

# **FDA Progress in Implementing the Food Safety Modernization Act What Growers Should Expect**

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# History

- Passed in Lame Duck session **December 2010**
- 111<sup>th</sup> Congress: Food safety broadly bipartisan
  - **What politician is against safe food?**
- North Carolina Senators very active
  - *Sen. Burr Sponsor (staff listened to farmers!)*
  - *Sen. Hagan--exemption amendment*
- Lots of opinions/Groups weighing in

# The Big Picture

- **From Detect → Prevent**
  - Monitor, Correct, Verify, Recordkeeping
  - On Farm Production
  - Registered Facilities
- **New FDA Powers**
  - FDA has the authority to **order a recall of food.**
  - FDA has the authority to administratively **detain food based only on a “reason to believe” the food is adulterated or misbranded.**

# What's in the law?

## Standards for Produce Safety

- **FDA must develop science-based minimum standards for the safe production and harvesting of fruits and vegetables.**
- **Secretary may exclude low risk fruit/vegetables in rule making or may modify regulations**
- **Rules developed based on prioritization of *known risks***
- **Some farms exempt:**
  - Sales to qualified end users exceed sales to all other buyers
    - End users in the same state or within 275 miles
  - Average annual sales of "all food" of \$500,000 or less adjusted for inflation
  - Exemption can be withdrawn if foodborne illness outbreak is directly linked to an exempted farm
  - Does not preempt state/local food safety law
  - Food must be labeled w/farm identification--name and business address of the farm
  - FDA may still inspect a farm
- **When? Expect publication in the Federal Register in Early 2012. Have heard draft is in review currently.**

# What's in the law?

## Registered Facilities

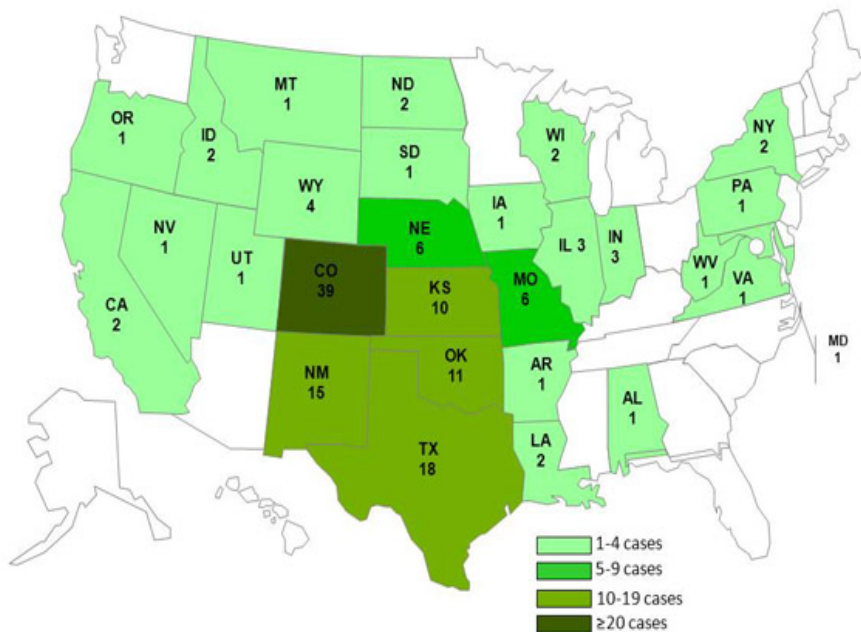
- **Covered Food Facilities**
  - Definition excludes farms and retail (now clear that farmers markets, roadside stands, CSAs are retail)
  - Registered Facility: “Any factory, warehouse, or establishment (including importers) that manufactures, processes, packs, or holds food.”
- **HACCP**
  - Registered facilities required to conduct a hazard analysis and develop and implement a written preventive controls plan.
- **FDA will be proposing regulations on what constitutes on-farm processing.**
- **Exempts *small facilities* selling to qualified end users (includes internet sales)**
  - Qualified end users in same state or w/i 275 miles; Value of food (manufactured, processed, packed, held) sold directly to “qualified end-users” exceeds sales to all other purchasers; Value of all food less than \$500,000 annually, adjusted for inflation
  - Must document hazards and implement preventive controls. Guidance to be issued within 1 year.
  - Food must be labeled, or company info conspicuous to end user
- **When? Expect publication in the Federal Register in Late 2011/Early 2012. Have heard draft is in review currently.**

