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# INVESTIGATION OF A *CLOSTRIDIUM BOTULINUM* OUTBREAK IN 2014 ASSOCIATED WITH VR GREEN FARMS PINE NUT BASIL PESTO

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## **Final Report**

September 2014

Prepared by:

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Emergency Response Unit - Food Safety Inspection Unit

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## COMPLAINT INVESTIGATION REPORT

FIRM/CONSUMER: VR Green Farm (VRGF)		FDB COMPLAINT NUMBER: via ERU	INVESTIGATION DATE: 07/29,30,31 and 08/05 -07 /2014
ADDRESS: 200 Avenida La Pata			FIRM NUMBER: UNR
CITY: San Clemente	ZIP: 92673	PHONE: 949-697-0032	FAX: -
PERSON INTERVIEWED:	Nic Romano	POSITION Owner/Farmer	
INVESTIGATOR:	Melissa DeHart	BADGE #: 062	
<b>INVESTIGATION FINDINGS</b>			
<input checked="" type="checkbox"/> Allegation(s) were substantiated		<input type="checkbox"/> Allegation(s) were not substantiated	
<input checked="" type="checkbox"/> NOTICE OF VIOLATIONS ISSUED	<input checked="" type="checkbox"/> SAMPLES TAKEN	<input checked="" type="checkbox"/> LAB ANALYSIS REQUESTED	
PROBLEM:			
<input type="checkbox"/> TAMPERING	<input type="checkbox"/> USER ERROR	<input checked="" type="checkbox"/> DESIGN / FORMULATION PROBLEM	<input checked="" type="checkbox"/> MANUFACTURING PROBLEM
<input checked="" type="checkbox"/> ADULTERATED / SECTION: Whereby: 110565		<input checked="" type="checkbox"/> MISBRANDED / SECTION: 110661, 110673 Lack of registration/labeling/FALCPA	
CONTAMINANTS:			
<input checked="" type="checkbox"/> MICROBIOLOGICAL <input type="checkbox"/> PESTICIDE <input type="checkbox"/> CHEMICAL <input type="checkbox"/> INSECT/FILTH <input type="checkbox"/> OTHER			
DESCRIBE: Two possible cases of <i>C. Botulinum</i> linked to consumption of VRGF Basil Pine Nut Pesto.			
On 7/29/14, Ohio Department of Health (ODH) reported to the Food and Drug Branch (FDB) that two patients were hospitalized after consuming a chicken/pesto dish (made from VRGF Basil Pine Nut Pesto) and were diagnosed and treated for botulism toxin exposure. FDA (CORE Signals) informed FDB that a left-over food sample composed of pasta and pesto sauce had been collected by ODH was preliminary positive for <i>C. botulinum</i> toxin. The sample of left-over food was subsequently confirmed positive for <i>C. botulinum</i> toxin type B. A closed, intact sample of VRGF Basil Pine Nut Pesto, the same brand of pesto as used in the left-over food sample, tested negative for <i>C. botulinum</i> toxin. EXHIBIT #1 Suspect Pesto product label.			
VRGF was identified by the labeling as VR Green Farms, located at 200 Avenida La Pata in San Clemente, CA.			

SUMMARY OF FINDINGS (CHRONOLOGY):
The firm, VRGF, was not registered or licensed with CDPH.
In a review of the firm's website, <a href="http://www.vrGF.com">www.vrGF.com</a> , a variety of processed food were advertised as offered for sale, both on-line and at the farm stand located at 200 Avenida La Pata.
<a href="http://vr-green-farms.myshopify.com/collections/fresh-weekly-produce?page=1">http://vr-green-farms.myshopify.com/collections/fresh-weekly-produce?page=1</a>
The following products were located on the website and identified as a possible <i>C. botulinum</i> risk if manufactured improperly:
<ul style="list-style-type: none"> <li>• VR Green Farms Pine Nut Basil Pesto – 12 ounce</li> <li>• VR Green Farms Sweet Red Pepper Hot Jelly – 12 ounce</li> <li>• VR Green Farms Old World Tomato Sauce – 12 ounce</li> <li>• VR Green Farms Tuscan Grilling Sauce – 12 ounce</li> <li>• VR Green Farms Pickled Farm Mix – 16 ounce</li> <li>• VR Green Farms Pasta Sauce – 12 ounce</li> <li>• VR Green Farms Marinated Goat Cheese Balls – 8 ounce</li> <li>• VR Green Farms Extra Virgin Olive Oil with Garlic – unknown size</li> </ul>
See Photos from website below:

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Homemade Pasta Tomato Sauce

\$14.00

8 oz. Marinated Goat Cheese Balls

\$10.00

Homemade Pickled and Spicy Blue  
Lake Beans

\$12.00

VRGF Extra Virgin Olive Oil w/Garlic

Powder Top  
\$24.00

7/29/14: Dominic (Nic) Romano, Owner of VR Green Farms was contacted by telephone for preliminary information. He verbally reported the following to FDB Regional Administrator, Mary Kate Miller:

1. Only about 12 jars of pesto were made (as a test run) back in May/June of 2014\*.
2. The pesto was not made in commercial facility or pursuant to license or scheduled process. The pesto was made for him by a friend, Rose Schwinn.
3. It was only sold at the VR Green Farms Farm Stand and was not available for purchase on the internet. All containers of pesto sauce had been purchased with no remaining inventory available. The VR Green Farms Farm Stand was only open on Saturdays.
4. The pesto sauce did contain fresh garlic.
5. No traceable records of sale of pesto sauce were available for review.

