

FDA/MSDC Recalls 4.3.3.2

FDA/ORA General Recall General Recall Specific

Home

Event ID: 62910 Status: Ongoing Updated: 08/21/2012 Role: District Recall Coordinator

Recall Details

- Event Information
- Summary and Termination Information
- Center Information
- Product Information
- Firm and Contact Information
- Recall Summary

Event Information

Recall Event ID 62910 (b) (4)
District San Francisco District Office
Coordinator Marjorie D. Schultz
Firm Awareness Date 08/18/2012
District Awareness Date 08/18/2012
Center (Int) Center for Food Safety and Applied Nutrition
Coordinator
Recalling Firm FEI 1000507265
Name (Int) Tanimura & Antle
Manufacturer FEI 1000507265
Name (Int) Tanimura & Antle
Responsible Firm FEI 1000507265
Name Tanimura & Antle
Public Reason for Recall FDA was notified by CFIA of a positive result for E-coli O157:H7 in Romaine Lettuce with the brand name of Tanimura & Antle, Salinas, CA.
Edit Mode Viewable
Recall Status (Int) Ongoing
Voluntary/Mandated (Int) FDA Initiated
Date (Int) 08/19/2012
Firm Recommended Recall Depth Consumers/User
Date Distribution Chain Notified 08/19/2012
Recall Initiation Date (Int) 08/19/2012
Firm Initial Notification Press Release
Classification Date
Center Coordinator Assigned Date
FDA Sample Number
Complete Reason for Recall CFIA notified FDA of August 18, 2012 of a press release they issued on August 17, 2012 due to a positive result of e-coli O157:H7 in Romaine lettuce sample collected by CFIA on August 8, 2012. Upon notification by the FDA on August 18, 2012, the firm immediately agreed to recall; however, they were surprised that CFIA had issued press as they had not been notified of the confirmed positive sample. Firm officials stated that they had originally been notified on August 14th by CFIA of a preliminary positive, but when the firm contacted CFIA later in the week was told that it had been confirmed negative. The lettuce was harvested on August 2, 2012, field packed and held in a firm owned cooler in Salinas CA until shipment later that day. The product has a 17 days shelf life. The firm is recalling the entire days run of the product. E-Coli can cause diarrheal illness. Some people can develop kidney failure. This is most likely to occur in young children and the elderly.
Root Cause Other
Root Cause Narrative Unknown at this time
Center Comments
Type Of Injury No reports of injury of illness.
Quantity Manufactured 2095 cases (12 or 18 heads per case) 126 cases to Canada, 1969 cases in US.
Quantity Distributed (Int) 2095 cases
Number of Domestic Consignees 28
Number of Foreign Consignees 3
Distributed From 08/02/2012 To 08/02/2012
Distribution Pattern (Int) AL, AR, AZ, CA, GA, KS, KY, MD, NC, NM, NV, NJ, PA, SC, TN, TX, VA and WA and Canada.
Manufactured From 08/02/2012 To 08/02/2012
Public Summary of Recall Press release issued on August 19, 2012. All direct accounts notified by phone on August 18 or 19, 2012.
Strategy (Int)
Recall Strategy Press issued on August 19, 2012. Consumers were alerted to the recall, the product affected, dates available for sale and may have a Best By sticker of 8/19/12. Customers are urged to destroy product and call Tanimura and Antle at 877-827-7388 with questions. Distributors were notified by phone and asked to alert all locations where product was shipped for removal for sale.
Audit/Effectiveness Check
Modification
Effectiveness Check Level A Percent 100
Audit Check Level E Percent 0
What Consumers Should Do (Int)
Expanded Comments for
What Consumers Should Do (Int)
Firm Press Issued (Int) 08/19/2012 **URL (Int)**
State Press Issued (Int) **URL (Int)**
FDA Press Issued (Int) **URL (Int)**
Additional Medical Product **URL (Int)**
Information (Int)

Consignee Details

List of Domestic and/or Foreign Government accounts,MPG (Military) Norfolk, 1106 Ingleside Rd., Norfolk, VA 23502. Canadian Distribution: Consignees, Distribution addresses or comments (b) (4)

Consignees	Approx. Number	Consignees	Approx. Number

Distributor	27	Repacker/Relabeler	0
Retailer	0	Direct Accounts	0
Institution	0	Veterans Administration	0
Medical Facility	0	Department of Defense	1
Internet Sales	0	Manufacturer	0
Physician	0	USDA	0
Consumer/Patient	0	Other	0

[Top of Page](#)