# What's in the law? Traceability

- FDA is required to establish a product tracing system within FDA to effectively and rapidly track and trace food.
- FDA can come onto your farm during an active investigation if they have a traced a problem to you or if they believe it's necessary to prevent or mitigate an outbreak
- You do not have to develop new records.
  - No New Records!
- There are limits on what FDA can request. The following is not allowed:
  - Information relating to the finances,
  - Pricing of commodities produced
  - Personnel
  - Research
  - Sales (other than information relating to shipping)
  - Or other trade secrets or confidential information
- **Timing: Announced Traceability Study Partners and are Soliciting Participants**

# What do cantaloupes have to do w/ FSMA?

- **Listeria cases traced to Jensen Farms**



- **Growing field samples taken were negative**

- **FDA Environmental Swabs Positive Results for Listeria** (13/29 samples positive)

- **Processing Line**

- 9 positive samples from the grading belt
- 2 positive samples from the conveyor
- 1 positive from the felt rollers

- **Packing Area**

- 1 positive sample from the conveyor belt

- **FDA Product Sample Results**

- **Sample #643701**

- 1 product sample of Jensen Farms cantaloupe (10 cantaloupes or "subs") was collected on September 9, 2011 from a retail store in Denver, Colorado. 9 of the 10 cantaloupes ("subs") in this sample tested positive for Listeria monocytogenes with a PFGE pattern matching the outbreak strain #2.

- **Sample #713431**

- 1 product sample (10 cantaloupes or "subs") was collected on September 10, 2011 from the cooler at Jensen Farms' packing facility during FDA's regulatory inspection. 5 of the 10 cantaloupes ("subs") in this sample tested positive for Listeria monocytogenes.

# Cantaloupes and FSMA

- Language: Certain aspects of the packing facility, including the location of a refrigeration unit drain line, allowed for water to pool on the packing facility floor in areas adjacent to packing facility equipment. Wet environments are known to be potential reservoirs for Listeria monocytogenes and the pooling of water in close proximity to packing equipment, including conveyors, may have extended and spread the pathogen to food contact surfaces.”
- “The packing facility floor was constructed in a manner that was not easily cleanable. Specifically, the trench drain was not accessible for adequate cleaning. This may have served as a harborage site for Listeria monocytogenes and, therefore, is a factor that may have contributed to the introduction, growth, or spread of the pathogen.”
- “Several areas on both the washing and drying equipment appeared to be un-cleanable, and dirt and product buildup was visible on some areas of the equipment, even after it had been disassembled, cleaned, and sanitized. Corrosion was also visible on some parts of the equipment. Further, because the equipment is not easily cleanable and was previously used for handling another raw agricultural commodity with different washing and drying requirements, Listeria monocytogenes could have been introduced as a result of past use of the equipment.”
- “The design of the packing facility equipment, especially that it was not easily amenable to cleaning and sanitizing and that it contained visible product buildup, is a factor that likely contributed to the introduction, growth, or spread of Listeria monocytogenes. Cantaloupe that is washed, dried, and packed on unsanitary food contact surfaces could be contaminated with Listeria monocytogenes or could collect nutrients for Listeria monocytogenes growth on the cantaloupe rind...”
- “In addition, free moisture or increased water activity of the cantaloupe rind from postharvest washing procedures may have facilitated Listeria monocytogenes survival and growth. After harvest, the cantaloupes were placed in cold storage. The cantaloupes were not pre-cooled to remove field heat before cold storage. Warm fruit with field heat potentially created conditions that would allow the formation of condensation, which is an environment ideal for Listeria monocytogenes growth. The combined factors of the availability of nutrients on the cantaloupe rind, increased rind water activity, and lack of pre-cooling before cold storage may have provided ideal conditions for Listeria monocytogenes to grow and outcompete background microflora during cold storage. Samples of cantaloupe collected from refrigerated cold storage tested positive for Listeria monocytogenes with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains. Cantaloupes collected directly from the field tested negative for Listeria monocytogenes. Based on the positive results from the environmental samples collected from the packing facility and from cantaloupes collected from cold storage, it is likely that the contamination occurred in the packing facility. It is also likely that the contamination proliferated during cold storage.”



