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Food Safety Training for County Extension Service Agents
Sponsored by the Southern Region Small Fruit Consortium
Room 100
Savannah International Convention and Trade Center
Savannah, Georgia
January 9-10, 2008

AGENDA

Wednesday, January 9, 2008

1:00 – 6:00 PM  Tour of Gerrald’s Vidalia Sweet Onions – a packinghouse/farm with a food safety plan – Statesboro, GA.

6:30 PM  Dinner on your own

Thursday January 10, 2008

8:00 – 8:15 AM  Coffee and registration

8:15 – 8:30 AM  Welcome and Introductions – Tom Monaco, Powell Smith, and Dave Lockwood

8:30 – 9:30 AM  Bill Morris, UT ‘Microbiology of Water’

9:30 – 10:30 AM  Drew Falkenstein, Marler Clark, LLP, PS ‘The Legal Basis of Foodborne Illness Litigation’

10:30 – 10:45 AM  Break

10:45 – 11:45 AM  Chris Gunter, NCSU ‘Good Agricultural Practices (GAP’s) for the Field’

11:45 – 1:00 PM  Catered Lunch

1:00 – 2:00 PM  Bill Hurst, UGa ‘GAP’s for Packinghouses’

2:00 – 3:00 PM  Linda Stewart, FDA ‘The HAACP Approach to Analyzing and Managing Food Safety’

3:00 – 3:15 PM  Break

3:15 – 4:15 PM  Pete Hatfield, AIB International ‘The Third Party Audit Process’
FOOD SAFETY

SRSFC SPONSORED COUNTY AGENT TRAINING
January 9-10, 2008
Savannah International Convention and Trade Center
Savannah, Georgia
in cooperation with

2008 Southeast Regional Fruit and Vegetable Conference
Microbiology of Water

William C. Morris
Department of Food Science & Technology
Some Water Factoids

• Number of people plagued by water shortage: $0.5 \times 10^9$

• Average gallons used by average American per year: 183 gal.

• Estimated number of people who will be short of water by 2025: $2.8 \times 10^9$
The Essentialness of Water

- Blood in our veins approximates composition of sea water

- Concept of *hydrophilic* and *hydrophobic* nature of biological molecules

- These molecules determine shape of biological molecules and thus decide the specificity of all living processes

**Essential for All living organisms**

Water covers 70% of the world

97% of the water is in the oceans
We are a burgeoning human population unable to move away from its waste

asparagus irrigation
All Microbes Live in an Aqueous Environment

- Ecology of aquatic environments is complex
- Most aquatic environments are teeming with life
- Microbes have evolved to live in:
  - Saturated salt solutions
  - Below freezing to >110°C
  - Waters full of toxic substance, i.e. copper, cyanide, lead, silver, gasoline, oil, benzene, and many others
Water Quality in TN (2004)*

- Sources of Agricultural Pollution in Assessed Streams and Rivers
  - Grazing related 60%
  - Crop related 37%
  - Intensive Animal Ops. 3%

* TN 305 (b) Report 2004
Terminology

- **Potable** - (clean) water – free of all objectionable material, including pathogens, tastes, odors, colors, toxins, radioactive material, organisms, oils, gases, etc.

- **Fresh** – non-salt or sea water

- **Pollution** – anything that makes it Non-Potable

- **Sewage** – the community waste or garbage that mother nature and we dump onto sewers or land
Typical Water Quality Standards

- **Drinking Water**
  - No coliforms contamination acceptable

- **Recreational water**
  - 200 fecal coliforms /100 ml

- **Fish and wildlife habitat**
  - 5000 fecal coliforms/100 ml

- **Shellfish**
  - 14 fecal coliforms/100 ml
Most Probable Number

- 10 ml, 1 ml and 0.1 ml of water inoculated in lactose broth
- Coliforms identified by gas production
- Refer to tables and determine statistical range of number of coliforms

**Does not:**
Detect total number of bacteria
Specific pathogens
Knox County Tennessee

• Environmental Health Department
• They come to the farm and take the sample (use 100 ml)
• Test for total coliforms and *E. coli*
• Only report negative or positive results
  
  (quite doing counts ~12 years ago)

• $40.00 fee
# Bacteria Found In Surface Water

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Disease/ infection</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Aeromonas</em></td>
<td>Enteritis</td>
<td>Very thin, blood- and mucus-containing diarrhea</td>
</tr>
<tr>
<td><em>Campylobacter jejuni</em></td>
<td>Campilobacteriose</td>
<td>Flue, diarrhea, head- and stomachaches, fever, cramps and nausea</td>
</tr>
<tr>
<td><em>Escherichia coli</em></td>
<td>Urinary tract infections, neonatal meningitis, intestinal disease</td>
<td>Watery diarrhea, headaches, fever, homiletic uremia, kidney damage</td>
</tr>
<tr>
<td><em>Plesiomonas shigelloides</em></td>
<td>Plesiomonas-infection</td>
<td>Nausea, stomachaches and watery diarrhea, sometimes fevers, headaches and vomiting</td>
</tr>
<tr>
<td><em>Typhus</em></td>
<td>Typhoid fever</td>
<td>Fevers</td>
</tr>
<tr>
<td><em>Salmonella</em></td>
<td>Salmonellosis</td>
<td>Sickness, intestinal cramps, vomiting, diarrhea and sometimes light fevers</td>
</tr>
<tr>
<td><em>Streptococcus</em></td>
<td>(Gastro) intestinal disease</td>
<td>Stomach aches, diarrhea and fevers, sometimes vomiting</td>
</tr>
<tr>
<td><em>Vibrio El Tor</em> <em>(freshwater)</em></td>
<td>(Light form of) Cholera</td>
<td>Heavy diarrhea</td>
</tr>
</tbody>
</table>
Pathogens of Most Concern on Fresh Produce

- Salmonella
- Escherichia coli
- Yersinia entercolitica
- Clostridium species
- Vibrio species
- Shigella
- Campylobacter
- Staphylococcus aureus
- Bacillus cereus

- Viruses (Hepatitis A, Norwalk)
- Parasites/Protozoa- (Giardia, Entamoeba, Toxoplasma, Sarccystis, Isopora, Cryptosporidium, Eimeria, Cyclospora)
### Waterborne Infectious Disease
(U.S. 1997-1998)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Agent</th>
<th>Outbreaks</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shigellosis</td>
<td><em>Shigella sonnei</em></td>
<td>1</td>
<td>183</td>
</tr>
<tr>
<td>Giardiasis</td>
<td><em>Giardia lambia</em></td>
<td>4</td>
<td>159</td>
</tr>
<tr>
<td>Cryptoporidiosis</td>
<td><em>Cryptosporidium parvum</em></td>
<td>2</td>
<td>1432</td>
</tr>
<tr>
<td>Gastroenteritis</td>
<td><em>E. Coli 0157:H7</em></td>
<td>3</td>
<td>164</td>
</tr>
<tr>
<td>Acute gastrointestinal illness</td>
<td>Unknown</td>
<td>5</td>
<td>163</td>
</tr>
</tbody>
</table>
Other Important Water Transmitted Organisms

- **Vibrio cholerae**
  - Prevalent in U. S. in 1800’s
  - Currently common in Asia, Africa, Latin America
  - Over 100,000 deaths and 2345 deaths in 2004
  - Transmitted through water, fresh vegetables and shellfish
# Protozoa Found in Surface Water

