

*CASOS DE RECALL Y  
OBSERVACIONES SOBRE LA  
APLICACIÓN (CASES OF  
RECALL AND HINTS FOR  
APPLICATION)*

Ronald H. Schmidt  
Professor Emeritus  
University of Florida  
Gainesville, FL USA

[schmidt2@ufl.edu](mailto:schmidt2@ufl.edu)

**INOFOOD**  
7 y 8 de noviembre / Casa Piedra / Santiago  
**CUMBRE / EXPO 2011**  
INTERNACIONAL DE INOCUIDAD ALIMENTARIA

# RECENT HIGH PROFILE FOOD RECALLS IN THE NORTH AMERICA – HOW THEY DIFFER & LESSONS LEARNED



# WHAT I PLAN TO COVER

## o **Two Contrasting Food Recalls**

- **Maple Leaf Foods, Canada**
- **Peanut Corporation, USA**

## o **Fresh Produce Recalls**

- **Time Permitting**





®



# MAPLE LEAF FOODS, TORONTO, ONTARIO, CANADA

- o Since 1927
- o Deli Meat Products & Other
- o > \$5 Billion Annual Sales



# *MAPLE LEAF FOODS – LISTERIA MONOCYTOGENES OUTBREAK 2008*

## o **Summary of Outbreak**

- **57 Confirmed Cases**
- **23 Deaths**

## o **Products Involved**

- **Deli Meats**
  - o **Sandwiches**
  - o **Related Products**



# ***MAPLE LEAF FOODS – TIMELINE OF OUTBREAK & RECALL***

## **○ Mid-July 2008**

- **Listeriosis Discovered in Nursing Home**
- **Canadian Food Inspection Agency (CFIA) Investigation Launched**

## **○ 6 August 2008**

- **Positive Microbiological Test**

## **○ 12 August 2008**

- **CFIA Notified *Maple Leaf* of Investigation Underway**

## **○ 13 August 2008**

- ***Maple Leaf* Notified Distributors**



# ***MAPLE LEAF FOODS – TIMELINE (CONTINUED)***

## **○ 16 August 2008**

- **Maple Leaf *Sure Slice* Roast Beef and Corned Beef Implicated**

## **○ 17 August 2008**

- **Maple Leaf Recalls *Sure Slice* Products**

## **○ 20 August 2008**

- **Other Products Implicated by CFIA**
- **Outbreak Nationwide**
- ***Maple Leaf* Expands Recall to 23 Product Lines**