# Cantaloupes and FSMA Language

- III. Recommendations for Prevention of Listeria Monocytogenes Contamination Based on these Findings
  - Fresh fruit and vegetable **producers should employ good agricultural and management practices** recommended for the growing, harvesting, washing, sorting, packing, storage, and transporting of fruits and vegetables sold to consumers in an unprocessed or minimally processed raw form. These practices are set forth in FDA and USDA’s “Guidance for Industry -- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables.”
  - FDA’s findings regarding this particular outbreak highlight the importance for the industry to employ good agricultural and **management practices in their packing facilities** as well as in growing fields. Specifically, FDA recommends that firms:
    - **Assess produce facility and equipment design to ensure adequately cleanable surfaces and eliminate opportunities for introduction, growth, and spread of Listeria monocytogenes and other pathogens.**
    - **Assess and minimize opportunities for introduction of Listeria monocytogenes and other pathogens in packing facilities.**
    - **Implement cleaning and sanitizing procedures.**
    - **Verify the efficacy of cleaning and sanitizing procedures.**
    - **Periodically evaluate the processes and equipment used in packing facilities to assure they do not contribute to fresh produce contamination.**
- **Please note HACCP (Hazard Analysis and Critical Control Point) style language**

## **Jensen/Precedent and implications**

- **“Outbreak lawsuits target Wal-Mart, PrimusLabs,” *The Packer 11/11/11***
- **Produce industry is highly concerned**
- **Will growers weigh potential food safety risk before selecting crops to produce?**

# Exemptions

- The Tester/Hagan Amendment
- Divisive in the produce industry
- What does it say? What doesn't it say?

# Tester/Hagan Amendment

## What it says

- **Some farms exempt from Produce Safety Standards**
  - Sales to qualified end users exceed sales to all other buyers
    - End users in the same state or within 275 miles
  - Average annual sales of “all food” of \$500,000 or less adjusted for inflation
  - Exemption can be withdrawn if foodborne illness outbreak is directly linked to an exempted farm
  - Food must be labeled w/farm identification--name and business address of the farm
  - Does not preempt state/local food safety law
  - FDA may still inspect a farm
- **Registered Facilities :Exempts *small facilities* selling to qualified end users (includes internet sales)**
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  - Must document hazards and implement preventive controls. Guidance to be issued within 1 year.
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# Tester/Hagan Amendment

## What it does not say

- You are not exempt if you have an issue
  - Language clearly does not exempt ANYONE from following the law
- Preempt a state, local or county government or other non-federal law regarding the safe production, harvesting, holding, transportation and sale of fresh fruits and vegetables.
  - NC could develop rules
  - Now is the time for industry to discuss that idea/possibility
- Beware of misinformation: Exemptions within the FDA Food Safety Modernization Act do not prevent any buyer from mandating food safety programs or certification
  - Farm2School. Must be USDA GAPs audited
  - Most supermarkets/chains food safety programs and audits
  - Ditto for institutional buyers such as Classic, Sysco, Monarch, etc.

