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Committee Staff
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Report on the Investigation of the Outbreak of *Listeria monocytogenes* in Cantaloupe at Jensen Farms

Prepared for:

Henry A. Waxman
Ranking Member

Fred Upton
Chairman

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

Joseph R. Pitts
Chairman
Subcommittee on Health

John D. Dingell
Member

Overview

The Energy and Commerce Committee has conducted a bipartisan investigation of the recent outbreak of *Listeria monocytogenes* in cantaloupes grown and processed at Jensen Farms, a family-owned operation in Granada, Colorado. According to the Centers for Disease Control and Prevention (CDC), 146 people in 28 states have been infected, 30 people have died, and one person has miscarried as a result of this outbreak. It was the deadliest foodborne illness outbreak in over 25 years. As part of its investigation into this outbreak, the Committee has obtained documents from and conducted interviews of high-ranking officials at the Food and Drug Administration (FDA), Jensen Farms, Primus Labs (the third-party auditor that inspected Jensen Farms before the outbreak occurred), and Frontera Produce (the sole distributor of the cantaloupes). The purpose of this staff report is to provide facts gathered during the course of the Committee's investigation and to provide information helpful to the FDA, state authorities, growers, distributors, and others to better protect the nation's food supply.

The *Listeria* outbreak began in late summer 2011. On September 2, 2011 the Colorado Department of Public Health and Environment notified CDC of seven recent cases involving individuals who had eaten cantaloupe before becoming ill. As part of the investigation of these outbreaks, FDA visited and inspected the Jensen Farms facility on September 10, and on September 22, and 23, 2011.

During its unannounced visit on September 10, FDA took 39 samples from throughout the facility, finding that 13 of these samples contained *Listeria* contamination. During its announced second visit, with the knowledge of the positive samples, the FDA team conducted an environmental assessment to identify the factors that led to the introduction, growth, or spread of the *Listeria* contamination. FDA identified multiple potential problems during this investigation. These included the lack of a pre-cooling step to remove field heat before the cantaloupes were moved into cold storage; the inability to easily clean the packing facility floor and packing equipment; facility design flaws that allowed water to collect in proximity to equipment and employees walkways; and washing and drying equipment that was originally used on a different agricultural commodity.[1] On October 18, 2011, the FDA issued a warning letter to Jensen Farms in relation to these findings.[2]

Staff Briefings with FDA

Committee staff met with FDA and CDC officials on October 19, 2011, and again with FDA officials on December 8, 2011.[3] FDA officials summarized the agency's investigation of

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[1] Food and Drug Administration, *Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis* (Oct. 19, 2011) (online at www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm) (accessed on Nov. 30, 2011).

[2] Food and Drug Administration, Warning Letter to Jensen Farms (Ref: DEN-12-01 WL) (Oct. 18, 2011).

[3] FDA, Energy and Commerce Committee Staff Briefing (Oct. 19, 2011); House Committee on Energy and Commerce, Interview with Jeff Farrar (Associate Commissioner for Food

the *Listeria* outbreak and efforts to prevent future outbreaks. The investigation conclusively linked the outbreak to cantaloupes grown at Jensen Farms, including 13 positive samples of *Listeria monocytogenes* obtained from processing equipment and cantaloupes in a Jensen Farms packing facility. FDA officials cited several deficiencies in Jensen Farms' facility, which reflected a general lack of awareness of food safety principles and may have contributed to the outbreak, including:

- Condensation from cooling systems draining directly onto the floor,
- Poor drainage resulting in water pooling around the food processing equipment,
- Inappropriate food processing equipment which was difficult to clean (i.e., *Listeria* found on the felt roller brushes),
- No antimicrobial solution, such as chlorine, in the water used to wash the cantaloupes, and
- No equipment to remove field heat from the cantaloupes before they were placed into cold storage.

FDA officials were highly critical of the processing methods used at Jensen Farms. According to these FDA officials, the probable causes of the melon contamination at Jensen Farms included "serious design flaws" in the processing technique used at Jensen Farms, "poor sanitary design of the facility itself," and "lack of awareness of food safety standards by Jensen Farms." In particular, FDA emphasized to Committee staff that the processing equipment and the decision not to chlorinate the water used to wash the cantaloupes were two probable causes of the contamination. Both of these significant factors were changes implemented at the packing facility after the 2010 audit.

