Good Agricultural Practices (GAP) for Fresh Fruit and Vegetable Growers
Good Agricultural Practices (GAPs)

A “PREVENTION” FOCUSED FOOD SAFETY MANAGEMENT PROGRAM

The goal is to reduce microbial risks in fresh or minimally processed fruits and vegetables—making produce safer.

Voluntary Program
What is the Food Safety Problem?
We have the safest food supply in the world!!
Harris Poll: 2/2014, 2,236 Americans around the country

- Are consumers concerned about food safety?
- Do consumers want more or less government oversight of food?
- 86% - somewhat or seriously concerned about food safety due to recalls
- 73% - should be more government oversight over food safety
Denial is not a strategy!
Stages of Food Safety Attitudes

- **Denial:** We haven’t had a problem in 40 years I have been in business
- **Anger:** You $&@#* are just looking for problems that aren’t there
- **Bargaining:** Maybe if I just sit here and get this training certificate we’ll be okay
- **Sadness:** It’s no use, I should just get out of business
- **Acceptance:** I guess we can make this work!
Farm: Produce Food Safety Challenges
Guidance for Industry: 1998

FDA/USDA

Good Agricultural Practices (GAP)

MICROBIAL ONLY
2012: EPA/FDA

- 99.4% tested well within EPA tolerances
- Tolerances are 110X safety factor
- 10,801 samples tested
  - 7715 fresh
  - 3036 processed
2014: EPA/FDA PDP

- > 99% tested below EPA tolerances
- Tolerances: 110X safety factor
- 10,619 samples tested
  - 80.8% = fresh/processed fruits and vegetables
  - 75.5% = domestic
  - 22.9% = imports
- > 41% no detectable residue
- 0.36% (38) > tolerance
  - 50% = domestic/imported
GAP – Why?

- Consumption of fresh produce steadily increasing for health.
- Increases in the number of produce associated with foodborne disease outbreaks in the U.S.
- A variety of fruits and vegetables implicated--domestic and imported
- Pathogens normally associated with animal origin on fruits and vegetables
What are the facts?

Is there really a problem?
Fruit/Vegetable Outbreaks: Agents and Origin of Produce

- **1990 – 1998:** Origin: 75.3% outbreaks of related to produce grown domestically

- **1990-2004:** 639 documented outbreaks (inc.prepared), 31496 cases

- **1988 – 1998:** Major bacterial outbreaks caused by Salmonella and E.coli. Other identified Shigella, Campylobacter and others.

- **1988 – 1998:** Parasitic outbreaks caused by Giardia (3) and Cyclospora (5).

- **1998 – 2004:** 25% foodborne illness outbreaks implicated with fresh-cut produce

- **1998 – 44 outbreaks in produce; 2004 – 85 outbreaks**

- Since **FY2000** Traceback: FDA investigated 57 outbreaks, 47 involving fresh produce

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From Food Safety Begins on the Farm. Robert B. Gravani and Elizabeth A. Bihn, Cornell University.

CDC Foodborne outbreak surveillance


CSPI. 2006. Behind CSPI’s Outbreak Data: A look at Produce Outbreak Numbers
Fruit/Vegetable Outbreaks: Agents and Origin of Produce

- **1996-2006:** 71 outbreaks due to produce source alone (not prepared) – tomatoes, leafy greens, melons, raspberries, green onions, almonds, basil, parsley
- **1998-2006:** 18 outbreaks, fresh cut
- **1995-2006:** 10 outbreaks due to leafy greens (primarily CA, *E. coli 0157:H7*)
- **1998-2006:** 6 outbreaks due to tomatoes (primarily east coast - FL, VA, OH - *Salmonella*)
- **1998-2006:** FDA investigated outbreaks associated with ~20 fresh produce commodities. More then half related to leafy greens, tomatoes and melons. (*)


What happened between 1990-2006?

- Documentation of increased outbreaks
- Bacterial/parasitic pathogens implicated: Salmonella, E.coli, Shigella/Giardia, Cyclospora
- 1998 vs. 2004
  - 44 vs 85 outbreaks documented
- Produce source alone, not prepared:
  - tomatoes, leafy greens, melons
  - raspberries, green onions, almonds, basil, parsley

Michelle A Smith. 2007. Public hearing on safety of fresh produce. CFSAN/FDA.
www.fda.gov/ohrms/dockets/dockets/07n0051/07n-0051-ts 00004.smith.pdf. *
Figure 3. Average Cases Per Outbreak by Food Category 1990-2005

Caroline Smith Dewaal and Farida Bhuiya. 2007. Presented at IAFP. Center for Science in the Public Interest
### 69 Produce Outbreaks 1996-2006 by Commodity

