed S. 510, the FDA Food Safety Modernization Act
- December 2010, Senate and House pass S. 510 equivalent as H.R. 2751
- January 4, 2011, President signs bill into law

II

111TH CONGRESS  
1ST SESSION

**S. 510**

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

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IN THE SENATE OF THE UNITED STATES

MARCH 3, 2009

Mr. DENNIS (for himself, Mr. GRASS, Mr. KROENKE, Mr. BUNN, Mr. DODD, Mr. ALEXANDER, and Mr. ISAKSON) introduced the following bill which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*  
3 SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-  
4 TENTS.  
5 (a) SHORT TITLE.—This Act may be cited as the  
6 “FDA Food Safety Modernization Act”.  
7 (b) REFERENCES.—Except as otherwise specified,  
8 whenever in this Act an amendment is expressed in terms  
9 of an amendment to a section or other provision, the ref-

# Passage Was Never Certain

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- **Senate Votes for FDA Food Safety Overhaul**, ABC News, Dec. 1, 2010
- **Constitutional provision jeopardizes sweeping food safety bill**, Washington Post, Dec. 2, 2010
- **Democrats attempt to revive food safety bill**, Assoc. Press, Dec. 8, 2010
- **Senate May Clear Path to Food Safety This Week**, Food Safety News, Dec. 14, 2010
- **Food Safety Bill in Doubt After Budget Concession**, Food Safety News, Dec. 17, 2010
- **Senate Passes Food Safety Bill**, Washington Post, Dec. 20, 2010
- **House Passes Overhaul of Food Laws**, New York Times, Dec. 22, 2010

# Main Elements of New Law

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1. New Responsibilities on Food Companies
2. New Controls over Imported Food
3. New or Enhanced Enforcement Powers for the FDA
4. New Fees on Food Companies and Importers

# 1. New Responsibilities for Food Companies

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- Impacting daily operations
  - Food Safety Plans/Preventive Controls
  - Supply Chain Management
  - Records Maintenance and Access
  - Food Defense Plans
- Applies to all Registered facilities

# Hazard Analysis and Preventive Controls

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- Conduct hazard analysis of hazards reasonably likely to occur
- Put into place controls designed to significantly reduce or prevent those hazards
- Implement preventive controls through monitoring, corrective actions, and verification activities
- Verification activities include environmental and finished product testing
- Reanalysis required every 3 years
- Food safety plan and all related records available to FDA during inspection

# Food Safety Plans – Hazard Analysis

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For hazards that may occur naturally or may be unintentionally introduced, identify and evaluate *known or reasonably foreseeable hazards* that may be associated with the facility:

- Biological
- Chemical
- Physical
- Radiological
- Natural toxins
- Pesticides
- Drug residues
- Decomposition
- Parasites
- Allergens
- Unapproved food and color additives

# Types of Controls Defined

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- Sanitation for food contact surfaces and utensils, including food contact surfaces of equipment
- Supervisor, manager, and employee training
- Environmental monitoring program
- Food allergen control program
- Recall plan
- Current Good Manufacturing Practices
- Supplier verification activities that relate to the safety of food

# Food Safety Plans – Critical Control Points

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- Identify and implement preventive controls at critical control points, *if any*
  - Critical Control Point: “...a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level”
- Congress envisions that some facilities might not have any critical control points

# Food Safety Plans – Verification

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Operator must verify that

- Preventive controls are adequate to address the identified hazards
- Monitoring of the controls is in place
- Appropriate decisions are being made regarding corrective actions
- Preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards
  - “including through the use of environmental and product testing programs and other appropriate means”
- Documented, periodic reanalysis of the hazard plan to ensure it is still relevant to the facility and to new and emerging threats

# Supply Chain Management

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- Know who your suppliers are (not just distributors)
- Have a plan for assuring adherence to food safety requirements
- Appropriate to make plan risk-based according to product type and facility history
- Goal is to assure product not adulterated or misbranded (due to undeclared allergens)

# Records Maintenance and Access

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- FDA will have legal access to see and copy records related to:
  - Food safety plan and related documents
  - Includes environmental and finished product testing
  - Includes corrective actions and related rationale
  - Includes monitoring of supply chain
- Good documentation practices will be critical

# Exemptions

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- Deemed compliance for facilities subject to seafood HACCP, juice HACCP, and Low Acid Canned Food (microbiological elements)
- Limited exemption for very small businesses with sales less than \$500,000, where majority of food is distributed directly to consumers or restaurants, and distribution is intrastate or within 275 mile radius
- FDA has authority to modify or exempt
  - Warehouses for packaged food
  - Storage facilities for raw agricultural commodities
  - Animal food or feed

# Intentionally Introduced Hazards (Food Defense)

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- To be included in hazards analysis, including hazards that may be introduced by acts of terrorism
- “Reasonably foreseeable standard” does NOT apply
- Implement appropriate mitigation steps
- FDA to issue regulations

# Not To Be Forgotten

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- Bi-annual registration
- Safety standards for fruits and vegetables
- Traceability
- Records access under Bioterrorism Act

# Traceability

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- Limited to “high risk” foods
- FDA to conduct pilot projects, gather additional data, assess the cost and benefits and feasibility, and consider international systems
- May not prescribe the use of specific technologies or require creation of duplicate records
- May not require “full pedigree”
- Exemption for “commingled raw agricultural commodities”
- FDA has access to farm distribution information in case of an outbreak
- FDA to propose regulations within 2 years

## 2. New Controls Over Imported Food

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- Supply chain verification procedures
- Foreign facilities subject to all the same requirements as U.S.-based facilities
- FDA authority to require third party certification for food safety-related reason
- Accredited laboratory must be used for certain testing
- Expedited entry at border if safety and security guidelines met