<table>
<thead>
<tr>
<th>Microrganism</th>
<th>Disease</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amoeba</strong></td>
<td>Amoebic dysentery</td>
<td>Severe diarrhea, headache, abdominal pain, chills, fever; if not treated can cause liver abscess, bowel perforation and death</td>
</tr>
<tr>
<td><strong>Cryptosporidium parvum</strong></td>
<td>Cryptosporidiosis</td>
<td>Feeling of sickness, watery diarrhea, vomiting, lack of appetite</td>
</tr>
<tr>
<td><strong>Giardia</strong></td>
<td>Giardiasis</td>
<td>Diarrhea, abdominal cramps, flatulence, belching, fatigue</td>
</tr>
<tr>
<td><strong>Toxoplasma gondii</strong></td>
<td>Toxoplasmosis</td>
<td>Flu, swelling of lymph glands With pregnant women subtle abortion and brain infections</td>
</tr>
</tbody>
</table>
Giardiasis and Cryptosporidiosis

• Both are protozoans

• Transmission through water (97% of all surface water carry cysts)

• Resistant to chlorine, but can be filtered

• 1993 Milwaukee outbreak (100,000)
Some Costly Cases

- *Cryptosporidium*, 1993, Milwaukee, $55 million
- *Pfiesteria piscicida*, 1997, Chesapeake bay, $43 million
- 3700 beach closing in 1996

Mild case of diarrhea cost ~$280 for treatment and diagnosis
Life cycle of *Cryptosporidium*

Transmission occurs mainly through Contaminated water.
Agricultural Water

- **Identify source** and distribution of water used
- Be aware of current and **historical use of land**
- Review existing practices and conditions to identify **potential sources of contamination**.
- Maintain wells in **good working condition**
- How are you applying the water? **Minimize contact of edible portion of fresh produce with contaminated irrigation water.**
## Water Quality Evaluation Log

<table>
<thead>
<tr>
<th>Water Source</th>
<th>Irrigation</th>
<th>Pesticide App.</th>
<th>Hand wash</th>
<th>Produce wash</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open source, canal, Reservoir, pond, etc.</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Munciple water source</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Capped well, <strong>Annual test date</strong></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td>Uncapped well, canal, reservoir, etc.</td>
<td><strong>Quarterly test date</strong></td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Municipal water source</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Quality report date</strong></td>
<td></td>
</tr>
</tbody>
</table>
Routine monitoring of water quality using **indicator organisms**, indicating fecal contamination.

To determine if fecal coliforms are from humans or other animals – must test for fecal streptococci
Fecal coliform/fecal streptococci ratios for humans and other animals

<table>
<thead>
<tr>
<th>Animal</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human</td>
<td>4.4</td>
</tr>
<tr>
<td>Duck</td>
<td>0.6</td>
</tr>
<tr>
<td>Sheep</td>
<td>0.4</td>
</tr>
<tr>
<td>Chicken</td>
<td>0.4</td>
</tr>
<tr>
<td>Pig</td>
<td>0.4</td>
</tr>
<tr>
<td>Cow</td>
<td>0.2</td>
</tr>
<tr>
<td>Turkey</td>
<td>0.1</td>
</tr>
</tbody>
</table>
Characteristics of a Useful Indicator

• Useful for all water types
• Always present when pathogens are present
• Not present in the absence of the pathogen
• Correlated with degree of pollution
• More easily detectable than a pathogen
• Survive longer than the pathogen
• Not dangerous to work with
Bacterial-Indicator Organisms
Common Groups

• Coliforms
  - Total coliforms
  - Fecal coliforms
  - *Escherichia coli*

• Streptococci
  - *fecal streptococci*
  - *enterococci*

• Spore Formers
  - *Clostridium perfringens*
Indicator Organisms

- **General coliforms** – indicate water in contact with plant or animal life (universally present)

- **Fecal coliforms** – mammal or bird feces in water

- **Enterococcus bacteria** (type of fecal streptococci) – feces from warm blooded animals in water

These are not what generally make people sick
Problems With the Coliform Indicator Test

False Positives

*Enterobacter areogenes*

False Negatives

*Salmonella typhi*
Some Factors Affecting Ratio of Indicator Organisms to Pathogens

• Feces from human populations with higher infection rates are of greater concern

• All treatment methods and environmental conditions affect pathogens and indicators differently
  - Chlorinated water may have zero indicators and pathogens, but loaded with viruses.
  - Pathogens can “hide” from treatment inside suspended solids.

The ratio of indictors to actual pathogens is not fixed
Direct Tests For Pathogens

• **Involves selective cultivation to large numbers**
  – Time consuming
  – Expensive
  – Potentially dangerous to lab personnel

• **Molecular tests**
  – Require testing for each pathogen
  – Expensive
  – Require expertise
Viral Sources of Waterborne Disease

- **Hepatitis A**: inflammation and necrosis of liver
- **Norwalk-type virus**: acute gastroenteritis
- **Rotaviruses**: acute gastroenteritis, especially in children
- **Enteroviruses**: many types affect intestines and upper respiratory tract
- **Reoviruses**: infects intestines and upper respiratory tract
Virus Detection

Very difficult and costly

- Electron microscopy
- Immunoassays
- Cell cultures
- Reverse transcription-polymerase chain reaction (RT-PCR)
Chlorination of Water

The most commonly used sanitizer!
Methods of Treatment

• **Shock Chlorination** (50-100 ppm, contact of at least 6 hours)

• **Continuous Chlorination** — for recurring bacterial contamination problems — a measurable amount of free residual chlorine
Chlorine Terms

• Chlorine **Dosage** – total added
• Chlorine **Demand** - inorganic
• **Combined Residual Chlorine** - organic
• **Free Residual Chlorine**
Chlorine Dosage
Chlorine Dosage

Chlorine Demand

Residual Chlorine
Free Residual Chlorine

• Chlorine remaining after combining with organic matter

• **Bacteria kill rate proportional to concentration of free residual**

DPD, N,N-diethyl-p-phenylene-diamine
Bottom Line

• Test your water as required and anytime you suspect a problem

• Work with your County Environmental Health Department

• Seek advise on interpreting the results – what do they mean?

• If you question the results, resample and retest
PROFITING FROM UNSAFE FOOD: The Economics, Law, and Politics of Foodborne Illness Litigation.

David W. Babcock, J.D.
dbabcock@marlerclark.com

2008 SOUTHERN REGION SMALL FRUIT CONSORTIUM CONFERENCE
“Food safety…would seem to be the least political of food issues. **WHO COULD POSSIBLY NOT WANT FOOD TO BE SAFE?** Consumer do not want to worry about unsafe food and do not like getting sick. Unsafe food is bad for business (recalls are expensive, and negative publicity hurts sales) as well as for government (through lost trust).”

See Preface at x.
ECONOMICS OF FOOD SAFETY:

ISN’T FOOD SAFETY A NO-BRAINER?

“When industry successfully innovates to produce safe food, a win-win situation arises, with the innovating firm, consumers, and government all benefiting from improved food safety.”

Elise Golan, et al., Food Safety Innovation in the United States, USDA AER # 831
Food: The most dangerous product in the United States?

“In fact, contaminated food products caused more deaths each year than the combined totals of all 15,000 products regulated by the U.S. Consumer Product Safety Commission; these products caused only 3,700 deaths in 1996.”

Estimated 76 million cases of foodborne illness each year
325,000 hospitalizations, and over 5,000 deaths.

UNKNOWN AGENTS account for 81% of illnesses and hospitalizations, and at least 64% of total deaths.

Adding Up the Price We Pay

For **FIVE** foodborne pathogens, medical costs, productivity losses, and the costs of premature death total:

**$6.9 BILLION**

But there are over **FORTY** different foodborne pathogens thought to cause human illness.

“This [$6.9 billion estimate] represents only a fraction of the total costs due to foodborne illness, which include some costs, such as pain and suffering, that are difficult to quantify, and other costs, such as public health expenditures, that are often overlooked.” (Buzby at 1).

“Using [the FDA $5 million per-life] value and the Mead study, the annual costs of deaths caused by unknown foodborne agents would be $17 billion….Despite the uncertainty about the benefits of reducing deaths from unknown foodborne agents, the possible economic losses are so large that increased efforts to identify [such] agents appears to be warranted.”

