Quantitative assessment of the risk of human salmonellosis associated with the consumption of tree nuts
Tree nut commodities in the U.S.

1. Agricultural relevance (USDA ARS data)
   - Approx. $4 billion / year industry in U.S.
   - Primarily almonds, walnuts, pistachios & pecans
   - Production significantly increased over past 30 years
     - Production: 306 million lbs in 1970's to 2 billion lbs today
     - Exports: 24% in 1970's to 40% today
   - Consumption has nearly doubled since 1977
     - 1.7 lbs / person/year in 1977; 3.0 lbs /person/year today

2. Nutritional value
   - Nuts have considerable nutritional value
     - E.g., unsaturated fats, fiber, protein & minerals
### Salmonella as a public health problem

<table>
<thead>
<tr>
<th>Salmonella spp.</th>
<th>Epidemiology of salmonellosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Gram negative bacterium</td>
<td>- Foodborne illness (~ 6% non-foodborne)</td>
</tr>
<tr>
<td>- &gt; 2,500 serotypes</td>
<td>- Considerable public health relevance*:</td>
</tr>
<tr>
<td>- Zoonotic pathogen</td>
<td>~ 1 million foodborne illnesses / year (in U.S.)</td>
</tr>
<tr>
<td>- Variable host range</td>
<td>~ 20,000 hospitalizations / year (in U.S.)</td>
</tr>
<tr>
<td>- Stable in environment</td>
<td>&gt; 350 deaths / year (in U.S.)</td>
</tr>
</tbody>
</table>

- **Symptoms vary by serotype & population**
  - mostly benign, self-limiting gastro-intestinal
  - invasive disease possible (young children, elderly)

* based on: Scallan et al. 2011
Salmonella in low-$a_w$ foods

1. Low-$a_w$ foods
   - Water activity ($a_w$) < 0.7
   - E.g., peanut butter, infant formula, cereal, spices
   - Traditionally considered ‘Salmonella safe’
     - Do not support Salmonella growth
     - **But:** Salmonella is resistant to desiccation
       - Increased survival & heat tolerance of Salmonella
       - Salmonella eradication in dry facilities very difficult

2. Salmonellosis outbreaks with low-$a_w$ foods
   - Repeated outbreaks with various low-$a_w$ foods
     - E.g., peanut butter, cereal, chocolate, dog food & tree nuts
Salmonella contaminated tree nuts are a concern

1. Outbreaks of salmonellosis, e.g.:
   - Pine nuts (2011)

2. Product recalls due to Salmonella contamination, e.g.:

3. Salmonella isolation from product in surveys, e.g.:
   - Almonds  - Hazelnuts  - Walnuts
   - Brazil nuts  - Macadamia nuts  - Pine nuts
   - Cashew nuts  - Pistachio nuts
FDA’s risk assessment framework

The Center for Food Safety and Applied Nutrition, Food and Drug Administration

Initiation and Conduct of All 'Major' Risk Assessments within a Risk Analysis Framework

A Report by the CFSAN Risk Analysis Working Group

March 2002

Conduct & Manage Process

Step 1: Commission
Step 2: Data collection & evaluation
Step 3: Develop model/report
Step 4: Review & clearance
Step 5: Issue
Risk Assessment

Hazard Identification

Hazard Characterization

Exposure Assessment

Risk Characterization
Evaluate the impact of preventive treatments, defined as a safety performance criterion, on the risk of human salmonellosis arising from consumption of untreated and treated tree nuts.
Tree nuts to include in risk assessment

- Definition: 201(qq) FALCPA & corresponding guidance
- The following nuts will likely be excluded:
  - beech nuts, chinquapins, gingko nuts, hickory nuts, lychee nuts, pili nuts, and shea nuts, coconuts
- This strategy results a tentative list of 10 tree nuts:

<table>
<thead>
<tr>
<th>Common name</th>
<th>Scientific name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Almond</td>
<td>Prunus dulcis (Rosaceae)</td>
</tr>
<tr>
<td>2. Brazil nut</td>
<td>Bertholletia excels (Lecythidaceae)</td>
</tr>
<tr>
<td>3. Cashew nut</td>
<td>Anacardium occidentale (Anacardiaceae)</td>
</tr>
<tr>
<td>4. Chestnut</td>
<td>Castanea spp. (Fagaceae)</td>
</tr>
<tr>
<td>5. Filbert/hazelnut</td>
<td>Corylus spp. (Betulaceae)</td>
</tr>
<tr>
<td>6. Macadamia nut/Bush nut</td>
<td>Macadamia spp. (Proteaceae)</td>
</tr>
<tr>
<td>7. Pecan</td>
<td>Carya illinoensis (Juglandaceae)</td>
</tr>
<tr>
<td>8. Pine nut / Pinon nut</td>
<td>Pinus spp. (Pineaceae)</td>
</tr>
<tr>
<td>9. Pistachio</td>
<td>Pistacia vera L. (Anacardiaceae)</td>
</tr>
<tr>
<td>10. Walnut / Heartnut / Butternut</td>
<td>Juglans spp. (Juglandaceae)</td>
</tr>
</tbody>
</table>
Risk assessment approach?

1. Desired model outputs:
   - Expected number of cases / serving or year (+uncertainty)
   - Impact of post-harvest treatments on disease risk
   - Potential analysis of additional “what-if” scenarios
     ⇒ Fully quantitative approach (farm-to-table)

2. Published risk assessment models for tree nuts
   - Lambertini et al. 2012
     - Developed for U.S. almonds
     - Quantitative microbial risk assessment
     - Evaluates complete product pathway
     ⇒ Good starting point, adaptations needed
Charge & approach: Potential conceptual model outline

- Salmonella prevalence at harvest
- Salmonella concentration at harvest
  - Pre-process storage
  - Post-harvest treatment
  - Post-process storage
  - Retail storage
  - Consumer home storage

- Serving size
- Number of servings

- Risk of illness per annum & risk per billion servings
- Dose-Response model
Treatments to consider?

