The “Nuts” and Bolts of Food Safety—Implications for Almonds

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Given by Barbara Cassens, Director of FDA San Francisco District on 8-4-10

*For Posting*
Salmonella Continues to be a Challenge

- 7,039 infections
- 15.2 infections/100,000 population
- US population = 309,277,115
- ~47,000 cases a year (X 38=1.79 million)
- 45% of cases ≥ 50 were hospitalized
- 1.2% of cases ≥ 50 died

Preliminary 2009 FoodNet Data (active surveillance)
Relative Rates of Laboratory-Confirmed Infections

![Graph showing relative rates of laboratory-confirmed infections for different bacteria species over the years 1996-2008. The graph indicates fluctuations in the relative rates of Vibrio, Salmonella, Campylobacter, and Listeria.](image)
Recent *Salmonella* outbreaks linked to Peanuts and Peanut Butter

<table>
<thead>
<tr>
<th>Year</th>
<th>Product implicated</th>
<th><em>Salmonella</em> Serovar</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>Peanut butter</td>
<td>S. Mbandaka</td>
<td>Australia</td>
</tr>
<tr>
<td>1996</td>
<td>Peanut-flavored maize snack</td>
<td>S. Agona</td>
<td>Multiple (^a)</td>
</tr>
<tr>
<td>2001</td>
<td>Peanuts</td>
<td>S. Stanley, S. Newport</td>
<td>Multiple (^b)</td>
</tr>
<tr>
<td>2006-07</td>
<td>Peanut butter</td>
<td>S. Tennessee</td>
<td>US</td>
</tr>
<tr>
<td>2008-09</td>
<td>Peanut butter, peanut butter-containing products</td>
<td>S. Typhimurium</td>
<td>US, Canada (^c)</td>
</tr>
</tbody>
</table>

\(^a\) Including UK, US, and Israel.
\(^b\) Including Australia, Canada, and UK.
\(^c\) One case was reported in Canada.

Data adapted from Scott et al., 2009
Recent *Salmonella* outbreaks linked to Tree Nuts

<table>
<thead>
<tr>
<th>Year</th>
<th>Product implicated</th>
<th>Salmonella Serovar</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000-01</td>
<td>Raw almonds</td>
<td>S. Enteritidis</td>
<td>US, Canada</td>
</tr>
<tr>
<td>2003-04</td>
<td>Raw almonds</td>
<td>S. Enteritidis</td>
<td>US, Canada</td>
</tr>
<tr>
<td>2005-06</td>
<td>Raw almonds</td>
<td>S. Enteritidis</td>
<td>Sweden&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>Suspected
## Isolation of *Salmonella* from Nuts

<table>
<thead>
<tr>
<th>Nut / Nut Products</th>
<th>Serovar</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almond</td>
<td>Enteritidis [+34, Danyluk et al., 2007]</td>
</tr>
<tr>
<td>Cashew</td>
<td>Mbandaka, Weltevreden</td>
</tr>
<tr>
<td>Hazelnut</td>
<td>Thompson, Typhimurium</td>
</tr>
<tr>
<td>Lotus nut</td>
<td>Meleagrisidis</td>
</tr>
<tr>
<td>Macadamia nut</td>
<td>Aberdeen</td>
</tr>
<tr>
<td>Peanut</td>
<td>Altona, Mbandaka, Tennessee, Typhimurium, Livingstone, Newport, Senftenberg, Lexington</td>
</tr>
<tr>
<td>Pecan</td>
<td>Anatum, Typhimurium, Hadar, Javiana, Newport, Panama, Kentucky, Sandiego</td>
</tr>
<tr>
<td>Pistachio</td>
<td>Montevideo, Cubana, Senftenberg, Newport</td>
</tr>
<tr>
<td>Walnut</td>
<td>None Found</td>
</tr>
</tbody>
</table>

Courtesy of Dave Melka, FDA
RFR *Salmonella* Contamination Events

- Granola bars, nutrition bars
- Spices: leaf savory, pepper, cumin
- Soy grits, soy flour, soy protein concentrate
- Rice flour
- Nuts: pine nuts, hazelnuts, macadamias
- Seeds: sesame
- Non-fat dry milk
- Hydrolyzed vegetable protein
Prevalence and Numbers of *Salmonella* in Nuts

- Expected to be low, but data lacking
- **Almonds** (Danyluk et al., 2007. J Food Prot. 70:820-827)
  - 0.87% of 9,274 samples
  - 1.2 - 2.9 MPN/100g
- **Brazil nuts; mixed nuts** (Little et al., 2010. Food Micro. 27:171-174)
  - 0.4% of 469 samples; 0.9% of 105 samples
  - <0.01-0.23/g
## Low Numbers Can Cause Illness

