Enhancement of Food Safety in Leafy Greens

The California Leafy Greens Marketing Agreement Case Study
Discussion Topics

- Traditional Approach to Food Safety
- Outbreak History
- Identifying A Solution
- Leafy Greens Model
Food safety was focused on inspection and testing to document that you did everything right.

- Conventional Process Wisdom
  - D-value
  - Water activity
  - pH
  - Storage temperature
- Process Registration and/or Process Authority
  - Process Control
  - Documentation
In the 1990’s the playing field began to change...

- **Eating Trends**
  - Increased “fresh” consumption
  - Increased meals “away from home”
  - Increased pre-preparation and assembly
  - Increased time and handling between farm and fork

- **External Factors**
  - Emerging pathogens
  - [Media Attention, Public Interest Cause](#)
  - Assigned liability for failure
    - 1995 Jack-in-the-Box E. coli outbreak
In the new millennium government agencies began to make their mark...

- Prevention over Inspection and Testing
  - Mandatory HACCP regulation
    - Seafood 1997
    - Juice 2001
- PulseNet - Coordinated by CDC
  - Detect food-borne disease clusters by PFGE
  - Promote real-time communication
  - Facilitate early identification
  - Identify opportunities for improvements
## Leafy Greens Industry Response

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1984</td>
<td>Lot ID and trace back extended to RAC</td>
</tr>
<tr>
<td>1994</td>
<td>Transportation SOP: time-temperature</td>
</tr>
<tr>
<td>1996</td>
<td>Industry initiative to ID risks of growing and harvesting</td>
</tr>
<tr>
<td>1997</td>
<td>Extension of water standards to cooling operations</td>
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<tr>
<td>1998</td>
<td>Extension of water standards to all field operations</td>
</tr>
<tr>
<td></td>
<td>FDA Guide to Minimize Food Safety Hazards...</td>
</tr>
<tr>
<td>1999</td>
<td>Scheduled testing of irrigation water</td>
</tr>
<tr>
<td>2000</td>
<td>Field and harvest worker SOPs</td>
</tr>
<tr>
<td>2001</td>
<td>Pre-season and pre-harvest environmental evaluation</td>
</tr>
<tr>
<td>2002</td>
<td>Comprehensive daily sanitation and employee hygiene</td>
</tr>
<tr>
<td>2005</td>
<td>Leafy Greens Commodity Specific GAP Guidance</td>
</tr>
</tbody>
</table>
# Illness Vehicle Categories 1996-2005

<table>
<thead>
<tr>
<th>Category</th>
<th>Outbreaks</th>
<th>Illnesses</th>
</tr>
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<tbody>
<tr>
<td>Processed</td>
<td>43</td>
<td>3,026</td>
</tr>
<tr>
<td>Produce</td>
<td>63</td>
<td>8,040</td>
</tr>
<tr>
<td>Sprouts</td>
<td>25</td>
<td>1,565</td>
</tr>
<tr>
<td>Seafood</td>
<td>120</td>
<td>2,567</td>
</tr>
<tr>
<td>Eggs</td>
<td>234</td>
<td>6,572</td>
</tr>
</tbody>
</table>
Leaf Greens account for 34% of produce related illness outbreaks…
Crisis in Confidence

- FDA chides industry to improve food safety
- FDA develops produce safety action plan
- FDA inaugurates Lettuce Safety Initiative
- Basic messages
  - Industry is not doing enough
  - Waiting to act until you know what to do is unacceptable
The depths of despair

- A succession of 3 food borne illness outbreaks rock the foundation of the leafy green industry
  - September 2006
    - Natural Selections Spinach
  - December 2006
    - Taco Bell Lettuce*
  - December 2006
    - Taco John Lettuce
September 2006
- 206 confirmed cases of *E. coli* O157 infection reported between Sept 1 – Oct 1, 2006
  - 104 hospitalized
  - 31 HUS
  - 3 deaths

- 26 states and Canada
- Shut down the entire industry for 10 days
Critical Learnings

- Contamination was found in opened and unopened bags
- Field investigation found identical PFG fingerprint in proximity of implicated field in soil, water, cows and feral pigs.
- Plaintiff lawyer’s announce intention to sue 1 day before FDA issues public alert.
Devastating Financial Impact

FDA CAN SHUT DOWN AN ENTIRE INDUSTRY

- **Before the FDA Spinach Alert**
  - More than 100 tons of spinach was being sold every day
  - The price was more than $8 per carton

- **After the FDA Spinach Alert**
  - Sales virtually stopped for 10 days
  - Even after Oct. 1st, price and volume were 50% of what they were before the press conference

*Source: USDA Agricultural Marketing Service*
The impact is not short lived...

<table>
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<tr>
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<tbody>
<tr>
<td>Bagged Spinach</td>
<td>-22%</td>
<td>-43%</td>
</tr>
<tr>
<td>Bagged Salad w/Spinach</td>
<td>-21%</td>
<td>-42%</td>
</tr>
<tr>
<td>Bagged Salad</td>
<td>-5%</td>
<td>-3%</td>
</tr>
</tbody>
</table>
A New Beginning

- The Leafy Greens Industry recognized a systemic failure of **ALL** aspects of the food safety system...
  - Voluntary compliance with GAPs
  - Regulatory oversight
  - Lack of harmonized Customer mandated requirements
  - Limited 3rd Party Audit utility
What is the answer?