## **○ 22 August 2008**

- ***Royal Touch* Recalls *Shopsy's Reuben* Sandwiches**





# ***MAPLE LEAF FOODS – TIMELINE (CONTINUED)***

## ***○ 23 August 2008***

- Tests Firmly Establish Link to Toronto Plant***

## ***○ 24 August 2008***

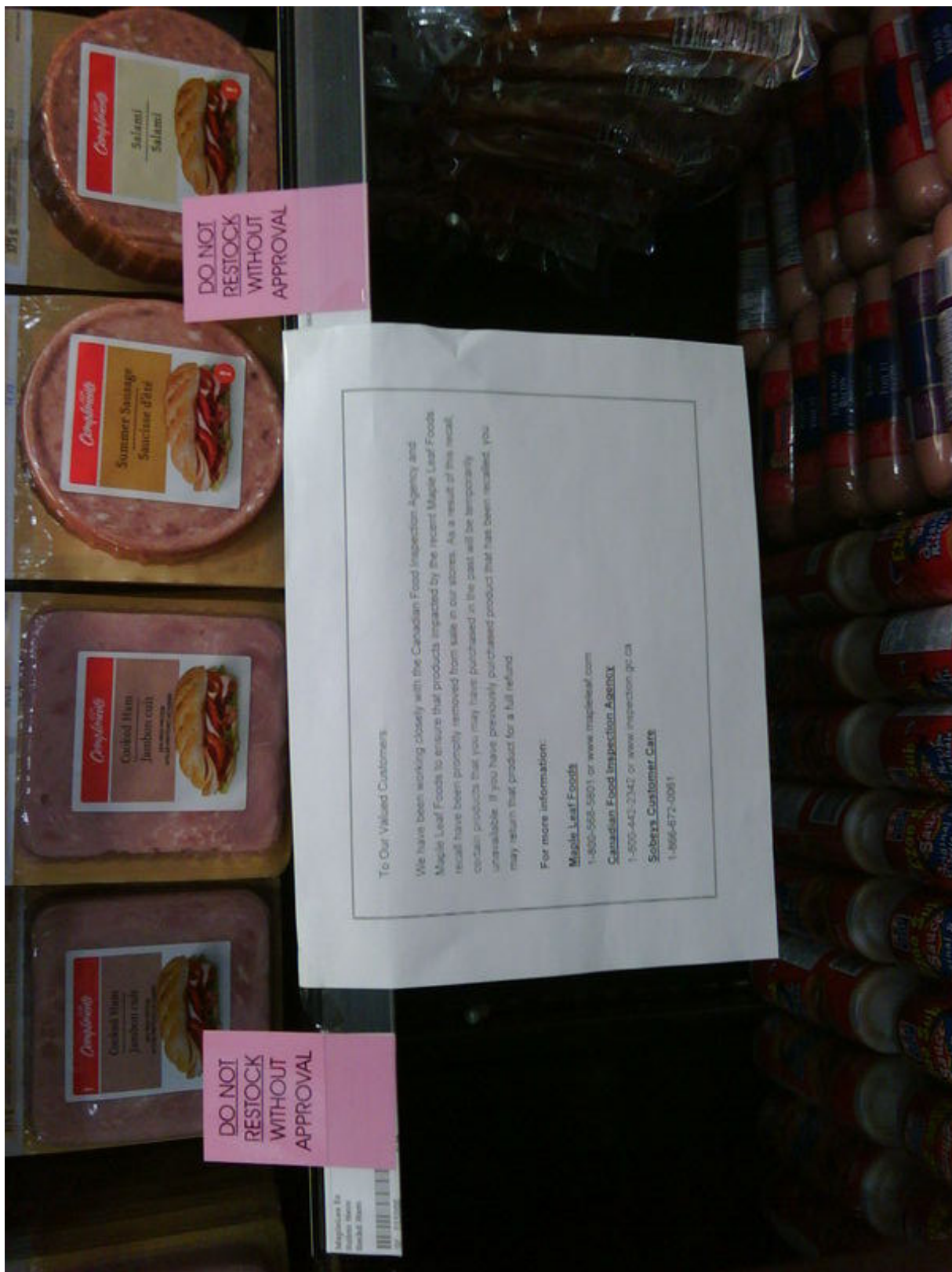
- Maple Leaf Expands Recall***
  - All 220 Items Produced In Toronto Plant***

## ***○ 25 – 27 August 2008***

- Recall Expands to Other Sandwich Manufacturers Linked to *Maple Leaf Foods****
  - Lucerne Meats***
  - Atlantic Prepared Foods, Ltd.***
  - Metro Ontario, Inc.***

## ***○ Approximately 6 Weeks From First *Listeriosis* Case***





**To Our Valued Customers:**

We have been working closely with the Canadian Food Inspection Agency and Maple Leaf Foods to ensure that products impacted by the recent Maple Leaf Foods recall have been promptly removed from sale in our stores. As a result of this recall, certain products that you may have purchased in the past will be temporarily unavailable. If you have previously purchased product that has been recalled, you may return that product for a full refund.

**For more information:**

- Maple Leaf Foods**  
1-800-968-9801 or [www.mapleleaf.com](http://www.mapleleaf.com)
- Canadian Food Inspection Agency**  
1-800-443-2342 or [www.inspection.gc.ca](http://www.inspection.gc.ca)
- Sebra's Customer Care**  
1-866-872-0081

**DO NOT  
RESTOCK  
WITHOUT  
APPROVAL**

**DO NOT  
RESTOCK  
WITHOUT  
APPROVAL**

Maple Leaf Foods  
1-800-968-9801  
www.mapleleaf.com

# *MAPLE LEAF FOODS – RECOVERY*

- September 2008

- Toronto Plant Reopened

- February 2009

- Maple Leaf Class-action Suit Settlement
  - \$27 M Nationwide

- October 2011

- Closing Toronto Plant
- “Not Related To Outbreak”
- New “State Of The Art” Plant In Hamilton, Ont.
  - \$395 M



