

Food Safety Training for County Extension Service Agents - Jan 9-10, 2008

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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

 $8{:}15-8{:}30~\text{AM}\,$ 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 - 2:00PM 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

THEUNIVERSITY of TENNESSEE

Microbiology of Water

William C. Morris Department of Food Science & Technology





Some Water Factoids

- Number of people plagued by water shortage: 0.5X10⁹
- Average gallons used by average American per year: 183 gal.
- Estimated number of people who will be short of water by 2025: 2.8X10⁹



The Essentialness of Water

- Blood in our veins approximates composition of sea water
- Concept of <u>hydrophilic</u> and <u>hydrophobic</u> 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







All Microbes Live in an Aqueous Environment

- Ecology of aquatic environments is complex
- Most aquatic environments are teaming 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)*

3 %

- Sources of Agricultural Pollution in Assessed Streams and Rivers
 - Grazing related 60 %
 - Crop related 37 %
 - Intensive Animal Ops.
- * 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
- **<u>Pollution</u>** anything that makes it Non-Potable
- <u>Sewage</u> 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
- <u>Recreational water</u>
 - 200 fecal coliforms /100 ml
- Fish and wildlife habitat
 - 5000 fecal coliforms/100 ml
- <u>Shellfish</u>
 - 14 fecal coliforms/100 ml



Most Probable Number

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

<u>Does not:</u>

- 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

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

Pathogens of Most Concern on Fresh Produce

- Salmonella
- Escherichia coli
- Yersinia entercolitica
- Clostridium species
- Vibrio species
- Viruses (Hepatitis A, Norwalk)
- Parasites/Protozoa- (Giardia, Entamoeba, Toxoplasma, Sarccystis, Isopora, Cryptosporidium, Eimeria, Cyclospora)

Shigella Campylobacter Staphylococcus aureus

Bacillus cereus



Vibrio species

Waterborne Infectious Disease (U.S. 1997-1998)

<u>Disease</u>	<u>Agent</u>	<u>Outbreaks</u>	<u>Cases</u>
Shigellosis	Shigella sonnei	1	183
Giardiasis	Giardia lambia	4	159
Cryptoporidiosis	Cryptosporidium parvum	2	1432
Gastroenteritis	E. Coli 0157:H7	3	164
Acute gastrointestinal illness	Unknown	5	163

Shigella



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

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

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 Cryptospoidium

Transmission occurs mainly through Contaminated water.



Agricultural Water

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





Water Quality Evaluation Log

Water Source	Irrig	ation	Pest	icide App.	Ha wa	nd ash	Prod w	uce ash
Open source, canal, Reservoir, pond, etc.	Y	Ν	Y	Ν	Y	N	Y	N
Munciple water source	Y	Ν	Y	Ν	Y	N	Y	Ν

Capped well, Annual test date

Uncapped well, canal, reservoir, etc. <u>Quarterly</u> test date

Municipal water source Quality report date



Public Health and Water Supply

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

Human	4.4
Duck	0.6
Sheep	0.4
Chicken	0.4
Pig	0.4
Cow	0.2
Turkey	0.1

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



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Indicator Organisms

- <u>General coliforms</u> 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





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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





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 Dosage



Free Residual Chlorine

- Chlorine remaining after combining with organic matter
- Bacteria kill rate proportional to concentration of free residual



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





OF FOOD POLITICS

MARION NESTLE

AUTHOR

BY THE

"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.

MARLER CLARK

ECONOMICS OF FOOD SAFETY: ISN'T FOOD SAFETY A NO-BRAINER? Food Safety Innovation

"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."

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in the United States

Evidence from the Meat Industry

Elles Golas

Jie Cassel wheel Olivia



Elise Golan, et al., Food Safety Innovation in the United States, USDA AER # 831

FODE 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."



Product Liability and Microbial Foodborne Illness



<u>See</u> Buzby, *et al.* <u>Product Liability and Microbial Foodborne Illness</u> (2001) ERS Agricultural Economic Report No. 799.



