Best Industry Practices and Current Good Manufacturing Practices for Peanut and Peanut Product Manufacturers*

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Topics to be Addressed

- Recent *Salmonella* events in the nut industry
- Characteristics of *Salmonella*
- Current Good Manufacturing Practices for peanut processors
- Hazard Analysis Critical Control Point System for peanut processors
- Verification of *Salmonella* controls
- Corrective actions for *Salmonella* contamination

Peanut Corporation of America

- 714 cases of *Salmonella* Typhimurium infection in 46 states between Nov 2008 - Apr 2009
- Associated with peanut butter and peanut paste produced by Peanut Corporation of America, Blakely, GA
  - *S*. Typhimurium and several other *Salmonella* serotypes isolated from intact peanut butter products
  - Austin and Keebler peanut butter crackers made from PCA peanut paste were associated with human illnesses, and outbreak strain was isolated several peanut butter crackers
  - More than 3000 peanut-containing products produced by many companies were recalled

Centers for Disease Control and Prevention, Morbid. Mortal. Weekly Rep. 58:1-6, Jan 26, 2009

What Went Wrong?

- *Salmonella* detected in ca. 12 PCA peanut products by third-party laboratories over 2-year period
  - Company had *Salmonella*-contaminated products retested and released them into commerce after retest results were *Salmonella*-negative
- Recent third party audit report gave high, passing rating with few comments
  - Company was given prior notice (several weeks) to prepare for audit

What Went Wrong?

- Georgia Department of Agriculture inspections (at least 2 annually) did not for prior 2 years report serious deficiencies
- FDA inspectors following outbreak reported leaky roof, gaping hole in roof, vermin (insect and rodent) activity, peanut roaster not validated to kill *Salmonella*, water accumulation in dry side of processing plant, did not clean and sanitize plant after *Salmonella* was isolated from product and continued manufacturing on the line for more than 3 months

Setton Pistachio of Terra Bella

- U.S. Food and Drug Administration informed by Kraft that pistachio-containing products collected over several months (2008-2009) were contaminated with several serotypes of *Salmonella*
  - Some of the *Salmonella* isolates matched DNA pulsotypes of isolates in CDC PulseNet data base

Setton Pistachio of Terra Bella

- All of the contaminated pistachios came from Setton Pistachio of Terra Bella, CA
  - All pistachios from 2008 and some from 2007 crops were recalled
  - Contaminated pistachios were used in cakes, cookies, puddings, trail mix, snack bars and ice cream
  - More than 660 product entries were recalled

Centers for Disease Control and Prevention, Morbid. Mortal. Weekly Rep., April 14, 2009

What Went Wrong?

- FDA isolated *S*. Montevideo from 3 environmental samples in processing plant
- Failure to segregate raw and RTE products
  - Some common handling equipment was used for raw and RTE products without cleaning and sanitation in between

Sources of *Salmonella* Contamination

- Primary sources of salmonellae are intestinal tracts of animals (domestic and wild) and humans; shed in feces
  - Feces can contaminate soil and water (irrigation and processing)
  - Salmonellae can survive in some soils for months to years; in water for weeks to months

Examples of Potential Sources of *Salmonella* Contamination of Peanuts During Production

- Field fertilized with untreated manure or sewage as a soil amendment
  - *Salmonella* can survive in soil for months or years
- Field irrigated with water contaminated with animal waste
  - Untreated surface water (ponds, rivers) with runoff from livestock operations
- Wildlife grazing on or near fields

Examples of Potential Sources of *Salmonella* Contamination of Peanuts During Storage

- Leaks in roof on which birds congregate
- Rodent and insect activity, especially if facility is near livestock operations
- Forklift and transport equipment exposed to mud, water or contaminated soil outdoors brought into sheds and warehouses without prior cleaning and disinfection

Essential Conditions for *Salmonella* Growth

- Food/Nutrients
- Water/Moisture Content
- Temperature

Characteristics of *Salmonella* in Association with Peanut Products

- *Salmonella*
  - Can survive for months to years in low moisture foods such as nonfat dry milk, peanut butter, chocolate
  - Small numbers of this bacterium can produce illness when consumed in high-fat foods such as chocolate (< 1 *Salmonella*/g), peanut butter, cheese

Characteristics of *Salmonella* in Association with Peanuts and Peanut Products

- *Salmonella*
  - Heat resistance increases with decreased moisture content/water activity