While this is the first *Listeria* outbreak linked to a raw agricultural commodity, the risks identified by FDA at the Jensen Farms packing facility were not new or unknown. In fact, the FDA classifies fresh produce generally as a "high risk" product for purposes of inspection priority under the Food Safety Modernization Act signed into law by President Obama on January 4, 2011. In addition, in July 2009, the FDA released draft guidance to the industry to minimize the risk of foodborne illness from melon production and distribution.[4] FDA officials stated that the outbreak could have likely been prevented if Jensen Farms had maintained its facilities in accordance with existing FDA guidance. FDA emphasized that the operating firm is responsible for adhering to FDA standards, comprised of four steps: hazard analysis; development of a preventative plan; validation; and verification.

Staff Briefing with Jensen Farms

Protection), Roberta Wagner (Deputy Assistant Commissioner for Regulatory Affairs of Field Operations), and James Gorny (Senior Advisor for Food Safety), FDA (Dec. 8, 2011).

[4] FDA, *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons; Draft Guidance* (July 2009).

Committee staff met with Eric and Ryan Jensen, the current owners of Jensen Farms, on November 8, 2011.[5] Jensen Farms has been in operation for several generations and has grown and packaged cantaloupes for the past twenty years. Eric and Ryan Jensen inherited the farm from their father, who recently passed away. Prior to the *Listeria* outbreak, Jensen Farms had no reported food safety problems.

Jensen Farms has had a business relationship with Frontera Produce for almost a decade. In 2003, Frontera Produce began distributing the farm's onions. Later, in addition to the onions, Frontera Produce began distributing Jensen Farms' cantaloupes to major retailers throughout the country. Most large retail purchasers of produce, including those to whom Jensen Farms sold their goods, require third-party audits of its growers and producers. One of Jensen Farms' large retail purchasers provided Frontera Produce with a list of roughly ten acceptable auditors. Frontera Produce shared this list with Jensen Farms and, from this list, Jensen Farms contracted with Primus Labs.

Primus Labs has audited Jensen Farms during the course of Jensen Farms' relationship with Frontera Produce. Primus Labs hired a subcontractor, Bio Food Safety, Inc., to conduct its recent audits of Jensen Farms. On August 5, 2010, Jerry Walzel, the President of Bio Food Safety, audited the Jensen Farms packing facility and gave it a 95% grade - a "superior" rating, despite finding several major and minor deficiencies.[6] On precaution that Jensen Farms took in 2010, which it dropped in 2011, was to use an antimicrobial solution, such as chlorine, in the cantaloupe wash water. The front page of the August 2010 audit stated, "[t]his facility packs fresh cantaloupes from their own fields into cartons. The melons are washed and then run through a hydro cooler which has chlorine added to the water. Once the product is dried and packed into cartons it is placed into coolers."[7]

After the August 2010 audit was completed, one of the Jensen brothers informed Mr. Walzel that they were interested in improving their processes. According to Jensen Farms, in response to this inquiry, Mr. Walzel indicated that they should consider new equipment to replace the hydrocooler the farm used to process cantaloupe.[8] Mr. Walzel stated that the hydrocooler, with its recirculating water, was a potential food safety "hotspot," and advised them to consider alternate equipment. Based on his comments, and input from a local equipment broker, Jensen Farms purchased and retrofitted equipment previously used to process potatoes. The Jenson brothers stated that they changed from the hydrocooler to the new food processing equipment in an attempt to strengthen their food safety efforts.

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[5] House Committee on Energy and Commerce, Interview of Eric Jensen and Ryan Jensen (Nov. 8, 2011).

[6] Jerry Walzel had previously done consulting work for Jensen Farms, in addition to conducting audits of its facilities.

[7] Primus Labs, *Primus Labs Audit #127817* (Aug. 5, 2010).

[8] One of the FDA officials who briefed Committee staff had previously served as a third-party auditor. He stated that it was an inherent conflict of interest for an auditor to provide advice like the kind provided by Mr. Walzel to Jensen Farms. He noted that operators should seek such advice from independent consultants, not auditors.