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomatoes</td>
<td>12</td>
</tr>
<tr>
<td>Lettuce</td>
<td>14</td>
</tr>
<tr>
<td>Romaine lettuce</td>
<td>4</td>
</tr>
<tr>
<td>Mixed lettuce</td>
<td>1</td>
</tr>
<tr>
<td>Cabbage</td>
<td>1</td>
</tr>
<tr>
<td>Spinach</td>
<td>2</td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>7</td>
</tr>
<tr>
<td>Melons</td>
<td>2</td>
</tr>
<tr>
<td>Honeydew melon</td>
<td>2</td>
</tr>
<tr>
<td>Squash</td>
<td>1</td>
</tr>
<tr>
<td>Green onions</td>
<td>3</td>
</tr>
<tr>
<td>Parsley</td>
<td>2</td>
</tr>
<tr>
<td>Basil</td>
<td>4</td>
</tr>
<tr>
<td>Basil or Mesclun</td>
<td>2</td>
</tr>
<tr>
<td>Green grapes</td>
<td>1</td>
</tr>
<tr>
<td>Mango</td>
<td>2</td>
</tr>
<tr>
<td>Raspberries/berries</td>
<td>6</td>
</tr>
<tr>
<td>Snow Peas</td>
<td>1</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: FDA CFSAN
Outbreaks – Domestic or Foreign Source?

Animal source
- 21 E. coli 0157:H7
- 28 Salmonella spp.

Human source
- 16 Cyclospora
- 3 Hepatitis A
- 2 Shigella

Source
- 27 Domestic
- 7 Foreign
- 15 Unknown

Ongoing Challenges

- Leafy Greens
- Tomatoes
- Green Onions
- Cantaloupe
- Parsley, Cilantro

From R. Buchanan presentation. FDA
1998-2006 Produce Outbreaks

5 commodity groups make up >75 percent of produce related outbreaks

<table>
<thead>
<tr>
<th>Commodity</th>
<th>% produce outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce/leafy greens</td>
<td>30%</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>17%</td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>13%</td>
</tr>
<tr>
<td>Herbs (Basil, parsley)</td>
<td>11%</td>
</tr>
<tr>
<td>Green onions</td>
<td>5%</td>
</tr>
</tbody>
</table>

Total % of 5 top commodities 76%

Wes Kline, From Rutgers NJ Agricultural Experiment Station

US Food and Drug Administration, 2007
2006 – A Banner Year

- **Spinach – September, 2006:**
  - 204 cases *E. coli O157:H7*
  - 31 cases HUS
  - 104 hospitalizations
  - 3 deaths
  - 26 states
  - Source – Salinas Valley, CA
  - Cattle manure from California Ranch??
FDA can shut down an entire industry

Fresh bunched spinach shipments: September-October 2006

Source: USDA-Agricultural Marketing Service

Wes Kline, From Rutgers NJ Agricultural Experiment Station
2006 Outbreaks/Recalls – A Banner Year

- Shredded Lettuce (Taco Bell) – December, 2006:
  - 71 cases *E. coli* 0157:H7
  - 8 cases HUS
  - 53 hospitalizations
  - 0 deaths
  - 5 states
  - Source – still under investigation, Central Valley, CA???
2006 Outbreaks/Recalls – A Banner Year

- **Lettuce Recall – October, 2006**
  - Nunes Lettuce, Salina, CA
  - Foxy Brand
  - *E. coli* contamination of irrigation water

- **Tomato – November, 2006**
  - 183 cases, *Salmonella typhimurium*
    - 21 states
    - Served in restaurants
  - 100 cases, *Salmonella typhimurium*
    - 19 states

- **Cantaloupe Recall – November, 2006**
  - Rio Vista, Ltd., Rio Rico, AZ
  - Llano, Nature’s Partner brands
  - Salmonella
2006: Food commodities associated with largest illness numbers:
- Poultry (21%), **Leafy vegetables (17%)**, fruits or nuts (16%)
1998-2007: Confirmed Illnesses most Common Food Categories

- **Seafood**
  - Outbreaks: 838
  - Cases: 7,298

- **Produce**
  - Outbreaks: 684
  - Cases: 26,735
    - Fruits: 111
      - Cases: 3,871
    - Vegetables: 228
      - Cases: 11,197
    - Dishes: 345
      - Cases: 11,667

- **Poultry**
  - Outbreaks: 538
  - Cases: 13,498

- **Beef**
  - Outbreaks: 428
  - Cases: 9,824

- **Pork**
  - Outbreaks: 200
  - Cases: 4,934

**Illness/outbreak produce = 39; 14.8% outbreaks; 22.8% illnesses**

CSPI, 2009 Outbreak Alert!