# **MAPLE LEAF FOODS OUTBREAK – TIMELINE OF REGULATORY, POLITICAL & MEDIA ISSUES**

## **○ 3 September 2008**

- **Prime Minister Pledges an Independent Investigation**

## **○ 4 September 2008**

- **Liberal Party Calls for the Resignation of Agriculture Minister**
  - **Accusing Him of “Staging a Cover-up”**

## **○ 12 September 2008**

- **Ontario Health Department – Laboratory Director**
  - ***“Canadians Should Have Known About the Outbreak Earlier .....*”**



# ***MAPLE LEAF FOODS OUTBREAK – TIMELINE OF REGULATORY, POLITICAL & MEDIA ISSUES***

## **○ 20 January 2009**

- **Independent Investigation Commenced**
- **Report to be Issued by July 2009**

## **○ 17 April 2009**

- **Ontario Department of Health Issued a Report**
  - **Recommended Strengthening Ability to Respond**
- **Federal Agencies Issued Reports**
  - **CFIA, Health Canada, Public Health Agency**
  - **Suggested Lack of Expertise in Meat Hygiene**



# **MAPLE LEAF FOODS OUTBREAK – TIMELINE OF REGULATORY, POLITICAL & MEDIA ISSUES**

## **○ 11 June 2009**

- **Media Investigative Report (*CBS* and *Toronto Star*)**
  - **Critical of Federal Inspection Program**

## **○ 20 July 2009**

- **Independent Investigation Report Issued**
  - **57 Recommendations**
- **Media Calls for Report to be Released and Made Public**

## **○ 11 September 2009**

- **Federal Government Announces Plan to Implement the 57 Recommendations**



# MAPLE LEAF FOODS – HIGH GRADES RECEIVED ON RECALL

## ○ Reacted Rapidly

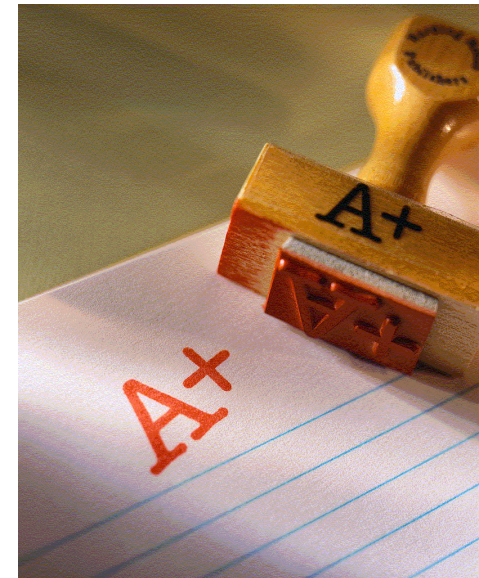
- Initiated Recall of 23 Products within a Day of Notification
- Upgraded Recall to 220 Products a Day Later

## ○ Reacted Efficiently

## ○ Reacted Professionally

- High Positive Visibility with Media
- CEO, Michael McCain
  - Became Spokesperson
  - Press Conferences
  - Apology on Website

## ○ Spent Some \$\$\$\$



## Michael McCain, *Maple Leaf Foods*, CEO – At Press Conference



*“It is not about the money. It is about Public Health”*



**WAS IT JUST GOOD LUCK OR BECAUSE THEY HAD (AND PROPERLY IMPLEMENTED) A PLAN?**

## **oLuck?**

- Some Luck Involved**
- There Was Negative Press**
- Media Focused More on the Regulatory Agencies**

## **oImplemented a Plan?**

- Definitely A Key Factor**





# *PEANUT CORPORATION OF AMERICA (PCA)*

## ○ **Founded in 1977**

- **Lynchburg, Virginia**

## ○ **Processing facilities**

- **Blakely, Georgia**
- **Suffolk, Virginia**
- **Plainview, Texas**

## ○ **Products**

- **Peanuts, Peanut Butter**
- **Peanut Meal, Peanut Paste**

## ○ **Widespread Distribution**

- **Supplied Institutions and Food Processors**
- **Approximately 2.5% of US Processed Peanuts**

## ○ **Approximately \$25 M Annual Sales**



# *PEANUT CORPORATION OF AMERICA (PCA)*

## oPCA Facilities

- **Blakely, Georgia**

- o Packed Peanut Butter in Bulk
- o Peanut Paste

- **Plainview, Texas**

- o Blanched, Split, Granulated and Roasted Peanuts
- o Peanut Meal

## oSubsidiary Facilities



# PCA OUTBREAK AND RECALL – *SALMONELLA* TYPHIMURIUM 2008-2009

## ○ **Outbreak Summary**

- **>700 Cases in 46 States**
- **Approx. 50% Children**
- **23% Hospitalized**
- **9 Deaths**