<table>
<thead>
<tr>
<th>Year</th>
<th>Serovar</th>
<th>CFU/g</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006-07</td>
<td>S. Tennessee</td>
<td>0.1-1</td>
<td>Peanut butter</td>
</tr>
<tr>
<td>2000-01</td>
<td>S. Enteritidis</td>
<td>0.07-0.10</td>
<td>almonds</td>
</tr>
</tbody>
</table>
Characteristics of *Salmonella* in Foods

- **Growth in foods**
  - Temperature: from 5.2°C to 46.2°C
  - pH: from 3.8 to 9.5
  - $a_w$: from 0.94 to >0.99

- **Heat resistance in foods**
  - Wide strain-to-strain variation
  - Dependent on pH, $a_w$, and food matrix

- Freezing is not effective in eliminating *Salmonella* from foods

- *Salmonella* survives long periods of dehydration
# Heat Resistance of *Salmonella*

<table>
<thead>
<tr>
<th>Salmonella Serovar</th>
<th>Product</th>
<th>Water Activity</th>
<th>Temperature (°F)</th>
<th>D-value (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Typhimurium</td>
<td>Chocolate Syrup</td>
<td>0.83</td>
<td>150</td>
<td>3.2</td>
</tr>
<tr>
<td>S. Typhimurium</td>
<td>Salt solution</td>
<td>0.42</td>
<td>248</td>
<td>8.9</td>
</tr>
<tr>
<td>S. Typhimurium</td>
<td>Salt solution</td>
<td>0.31</td>
<td>248</td>
<td>10.6</td>
</tr>
<tr>
<td>S. Typhimurium</td>
<td>Milk Chocolate</td>
<td>?</td>
<td>158</td>
<td>816</td>
</tr>
<tr>
<td>S. Typhimurium</td>
<td>Milk Chocolate</td>
<td>?</td>
<td>194</td>
<td>75</td>
</tr>
<tr>
<td>S. Enteritidis</td>
<td>Almonds – oil roasted</td>
<td>? [&lt;0.65]</td>
<td>250</td>
<td>0.85</td>
</tr>
<tr>
<td>S. Enteritidis</td>
<td>Almonds - blanched</td>
<td>? [&lt;0.65]</td>
<td>158</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Data adapted from Chen et al., 2009
Thermal Inactivation of *Salmonella*

Data from Li Ma et al., 2009. J. Food Protect. 72:1596 – 1601.
Peanut Butter Processing

- Heating of peanut butter at 190°F for less than 30 min is not sufficient to kill large populations (5 log CFU/g) of Salmonella in highly contaminated peanut butter.
Heat resistance of *Salmonella* on Nuts

• Heat resistance at low water activity
  – Because heat resistance of *Salmonella* increases with reduction of water activity, the ability to destroy *Salmonella* on nuts is complicated by the low water activity of nuts.

• Dry Heat is less effective than moist heat
  – The ability to destroy *Salmonella* on nuts during roasting is dependent on the moisture status at the surface of the nut, not the humidity of the bulk air.
Survival in Peanut Butter

• 5 serotype composite (Agona, Michigan, Montevideo, Enteritidis, Typhimurium)
• Stored at 5°C or 21°C
• With an inoculum of 5.7 log CFU/g, after 24 weeks
  – at 21°C, log reduction was 4.1-4.5
  – at 5°C, log reduction was 2.9-4.3
• With an inoculum of 1.5 log CFU/g, after 24 weeks
  – 6 of 7 products stored at 5°C were positive for Salmonella
  – 6 of 7 products stored at 21°C were negative for Salmonella

Survival on Pecans

• In-shell pecans
  – S. Senftenberg 775W and S. Anatum survived > 8 weeks, S. Typhimurium >32 weeks at 21°C
  – Less reduction at lower temperatures (5, -7 and -18°C)

• Pecan halves
  – S. Senftenberg 775W and S. Typhimurium survived > 16 weeks, S. Anatum >32 weeks at 21°C
  – Only slight reduction at lower temperatures (5, -7 and -18°C)

Survival of SE PT30 on Almonds

Uesugi et al. 2006. J. Food Protect. 69: 1851-1857
Challenges with *Salmonella* and Nuts

- Nut processing is a dusty environment – easy to spread *Salmonella* on dust particles
- Nut processing facilities are relatively dry environments where *Salmonella* can survive
- The introduction of water can allow *Salmonella* in the environment to multiply, enhancing the potential for contamination
Challenges with *Salmonella* and Nuts

- Not all nuts are treated with a kill step.
- When nuts do receive a kill step, strict controls to prevent recontamination are not always in place.
- There has been limited validation of kill steps.
Salmonella kill steps

• A process validated for one nut does not necessarily apply to another.
• Nut roasters are generally not designed to “pasteurize” nuts in a controlled and verifiable way.
  – Lack of data on actual product time-temperature profiles
  – Improved designs are needed for dry nut roasting equipment
Recontamination is a Concern

• A validated kill step can be compromised by recontamination
  – Physical separation of raw and processed areas
  – Personnel and traffic control – prevent transfer of contamination between areas
  – Environmental monitoring – seek to find
FDA Activities

• As a result of contamination of nuts with *Salmonella* in 2009, FDA issued an assignment to the field to inspect nut processing facilities in FY 2010.

