

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 01/16/2016 - 02/05/2016*
	<small>FEI NUMBER</small> 3001596594

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Phillip R. Bradway, Senior Vice President of Engineering, Science, & Technology**

<small>FIRM NAME</small> Dole Fresh Vegetables Inc	<small>STREET ADDRESS</small> 600 Benjamin Drive
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Springfield, OH 45502-8860	<small>TYPE ESTABLISHMENT INSPECTED</small> Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination.


Specifically,

- a. On 01/16/2016 we collected from your facility a sample of finished product Dole Salade Kit-Ultimate Caesar (SKU 953) with bag code "A01601A 09:00," which was manufactured by your facility. We also collected sixteen sub-samples containing in-process romaine lettuce used in this product from various stages of production, raw material through finished product packaging. The finished product sample, as well as the in-process sub-samples collected from the water knife, the trans-slicer, and the metal tray beneath the cross-conveyor, all on Trim Line were found by FDA laboratory analysis to be positive for *Listeria monocytogenes*.

Additionally, on 01/26/2016 the Vice President of Quality Assurance (QA) and Food Safety stated your firm was aware the Canadian Food Inspection Agency (CFIA) identified *Listeria monocytogenes* in four finished product samples collected by that agency on or about 01/18-19/2016 from distribution points in Canada:

- Dole Colourful Coleslaw (SKU 2662) with bag code "A01008A 22:20"
- Dole Caesar Salade Kit (SKU 678) with bag code "A01101B0 09:38"
- Dole Caesar Salade Kit (SKU 678) with bag code "A00901B 10:31"
- Dole Chopped Romaine (SKU 675) with bag code "A014007 06:51"

Furthermore, information provided by the FDA and CFIA laboratories indicate a common

<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Holly J. Rapier, Investigator Heather A. Mccauley, Investigator Thomas J. Prigge, Investigator Roy C. Stephens, Investigator Andrew M. Kupper, Investigator	<small>DATE ISSUED</small> 02/05/2016
		

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PFGE-Ascl-pattern of GX6A16.0135 and a common PFGE-Apal-pattern of GX6A12.0349 for the *Listeria monocytogenes* isolated from each of the above-described finished product samples. Information provided by the Centers for Disease Control (CDC) indicates these PFGE patterns match PFGE-Ascl and PFGE-Apal-patterns from *Listeria monocytogenes* isolates recovered from multiple patients involved in an outbreak of *Listeria monocytogenes*, which currently has isolation dates ranging from 07/05/2015 through 01/03/2016.

- b. On 01/19/2016 the Quality Assurance (QA) Manager reported your firm does not collect environmental swabs for *Listeria spp.* analysis from zone 1 (food contact) surfaces. Additionally, on 01/26/2016 the QA Manager and the Vice President of QA and Food Safety reported environmental swabs for *Listeria spp.* analysis are collected during pre-production hours, following cleaning and prior to sanitization.
- c. On 01/19/2016 the QA Manager provided a copy of your firm's "TESTING PROCEDURE # DFV 114 COLLECTION OF LISTERIA ENVIRONMENTAL SWABS," which indicates two corrective action steps:
  - "Locations, which test positive for the presence of *Listeria*, will be thoroughly cleaned and retested until results are negative. Once a negative test has been confirmed, 3 weekly consecutive tests will be performed thereafter."
  - "Complete the Environmental Program Corrective Action Report."

The QA Manager stated on 01/26/2016 the "Environmental Program Corrective Action Report" is a new requirement in the "TESTING PROCEDURE # DFV 114 COLLECTION OF LISTERIA ENVIRONMENTAL SWABS," which was revised on 01/07/2016 to include this requirement. The QA Manager stated this form was used for the first time on 01/08/2016, when your firm was notified by your third-party laboratory of a positive *Listeria spp.* ("suspect") result from the "Cull belt roller on line [redacted] in the trim room," which was collected by your firm on 01/07/2016 as a follow-up to an initial *Listeria spp.* positive ("suspect") swab collected by your firm on 01/05/2016. She stated previous to that date no follow-up investigations were performed after being notified of positive ("suspect") results other than your firm's standard practices of focused cleaning/sanitization and follow-up testing in the areas where the positive ("suspect") swabs were obtained. Your environmental monitoring records from 03/04/2014 through