THE COST OF FOODBORNE

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.



FRGING Tracking treads and analyzing new and reamanging

See Paul S. Mead, et al., Food-Related Illness and Death in the United States, 5 Emerging Infect. Dis. (No. 5) 607, 614 (1999).



Adding Up the Price We Pay

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

\$6.9 BILLION¹

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



1. USDA ERS 2000 Cost-estimate, cited in S. Crutchfield & T. Roberts, "Food Safety Efforts Accelerate in the 1990's," Food Review, 23:3, p. 48 (September-December 2000).



FBI cost estimates omit a lot

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

<u>See also</u> D. Stearns "Recouping Outbreak Costs: Who Should Pay?" delivered at 2007 Rocky Mountain Food Safety Conference online at http://www.rmfoodsafety.org/2007pdf/DenisStearns.pdf



Death Cost-Estimates Too Low

"Using [the FDA \$5 million per-life] value and the Mead study, <u>the annual costs of deaths</u> <u>caused by unknown foodborne agents</u> <u>would be \$17 billion</u>....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

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."



Unsafe Food: What is the true cost?



"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....<u>The price</u> <u>of foodborne illness is too high."</u>

~ Comments by Barbara Kowalcyk, presented to the U.S. House of Representatives' Food Safety Caucus, September 22, 2004.



The Law & Politics of Food Safety

- → 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.



Ironically, early food laws were intended to prevent "economic adulteration."

 \rightarrow e.g., use of inferior ingredients, fillers, and mislabeling.



Fake and substandard ingredients give competitors an economic edge via low costs.

The food industry **<u>DEMANDED</u>** regulation to level the competitive playing-field.





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
- Iowers the cost of production, or
- \checkmark 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



"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]."¹

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

> CREDENCE = TRUST

RIFR

1. <u>See</u> E. Golan, et al., Savvy Buyers Spur Food Safety Innovation in Meat Processing, *Amber Waves, April 2004, available online at http://www.ers.usda.gov/AmberWaves/April04/Features/SavvyBuyers.htm*

Who Pays for the decision <u>NOT</u> to invest in food safety?



June Dunning



Ruby Trautz

Betty Howard

"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 <u>costs not borne by</u> <u>those whose actions create them</u>."

Helen H. Jensen, *Food-system risk analysis and HACCP*, p. 63, in NEW APPROACHES TO FOOD-SAFETY ECONOMICS, G.J. Velthius, et al. (eds.) (2003).

OUR (IM)PERFECT WORLD



"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,





Source: U.S. Food and Drug Administration.

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 produces 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.



LAWYERS to the Rescue? MARKET FAILURE: The Need for Litigation.

"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 <u>COST-SHIFTING</u> 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?

H R

In the United States, nearly all personal injury cases are handled on a contingency fee basis.

Some Cases We Took a Pass On:



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? "



Christening the Carpet

"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."





Lending a Helping Hand

"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

PATHOGEN	INCUBATION PERIOD
Staphylococcus aureus	1 to 8 hours, typically 2 to 4 hours.
Campylobacter	2 to 7 days, typically 3 to 5 days.

COMMON LOGICAL FALLACY ~ Post Hoc Ergo Propter Hoc

Hepatitis A	15 to 50 days, typically 25-30 days.
Listeria	3 to 70 days, typically 21 days
Norovirus	24 to 72 hours, typically 36 hours.



Using PFGE Testing to Link an Infection to a Common Source

C - Control P - Patient R – Recalled Meat

PFGE testing has improved outbreak investigation while also raising the evidentiary bar on proving a FBI claim.