## ○ **Products**

- **Peanut Butter, Peanut Paste, Peanut Meal**



# PCA – Historical Issues

## ○ Sanitation Issues

- Dating Back to 1980s

## ○ 1990s

- Peanut and Peanut Product Recall
  - Aflatoxin
- Lawsuits
  - American Candy Company – Peanut Butter (Aflatoxin)
  - Zachary Confections Inc - Peanuts (Aflatoxin)

## ○ 2001

- FDA Inspection
  - Equipment Maintenance and Repair Issues
  - Sanitation Issues
  - Insects



# PCA – TIMELINE (CONTINUED)

## ○ 1 September 2008

- First Illness Case

## ○ 23 October 2008

- Second Death (Tennessee)

## ○ 24 November 2008

- Facility Inspection (Georgia Dept. of Agriculture)
  - Equipment Maintenance and Repair Issues
  - Sanitation Issues

## ○ 25 November 2008

- Incidences Reported in 16 States
- Peanut Butter Likely Cause



# PCA – OUTBREAK & RECALL TIMELINE

## ○ December 2008

- Clear Association with Peanut Butter

## ○ 21 December 2008

- First Death (Nursing Home, Minnesota)
- *King Nut* Peanut Butter Implicated

## ○ January 2009

- *King Nut* Peanut Butter Tested Positive
- Road led to *Peanut Corp. of America*
- Recall Began
- Approximately 3.5 Months Since First *Salmonellosis* Case

## ○ March 2009

- Westco Fruit & Nut (PCA Customer) Refused to Recall
- FDA Seizure





# Timeline of Infections: Multistate Outbreak of Salmonella Infections Associated with Peanut Butter and Peanut Butter-Containing Products — United States, 2008–2009

## Outbreak Identification & Source Implication

**November 25, 2008**  
Epidemiologic assessment of first Salmonella typhimurium cluster begins (35 cases in 16 states)

**November 24, 2008**  
CDC PulseNet identifies first multistate cluster of Salmonella typhimurium infections (19 cases in 12 states). CDC begins searching for additional reports of cases with same DNA fingerprint

**December 2, 2008**  
Epidemiologic assessment of second Salmonella typhimurium cluster begins (41 cases in 17 states)

**December 4, 2008**  
Both clusters followed with parallel assessments

**January 3 & 4, 2009**  
First case-control study data collection

**January 12, 2009**  
Results of first case-control study indicate association with consumption of peanut butter

**January 15, 2009**  
International Health Regulation notice posted

**January 17, 2009**  
CDC & FDA advisory regarding peanut butter & peanut butter-containing products

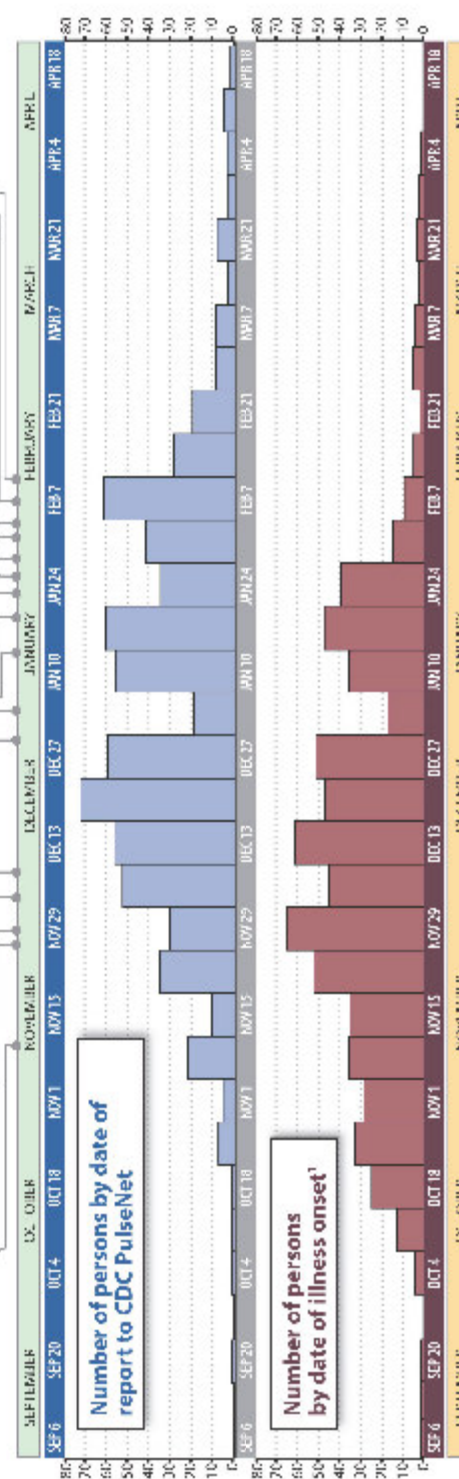
**January 19, 2009**  
Second case-control study data collection