1. See Paul Frenzen, *Deaths Due to Unknown Agents*, Emerging Infect. Dis., 10; 9, at p. 1542 (Sept. 2004) (arguing the Mead estimate underestimated the number of deaths attributable to foodborne agents).
“And what about the losses you can’t put a price on? The parents of a four year old are informed that their child will likely need a kidney transplant before she is fifteen. A perfectly healthy six year old loses her pancreas, becomes a diabetic, and has to take 40 pills a day. A nine year old is terrified to go to sleep for fear she will never wake up again…. The price of foodborne illness is too high.”

Regulations are depicted as imposing costs and market-inefficiencies on business.

Government agencies are depicted as either hapless bureaucracies or industry-stooges.

Public Interest Groups tend to be weak, except in the wake of a large outbreak.

“Rather than collaborating to reduce foodborne pathogens, the agencies and companies shift attention to consumer education as the best way to ensure safe food.”

See Nestle, Safe Food, at 113.
Fake and substandard ingredients give competitors an economic edge via low costs.

The food industry **DEMANDED** regulation to level the competitive playing-field.

→ *e.g.*, use of inferior ingredients, fillers, and mislabeling.

"Ironically, early food laws were intended to prevent "economic adulteration.""
So, why is there unsafe food rather than only safe food?
The Existing Incentives for Companies to Produce Safe Food Products

• *Market Forces* ~ risk of damage to business reputation, market share, and sales revenue;

• *Food Safety Laws and Regulations* ~ violations can result in fines, product-recalls, or plant-closures;

• *Product Liability Law* ~ firms found legally liable for injuries caused by a defective food product may be forced to financially compensate the victim and, in some cases, pay punitive damages.

These are all *NEGATIVE* incentives, and they’re weak.
A “Rational” Actor Will Not Invest in Food Safety, Unless:

✓ receives higher prices for higher quality good, or
✓ lowers the cost of production, or
✓ reduces risk of loss or damage.

“Appropriability, the ability to control and exploit the benefits from innovation, play a key role in driving investment in innovation. Only if firms expect to be able to reap the benefits of an innovation will they have an incentive to innovate.” (Golan at 3)
“Food Safety” Is Difficult to Sell

Because it is impossible to detect, even when food is consumed.

“For the most part, food safety is a credence attribute, meaning the consumers cannot evaluate the existence or quality of the attribute before purchase, or even after they have consumed [it].”

CREDENCE = TRUST

Who Pays for the decision **NOT** to invest in food safety?

“Private markets often fail to provide adequate food safety because information costs are high, detection often very difficult, and the nature of contamination is complex. Underlying many of the food safety failures is the existence of externalities, or **costs not borne by those whose actions create them.**”

“In a world of perfect information and competition, markets should penalize firms that produce unsafe products. Firms would receive negative signals about their errors and markets would correct themselves.” (Buzby at 8).
Asymmetric Information, or “The Market for Lemons”

- Sellers knows more than buyers.
- Buyers cannot detect quality.
- Sellers can’t charge more for quality.
- Increased quality = Increased costs.

“there is an incentive to for sellers to market poor quality merchandise since the returns for good quality accrue mainly to the entire group…rather than to the individual seller.” ~ George Akerlof, Ph.D.
An Example: Fresh Spinach

“With the fall 2006 outbreak, all spinach growers suffered from decreased consumer demand for their product, even though only one grower’s spinach was contaminated.”

See L. Calvin, *Outbreak Linked to Spinach Forces Reassessment of Food Safety Practices*, Amber Waves, June 2007,
HACCP to the Rescue?

MARKET FAILURE: The Need for Regulation.

“When consumers cannot trace an illness to any particular food…, food retailers and restaurateurs are not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable. This lack of marketplace accountability for foodborne illness means that meat and poultry producers may have little incentive to incur costs for more than minimal pathogen and other hazard controls. HACCP Rules, 60 Fed. Reg. 6774 (Feb. 3, 1995).

In 2003, USDA estimated compliance with HACCP regulations raised a plant’s costs of production 1.1%: 0.4 cents per pound for poultry and 1.2 cents for beef.
"Lawsuits by consumers to recover damages due to foodborne illness can affect the behavior of firms that make or distribute food products. The magnitude of this effect is unknown, however, because information about litigation involving injuries due to food products contaminated by microbial pathogens is scarce. Firms...generally prefer to resolve consumer complaints about foodborne illness outside the courtroom, where they can keep the compensation payments confidential, and avoid or reduce adverse publicity about their products.” (Buzby, et al., Chapter 1, at p. 2)
Economically-speaking, a product liability lawsuit is a **COST-SHIFTING** mechanism.

Person injured by unsafe food pays cost in medical bills, lost wages, and pain.

Lawsuit seeks recovery of damages caused by (profits of) sale of unsafe food.

**BUT:** “Filing lawsuits is an expensive proposition—in time and emotion—for the victims of outbreaks and is another end-stage solution for a problem that should be prevented in the first place.” (Nestle, at 130.)
A “Rational” Lawyer Will Not Invest in a Lawsuit, Unless

- facts and law support a claim, and
- likely recovery is high enough for both client and lawyer to recover, and
- likelihood of settlement is high.

As of October 2007, Marler Clark had over 750 active case-files, not counting Peanut Butter and Pot Pie cases.
SEPARATING WHEAT FROM THE CHAFF: the evaluation of a foodborne illness claim.

“By presenting to the court...a pleading...an attorney...is certifying that to the best of the person’s knowledge, information and belief, formed after an inquiry reasonable under the circumstances,—

the claims...are warranted by existing law...

the allegations and other factual contentions have evidentiary support...”

~ Requirements of Rule 11
TAKING A CASE ON: A Combined Legal and Business Decision

Are the facts credible?
Is there a theory of liability?
Is the liable entity solvent?
Does the value of the case justify the risk/investment?

In the United States, nearly all personal injury cases are handled on a contingency fee basis.
There is a Worm in my Freezer!

“I recently found a whole, 2-cm long worm packaged inside a Lean Cuisine frozen dinner. I have the worm in my freezer. I'm interested in discussing my rights in this matter. Could you please contact me, or refer me to a firm that may be able to give me assistance?”
“I opened a box of Tyson Buffalo wings and dumped them out on a plate to be cooked in the microwave. An unusually shaped piece caught my eye and I picked it up. When I saw that the ‘piece’ had a beak, I got sick to my stomach. My lunch and diet coke came up and I managed to christen my carpet, bedding and clothing. I want them to at least pay for cleaning my carpet etc.”
“After taking two bites and tasting rather badly, he found what appeared to be a rather large piece (approx. the size of the back of an adult's fist) of human or animal flesh. Even though he didn't seek medical attention, he did become very nauseated. I do feel that the manufacturer should be held responsible for this mishap.”
Searching for Proof of a Valid Claim

- Laboratory testing
- Matching symptoms with incubation periods of specific pathogens
- Matching symptoms with specific characteristics of pathogens

Without knowing the pathogen, it is difficult—if not impossible—to rule out food or exposure possibilities.
# Matching Symptoms with Incubation Periods

## Incubation Periods Of Common Pathogens

<table>
<thead>
<tr>
<th>PATHOGEN</th>
<th>INCUBATION PERIOD</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Staphylococcus aureus</em></td>
<td>1 to 8 hours, typically 2 to 4 hours.</td>
</tr>
<tr>
<td><em>Campylobacter</em></td>
<td>2 to 7 days, typically 3 to 5 days.</td>
</tr>
<tr>
<td><em>Hepatitis A</em></td>
<td>15 to 50 days, typically 25-30 days.</td>
</tr>
<tr>
<td><em>Listeria</em></td>
<td>3 to 70 days, typically 21 days</td>
</tr>
<tr>
<td><em>Norovirus</em></td>
<td>24 to 72 hours, typically 36 hours.</td>
</tr>
</tbody>
</table>

**COMMON LOGICAL FALLACY ~ Post Hoc Ergo Propter Hoc**
Using PFGE Testing to Link an Infection to a Common Source

PFGE testing has improved outbreak investigation while also raising the evidentiary bar on proving a FBI claim.
“Most plaintiffs failed to convince juries that defendants were legally responsible for causing their illness. One-third of verdicts (31.4 percent) resulted in a monetary award for the consumer. For the 55 cases where the plaintiffs prevailed, the mean award was $133,280 [while the median was $25,560].” (Buzby at 15)

**But Note:** The Marler Clark Law firm was formed in June 1998.
Civil Litigation - How it works
(by Bill Marler)

• Strict Liability - it is your fault - period
• The only defense is prevention
• Wishful thinking does not help
• If you manufacture a product that causes someone to be sick you are going to pay
Strict Liability is the legal standard (usually) applied to manufacturers.