Summary/Termination Information

- Quantity Recovered/Number of Units Corrected
- Product Disposition
- Number of Consignees Responding to Notification
- Effectiveness Check Information
- Audit Check Information
- Section of Law Violated
- Preventive Action Taken by Firm
- District Follow-Up
- District Review
- Legal Action
- Class I Termination Recommendation
- Recommended/Prepared By
- District Management Approval **Date**
- Center Concurrence
- Recall Completed Date
- Termination Letter Date

[Top of Page](#)

CFSAN Center Information

- Docs Rcvd at Ctr Date
- HHE Sent
- HHE Signed
- HHE Precedent
- Outbreak Associated
- Outbreak Event Number

[Top of Page](#)

Product Information

Product : 1

- Industry-Product Code 24-TGC32
- Precedent Recall
- Precedent Policy
- Precedent Policy Comment
- Product Description (Int) Tanimura & Antle Romaine Lettuce (Laitue Romaine) in plastic bag Wrapped Single Head Romaine marked (Label/Packaging) Field Packed for Freshness.. Distributed by Tanimura & Antle, Salinas, CA.
- Trade Name (Int)
- Generic Name (Int)
- Product Usage Human consumption
- Product Quantity Distributed (Int) 2095 cases: 1969 cases in US, 126 cases in Canada - 12 to 18 heads per case.
- Recall Number (Int)
- Product Public Reason for Recall FDA was notified by CFIA of a positive result for E-coli O157:H7 in Romaine Lettuce with the brand name of (Int) Tanimura & Antle, Salinas, CA.
- Field Recommended Classification Class I
- Center Classification (Int)
- Center Recommended Depth
- Product Effectiveness Check A Percent 100 Level
- Product Audit Check Level M Percent 0
- Code Information (Int) May have a best buy date of 8/19/12 and available at retail locations from August 2 to 19, 2012.
- Expected Life 17 days
- Shelf Life
- CFSAN Reason Micro

[Top of Page](#)

Recalling Firm Information

- FEI 1000507265
- Firm Name (Int) Tanimura & Antle
- Address (Int) 1 Harris Rd

City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-2950 **Ext** **Country Code**
Comment

Most Responsible Individual

Official's Name Michael Antle
Title Owner
Firm Name (Int) Tanimura & Antle
Address (Int) 1 Harris Rd
City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-2950 **Ext** **Country Code**
Facsimile - Ext **Country Code**
E-mail Address
Comment

Manufacturer Information

FEI 1000507265
Firm Name (Int) Tanimura & Antle
Address (Int) 1 Harris Rd
City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-2950 **Ext** **Country Code**
Comment

Responsible Firm Information

FEI 1000507265
Firm Type Manufacturer
Firm Name (Int) Tanimura & Antle
Address (Int) 1 Harris Rd
City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-2950 **Ext** **Country Code**
Comment

Recall Contact

Official's Name Gurmail Mudahar
Title R&D, Food Safety
Firm Name (Int) Tanimura & Antle
Address (Int) 1 Harris Rd
City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-3696 **Ext** **Country Code**
Facsimile - Ext **Country Code**
E-mail Address Gurmail@taproduce.com
Comment

Public Contact

Official's Name Gurmail Mudahar
Title R&D, Food Safety
Firm Name (Int) Tanimura & Antle
Address (Int) 1 Harris Rd
City (Int) Salinas
State/Province (Int) California
Country (Int) United States
Postal Code (Int) 93908-8608
Telephone 831-455-3696 **Ext** **Country Code**
Facsimile - Ext **Country Code**
E-mail Address Gurmail@taproduce.com

Comment

WARNING! Sensitive/critical information. This information is proprietary and confidential. It should not be disclosed to unauthorized parties and should be maintained in a secure environment.
Printed by: Marjorie D. Schultz

Recalls 4.3.3.2 | Copyright 2008 | U.S. Food and Drug Administration

Robles, Karen L

From: Krolczyk, Sherrie L
Sent: Saturday, August 18, 2012 11:20 AM
To: Yuen, Nicole
Cc: Wolyniak, Cecilia M; Oliver, Sheri; Dey, Manashi; Schultz, Marjorie; Harris-Garner, Kerri L.; CFSAN Recall
Subject: Fw: HEALTH HAZARD ALERT - HEALTH HAZARD ALERT - Certain TANIMURA & ANTLE brand ROMAINE LETTUCE may contain E. coli O157:H7 bacteria
Attachments: CAL-FD-2012-MI-0424 final report-unsatisfactory.pdf

See the analytical results from CFIA attached.

Sherrie L. Krolczyk
ORA/OE/DCMO Recalls
Phone: 214-253-5312
(b)(6) (b)(7)(c) (b)(5)

From: Garfield Balsom [mailto:Garfield.Balsom@inspection.gc.ca]
Sent: Saturday, August 18, 2012 01:30 PM
To: Krolczyk, Sherrie L
Subject: Re: HEALTH HAZARD ALERT - HEALTH HAZARD ALERT - Certain TANIMURA & ANTLE brand ROMAINE LETTUCE may contain E. coli O157:H7 bacteria

As requested

Garfield

Sent from/Envoyé du BlackBerry.

