A Multi-Hurdle Approach to Food Safety

COLLABORATIVE FOOD SAFETY FORUM
Role of Testing in FDA’s Hazard Analysis and Risk-Based Preventive Controls Rule
March 22, 2013
Earthbound’s History

• Fresh Cut and produce since 1984
  – Development of fresh cut processing
• Became national circa 2000
  – Shelf life challenge
• Summer of 2006
• What did we do?
  – Risk assessment lead to multi-hurdle approach with strong emphasis on testing
Testing Programs

• Input testing in the field
  – O0157-H7, EHEC, Salmonella
  – Water, fertilizer, transplants, seed?

• Environmental testing in our facility
  – Listeria zone program, weekly; 15 sites, zone 2 and 3
  – Air monitoring, monthly; TPC, Yeast and Mold
  – Water samples, weekly; TPC
  – Weekly zone 1; TPC

• Field tissue testing
  – O0157-H7, EHEC, Salmonella
  – Mostly for fields with dual purpose

• Raw and Finished Goods Tissue Testing
Development of the Tissue Sampling Plans

- Looked outside of produce
  - Beef industry trim sample program
  - ICMSF case 15
- Designed to catch a gross contamination event.
  - Paicines Ranch 2006: 500 pounds harvested from an acre (acre’s harvest = approximately 7500 pounds)
  - We challenged our scientists to devise a plan that would catch this level of contamination and let us remove it from the stream of commerce.
- This precise sampling plan was developed with a confidence interval of 99.9% assuming uniform contamination.
  - Over time we have learned this is usually not the case
The Field Sampling Plan

- Field is broken down into 1 acre sample lots in fields used for commodity field pack and processing
- 60 grabs are taken from each acre, for a total sample of 150 grams. Grabs taken in z pattern.
- Other methods tried with no apparent improvement in detection
- Head lettuce vs baby greens
- Sampling has changed on head lettuce with greater efficacy
- PCR analysis: O0157-H7, EHEC, Salmonella
1 truckload = approx 24 pallets of greens, all harvested from the same part of the same field

Truckload segregated into 6 production units, comprising 4 pallets each (approx 1500 pounds)

60 grabs are taken from each 4-pallet production unit, for a total sample of 150 grams. Grabs taken from all over.

Will move to n=300 when in high risk situation

PCR: O0157-H7, EHEC, Salmonella, Shigella
Finished Goods Sample Program

- Production day broken down into 2 hour manufacturing units
  - Each pack line is sampled from (15 lines)
  - 60 grabs, 150 g sample
  - Auto-sampling
  - PCR, O0157-H7, EHEC, Salmonella

- In the event of a positive:
  - Libraryed water samples tested
  - Matrix developed
    - Like materials, test history
    - Like washlines
    - Other testing results during day

- Flanking units remain on hold
The Nature of Contamination Events

• Likely to be sporadic and localized, not widespread in a particular field
• Remember Paicines
  – Small amount of product involved
• Anything likely to cause widespread contamination would be cause to disc an entire block – such as a flood
Customer Testing Requirements

- Costco, YUM! Brands
- Costco: **Ready-to Eat Microbiological Finished Product Specifications**
  - TPC  Target < 5,000,000 cfu/g  Maximum 10,000,000 cfu/g
  - Generic E.coli  Target < 10  Maximum 100 cfu/g
  - EHEC  Negative
  - Salmonella:  Negative
- Pesticide Residues  PRODUCT IS REQUIRED TO HAVE RESIDUE LEVELS BELOW LEGAL LIMIT FOR ALLOWED PESTICIDES.
- ORGANIC PRODUCT must comply with NOP Regulations regarding pesticide residues.
- NO PRODUCT CAN BE DELIVERED UNTIL ALL TEST RESULTS ARE COMPLETED (TEST AND HOLD)
## Test & Hold