C P R C


Foodborne Illness Litigation: 1988-97

"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)



Product Liability and Microbial Foodborne Illness



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

QUERY: Is a bag of pre-cut, pre-washed lettuce a *manufactured* product?

consumer...." RCW 7.72.010(2); <u>see also</u> *Washburn v. Beatt Equipment Co.*, 120 Wn.2d 246, 258-59, 840 P.2d 860 (1992)



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

Res Ipsa Loquitur: Type of Event

Restatement 2d, sec. 328D, cmt c

On the other hand there are many events, such as those of objects falling from the defendant's premises, the fall of an elevator, the escape of gas or water from mains or of electricity from wires or appliances, the derailment of trains or the explosion of boilers, where the conclusion is at least permissible that such things do not usually happen unless someone has been negligent. To such events res ipsa loquitur may apply.



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.



Jury awards hotel guests \$25 million for foodborne illness

RENO GAZETTE-JOURNAL 5/26/2002 11:37 pm

A Washoe County jury awarded <u>\$25.2 million in punitive</u> <u>damages</u> 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

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

* Arbitration ruling this year issued a multimillion 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.

Chi Chi's Class Action Settlement

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 hepatitiscontaminated 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, <u>The Economics of Food</u> <u>Safety: The Case of Green Onions and Hepatitis A</u> <u>Outbreaks</u>, 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

RLER

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 prepackaged 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





<u>The Rise of Class Actions</u>: Peter Pan Class Definition: 1.0

5.3 <u>CLASS DEFINITION</u>: 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





SAM'S CLUB/CARGILL MEAT RECALL

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

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



RTE= Ready to eat

RAC=Raw agricultural commodity Fresh Produce Foodborne Outbreaks

Known/ Suspected Vehicle	Type of product	Year	Brand/Source of contamination	Recall/ FDA Alert	Pathogen	Location	Venue	No. of Cases/ Deaths
Lettuce	RTE	1983			Shigella sonnei	Texas	University	140/0
Lettuce/ salad	RTE	1986	Possibly infected food handler (shredded by hand)		Hepatitis A	Florida	Restaurant	103/0
Shredded lettuce	RTE	1986	Possibly infected food handler at shredding facility		Shigella sonnei	Texas	Restaurant	347/0
Iceberg lettuce	RTE	1988	Bags of lettuce		Hepatitis A	Kentucky	Restaurant	202/0
Lettuce/ onions	RTE	1989	Potable water used in washing the vegetables		Giardia	New Mexico	Church dinner	21/0
Cantaloupe	RAC	1989- 90	Mexico		Salmonella spp	Multi-state, US	Unknown	>245/2
Tomatoes	RTE	1990	Contamination of water bath used by packer		Salmonella spp	South Carolina	Various	174/0
Watermelon	RAC	1991			Salmonella spp	Michigan	Indoor	26/0
Cantaloupe	RAC	1991	Central America		Salmonella spp	Multi-state, US	Unknown	>400/0
Lettuce	RAC	1992			Salmonella spp	Vermont		12/0
Salad	RTE	1992	Cross contaminated by an infected food handler		Calcivirus	Ontario, Canada	Catered event	27/0
Salad	RTE	1993	-		Clostridium perfringens	Ontario, Canada	Wedding	48/0
Cantaloupe	RTE	1993	Cross contamination with raw beef juice	NO	E.coli 0157H:7	Oregon	Restaurant	9/0
Tomatoes	RTE	1993	Contamination of water bath used by packer		Salmonella montevideo	Multi-state, US	Various	84/0
Diced tomatoes	RTE	1994	Possibly Infected food handler		Hepatitis A	Arkansas	NR	92/0
Green onions	RAC	1994	Contamination during harvest-Mexico		Shigella flexneri 6A	Multi-state,	Various	72/0
Kaspbernes	RAC	1995	Guatemala		Cyclospora cayetanensis	FIOTIDA	Social events	8//0
----------------------	-----	------	---	---	----------------------------	--------------------	------------------------------	--------
Lettuce	RTE	1995	Possibly infected food handler	NO	E.coli O157:H7	Idaho	Various	11/0
Iceberg lettuce	RTE	1995	Cross contamination with raw hamburger juice	NO	E.coli 0157:H7	Maine	Scout camp	30/0
Iceberg lettuce	RTE	1995	,		E.coli 0157:H7	Ontario, Canada	Acute care Hospital	23/0
Caesar salad	RTE	1995		+	E.coli O157:H7	Alberta, Canada	Restaurant	31/0
Mesculin/red leaf	RTE	1996	Processor		E.coli O157:H7	CT, IL, NY		61/0
Red leaf lettuce	RAC	1996	Queensland, Australia		E.coli 0157:H7	Chicago		27/0
Lettuce	RTE	1996	Cross contamination from raw chicken juices		Campylobacter jejuni	Oklahoma		
Raspberries	RAC	1996	Guatemala	Import alert-EDA	Cyclospora cayetanensis	US and Canada	Various	1400/0
Green onions	RTE	1997	Possible contamination by a food handler		Cryptosporidium parvum	Washington	Restaurant	54/0
Baby lettuce	RTE	1997	Possibly Peru	NO	Cyclospora cayatenesis	Florida	Restaurants / cruise ship	1465/0
Raspberries	RAC	1997	Guatemala - Raw agricultural commodity	Growers voluntarily suspended shipment	Cyclospora cayatenesis	US and Canada	Various	1012/0