    Example

    165°F (instantaneous) kills > 10,000,000 (>7 log) *Salmonella*/g in ground beef, milk, poultry

    194°F for 50 min kills 100,000 (5 log) *Salmonella*/g in peanut butter

    305°F (oven dry heat) for 15 min kills 100,000 (5 log) *Salmonella*/g on peanuts

Characteristics of *Salmonella* in Association with Peanut Products

- *Salmonella*
  - Growth prevented by low moisture content (water activity < 0.95)
  - Growth typically prevented by temperature less than 5°C (41°F) or greater than 46°C (115°F)
    - Optimum temperature for growth is 35 - 37°C (95 - 99°F)

Principles Used in Mitigating Risks of Pathogen Contamination of Peanut

- Preventing contamination throughout the entire cycle, from production to mouth
- Applying control interventions from production to mouth
  - Moisture, temperature, vermin controls
  - Detection of pathogens and indicators of pathogen contamination by testing
  - Chemical antimicrobials
  - Thermal treatments
  - Non-thermal physical treatments (e.g., irradiation, high pressure)
- Responding rapidly to pathogen contamination and taking effective corrective action

The principles used in mitigating risks of pathogen contamination of foods such as peanut products are applied by the food industry using a systems approach that includes:

- Sanitation Standard Operating Procedures (SSOP)
- **Current Good Manufacturing Practices (cGMP)**
- **Hazard Analysis Critical Control Point Systems (HACCP)**

Current Good Manufacturing Practices

- Some basics of any food safety program described in the Code of Federal Regulations Part 110 – Current GMPs in Manufacturing, Packing or Holding Human Food
  - Describe general rules for maintaining sanitary conditions that must be followed for all food processing facilities

cGMPs for Peanut Processors

- Personnel Practices
- Buildings and Facilities
- Equipment
- Process Controls

cGMPs – Personnel Practices

- Train employees and monitor implementation of basic sanitation and good hygienic practices
  - Formal training program in basic hygienic principles
  - Emphasize proper hand washing techniques
  - Prevent cross contamination between “dirty” and clean areas

cGMPs – Buildings and Facilities

- Grounds maintained to prevent pest harborage
- Buildings designed to facilitate safe food production, and maintenance and sanitation operations
- **Establish a "Primary *Salmonella* Control Area" that begins at the roaster and ends after packaging**
- Maintain sanitary condition and repair of facilities

Buffer Area at Entrance to Primary *Salmonella* Control Area

- Entry and exit doors to PSCA tightly fitted, internal cores filled, and self-closing
- Floor properly sloped towards non-critical side; no drains
- Bench provided for shoe change; shelves for dirty and clean shoes
- Hands-free hand washing sink; located on non-critical side or just outside of buffer area; paper towels to dry hands; minimize and contain any moisture on floor
- Treat hands with disinfectant after shoe change

Barriers and Controls to Maintain Hygiene in Primary *Salmonella* Control Area

- Identify areas in facility in relation to stringency of necessary hygienic requirements
  - First priority – prevent product contact surface contamination with *Salmonella*
- Map all circulation of people, incoming materials, waste, rework, etc. on flow chart
  - Restrict access to PSCA to essential personnel and activities
- Establish barriers (e.g., sampling, maintenance)
- Controls to Maintain Hygiene in Primary *Salmonella* Control Area

Controls to Maintain Hygiene in Primary *Salmonella* Control Area

- Define construction and equipment design standards to meet hygiene requirements
- Protect PSCA during equipment installation to prevent uncontrolled access by personnel/items
- Establish routine procedures that describe barriers and protocol for passing into PSCA
- Establish procedures to monitor and document barrier efficiency
- Establish procedures for maintenance (routine and unscheduled)
- Establish master sanitation schedule for equipment and processing environment
- Train all personnel regarding entry into PSCA

cGMPs – Sanitation Best Practices

- Establish a master sanitation schedule
- Use wet or dry cleaning procedures as appropriate
  - Dry cleaning uses vacuum cleaners, cloths, brooms and brushes
  - Wet cleaning should include complete cleaning and sanitizing cycles
    - Avoid partial wet cleaning without sanitizing
    - Thorough cleaning with water **must** be followed by sanitizing and drying
- Use dry cleaning as the routine cleaning practices in Primary *Salmonella* Control Area
  - Keep this area dry; preferably no floor drains; no cracked or damaged floors; keep air in this area dry
  - No product accumulation on walls, pipes, ceilings, equipment

