

ERU ACTIVITY SUMMARY REPORT

INVESTIGATION NAME: GillsOnions_Onions_ListeriaMono		ASSIGNMENT DATE: May 2012 – September 2012	
ERU LEAD: Nicole Zugsmith, Amber Barnes, Karl Birusingh, Ken Namba			
FIRM NAME: Gills Onions LLC			
ADDRESS: 1051 Pacific Avenue		CITY: Oxnard	ZIP CODE: 93030
FIRM CONTACT: Steven Gill		POSITION: Partner	PHONE: 805-240-1983 x 433
E-MAIL ADDRESS: stevegill@gillsonions.com		FAX: 805-240-1953	CELL PHONE: [REDACTED]
REPORTING PERSON:		AGENCY:	PHONE:
<p>ACTIVITY: <input type="checkbox"/> PRODUCE INVESTIGATION <input type="checkbox"/> PFR ENVIRONMENTAL <input type="checkbox"/> RETAIL ENVIRONMENTAL <input type="checkbox"/> TRACEBACK INVESTIGATION</p> <p><input type="checkbox"/> TAMPERING <input type="checkbox"/> COMPLAINT <input checked="" type="checkbox"/> SAMPLING <input type="checkbox"/> TECHNICAL ASSISTANCE <input checked="" type="checkbox"/> OTHER: Multiple environmental and product samples tested positive for <i>Listeria monocytogenes</i>.</p>			
<p>BACKGROUND:</p> <p>On 5/18/2012, the United States Food and Drug Administration (FDA) notified the California Department of Public Health (CDPH), Food and Drug Branch (FDB) about a retail sample of onions that tested positive for <i>Listeria monocytogenes</i>. The pulsed field gel electrophoresis (PFGE) pattern was reported by CFIA as Ascl-GX6A16.0018 / Apal-GX6A12.0022. The sample was collected on 5/9/2012 by the Canadian Food Inspection Agency (CFIA) at Laura's Independent Grocer in Kanata, Ontario, Canada. The sample was identified as fresh, diced, red onions with the following labeling:</p> <ul style="list-style-type: none"> • UPC: 64355000045 • Lot #: 51RDA1A2119 • Best Before: 5/17/2012 • Producer: Gills Onions (1051 S. Pacific Avenue, Oxnard, CA 93030) <p>After notification, Gills Onions initiated a recall of the affected products in the United States and Canada (Attachment A).</p>			
<p>SUMMARY OF ACTIVITY:</p> <p>On 5/30/2012, FDB and FDA conducted an environmental investigation at Gills Onions in Oxnard, CA. A record review (1/2/2012 – 5/25/2012) indicated that prior to the investigation, the firm had received 11 positive environmental test results for <i>Listeria spp.</i> The affected areas were subsequently washed, rinsed, and sanitized and re-evaluated through environmental sampling. All areas tested negative for <i>Listeria spp.</i> when re-analyzed. FDB and FDA collected a total of 167 environmental samples (swabs) at Gills Onions. Areas sampled included locations within production areas designated as Building 2 and Building 5 from which positive samples were previously obtained. These samples were transported and evaluated by the FDA – Pacific Regional Laboratory, Southwest (PRLSW). 13 of the 167 samples tested positive for <i>Listeria monocytogenes</i> (Attachment B). 11 of the 13 positive samples that tested positive for <i>Listeria monocytogenes</i> were collected in Building 5, while the remaining 2 positive samples were collected in Building 2. All 13 samples matched the PFGE pattern from CFIA (Ascl-GX6A16.0018 / Apal-GX6A12.0022). See attachment C.</p> <p>On 7/5/2012, FDA collected surveillance onion samples from various distributors that had been processed and packaged by Gills Onions. A single sample tested positive for <i>Listeria monocytogenes</i>. However, the sample did not match the PFGE pattern reported by CFIA.</p> <p>On 7/10/2012, FDB and FDA conducted a second environmental investigation at Gills Onions in Oxnard, CA. A total of 152 environmental samples were collected in Building 2 and Building 5. Samples consisted of in-process yellow diced onions, water, and environmental swabs. 18 of the 152 samples tested positive for <i>Listeria monocytogenes</i> (Attachment D). 17 of the 18 positive samples that tested positive for <i>Listeria monocytogenes</i> were collected in Building 5, while the remaining single sample was collected in Building 2. Three of the positive <i>Listeria monocytogenes</i> samples collected in Building 5, were collected from food contact surfaces including; a chute under an inspection table, a metal</p>			

shroud on a peeling machine, and a hopper on a peeling machine. All 18 samples matched the PFGE pattern reported by CFIA and from the joint investigation conducted by FDB and FDA in May 2012 (Attachment E).

On 7/18/2012, Gills Onion initiated a voluntary recall resulting from the positive *Listeria monocytogenes* finding on product collected by FDA on 7/5/2012 (Attachment F).

On 7/25/2012, Gills Onions expanded the voluntary recall issued on 7/18/2012 after receiving notification of the 18 positive *Listeria monocytogenes* samples collected on 7/10/2012 (Attachment G).