1. Treatments to inactivate *Salmonella* on almonds
   - Various different methods available
     - Differ in efficacy, sensory impacts & variability
   - E.g., oil roasting, dry roasting, blanching, gas treatments
   - Regulatory requirements for California almonds:
     - USDA marketing order (7 CFR 981.442); since 2007:
       - Mandatory treatment (approved, 4 log10 reduction)

2. Considerations for risk assessment
   - Charge suggests evaluation of performance criteria
     - Compare different levels of efficacy
     - Evaluation of individual treatments likely beyond charge
Data sources

1. *Salmonella* prevalence & concentration
   - Data available for some nuts & processing stages

2. *Salmonella* survival & inactivation
   - Data available for some nuts & storage conditions

3. *Salmonella* dose-response relationships
   - Published dose-response model for *Salmonella* available
     - limited to specific food (i.e., eggs), serotype, etc.

4. Tree nut consumption in the U.S.
   - Data available for some nuts, limited for others
     - NHANES WWEIA, USDA ERS food availability, etc.

⇒ Request unpublished data from industry & other stakeholders (Federal Register Notice)
Outreach to industry & stakeholders for data

Federal Register Notice (published 07/17/2013)
⇒ Submission of data and comments

Stakeholder Webinar (held 07/22/2013):
⇒ Raise awareness of FR notice & risk assessment
⇒ Outreach plan:
  1. Constituent update announcing FR notice & webinar
  2. Live webinar (~100 participants)
  3. Recording & webinar slides posted on FDA website

Federal Register Notice extending comment period
⇒ Response to industry requests
Federal Register notice content

1. Background

2. Request for Comments, Scientific Data & Information:
   1. *Salmonella* prevalence & concentration on tree nuts
   2. *Salmonella* survival, growth or inactivation dynamics
   3. Relevant food consumption practices in the U.S.
   4. Storage, handling and processing conditions
   5. Other comments (e.g., types of tree nuts to include)

3. Instructions for submission of comments & data

4. References
Responses to Federal Register notice

Federal Register Notice published 07/2013 (n=11 submissions):
- Data submissions (n=3)
- Extension requests (n=7); Public comments (n=1)

Federal Register Notice published 10/2013 (n=655 submissions):
- Data submissions (n=12) included for example:
  - Almond Board of California;
  - California Walnut Board;
  - Peanut and Tree Nut Processors Association;
  - National Pecan Sheller’s Association;
  - Administrative Committee for Pistachios;
  - Hazelnut industry groups;
  - Other industry stakeholders

- Public comments / other submissions (n=643)
Despite data submissions important gaps remain

<table>
<thead>
<tr>
<th>Nut type</th>
<th>Nut consumption data</th>
<th>Salmonella Survival data</th>
<th>Salmonella Prevalence data</th>
<th>Salmonella Concentration data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Brazil nuts</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
</tr>
<tr>
<td>Cashew</td>
<td>yes</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
</tr>
<tr>
<td>Chestnuts</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
</tr>
<tr>
<td>Hazelnuts</td>
<td>limited</td>
<td>yes/limited</td>
<td>(expected)</td>
<td>(expected)</td>
</tr>
<tr>
<td>Macadamia</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
</tr>
<tr>
<td>Pecan</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Pine nut</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
<td>limited</td>
</tr>
<tr>
<td>Pistachios</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes/limited</td>
</tr>
<tr>
<td>Walnuts</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>limited</td>
</tr>
</tbody>
</table>
Ongoing data collection efforts

1. Targeted data acquisition

2. Site visits

3. Analysis of FRN data submissions
   - Analysis of previously unpublished data (e.g., new survey years)
   - Re-analysis of raw data with new statistical methods

4. Monitor literature for new publications
Risk assessment for almonds: Preliminary model outline

- **Salmonella prevalence at harvest**
- **Salmonella concentration at harvest**
  - Pre-process storage
  - Post-harvest treatment
  - Post-process storage
  - Retail storage
  - Consumer home storage

- **Serving size**
- **Number of servings**

- **Dose-Response model**

Risk of illness per annum & risk per billion servings
Risk assessment: Our model vs. Lambertini et al.

1. **Potential differences in modeling approach**
   1. Explicitly model uncertainty & variability separately
      => Evaluate impact of assumptions & data gaps

2. **Potential differences between models**
   1. Modeling of post-harvest treatments
   2. Modeling of storage & handling practices
   3. Modeling of tree nut consumption

3. **Potential differences in input data**
   1. Additional data (e.g., additional survey years)
   2. New data analysis tools (e.g., new statistical methods)
   3. New data sources (e.g., NHANES consumption data)
Risk assessment: Preliminary model for the rest of the tree nuts

1. Model will have a similar approach as for almonds
2. Model will be adapted to incorporate specific
   1. Process steps,
   2. Conditions, and
   3. Consumption data
   As they apply to each tree nut
3. Will have a single risk assessment document for all tree nuts
Questions for the NPSA

- Based on your experiences, at what [points/steps/stages] do you think *Salmonella* contamination and cross-contamination are most likely to occur? And what steps are most likely to contribute to mitigating the risk.

- Are there specific and/or exceptional situations that would be important for us to consider in the model
  - *Examples*
    - A rain event on the orchard floor
    - Mixing of raw materials with processed product possibly leading to *Salmonella* cross contamination
Questions for us?