**January 29, 2009**  
MMWR summarizing investigation findings published

**February 5, 2009**  
OR Dept of Health reports dog pet treats Salmonella +

**February 10, 2009**  
OR Dept of Health confirms outbreak strain in dog pet treats

**January 30, 2009**  
CO Dept of Health reports cases among persons who ate fresh ground peanut butter from 3 locations of a health food store chain



## Regulatory Actions, Recalls, & Results of Product Testing

**January 9, 2009**  
MN Dept of Health reports Salmonella from spoiled container of King Nut peanut butter — FDA begins investigation of FPCW facility in Bibbity, GA

**January 10, 2009**  
King Nut Co. issues recall of peanut butter

**January 12, 2009**  
MN Dept of Health confirms outbreak strain in spoiled container of King Nut peanut butter

**January 14, 2009**  
Kellogg Co. announces recall of Austin & Keebler brands of peanut butter crackers

**January 16, 2009**  
CT Dept of Health finds outbreak strain in unopened container of King Nut peanut butter — PCA announces recall of peanut butter & paste — Kellogg Co. recalls Austin & Keebler brands of peanut butter crackers

**January 21, 2009**  
FDA begins investigation of PCA facility in Plainview, TX

**January 23, 2009**  
PCA expands recall

**January 29, 2009**  
Peanut paste from tanker truck reported to be Salmonella +

**February 2, 2009**  
Peanut paste from tanker truck confirmed to be outbreak strain

**February 12, 2009**  
TX issues order directing PCA Texas facility to stop production and distribution of all products and to recall all manufactured since 01/01/09

**February 15, 2009**  
Outbreak strain confirmed in fresh ground peanut butter from CO health food chain and peanut meal from PCA Texas facility

**February 20, 2009**  
PCA issues a statement informing customers to cease distribution and use of products from Georgia and Texas plants

\*Some illness onset dates have been estimated from other reported information  
†There is an inherent delay between the date that an illness starts, and the date that someone who got sick first went to a health care provider  
‡The name of someone who got sick first went is very unlikely to have been reported yet, and someone who got sick three weeks ago may not be reported now  
§Peanut Corporation of America

(Data as of 04/20/09)  
05230489

# PCA RECALL SUMMARY

## ○ PCA

- **Everything Produced at Blakely, Georgia Facility**
- **Everything Produced at Plainview, Texas Facility**
  - **Since 2005**

