Overview of the Revised FSMA Rule on Produce Safety Standards

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February 12, 2015
Outlines

- Food Safety in the U.S.
- FSMA Fresh Produce Rule
  - Use of Raw Manure
  - Agricultural Water
  - Wildlife and Animal Habitat
  - Farms Excluded from Coverage
  - Packing or Holding of Own or Other Raw Agricultural Commodity (RACs)
Food Safety in the U.S.
Fun Quiz
Fun Quiz
Food Safety in the U.S.

- 1999: 76,000,000 Infections, 325,000 Hospitalizations, 5000 Deaths
- 2011: 48,000,000 Infections, 125,000 Hospitalizations, 3000 Deaths

Legend:
- Infections
- Hospitalizations
- Death

Source: CDC
Outbreaks-Associated Commodities

- Vine: 3%
- Grains-beans: 5%
- Mollusk: 6%
- Pork: 9%
- Fruits-Nuts: 9%
- Eggs: 4%
- Sprouts: 2%
- Other: 5%
- Dairy: 10%
- Leafy: 10%
- Beef: 10%
- Poultry: 13%
- Fish: 14%
Produce-related Outbreaks & Illnesses
Consumption of Fresh Produce

<table>
<thead>
<tr>
<th>Year</th>
<th>Lbs/Capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>1976</td>
<td>247</td>
</tr>
<tr>
<td>2009</td>
<td>310</td>
</tr>
</tbody>
</table>
Risk of Illness-Per-Pound Consumed (2001-2010)

Number of illnesses relative to those caused by fruit
## Riskiest Produce 2001-2010

<table>
<thead>
<tr>
<th>Produce</th>
<th>Outbreaks</th>
<th>Illnesses</th>
<th>Pathogen #1</th>
<th>Pathogen #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greens-based salad</td>
<td>221</td>
<td>5,373</td>
<td>Norovirus</td>
<td>E. coli</td>
</tr>
<tr>
<td>Lettuce</td>
<td>117</td>
<td>3,455</td>
<td>Norovirus</td>
<td>E. coli</td>
</tr>
<tr>
<td>Fruit salad and mixed fruits</td>
<td>51</td>
<td>1,911</td>
<td>Norovirus</td>
<td>E. Coli</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>41</td>
<td>4,859</td>
<td>Salmonella</td>
<td>Norovirus</td>
</tr>
<tr>
<td>Salsa</td>
<td>41</td>
<td>1,539</td>
<td>Norovirus</td>
<td>Salmonella</td>
</tr>
<tr>
<td>Melon</td>
<td>29</td>
<td>1,593</td>
<td>Salmonella</td>
<td>Norovirus</td>
</tr>
<tr>
<td>Sprouts</td>
<td>29</td>
<td>872</td>
<td>Salmonella</td>
<td>E. coli</td>
</tr>
<tr>
<td>Chili Peppers</td>
<td>7</td>
<td>1,662</td>
<td>Salmonella</td>
<td>Clostridium</td>
</tr>
</tbody>
</table>

Outbreaks N= 536  Illnesses N= 21,264

Source: CSPI Outbreak Alert! Database
Top Hazards in Produce

Pathogens in Produce, 2001-2010, Outbreaks=667

Salmonella, 135
Norovirus, 384
Staphylococcus, 12
Cyclospora, 9
Calicivirus, 1
Giardia, 1
Hepatitis A, 10
Listeria, 1
Shigella, 11
Bacillus, 18
Campylobacter, 23
Clostridium, 16
E. coli, 46

Source: CSPI Outbreak Alert! Database
Colorado Cantaloupe/Listeria Outbreak

• 33 people died in 2011
• The owners received:
  • 5 years probation
  • 6 months home detention
  • Each paid $150,000
  • Each performed 100 h of community service
FSMA
Fresh Produce Rule
The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011.
Main Themes of the Legislation

Prevention

Enhanced Partnerships

Inspections, Compliance, and Response

Import Safety
FSMA Rules Apply to Everything Except

• Low Acid Canned Food
• Seafood
• Meat and Poultry
• Juices
# Standard Setting

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Proposal</th>
<th>Final (consent decree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive Controls (Human Food)*</td>
<td>Jan 16, 2013</td>
<td>Aug 30, 2015</td>
</tr>
<tr>
<td>Foreign Supplier Verification Program*</td>
<td>Jul 29, 2013</td>
<td>Oct 31, 2015</td>
</tr>
<tr>
<td>Intentional Adulteration</td>
<td>Dec 24, 2013</td>
<td>May 31, 2016</td>
</tr>
</tbody>
</table>
Stakeholder Input