cGMPs – Pest Control

- No pests allowed in any area of food plant
- Pest-proof facility

cGMPs – Process Controls: Raw Materials

- Obtain *Salmonella*-sensitive ingredients (including nutmeats) from approved supplier
- Develop a testing program for sensitive ingredients
  - Implement a hold and release program
  - Use approved testing laboratories
  - Use FDA or ICMSF sampling plan
  - If sample tests *Salmonella*-positive, the tested lot is considered adulterated and not released into commerce
    - Retesting to negate the initial test results is not an option
- Store *Salmonella*-sensitive ingredients in separate area

cGMPs – Process Controls: Raw Materials

- All sensitive ingredients (including peanuts and other nut meats) should be sampled and tested prior to use
  - Aflatoxin, moisture content, grade and microbiological testing (especially when cross contamination potential exists) are recommended using approved AOAC testing methods
- Establish controls to segregate ingredients known to be potentially contaminated with *Salmonella* such as raw nuts

cGMPs – Process Controls: Raw Materials

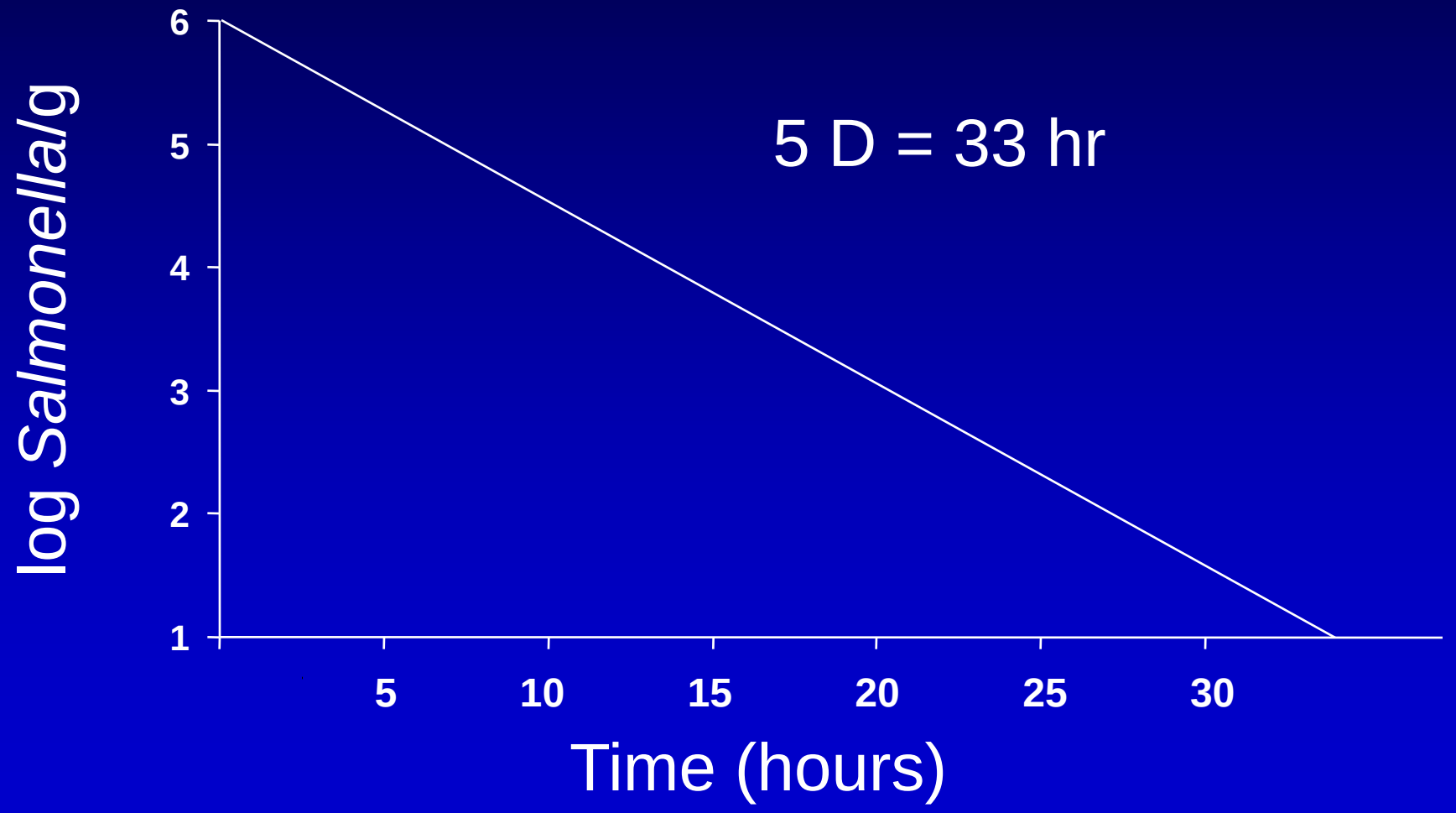
- Prevent cross contamination
  - Raw or unprocessed nuts should be separated from processed or RTE foods
  - Use dedicated forklifts, utensils and maintenance tools for the Primary *Salmonella* Control Area (post lethality area vs. raw or pre-lethality area)
  - Outline traffic patterns and ensure employee compliance through training
  - Maintain the highest room air pressure in PSCA and include the air handling system in the master sanitation schedule