Total outbreaks/cases: 4638/117136
Contribution of different foods to domestic illnesses: 1998-2008 (CDC)
Foodborne Illnesses from Leafy Greens on the Rise (www.foodhaccp.com, 3/08)

- 1973 – 2006: significant increase outbreaks
  - involved in 5% of all outbreaks
  - norovirus (60%), salmonella (10%) and E.coli (9%)
- From 1986 – 1995
  - consumption increased 17% over previous decade
  - foodborne disease increased 60%
- From 1996 – 2005
  - consumption increased by 9%
  - foodborne disease increased by 39%
- Increased consumption can’t explain it all!!

% of Outbreaks attributed to foods
17 food commodities examined: 1998-2008

<table>
<thead>
<tr>
<th>Rank</th>
<th>Leafy greens</th>
<th>Dairy</th>
<th>Poultry</th>
<th>Beef</th>
<th>Eggs</th>
<th>Pork</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>22.3</td>
<td>13.8</td>
<td>9.8</td>
<td>6.6</td>
<td>6.0</td>
<td>5.4</td>
</tr>
<tr>
<td>% of Outbreaks</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
</tbody>
</table>

#3 (fruits, nuts); #5 (vine related); #12 (fish)

All produce commodities accounted for 46% of illnesses; meat-poultry accounted for most deaths 29% (with poultry at 19%) and produce 23%.

Volume 19, Number 3—March 2013
Salmonella Saint Paul - Jalapeno Peppers/2008

- 4/14/2008 – 8/16/2008
- 1,442 ill, 43 states, DC and Canada
- June/July – FDA: Certain tomato types implicated. Specified areas to purchase from
- June/July – FDA lifts tomato advisory, implements Jalapeno pepper advisory
- August – Traceback – distributor in Texas, peppers from Mexico. Pathogen found in irrigation water

Cost to tomato industry – Approx. $100 million.
Peanuts and peanut products

- 9/1/2008 – 2/24/2009
- Salmonella typhimurium
- 691 persons, 46 states
- 5 deaths
- 2100 + recalls
Romaine Lettuce – Fall, 2011

- E. coli 0157 H7
- 58 people, 9 states
- St Louis supermarket salad bar and shelves
- 33 hospitalized
- 3 hemolytic uremic syndrome (HUS)
- No deaths
- Single common lot of romaine lettuce/one farm
  - Contamination before grocery
  - By time origin figured out, farm not producing, not possible to determine route contamination
- Law suits
Cantaloupe Outbreak

- Jensen Farm, Colorado. 7/2011-12/2011
- 147 hospitalized, 28 states, 33 deaths, 1 miscarriage
- Deadliest outbreak
- **Listeria monocytogenes.** 50 days!!
  - 2/22/2012 – Victim dies after 5-month battle
Jensen Farm Cantaloupe Outbreak

What did they do wrong in packing house?

• Installed potato washer to wash cantaloupes
• Did not wash cantaloupes well, did not cool them down, not easy to clean
• Served as a source of contamination
• No cooling, warmer temperatures good growing conditions for Listeria on outside of produce
• Chlorine sanitizer spray system not operating
Jensen Farm Cantaloupe Outbreak: **Update**

What has happened since? **Bankruptcy**

- Brothers pleaded guilty six counts of selling adulterated food interstate
- Penalty/sentencing January, 2014
- Maximum sentence: Prison up to 6 years and up to $1.5 million fines
- Got 5 years probation, 6 months home detention, $150,000 fines
- Sued Primus Labs: farm a superior rating, 96%, July 2011, prior to shipping
Cantaloupe Outbreak #2

- Chamberlain Farms Produce, Indiana
  Organic farm, 100 acres
- August 22, 2012 announcement, CDC
- 261 ill, 24 states, 94 hospitalized, 3 deaths,
- **Salmonella typhimurium, Salmonella newport.**
- Recall – Mostly Indiana, some Illinois
Cantaloupe Outbreak #2

What went wrong? Per FDA:

- Poor sanitation
- Environmental swabs positive
- Cantaloupe cardboard bin – positive
- Food contact surfaces not constructed for cleaning
- Lack of cleaning, standing water in packing shed
- Failure to remove waste, litter, harborage for pests
Organic Spinach/ Spring Mix Blend

- State Garden of Chelsea, Massachusetts
- November/December 2012
- 33 ill, 5 states, 13 Hospitalizations, 32 developed hemolytic uremic syndrome (HUS)
- E. coli 0157:H7 in prepackaged leafy greens
- Recall
2015 Outbreaks