- Jan. 16, 2013
- 3 Public Meetings
- Comment period closed on Nov. 22, 2013
- 15,000 comments

- Sep. 29, 2014
- Re-opening the docket/seek public comments on revised provisions
- Comment period closed on December 15, 2014
Issues Addressed in Supplemental Proposed Rule

- Use of Raw Manure
- Agricultural Water
  - Microbial quality standard for irrigation water
  - Frequency of testing
- Wildlife and Animal Habitat
- Withdrawal of qualified Exemption
- Farms Excluded from Coverage
- Packing or holding of own or others; RACs
Use of Raw Manure

**Proposed**
- Raw Manure (9 months)
- Compost (45 days)

**Revised**
- Raw Manure
  - 120 days for crops in contact with the soil
  - 90 for crops NOT in contact with the soil
- Compost (0 days)
Agricultural Water: a) Quality Profile

Before use
2 years
20 samples

Proposed
Geometric Mean (GM)
No More than 126 CFU
Generic *E. coli*
per 100ml

Revised
Geometric Mean (GM)
No More than 126 CFU
Generic *E. coli*
per 100ml

Single Sample Maximum of 235 CFU
Generic *E. coli*
per 100ml

Statistical Threshold Value not to exceed 410 CFU
Generic *E. coli*
per 100ml

90%
Frequency of Agricultural Water Quality Profile

Every 10 years

Or

If a substantial deviation of 0.5 log or greater change in GM or STV in any single year.

Or

If the grower knows or has reason to believe that the current water quality Profile has been changed.
Agricultural Water Performance Standard

• No reconsideration of using *E. coli* as indicator of water quality

• Agriculture water used at harvest, postharvest, for sprouts, on food contact surfaces, to make ice or to wash hands (0 CFU of generic *E. coli* per 100 ml of water)
Agricultural Water; b) Frequency of Testing

Proposed

- Untreated surface water
  - Every 7 days

- Untreated ground water
  - At the start of growing season
  - Every 3 months during growing season
Agricultural Water; b) Frequency of Testing

- Untreated surface water
  - 5 samples per year

- Untreated ground water
  - 4 samples in one year, if all 4 samples meet the FDA performance standard then once a year

- Public Water (no requirement)
- Treated water (no requirement)
Sharing of Agricultural Water Data

Meat the requirements related to the monitoring of agricultural water

There is NO microbiological contamination between the sampling sites

Share testing results
Actions Required for Water that Does Not Meet Microbial Standards

• Discontinue use the source of the water
• Treat the water
• Establish time intervals
  • *Between irrigation to harvest* to allow time for potentially dangers microbes to *die-off* based on a 0.5 log/day.
  • *Between harvest and end of storage* using an appropriate reduction rate (e.g., removal during commercial washing or natural *die-off* during extended storage)
Wildlife & Animal Habitat

**Proposed**

- If evidence of animal intrusion occurred then take all required *measures* to prevent contamination

**Revised**

- The rule will not authorize/require taking actions that:
  - Would constitute the taking of endangered species, or
  - Destroy animal habitat
Withdrawal of Qualified Exemption

The FDA may withdraw a qualified exemption if:

• An active investigation of foodborne outbreak directly linked to the farm

• The FDA determines that it is necessary to protect the public health and prevent a foodborne illness outbreak based on conditions associated with the farm
Withdrawal of Qualified Exemption

The FDA may consider one or more actions prior to withdrawal such as:

• Issuance of a warning letter

• Recall

• FDA provides an opportunity for the farm to respond & consider actions taken by the farm to address the issues raised by FDA
Farms Excluded from Coverage

Proposed

• Rule would not cover farms that have and average annual value of FOOD sold during the previous 3-year period of $25,000 or less

Revised

• Rule would not cover farms that have and average annual value of PRODUCE sold during the previous 3-year period of $25,000 or less
Packing or Holding of Own or Others’ RACS

**Proposed**

- Different requirements would apply when a farm packs/holds its own RACs than when it packs/holds others’ RACs

**Revised**

- Modify the farm definition so it would include establishments that pack or hold food that is grown or raised on another farm whether or not under the same ownership
Compliance Dates

- Very small farms (> $25,000 - ≤ $250,000) → 4 years
- Small farms (> $250,000 - ≤ $500,000) → 3 years
- Large farms (> $500,000) → 2 years
Questions