Hazard Analysis Critical Control Point System (HACCP)

HACCP for Peanut and Peanut Product Processors

- Thermal processing is a common treatment (CCP) employed by the nut industry for mitigating pathogenic bacterial hazards

Theoretical Thermal Inactivation Curve for *Salmonella* in Milk Chocolate at 160°F (71°C)



Thermal Inactivation of Pathogens

- Thermal processes are designed to kill a minimum number of a target pathogen (e.g., *Salmonella* or *E. coli* O157:H7)
  - Heat ground beef to internal temperature of 160°F to kill 100,000 (5 log) *E. coli* O157:H7/g
  - Heat canned foods to kill 12 log (12D) of *Clostridium botulinum* spores/g
  - Heat poultry to internal temperature of 165°F to kill 5 log *Salmonella*/g
  - Heat almonds (peanuts) to kill at least 10,000 (4 log) *Salmonella*/g

What Should Be the Targeted Log Reduction for *Salmonella* on Nuts/Nut Products to Ensure Safety?

Thermal Inactivation of *Salmonella* in Peanut Butter[a]

Internal Temperature (°C / °F)	Mean maximum time (min)		
	3-log reduction	5-log reduction	7-log reduction
71 / 160	107	402	965
77 / 170	62	197	423
83 / 181	33	110	227
90 / 194	21	49	120

[a] Commercial, creamy-style peanut butter; a_w = 0.45, pH = 5.1

Ma et al., J. Food Protect. July 2009

Considering the high temperature and extended heating time needed to kill 5 log of *Salmonella* in peanut butter (49 min at 194°F or 3.3 h at 170°F), this is not likely a suitable treatment to render a product of acceptable quality

Therefore, the key **critical control point** to ensure safety from *Salmonella* contamination from raw nuts in peanut butter/product manufacture is the whole nut roaster

If the roaster conditions are designed to kill 100,000 (5 log) *Salmonella*/g, then the incoming load of *Salmonella* on peanuts must be less than 5 log or greater than 1 *Salmonella* will be present per gram of peanuts

- Areas of localized *Salmonella* growth, as occurs with *A. flavus* for aflatoxin production, can be a confounding factor

Thermal Inactivation of *Salmonella* on Unblanched Virginia Peanuts by Dry Roasting

Oven Temp (°C / °F)	Time (min)	log reduction
129 / 264	45	4.3
146 / 295	15	4.9
163 / 325	10	5.8

S. Goodfellow (Deibel Lab)

Verification of *Salmonella* Controls

- Verify adequacy of *Salmonella* controls on an ongoing basis
  - Implement a robust environmental monitoring program
    - Provides a microbiological assessment of plant's environment, effectiveness of sanitation program, and overall *Salmonella* control program
    - Use to correct problem areas before they pose risk to finished product

Verification of *Salmonella* Controls

- *Salmonella* should be the target microbe for environmental monitoring of low-moisture foods
  - A suitable indicator for *Salmonella* has not been identified; it is more persistent in environment than indicator microbes such as fecal coliforms
- Emphasize testing Primary *Salmonella* Control Area but also areas of wet processing and handling of raw materials
- Highest frequency of testing in areas near product contact surfaces