○ **>1,550 Peanut Products**

○ **>350 Companies**

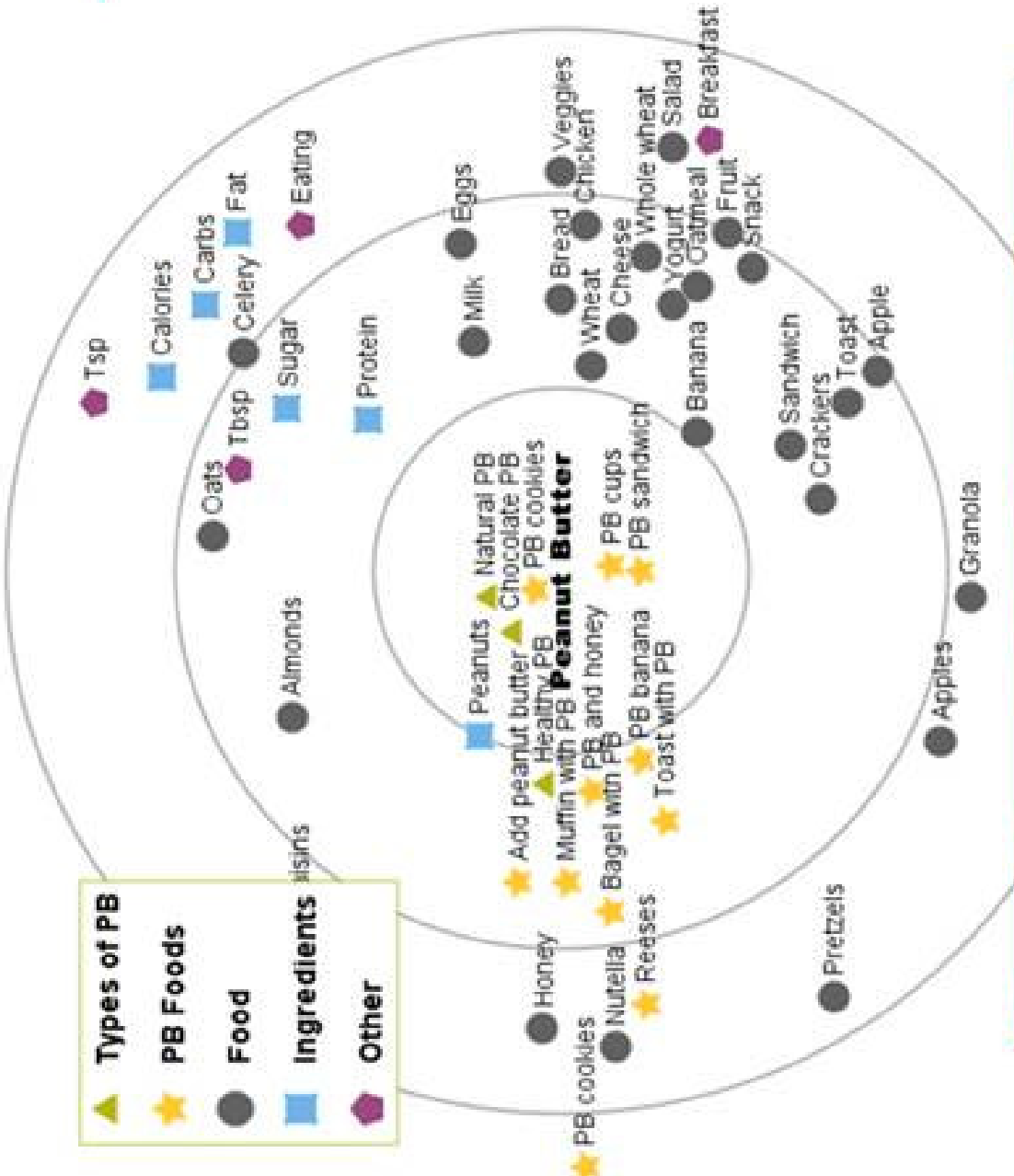
○ **Largest in US History**



# THE RECALL

- **Very Far Reaching “Ingredient Driven” Recall**
  - **Involving Many Companies**
  - **PCS Supplied Some of the Largest Food Makers In US**
  - **Products Found in Nearly Every Retail Grocery Chain in US**
- **List of Recalled Products Kept Expanding**
  - **<http://www.accessdata.fda.gov/scripts/peanutbutterrecall/index.cfm>**
  - **Cereals, Cookies, Crackers, Candy, Ice Cream (To Name A Few)**





# Brand Association Map: Pre-Recall

Period Reviewed: 12/15/2008 – 1/9/2009 Source: All content sources:



# OTHER ISSUES WITH PCA



# FDA INSPECTION - BLAKELY, GEORGIA (9 JANUARY 2009)

## ○ General Sanitation Issues

- Mold growing on ceiling and walls
- Foot-long gaps in its roof
- Insects near peanuts
- Holes in the plant big enough for rodents to enter

## ○ Improper Equipment Cleaning & Sanitizing

## ○ Raw and Finished Product Not Properly Segregated



# FDA INSPECTION OF OTHER PCA FACILITIES

## ○ Plainview, Texas Facility

- Never Licensed in Texas
- Fined \$14.6 M
- Major Sanitation Issues
  - Rodents

## ○ Subsidiary Facilities

- Sanitation Issues
- Many not Licensed



# FDA FINDINGS

## ○ Refused Records Access

- FDA Used Provisions of the Bioterrorism Act to Gain Access

## ○ *Salmonella* Testing Irregularities

- If Positive *Salmonella* - Test Until Negative Obtained – Then Ship
- Positive *Salmonella* Results – Product Shipped