Jensen Farms stated that they contracted with Primus Labs to perform an audit in July 2011. Again, Primus Labs subcontracted with Bio Food Safety to conduct the audit. Mr. Walzel did not conduct this audit; a new auditor from Bio Food Safety, James Dilorio, conducted the audit on July 25, 2011, and, after spending approximately four hours inspecting the facility, gave Jensen Farms a 96% grade - again a "superior" rating. Despite this high rating, Mr. Dilorio identified several deficiencies, including three "major deficiencies": (1) wood (which can house bacteria and cause splinters) covered the unloading and packing tables, (2) lack of hot water at hand washing stations, and (3) doors left open during operating hours, potentially allowing pests to enter the facility. Dilorio also identified three "minor deficiencies": the storage area was left open during operating hours; there were no records of corrective actions taken based on previous audits; and stickers on pest control devices were in the wrong location.[9] Five additional instances of "non-compliance" at the facility were also identified.[10]

The auditor noted on the front page of the audit that Jensen Farms did not use an anti-microbial wash in 2011, writing, "This is a packing facility for cantaloupes which are washed by a spraybar roller system, graded, sorted by size, packed into cartons and stored in dry coolers. No anti-microbial solution is injected into the water of the wash station."[11] According to FDA, the failure to use an anti-microbial wash was not consistent with agency guidance and was a probable cause of the contamination.

Jensen Farms noted that it received a visit from a representative of Frontera Produce, its distributor, shortly before the 2011 audit. According to the Jensen brothers, this representative provided them with advice about preparing for the audit, but did not note any problems. Jensen Farms informed Committee staff that quality control representatives from various retailers have visited the farm as well. The Jensen brothers stated that based on these inspections and their prior food safety record, they had no concerns about their operations prior to the recent outbreak.

Staff Briefing with Frontera Produce

Committee staff met with representatives of Frontera Produce on November 18, 2011.[12] Will Steele and Amy Gates, the CEO and Executive Vice President of Frontera Produce, told Committee staff that they had visited Jensen Farms to inspect its facilities and provide business advice. Mr. Steele indicated that he had been to the farm approximately six times in the past six years, but not in the past two years. Ms. Gates visited Jensen Farms shortly before its July 2011 audit. She stated that, due to the nature of their business relationship, she focused on Jensen Farms' documentation, noting that the primary concern is the formatting of shipment records.

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[9] Primus Labs, *Primus Labs Audit #150236* (July 25, 2011).

[10] Primus Labs, *Primus Labs Audit #150236* (July 25, 2011). In 2011, Primus found the following non-compliances: there were no written procedures for calibrating thermometers, there were no background checks were conducted on personnel, there were no records of food security training for employees, there was no certificate of inspection of the backflow prevention system for water lines, and employees were not required to sign documents promising to comply with Jensen Farms' hygiene, health, and occupational safety policies. *Id.*

[11] Primus Labs, *Primus Labs Audit #150236* (July 25, 2011).

[12] House Committee on Energy and Commerce, Interview of Will Steele and Amy Gates (Nov. 18, 2011).

Mr. Steele and Ms. Gates said that many major retailers require that growers obtain annual audits from third-party auditors such as Primus Labs. They stated that if a buyer identifies deficiencies that they want rectified, Frontera Produce will communicate those concerns to the grower or producer in question. They could not recall, however, a situation in which a grower gets a passing grade on an audit and the buyer asks them to "go back and fix things."

Frontera Produce incurred significant costs from the recall. According to a Frontera Produce representative, as of December 12, 2011, it has received direct bills and invoice adjustments totaling approximately $500,000 for recall-related costs incurred by customers who purchased Jensen Farms cantaloupe through Frontera Produce.

When questioned, both Mr. Steele and Ms. Gates were critical of the current standards for third-party audits and had concerns about inadequate standards. Ms. Gates indicated that there is "no industry standard for validation points" after an audit, while Mr. Steele stated that "this is the industry standard. I've always believed there's got to be more validation points. This case clearly demonstrates that."[13]

Ms. Gates stated that Frontera Produce is currently working with NSF International and other firms to improve the audit system.

Staff Briefing with Primus Labs

Committee staff met with the President of Primus Labs, Robert Stovicek, on November 7, 2011.[14] Primus Labs is one of the nation's largest third-party food safety auditors. Primus Labs conducts approximately 15,000 audits per year, primarily involving fresh produce facilities, for over 3,000 clients worldwide. A typical facility is audited once per year, and a Primus Labs audit results in a pass/fail determination, a score from 0-100%, and a report that lists any violations. Passing scores can differ greatly: a company can pass with comment, pass without comment, or pass with either major or minor compliance issues. A company fails if it has one "egregious" non-compliance or if it scores less than 80% overall. According to information provided by Primus Labs, the vast majority of the thousands of audits it conducts each year receive passing grades: 98.7% in 2010, 97.5% in 2009, and 98.1% in 2008.