A “manufacturer” is defined as a “product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer....” RCW 7.72.010(2); see also Washburn v. Beatt Equipment Co., 120 Wn.2d 246, 258-59, 840 P.2d 860 (1992)

**QUERY**: Is a bag of pre-cut, pre-washed lettuce a *manufactured* product?
PROVING A PRODUCT DEFECT: The CONSUMER EXPECTATION Test.

A Food Product Is DEFECTIVE if it is not Reasonably Safe—

That is, unsafe beyond that which is expected by a reasonable consumer.

Is it reasonable for consumers to expect that all food should be pathogen-free?
How do you prove a product is defective if it no longer exists (because it was eaten)?
In Food Product Cases, the “malfunction doctrine” makes proof of defectiveness easy.

The fact of the injury proves the fact of defect.

Used as intended, the product did not perform as designed.

CONTRAST: Design or “Generic” Defect Cases.
Res Ipsa Loquitur

THE THING SPEAKS FOR ITSELF

“A barrel could not roll out of a warehouse without some negligence, and to say that a plaintiff who is injured by it must call witnesses from the warehouse to prove negligence seems to me preposterous. “

~ Byrne v. Boadle, 1863
STRICT LIABILITY: In Sum.

- The focus is on the product; not conduct.
- You are liable if:
  - The product was unsafe and thus defective
  - The defective product caused an injury

STRICT LIABILITY IS A VERY PLAINTIFF-FRIENDLY STANDARD.
Full Arsenal of Product Liability Claims:

- **Strict Liability**
- **Negligence**
- **Breach of Warranty**
  - Express
  - Implied

Although proof of negligence is not necessary, it is often offered to inflame the jury, and inflate the jury’s likely award of damages.
Compensatory Damages:

- **Special damages**
  - Medical bills
  - Wage loss

- **General damages**
  - Pain, suffering, loss of enjoyment of life, and mental anguish

Usually the severity of a damage claim is determined by the amount of medical bills. With foodborne illness cases that rule-of-thumb often does not hold true.
Punitive (or Exemplary) Damages:

- Punish the defendant for its conduct;
- Deter others from similar conduct.

Historically, such damages were awarded to discourage intentional wrongdoing, wanton and reckless misconduct, and outrageous behavior.
A Washoe County jury awarded $25.2 million in punitive damages on Thursday to five Reno Hilton guests who became ill six years ago during a viral outbreak caused by company negligence.

An outbreak of gastrointestinal Norwalk virus affected 642 guests and 365 employees between May 15 and June 29, 1996, health officials said, and was traced to sick employees being on the job.
Where the Action Is:

Fresh Produce

(until lately)
AN EXAMPLE: Chi-Chi’s Hepatitis A Outbreak, 2003

- Over 660 persons infected
- Four death cases
- 9,489 exposures cases
- Over $46 Million in settlements
- $800,000 class action settlement for exposure cases
- Sued by health department for outbreak-related costs
- Filed for bankruptcy and business-assets liquidated
Another Cause of the Outbreak:

“The ice water in the bucket became, essentially, "hepatitis soup," said Dr. Michael Osterholm, an epidemiologist at the University of Minnesota who has investigated many hepatitis outbreaks.”

“Government Makes It Official: Blame Scallions for Outbreak,” by Denise Grady, NEW YORK TIMES, November 22, 2003

NB: This also made it nearly impossible to identify the upstream supplier of the contaminated onions. *

* Arbitration ruling this year issued a multi-million dollar award to Chi-Chi’s as against processor/supplier of green onions.
Richard Miller’s Settlement
(as reported in the news)

$6.25 million total settlement to hepatitis victim

U.S. District Judge Terrence McVerry approved the settlement on Thursday, September 29, 2006, a week before Richard Miller turned 59.

About $4.1 million will be put into the trust, which will be administered by US Bank. Miller's wife, Linda, and their three children each will receive $100,000.
Class-action notices to be mailed in Chi-Chi's outbreak

JOE MANDAK  
Associated Press  
Fri, Aug. 05, 2005

PITTSBURGH - More than 9,000 people who received shots to ward off hepatitis A after an outbreak at a Chi-Chi's restaurant will be mailed forms later this month so they can claim their share of an $800,000 class-action settlement.

The federal judge overseeing Chi-Chi's bankruptcy last month approved a schedule to mail the notices by Aug. 24 to the 9,489 people who got immune globulin shots from the Pennsylvania Department of Health after the outbreak was publicized in early November 2003.
Economic Costs to Growers:

~ On November 14, 2003, price of green onions peaked at $18.30 per box.

~ On November 20, FDA announced hepatitis-contaminated onions came from Mexico.

~ Next day, price of green onions declined to $12.43.

~ One week later, price was at $7.23 per box.*

And thus the mad-scramble for GAP-audits began.

* Figures from L. Calvin, The Economics of Food Safety: The Case of Green Onions and Hepatitis A Outbreaks, USDA/ERS Report, VGS-305-01, 12/04.
Recent *E. coli* Outbreaks

- **July 2002 – WA Dance Camp**
  - 50 dance campers sickened, several hospitalized, one with life-long kidney damage
  - “Pre-washed” lettuce

- **September 2003 – CA Restaurant**
  - 40 patrons ill
  - Salads prepared with bagged, “pre-washed” lettuce

- **October 2003 – CA Retirement Center**
  - 13 residents sickened, 2 died
  - “Pre-washed” spinach
2005 Lettuce *E. coli* Outbreak

- 23 laboratory-confirmed cases of *E. coli* O157:H7; 7 “probable” (epi-linked) cases
- September 16 to September 30 onset
- 2 cases of HUS
- Cases in MN, OR, and WI
- Statistically associated with eating Dole pre-packaged lettuce
- “Smoking Gun” – found in bag
2006 Wendy’s *E. coli* Outbreak

- Utah - June 2006
- *E. coli* O21:H19 - only 3 culture-positive case, although over 50 cases deemed “probable”
- 3 HUS, 2 adult women, 1 with 30 days dialysis, the other with 4 months
- Likely source: lettuce from California
2006 Spinach Outbreak

- 199 persons infected with outbreak strain of E. coli O157:H7 from 26 states.
- 102 (51%) hospitalized.
- 31 (16%) developed hemolytic–uremic syndrome (HUS).
- Four confirmed deaths.
- Outbreak strain isolated from 13 bags in 10 States.
- 11 bags with lot-codes for a single day’s production.