# FDA FINDINGS

- **“Less Than Desirable” Lot Identification System**
  - **Increased the Number of Products Recalled by Manufacturers**
- **State Regulatory Inspection?**
  - **Noted Sanitation Violations on Inspection Form**
    - **Deemed Them to be Minor**
- **Third Party Audit?**
  - **Auditor Gave “High Scores” to the Facilities**



# PCA CEO/OWNER - STEWART PARNELL AT CONGRESSIONAL HEARING



# PARNELL – UNCOVERED EMAIL STATEMENTS REGARDING SALMONELLA TESTING AT PCA

## ○ To FDA Official

- *"we have never found any salmonella at all. No Salmonella has been found anywhere in our products or in our plants"*

## ○ To PCA Personnel Regarding Positive Samples

- *"costing us huge \$\$\$\$\$" ..... "Let's turn them loose"*
- *"I go thru this about once a week,"*
- *"I will hold my breath ... Again."*



# AFTERMATH OF RECALL

## ○ Congressional Investigation Hearings

- Parnell Repeatedly Refused to Respond to Questions

## ○ Criminal Investigation

- Pending
- Federal Bureau of Investigation (FBI) Sealed the Facilities (February 2009)



# AFTERMATH OF THE RECALL

- **Litigations Pending**
- **Estimated Cost (Several \$ Billion)**
  - **Food Processing Industry**
  - **Peanut Growers**
  - **Human Costs, Medical Costs**
  - **Regulatory Costs (e.g. Cost of Inspection, Epidemiology, Recall)**



# AFTERMATH OF THE RECALL

- **Peanut Corporation of America Filed Bankruptcy**
  - February 2009 - 24 hours after the Texas Recall
  - “Attempt to Shield Itself from Liability Suits” (Consumers Union)
- **Other Companies Involved?**
  - Some Recovered
  - Many Are Out of Business
- **Regulatory**
  - Major Factor in the *FDA Food Safety Modernization Act (2011)*



# DID PCA GET HIGH GRADES ON THE RECALL AND THE RECOVERY FROM THE RECALL?



# PEANUT CORPORATION OF AMERICA – LOW GRADE

- Reacted Slowly & Deceitfully
- Reacted Inefficiently
- Reacted Unprofessionally
  - **High Negative Visibility with Media**
- Tried to Avoid Spending \$\$\$\$





WAS IT JUST BAD LUCK OR BECAUSE THEY DID NOT HAVE (AND/OR DID NOT PROPERLY IMPLEMENT) A PLAN?

oLuck?

- Yes... Who Expects to Get Caught?

oLack of An Implemented Recall Plan?