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Holly J. Rapier, Investigator Heather A. Mccauley, Investigator Thomas J. Prigge, Investigator Roy C. Stephens, Investigator Andrew M. Kupper, Investigator	DATE ISSUED 02/05/2016
	<i>HJR</i> <i>AMK</i>	

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01/14/2016, which were provided collectively on 01/19/2016, 02/02/2016, and 02/05/2016, indicate your firm obtained *Listeria spp.* positive results from a total of nine additional swabs between 03/04/2014 and 01/14/2016, specifically on dates 07/21/2014, 09/03/2014, 09/10/2014, 09/21/2014, 09/22/2014 (x2), 09/29/2015, 11/02/2015, and 12/21/2015.

\* DATES OF INSPECTION:  
 01/16/2016(Sat), 01/19/2016(Tue), 01/26/2016(Tue), 02/02/2016(Tue), 02/05/2016(Fri)

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: John F. Lochra, Plant Manager**

FIRM NAME Dole Fresh Vegetables Inc	STREET ADDRESS 600 Benjamin Drive
CITY, STATE, ZIP CODE, COUNTRY Springfield, OH 45502-8860	TYPE ESTABLISHMENT INSPECTED Fresh-Cut Produce Manufacturer

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**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

Specifically, on 03/17/2014 at the opening meeting, the plant manager reported that your firm had concluded sanitation and we observed the following upon inspection of the processing area:

- a. There was a cutting board bearing deep grooves and stains on the right side of the raw product in-feed belt of line 1-B in the Trim Room.
- b. There was food residue on the vibrating de-watering shaker screens for carrots and color in the color blend area in the Trim Room.

**OBSERVATION 2**

The plant is not constructed in such a manner as to allow floors and walls to be kept in good repair.

Specifically, we observed the following:

03/17/2014

- a. There is an approximately 1/2 inch by six-inch crack in the floor in the Trim Room between the red cabbage and carrot lines.
- b. The floor is eroded around a vestigial pipe that is cut off at the surface of the floor in the Trim Room between lines four and five.
- c. There is an eroded area around a circular metal plate in the floor in the Trim Room between lines four and five.
- d. The floor is eroded around the long rectangular drain between the end of the carrot line and the color blend area in the trim room.

03/18/2014

- e. There is no caulk between the wall and the stainless steel curb on the wall between the Dryer Room and the area where (b) (4) line three is planned for installation.

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Holly J. Wilson, Investigator <i>Holly J. Wilson</i> Maney P. Sturgill, Investigator John P. Roetting II, Analyst <i>John P. Roetting II</i>	03/21/2014

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- f. There is a rough-edge uneven section of floor downstairs between (b) (4) lines one and two in the Dryer Room.
- g. There are thirteen holes, each approximately 1/4 inch in diameter, in the floor downstairs between (b) (4) lines one and two in the Dryer Room.
- h. There are several ruts in the yellow floor, some containing standing water, and an approximately 1/2 inch gap between sections of the floor, in front of the observation window in the Dryer Room.
- i. There are several raised rough-patches in the floor in the Dryer Room in front of dryer deck numbers one, two, and three.
- j. There is peeling paint and rust, and the caulk between the wall and stainless steel curb is in poor repair, behind dryer deck number four in the Dryer Room on the wall between the Dryer Room and the Trim Room.
- k. The electrical line conduit is broken on the back of dryer deck number four and food residue came out of the inside of the conduit when it was swabbed.

03/20/2014

- l. There are ruts in the floor, containing standing water, between lines 1-A and 1-B in the Trim Room. At the time this observation was made you were manufacturing Leafy Romaine on lines 1-A and 1-B.

**OBSERVATION 3**

Failure to provide adequate screening or other protection against pests.

Specifically, on 03/20/2014 we observed the following:

- a. An approximately 1/2 inch by one-foot gap along the right side of the dock plate for dock door number eight on the receiving dock.
- b. An approximately 1/2 inch by two-foot gap beneath the right side of dock door number 19 in the shipping warehouse.

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