“...a number of conditions were observed that may have provided opportunities for the spread of pathogens, if [they] arrived on incoming spinach.” CalFERT Report, at 3 (March 2007).
2006 Taco *E. coli* Outbreaks

- At least 150 sickened in 7 Different States
  - dozens hospitalized
  - several HUS cases
- 2 outbreaks separated by a few weeks at two different restaurant chains.
- Different suppliers and growers for each restaurant.
- Lettuce grown in California
The Rise of Class Actions:
Peter Pan Class Definition: 1.0

5.3 **CLASS DEFINITION:** The proposed class is defined to include all persons who: (1) purchased Peter Pan or Great Value peanut butter since May 2006 with a product-code beginning with 2111 imprinted on the lid; and (2) as a result suffered either (a) a lab-confirmed *Salmonella* infection, or (b) symptoms consistent with a *Salmonella* infection—*i.e.*, fever, abdominal cramps, headache, and diarrhea—that otherwise fit the CDC case-definition for the subject outbreak. As the class is defined, it is not intended to include atypical *Salmonella* infection cases—*e.g.*, those where death resulted, or that required extended hospitalization.

*By the time of transfer by the MDL panel, over 50 class action lawsuits had been filed.*
Another Bad Day for ConAgra

As of October 10, there were 139 cases of Salmonella poisoning in 30 states, which led to a Banquet pot pie recall for both Banquet brand pot pies and their store brand generic equivalents.

On October 24, a Google search for “pot pie lawyer” over 10 pages of hits for law firm web-sites and ads.
And here we go again...

TOPPS MEAT RECALL

From a recent Marler Clark lawsuit press release:
Marler continued, “As The Terminator would say, ‘E. coli in ground beef is baaaack.’”

SAM’S CLUB/CARGILL
MEAT RECALL
Why is there unsafe food?

Because it’s profitable.
And why are there lawsuits?

Because it’s profitable.

(And someone has to do it.)
Questions? Comments?
Marler Clark
ATTORNEYS AT LAW, L.L.P., P.S.

6600 Bank of America Tower
701 Fifth Avenue
Seattle, WA 98104

Tel: 206.346.1888
Fax: 206.346.1898
email: dstearns@marlerclark.com
web: www.marlerclark.com
Good Agricultural Practices (GAPs) for the Field

Chris Gunter, PhD
Department of Horticultural Science
Chris_gunter@ncsu.edu
Why Should We Care?

- 76 million cases of food borne illness
- 325,000 people hospitalized for foodborne illness
- 5,200 needless deaths each year
- Economic losses between 10-83 billion dollars
Produce Associated Outbreaks Affect Business

• Strawberry industry lost an estimated $50 million in 1996 after mistakenly being indicated as the source of pathogens in an outbreak

• Odwalla shareholder value dropped approximately 41% ($12.4 million) in six months after outbreak

• May result in unwanted legislation or regulation

• Work against produce promotions campaigns
Microbes That Cause Foodborne Illness

- **Bacteria** – Single-celled organisms that live independently.
- **Viruses** - small particles that live and replicate in a host.
- **Parasites** - intestinal worms or protozoa that live in a host animal or human.
Number of Produce Associated Outbreaks by Decade, 1973 - 1997

Outbreaks / year

Decade

1973-79: 3.7
1980-89: 6.5
1990-97: 10.5
<table>
<thead>
<tr>
<th>Known/Suspected Vehicle</th>
<th>Type of product</th>
<th>Year</th>
<th>Brand/Source of contamination</th>
<th>Recall/FDA Alert</th>
<th>Pathogen</th>
<th>Location</th>
<th>Venue</th>
<th>No. of Cases/Deaths</th>
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<tbody>
<tr>
<td>Lettuce</td>
<td>RTE</td>
<td>1983</td>
<td></td>
<td></td>
<td>Shigella sonnei</td>
<td>Texas</td>
<td>University</td>
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<td>Lettuce/salad</td>
<td>RTE</td>
<td>1986</td>
<td>Possibly infected food handler (shredded by hand)</td>
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<td>Hepatitis A</td>
<td>Florida</td>
<td>Restaurant</td>
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<td>RTE</td>
<td>1986</td>
<td>Possibly infected food handler at shredding facility</td>
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<td>Texas</td>
<td>Restaurant</td>
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<td>Iceberg lettuce</td>
<td>RTE</td>
<td>1988</td>
<td>Bags of lettuce</td>
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<td>Hepatitis A</td>
<td>Kentucky</td>
<td>Restaurant</td>
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<td>RTE</td>
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<td>Giardia</td>
<td>New Mexico</td>
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<td>RTE</td>
<td>1990</td>
<td>Contamination of water bath used by packer</td>
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<td>Salmonella spp</td>
<td>South Carolina</td>
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<td></td>
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<td>Multi-state, US</td>
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<td></td>
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<td>Salmonella montevideo</td>
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<td>Oregon</td>
<td>Restaurant</td>
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<td>Guatemala</td>
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<td>Florida</td>
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<td>Idaho</td>
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<td>RTE</td>
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<td>Cross contamination from raw chicken juices</td>
<td>Campylobacter jejuni</td>
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<td>Guatemala</td>
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<td>Cyclospora cayetanensis</td>
<td>US and Canada</td>
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<td>Possibly Peru</td>
<td>NO</td>
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<td>Pathogen</td>
<td>Location</td>
<td>Venue</td>
<td>No. of Cases/ Deaths</td>
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<td>1997</td>
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<td>California</td>
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<td>Voluntary</td>
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<td>E.coli O157:H7</td>
<td>California</td>
<td>Restaurant</td>
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<td>Voluntary</td>
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<td>E.coli O157:H7</td>
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<td>KFC</td>
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<td>E.coli O157:H7</td>
<td>Indiana</td>
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<td>Agricola Herendira S. de R.L. de C.V., Mexico</td>
<td>Market Recall</td>
<td>Shigella sonnei</td>
<td>MN, MA, CA</td>
<td>Restaurants</td>
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<td>Baja, Mexico</td>
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<td>E.coli O157:H7</td>
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<td>E.coli O157:H7</td>
<td>Pennsylvania</td>
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<td>1999</td>
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<td>E.coli O157:H7</td>
<td>California</td>
<td>Community</td>
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<td>Coleslaw (cabbage)</td>
<td>RTE</td>
<td>1999</td>
<td>KFC</td>
<td>NO</td>
<td>E.coli</td>
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<td>Community</td>
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<td>E.coli O157:H7</td>
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<td>Affected States</td>
<td>Type</td>
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<td>&quot;Viva&quot;-Mexico</td>
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<td>S. poona</td>
<td>Multi-state US</td>
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<td>Camp</td>
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<td>2003</td>
<td>&quot;Gold Coast Produce, F.T. Produce Inc.&quot;- packaged, pre-washed</td>
<td>NO</td>
<td>E.coli O157:H7</td>
<td>California</td>
<td>Restaurant-Pat and Oscar’s</td>
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<td>Apio Fresh, LLC Importer from Baja-Mexico</td>
<td>Market Recall</td>
<td>Norovirus</td>
<td>Pennsylvania</td>
<td>Chi Chi Restaurant</td>
<td>601/4</td>
</tr>
<tr>
<td>Spinach</td>
<td>RTE</td>
<td>2003</td>
<td></td>
<td></td>
<td>E.coli O157:H7</td>
<td>California</td>
<td>Nursing home</td>
<td>16/2</td>
</tr>
<tr>
<td>Mesclin/spring mix salad</td>
<td>RTE</td>
<td>2004</td>
<td>Food handler</td>
<td>NO</td>
<td>Cyclospora</td>
<td>Texas</td>
<td>Restaurant</td>
<td>38/0</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>RTE</td>
<td>2004</td>
<td>Coronet Foods - packaged</td>
<td>Stopped production</td>
<td>Salmonella spp</td>
<td>US and Canada</td>
<td>Various</td>
<td>561/0</td>
</tr>
<tr>
<td>Mesclin/spring mix salad</td>
<td>RTE</td>
<td>2004</td>
<td>Food handler</td>
<td>NO</td>
<td>Cyclospora</td>
<td>Illinois</td>
<td>Restaurant</td>
<td>57/0</td>
</tr>
<tr>
<td>Iceberg lettuce</td>
<td>RTE</td>
<td>2004</td>
<td></td>
<td></td>
<td>Salmonella newport</td>
<td>Maryland</td>
<td>Restaurant / deli</td>
<td>97/0</td>
</tr>
<tr>
<td>Parsley</td>
<td>RAC</td>
<td>2005</td>
<td>Cal Farms, LLC</td>
<td></td>
<td>E.coli O157:H7</td>
<td>WA, OR</td>
<td>Restaurant</td>
<td>60/0</td>
</tr>
<tr>
<td>Lettuce</td>
<td>RTE</td>
<td>2005</td>
<td></td>
<td>YES</td>
<td>E.coli O157:H7</td>
<td>WI, OR, MN</td>
<td>Various</td>
<td>23/0</td>
</tr>
<tr>
<td>Lettuce</td>
<td>RTE</td>
<td>2005</td>
<td>Food handler</td>
<td></td>
<td>Norovirus</td>
<td>Michigan</td>
<td>Restaurant</td>
<td>55/0</td>
</tr>
<tr>
<td>Spinach</td>
<td>RTE</td>
<td>2006</td>
<td></td>
<td>YES</td>
<td>E.coli O157:H7</td>
<td>Multi-state US</td>
<td>Various</td>
<td>204/3</td>
</tr>
</tbody>
</table>
## Harmful Microorganisms & Outbreaks Associated with Produce