Mr. Stovicek informed Committee staff that his company's role is to conduct an impartial assessment of a client's operations and provide its findings to the client. He stated that the audits are intended to assess whether the client's operations are in compliance with current baseline industry standards—not to improve those standards or push a client towards best practices. Mr. Stovicek said that Primus Labs would "be a rogue element if they tried to pick winners and

[13] Validation consists of collecting scientific and technical information to determine if a Hazard Analysis and Critical Control Points (HACCP) plan, when properly implemented, will effectively control food safety hazards

[14] House Committee on Energy and Commerce, Interview of Robert Stovicek, President, Primus Labs (Nov. 7, 2011).

losers" by holding industry to higher standards. He also said that Primus Labs did not have the "expertise to determine which best practices should be pushed by the industry."

Staff Briefing with Bio Food Safety

On January 6, 2012, Committee staff interviewed Jerry Walzel, the President of Bio Food Safety, by telephone.[15] The purpose of the discussion was to verify several statements made about Mr. Walzel's involvement with Jensen Farms and the 2010 audit he conducted at the Jensen Farms' cantaloupe packing facility. Mr. Walzel indicated that he had little memory of the details surrounding the 2010 audit. He said he did not remember whether he did or did not provide advice to Jensen Farms following this audit.

Mr. Walzel also provided additional information on the 2011 audit. He explained why Jensen Farms was given a "superior" rating on this audit despite the fact that FDA officials indicated that the processing methods used at Jensen Farms were not consistent with FDA guidance. Mr. Walzel indicated that – consistent with Primus Labs policy – the audits only deducted from the score if a method or technique was inconsistent with FDA regulations; they did not deduct from the score if FDA guidance was not being followed. Mr. Walzel stated that Primus conducted a "check-off audit…and if it was not required, there were no deductions." He stated that Bio Food Safety auditors were "roped in by regulation and Primus training," and that "guidelines are opinions…. regulations are law."

Additionally, he noted, "we are not supposed to be opinionated on this, we are supposed to go by FDA's regulations…FDA should have mandated that you cannot sell cantaloupes that have not been sanitized." While Dilorio noted on the front page of the audit that no anti-microbial solution was used in the wash water, he did not deduct any points based on this omission.

Conclusions

The recent multi-state *Listeria* outbreak involved cantaloupe produced by a single grower that was processed at its on-site packing facility. FDA has published the findings of its investigation into this matter and has posted a letter on its website reiterating the importance of growers and producers following its existing food safety guidance regarding the prevention of *Listeria* contamination. According to FDA, the outbreak would have likely been prevented if Jensen Farms had maintained its facilities in accordance with existing FDA guidance. In the case of cantaloupe processing, FDA has no specific regulations, only guidance. The guidance which Bio Food Safety did not consider in its audit represents the agency's best and most timely advice on how processing should be handled.

FDA officials emphasized to Committee staff that the new processing equipment and the decision to use a packing and washing technique involving non-chlorinated water were two

[15] House Committee on Energy and Commerce, Interview of Jerry Walzel, President, Bio Food Safety (Jan. 6, 2011).

probable causes of the outbreak. Both of these significant changes were implemented at the packing facility in 2011.

According to Frontera Produce, in response to the outbreak, many major retailers have already instituted end-product testing of cantaloupe to identify *Listeria, Salmonella* and other pathogens. Frontera Produce officials also informed Committee staff that retailers and industry groups are studying the possible implementation of additional checks at different critical control points in the supply chain, including risk-based assessments and sample testing. Primus Labs noted, and FDA confirmed, that buyers will immediately start requiring auditors to take environmental swabs while auditing food facilities.

FDA does not regulate domestic third-party auditors and did not review the recent Jensen Farms audits while conducting its investigation. With respect to imported foods, the Food Safety Modernization Act requires that FDA establish an accreditation system and model auditing standards for third-party audits. According to industry observers, these standards will influence domestic auditing standards as well.

The cantaloupe industry, academics, and government officials, including representatives from FDA, are planning to attend an upcoming conference at the University of California, Davis on January 12, 2012, to examine the findings from the investigation of the *Listeria* outbreak, and to reduce the food safety risks associated with cantaloupe. The Committee will monitor that conference and its proposals for the prevention of further outbreaks.