# Supply Chain Management – Foreign Suppliers

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## Foreign Supplier Verification Program

- Each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer is
  - Produced in compliance with the Food Safety Plan requirements
  - Produced in compliance with produce safety regulations to be promulgated by FDA
  - Not adulterated or misbranded under 403(w)
- Importer: “...the United States owner or consignee of the article of food at the time of entry of such article into the United States” or the U.S. agent or representative of a foreign owner or consignee

# Supply Chain Management – Foreign Suppliers

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Verification activities may include (but are not limited to)

- Monitoring records for shipments
- Lot-by-lot certification of compliance
- Annual on-site inspections
- Checking the hazard analysis and risk-based preventive control plan of the foreign supplier
- Periodically testing and sampling shipments

# Supply Chain Management – Foreign Suppliers

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FDA is required to take action to flesh out the foreign supplier verification program

- FDA will issue guidance documents to assist importers in developing their foreign supplier verification programs
- FDA will promulgate regulations to provide content for the foreign supplier verification program
- For sneak preview, see FDA's draft guidance on Good Importer Practices, January 2009

### 3. New or Enhanced Enforcement Powers for FDA

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- Increased inspection frequency
  - High Risk Domestic – every 3 years
  - Low Risk Domestic – every 5 years
  - Ramp up Foreign inspections  
(600 to 9,600 over 5 years)
- Suspension of registration
- Mandatory recall
- Expanded administrative detention authority



## 4. New Fees on Food Companies and Importers

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- Reimbursement to FDA
  - Reinspections
  - Recall (very limited)
- Export certificates
- Fast lane for imports
- Note that reinspection fees and export certificate fees may start in 2011



# Provisions NO LONGER in Bill

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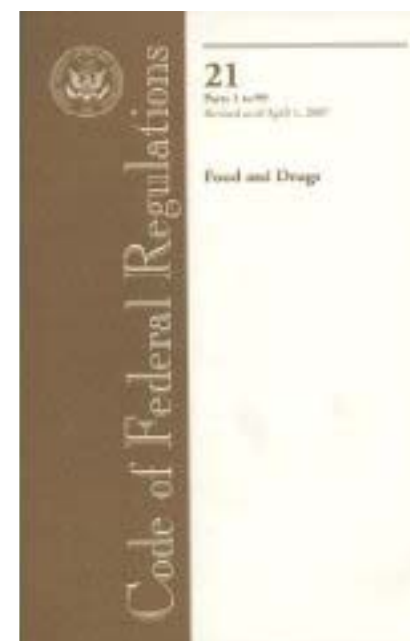
- Registration Fees
- Civil Money Penalties
- Increased Criminal Penalties
- Quarantine Authority
- Subpoena Authority
- Reports of Finished Product Testing
- Remote Access to Records by FDA
- “Full Pedigree” Traceability
- Country-of-Origin Labeling
- BPA



# Implementation Timetable

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- Various effective dates for different provisions
- Longer implementation time for small and very small businesses
- Basic timeline
  - 18 months – food safety plans
  - 24 months – foreign supplier verification
  - Longer for traceability
  - Bi-annual registration begins 2012
- Detailed schedule for FDA regulations and guidance
- Key provisions become effective even without FDA regulations



# Implementation Timetable

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- Provisions immediately effective
  - Mandatory Recall
  - Records Access under Bioterrorism Law

# Due Dates for Regulations

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The statute includes the following due dates for required rulemakings:

- **120 days:**
  - § 304 – Prior Notice (interim final rule)
  - § 207 – Administrative Detention of Food (interim final rule)
- **1 year:**
  - § 301 – Foreign Supplier Verification Program (final rule)
  - § 105 – Produce Safety (proposed rule; final rule within 1 year of close of comment period)
- **18 months:**
  - § 103 – Preventive Controls (final rule)
  - § 106 – Food Defense (final rule)
  - § 111 – Sanitary Transportation of Food (final rule)
- **2 years:**
  - § 204 – Traceability (proposed rule for “high risk” foods)
- **No deadline:**
  - § 102 – Suspension of Registration (interim final rule)

# Due Dates for Guidance Documents

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The statute includes the following due dates for Guidance Documents:

- **1 year:**
  - § 105 – Produce Safety (Updated Good Agricultural Practices)
  - § 106 – Food Defense
  - § 301 – Foreign Supplier Verification Program
- **18 months:**
  - § 302 – Voluntary Qualified Importer Program
- **No Deadline:**
  - § 103 – Preventive Controls

# How to Prepare: Items for immediate focus

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- Food Safety Plans (and Food Defense Plans)
  - Hazard analysis
  - Prevention controls
  - Verification, including testing
- Supply claim management
  - Domestic
  - Foreign
- Records maintenance and access
  - Routine
  - Under Bioterrorism Act

# Key Issues for Nut Industry

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- Nuts will likely be considered “high risk”
- Added emphasis on suppliers
- Added emphasis on testing
- Added emphasis on food allergen control

# Conclusion

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- Food companies should focus on 3 areas
  - Food safety plans (including food defense)
  - Supply chain management (foreign and domestic)
  - Records maintenance and access policies
- FDA to issue regulations and guidance
  - Past is prologue
  - Review mandatory HACCP regulations
  - Review draft guidance documents

# Resource Materials

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- Client Memorandum dated December 21, 2010, entitled, “Congress Passes Landmark Food Safety Legislation”
- Section-by-Section Analysis, dated December 21, 2010
- Side-by-Side Comparison of New Law with Current Law, dated December 21, 2010
- Highlights of Major Provisions of New Food Safety Legislation, attached to January 5, 2011 client memorandum announcing President signing new law.

# Contact Information

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