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Produce</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>E. coli</em> O157:H7</td>
<td>Iceberg lettuce, radish sprouts, unpasteurized apple cider/ juice</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>Tomatoes, bean sprouts, sliced watermelon, sliced cantaloupe, coleslaw &amp; onions, alfalfa sprouts, root vegetables, dried seaweed</td>
</tr>
<tr>
<td><em>L monocytogenes</em></td>
<td>Cabbage</td>
</tr>
<tr>
<td><em>B. cereus</em></td>
<td>Sprouts</td>
</tr>
<tr>
<td><em>Hepatitis A</em> virus</td>
<td>Iceberg lettuce, raspberries, strawberries</td>
</tr>
<tr>
<td><em>Cryptosporidium</em></td>
<td>Apple cider</td>
</tr>
<tr>
<td><em>Cyclospora</em></td>
<td>Raspberries</td>
</tr>
</tbody>
</table>
It is a local problem!

• 19 produce related outbreaks
  – 2003-2005 FL, Georgia, North and South Carolina and Tennessee
• Over 1,413 people became ill
• Largest single out break 425 school children
• Most common source was leafy greens and the agent was norovirus
Frequency of Pathogens on Produce

• Vegetables (from literature):
  – *Salmonella* 1-8%
  – *L. monocytogenes* 2-30%
  – *Shigella* 1%
  – No difference was found between organic and conventional

• FDA Produce Surveillance Program
  – Imports - 4% positive rate (*Salmonella & Shigella*)
  – Domestic - currently being conducted
One Recent Example

E. coli on bagged Spinach
Economic Loss
Info from Thomas’ Slides

Charles Dharapak/Associated Press
What can we do?
Educate the Industry
Where do they attach
No Magic Bullet
Pre-Harvest
- Irrigation water cleanliness
- Water used for pesticide mixing
- Frost-protection water cleanliness
- Animal exclusion
- Soil contaminants

Harvest & Packaging
- Pesticide residuals
- Animal exclusion
- Culling – damaged and soiled fruit
- Basket, clamshell and tray cleanliness/sanitation

Storage
- Documentation and record-keeping
- Forced air cooling:
  - Temperature considerations
  - Equipment sanitation
- Modified atmosphere

Personnel Cleanliness
- Human disease symptoms and recognition
- Exclusion of ill workers
- Transmission of disease: cross contamination
- Proper hand-washing is critical
- Restroom facilities

Transport
- Vehicle cleanliness
- Reefer maintenance
- Receiver unload system
- Temperature control
- Impact of personnel, handling, loading and unloading on product safety

Unpacking and Display
- Product quality issues
- Limit consumer handling
The large picture

• Consider the process (3)
  – PreHarvest
  – Harvest and Handling
  – Postharvest
• Consider the areas (3)
  – Employee hygiene
  – Water
  – Manure
• Equipment
Iceburg lettuce field and harvest unit
Field conveyor

Field packing into bins
Documented Food Safety Plan

Safety Program has Been Implemented

Implementation of “The Guide”

Who Will Teach?
How will we entice industry to participate?
New regulations? Enforcement?

Simple Solution is Voluntary Compliance with Recognized Good Management Practices
An Individual is Responsible

The Operation has a Food Safety Officer

Officer has Authority to Stop Production to Ensure Compliance
Have a WRITTEN Plan

Printed Plan that can be Easily Reviewed

Already doing this for Pesticides etc.
Personalize Your Plan

Make it Fit Your Operation

Remember what you put in the plan you MUST do
Self Audit

Check that your plan is being used and works!

More about this later!
Clean and Sanitize Equipment

Harvest Containers
Field Equipment
Field Packing
Bins
Water Supply Testing

Remember:
Agricultural Water
Irrigation
Pesticide and Nutrient Sprays
Processing Water
Dump, wash, rinse, cool
Water Quality Management
Sanitation Practices
Microbial Testing
Assign Responsibility

Change in Practices....

.....requires trust in new practices
Pesticide Records and WPS Training
Employee Hygiene/Toilet Systems

• We could spend the whole day talking about this topic
  – Handwashing
  – Injuries
  – Personal Health
  – Training
  – Pick-your-own operations
Proper hand-washing is the best method of reducing contamination.

The #1 source of food borne illness is unsanitary worker conditions.
Remember: proper facilities reduce risk
Animal and Pest Control
Bird Droppings on Harvest Equipment

Photo Courtesy Dr. Jim Rushing
Transportation – Field and Market

Inspect the Truck
Cleanliness
Proper Temperature
Loading Pattern
Worker Hygiene
UFL Cantaloupe Netting Infiltration Research

Courtesy Dr. Jerry Bartz
UFL Cantaloupe Dye Infiltration Research

Could Be Bacteria

Courtesy Dr. Jerry Bartz
Land Use History

- Grazing Animals
- Hazardous Chemical Exposure
- Cull Piles, refuse dumps, debris proximity
Assess Potential for Contamination

Farm diagram/layout
Farm Layout/Topography
Adjacent Use of Land

“Are there animals close by?”
Sings of Problems and Harvest

- Avoid Contact with Soil
- Avoid Bruised or Cut Fruit
- Avoid Improper Handling/Contact
Hmm – Tastes Good!
Top 15 Actions To Address GAPs

1- Document
2- Document
3- Document
4- Document
5- Document
6- Document
7- Document
8- Document
9- Document
10-Document
11-Document
12-Document
13-Document
14-Document

15- If it is not written down, it did not happen.
Workers document training
Signs posted and check list posted for restroom facilities
Self Certification and 3rd Party Audits
Self Certification

- Means going through the process of food safety on the farm
- No cost
- No Certification to show end marketers
- UC Davis Self-Checklists
- Cornell GAP
3rd Party Audits

• Annual Certification
  – During growing season
• Costs $$
• Neutral party audits the process or procedures
• Auditors
  – Primus Labs
  – Davis Fresh
  – NCDA
  – others
The “Skinny” on the GAP

1. Prevent Microbial contamination
2. Start program of GAPs
3. Human/animal feces
4. Water
5. Animal manure (proximity and days)
6. Worker hygiene/sanitation
7. Follow all applicable laws (pesticides, etc)
8. Traceback/recordkeeping/documentation
USDA Audit Criteria

• One to Eight Parts to audit- 80% passing – DON”T HAVE TO HAVE ALL 8!