RTE= Ready to eat

RAC=Raw agricultural commodity

Known/ Suspected Vehicle	Type of product	Year	Brand/Source of contamination	Recall/ FDA Alert	Pathogen	Location	Venue	No. of Cases/ Deaths
Basil	RTE	1997	Basil-pesto sauce		Cyclospora - cayatenesis	Multi-state US	Retail/Catered events	>308/0
Lettuce	RAC	1997	i î		E.coli 0157:H7	Montana	Retail	70/0
Cantaloupe	RAC	1997	Mexico	Voluntary	Salmonella spp	California	Home, stores	24/0
Raspberries	RAC	1998	Guatemala	Import alert- FDA	Cyclospora cayetanensis	Ontario, Canada	Various	315/0
Salad	RTE	1998		1	E.coli O157:H7	California	Restaurant	2/0
Fruit salad	RTE	1998		+	E.coli O157:H7	Wisconsin	Catered event	47/0
Coleslaw	RTE	1998	KFC	NO	E.coli O157:H7	Indiana	Restaurant	33/0
Lettuce	RTE	1998	-		Shigella sonnei	Minnesota	Various	160/0
Parsley	RAC	1998	Agricola Herendira S. de R.L. de C.V., Mexico	Market Recall	Shigella sonnei	MN, MA, CA	Restaurants	400/0
Parsley	RAC	1998	Baja, Mexico	Import alert - FDA	Shigella sonnei	Canada	Food fair	35/0
Tomatoes	RAC	1998- 1999		*	Salmonella spp	Florida	Various	85/3
Blackberries	RAC	1999	Guatemala	Import alert- FDA	Cyclospora cayetanensis	Ontario, Canada	Banquet hall	104/0
Romaine lettuce	RTE	1999			E.coli O157:H7	Oregon	Community	3/0
Romaine lettuce	RTE	1999			E.coli O157:H7	Pennsylvania	Retirement Community	41/0
Romaine lettuce	RTE	1999			E.coli O157:H7	California	Community	8/0
Coleslaw (cabbage)	RTE	1999	KFC	NO	E.coli	Indiana		27/0
Coleslaw (cabbage)	RTE	1999	KFC	NO	E.coli	Ohio		19/0
Romaine lettuce		1999	•		E.coli O157:H7	Washington	Community	6/0

