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Environmental Assessment: Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Listeriosis

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This document provides an overview of factors that potentially contributed to the contamination of fresh, whole cantaloupe with the pathogen *Listeria monocytogenes*, which was implicated in a 2011 multi-state outbreak of listeriosis.

Background**Environmental Assessment Team Approach**

- I. [Factors Potentially Contributing to the Introduction, Growth, and Spread of *Listeria monocytogenes*](#)
 - A. [Growing Environment](#)
 - B. [Packing Facility and Cold Storage](#)
- II. [Summary](#)
- III. [Recommendations for Prevention of Listeria Monocytogenes Contamination Based on these Findings](#)
- IV. [Relevant Links](#)

Background

In early September 2011, the Food and Drug Administration (FDA), in conjunction with the Centers for Disease Control and Prevention (CDC) and state health departments, began to investigate a multi-state outbreak of listeriosis. Early in the investigation, cantaloupes from Jensen Farms in the southeast region of Colorado were implicated in the outbreak.

On September 10, 2011, FDA, along with Colorado state officials, conducted an inspection at Jensen Farms during which FDA collected multiple samples, including whole cantaloupes and environmental (non-product) samples from within the facility, for laboratory culturing to identify the presence of *Listeria monocytogenes*. Of the 39 environmental samples collected from within the facility, 13 were confirmed positive for *Listeria monocytogenes* with pulsed-field gel electrophoresis (PFGE) pattern combinations that were indistinguishable from three of the four outbreak strains collected from affected patients. Cantaloupe collected from the firm's cold storage during the inspection was also confirmed positive for *Listeria monocytogenes* with PFGE pattern combinations that were indistinguishable from two of the four outbreak strains.

As a result of the isolation of three of the four outbreak strains of *Listeria monocytogenes* in the environment of the packing facility and whole cantaloupes collected from cold storage, and the fact that this is the first documented listeriosis outbreak associated with fresh, whole cantaloupe in the United States, FDA initiated an environmental assessment in conjunction with Colorado state and local officials. FDA, state, and local officials conducted the environmental assessment at Jensen Farms on September 22-23, 2011. The environmental assessment was conducted to gather more information to assist FDA in identifying the factors that potentially contributed to the introduction, growth, or spread of the *Listeria monocytogenes* strains that contaminated the cantaloupe. The firm cooperated in the environmental assessment.

Environmental Assessment Team Approach

The environmental assessment was completed by a multi-disciplinary team with expertise in produce safety, agriculture, veterinary medicine, epidemiology, microbiology, environmental health, and sanitation from FDA, the Colorado Department of Public Health and Environment, the Colorado Department of Agriculture, and Prowers County Department of Health.

The team used Good Agricultural Practice (GAP) guidance and principles to develop hypotheses regarding potential routes for contamination of cantaloupes in the field. Areas of focus for the agricultural production operations included:

- agricultural water
- soil amendments
- growing and harvesting practices
- animal intrusion
- adjacent land use
- employee health and hygiene practices

Similarly, the team used GAP guidance and principles to develop hypotheses for potential routes of contamination during operations in the packing facility and cold storage. Areas of focus for the packing

operations included:

- facility and equipment sanitary design
- cleaning and sanitizing practices
- washing and drying of cantaloupes
- cooling of cantaloupes
- storage of cantaloupes
- transportation

The environmental assessment included an in-depth interview with Jensen Farms management regarding their food safety practices and procedures, as well as on-site visits to the farm, packing facility, and cold storage, and environmental and finished product sampling.

The cantaloupes implicated in the outbreak were harvested from the end of July through mid-September 2011 and packed at a single off-farm packing facility. At the time of the environmental assessment, no cantaloupe harvest or packing activities were in progress. However, the environmental assessment team visited cantaloupe growing fields, the packing facility, and cold storage, and observed adjacent areas. FDA officials observed production, postharvest practices, and packing practices during the regulatory inspection.

I. Factors Potentially Contributing to the Introduction, Growth, and Spread of *Listeria monocytogenes*

This is the first listeriosis outbreak associated with a whole fruit or vegetable raw agricultural commodity. *Listeria monocytogenes* contamination has historically been associated with ready-to-eat and processed food products, such as deli meat, unpasteurized cheese, raw milk, fresh-cut fruit, and fresh-cut vegetables, and is typically thought of as an environmental contaminant of food plants. Known reservoirs for *Listeria monocytogenes* include ruminant animals (e.g., cattle, goats, and deer), decaying vegetation, and cold, wet, and difficult to clean environments.