- January 6, 2015 - Bidart Bros., CA
  - Granny Smith and Gala apples
  - Lm in apple-packing facility
  - 35 people ill, 12 states, 3 deaths

- Started August, 2015 – Andrew and Williamson Fresh Produce, CA
  - Grown in Mexico, distributed in US
  - Cucumbers
  - Salmonella Poona
  - 888 ill, 39 states, 191 hospitalized, 6 deaths
Commodities Related to Outbreaks Change Frequently

Why doesn’t the proposed Produce Safety Rule only target fruits and vegetables that are known to have caused outbreaks of foodborne illness? Why include produce that has not been involved in outbreaks of foodborne illnesses? As you can see here, new players join the cast regularly. The below infographic shows produce-associated outbreaks that occurred between 1996 and 2009. It only shows the years a new type of produce was related to outbreaks during that time period. Because we cannot anticipate with certainty which foods could be contaminated in the growing, harvesting or production process, the rules that we propose would cover a variety of produce.

Produce Associated with Outbreaks 1996–2009:

- 1996: New: LEAFY GREENS BERRIES SPROUTS
- 1997: New: CANTALOupe HERBS
- 1999: New: MANGO
- 2001: New: ALMONDS GREEN GRAPES
- 2003: New: HONEYDEW
- 2004: New: SQUASH SNOW PEAS
- 2008: New: PEPPER (HOT)
- 2009: New: CUCUMBER

U.S. Food and Drug Administration
Frequent Contributors

- **Salmonella**: cantaloupes, tomatoes, sprouts
- **E.coli 0157:H7**: leafy green vegetables
- **Cycolspora**: raspberries
- **Hepatitis A**: green onions
- **Listeria**: Making a strong showing recently
Cost – one estimate

Produce (fresh, canned, processed) – 19.7 million illnesses, $1,960/case (higher than average) and $39 billion annually economic losses (CDC surveillance system)

Source: produce safety project.org
So – Is it only the big farms?

- 2005-80 people in Oregon and Washington were sickened by E. coli O157:H7 from small Oregon parsley grower
- 2008-13 people fell ill from spinach grown by a small grower in Washington.
- 10 other outbreaks traced to small growers/processors in Oregon since 2005
Strawberries – Northwest Oregon, 2011

- Jaquith Strawberry Farm
  - E. coli 0157 H7
  - Sold locally – supermarkets, pick your own, roadside stands, farmers markets
  - Local counties
  - 15 ill, 1 death
  - Deer confirmed source
Other incidents

- 2002, Massachusetts roadside market
  - Cryptosporidium
  - 8 illnesses
  - Linked to lettuce

- 2002, Colorado, Farmers Market
  - E. coli 0157:H7
  - 14 ill
  - 2 children required dialysis

- 2008 Alaska Farmer’s Market
  - Campylobacter, Peas, 5 markets affected, 18 illnesses
Large vs. Small

- Large farms have issues (i.e. mingling of sources, many hands touch the product before it gets to the consumer) and huge product reach—an outbreak has a bigger impact.
Large vs. Small

- Small farms – hard to trace, hard to notice illnesses
- Small farmers beginning to be proactive. Training to change practices
  - Small farms with advantages
    - More control over what they are producing
    - Easier to keep track, records (farmer, produce alliance)
    - Don’t ship as far
- Most important – when berries OR. had E.coli, berry growers in neighboring states were fearful that outbreak could impact them.
Why is this so hard to find?
Why don’t you know? Believe?
Why is this so hard to find? Why don’t you know?

- The Food that Made You Ill Is Probably Not the Last Food that You Ate

- **Incubation Period**
  - Norovirus: 12-48 hours
  - Salmonella: 6 to 72 hours
  - E. coli O157:H7: 1 to 10 days
  - Listeria: 3 to 70 days

From E. Julian talk, 2012, Food Safety conference
Mathematics of an outbreak

- A report first needs to be made
- Minimum of 2 illnesses = outbreak or cluster
- 1 out of 31 reports illness
- If 200 illnesses documented = 6000 actually sick
What are the Issues?

- **The Consumer**
  - Increase in “at risk” populations
  - Awareness
  - Activism and concerns/perceptions
  - Buyer demands
  - Health concerns
  - ????

- **The Micro World**
  - Increase “virulence” and adaptation
  - Better detection

- **Technology/transportation**

- **Global food supply**

- **Media**
Approaches to Food Safety

- Become proactive—anticipate challenges
- Do your own “audit”. Take notice.
- Make communication a priority
- Everyone—from farm to table—needs to take responsibility for food safety. We need to talk with each other and work together to improve the safety of our food supply
- We need to inform and educate the industry and the public about public policy issues and risk analysis
What Are the Potential Sources of On-Farm Contamination?