# Making it work: Bright lines

- **Tester Amendment**
  - Will farms and food facilities that meet the criteria fall under state jurisdiction? Need clarity of state/federal role.
- **FDA, when exactly is it processing?**
  - Will FDA deem use of water in packing sheds “processing”
  - Is placing fruit/vegetables into a clamshell or bag adding value? Is that considered processing?
    - Common post-harvest handling: Mixing different types of greens in Ziplocs. NO CUTTING

# Challenge: Small farms

## CFSA/NCSU research project

- **Food safety is not on the radar screen of most small farms**
  - Generally customers ask about sprays, organic, manure, not food safety
  - Many of NC' s small farmers like current customer mix and do not seek to expand to new markets
  - There are also many who seek to expand into markets that may require GAPs certification: **Buyer driven**
    - FSMA does not prevent buyers from mandating GAPs
  - Waiting on FSMA implementation
  - Many seek info to learn how to do a better job and how to produce safe food.
  - Many “get” why focus on food safety when you talk to them about policies for:
    - Sick employees, injured employees, visitor log, etc.
    - “What ifs“

# Challenge: NC is Diverse Economic, Geo and Demographic

- **Business model: Multiple crops continually in rotation year-round. Small farms have an especially diverse operation.**      **Sales:** Farmers markets 76%; Roadside stands 43%, Restaurants 28%, Grocery stores 22%, CSA 21%
- **Livestock is economically important 1,484 farms statewide w/ F/V and livestock**
  - 8% of all F/V farmers and ~3% of all NC farmers
- **NC geography and geology is highly diverse. You cannot drill wells in much of Central/Western NC**



# Making Food Safety Work for Small Farms

- **No. 1 concern expressed is added expense for implementing GAPs and recordkeeping**
  - Time, 1-2 person shops
    - Have templates for food safety manuals and logs. NC's Tiered Produce Safety trainings complete the background information on GAPs. We need a guidance document for working through the GAP audit for small farmers.
  - Financing big ticket items is difficult, provide help
    - National couponing program for plastic boxes to replace tomato/cardboard boxes?
    - Could USDA assist with hand washing stations, porta johns, etc.?
- **NC used Specialty Crops Block Grant funds for GAPs audit cost share (up to \$600) and water testing cost share (up to \$200)**
- **NC has used grants (Phase II Tobacco Buyout Payments, future uncertain) to develop traceability with FoodLogiQ and Eastern Carolina Organics**
- **National Cost share**
  - Leverage Farm Bill, NRCS other USDA programs for food safety expenses
  - Clean water funding, allow food safety expenses
  - Politics state-by-state

# North Carolina resources

## You are not alone

- **North Carolina Fresh Produce Safety Task Force (est. 2007)**
  - Part of NC Food Safety & Defense Task Force (est. 2005). New way of working, open source/wiki style. Amazing group of people. Interagency, public/private. NCSU, NCA&T, NCDA&CS, FDA, Farm Bureau, CFSA, Food LogIQ and more. 6 Working Groups, meet monthly
- **NCSU/NCA&T Cooperative Extension**
  - Dozens of County Extension Agents have been trained in GAPs education and in working with farmers to implement the basics
- **NCDA&CS**
  - NC used Specialty Crops Block Grant funds for GAPs audit cost share (up to \$600) and water testing cost share (up to \$200)
  - NCDA&CS provides USDA GAPs audits
  - NCDA&CS Food&Drug Division is nationally and internationally renowned
- **CFSA /NCSU Small Farms Research**
  - Dr. Audrey Kreske, Extension Associate, NCSU/12 farms, multiple visits through year starting May 2011
  - Resources delivered to farmers through onsite visits, Opening Markets website (<http://gapsmallfarmsonc.wordpress.com/>) and email. Determining economic impact of GAP implementation on small farms. Self diaries completed by farmers. Guidance materials and tools clarify risk reduction practices relative to USDA GAPs audits for small producers (< 30acres, 8+ commodities). Already available at: <http://gapsmallfarmsonc.wordpress.com/>
- **Produce Safety Alliance**
  - Headquartered at Cornell
  - NCDA&CS is on Steering Committee
  - Several NC Fresh Produce Safety Task Force members are on various committees, including chairing important committees

# More information:

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