The purpose of the risk assessment will be to quantify the public health risk associated with the consumption of potentially *Salmonella* contaminated tree nuts and to evaluate the impact of risk-based preventive controls on the risk of human salmonellosis arising from consumption of tree nuts.

http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm361206.htm

For references: please see Federal Register notice or contact the presenters.

http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM362297.pptx

We anticipate the following model outputs:

- Expected number of cases / serving or cases / year
- Quantified impact of interventions through "what-if" scenarios

Model likely based on peer-reviewed risk assessment models:

- e.g. Lambertini et al., 2012 (developed for U.S. almonds)
- Plan to evaluate product pathway: harvest to consumption

Expected extensions beyond currently published models:

- Adaptation to consider other tree nuts in addition to almonds
- Quantification of uncertainty
- Sensitivity analysis

http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM362297.pptx
Data Request: *Salmonella* prevalence and concentration

Example: Prevalence of *Salmonella* in 100-g Raw Almond Kernels With 95% Confidence Intervals (Wilson Score)

![Graph showing prevalence of Salmonella in almonds](image)

Danyluk et al., 2007; Bansal et al., 2010; Lambertini et al., 2012, unpublished

Example: Levels of *Salmonella* in almonds per 100 g

![Graph showing levels of Salmonella in almonds](image)

Danyluk et al., 2007; Bansal et al., 2010; Lambertini et al., 2012, unpublished
**Harris calculations**

- **Average prevalence**
  - Almonds (kernel):
    - 0.98% (100 g; 95% CI, 0.83 to 1.2%; 137 of 13,972)
  - Almonds (inshell):
    - 1.3% (100 g; 95% CI, 0.61 to 2.8%; 6 of 455)
  - Pecans (inshell):
    - 0.95% (100 g; 95% CI, 0.70 to 1.3%; 44 of 4,641)
  - Walnuts (inshell):
    - 0.14% (375 g; 95% CI, 0.054 to 0.35%; 4 of 2,903)
  - Pistachio (inshell)
    - Sinkers: 0.37% (100 g; 95% CI 0.21 to 0.67; 11 of 2,934)
    - Floater: 2.0% (100 g; 95% CI 1.3 to 3.0; 21 of 1,032)

- Data Request:
  - *Salmonella* survival, growth or inactivation
  - Impacts of nut composition, water activity, storage temperature
  - Different stages on farm-to-fork continuum
    - Impact of relative humidity during storage, geographic region or season
    - In different foods made with tree nuts as ingredients

**Prevalence equivalent?**

**Survival of *Salmonella* during storage at 23°C, 4°C, and -20°C on almonds and pistachios.**

All enrichments were positive

- Slope of line = -0.15 log CFU/month
- Slope of line = -0.24 log CFU/month

Kimber et al., submitted to Journal of Food Protection.
**Salmonella decline in pistachios and almonds**  
(Harris laboratory, various sources)

<table>
<thead>
<tr>
<th>Data set (23°C)</th>
<th>Reduction Rate (log CFU/day)</th>
<th>Reduction Rate (log per 30 days)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almonds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. enteritidis PT30: 171 days</td>
<td>0.0105</td>
<td>0.32</td>
<td>&lt;2·10^-6</td>
</tr>
<tr>
<td>365 days</td>
<td>0.0069</td>
<td>0.21</td>
<td>&lt;2·10^-6</td>
</tr>
<tr>
<td>560 days</td>
<td>0.0079</td>
<td>0.24</td>
<td>&lt;2·10^-6</td>
</tr>
<tr>
<td>Log 9 180 days</td>
<td>0.0055</td>
<td>0.16</td>
<td>2.5·10^-7</td>
</tr>
<tr>
<td>Log 7 180 days</td>
<td>0.0071</td>
<td>0.21</td>
<td>4.6·10^-7</td>
</tr>
<tr>
<td>Log 5 180 days</td>
<td>0.0083</td>
<td>0.25</td>
<td>3.6·10^-7</td>
</tr>
<tr>
<td>Log 3 180 days</td>
<td>0.0068</td>
<td>0.20</td>
<td>5.7·10^-8</td>
</tr>
<tr>
<td>Salmonella cocktail 201 days</td>
<td>0.00929</td>
<td>0.28</td>
<td>&lt;2·10^-6</td>
</tr>
<tr>
<td>Pistachios</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salmonella cocktail</td>
<td>0.00513</td>
<td>0.15</td>
<td>1.4·10^-7</td>
</tr>
</tbody>
</table>