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of Sample Sites	Frequency	Number of Samples
Zone 1	Product contact surfaces (PCS) in the Primary *Salmonella* Control Area	Conveyors, filler hoppers, scrapers/utensils, packaging equipment	Post-Sanitation or as needed for verification purposes	Line Dependent
Zone 2	Non-PCS within close proximity to PCS in Zone 1. - areas that, if contaminated, could reasonably lead to PCS contamination	Exterior of equipment, legs/frameworks, catwalks, control panels, scrap carts, HVAC vents, air filters	Weekly, Biweekly, or Monthly	5-10

Example of an environmental monitoring program for production of low-moisture foods

Sampling Zone	Definition	Examples of Sample Sites	Frequency	Number of Samples
Zone 3	Non-PCS within process area but more removed from PCS. - areas that, if contaminated, could **not** reasonably lead to PCS contamination without mechanical or human intervention	Cleaning tools, floor scrubbers, forklifts, floor drains, ingredient storage areas	Weekly or Monthly	3-6
Zone 4	Non-PCS outside processing areas - areas that, if contaminated, could spread to the processing area via foot or equipment	Compactor areas, employee entrances, locker rooms, labs	Monthly or Quarterly	2-4

Verification of *Salmonella* Controls

- Periodic finished product testing
  - Sampling plans described in FDA BAM and by ICMSF; official testing method (FDA BAM or ISO 6579) should be used
  - Tested lot should be isolated, placed on hold and not released into commerce until *Salmonella*-negative results are received
  - If product sample tests positive for *Salmonella*, the lot is considered adulterated and should not be released into commerce

USDA Commodity Microbiological Criteria

Microbe	Criterion
Salmonella	Negative/25g
E. coli	< 3.6/g MPN
Coliforms	< 10/g MPN
Aerobic Plate Count	< 10,000 CFU/g
Yeast	< 100 CFU/g
Mold	< 100 CFU/g

Corrective Actions for *Salmonella* Contamination

- Corrective actions **must** be taken when *Salmonella* is detected in environmental or finished product sample
  - Corrective actions taken should be based on an assessment of the potential for finished product contamination

Examples of Corrective Action Following Positive *Salmonella* Findings in the Plant Environment

- Initiate pre-assigned response team to conduct a preliminary investigation to determine potential cause or source for the contamination.
- Take immediate actions to correct any GMP deficiencies based on findings. These may include:
  - Quarantine the suspect area and limit access to the area.
  - Reinforce hygienic practices with appropriate employees (retrain if necessary)
  - Re-examine cleaning frequencies and revise as appropriate.
  - Eliminate water and water collection points, if present.
  - Repair damaged floors/walls and other structural damage as appropriate.
  - Re-examine traffic patterns. Where necessary and feasible, limit traffic flows (both employees and mobile equipment) through the area, restrict fork truck movement, redirect high risk traffic patterns from adjacent areas, etc.

Conclusions

- Peanuts are now considered high-risk foods and sensitive ingredients with regard to *Salmonella* contamination
- The low-moisture, high-fat content of peanuts contributes to the:
  - High temperature, extended time required to kill *Salmonella*
  - Lower infectious dose of *Salmonella*
  - Long-term persistence of *Salmonella* in peanut products

Conclusions

- Mitigation of *Salmonella* contamination of peanuts should be addressed from production to consumption
- Peanuts should be produced and stored under conditions to prevent *Salmonella* growth
- The roaster is critical to ensuring the safety of peanuts
  - Temperature-time conditions for nut roasting must be validated to ensure efficacy in killing the targeted number of *Salmonella*
  - Roaster conditions, including peanut bed depth and uniform loading, and accurate monitoring of temperatures and time, must be properly controlled

Concluding Comments

- FDA will be introducing more advanced methods for detecting foodborne pathogens and toxicants, and substantially increasing the percentage of food imports sampled and tested

Concluding Comments

- Continuing advances in the U.S. foodborne disease surveillance system will result in detection of more outbreaks and tracebacks that previously would not have been detected or the source identified, including minor ingredients

Concluding Comments

- Federal agencies will likely place greater responsibilities on food-associated companies to ensure safety of foods and food ingredients

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  - Control of *Salmonella* in Low Moisture Foods report