During August 2012, FDB and FDA collected surveillance samples of onions processed and packaged by Gills Onions in commercial distribution. FDB sample collection information is provided in Table 1, below:

Table 1:
Gills Onion Surveillance Samples
August 2012

Collection Date	Product	Sample Size	Collection Location
8/8/2012	Gills Onions 3/16 inch slivered yellow onion	10 (5) pound bags	Sysco 5900 Stewart Avenue Fremont, CA
8/8/2012	Cross Valley Farms 1/8 inch slivered fresh-cut onions	10 (5) pound bags	US Foodservice 300 Lawrence Drive Livermore, CA
8/8/2012	Nourish & Delight ¼ inch diced yellow onion	10 (5) pound bags	Fresh Point 5900 N Golden State Blvd. Turlock, CA
8/20/2012	Gills Onions fresh cut onions ½ inch diced yellow	10 (5) pound bags	Fresh Point Produce 30340 Whipple Road Union City, CA
8/22/2012	Gills Onions fresh jumbo yellow onions	10 (2) pound bags	GH Foods 8425 Carbide Court Sacramento, CA

Each of these samples was collected by FDB and analyzed by FDA - PRLSW. All samples were reported negative for *Listeria monocytogenes*.

However, on 9/7/2012, Gills Onion initiated a voluntary recall resulting from positive *Listeria monocytogenes* findings in an institutional package of diced, yellow, onions collected by FDA at a commercial distribution facility. This sample was analyzed by FDA - PRLSW. FDA indicated that this sample matched the PFGE pattern reported by CFIA on 5/18/2012 and the environmental samples collected jointly by FDB and FDA on 5/30/2012 and 7/10/2012. A recall press release was not issued because the implicated products were distributed to institutional facilities and not directly to the public.

FINDINGS AND CONCLUSIONS:

Gills Onions reported that they stopped food processing operations in Building 5 on 7/17/2012, due to the positive *Listeria monocytogenes* findings in multiple areas by FDB and FDA. Firm management stated that the firm had undertaken significant remodeling in Building 5, including improvements to floors, walls, drains, and equipment. Gills Onions continued food processing in Building 2. However, the Gills Onion recall issued on 9/7/2012 resulted from the isolation of *Listeria monocytogenes* in diced, yellow onions manufactured in Building 2. This sample was eventually PFGE matched to those collected in Building 5. Firm management reported that on or about 9/6/2012 half of Building 2 was closed for similar renovation work as reported for Building 5.

FDB issued a Regulatory Letter to Steven Gill with Gills Onions on 9/21/2012 (Attachment H). This letter summarized the findings of the FDB and FDA investigations. The letter also provided a notice of regulatory Office Hearing scheduled for 9/25/2012 in Glendale, CA. FDB and representatives of Gills Onions met on 9/25/2012 to discuss the firm's response to FDB and FDA findings. Firm management was advised of the seriousness of manufacturing foods in a facility with a resident population of *Listeria monocytogenes*. Gills Onions' representatives were confident that the remodeling that had been completed in Building 5 and was in process in Building 2 would alleviate any further problems with pathogens.

On 9/28/2012, the owner of Gills Onions, Steven Gill, submitted a corrective action letter to FDB (attachment I). The

letter stated that Building 5 resumed food processing operations on 9/18/2012. Food processing operations in Building 2 were stopped on 9/28/2012 until remodeling was completed. The corrective actions letter indicated that significant remodeling was completed in Building 5 and subsequently in Building 2. The letter stated, "Gills believes that corrective actions implemented in Building 5 and validation processes of the facility have been sufficient to warrant renewed manufacturing and distribution from this facility. Gills also believes the company has taken proper corrective actions to eradicate any resident colony of *Listeria monocytogenes* from Building 5."

Although human illness could not be directly linked to the consumption of Gills Onions products, evidence collected by FDB and FDA indicated *Listeria monocytogenes* was present in multiple buildings and food processing areas. On three occasions *Listeria monocytogenes* was isolated from processed onions in commercial distribution. Two of these three onion samples were PFGE matched to environmental samples collected in food processing areas. The volume of positive environmental samples collected on multiple dates, the food products in commercial distribution that tested positive for *Listeria monocytogenes*, and the matching PFGE patterns all indicate that Gills Onions repeatedly shipped adulterated foods.

SUPPORTING DOCUMENTATION:

- Attachment A – Gills Onion recall dated 5/19/2012
- Attachment B – Notification of laboratory results from FDA, e-mail correspondence 6/14/12
- Attachment C – ERU Activity Summary Report dated 5/29/2012
- Attachment D – FDB testing results – environmental sampling dated 7/10/2012
- Attachment E – ERU Activity Summary Report dated 7/2/2012
- Attachment F - Gills Onion recall dated 7/18/2012
- Attachment G – Gills Onion expanded recall dated 7/25/2012
- Attachment H – FDB Regulatory letter dated 9/21/2012
- Attachment I – Corrective Action Letter and supporting documentation from Gills Onion dated 9/28/2012

ERU ELECTRONIC FILE LOCATION: J:\ERU\Investigations\Investigations 2012\GillsOnions_Onions_ListeriaMono

ENFORCEMENT ACTIONS: NOV ISSUED EMBARGO VC & D REG. LETTER REFERRAL
 OTHER: Office Hearing

RECOMMENDATIONS: NAI MINOR VIOLATIONS / FIRM CORRECTING OTHER:

COMMENTS / FOLLOW-UP ACTION: Recommend continued monitoring of Gills Onion food processing facility along with routine monitoring of California case patients diagnosed with listeriosis.

ERU LEAD SIGNATURE: Emergency Response Unit	IN	REPORT DATE: 2/1/2013
SUPERVISOR SIGNATURE: Michael D. Neadham #094		DATE REVIEWED: 2/20/2013
SUPERVISOR DISPOSITION:		

- continue rank 1 renewal inspections
- monitor for any listeriosis illnesses or outbreaks in CA & nationwide

C #094