



**CherryCentral**  
Growing, Processing and Marketing Fruit

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# **Food Safety Modernization Act**

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*Director of Technical Services*

**January 29, 2013**

**GM-BKTH**

**“FDA SAYS HELLO TO GROWERS”**



# **Food Safety Modernization Act FSMA**

- Developed over several years involving industry, consumer groups and regulatory agencies both State and Federal.
- Strong bi-partisan support.
- Signed into law by President Obama in January 4, 2011



## Why?

- ❖ **Center for Disease Control (CDC) reports 44 million Americans each year experience food related illness**
- ❖ **120,000 require hospitalization**
- ❖ **3,000 die**

## Past Cases:

- 30 people died from Listeria contaminated cantaloupe.
- 1 death in Newberg, OR from E. coli in strawberries, 10 people hospitalized.
- 1 dead in California and 76 people sick in 26 states from Salmonella in ground turkey.
- 425 cases in 44 states from Salmonella in Peanut Butter.
- 3 dead, 198 people sick in 25 states from E. coli in bagged spinach.



## **Three major objectives in this Act**

1. Improved capacity to prevent food safety problems.
2. Improved capacity to detect and respond to food safety problems.
3. Improved the safety of imported food.



# Improved Capacity to Prevent Food Safety Problems

[Sec. 101. Inspections of records.](#)

[Sec. 102. Registration of food facilities.](#)

[Sec. 103. Hazard analysis and risk-based preventive controls.](#)

[Sec. 104. Performance standards.](#)

[Sec. 105. Standards for produce safety.](#)

[Sec. 106. Protection against intentional adulteration.](#)

[Sec. 107. Authority to collect fees.](#)

[Sec. 108. National agriculture and food defense strategy.](#)

[Sec. 110. Building domestic capacity.](#)

[Sec. 111. Sanitary transportation of food.](#)

[Sec. 112. Food allergy and anaphylaxis management.](#)



# Standards for Produce Safety

On January 16<sup>th</sup>, the FDA issued Proposed Rules on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

## **Covered Produce:**

-Cherries, Apples, Peaches

## **The proposed rule sets both a general duty and specific standards in five areas:**

- Worker Training and Health and Hygiene
- Agricultural Water
- Biological Soil Amendments
- Domesticated and Wild Animals
- Equipment, Tools, and Buildings

## **Drops**



# Improving Capacity to Detect and Respond to Food Safety Problems

[Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry.](#)

[Sec. 202. Laboratory accreditation for analyses of foods.](#)

[Sec. 204. Enhancing tracking and tracing of food and recordkeeping.](#)

[Sec. 205. Surveillance.](#)

[Sec. 206. Mandatory recall authority.](#)

[Sec. 207. Administrative detention of food.](#)

[Sec. 210. Enhancing food safety.](#)

[Sec. 211. Improving the reportable food registry.](#)



# Proposed Rules

Issued 1/4/2013

**680 pages that.....**

- ✓ Defines who/what operations must comply
- ✓ Defines the programs needed by companies to comply
- ✓ Defines who is responsible for compliance
- ✓ Defines the increased authority given the FDA
  - Mandatory Recall Authority
  - Access to records
  - Impose fees





## Is your operation subject to FSMA?

- If you are required to register your facility with the FDA you are subject to FSMA.
- If you manufacture, process, pack or hold food for consumption off your farm, you are required to register with the FDA.
- **Farms are not subject to the registration requirement.**
- Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of and cooling produce are considered part of harvesting.
- Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.



**Proposed Standards for Produce Safety - Coverage and Exemptions/Exclusions for Proposed 21 PART 112**

<p>Does your farm grow, harvest, pack or hold produce? Sections 112.1 and 112.3(c)</p> <p style="text-align: center;">YES</p> <p style="text-align: center;">↓</p>	<p>NO →</p>	<p>You are NOT covered by this rule.</p>
<p>Is your produce rarely consumed raw? Section 112.2(a)(1)</p> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule.</p>
<p>Is your produce for personal/on-farm consumption? Section 112.2(a)(2)</p> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule.</p>
<p>Does your farm manufacture/process, pack, or hold produce that is not a Raw Agricultural Commodity (RAC)? Section 112.2(a)(3)</p> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>Produce that is not a RAC is NOT covered by this rule.</p>
<p>Is your produce intended for commercial processing with a "kill step"? Section 112.2(b)(1)</p> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>This produce is NOT covered by this rule, EXCEPT as per Sections 112.(b)(2) and (3)</p>
<p>Does your farm on average (in the previous 3yrs) have &lt; \$25k annual food sales? Section 112.4(a)</p> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>You are NOT covered by this rule.</p>
<p>Does your farm on average (in the previous 3yrs) as per Section 112.5:</p> <ul style="list-style-type: none"> <li>• have &lt; \$500k annual food sales, AND</li> <li>• a majority of the food (by value) sold directly to "qualified end-users"?</li> </ul> <p>"Qualified End-User" Section 112.3(c) means:</p> <ul style="list-style-type: none"> <li>• the consumer of the food ("consumer" is not a business) OR</li> <li>• a restaurant or retail food establishment that is located—               <ul style="list-style-type: none"> <li>(i) in the same State as the farm that produced the food; OR</li> <li>(ii) not more than 275 miles from such farm.</li> </ul> </li> </ul> <p style="text-align: center;">NO</p> <p style="text-align: center;">↓</p>	<p>YES →</p>	<p>You are EXEMPT from this rule except as per Section 112.6</p>
<p>You are COVERED by this rule.</p>		



# Recommendations

## **1. Get HACCP Training**

### **Hazard Analysis Critical Control Point**

- ✓ Make a flow chart of your operation
- ✓ Do a Hazard Analysis for each step
- ✓ Address the Hazards with written procedures
- ✓ Review yearly....Does it still apply? Will it prevent the hazard in the future?