>>> "Krolczyk, Sherrie L" <Sherrie.Krolczyk@fda.hhs.gov> 18/08/2012 12:01:20 PM >>>
Hi Garfield. We are following up on this. Could you please provide us the analytical records for the positive sample(s). Thanks!!

Sherrie L. Krolczyk
ORA/OE/DCMO Recalls
Phone: 214-253-5312
(b)(6) (b)(7)(c) (b)(5)

From: Garfield Balsom [mailto:Garfield.Balsom@inspection.gc.ca]
Sent: Friday, August 17, 2012 10:48 PM
To: Wolyniak, Cecilia M
Cc: Mathew, Lisa; Welsh, Sheri; Ken Marcynuk; ORA HQ Recall OE
Subject: HEALTH HAZARD ALERT – HEALTH HAZARD ALERT – Certain TANIMURA & ANTLE brand

12/27/2012

Robles, Karen L

From: Krolczyk, Sherrie L
Sent: Saturday, August 18, 2012 10:19 AM
To: Yuen, Nicole; ORA SAN Recalls
Cc: Wolyniak, Cecilia M; Oliver, Sheri; Dey, Manashi; CFSAN Recall; Harris-Garner, Kerri L.
Subject: RE: HEALTH HAZARD ALERT - HEALTH HAZARD ALERT - Certain TANIMURA & ANTLE brand ROMAINE LETTUCE may contain E. coli O157:H7 bacteria

I've requested the analytical results from CFIA. I will forward them as soon as they are received.

Thanks,

Sherrie L. Krolczyk
ORA/OE/DCMO Recalls
Phone: 214-253-5312
(b)(6) (b)(7)(c) (b)(5)

From: Yuen, Nicole
Sent: Saturday, August 18, 2012 12:13 PM
To: Krolczyk, Sherrie L; ORA LOS Recalls; ORA SAN Recalls
Cc: Wolyniak, Cecilia M; Oliver, Sheri; Dey, Manashi; CFSAN Recall; Harris, Kerri L.
Subject: Re: HEALTH HAZARD ALERT - HEALTH HAZARD ALERT - Certain TANIMURA & ANTLE brand ROMAINE LETTUCE may contain E. coli O157:H7 bacteria

Hello: We have not received the analytical lab results. We would like to receive the lab reports prior to contacting the firm today. Also, please advised if we need ORS concurrence before notifying the firm.
Regards,

Nicole Yuen, SAN-DO ERC
E-mail sent from BB

From: Krolczyk, Sherrie L
Sent: Saturday, August 18, 2012 11:58 AM
To: ORA LOS Recalls; ORA SAN Recalls
Cc: Wolyniak, Cecilia M; Oliver, Sheri; Dey, Manashi; CFSAN Recall; Harris, Kerri L.
Subject: FW: HEALTH HAZARD ALERT - HEALTH HAZARD ALERT - Certain TANIMURA & ANTLE brand ROMAINE LETTUCE may contain E. coli O157:H7 bacteria

Not sure if Salinas, CA is in LOS-DO or SAN-DO. So, I'm sending to you both. We received information late last night from Canadian officials that lettuce from Tanimura & Antle, Salinas, CA, was found to be contaminated with E. coli O157:H7. You may already be aware of the issue. Please follow-up as necessary. OE will request the analytical records from CFIA.

12/27/2012

Robles, Karen L

From: Schultz, Marjorie
Sent: Monday, August 20, 2012 11:17 AM
To: Yuen, Nicole
Subject: T & a Minutes

Attachments: Minutes T & A Aug 2012 pg1.doc; Minutes T & A Aug 12 pg2.doc



Minutes T & A Aug 2012 pg1.do...
Minutes T & A Aug 12 pg2.doc (...)

Need some help with clarification of second set of number in the lot #.

Thanks. Feel free to edit as you wish.

Marjorie D. Schultz
District Recall Coordinator
US Food and Drug Administration
San Francisco District Office
Tel: 510-337-6898
Fax: 510-337-6705
(b)(6) (b)(7)(c) (b)(5)
E-mail: marjorie.schultz@fda.hhs.gov

Robles, Karen L

From: Yuen, Nicole
Sent: Wednesday, August 22, 2012 1:23 PM
To: Gustavson, Steven; Kuntz, Thomas
Cc: Gonzalez, Fernando; Nolan, Nichole; Nieves, Kenneth
Subject: RE: To confirm Romaine Lettuce contaminated by Escherichia coli O157:H7 did not and will not be export to Taiwan (b) (4)

Hello all: The positive lot was not distributed to Taiwan. It was distributed domestically and to Canada.