Cantaloupe	RAC	2000	"Viva"-Mexico	Voluntary Recall	S. poona	Multi-state US	Various	43/2
Cantaloupe	RAC	2001	Mexican farms - imported by Shipley Sales Service	NO	S. Poona	8 states	Various	30/0
Lettuce	RTE	2002	"Spokane Produce"- packaged	NO	E.coli O157:H7	Washington	Camp	28/0
Lettuce	RTE	2003	"Gold Coast Produce, F.T. Produce Inc." - packaged, pre-washed	NO	E.coli O157:H7	California	Restaurant-Pat and Oscar's	50/0
Green onions	RAC	2003	Apio Fresh, LLC importer from Baja-Mexico	Market Recall	Norovirus	Pennsylvania	Chi Chi Restaurant	601/4
Spinach	RTE	2003			E.coli 0157:H7	California	Nursing home	16/2
Mesculin/spring mix salad	RTE	2004	Food handler	NO	Cyclospora	Texas	Restaurant	38/0
Tomatoes	RTE	2004	Coronet Foods - packaged	Stopped production	Saimonella spp	US and Canada	Various	561/0
Mesculin/spring mix salad	RTE	2004	Food handler	NO	Cyclospora	Illinois	Restaurant	57/0
Iceberg lettuce	RTE	2004			Salmonella newport	Maryland	Restaurant / deli	97/0
Parsley	RAC	2005	Cal Farms, LLC		E.coli 0157:H7	WA, OR	Restaurant	60/0
Lettuce	RTE	2005	1	YES	E.coli 0157:H7	WI, OR, MN	Various	23/0
Lettuce	RTE	2005	Food handler		Norovirus	Michigan	Restaurant	55/0
Spinach	RTE	2006		YES	E.coli O157:H7	Multi-state US	Various	204/3

Harmful Microorganisms & Outbreaks Associated with Produce

Pathogen

Produce

E. coli O157:H7

Salmonella spp.

L monocytogenes B. cereus Hepatitis A virus Cryptosporidium Cyclospora Iceberg lettuce, radish sprouts, unpasteurized apple cider/juice Tomatoes, bean sprouts, sliced watermelon, sliced cantaloupe, coleslaw & onions, alfalfa sprouts, root vegetables, dried seaweed Cabbage Sprouts Iceberg lettuce, raspberries, strawberries Apple cider Raspberries

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



JFP vol65 p18-23

No Magic Bullet



JFP vol65 p18-23

Pre-Harvest

Irrigation water cleanliness
Water used for pesticide mixing
Frost-protection water cleanliness
Animal exclusion
Soil contaminants

Storage

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

Transport

Vehicle cleanliness
 Reefer maintenance
 Receiver unload system
 Temperature control

 Impact of personnel, handling, loading and unloading on product safety

Harvest & Packaging

- Pesticide residuals
- Animal exclusion
- Culling damaged and soiled fruit
- •Basket, clamshell and tray cleanliness/sanitation

Personnel Cleanliness

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

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? Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition (CFSAN) October, 1998

ourtesy of Jim Rushing

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

NC STATE UNIVERSITY

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

Courtesy Dr. Jim Rushing

Remember: proper facilities reduce risk











Animal and Pest Control



Courtesy of Trevor Suslow



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

5 9 10 11 12 13 14 5 Continuitors

Courtesy Dr. Jerry Bartz

Could Be Bacteria

Land Use History

- Grazing Animals
- Hazardous Chemical Exposure
- Cull Piles, refuse dumps, debris proximity



Assess Potential for Contamination



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-Document12-Document13-Document14-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

- Means going through the process of food safety on the farm
- No cost
- No Certification to show end marketers
- UC Davis Self-Checklists
 - <u>http://groups.ucanr.org/UC_GAPS/GAP_self-audits/</u>
- 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



General Questions

Implementation of a Food Safety Program

Questions		Points	YES	NO	N/A	Doc]
G-1	A documented food safety program that incorporates GAP and/or GHP has been implemented.	15				D	1
G-2	The operation has designated someone to implement and oversee an established food safety program. Name	15				D	

Worker Health & Hygiene

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

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.

