

Safe Production and Handling of Produce: How FSMA Impacts the NC Fresh Fruit and Vegetable Industry

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History

Passed in Lame Duck session **December 2010**

111th 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Exemption can be withdrawn if foodborne illness outbreak is directly linked to an exempted farm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 Jan. 4, 2012. In OMB until...

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

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 the farm during an active investigation if they have a traced a problem there or if they believe it's necessary to prevent or mitigate an outbreak

Farmers 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

Cantaloupes an Example w/FSMA

Growing field samples taken were negative

Listeria cases traced to Jensen Farms

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

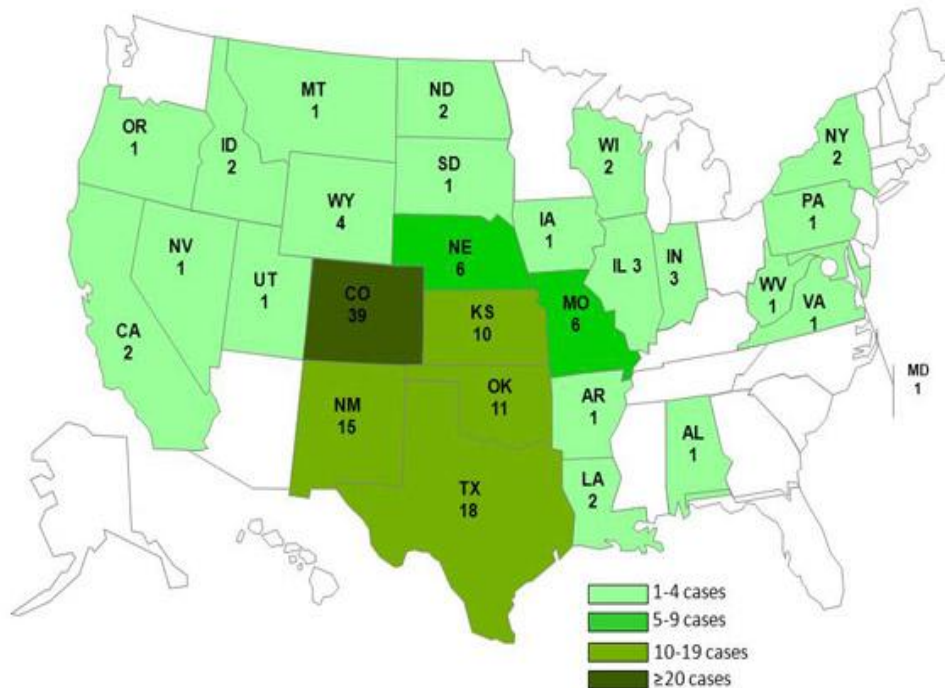
FDA Product Sample Results

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.

More 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

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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 is 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 Grower Resources

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://gapsmallfarm SNC.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://gapsmallfarm SNC.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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