- Soil
- Irrigation Water
- Animal Manure
- Wild and Domestic Animals
- Inadequate Field Worker Hygiene
- Transport Containers (field to packing facility)
- Wash and Rinse Water
- Inadequate Processing Equipment Cleaning and Sanitation - equipment used to soak, pack, or cut produce
Potential Sources Contamination: On the Farm

• Soil
• Contaminated irrigation or wash/rinse water
• Infected workers and /or poor personal hygiene
• Fresh/uncomposted manure/fecal material
• Incomplete compost
Potential Sources Contamination:
On the Farm

- Wild and domestic animals
- Cross-contamination
  e.g. Transport Containers
  (field to packing)
- No time/temperature control when needed
- Inadequate Processing Equipment
  Cleaning and Sanitation
  (soak, pack, cut)

Adapted from Rutgers University- NJ Ag Station
FDA/CFSAN Conclusions

- Animals and contaminated water implicated
- Pre-harvest/harvest phases of production most likely opportunity for contamination
- Post-harvest practices may contribute to spread
- Pre-harvest/post-harvest sanitation treatments on produce – little effectiveness. Antimicrobial applications impact adequate reduction, quality implications

Response?

2004-2008

- FDA
  - Initiatives, guidance for produce
  - Guidance for fresh-cut fruits/vegetables
  - Commodity specific (e.g. lettuce, tomatoes)

- Industry/States
  - CA, AZ mandatory GAP, state inspection

- USDA
  - USDA – mandatory GAP for produce supplied to its programs
  - GAP volunteer program

- Consumer groups
  - CSPI – petition FDA for regulations
How did FDA Respond?

- **FDA, 2004**: Produce safety from production to consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption.  
  http://www.cfsan.fda.gov/~dms/prodpla2.html


- **FDA, 2006**: Lettuce Safety Initiative  
  http://www.cfsan.fda.gov/~dms/lettsafe.html

- **FDA, 2006**: Guidelines for the Fresh Tomato Supply Chain  
  http://www.cfsan.fda.gov/~dms/tomatsup.html

- Industry initiatives – CA, AZ 3,000 growers calling for mandatory GAP (Food Protection Report, **Nov.2006**, 22(11)).
Response (con’t)

- **USDA, May 31, 2006.** Requirement for GAP verification for all fresh products supplied to USDA programs beginning **July 1, 2007** with voluntary audits beginning July 1, 2006. Suppliers meeting GAP verification listed on USDA GAP/GHP website.

- **CSPI, Citizen Petition, November 15, 2006.** Urging FDA to issue standards and regulations to ensure safe food production of fresh fruits and vegetables. Requesting mandatory hazard control programs for farms and processors in the GAP areas such as manure, water and sanitation.

- **California legislation, February 2, 2007** – Leafy green vegetables

- **CA Department of Food and Agriculture, February 7, 2007** – Leafy Green Marketing Agreement – inspection program for handlers of leafy greens certified by CDFA.
Response (con’t)

- **FDA, June 12, 2007.** Tomato safety initiative to reduce tomato-related foodborne illnesses due to *Salmonella*. To begin with VA farms and packing facilities as to degree implement GAP and GMP’s.

- **FDA, September, 2008.** Original guidance document revisited for updating in response to 10 years of outbreaks.

- **Food Safety Enhancement/Modernization Acts 2009.** Proposed, House and Senate. Incorporates all food products. Proposed requirement for food safety plans and/or standards for fresh produce.
Congressional and FDA Response

- **FDA, 2/23/2010**: Request for comments on preventive controls for fresh produce
  - Risk factor identification
  - Assessment hazards and pathways to contamination
  - Preventive controls for hazards
  - Microbial testing
  - Post-harvest operations and GMP’s
  - Records and other documentation
  - GAP integration
  - Role of standards for domestic and foreign growers/processors
FDA Food Modernization Act of 2010

New Food Safety Standards and Regulations: Impact on the Produce Industry and all Food Industry
The RI GAP Program for Small Producers of Fruits and Vegetables (based on the FDA/USDA Guide) addresses these sources of contamination.
Be sure to think about the following when developing a GAP program for your operation:

- Water safety
- Safe use of manure, compost and biosolids
- Worker health and hygiene
- Sanitation in the field, packing area, and PYO operations
- Temperature control
- Traceback
Liability Insurance

Farm Family Insurance : Liability credit of ~ 3-5%

Contact John Howard