\*Mr. Romano's statement about the pesto being a one-time test run was later found to be inaccurate.

7/30/14: FDB Investigator Melissa DeHart and FDA Consumer Safety Officer, Sara Dent-Acosta initiated an inspection at the VRGF Farm Stand. Mr. Romano repeated the information above.

The canned products were produced seasonally based on what was available from harvest at the VR Green Farms farm location

FDB collected all available inventory as samples, and one jar of each was tested by the University of California Laboratory for Research in Food Preservation for pH and water activity. The pH of all products was below 4.3, and the Aw was above 0.90.

EXHIBIT # 4 Sample /Evidence Receipt.

EXHIBIT # 5 pH /Aw results.

The following products and specific manufacturing locations were discussed during this investigation:

Pickled Farm Mix (contains green beans, peppers) – 13 total jars – made by Christy Rumbaugh (farm stand helper) at her home (unlicensed/unpermitted).

Pickled Carrot Mix – 35 total jars – Made by Christy Rumbaugh (see above)

Pickled Cucumbers (Farm Mix label) – 10 total jars – Made by Christy Rumbaugh (see above)

Pasta Sauce (with fresh herbs) – 36 jars – Made by a local restaurant chef at the restaurant kitchen (no PFR or cannery license)

Sundried Tomatoes in Olive Oil – 5 oz. jar, 9 jars 12 oz. jars, 8 jars – Made by Nic Romano at his unregistered/unpermitted home).

VRGF also sold flavored honey at the Farm Stand, which was manufactured by Honey Pacifica, PFR# 23357.

Mr. Romano was advised of cannery and PFR requirements. In addition, Mr. Romano was advised that he must immediately cease the unlicensed manufacturing and sale of low-acid canned and acidified foods. A Notice of Violations (NOV) was issued to Mr. Romano for lack of license/registration.

The firm initiated a voluntary recall of all suspect low-acid canned and acidified foods. The firm submitted their recall press release to Los Angeles Associated Press on 7/29/2014. In addition, firm management agreed to post the press release on their website and at the Farm Stand. EXHIBIT # 2. VRGF press release

The California Department of Public Health (CDPH) issued a press release warning the public not to consume the

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recalled VRGF products. EXHIBIT # 3.

FDB attempted to review sales records with Mr. Romano to determine what foods would be subject to recall; however, no records existed. Mr. Romano was able to provide a summary of sales from their shopping page on Shopify.com. EXHIBIT # 6 - VRGF shopping page.

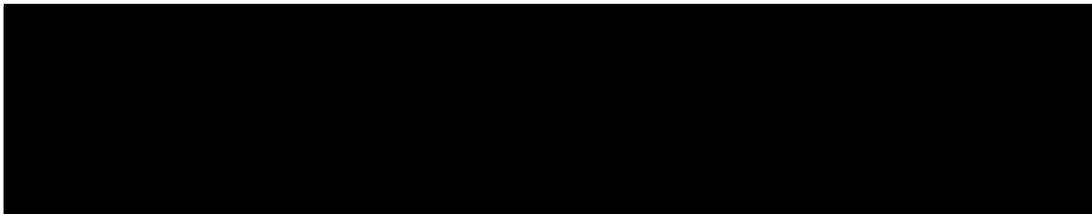
The VR Green Farms Farm Stand did not have a County license/permit to sell processed food at retail. Orange County Environmental Health was notified and they agreed to conduct a follow up inspection at the Farm Stand to ensure they were no longer operating without a permit.

**EXHIBIT # 7 - Photographs of VRGF Farm Stand.**

7/31/14:

FDB Inv. DeHart contacted the manufacturer of the pesto sauce, Rose Schwinn, regarding the specific processing steps used to manufacture the pesto sauce. Ms. Schwinn reported that she manufactured this product in her home kitchen and provided the recipe as follows:

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Ms. Schwinn cleaned new jars by placing them in her household dishwasher on the hot cycle with dish detergent and bleach. The jars were then filled with water and placed in the microwave until boiling. The lids were maintained in hot water until use.

The ingredients were mixed together without a heat step to form a sauce and then filled into hot mason jars. Lids were applied and the jars were placed into a stove top water bath canning unit. The water in the canning unit was brought to a boil and the product was heated for 16 minutes. A thermometer was not used. The jars were then allowed to cool, the seal around the lid was checked, and the product was labeled for distribution. The label did not include a complete ingredient statement, lot code, best by date, or a "Perishable Keep Refrigerated" statement.