Documentation – Worker Training for Food Handlers

Worker Training for Food Handlers Manejo de Alimentos: Deberes y Cuidados

Name of operation: Fanning-Fletcher Farm Trainer: Tim Greenthumb or Jack Crewchief	Date:	August 21, 2007
Interpreter: Dawn Williams-Tox Location: Haywood County, NC		Training Time:
I am committed to working safely with food to ensure the we this produce. I am informed of and will abide by these s Me encuentro comprometido a trabajar en forma segura y re salud de mi familia y de aquellos que coman nuestro pro con las practicas seguras de manejo de los alimentos.	ell-being and l safe food hand esponsable co oducts. Afirma	nealth of my family and those who eat dling practices. n alimentos para asegura el bienestar y o que estoy informado y comprometido
Employee Name (please print)	Employe	e Signature
Nombre Empleado		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!



Southern Region Small Fruit Consortium 2008

From Cornell GAPs program – used with permission.

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



Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition (CFSAN) October, 1998 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











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!













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.





Southern Region Small Fruit Consortium 2008

J. Guzewich, Food Protection Mtg. 2003

Field Container Sanitation



Clean harvest containers and tools daily.



Field Washing of Produce





Packing Facility Sanitation and Worker Hygiene



Employees

Sanitation is about attention to details.







Equipment

Harvesting bins

Arrival at Packing Facility



Protect harvested product from animals and animal feces



Southern Region Small Fruit Consortium 2008 mage courtesy of Trevor Suslow

Packing Facility Grounds







Is stagnant water controlled?



Bird Nesting = A Problem



Why is packing line sanitation important?

 To prevent human pathogen contamination of product by ...



Listeria monocytogenes





Southern Region Small Fruit Consortium 2008

Salmonella





Salmonella Recovery from Conveyor Belt Surfaces



Salmonella Recovery from PVC Surfaces



Surfaces



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?

Method of Teaching	How much information is recalled?			
	3 hours later	3 days later		
Lecture	70%	10%		
Lecture + Demonstration	85%	65%		



Effective communication is critical in employee sanitation training





Unwashed hands



Unwashed gloves

What microbial load do YOU carry?



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



Irrigation

Water is critical to all phases of produce handling!



Washing



Icing



Cooling



On-Farm Packing Facility Water Issues

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





Quality Control Tools



"Free" chlorine test kit



pH meter



Chlorine/pH Daily Monitoring

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

	Free Chlorine				pН		Operator
Date	Time	Time	Time	Time	Time	Time	Initials

Verified by:



Tomato Line Supervisor

Blueprint for an On-Farm Food Safety Plan

- 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.
- 5. Keep field, facility & equipment sanitation records on file.
- 6. Document sanitation system is working by conducting internal farm inspection audits.
- 7. Continuously train <u>all</u> 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.



Southern Region Small Fruit Consortium 2008



REMEMBER ...

While FOOD QUALITY is an <u>option</u> ...





... FOOD SAFETY is an <u>entitlement</u>.







Thank you for your attention!

Any questions?





Southern Region Small Fruit Consortium 2008

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"The HACCP Approach to Analyzing and Managing Food Safety"

January 10, 2008

HACCP

Hazard Analysis and Critical Control Point

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



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



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



How well we are doing Inspections/Audits Performance Indicators



INSPECTION & AUDIT DEFINED

- Inspection: Evaluating a brief/given moment in time
- Audit: Historical perspective of program conformance



- Why Inspect & Audit a Food Plant?
 - Legal
 - Moral
 - Market
 - Economic & Financial



Legal

- U.S. Food, Drug and Cosmetic Act 1938
 - Section 402(a)(3)
 - A food <u>shall</u> 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 <u>shall</u> be deemed adulterated if it has been prepared, packed, or held under unsanitary conditions whereby it <u>may</u> have become contaminated, or whereby it <u>may</u> have been rendered injurious to health.



- 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



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

Determine effectiveness of the organizational goals

Provide positive and negative feedback

Satisfy regulatory, customer, and precontract requirements

Identify opportunities for improvement and corrective action projects





Assess areas of known risk to the organization

Assess resource requirements

Evaluate compatibility of departmental goals, objectives, and quality policy statements

Confirm conformance to procedures and work instructions

Stay in touch with the organizational changes