Reduction rates based on the linear fit: log (CFU) = log (CFU0) – rate * time

**FDA analysis of storage data**


Santillana Farakos et al., 2016. *Int. J. Food Microbiol.* 227:41
Survival of Salmonella in tree nuts

Calculated Reductions of Salmonella During Storage

<table>
<thead>
<tr>
<th>Nut type</th>
<th>Method</th>
<th>Weeks (Log CFU Reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Almonds</td>
<td>FDA</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>Harris</td>
<td>0.055</td>
</tr>
<tr>
<td>Pistachios</td>
<td>FDA</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>Harris</td>
<td>0.035</td>
</tr>
<tr>
<td>Walnuts</td>
<td>FDA</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Lamberti et al., 2012. Food Research International 45:1166–1174.

FDA calculations

- Uncertainty dimension
  - Median, mean, 2.5%, 97.5%
- Variability dimension
  - Include standard deviation

Calculated Reductions of Salmonella During Storage of Almonds

<table>
<thead>
<tr>
<th>Method</th>
<th>Uncertainty</th>
<th>Weeks (Log CFU Reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>FDA</td>
<td>97.5%</td>
<td>0.33</td>
</tr>
<tr>
<td>Median</td>
<td>0.40</td>
<td>0.83</td>
</tr>
<tr>
<td>Mean</td>
<td>0.40</td>
<td>0.84</td>
</tr>
<tr>
<td>2.5%</td>
<td>0.49</td>
<td>1.00</td>
</tr>
<tr>
<td>Harris</td>
<td>0.055</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Lamberti et al., 2012. Food Research International 45:1166–1174.

FDA uncertainty analysis

- Prevalence
- Survival
- Concentration
- Consumption amount
- Treatment
- Treatment variability
Data request:
Storage, handling and processing

- Typical storage conditions
  - Time, temperature, relative humidity
  - From harvest to processing
- Types of treatments used to reduce bacteria
  - Frequency applied
  - Process conditions
  - Efficacy of treatments
- Storage conditions post treatment
- Handling practices that are typically applied by the consumer

Almond Risk Assessment


Process Validation

Oil Roasting June 2005  PPO September 2004  Blanching June 2005

Data request:
Food consumption practices

- Frequency consumed by population subgroups
- Frequency consumed raw by different population subgroups
- Frequency with which tree nuts that have undergone treatments are consumed by different population subgroups
- Serving sizes

Data request:
Storage, handling and processing

- Typical storage conditions
  - Time, temperature, relative humidity
  - From harvest to processing
- Types of treatments used to reduce bacteria
  - Frequency applied
  - Process conditions
  - Efficacy of treatments
- Storage conditions post treatment
- Handling practices that are typically applied by the consumer

Almond Risk Assessment

- Initial Risk Assessment in 2006 helped establish target 4-log reduction for regulation
- Elisabetta Lambertini (PostDoc), Don Schaffner (Rutgers), Michelle Danyluk (UFL), Carl Winter (UCD), Linda Harris (UCD)
- Significant modification of 2006 risk assessment:
  - Added new prevalence data, recalculation of levels, assumes mandatory treatment (with portions and validation data used in model), new information on consumer handling, updated consumption, reassessment of 2001 outbreak
Model format – @Risk software

- Select positive or negative sample and level based on 8 year survey.
- Select pre-processing storage time/temperature based on industry data. Calculate decline.
- Select process based on industry data. Determine reduction achieved in that process based on validation data.
- Select post-processing storage time/temperature based on industry and consumer data. Calculate decline.
- Select amount consumed (average 31.5g (1g to 100g))
- Determine illness based on FAO/WHO dose-response curve for Salmonella.

Dose response

- There is no such concept as the “infectious dose”
- One cell can make you sick
- 1 cell = 0.02% prob of illness, 1/392 people
- DR model

Risk Assessment Model Output – Single Run 100,000 Iterations

- Baseline
- Concentration: 100 MPN/100g
- Prevalence: 65%
- Percent untreated: 10%

Summary

- FDA tree nut risk assessment for almonds is under review
  - Unknown publication date
- Risk assessments can be used to inform risk management decisions
  - Example of management decisions
    - Appropriate level of pathogen reduction
    - Criterion for “pasteurized” label.
Questions?