Ms. Schwinn reported that she was a family friend of Mr. Romano and only made small batches on and off for a few years. Ms. Schwinn believed that she last manufactured pesto sauce between January and May 2014. She did not maintain any production records or food safety records including pH or water activity data. Ms. Schwinn did not maintain a PFR or Cannery License with CDPH to manufacture these types of foods.

She invoices VRGF for sales (EXHIBIT # 8, Rose Artisan Creations). According to the invoices, in 2014 she billed VRGF for Basil Pine Nut Pesto, as follows:

March 22- 12 jars  
May 3 – 12 jars  
May 24 – 6 jars  
May 28 – 6 jars  
June 7 – 6 jars

Ms. Schwinn relied on her memory when interviewed about pesto production and delivery dates. She stated that her batch yield was typically 9 - 12 jars (12 max). She recalled that sometime in May, 2014, Nic Romano had brought 3 Pesto jars back to her with lids that had "popped up". The jars had been in his car for a few days and the he wanted to know if Rose could re-process/re-pack them. Rose reported that she told him "no" and she threw them out.

7/31/14:

FDB Inv. DeHart contacted [REDACTED] [REDACTED] is the father of one the patients, and he had purchased the pesto sauce from VRGF. He reported to Inv. DeHart that he drove to Colorado and Ohio, with the pesto, and gave it to friends and family as gifts. At the time of contact, he and his wife [REDACTED] were in Ohio with their sick daughter. [REDACTED] was expected back in Orange County on Tuesday, 8/5/14. She agreed to coordinate with FDB to collect an unopened sample of the same pesto product, purchased at the same time as the implicated jar.

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reported having moved to Irvine from Ohio in Nov. 2013. He claims that he started going to the farm stand in Jan 2014 – and believes he bought Pesto starting Jan.-May. He stated affirmatively that the Pesto implicated in daughter's illness was purchased the last Saturday in May (May 31). He and his daughter store the unopened Pesto in pantry – ambient temperature.

8/5/14:

A sample of an unopened jar of VRGF Basil Pine Nut Pesto was collected from EXHIBIT # 9. The sample was submitted to Food and Drug Laboratory Branch (FDLB) for pH, water activity, and Elisa screening for *C. botulinum* toxins. The results are pending. *attached EXHIBIT # 9(a)*

On 8/06/14 and 8/07/14: Individual inspections and interviews were conducted with each processor identified as producing "canned" foods for VRGF.

Refer to inspection reports (FACT) for processors: Christy Rumbaugh; Nic Romano, Rose Schwinn, and Pub Thirty-Two. EXHIBITS # 10 - 13

**ATTACHMENT:**

**NOTICE OF VIOLATIONS – ISSUED 7/30/14**

**EXHIBITS:**

1. Suspect Pesto label (from CORE).
2. VRGF Press Release
3. CDPH issued a Press Release
4. Sample Evidence Receipt - VRGF.
5. pH and Aw report – UCLRFP
6. Shopify invoices
7. Photographs – Farm Stand
8. Rose [Schwinn] Artisan Food – Invoices to VRGF
9. Sample Evidence Receipt – Consumer for unopened jar of VRGF pesto *+ 9a. Test results (MDL)*
10. FACT Rumbaugh
11. FACT Romano (includes written response from Nic Romano stating he has ceased processing operations)
12. FACT Schwinn
13. FACT Pub Thirty Two

*9/10/14 : pH and aW results for VRGF Basil Nut Pesto :  
 pH = 5.3  
 aW = 0.965  
 IS# 062080514 (consumer sample)*

*EXHIBIT 14 FDL Test results*

*mdl*

INVESTIGATOR SIGNATURE: <i>Melissa DeHart</i>	INV.# <i>062</i>	REPORT DATE <i>09/02/14</i>
SUPERVISOR SIGNATURE: <i>[Signature] #10</i>		DATE REVIEWED <i>9/8/14</i>

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**SUPERVISOR DISPOSITION:** Review the FDLB laboratory reports on pesto sample submitted. Nic Romano responded in writing to the NOV issued on 8/6/14, stating he will no longer manufacture food products. Neither Rose Schwinn nor Christy Rumbaugh submitted written responses to NOVs. Pub Thirty Two was not issued an NOV, as no sauce from the restaurant ever reached commerce..

9/10/14: FDLB report shows that the canned, shelf stable, VRGF Pine Nut Basil Pesto Sauce has a pH of 5.3 and water activity of 0.965.

Non-refrigerated foods that are packed in hermetically sealed jars, with a pH above 4.6 and water activity above 0.85, are at risk for supporting *C. botulinum* toxin formation - and must be manufactured in accordance with an approved scheduled process, controls, and (in CA) pursuant to a Cannery License.

VRGF Pine Nut Basil Pesto Sauce (LACF) was packed without a scheduled process on file, without compliance with the federal low acid food regulations (21 CFR Part 113); and without a Cannery License or compliance with the CA Cannery laws and regulations.

Failure to properly manufacture LACF products, such this Pesto, places consumers of the product at risk for *C. botulinum* toxin illness.

Refer to Orange County DDA.

Cc: Unit Chief