Thank you,
Nicole Yuen
Emergency Response Coordinator
U.S. Food & Drug Administration
San Francisco District Office (SAN-DO)
Stockton Resident Post (STK-RP)
Office (209) 954-0171 x102

(b)(6) (b)(7)(c) (b)(5)
Fax (209) 954-0175

"The information contained in this e-mail document is confidential and intended only to be viewed by the recipient listed above. If you are not the intended recipient (or the employee or agent responsible to deliver this to the intended recipient), you are hereby notified that any distribution or copying of this document is strictly prohibited. If you have received this document in error, please contact the sender listed above and destroy the document."

From: Gustavson, Steven
Sent: Wednesday, August 22, 2012 11:48 AM
To: Kuntz, Thomas
Cc: Gonzalez, Fernando; Nolan, Nichole; Nieves, Kenneth; Yuen, Nicole
Subject: RE: To confirm Romaine Lettuce contaminated by Escherichia coli O157:H7 did not and will not be export to Taiwan (b) (4)

I don't have any shipment data. the district will want to know you concur with the lab findings

From: Kuntz, Thomas
Sent: Wednesday, August 22, 2012 2:45 PM
To: Gustavson, Steven
Cc: Gonzalez, Fernando; Nolan, Nichole; Nieves, Kenneth
Subject: FW: To confirm Romaine Lettuce contaminated by Escherichia coli O157:H7 did not and will not be export to Taiwan (b) (4)

Steve,

Do you or SAN-DO know of any shipments to Taiwan? Please see below.

FYI, we had a conf call with CFIA confirming their results for 0157 in the lettuce and CFSAN's questions about methodology this afternoon.

Thanks

Tom Kuntz
Lead RFR Coordinator
FDA/CFSAN/OC/DE/RPRT
Phone: 240-402-1725

From: Nieves, Kenneth
Sent: Tuesday, August 21, 2012 4:32 PM
To: Gonzalez, Fernando; Kuntz, Thomas
Cc: Nolan, Nichole
Subject: RE: To confirm Romaine Lettuce contaminated by Escherichia coli O157:H7 did not and will not be export to Taiwan
Importance: High

Fernando,

This seems to be related to the following (b) (4). I'm not sure if the RFR team has information on foreign distribution to Taiwan. We learned about it from a positive sample obtained by CFIA in Canada.

Tom,

Taiwan-FDA would like to know if we have information on foreign distribution of Romaine lettuce from Tanimura & Antle. As per their note below, this particular brand is normally distributed to Taiwan. I'm not sure if SAN-DO has been able to obtain information on the farm's distribution at this point.

(b) (4)	Open	Romaine lettuce	Sender - Tanimura & Antle salinas, CA Adulteration Site - Tanimura and Antle Inc. Salinas, CA	SAN-DO	E. coli O157:H7 in romaine lettuce, this meets the definition of a reportable for (b) (4) Positive found by CFIA through routine testing. Expiration date of 8/19 (b) (5) for concurrence but missing a few pages. OE inquiring about PFGE from CFIA. Conf call scheduled with CFIA to discuss findings.
---------	------	-----------------	---	--------	---

--Ken

12/27/2012

Robles, Karen L

From: Yuen, Nicole
Sent: Thursday, August 23, 2012 7:44 AM
To: Kuntz, Thomas; Gustavson, Steven
Cc: Nolan, Nichole
Subject: Re:(b) (4) E. coli 0157:H7 in romaine lettuce

Thanks. The produce industry here in CA had requested for CFSAN concurrence on the positive findings.
Regards,

Nicole Yuen, SAN-DO ERC
E-mail sent from BB

From: Kuntz, Thomas
Sent: Thursday, August 23, 2012 08:02 AM
To: Gustavson, Steven; Yuen, Nicole
Cc: Nolan, Nichole
Subject: FW: (b) (4) E. coli 0157:H7 in romaine lettuce

Not sure it's needed but just to make it official. SME's concurrence with CFIA's findings below.

From: Feng, Peter
Sent: Thursday, August 23, 2012 6:27 AM
To: Kuntz, Thomas; Crowley, Cecilia (Maria)
Cc: Nolan, Nichole
Subject: RE: (b) (4) E. coli 0157:H7 in romaine lettuce

Hi Tom:

I concur that the isolate is an O157:H7 strain. Still puzzled that the sample had very low generic E. coli count and seemed to have had low background flora. But pathogens have been isolated from such samples before.

Peter

Peter Feng, Ph.D.

Research Microbiologist

U.S. FDA, HFS-711

5100 Paint Branch Parkway

College Park, MD 20740

12/27/2012