- Definitely A Key Factor



# **A FEW WORDS ABOUT FRESH PRODUCE**



# FRESH PRODUCE – DIFFICULT SYSTEM

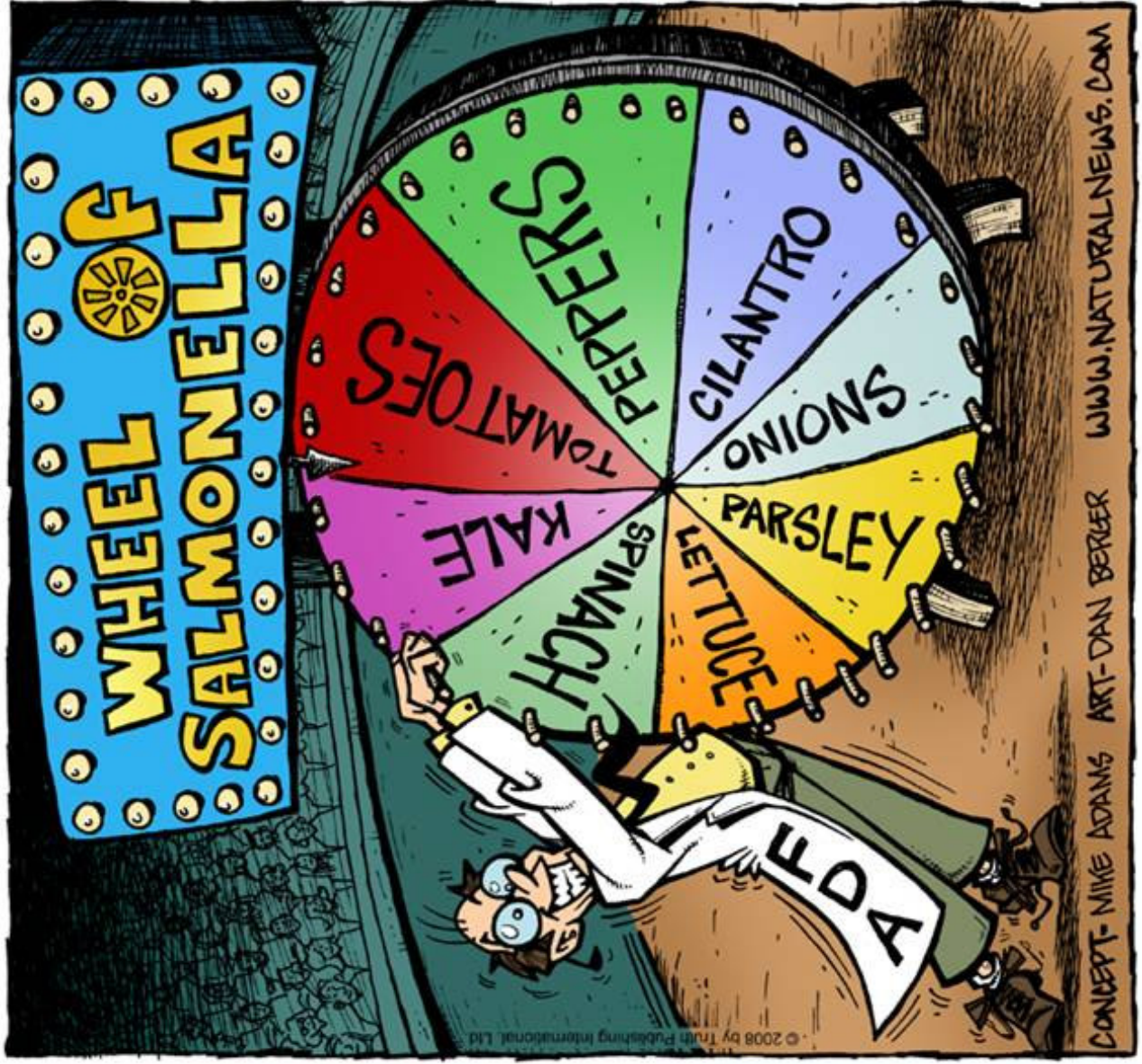
- **Open Environment**
- **Culture Issues**
  - **Growing, Packing Practices**
    - **Have Always Done it This Way**
  - **Transient Work Force**
- **Complexity of Distribution System**
- **Complexity of Epidemiology**
- **Complexity of Traceback**
- **Complexity of Recalls**



# 2008 TOMATO RECALL – ERROR IN EPIDEMIOLOGY



COUNTER THINK - "WHEEL OF SALMONELLA"



CONCEPT- MIKE ADAMS ART-DAN BERBER WWW.NATURALNEWS.COM



# AFTERMATH OF TOMATO RECALL

- **Estimated Cost in > \$40 M for Florida Tomato Industry**
  - Similar in other states
- **Pending Litigation**
- **Mandatory Tomato Good Agriculture Practices (tGAPs) Program in Florida**
- **Possibly Better Epidemiology (???)**
  - Fresh Produce Very Difficult
- **Punctuated the Need for Better Trace-back System**





# JENSON FARMS – COLORADO (SEPTEMBER 2011)

- **Outbreak**
  - 133 Cases Increasing?)
  - 29 Dead (And Increasing?)
- **Source of Contamination**
  - Poor Sanitary Design
  - Field to Packing House
- **Third Party Auditor Under Scrutiny**
  - Gave High Score
- **What They Are Saying**
  - Underscores Weak Points in System
  - Suggests Need for More Efficient Oversight
  - Etc. Etc. Etc.
- **Recall Effectiveness?**
  - Too Early to Tell





# FOOD RECALL

- Do Not Assume That It Could Not Happen to You
- Follow a Plan Involving Best Practices
- Test the Plan and Practice, Practice, Practice
- React Professionally, Rapidly & Efficiently



GRACIAS

