Quantitative Risk Assessment (QRA) to Support the Proposed Produce Rule
QRA - Summary

- Referenced in the proposal; not published in the Federal Register for comment
- Developed with good scientific methodology and algorithms appropriate for their use in a quantitative risk assessment
- Inputs to those calculations are largely based on assumptions, “expert opinion”, and data taken from published studies with unclear context
- Establishes a protocol that commodities and practices can use to demonstrate “low risk”
The scenarios...

- Looks at a specific situation: the illness risk associated with pathogenic E. coli (EHEC) contamination of irrigation water used on a lettuce field harvested for fresh-cut.

- They quantify and compare the risks for six contamination scenarios, all assuming that additional risks of contamination are minimal and constant across the scenarios.
The scenarios...

- Hazard identification: EHEC from irrigation water prior to harvest.

- Measurement of the hazard: based on levels of generic E. coli (Ec) detected in the irrigation water as an indicator,
  - Assumes 1:100 ratio of EHEC to Ec.
  - Also looks at ratios of 1:10 and 1:1
Estimation of exposure

- Based on overhead irrigation of an industry-average one acre lot of lettuce.
- 127,000 servings of fresh-cut lettuce per acre at a range of 0-125 (average 40) g per serving
- 30% of all lettuce acreage is irrigated overhead at a rate of 13,500 gal/A
- 50% of the water hits the edible portion, and that the edible portion holds 2.5 mL water/g lettuce.
Estimation of exposure

Deactivation after irrigation
• Estimates that EHEC dies on the lettuce at a rate of 0.11 to 2.44 (w/most likely 0.50) log CFU/g during 3-5 (most likely 4) days between final irrigation and harvest.

Growth/deactivation post-harvest
• Neutral impact on overall risk in this example.

Cross contamination from handling
• Minimum of -1 (i.e., 10-fold decrease), most likely 1 and maximum 4 logs/g increase in contamination due to mishandling at the point of service.
Estimation of consumption

- Estimated 127,000 servings of fresh-cut lettuce per acre based on industry data of average production per acre, minus average culled and average not sold.
Dose-response

- They use a Beta-Poisson distribution with alpha 0.248, beta 48.80, based on published studies. This number is pathogen specific, independent of the commodity. Any calculation on EHEC would use the same distribution; other pathogens could have a different distribution shape and parameters.
Total DALYs

- Disability Adjusted Life Years: They use estimates from published studies on health impacts from the symptoms of EHEC infection, including the frequency of non-hospitalized illness, hospitalized illness (e.g., bloody diarrhea and HUS) and death per illness event, multiplied by the calculated average number of illness events.
The scenarios, all in MPN Ec/100 ml

- Farm A, gross fecal contamination: 10,000 to 30,000
- Farm F, very high contamination: 700 to 4840
- Farm E, high contamination: 700 to 2420
- Farm B, moderate contamination: 50 to 700
- Farm D, low contamination, compliant with the proposed water quality standard: 50 to 235
- Farm C, no contamination introduced from irrigation (baseline).
Conclusions on risk...

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Final Concentration (log cfu or pfu/g microbial, g/g chemical)</th>
<th>Final Prevalence</th>
<th>Mean Risk of Illness</th>
<th>Total EO or Consumers</th>
<th>Total DALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm A (1:100 EHEC vs. E. coli)</td>
<td>-0.69</td>
<td>0.11</td>
<td>0.0042</td>
<td>1.3E+5</td>
<td>200</td>
</tr>
<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm F (1:100 EHEC vs. E. coli)</td>
<td>-0.24</td>
<td>0.00073</td>
<td>9.3E-6</td>
<td>1.3E+5</td>
<td>0.44</td>
</tr>
<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm E (1:100 EHEC vs. E. coli)</td>
<td>-0.19</td>
<td>0.00034</td>
<td>3.5E-6</td>
<td>1.3E+5</td>
<td>0.17</td>
</tr>
<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm B (1:100 EHEC vs. E. coli)</td>
<td>-0.039</td>
<td>9.4E-6</td>
<td>9.9E-8</td>
<td>1.3E+5</td>
<td>0.0047</td>
</tr>
<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm D (1:100 EHEC vs. E. coli)</td>
<td>-0.024</td>
<td>5.6E-6</td>
<td>8.5E-8</td>
<td>1.3E+5</td>
<td>0.0041</td>
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<tr>
<td>EHEC in Lettuce Fresh-Cut from Farm C (Baseline)</td>
<td>-0.016</td>
<td>4.4E-6</td>
<td>7.8E-8</td>
<td>1.3E+5</td>
<td>0.0037</td>
</tr>
</tbody>
</table>
## Conclusions on risk...

### Table 1. Impact of Irrigation Water Quality on Predicted Illnesses

<table>
<thead>
<tr>
<th>Farm Description</th>
<th>Predicted Cases per Acre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross contamination of irrigation water (Farm A)</td>
<td>546.0</td>
</tr>
<tr>
<td>Very high contamination of irrigation water (Farm F)</td>
<td>1.209</td>
</tr>
<tr>
<td>High contamination of irrigation water (Farm E)</td>
<td>0.455</td>
</tr>
<tr>
<td>Moderate contamination of irrigation water (Farm B)</td>
<td>0.0129</td>
</tr>
<tr>
<td>Low contamination, in compliance with proposed standard for irrigation water (Farm D)</td>
<td>0.0111</td>
</tr>
<tr>
<td>No contamination of irrigation water (Farm C, baseline)</td>
<td>0.0101</td>
</tr>
</tbody>
</table>

*a Predicted illnesses associated with the consumption of fresh-cut lettuce harvested from different one-acre farms, irrigated by overhead sprinkler 3-5 (most likely 4) days prior to harvest.*
What data does Y commodity need?

Exposure of Y to pathogens from water
- Pathogen of concern (prevalence X survival)
- Min/mode/max levels in water (indicator?)
- % of all Y acreage irrigated overhead (or other direct water contact preharvest)
- Frequency of irrigation
- Gallons/acre/irrigation event
- % of the water that hits the edible portion
- mL of water that sticks to the edible portion
- Last contact with water preharvest (days)
What data does Y commodity need?

Growth/deactivation pre-, post-harvest

- Fate on Y in the field (min/mode/max rate of pathogen death under range of conditions)
  - % of Y exposed to those conditions
- Fate on Y post-harvest (any treatments that may increase/decrease levels?)
  - % of Y exposed to those treatments
- Effect of removing non-edible portion (min/mode/max)
- Cross contamination from handling
- Consumer handling practices
What data does Y commodity need?

Estimation of consumption

- Servings of Y per year
- Size of a serving (min/mode/max)

Dose-response and DALYs

- Can use FDA’s numbers if EHEC
- Numbers for other pathogens available
Putting it all together

- Use the same calculations as FDA did
  - Work with the same FDA scientists
- Compare the DALYs results to baseline estimate
- If DALYs calculated for Y are at or lower than in the QRA, then the scenario provides the same or better estimated level of public health protection
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Comments / Questions?