## **2. Train you employees**

- ✓ Written procedures on their job expectations.

## **3. Document, Document, Document**

- ✓ “If it is not written down, it did not happen.”



Home Inspections, Compliance, Enforcement, and Criminal Investigations Enforcement Actions Warning Letters  
**Inspections, Compliance, Enforcement, and Criminal Investigations**

**Chamberlain Farms, Inc. 12/14/12**



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Detroit District  
300 River Place  
Suite 5900  
Detroit, MI 48207  
Telephone: 313-393-8100  
FAX: 313-393-8139

**WARNING LETTER  
(2013-DET-04)**

December 14, 2012

VIA UPS

Tim D. Chamberlain  
President  
Chamberlain Farms, Inc.  
5584 W 250 South  
Owensville, IN 47665

Dear Mr. Chamberlain:

From August 14 to 31, 2012 the U.S. Food and Drug Administration (FDA) conducted an inspection of your produce packinghouse and growing fields located at 5884 W. 200 South, Owensville, IN 47665. FDA subsequently further inspected your growing fields between September 19 to 21, 2012. FDA conducted these inspections under its authority in section 704 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §374] as a result of epidemiological investigations, traceback investigations, and analytical results that linked cantaloupes grown and packed on your farm to a nationwide outbreak involving two strains of *Salmonella enterica*: *Salmonella* Typhimurium and *Salmonella* Newport. As of October 4, 2012 this outbreak sickened approximately 261 persons, including 3 deaths, in 24 states between July 6, 2012 and September 16, 2012. You may read more about the outbreak at the following web address:  
<http://www.cdc.gov/salmonella/typhimuriumcantaloupe-08-12/index.html>.

Salmonella is an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with Salmonella often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.

On August 16, 2012, during the FDA inspection at your firm, FDA investigators collected multiple cantaloupe samples from your packinghouse. Each sample consisted of twenty cantaloupes taken from cardboard boxes in your packinghouse. One subsample (one cantaloupe) yielded a strain of



## Chamberlain Farms-Warning Letter

1. From August 14 to 31, 2012 the FDA conducted and inspection of your produce packing house and growing fields...
2. Further inspected your growing fields between 9/19 and 9/21. Melon samples positive for Salmonella.
3. Reason for the inspection: 3 deaths, 261 people sick in 24 states due to Salmonella. Melons were traced to Chamberlain Farms.
4. Accumulated organic material on multiple locations of the cantaloupe line. Swabs found Salmonella on the line genetically linked to the cause of the outbreak.
5. Bird excrement in the rafters above the line. Birds roosting above the lines.
6. Well heads not capped and/or properly sealed. Well and plant water tested positive for Coliform and E. coli. Same water used to wash the melons prior to packing.
7. Corrections required in writing to the FDA within 15 days.



## More Information

### **Full Text of the Law**

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm>

**Proposed Rules:** Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

[http://www.ofr.gov/\(X\(1\)S\(v3yf3je4uhgifjgft2sscuim\)\)/OFRUpload/OFRData/2013-00125\\_PI.pdf](http://www.ofr.gov/(X(1)S(v3yf3je4uhgifjgft2sscuim))/OFRUpload/OFRData/2013-00125_PI.pdf)

### **Standards for Produce Safety**

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm334114.htm>

### **Recalls and Safety Alerts**

<http://www.fda.gov/Safety/Recalls/default.htm>

### **HACCP**

<http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpoints/haccp/default.htm>

<http://www.fao.org/docrep/005/Y1579E/y1579e03.htm>



## Invitation to FDA Webinar

**FDA's Proposed Produce Safety Rules**  
**Feb. 7, 2013**  
**2:30 - 3:30 p.m. Eastern Time**

The U.S. Department of Agriculture (USDA) invites you to take part in a free, interactive webinar on the Food and Drug Administration's (FDA) proposed produce safety rules. **While the USDA has no formal role in the development or implementation of the proposed rules for the FDA Food Safety Modernization Act**, the agency's Agricultural Marketing Service (AMS) [Fruit and Vegetable Program](#) is hosting the webinar as a service to the produce industry.

Dr. Jim Gorny, Senior Advisor, Produce Safety, for FDA's Center for Food Safety and Applied Nutrition will deliver a presentation on two groundbreaking FDA proposed rules under the FDA Food Safety Modernization Act, or FSMA, with an emphasis on the proposed *Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*. The proposed rules published in the Federal Register on Jan. 16, 2013 provide for a 120 day comment period.

Dr. Gorny's formal presentations will be followed by a real-time, interactive question and answer session.

This informative session is part of AMS's ongoing webinar series designed for fruit and vegetable growers, packers, shippers, processors, wholesalers, and retailers of all sizes. The webinar is free and available to anyone with Internet access. Registration is required and space is limited.

**[REGISTER HERE](https://amsfv.webex.com/amsfv/onstage/g.php?t=a&d=295501163)** (<https://amsfv.webex.com/amsfv/onstage/g.php?t=a&d=295501163>)

To view previous USDA AMS Fruit and Vegetable Program webinars online, visit our [Webinar Archive](#).