### Molecular Confirmation Incident Rate - Data

<table>
<thead>
<tr>
<th>Field MC</th>
<th>Yuma 07/08</th>
<th>SJB 2008</th>
<th>Yuma 08/09</th>
<th>SJB 2009</th>
<th>Yuma 09/10</th>
<th>SJB 2010</th>
<th>Yuma 10/11</th>
<th>SJB 2011</th>
<th>Yuma 11/12</th>
<th>SJB 2012</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of MCs</td>
<td>1</td>
<td>15</td>
<td>1</td>
<td>20</td>
<td>6</td>
<td>10</td>
<td>26</td>
<td>4</td>
<td>35</td>
<td>30</td>
<td>148</td>
</tr>
<tr>
<td>Samples</td>
<td>500</td>
<td>2458</td>
<td>1074</td>
<td>2017</td>
<td>904</td>
<td>2351</td>
<td>2191</td>
<td>2295</td>
<td>1622</td>
<td>1649</td>
<td>17061</td>
</tr>
<tr>
<td>% of Field MCs</td>
<td>0.200%</td>
<td>0.610%</td>
<td>0.093%</td>
<td>0.992%</td>
<td>0.664%</td>
<td>0.425%</td>
<td>1.187%</td>
<td>0.174%</td>
<td>2.158%</td>
<td>1.819%</td>
<td>0.867%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Raw MC</th>
<th>Yuma 07/08</th>
<th>SJB 2008</th>
<th>Yuma 08/09</th>
<th>SJB 2009</th>
<th>Yuma 09/10</th>
<th>SJB 2010</th>
<th>Yuma 10/11</th>
<th>SJB 2011</th>
<th>Yuma 11/12</th>
<th>SJB 2012</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of MCs</td>
<td>19</td>
<td>152</td>
<td>82</td>
<td>373</td>
<td>158</td>
<td>455</td>
<td>198</td>
<td>103</td>
<td>397</td>
<td>872</td>
<td>2925</td>
</tr>
<tr>
<td>Samples</td>
<td>47547</td>
<td>33547</td>
<td>40157</td>
<td>39340</td>
<td>42761</td>
<td>32521</td>
<td>37774</td>
<td>31920</td>
<td>39127</td>
<td>30677</td>
<td>375371</td>
</tr>
<tr>
<td>% of Raw MCs</td>
<td>0.040%</td>
<td>0.453%</td>
<td>0.204%</td>
<td>0.948%</td>
<td>0.369%</td>
<td>1.399%</td>
<td>0.524%</td>
<td>0.686%</td>
<td>1.015%</td>
<td>2.843%</td>
<td>0.779%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>FGS MC</th>
<th>Yuma 07/08</th>
<th>SJB 2008</th>
<th>Yuma 08/09</th>
<th>SJB 2009</th>
<th>Yuma 09/10</th>
<th>SJB 2010</th>
<th>Yuma 10/11</th>
<th>SJB 2011</th>
<th>Yuma 11/12</th>
<th>SJB 2012</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td># of MCs</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>9</td>
<td>9</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>20</td>
<td>26</td>
<td>82</td>
</tr>
<tr>
<td>Samples</td>
<td>32920</td>
<td>35420</td>
<td>28834</td>
<td>36572</td>
<td>34029</td>
<td>42699</td>
<td>34019</td>
<td>45206</td>
<td>38605</td>
<td>34966</td>
<td>363270</td>
</tr>
<tr>
<td>% of FGS MCs</td>
<td>0.000%</td>
<td>0.023%</td>
<td>0.000%</td>
<td>0.025%</td>
<td>0.026%</td>
<td>0.002%</td>
<td>0.006%</td>
<td>0.015%</td>
<td>0.052%</td>
<td>0.074%</td>
<td>0.023%</td>
</tr>
</tbody>
</table>
Raw MC's Vs Field MC's

Field A
Field B
Field C

Fields

Raw MCs
Field MCs

MCs Raw
MC's Field

0 0 0
5 10 15
20 25

Field MC's

20 25

Fields

0 0 0
Lot 84, Total acreage = 27 Acres. Second planting rotation = 24.65 acres, plantings A2 to D2, 88 beds
Sporadic Contamination Requires a Precise Sampling Plan

• If all contamination were widespread, then we wouldn’t need to do so much sampling – fewer samples would tell the tale and the whole field block would be indicted.

• But because contamination is likely to be localized and sporadic, we had to develop a sampling plan that touches every row of every field and lets us isolate those areas affected by the contamination.
Q & A

Will Daniels
SVP Operations and Organic Integrity
831.623.7880
will@ebfarm.com