• USDA Audit in Book

  General Farm
  – Part 1 – Farm Review
  – Part 2 - Field Harvest and Field Packing Activities
  – Part 3 - House Packing Facility
  – Part 4 – Storage and Transportation
  – Part 5 – Traceback
  – Part 6 – Wholesale Distribution Center/Terminal Warehouses
  – Part 6-A – Traceback
  – Part 7 – Preventive Food Security Procedures
Areas that typically fail in Audit

- Worker Health & Hygiene
- Water Usage
- Livestock proximately
Food Safety Plan

Dr. John Rushing – NCSU Food Science
Dr. Chris Gunter – NCSU Horticulture
Diane Ducharme – NC Cooperative Extension
Several Growers in Madison, Buncombe, Haywood, and Henderson Counties
## General Questions

### Implementation of a Food Safety Program

<table>
<thead>
<tr>
<th>Questions</th>
<th>Points</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Doc</th>
</tr>
</thead>
<tbody>
<tr>
<td>G-1 A documented food safety program that incorporates GAP and/or GHP has been implemented.</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-2 The operation has designated someone to implement and oversee an established food safety program. Name ______________________</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
</tbody>
</table>

## Worker Health & Hygiene

<table>
<thead>
<tr>
<th>Questions</th>
<th>Points</th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
<th>Doc</th>
</tr>
</thead>
<tbody>
<tr>
<td>G-3 Potable water is available to all workers.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-4 Training on proper sanitation and hygiene practices is provided to all staff.</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-5 Readily understandable signs are posted to instruct employees to wash their hands before beginning or returning to work.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-6 Employees are required to wash their hands before beginning or returning to work.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-7 All employees and all visitors to the location are required to follow proper sanitation and hygiene practices.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-8 Employees and visitors are following good hygiene/sanitation practices.</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-9 All toilet/restroom/field sanitation facilities are clean. They are properly supplied with single use towels, toilet paper, and hand soap or antibacterial soap and potable water for hand washing.</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-10 All toilet/restroom/field sanitation facilities are serviced and cleaned on a scheduled basis.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-11 Smoking and eating are confined to designated areas separate from where product is handled.</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>G-12 Workers with diarrheal disease or symptoms of other infectious disease are prohibited from handling fresh produce.</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td>D</td>
</tr>
</tbody>
</table>
Documented Food Safety Plan – Purpose Statement

Fanning-Fletcher Farms is committed to production of safe and high quality foods. We subscribe to the principle that the appropriate method to accomplish this is to minimize the microbial, chemical and physical contamination of produce at all points of the production process. In order to accomplish this, the following food safety plan is implemented and to be followed by all employees, contractors and visitors to Fletcher-Fanning Farms production sites and facilities. Suggestions to improve this plan are encouraged at any time. This plan will be reviewed and re-approved at least annually or at the beginning of the spring planting season.

Jim Farmboss, Owner and Operator
Statement on GAP Plans

• This plan shall be in effect until authorized changes are made in writing and recorded. Document with Date, Section Changed, Effective Date, Authorized by

• 2. Authorized changes to this document may be made at any time by Tim Greenthumb or Jack Crewchief who are designated to implement this plan.

• 3. Tim Greenthumb is GAP’s-trained and is designated to implement and to oversee this Food Safety Program. He will be responsible for training of employees and is provided with the authority and resources to fully accomplish this task.

• 4. All required documents are to be maintained at Fanning-Fletcher Farms Produce Packing offices after the date of their generation. Documents will be maintained according to the Document Log at Appendix I.
I am committed to working safely with food to ensure the well-being and health of my family and those who eat this produce. I am informed of and will abide by these safe food handling practices.

Me encuentro comprometido a trabajar en forma segura y responsable con alimentos para asegurar el bienestar y salud de mi familia y de aquellos que coman nuestro producto. Afirmo que estoy informado y comprometido con las prácticas seguras de manejo de los alimentos.

Employee Name (please print) 
Nombre Empleado

Employee Signature 
Firma

1. ________________________________

Tim Greenthumb ________________________________
Jack Crewchief ________________________________

*Training material to be attached with a staple. All Documents
Acknowledgements

• Trevor Phister
• Diane Ducharme
• Billy Little
• Bill Hurst
Keep Our Produce Safe

Any Questions?
Good Agricultural Practices for Field and Packing Facility Operations

County Agent Food Safety Training
Southern Region Small Fruit Consortium
January 9-10, 2008
Savannah, Georgia

William C. Hurst, Ph. D.
Extension Food Science Outreach Program
The University of Georgia, Athens
Food Quality vs. Food Safety

They don’t mean the same thing!
Who is the enemy?

Plant pathogen – a microorganism known to cause diseases or lesions in plant tissues.

Human or animal pathogen – a microorganism known to cause illness to humans or animals.
What Can Growers & Packers Do?

*Prevention is the key!*

- Learn about the risks
- Who is the enemy?
- Develop a food safety plan
- Document activities
Good Agricultural Practices (GAPs) Guidelines

Areas of Concern:
- Water quality
- Fertilizer use
- Worker health & hygiene
- Field & facility sanitation
- Transportation issues
- Traceback & recall
What are GAPs?

**Good Agricultural Practices (GAPs)** are sanitary procedures used during crop production, harvesting, packing and shipping to prevent or minimize produce contamination with human pathogens.
Field Worker Hygiene and Sanitation

- Are gloves worn?
- Is harvesting equipment clean?
- Are toilets well stocked?
Field Worker’s Hands – a major source of human pathogens
Methods of Infecting Produce

- Fecal material
- Open lesions, boils, sores, infected wounds
- Personal illness

Staph infection
Bandages

- Bandage on finger, no glove
- Cover bandage with waterproof glove
Why wear gloves?
Employee Sanitary Facilities

- Do you know FDA’s requirement for providing field restroom facilities?
Taking care of business!
Easy Access
Worker Health and Hygiene

- In 2003, at 21 of 24 farms surveyed, worker health and hygiene were the major hazards to produce safety.
- Inadequate hand washing was the most frequent hazard noted.
- Inadequate hygiene training ranked #2, followed by unsanitary worker facilities.
Field Container Sanitation

Clean harvest containers and tools daily.
Field Washing of Produce
Packing Facility Sanitation and Worker Hygiene

Sanitation is about attention to details.

Employees

Equipment

Harvesting bins

Foaming/rinsing packing line
Arrival at Packing Facility

Protect harvested product from animals and animal feces

Image courtesy of Trevor Suslow
Packing Facility Grounds

Is waste removed frequently from the packing shed?

Is stagnant water controlled?
Bird Nesting = A Problem
Why is packing line sanitation important?

- To prevent human pathogen contamination of product by ...
Salmonella Recovery from Conveyor Belt Surfaces

Graph showing the survival of Salmonella as Log_{10} CFU/ml Survivors over 28 days at different conditions:
- 80RH/30C
- 60RH/20C
Salmonella Recovery from PVC Surfaces

The graph shows the log survival of Salmonella in two different conditions: 80RH/30C (blue line) and 60RH/20C (pink line). The x-axis represents the number of days, while the y-axis shows the number of log CFU/ml survivors. The graph indicates a significant decrease in Salmonella survival over time in both conditions, with the 80RH/30C condition showing a steeper decline compared to 60RH/20C.
Salmonella Recovery from Wood Surfaces

Log$_0$ CFU/ml Survivors

Days

0 4 8 12 16 20 24 28

80RH/30C
60RH/20C
What’s wrong on this packing line?
What happens at break time?
E. coli in Produce
Employee Awareness
Is his mind on safety?
Handling Smocks, Aprons & Gloves
Is this a cultural problem?

- No! It’s an education issue.
## How do adults learn best?

<table>
<thead>
<tr>
<th>Method of Teaching</th>
<th>How much information is recalled?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 hours later</td>
</tr>
<tr>
<td>Lecture</td>
<td>70%</td>
</tr>
<tr>
<td>Lecture + Demonstration</td>
<td>85%</td>
</tr>
</tbody>
</table>
Effective communication is critical in employee sanitation training.
What microbial load do YOU carry?