A. Growing Environment

Environmental samples were collected in the growing fields because known reservoirs of *Listeria monocytogenes* include ruminant animals and decaying vegetation. These samples included soil, wild animal excreta, perimeter and furrow drag swabs, agricultural water, pond water, and cantaloupe. All environmental samples collected in the growing fields were negative for *Listeria monocytogenes*.

Because the samples collected in the growing fields were negative for *Listeria monocytogenes* whereas the environmental samples collected in the packing facility and cantaloupe collected in cold storage (discussed further below) were positive for *Listeria monocytogenes*, the growing fields are not a likely means of contamination. However, FDA has determined that the growing environment cannot be eliminated as a potential contributor in the introduction of *Listeria monocytogenes* contamination. Specifically, low-level sporadic *Listeria monocytogenes* contamination from the agricultural environment and incoming cantaloupes may have allowed for establishment of a harborage or niche for *Listeria monocytogenes* in the packing facility and cold storage. As discussed further below, FDA has identified a number of factors that are likely to have contributed to the introduction, growth, or spread of *Listeria monocytogenes* at Jensen Farms.

B. Packing Facility and Cold Storage

The following factors may have contributed to the introduction, growth, or spread of *Listeria monocytogenes* contamination: facility and equipment design and postharvest practices.

1. Facility Design

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.

Samples collected from areas where pooled water had gathered tested positive for an outbreak strain of *Listeria monocytogenes*. Therefore, this aspect of facility design is a factor that may have contributed to the introduction, growth, or spread of *Listeria monocytogenes*. This pathogen is likely to establish niches and harborages in refrigeration units and other areas where water pools or accumulates.

Further, the packing facility floor where water pooled was directly under the packing facility equipment from which FDA collected environmental samples that tested positive for *Listeria monocytogenes* with PFGE pattern combinations that were indistinguishable from outbreak strains. 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.

Another potential means for introduction of *Listeria monocytogenes* contamination into the packing facility was a truck used to haul culled cantaloupe to a cattle operation. This truck traveled to and from a cattle operation and was parked adjacent to the packing facility where contamination may have been tracked via personnel or equipment, or through other means into the packing facility.

2. Equipment Design

FDA evaluated the design of the equipment used in the packing facility to identify factors that may have contributed to the growth or spread of *Listeria monocytogenes*. In July 2011, the firm purchased and installed equipment for its packing facility that had been previously used at a firm producing a different raw agricultural commodity.

The design of the packing facility equipment, including equipment used to wash and dry the cantaloupe, did not lend itself to be easily or routinely cleaned and sanitized. 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.

Environmental samples collected from the packing facility equipment tested positive for *Listeria monocytogenes*

with PFGE pattern combinations that were indistinguishable from three of the four outbreak strains. After the firm discarded portions of the packing facility equipment and cleaned and sanitized the remaining packing equipment, environmental samples tested negative for *Listeria monocytogenes*.

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.

3. Postharvest Practices

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.

II. Summary

FDA has identified the following factors as those that most likely contributed to the contamination of fresh, whole cantaloupe with the pathogen *Listeria monocytogenes*, which was implicated in a 2011 multi-state outbreak of listeriosis.

Growing Environment:

- Low level sporadic *Listeria monocytogenes* in the agricultural environment and incoming cantaloupe may have contributed to the introduction of the pathogen into the packing facility.

Packing Facility and cold Storage:

- A truck used to haul culled cantaloupe to a cattle operation was parked adjacent to the packing facility and could have introduced contamination into the facility;
- Facility design allowed for the pooling of water on the packing facility floor adjacent to equipment and employee walkway access to grading stations;
- The packing facility floor was constructed in a manner that was not easily cleanable;
- The packing equipment was not easily cleaned and sanitized;
- The washing and drying equipment used for cantaloupe packing was previously used for postharvest handling of another raw agricultural commodity; and
- There was no pre-cooling step to remove field heat from the cantaloupes before cold storage.

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.

IV. Relevant Links

- [Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado, CDC](#)
- [CDC's Morbidity and Mortality Weekly Report \(MMWR Report\) on the Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado](#)
- [FDA Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh](#)

Fruits and Vegetables

- [FDA Melon Draft Guidance](#)
- [Information on the Recalled Jensen Farms Whole Cantaloupes](#)
- [Warning Letter Issued to Jensen Farms](#)
- [FDA Information on Environmental Assessments](#)

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