- Find X

Here it is

3 cm

4 cm

X

ALLIANCE OF TECHNICAL PROFESSIONALS
Return to the basics

- Risk Management
  - Simple goals:
    - Decrease the frequency
    - Limit the severity
  - No one can manage your risk better than you
- Build off of existing models
  - HACCP
  - Commodity Specific Guidelines
- Utilize available science
7 HACCP Principles

1. Hazard Analysis
2. Identify Critical Control Points
3. Establish Critical Limits
4. Monitor the CCPs
5. Establish Corrective Actions
6. Record Keeping
7. Verification
How does produce become contaminated?

- Domestic animals in the field?
- Herds of marauding wild beasts?
- Poorly maintained and unprotected water sources?
What does effective intervention look like?

Animals can’t read

Fields are in the great outdoors
How do you establish effective limits?

Are these cows too close?

How far do you have to be from a riparian zone?

Should 1 deer print disqualify An entire field?
What form should verification take?
The Development of the California Leafy Greens Marketing Agreement
Key Objectives

1. Meaningful food safety process that will regain stakeholder confidence in leafy greens
2. Harmonized standards across the California leafy greens industry
3. Mandatory compliance for all participants
4. Independent and certified verification of compliance
A novel approach

- USDA Marketing Agreement/Market Order
  - Marketing Agreement
    - Requires a majority of “Handlers” in a defined product group and or Region to approve.
      - Participation is VOLUNTARY
      - Compliance is MANDATORY once signed on
  - Marketing Order
    - Requires a super-majority of “growers” in a defined product and or region to approve
      - Participation and compliance are mandatory for all growers
AMS/USDA Fresh Produce Audit Verification Program

- USDA/State Department of Agriculture
  - Established in 1999
  - For fee program
  - USDA based GAP Audit
  - Trained State auditors
California Leafy Greens Marketing Agreement

- Member appointed oversight Board
  - Establishes member assessment
    - Marketing Agreement Staff
    - Reimburse Department of Agriculture for Audit costs
  - Accepts Leafy Greens Food Safety Metrics & Checklist
  - Certify/Decertify members
- USDA & State Department of Agriculture
  - Approves Leafy Greens Food Safety Metrics
  - Develops Audit Checklist
  - Establishes audit program and format
- Industry
  - Develop specific metrics for approval
Hazards to be Assessed

- Agricultural Water
- Soil Amendments
- Environmental Assessment
  - Proximate Adjacencies
  - Set Backs
- Sanitation Practices
  - Employee
  - Equipment
- Encroachment
Mandatory Programs

- Prerequisites
  - Trace back-Trace forward
  - Written Food Safety compliance plan
  - Updated Grower List (w/24-7 contacts)
- SOPs
  - Worker Health, Hygiene & Practices
  - Farm Access Control
  - Sanitary Operations
  - Harvest Activities
Environmental Assessments

- Pre-season and pre-harvest assessments are required to make sure conditions that can affect food safety, such as animal intrusions, flooding, proximity to animal feeding operations, etc. are not present, or have been properly mitigated.
Food Safety Practices

Water Use
- Extensive testing and record keeping for all sources of water used in the production of leafy greens is required by the program.

Soil Amendments
- Extensive testing, certification and record keeping for soil amendments including compost and fertilizers, are required by the program.

Worker Practices and Field Observations
- Field audits verify that farmers are in compliance with the program’s requirements in the areas of worker practices and field sanitation.
Mandatory Government Audits

LGMA Audits
The mandatory government audits required by the LGMA are conducted by CDFA inspectors who received USDA training and certification
- LGMA auditors are agricultural inspectors with extensive experience in produce
- LGMA auditors are trained and supervised by the US Department of Agriculture, under the auspices of the USDA GAP/GHP Program
In the first year of operation, the LGMA issued over 400 citations based on CDFA audits
- None resulted in unsafe product reaching consumers
- Many were paperwork and documentation related
- All have been corrected

Overall compliance is very high – audits found compliance with 99.3% of all audited checkpoints
What’s Next?

- LGMA is beginning third year of operation
  - All existing handlers are still on board
- National Program effort is underway
  - Eventually, all leafy greens marketed in the US should be certified through the program

- Other Initiatives
  - Tomatoes GAP metrics
  - Center For Produce Safety GAPs Validation
  - AFDOs model code
  - Produce traceability initiative
In Closing

- The LGMA-accepted Food Safety Practices represent the best practices available today to prevent food borne illnesses
- Commodity-specific and science-based
- Includes numerous risk assessments applying intervention protocols
- Developed by university and industry scientists, food safety experts, farmers, shippers and processors. Reviewed by state and federal government health agencies
Questions?
Is Food Safety ever good enough?

The absence of evidence is not evidence of absence.
Which worries you more?

- Food-borne illness; it's always around. 36%
- Swine flu; it's unpredictable. 18%
- Whichever one is in the news. 1%
- Neither one: Life's too short. 43%
PFGE Patterns Submitted to PulseNet Databases, 1996 - 2007