- Unwashed hands
- Unwashed gloves
- Hands washed & dipped in sanitizer
- Gloves washed & dipped in sanitizer
Employees must participate for effective training.

"Tell me, I'll forget. Show me, I may remember. But involve me and I'll understand.

-Chinese Proverb"
Worker Protection Safety (WPS)

- Combine *employee hygiene training* with EPA-mandated WPS (chemical safety) at the beginning of each harvest season
- Keep records of who attended what training and when, to document this training to an auditor.
Water Safety

Water is critical to all phases of produce handling!

Irrigation

Washing

Icing

Cooling

Southern Region Small Fruit Consortium 2008
In a 2004 survey of 36 on-farm produce packing operations, inadequate chlorination was the predominant problem.

Courtesy Jack Guzewich, USDA/CFSAN 2004
Wash Water Quality

Wash water must be properly chlorinated to keep it safe. Testing procedures must be implemented to insure the proper chlorination levels are consistently maintained in the water.
Factors Affecting Chlorine’s Effectiveness

- Water pH
- Chlorine concentration
- Contact time
- Organic Matter
- Water temperature
- Stage of pathogen growth
Effects of pH on Chlorine

% Chlorine present as HOCl

pH

0 1 2 3 4 5 6 7 8 9 10

0 20 40 60 80 100

HOCL  OCL
Quality Control Tools

“Free” chlorine test kit

pH meter
# Chlorine/pH Daily Monitoring

**Packing Line:** Tomato grading line  
**Specific Location:** Water in dump tank  
**Control Limits:** Free Chlorine = 100-150 ppm/ pH = 6.5-7.5

<table>
<thead>
<tr>
<th>Date</th>
<th>Free Chlorine</th>
<th>pH</th>
<th>Operator Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time</td>
<td>Time</td>
<td>Time</td>
</tr>
</tbody>
</table>

Verified by: _______________________
Tomato Line Supervisor

Southern Region Small Fruit Consortium 2008
Blueprint for an On-Farm Food Safety Plan

1. Designate “Farm Sanitarian” to develop, implement, monitor & document on-farm food safety program.

2. Identify GAPs/GMPs (minimum sanitary guidelines) specific to the agricultural environment (field, packing facility & transport operations).

3. Include SOPs for production, harvesting & field packing activities.
Food Safety Plan (cont.)

4. Develop *Master Sanitation Schedule* for the packing facility, including specific written SOPS for equipment.


6. Document sanitation system is working by conducting internal farm inspection audits.

7. Continuously train all personnel on sanitary procedures.
Fresh Produce GAPs/GMPs Workshop

- This three-day internationally attended workshop presents thorough training in Good Agricultural Practices (GAPs) and Good Management Practices (GMPs) necessary to prepare a comprehensive HACCP-based food safety program for an on-farm or packinghouse operation.

- Unique features include four hands-on break-out sessions which teach participants how to write SOPs, identify and prevent food safety hazards, develop control limits and monitoring procedures for those hazards and methods to document and verify the efforts.

- Also included is a hands-on laboratory where participants learn how to use microbial testing to verify sanitation efforts.
REMEMBER …

While FOOD QUALITY is an option …

… FOOD SAFETY is an entitlement.
Thank you for your attention!

Any questions?
Contact information

Dr. William C. Hurst
240 Food Science Bldg.
University of Georgia
Athens, GA 30602-2670
Phone 706/542-0993
Email bhurst@uga.edu
Website www.EFSonline.uga.edu
“The HACCP Approach to Analyzing and Managing Food Safety”

January 10, 2008
HACCP

- Is preventative, not reactive
- Is a management tool used to protect the food supply against biological, chemical and physical hazards
Origins of HACCP

• Pioneered in the 1960’s
• First used when foods were developed for the space program
• Adopted by many food processors in the U.S.
HACCP

- Is not a zero-risk system
- It is designed to minimize the risk of food safety hazards
Recommendation

“The HACCP approach be adopted by all regulatory agencies and that it be mandatory for food processors.”

National Academy of Sciences, 1985
National Academy of Sciences Recommendation led to formation of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
Seven Principles of HACCP

1. Conduct a hazard analysis
2. Determine the critical control points (CCPs) in the process.
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish record-keeping and documentation procedures.
International Use

- Codex Alimentarius
- European Union
- Canada
HACCP

A system for food safety control
Traditional inspection methods for food safety control versus The HACCP approach
HACCP Approach Complements Traditional Inspection Methods

• **HACCP:**
  – Emphasizes process control
  – Concentrates on points in the process that are critical to the safety of the product
  – Stresses communication between the regulator and industry
HACCP systems represent a systematic approach to the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur.
Develop an awareness of:

- Biological Hazards
- Chemical Hazards
- Physical Hazards
- Characteristics of certain microorganisms
Most spoiled foods do not present a health risk, and not all food that appears normal is safe to consume.
Produce Safety From Production to Consumption:

2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption
Produce is important

- Produce is a component of a healthy diet, a good source of vitamins, minerals, fiber, and antioxidants.
- Produce can play an important role in weight management.
Produce is vulnerable to contamination with pathogens

- Agricultural water quality
- The use of manure as fertilizer
- The presence of animals in fields or packing areas
- The health and hygiene of workers handling the produce
Objectives of the Plan

- Prevent Contamination of Fresh Produce with Pathogens
- Minimize the Public Health Impact When Contamination of Fresh Produce Occurs
- Improve Communication with Producers, Packers, Processors, Transporters, Distributors, Preparers, Consumers, and Other Government Entities about Fresh Produce
- Facilitate and Support Research Relevant to the Contamination of Fresh Produce
Questions?

Thank You!
INTRODUCTION TO PRINCIPLES OF INSPECTING / AUDITING FOOD PLANTS

Presented by
INSPECTING/AUDITING AND IQS

Values/Skills/Knowledge Creation
Education/Training
Plant Culture
Quality Policies

IQS

Prerequisite Programs

Quality Programs

Food Safety Program

How well we are doing
Inspections/Audits Performance Indicators
• **Inspection**: Evaluating a brief/given moment in time
• **Audit**: Historical perspective of program conformance
JUSTIFICATION

• Why Inspect & Audit a Food Plant?
  – Legal
  – Moral
  – Market
  – Economic & Financial
JUSTIFICATION

• Legal
  – U.S. Food, Drug and Cosmetic Act 1938
    • Section 402(a)(3)
      – A food *shall* be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substances, or if it is otherwise unfit for food.
    • Section 402(a)(4)
      – A food *shall* be deemed adulterated if it has been prepared, packed, or held under unsanitary conditions whereby it *may* have become contaminated, or whereby it *may* have been rendered injurious to health.
JUSTIFICATION

- Legal (cont)
  - Preamble to GMPs
    - Management shall take all reasonable measures and precautions
  - Regulated HACCP (U.S., Europe, other)
  - Plant Security
  - ISO/IQS
• **Moral Obligation**
  - Protect health of customers

• **Market Expectation**
  - Satisfy customers’ expectations
    • Value perceived for price paid
JUSTIFICATION

- **Economic/Financial**
  - External
    - Customer Retention
    - Brand Protection
    - Recalls
  - Internal
    - Process Improvements/Efficiencies
      - Raw materials
      - Waste
      - Non-conforming products
      - Finished product
    - Break Even Point
    - Return on investment
PURPOSE OF INSPECTING & AUDITING

Factual information for management decisions
Assess areas of known risk to the organization

Determine effectiveness of the organizational goals
Assess resource requirements

Provide positive and negative feedback
Evaluate compatibility of departmental goals, objectives, and quality policy statements

Satisfy regulatory, customer, and pre-contract requirements
Confirm conformance to procedures and work instructions

Identify opportunities for improvement and corrective action projects
Stay in touch with the organizational changes