• The assignment includes environmental monitoring to assess the potential for nut contamination from the environment.
FDA Activities

Guidance for Industry

Measures to Address the Risk for Contamination by *Salmonella* Species

– Food Containing a Peanut-Derived Product as an Ingredient (March 2009)
– Food Containing a Pistachio-Derived Product as an Ingredient; Draft Guidance (June 2009)
FDA Activities

Educational Visits to CA Tree-Nut Industry

• Growers and Processors of Pistachios, Almonds, and Walnuts
• Extensive work done by almond industry to address *Salmonella* contamination
• Pistachio industry initiating programs to address *Salmonella* contamination
• Walnut industry following what other nut industries are doing; FDA has not, to date, found *Salmonella* in walnuts; need to understand “why”; what is different?
FDA Activities

Reconditioning Proposals

• Recalled Pistachios

• Recalled Cashews, Hazelnuts, Macadamia Nuts
Customer Testing

- Customers of nuts to be used without a kill step, e.g., trail mix, cereal, are testing.
- There have been *Salmonella* positives that have led to nut recalls.
Why the continuing problem?

• Lack of understanding of the ecology of *Salmonella*
• Lack of understanding of the risks from *Salmonella* in low-moisture foods
• Lack of understanding of the factors that increase the risk from *Salmonella* in low-moisture foods
ABC and the Almond Industry Have Taken Action

- Research program to understand ecology of *Salmonella* in orchards
- Education program for industry on GAPs and GMPs
- Requirement to treat almonds to achieve a 4-log reduction of *Salmonella*
- Validation guidelines
- TERP – panel of scientific experts to evaluate technologies
- Pathogen environmental monitoring program
Industry Activities

• American Peanut Council (APC)
  – Good Manufacturing Practice and Industry Best Practices for Peanut Product Manufacturers
  – Prevalence of *Salmonella* in ‘Runner’ Variety Raw Peanuts
  – HACCP for Nut Processors Course
• California Pistachio Research Board
  – Funding studies on *Salmonella* prevalence in raw pistachios for conducting risk assessments
Other Efforts

• GMA\textsuperscript{a} – Industry Handbook for Safe Processing of Nuts

\textsuperscript{a}APC, CA Pistachio Research Board, Peanut and Tree Nut Processors Assoc. Western Pistachio Assoc., numerous nut companies and food manufacturers
FDA Concern

• Industry assuming the kill step eliminates the need for controls at earlier steps
  – Kill steps do not minimize the need for GAPs
  – Kill steps do not minimize the need for pre-process GMPs
Congress May Have an Impact on the Nut Industry

- Food Safety Enhancements Act of 2009 (HR 2749)
- Food Safety Modernization Act (S 510)
Food Safety Enhancement Act (FSEA) Provisions

• Requires each food facility to:
  – conduct a hazard analysis;
  – implement preventive controls; and
  – implement a food safety plan.
FSEA Provisions

• Preventive Controls:
  – Sanitation procedures and practices
  – Training (supervisor, manager and employee hygiene)
  – Process controls
  – Allergen control program
  – GMPs
  – Supplier verification activities
FSEA Provisions

- Food Safety Plan must include scientific/technical validation that the system of controls will prevent, eliminate or reduce hazards to an acceptable level.
- FDA would have access to all records relating to determining whether a food may be adulterated or misbranded.
FDA is revising its GMPs

- “Food CGMP Modernization – A focus on Food Safety” (2005)
White Paper: Opportunities for Modernization

• Require appropriate training for supervisors and workers (now only recommended)
• Require an allergen control plan for facilities using major food allergens
• Require written environmental pathogen control program
• Require that food processors develop and maintain written sanitation procedures
White Paper: Opportunities for Modernization

• Require that food processors maintain certain critical records and that these be made available for review and evaluation by FDA investigators to confirm compliance with GMPs

• Obtain further comments on removing the exclusion from cGMP compliance for establishments engaged in harvesting, storage, and distribution of raw agricultural commodities
The Bottom Line

• The nut industry will face new requirements sooner rather than later.
• It would be prudent for nut processors to develop and implement appropriate, validated controls for hazards such as Salmonella.
• Don’t wait for new laws and regulations.
• Don’t wait for an outbreak of illnesses to make necessary changes.
Thank you!